A New Soft Law Approach to Nanotechnology Oversight: A Voluntary Product Certification Scheme

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I.
INTRODUCTION

Regulatory oversight of nanotechnology is necessary yet problematic. The necessity of regulation is driven by two related concerns. First, some nanotechnologies, if left unregulated, are likely to pose very real, if currently unknowable, risks of significant health or environmental damage.[1] Second, public confidence in new technologies and in the regulatory agencies that govern them may be permanently damaged if injurious nanomaterials are released without adequate, or at least the perception of adequate, oversight.[2]

Despite these considerations, nanotechnology regulation remains problematic. Most regulatory hurdles are currently insurmountable because we still do not know exactly what "nanotechnology" means or encompasses, much less what concrete risks it may pose. "Nanotechnology" is a poorly defined, insufficiently understood set of diverse products, processes, and technologies that is not easily captured by any existing regulatory definition, model or system. This situation creates a problem for

1. *See generally* NANOTOXICITY: FROM *In Vivo* and *In Vitro* Models to Health Risks (Saura Sahu & Daniel A. Casciano eds., 2009); Vicki L. Colvin, *The Potential Environmental Impact of Engineered Nanomaterials*, 21 NATURE BIOTECHNOLOGY 1166 (2003).

2. Many have noted, although we remain somewhat skeptical, that a lack of government action may be a problem for public perceptions of nanotechnology risks. *See generally* Douglas J. Sylvester, Gary E. Marchant, and Kenneth W. Abbott, *Not Again! Public Perception, Regulation, and Nanotechnology*, 3 REG. & GOVERNANCE 165 (2009) (outlining many of the arguments related to public perception of risks of emerging technologies and their relationship to trust in government agencies). *See also* Ortwin Renn & Mihail C. Roco, *Nanotechnology and the Need for Risk Governance*, 8 J. NANOPARTICLE RES. 153, 156-62 (2006).

traditional regulatory tools. Government command-and-control regulations require, among many other things, clear definitions of what is to be regulated, understandable compliance requirements, and strong policy-based rationales to justify the regulation.[3] The impropriety, if not questionable legality, of employing traditional regulatory approaches, coupled with growing calls to "do something,"[4] has created an opportunity for new models of nanotechnology governance and oversight to emerge.[5]

Of late, we have seen numerous short term proposals for "soft law"[6] solutions and the implementation of some soft law mechanisms. None are based on the traditional command-and-control approach, under which government agencies enact detailed regulatory requirements enforced by the threat of penalty. Instead, all reflect a variety of voluntary, cooperative or partnership approaches.[7] However, although these approaches have many advantages, none of the currently operational regimes has fully achieved two obvious and oft-cited goals of nanotechnology regulation: (1) broad industry participation, with sufficient data submission to aid regulators in risk assessments; and (2) reassurance of public stakeholders as to government's role in regulating emerging technologies.[8]

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3. *See infra* notes 21-30 and accompanying text.

4. *See, e.g.*, J. Clarence Davies, Project on Emerging Nanotechnologies, *Nanotechnology Oversight: An Agenda for the New Administration*, July 2008, http://207.58.186.238/process/assets/files/6709/pen13.pdf; Daniel Barben, Erik Fisher, Cynthia Selin & David H. Guston, *Anticipatory Governance of Nanotechnology: Foresight, Engagement, and Integration, in* THE HANDBOOK OF SCIENCE AND TECHNOLOGY STUDIES 979 (Edward J. Hackett, Olga Amsterdamska, and Michael Lynch eds. 2007); Diana M. Bowman & George Gillian, *How Will the Regulation of Nanotechnology Develop? Clues from Other Sectors, in* NEW GLOBAL FRONTIERS IN REGULATION: THE AGE OF NANOTECHNOLOGY 353 (Graeme Hodge, Diana M. Bowman, and Karen Ludlow eds., 2006).

5. *See* Gary E. Marchant, Douglas J. Sylvester & Kenneth W. Abbott, *Risk Management Principles for Nanotechnology*, 2 NANOETHICS 43, 44 (2008) [hereinafter Marchant et al., *Risk Management*]; Diana M. Bowman & Graeme A. Hodge, *Nanotechnology: Mapping the Wild Regulatory Frontier*, 38 FUTURES 1060, 1068-69 (2006); Renn & Roco, *supra* note 2, at 183; Kenneth W. Abbott, Gary E. Marchant, and Douglas J. Sylvester, *A Framework Convention for Nanotechnology?* 36 ENVTL L. REP. 10931 (2006); Kenneth W. Abbott, Sandeep Gopalan, Gary Marchant, & Douglas Sylvester, *International Regulatory Regimes for Nanotechnology* (Arizona State, Working Paper No. 907353, 2006), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=907353 (last visited Oct. 1, 2009).

6. *See* Marchant et al., *Risk Management*, *supra id.*, at 50 (collecting sources).

7. *See id.* at 53-56.

8. Again, we are somewhat skeptical of this goal, but it is an oft-stated endpoint of numerous calls for soft-law initiatives. *See* Sylvester et al., *supra* note 2.

Therefore, this Article proposes another soft law option that may better achieve these goals. We propose a voluntary certification scheme under which companies that produce nanotechnology products may obtain a government-supervised certification for specific products if the firms subject those products to specified safety testing, data disclosure and risk management measures. Given differing national regulatory approaches, our proposal is designed primarily for the United States. However, there is nothing in the proposal that could not be adapted for use in other jurisdictions or prevent the creation of an equivalent international scheme.

Part II sets up the need for new approaches by explaining why regulation of nanotechnology is largely infeasible under traditional approaches. Part III summarizes the experience and promise of current soft law regimes, as well as some of their limitations. This Part also identifies some features of successful certification systems and discusses their relevance to a nanotechnology certification system. Part IV introduces our proposal for a voluntary safety testing certification scheme and discusses the ways in which such a scheme might gain the trust of consumers and other relevant audiences. Part V considers the elements of the scheme in greater detail. The final Part is a brief conclusion.

II.
THE FUTILE (NEAR TERM) QUEST FOR COMMAND-AND-CONTROL REGULATION

Many see a growing need for meaningful regulatory oversight of nanotechnology.[9] However, pressure for command-and-control regulation is frustrated by a number of obstacles. This Part addresses both the need for regulatory oversight and the impediments to traditional regulatory approaches.

9. *See* Sylvester et al., *supra* note 2; Davies, *supra* note 4; Marchant et al., *Risk Management*, *supra* note 5; JANE MACOUBRIE, INFORMED PUBLIC PERCEPTIONS OF NANOTECHNOLOGY AND TRUST IN GOVERNMENT (2005), *available at* http://www.wilsoncenter.org/news/docs/macoubriereport.pdf; INTERNATIONAL CENTER FOR TECHNOLOGY ASSESSMENT ET AL., PRINCIPLES FOR THE OVERSIGHT OF NANOTECHNOLOGIES AND NANOMATERIALS (2007) *available at* http://www.icta.org/doc/Principles%20for%20the%20Oversight%20of%20Nanotechnologies%20and%20Nanomaterials_final.pdf.

A. *Demand for Regulation*

Nanotechnology involves the manipulation and use of materials at the nanoscale. The nanoscale ranges from approximately one to one hundred nanometers. At this size range, materials tend to exhibit different properties than they do at the bulk scale, usually including greater activity and reactivity.[10] The exploitation of these unique properties is fueling a frenzy of new products, processes and technologies.[11] These applications have the potential to provide enormous societal benefits, including improved cancer detection and treatment, cleaner energy, more efficient computers and electronic equipment, stronger and lighter structural materials, and yes, odor-free socks. Unfortunately, the same traits responsible for the many potential benefits of nanomaterials—especially their small size and dynamic properties—also create health and environmental risks, through the potential for nanomaterials to penetrate and react with biological systems.

Current scientific evidence as to these risks is at best mixed. A few studies, some involving high exposures that may not be representative of human exposure levels, have induced toxic responses in animals.[12] Other studies, however, have produced relatively inert responses, suggesting the absence of significant health risks.[13] Whether these differences in result are based on

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10. *See generally* SPRINGER HANDBOOK ON NANOTECHNOLOGIES (Bharat Blusham ed., 2007); Marie-Christine Daniel and Didier Astruc, *Gold Nanoparticles: Assembly, Supramolecular Chemistry, Quantum-Size-Related Properties, and Applications toward Biology, Catalysis, and Nanotechnology*, 104 CHEM REV. 293 (2004); M C Hersam, N P Guisinger & J W Lyding, *Silicon-based Molecular Nanotechnology*, 11 NANOTECHNOLOGY 70 (2000).

11. The most important repository of information on current products is The Project on Emerging Nanotechnologies website at http://www.nanotechproject.org/inventories/consumer/ (last visited on Oct. 1, 2009).

12. Jirasek Wong-Ekkabut et al., *Computer Simulation Study of Fullerene Translocation Through Lipid Membranes*, 3 NATURE NANOTECHNOLOGY 363 (2008); Aihong Liu et al., *Toxicological Effects of Multi-Wall Carbon Nanotubes in Rats*, 10 J. NANOPARTICLE RESEARCH 1303 (2008); Craig A. Poland et al., *Carbon Nanotubes Introduced Into the Abdominal Cavity of Mice Show Asbestos Like Pathogenicity in a Pilot Study*, 3 NATURE NANOTECHNOLOGY 423 (2008); C. Medina et al., *Review: Nanoparticles: Pharmacological and Toxicological Significance*, 150 BRIT. J. PHARMACOLOGY 552 (2007); Gunter Oberdorster, Vicki Stone & Ken Donaldson, *Toxicology of Nanoparticles: A Historical Perspective*, 1 NANOTOXICOLOGY 2 (2007).

13. *See, e.g.*, Brian Priestly & Andrew Harford, *The Human Health Risk Assessment (HHRA) of Nanomaterials*, *in* NEW GLOBAL FRONTIERS IN REGULATION: THE AGE OF NANOTECHNOLOGY 134 (Graeme Hodge, Diana Bowman, & Karen Ludlow eds., 2007); Helene Dumortier et al., *Functionalized Carbon Nanotubes are Non-Cytotoxic and Preserve the Functionality of Primary Immune Cells*, 6 NANO LETTERS 1522 (2006); Andrew Maynard, *Safe Handling of Nanotechnology*, 444 NATURE 267

errors in the studies, variances in the materials studied, or other phenomena, the perplexing bottom line is that there is currently no methodology for predicting which nanomaterials will produce a toxic response and which will not. Indeed, a specific nanomaterial may present significant variations in risk. For example, single-walled carbon nanotubes differ widely in terms of manufacturing method, coatings, size and other parameters; the limited available toxicology data indicate that these differences may produce dramatic variations in risk.[14] Traditional toxicological methods for extrapolating risks between related substances, most importantly quantitative structure activity relationships (QSAR), do not appear to work for nanomaterials for which hazard differences are largely determined by factors other than chemical structure, including size, surface area and surface chemistry.

This highly ambiguous evidence leaves scientists and regulators in a position of toxicological purgatory, as explained by Kristen Kulinowski, director of the International Consortium on Nanotechnology (ICON): "We are in this awkward middle territory where we have just enough information to think there is an issue, but not enough information to really inform policymakers about what to do about it."[15] The highly uncertain and underdeveloped data sets on nanotechnology paralyze regulatory agencies under most existing statutes. The Toxic Substances Control Act[16] requires a finding of "unreasonable risk" while the Occupational Safety and Health Act[17] requires a finding of "significant risk" based on quantitative risk assessments. However, quantitative risk assessments are not currently available or feasible for nanotechnology exposures.

Yet scientific uncertainty is seldom a reason for concerned actors to sit on their hands. Instead, as each new study suggesting a potential hazard from some nanomaterial is released, the number and urgency of calls for a substantive regulatory response in-

(2006); Vicki L. Colvin, *The Potential Environmental Impact of Engineered Nanomaterials*, 21 NATURE BIOTECHNOLOGY 1166 (2003).

14. Vicki Colvin, Presentation, *Nanomaterials in the Environment: An Application and Comment on Implications*, Brussels, March 30, 2006, *available at* http://www.nanoforum.org/dateien/temp/Vicki%20Colvin.pdf?06062006102323 (citing more than 50,000 different formulations with different risk profiles); U.S. EPA, NANOTECHNOLOGY WHITE PAPER 32 (2007), *available at* http://www.epa.gov/OSA/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf.

15. S. R. Morrissey, *Understanding Nanotechnology*, CHEM. & ENG. NEWS, April 16, 2007, at 35.

16. 15 U.S.C. §§ 2601-29 (1976).

17. 29 U.S.C. §§ 651-78 (1970).

crease. For example, in 2007 a coalition of forty-five nongovernmental organizations (NGOs) issued its "Principles for the Oversight of Nanotechnologies and Nanomaterials," calling for adoption of "a *sui generis,* nano-specific regulatory regime."[18] Even some industry representatives have recognized a need for more rigorous regulatory oversight. For example, one industry expert testified to Congress:

> [W]hat we want to avoid is for the trajectory of nanotechnology to follow that of genetically-modified organisms (GMOs), the most recent 'magic' technology. In the case of GMOs, deployment of applications outpaced attention to the environmental, health, and safety implications of the technology. Public concerns that arose because of this have significantly retarded the realization of GMO's great commercial potential.[19]

Although it is unclear whether the GMO experience is as closely analogous to nanotechnology as this quotation suggests, many see a need for *some* regulatory response to the perceived dangers of nanotechnologies.

These voices and many others, including legislators, insurers, investors, journalists and scholars, are creating growing momentum for nanotechnology regulation.[20] Such regulation could serve two valid purposes. First, it could reduce and manage the real risks that some nanotechnology products and processes are likely to create, benefiting public health, the environment and the long-term viability of the industry. Second, it could help build public confidence and trust in nanotechnology, an important secondary purpose of regulation.

B. *Obstacles to Regulation*

Unfortunately, and perhaps not surprisingly, regulation of nanotechnology is not as straightforward as some proponents believe. Several obstacles stand in the way of a comprehensive, traditional regulatory response. One impediment is the lack of a

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18. International Center for Technology Assessment et al., *Principles for the Oversight of Nanotechnologies and Nanomaterials*, July 31, 2007, *available at* http://www.icta.org/doc/Principles%20for%20the%20Oversight%20of%20Nanotechnologies%20and%20Nanomaterials_final.pdf.

19. *U.S.-E.U. Regulatory Cooperation on Emerging Technologies: Hearing Before the S. Comm. on Foreign Relations*, 109th Cong. 1 (2005) (testimony of Stephen Harper, Director of Environment Health & Safety Policy, Intel Corporation).

20. *See generally* Sylvester et al., *supra* note 2.

universally recognized definition of "nanotechnology."[21] This is more than a semantic or conceptual barrier. In the United States, for example, administrative agencies are constrained by the substantial evidence doctrine required under the Administrative Procedure Act.[22] Under this doctrine, agency conclusions of fact (such as "nanotechnology is potentially dangerous") must be based on sound scientific evidence, and conclusions drawn from that evidence must be reasonably supported. If agencies regulate in the absence of substantial evidence or without reasonable evidentiary support, their regulations are unenforceable.[23] Thus, the lack of scientific evidence about the risks of nanotechnologies as a class and the lack of an accepted definition of what nanotechnology encompasses, doom any regulation that generically addresses all "nanotechnology" or "nanomaterials."

A second obstacle to regulation is the speed of nanotechnology's development. New applications and products are announced every week. Nanotechnology is already progressing from the use of relatively simple nanoparticles to more complex active materials, such as sensors, multi-functional drugs, and medical devices. It is difficult for a slow-moving regulatory apparatus to take aim against such a fast-moving target. As David Rajeski, director of the Wilson Center's Project on Emerging Nanotechnologies, cautions: "If you think that any existing regulatory framework can keep pace with this rate of change, think again."[24]

A third impediment is the problematic (if not legally unsupportable) nature of a regulation that imposes restrictions on a product or process simply because it uses, contains or is made using nanotechnology. Terry Davies once suggested that defining and regulating nanotechnology as a category based on size is

21. Mélanie Auffan et al., *Towards a Definition of Inorganic Nanoparticles from an Environmental, Health and Safety Perspective*, NATURE NANOTECHNOLOGY (advance online publication 2009), *available at* http://www.nature.com/nnano/journal/vaop/ncurrent/abs/nnano.2009.242.html (last visited Oct. 3, 2009).

22. 5 U.S.C. §§ 551-59 (1946).

23. *See e.g.*, Dickinson v. Zurko, 527 U.S. 150, 162 (1999) ("This Court has described the APA court/agency 'substantial evidence' standard as requiring a court to ask whether a 'reasonable mind might accept' a particular evidentiary record as "adequate to support a conclusion.").

24. David Rejeski, *The Next Small Thing*, THE ENVIRONMENTAL FORUM, March/April 2004, at 45.

as rational as regulating together everything that is blue.[25] Further, regulating a product based on the presence of nanotechnology in the product or its manufacturing process will discriminate improperly against nanotechnology products unless nanotechnology-as a class is inherently more risky than non-nanotechnology products, which has not been established. For example, some commentators propose mandatory testing for all nano products, yet in most cases no testing would be required for competing products made without nanotechnology, even if they present similar or even greater risks.[26] Such discrimination would have a number of counterproductive effects and incentives, including creating an arbitrary bias among producers for non-nano inputs and processes and encouraging strategic behavior to hide nano inputs and processes.

Finally, the enormous potential benefits of nanotechnology further complicate regulation. Applying precautionary adages such as "better safe than sorry" or "err on the side of safety" to restrict nanotechnology could end up doing more harm than good. In particular, nanotechnology is one of the most, if not *the* most, promising technologies for pursuing goals such as better cancer treatment and clean energy. Sacrificing these benefits might well outweigh any health or environmental benefits from regulating nanotechnology.[27]

Given these obstacles to traditional regulation, it is not surprising that no mandatory, *sui generis* nanotechnology regulations have been adopted anywhere in the world, except for a few reporting requirements.[28] Even as the pressure for regulation con-

25. J. Clarence Davies, Project on Emerging Nanotechnologies, *Managing the Effects of Nanotechnology,* http://www.wilsoncenter.org/events/docs/Effectsnanotechfinal.pdf (last visited Oct. 1, 2009).

26. *See, e.g.,* Michael R. Taylor, Project on Emerging Nanotechnologies, *Regulating the Products of Nanotechnology: Does the FDA Have the Tools it Needs?,* http://pewnanotech-project.us/process/assets/files/2705/110_pen5_fda.pdf (last visited Oct. 1, 2009) (urging that FDA be given authority to mandate safety testing and reporting); Karen Florini et al., *Nanotechnology: Getting it Right the First Time,* 3 NANOTECHNOLOGY L. & BUS. 39 (2006).

27. *See* Sylvester, *supra* note 2; Gary E. Marchant & Douglas J. Sylvester, *Transnational Models For Regulation of Nanotechnology*, 34 J.L. MED. & ETHICS 714 (2006).

28. *See* EPA, Significant New Use Rules of Certain Chemical Substances, 40 C.F.R. § 721 (2009); City of Berkeley, Municipal Code §§ 15.12.040, 15.12.050 (2006), http://www.ci.berkeley.ca.us/citycouncil/2006citycouncil/packet/120506/2006-12-05%20Item%2013%20Manufactured%20Nanoparticle%Health%20and%20Safety%20Disclosure.pdf (last visited Oct. 3, 2009); Letter from the Cal. Dep't of Toxic Substances Control on Chemical Information Call-In Carbon Nanotubes, (Jan.

tinues to build, there is no immediate prospect for these impediments to be overcome.

III.
THE LIMITS OF CURRENT SOFT LAW APPROACHES

The pincer effect of growing pressure for regulatory oversight combined with obstacles to traditional regulation has led regulators and industry to seek innovative techniques for controlling the threats nanotechnology may pose. The dominant approach relies on soft law: voluntary or cooperative measures.[29] Measures like these are ideally suited to situations like the one presently facing nanotechnology and its would-be regulators. In the face of uncertain futures, and with no clear path for traditional regulation, soft law approaches provide the important benefits of experimentation, learning and graduated action.

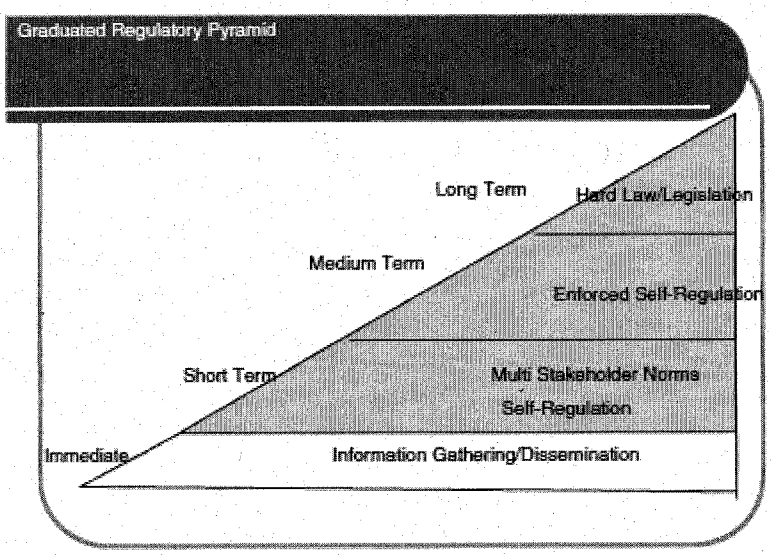
Figure 1 adapts the well-known Ayres and Braithwaite regulatory pyramid, with its increasingly coercive regulatory enforcement, to the current nanotechnology context. Figure 1 suggests a graduated approach to regulation, in which oversight becomes progressively more formal and "harder" over time, as additional data and experience are accumulated.[30] The graduated model begins with voluntary information gathering and dissemination programs and progresses to voluntary self-regulatory and multi-stakeholder oversight. Then the model advances to government enforced self-regulation and, finally, to traditional mandatory regulation in areas where that is shown to be necessary.

22, 2009), http://www.dtsc.ca.gov/TechnologyDevelopment/Nanotechnology/upload/Formal_AB289_Call_In_Letter_CNTs.pdf (last visited Oct. 3, 2009).

29. *See* Diana M. Bowman & Graeme A. Hodge, *Governing Nanotechnology Without Government?*, 35 SCIENCE & PUB. POL'Y 475 (2008) (defining soft law approaches and giving examples in the nanotechnology context); Marchant et al., *Risk Management*, *supra* note 5, at 51-58.

30. *See, e.g.*, Marchant et al., *Risk Management*, *supra* note 5, at 52-53.

FIGURE 1: GRADUATED REGULATORY PYRAMID[31]



A survey of the landscape of nanotechnology oversight confirms that the vast majority of current initiatives fall within the Immediate or at most the Short Term levels of the graduated regulatory pyramid. These involve information gathering, self-regulation and multi-stakeholder norm creation. Examples include:

- Voluntary Company Standards: Some individual firms, such as BASF, have adopted their own internal standards for the safe handling of nanomaterials.[32]
- Industry-NGO partnerships: DuPont and Environmental Defense have partnered to create a publicly available nanomaterials risk assessment/risk management framework, which any entity handling nanomaterials can implement.[33]
- Multi-Stakeholder Codes of Conduct: A diverse set of stakeholders, including the U.K. Royal Society and the Nanotechnology Industries Association, partnered to create

31. *Id.* at 54.

32. BASF, Code of Conduct Nanotechnology, http://www.basf.com/group/corporate/en/sustainability/dialogue/in-dialogue-with-politics/nanotechnology/code-of-conduct (last visited Oct. 3, 2009).

33. Nano Risk Framework, Environmental Defense Fund—DuPont Partnership, http://www.nanoriskframework.com/page.cfm?tagID=1095 (last visited Oct. 3, 2009).

the Responsible NanoCode, a voluntary code of conduct for companies handling nanomaterials.[34]

- Private Standards: Standard-setting bodies such as ISO and ASTM have adopted standards for the environmental, health and safety management of nanomaterials.[35]
- Governmental Voluntary Programs: EPA launched its Nanoscale Materials Stewardship Program ("NMSP") in 2008; it is a voluntary program that encourages companies handling nanomaterials to submit relevant data to the agency.[36] Under the basic NMSP program, firms submit existing information on nanoscale materials, i.e., their physical and chemical properties, hazards, exposure, use and risk management practices or plans; under the in-depth program, EPA invites participants to develop test data for representative nanoscale materials and to work with the Agency to devise a data development plan.

These varied soft law initiatives perform an important role—filling the nanotechnology oversight gap until more traditional regulation is appropriate and feasible. As discussed below, however, these initial approaches have been challenged by limited industry participation or a failure to achieve credibility in the eyes of relevant constituencies.[37] Notwithstanding some significant accomplishments, they have not produced (and in many cases were not intended to produce) sufficient data on an industry-wide scale to assess the potential risks and benefits of all nanotechnology applications or to reassure the public about the adequacy of regulation.

The EPA's NMSP and a similar UK program sponsored by the Department for Environment, Food and Rural Affairs

34. Responsible NanoCode Home Page, http://www.responsiblenanocode.org/ (last visited Oct. 3, 2009).

35. International Standards Organisation, *Nanotechnologies—health and safety practices in occupational settings relevant to nanotechnologies*, ISO/TR 12885:2008, http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=52093&commid=381983 (last visited Oct. 3, 2009).

36. U.S. EPA, NANOSCALE MATERIALS STEWARDSHIP PROGRAM: INTERIM REPORT (Jan. 2009), *available at* http://www.epa.gov/oppt/nano/nmsp-interim-report-final.pdf; *see also* U.S. EPA, Nanoscale Materials Stewardship Program, http://www.epa.gov/oppt/nano/stewardship.htm (last visited Oct. 19, 2009).

37. In spite of these challenges, these programs may be highly successful in other ways, including influencing public perceptions of risks and benefits, coordinating industry risk-assessment, and establishing minimal safety protocols.

(DEFRA)[38] are both government-sponsored voluntary reporting initiatives. Limited industry participation is most obvious in these programs. Of the hundreds, if not thousands, of companies in the United States producing nanotechnology products, only 29 have signed up for the basic NMSP program, reporting on 129 materials or products. Only 4 have pledged to participate in the in-depth program and only 13 companies participated in DEFRA's pilot program.[39] Based on this limited participation, EPA tentatively declared "the NMSP . . . successful," but noted that "a number of environmental health and safety gaps the Agency hoped to fill through the NMSP still exist."[40] In fact, limited industry participation has precluded any comprehensive risk assessment of nanotechnology products, while failing to reassure the public that nanotechnology is being properly overseen.

The question, of course, is why participation has been so limited. The most obvious answer is that most firms do not see sufficient benefits from participation.[41] NMSP reporting offers no real advantage except a slight possibility of good will from regulators or the public. On the other hand, a company that reports risk data on its nanotechnology products places itself squarely in the cross-hairs of scrutiny by regulators, journalists, NGOs and possibly plaintiffs' attorneys.

Disappointing participation in these schemes has led many consumers and activists to mistrust soft law initiatives as cynical public relations attempts or, worse, as indications that governments are unable or unwilling to regulate effectively. As a result, these programs may actually have strengthened calls for formal regulation or moratoria, even though command-and-control regulation remains inadvisable given the current state of knowledge. Clearly, something new is needed. Is it possible to design a vol-

38. *See* DEFRA, UK—Environmental Protection—Nanotechnology, http://www.defra.gov.uk/environment/quality/nanotech/policy.htm (last visited Oct. 1, 2009).

39. *See* U.S. EPA, *supra* note 36, at 3 (NMSP results); *see also* DEFRA, *supra* note 38 (UK results).

40. *See* U.S. EPA, *supra* note 36, at 3.

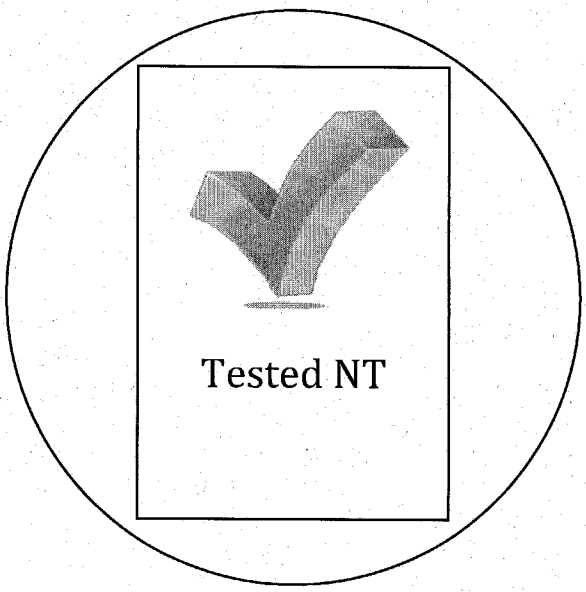
41. Some industry and government spokesmen have blamed the lack of industry participation, at least in part, on the expense and general uncertainty surrounding voluntary regimes. Some, for example, have blamed the lack of industry participation on a "reluctance to engage in expensive testing for a scheme which might not serve as the basis for future regulatory compliance . . ." Daniel Pruzin, *Regulators, Industry Cite Mixed Results from Voluntary Codes for Nanotechnology*, 31 INT'L ENV. REP. 906, 907 (2009) (quoting Steve Morgan, DEFRA nanotechnologies policy adviser).

untary scheme that would earn greater industry participation and public credibility?

IV.
A Voluntary Safety Testing Certification Scheme

The key to a successful scheme is to give firms *something of value* in return for cooperation to incentivize industry participation. At the same time, a scheme should create incentives for more than reporting data; it should encourage firms to undertake substantive risk management actions, such as safety testing and implementing risk management measures.

This Article proposes a government sponsored certification mark—the Tested NT mark. Companies could affix the mark to nanotechnology products once they satisfied government prescribed requirements for data collection, disclosure and substantive safety testing. For practical reasons, firms would conduct their own product testing and issue their own certifications. The Tested NT mark would consist of a recognizable and appealing symbol, perhaps something like the following:



Such a certification would provide numerous benefits to participating companies in exchange for data disclosure, product testing and other precautions. Firms that meet the requirements of the scheme could distinguish themselves in the marketplace by

use of the Tested NT mark, communicating to customers that specific products containing or using nanotechnology have been subjected to a reasonable set of government prescribed safety precautions. So long as the mark is understood and accepted by the relevant public, firms should be able to increase consumer confidence in their products and build confidence in their corporate future among employees, investors and other stakeholders.

Perhaps most important, the scheme could help participating firms defend their products against attacks by activists, journalists or business competitors based on unfounded claims that *all* nanotechnologies are unsafe and unproven. For example, if a nanotechnology product produced by a manufacturer not participating in the scheme were found to cause a health hazard, participating manufacturers might be able to distinguish their product from the hazardous product and avoid being tarred by the same brush. Given these benefits, industry participation in the certification scheme would likely be substantially greater than in the current voluntary programs.

Merely increasing participation, of course, is insufficient. What matters most, for both firms and consumers, is that certification *means something*. A successful scheme, then, must ensure that the certification is valuable and informative and must require a type and level of testing and other precautions that will be regarded as significant.[42] In short, consumers must trust the certification mark *and* the certifier. Without such trust, consumers will view the mark as meaningless, and any benefits of participation will disappear. All other considerations are secondary.

A. *Background on Certification Programs*

Certification programs have arisen in many fields—some technology related, others not. Some programs are administered by private entities: the Good Housekeeping Seal of Approval,[43] Forest Stewardship Council certification for forestry products,[44] Ko-

42. An additional issue, which we do not address here, is whether certification should carry any weight beyond its communicative value (e.g., burden-shifting in tort actions, immunity, liability caps). One suggestion, raised in the context of reforming current voluntary reporting mechanisms, is to grant companies that report risk assessment data immunity from criminal prosecution arising from any injuries caused by release of reported products.

43. *See* Good Housekeeping Seal of Approval, http://www.goodhousekeeping.com/product-testing/seal-holders/welcome-gh-seal (last visited Oct. 1, 2009).

44. *See* Forest Stewardship Council Home Page, http://www.fscus.org (last visited Oct. 1, 2009).

sher labeling for food,[45] and the TRUSTe label for privacy protections by e-commerce companies.[46] Others are administered by government agencies: the EPA's Energy Star program,[47] Germany's Blue Angel eco-label,[48] and the European Union's Flower eco-label.[49] These programs offer widely varying lessons. Certification and labeling programs have been widely used in diverse fields and communities and have largely been successful. Success is due in part to specific substantive requirements and procedures, but the broadest key to success has been the ability of schemes and labels to convey trusted messages about quality or responsibility to relevant audiences.

An initial obstacle to consumer trust in a certification scheme (especially one for nanotechnology) is the reality that no certification mark can guarantee that products are absolutely safe because no feasible set of toxicity tests could positively prove perfect safety. This lack of absolutes is bound to disappoint those who appear to want no less than a complete guarantee of safety before products are placed on the market.[50] However, there is no need for a certification mark to satisfy everyone. So long as it is widely accepted, a certification will create incentives for companies to participate and increase public confidence in the role of regulatory agencies. What standards, then, can gauge the likelihood of consumer trust in the proposed nano certification scheme?

B. *The Role of Trust in Certification Programs*

The key to any successful certification scheme is for the certifier to establish trust with consumers. If consumers do not trust a scheme, it cannot be effective no matter how stringent its sub-

45. *See* Guide to Popular Kosher Symbols, http://kosherfood.about.com/od/guidetokosherfoodlabels/ss/symbols.htm (last visited Oct. 1, 2009).

46. *See* TRUSTe Home Page, http://www.truste.com (last visited Oct. 1, 2009).

47. *See* EPA Energy Star Program Home Page, http://www.energystar.gov/ (last visited Oct. 1, 2009).

48. *See* Blue Angel Program Home Page, http://www.blauer-engel.de/en/index.php (last visited Oct. 1, 2009).

49. *See* European Union Eco-Label program Home Page, http://ec.europa.eu/environment/ecolabel/ (last visited Oct. 1, 2009).

50. Numerous advocacy groups, including Friends of the Earth, ETC Group and Greenpeace, argue that moratoria should be placed on nanotechnology research until safety is proven—a position unlikely to be satisfied by a certification mark backed by limited testing. The "Tested NT" mark would not purport to guarantee safety, and should not be understood as having that effect. As a result, use of the mark would fail to satisfy these groups, and indeed might be seen by them as a cynical attempt to dupe the public.

stantive requirements or how potent its enforcement mechanisms. Although if these two pieces were in place, trust could eventually be acquired. One can easily conjure up examples of certifiers who, no matter their substantive requirements, would not inspire trust. Imagine, for example, an Enron Certified retirement plan, a Chinese Government Seal of Approval for milk and toys, or a Hummer Energy Efficient mark. In the end, a mark must convey to the consumer that there is a sound reason for believing a product actually meets the standards the mark conveys.

With Good Housekeeping, for example, consumers must trust that the Seal of Approval means a good or service is of high quality; with the Energy Star program, that a product will save electricity; and with Kosher labeling, that a food has been prepared consistently with religious requirements. The question is how to establish this trust. The Parts below outline some of the ways that trust is generated between individuals and groups and assess their relevance for the Tested NT scheme.

1. Dispositional and Situational Trust

The first and most intuitive way to establish trust is referred to as dispositional trust.[51] Dispositional trust refers to the propensity of some individuals to "trust first and ask questions later." Thus, in a highly trusting society, one could expect that any certification mark would be accepted as worthy of respect until a failure occurs. Dispositional trust is highly contextual. For example, people in the United States may be highly trusting,[52] but they do not place the same trust in used-car salesmen as they do in physicians.[53] In the case of nanotechnology, unfortunately, it seems clear that both nanotechnology companies and the entities that

51. *See generally* Anthony M. Evans and William Revelle, *Survey And Behavioral Measurements Of Interpersonal Trust*, 42 J. RES. PERSONALITY 1585, 1585-93 (2008).

52. Although not uncontroversial, most studies reveal that Americans are more trusting than many other cultures. *See, e.g.*, FRANCIS FUKAYAMA, TRUST: THE SOCIAL VIRTUES AND THE CREATION OF PROSPERITY (1996); Paul Zak & Stephen Knack, *Trust and Growth*, 111 ECON. J. 295 (2001); Jan Delhey & Kenneth Newton, *Predicting Cross-National Levels of Social Trust: Global Pattern or Nordic Exceptionalism?*, 21 EUR. SOCIO. REV. 311 (2005).

53. Many of the trust-related themes of this paper were developed in an unpublished paper by one of the authors, Douglas J. Sylvester, *Trust, E-Commerce, and Privacy*.

regulate them are looked upon more as used-car salesmen than physicians.[54]

A related concept is situational trust,[55] which refers to trust that is given under specific circumstances.[56] Situational trust is often formed through repeated, successful interactions in a given setting. Think, for example, of hospitals. If an individual from Arizona, traveling in Massachusetts, is injured and in need of medical attention, she will in most cases go to a hospital she has never been to before and will subject herself to risk of harm from doctors she has never met. This is situational trust[57] because the individual is willing to trust that a hospital in the United States is a place where good care will be provided. Unlike dispositional trust, situational trust is based on personal experience with a given situation, supporting the view that "uncertainty and risk are reduced with experience."[58] In short, where an individual finds that "favorable conditions are in place that are conducive to situational success in an endeavor or aspect" of the person's life, that individual will trust in the situation as she has before.[59]

Situational trust does not, however, extend to new avenues of exchange or unfamiliar circumstances. Imagine, for example, the same scenario, except that now our injured party is visiting a developing country. It is far less likely that the she will trust a hospital in that country to the same extent she would one in the United States.[60] Similarly, one might trust a used-car salesman to sell you a car, but not to perform a surgical operation. Thus,

54. *See* Sylvester et al., *supra* note 2 (discussing mistrust of government agencies and technology industry).

55. *See, e.g.*, M.R. Dibben et al., Commentary, *Situational Trust And Co-Operative Partnerships Between Physicians And Their Patients: A Theoretical Explanation Transferable From Business Practice*, 93 QJM 55 (2000); D. Harrison McKnight & Norman L. Chervany, *What Trust Means in E-Commerce Customar Relationships: An Interdisciplinary Conceptual Typology*, 6 INT'L J. ELECTRONIC COM. 35, 45 (2002).

56. *See generally* J.D. Lewis & Andrew Weigert, *Trust as a Social Reality*, 63 SOC. FORCES 967 (1985); Peter Smith Ring & Andrew H. van de Ven, *Developmental Processes of Cooperative Interorganizational Relationships*, 19 ACAD. MGMT. REV. 90 (1994).

57. This assumes, of course, that the individual is not so severely injured that she would accept aid from anyone, or that her injury has not affected her capacity.

58. *See* Tamar Frankel, *Trusting and Non-Trusting on the Internet*, 81 B.U. L. REV. 457, 464 (2001).

59. McKnight & Chervany, *supra* note 55, at 45.

60. We make no claims about the validity of this view. It merely shows that trust reduces transaction costs in familiar situations, but that mistrust is often the initial reaction in unfamiliar settings, and that mistrust must be overcome using other means.

even previously trusted actors can find themselves mistrusted when they enter into new arrangements or fields. Given the novelty and unfamiliarity of nanotechnology, one may expect that even consumers who have trusted a company's ability to manufacture safe and reliable products will be less likely to extend dispositional trust towards that manufacturer's nanotechnology products.

2. Reputational Trust

Dispositional and situational trust are psychological states that reflect a consumer's state of mind toward particular settings. More familiarly, trust is often understood as a belief about the reputation of a potential partner. Reputational trust[61] is the most common way a consumer gains sufficient security to engage in trusting behavior, such as purchasing a product that is unfamiliar and unproven in the marketplace merely because it is sold by a trusted company. Reputational trust obtains where a consumer has specific information about the company's reputation for relevant behaviors, for example, for manufacturing safe and beneficial products. It is the *manufacturer's* reputation in the view of the consumer that matters.

There are two main ways in which a consumer may gain the necessary information, each with its benefits and pitfalls. The first is to personally acquire the information by interacting with a company. Thus, if a consumer has previously purchased a product from a company and found that product safe and useful, the willingness of that consumer to trust that company in the future, without close scrutiny, rises. Where the company has faithfully fulfilled promises in the past by producing safe and beneficial products, and where the current transaction is sufficiently similar to past interactions (situational trust), the consumer can determine whether to engage in trusting behaviors. A secondary path for building reputation is community knowledge, like that created by eBay's Feedback mechanism or the Better Business Bureau's consumer reports.[62]

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61. *See* Sylvester et al., *supra* note 2.

62. Given the focus of this article on the trustworthiness of a certification mark, these two avenues to the creation of reputational trust are most relevant. In other contexts, it is widely believed that signaling is the most important way by which a company conveys its trustworthiness to potential consumers. *See, e.g.,* Gertrud M. Fremling & Richard A. Posner, *Market Signaling of Personal Characteristics* (Univ. of Chi. Law Sch., John M. Olin Law & Econ. Working Paper No. 87, 1999), *available at* http://ssrn.com/abstract=193490; Helen Nissenbaum, *Securing Trust Online: Wis-*

Once gained, personal knowledge is often weighted more heavily than other forms of knowledge, allowing trusting behaviors to take place in more risky situations. "[T]here is something about the quality of deriving information first-hand that makes personal relations a key basis of confidence: 'one trusts one's own information best—it is richer, more detailed, and known to be accurate' . . . plus such information is 'cheap'."[63] Given consumers' unfamiliarity with nanotechnology, it seems unlikely that personal knowledge of past products will easily be transferred to a new and potentially dangerous situation like the purchase of a nanotechnology product. In addition, many of the companies that currently sell nanotechnology are not household names, or—as in the case of large chemical companies—are not associated with safe and effective products. Although reputational trust of nanotechnology producers may be gained over time, it is unlikely to be a source of trusting behaviors at the outset.

3. Institutional or System Trust

Institutional or system trust is "the belief that proper impersonal structures are in place to enable one to anticipate a successful future endeavor."[64] This form of trust may come into play where the consumer does not really trust the company or product in question. Instead, the consumer trusts that if the company does not meet certain standards, it will be punished or coerced through impersonal structures. These structures generally take one or both of two forms: (i) legal structures; or (ii) community enforcement. In creating a nano certification mark, it is essential to create trust in the mark itself, so the question is whether any external structures can promote such trust.

The most obvious candidate is law. Where individuals or other entities lack trust in one another, legal rules that enforce

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dom or Oxymoron?, 81 B.U. L. REV. 635, 644 (2001); Gordon L. Patzer, *Source Credibility as a Function of Communicator Physical Attractiveness*, 11 J. Bus. Res. 229 (1983); Chrysanthos Dellarocas, *Building Trust Online: The Design of Reliable Reputation Reporting: Mechanisms for Online Trading Communities* (MIT Sloan Working Paper No. 4180-01, 2001), *available at* http://ssrn.com/abstract=289967.

63. Marek Korczynski, *The Political Economy of Trust*, 37 J. MGMT. STUD. 1, 5 (2000) (quoting Mark Granovetter, *Economic Action and Social Structure: The Problem of Embeddedness*, 91 AM. J. SOC. 481, 490 (1985)).

64. *See* Cristiano Castelfranchi et al., *Trust In Information Sources as a Source For Trust: A Fuzzy Approach*, 382 PROC. 2D INT'L JOINT CONF. AUTONOMOUS AGENTS & MULTIAGENT SYS. 89 (2003), *available at* http://portal.acm.org (select "Search: The ACM Digital Library"; then search for article title; then follow article hyperlink) (last visited Oct. 1, 2009).

promises allow one party to act in trusting ways toward others.[65] Legal structures include safeguards, such as regulations, guarantees and rules, mandating the enforceability of contracts.[66] These structures have effect by shifting defection costs from promisee to promisor or, as in the case of nanotechnology products, from consumer to producer.[67] For obvious reasons, "trust and trustworthiness can be promoted through the use of explicit contracts, which involve monitoring and either the payment of incentives or provisions for third-party enforcement."[68] Trust is promoted by reducing the burdens placed on consumers through both "preventive regulation . . . before the fact, and compensation as well as punishing violators, after the fact."[69] Trustworthiness is equally promoted because the law both: (i) punishes defectors; and (ii) elevates promise-keepers economically *and* reputationally in comparison to violators.[70]

In the case of a certification mark, the principal role for law is to punish any firm that obtains a certification by fraud—either by submitting fraudulent data to the certifier or by placing the mark on a noncertified product. Such enforcement may promote some level of trust in the mark's ability to identify companies that have truthfully earned it, but enforcement alone cannot create trust in

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65. Note that trust does not actually exist between the parties; the trust is in the system—that it will punish defectors and enforce promises.

66. "Contract enforceability is necessary for any exchange but the necessity of enforcement is particularly important in exchange characterized by separation between the *quid* and the *quo*. In the absence of appropriate institutions, the best a borrower, for example, can do after obtaining a loan is to not repay his debt. Expecting such behavior *ex post*, a borrower would not lend *ex ante*. Similarly, a merchant who is paid to deliver goods in the future will find it optimal to retain possession of these goods, implying that the buyer would not be willing to pay *ex ante*. Hence, exchange characterized by separation over time and space between the *quid* and the *quo* requires contract enforcement institutions that enable the transacting parties to *ex ante* commit to carry out their contractual obligations *ex post*." Avner Greif, *On the Social Foundations and Historical Development of Institutions that Facilitate Impersonal Exchange: From the Community Responsibility System to Individual Legal Responsibility in Pre-modern Europe* 7 (Stan. U. Dept. Econ., Center for Econ. Stud. & Ifo Inst. for Econ. Res., Working Paper No. 97-016, 1997) [hereinafter *Social Foundations*], *available at* http://ssrn.com/abstract=47178 (last visited Oct. 1, 2009). *See also* Avner Greif, *Reputation and Coalitions in Medieval Trade: Evidence on the Maghribi Traders*, 49 J. ECON. HIST. 857 (1989).

67. Creation of "explicit and binding contract, enforced by a third party, requiring participants" to keep their promises. Harvey S. James Jr., *The Trust Paradox: A Survey of Economic Inquiries Into the Nature of Trust and Trustworthiness,* 47 J. ECON. BEHAV. & ORG. 291 (2002).

68. Greif, *Social Foundations, supra* note 66, at 11.

69. *See* Frankel, *supra* note 58, at 474.

70. *Id.*

the mark. The next Part outlines one final way trust can be engendered, one especially relevant for a certification scheme.

4. Associational Trust

The final method of trust-building involves the placing of confidence, not in the reputation or assurances of the company or other actor that seeks trust, but in that of a third party or intermediary that is trusted. Where the potential consumer has a high degree of pre-existing trust in the third party and a sufficient relationship with it, the consumer's security is embedded in that nexus, making trusting behaviors easier to establish. Here "the production of trust is a *transfer* of trust from the [intermediary] to the [manufacturer] where the amount of transference is proportional to the perceived trustworthiness of the [intermediary]."[71]

Intermediaries may be independent private organizations, the government, family members, friends or colleagues. Although it is not necessary for such an intermediary to explicitly vouch for the manufacturer, which would resemble the community knowledge model, intermediaries often play the implied role of advisor or guarantor. For most certification systems, trust is most easily, quickly and effectively garnered by associational means. In other words, the most effective certification system is based on the certifying organization's ability to convey to the public that its reputation stands behind the product. In short, the consumer trusts the certifier, rather than the product or manufacturer.

5. Trust and Certification Marks: Examples and Implications

Consider the Good Housekeeping Seal of Approval. Among its followers, this certification scheme is clearly viewed as a trusted source for recommendations about safe and effective products. Consumers who place trust in Good Housekeeping automatically believe that goods carrying its seal of approval are trustworthy. This associational trust is important for understanding the operation of certification systems. Note, for example, that when the Seal of Approval is placed on a product, consumers are seldom aware of the reasons. Good Housekeeping does

71. Jonathan W. Palmer et al., *The Role of Intermediaries in the Development of Trust on the WWW: The Use and Prominence of Trusted Third Parties and Privacy Statements*, 5 J. COMPUTER-MEDIATED COMM. (2000) (online journal available at http://jcmc.indiana.edu/vol5/issue3/palmer.html) (last visited Oct. 1, 2009).

not provide rigorous testing guidelines, nor does it spend time explaining to consumers exactly why one product is given the Seal while another is not. It could be, hypothetically, that products are granted the Seal as a result of closed-door payments.[72] The key is that consumers must trust the party that is vouching for the products.

This level of trust is usually hard-won yet easily lost. Consider, for example, the TRUSTe certification mark rolled out in the early 2000s. This mark certified that participating e-commerce companies employed adequate privacy protections for consumer data.[73] Many readers are probably unaware of TRUSTe's existence, but a scant 10 years ago, this scheme was hailed as a market-based solution to consumers' deepening concerns about online privacy.[74] The TRUSTe mark was awarded based on compliance with a set of "reasonable privacy practices."[75] Companies were allowed to self-certify compliance; after payment of a fee, they were then authorized to proudly display the TRUSTe mark. The mark was widely adopted and appeared on nearly every major e-commerce company website; still today it appears on more than 2000 sites. Yet few consumers are aware of its existence, and even fewer seem reassured about privacy issues by the appearance of the TRUSTe mark.

The reason for TRUSTe's failure was simple: its mark, intended to engender associational trust for companies that earned (or paid for) it, was present on the websites of the most notorious privacy violators.[76] As a result, consumers quickly came to view trustmarks themselves as untrustworthy. One survey purported to show that websites displaying the TRUSTe mark were 50 percent more likely to violate privacy norms than those that did not![77] As one commentator notes, trustmarks have had "questionable success because some businesses that carried [them] did not live up to the reasonable expectations of the consumers. [As a result] [c]onsumers reached the conclusion that [these

72. We are certainly *not* saying that this occurs, merely that whether it occurs or not does not seem to concern most consumers. Of course, if it became known that such activities did underlie certification, then trust could be eroded.

73. For a discussion of the pros and cons of TRUSTe as well as consumer privacy concerns, see Sylvester et al., *supra* note 2.

74. *Id.*

75. *Id.*

76. *See supra* Section II and accompanying text.

77. Benjamin Edelman, *Coupons.com and TRUSTe: Lots of Talk, Too Little Action*, March 20, 2008, http://www.benedelman.org/news/031808-1.html.

trustmarks] did not sufficiently monitor, enforce, or inform about, the promises" they were intended to enforce.[78] Without trust in the intermediary, there can be no associational value to the use of its marks. This is the problem that faces any certification program: how to create an effective intermediary capable of fostering associational trust.

In the case of nanotechnology, a new certification mark will not be able to engender trust based on consumers' past experience, the reputation of manufacturers, or the imposition of uncontroversial legal requirements for determining safety. The certification scheme cannot and should not be an onerous legal apparatus for determining safety and efficacy, like the FDA drug approval process.[79] As a result, it seems unlikely that a new mark will automatically gain trust among skeptical consumers. The best hope for garnering trust is to have an organization consumers already trust stand behind the mark. Just as Good Housekeeping can immediately convey that a product is worthy of purchase because it is Good without further review by consumers, consumers must place similar trust in the intermediary for nano certification.

V.
DESIGNING AND IMPLEMENTING A NANOTECHNOLOGY CERTIFICATION PROGRAM

For reasons discussed above and in other fora,[80] it seems unlikely that an industry-sponsored certification system would gain sufficient associational trust to make the scheme a success, at least in a reasonable timeframe. Indeed, given the goals of this proposal, only one intermediary seems appropriate: an agency of the federal government. Evidence suggests that American consumers trust government agencies more than they do industry.[81] In addition, while consumers may not trust agencies to regulate perfectly, they do trust them to police industry more than they trust nongovernment agents.

We recognize, of course, that government agencies are not without problems as models of associational trust. In particular, numerous studies reveal that consumer trust in agencies tasked

78. Frankel, *supra* note 58, at 474.

79. Unless, of course, it is a new drug or delivery device to which traditional FDA mechanisms would apply.

80. Sylvester et al., *supra* note 2.

81. *Id.*

with regulating technology has significantly eroded in recent years. However, health and safety agencies, such as the FDA, maintain some of the highest public trust ratings.[82] This decline in public trust stems from complex factors that may not be easily overcome.[83] Thus, although a government agency is in principle the best choice, it is likely that none of the relevant agencies are sufficiently trusted by American consumers to engender trusting behaviors without additional assurance. A "trust us" approach will not be enough.

Our proposal must therefore combine associational trust with other sources of trust. Some agency should be empowered to punish companies that do not comply with certification requirements or fraudulently display the mark (institutional trust). In addition, the certification process should be sufficiently transparent to give consumers the opportunity to learn how products were granted certification (reputational trust).[84] The remainder of this Part lays out some tentative thoughts about mechanisms through which a nano certification system could engender trust.

A. *Requirements of a Nano Safety Testing Certification Program*

Because government agencies cannot by themselves generate sufficient associational trust, the certification process itself must provide substantial indicators of the trustworthiness of certified products. To achieve this goal, a nano safety certification system might require four sets of actions by firms seeking certification of products: (i) disclosure and reporting of product data; (ii) pre-market safety testing; (iii) implementation of risk management measures; and (iv) post-market surveillance.

1. Disclosure and Reporting

A company seeking certification for one of its products would be required to report to the supervising government agency basic data on product characteristics, intended applications, and any available risk data. Rather than recreate the wheel, these report-

82. *See, e.g.*, Report, Pew Research Center for the People and the Press, *Performance and Purpose; Constituents Rate Government Agencies*, April 12, 2000, *available at* http://people-press.org/report/?pageid=225 (last viewed Oct. 3, 2009); Sylvester et al., *supra* note 2.

83. *See* Sylvester et al., *supra* note 2.

84. And, of course, rely on other intermediaries to engage in this fact-finding for them.

ing requirements could parallel those under the Basic Program of the EPA's NMSP. One significant difference, however, would be that a participating company could not cordon off reported data as confidential business information (CBI). Because a central purpose of the voluntary certification program is to build public confidence, full public disclosure is required to promote public trust. A firm could elect to obtain certification for only a subset of its nano products, but the certification would apply only to those products for which it has qualified. In other words, certification would apply on a product-by-product rather than manufacturer-by-manufacturer or facility-by-facility basis. This approach would greatly enhance transparency and the possibility of reputational trust.

To be sure, companies would presumably not participate in the program to the extent it requires disclosure of CBI or to the extent internal safety testing reveals significant risks. The transparency requirement would thus limit the number of products that are certified, while encouraging firms to seek certification for uncontroversial and perfectly safe products. One would expect the majority of early certifications to be uncontroversial. This would greatly reduce the likelihood that a certified product is later found to be harmful (hopefully avoiding the difficulties of TRUSTe). This is a useful result: consumers will find, at the precise moment when trust in the new mark is most precarious, that the certified goods they purchase are in fact safe and effective. This will enhance the trustworthiness of the mark, in turn creating increased value for industry participants and potentially increasing pressure for firms to participate, as products that do not display the mark may be seen as unsafe. In this way, requiring transparency can be viewed as an early stage value that outweighs the potential cost of reducing industry participation.

2. Pre-market Toxicity Testing

Because the certification mark is related to safety, it makes sense to require safety testing in order to obtain it. Yet there are no clear or proven toxicity tests capable of ensuring complete safety. Moreover, to require onerous testing would unduly impede participation in the program. As a result, this Article proposes that a nano product manufacturer be required, as a condition for certification, to conduct at least one screening toxicological assay from a prescribed list of approved tests. This could be a sub-chronic inhalation, drinking water, or dermal

animal study, with the route of exposure matching the most likely route of human exposure from the product's life cycle. This is similar to the sub-chronic inhalation study that the EPA requires for some carbon nanotube products subject to TSCA pre-manufacturing notices (PMNs). If the initial screening study produced results of concern, the supervising agency might require additional tests in order to obtain certification. Of course, it would be necessary to specify clearly what types of results in the initial screening assay would require follow-up testing and what those subsequent tests would entail. The tiered testing batteries under the Organisation for Economic Co-operation and Development (OECD) Screening Information DataSets (SIDS) program[85] or the EPA's high production volume (HPV) chemical testing program[86] could be used as models for designing a tiered testing scheme.

One issue that arises from the combination of safety testing and disclosure requirements is that companies whose testing produces questionable, as opposed to clearly adverse, results may decide not to submit the product in question for certification. This could be an impediment to the early success of the scheme: if many products are withheld as a result of inconclusive or uncertain results, the mark will suffer from limited exposure. However, as the mark gains prestige and its absence comes to suggest that a product is not safe, it should increase pressure on companies to engage in premarket safety testing.

3. Risk Management Practices

The third requirement for obtaining certification would be the implementation of specific risk management practices by the product manufacturer. The nature of the required practices would vary based on an individual product's exposure and risk profile and other relevant characteristics. As a result, those practices would have to be agreed upon by the manufacturer and supervising agency on a case-by-case basis, using some standardized risk management protocols as templates. Written guidance on risk management practices should be developed to

85. *See Chapter 2: SIDS, the SIDS Plan and the SIDS Dossier, in* OECD MANUAL FOR INVESTIGATION OF HPV CHEMICALS (last updated Aug. 2006), *available at* http://www.oecd.org/dataoecd/13/18/36045056.pdf (last visited Oct. 4, 2009).

86. *See* U.S. EPA, *About HPV Chemical Hazard Characterizations* (last updated September 29, 2008), http://www.epa.gov/hpvis/abouthc.htm (last visited Oct. 4, 2009).

provide consistency and predictability. The risk management procedures contained in the DuPont-ED Nano Risk Framework provide a useful model. Occupational exposure monitoring and appropriate work practices are two key provisions that should be included in all risk management plans. In addition, risk management practices should be made publicly available in order to increase trust through transparency.

4. Post-market Surveillance

Given the uncertainties and costs involved, premarket testing cannot be relied upon to identify all significant risks. Accordingly, it would be essential to supplement limited premarket testing and risk management measures with post-marketing surveillance, so that any residual risks or harms could be detected as rapidly as possible. The recent amendments to the Food, Drug and Cosmetic Act to strengthen post-market surveillance of pharmaceuticals is a recognition of the importance of such measures for comprehensive and effective risk management.[87] Nevertheless, design and implementation of a cost-effective post-market surveillance system is difficult, due in large part to the "noise" inherent in studying complex and diverse real-world situations.

A post-surveillance system should include both passive and active components. The passive component would require firms to provide a convenient process by which consumers, workers or others who claim they have been harmed by a product can report that information to the manufacturer. The active component would require firms to sponsor studies of people exposed to the product to look for problems or trends in health impacts. The supervising agency could enforce the surveillance requirement by ordering removal of the mark. It could also sanction firms that deliberately hide information or engage in willful ignorance (system trust combined with associational trust).

B. *Implementation of the Certification Program*

While certification could conceivably be administered by an independent private entity (and there are some arguments in favor of this approach), a federal government program would be preferable. A federal government program would not only capitalize

87. Food and Drug Administration Amendments Act of 2007, Public L. No. 110-85, § 915, 121 Stat. 823 (2007).

on the public's trust, but also satisfy public demands for government action and help restore trust in government oversight of emerging technologies. In addition, a government agency could utilize its existing regulatory resources and expertise to administer the certification program. Finally, government supervision would have the advantage of facilitating coordination between the certification program and other agency requirements, as well any transition between the certification scheme and any regulatory program designed to take its place.

The next question addresses which agency should administer the program. Nanotechnology products are regulated by a variety of federal agencies under many different statutes, depending on the categorization of the product as a drug, medical device, cosmetic, food, pesticide, industrial chemical or consumer product. One option might be to begin with a narrow certification scheme, available for only one category of products and administered by the relevant agency, e.g., a scheme for chemicals supervised by the EPA, a scheme for cosmetics supervised by the FDA, or a scheme for consumer products supervised by the Consumer Product Safety Commission (CPSC). A second option would be to initiate a more complex program covering a range of product categories, each supervised in a coordinated manner by the appropriate agency. The final option would be to entrust supervision of a comprehensive scheme to a single new agency, perhaps situated within the National Nanotechnology Initiative. However, this approach would not achieve the goal of aligning the certification program with the expertise and regulatory authority of the supervising agency. As between the first two options, then, a comprehensive program would be more useful and robust, so long as the coordination required of the supervising agencies is manageable.

C. *Limitations and Challenges of the Certification Program*

A voluntary certification program would not be without challenges. To be meaningful, the requirements would have to be substantial, and the associated costs of obtaining certification might then be substantial as well, although every effort should be made to minimize costs so as to maximize participation. These costs, as well as the incentive for many nano manufacturers to avoid publicity by remaining below the public radar, would prevent many companies, especially small firms, from participating in the scheme. However, if some uncertified nano products de-

velop real or perceived risk problems, the appeal of obtaining certification to distinguish one's product from troubled products would increase.

The other major potential limitation of the program may relate to its effectiveness. Would the actions necessary to obtain certification actually identify and control risks to an adequate degree? What would happen if the first nano products to cause demonstrated harm have received certification? Such an outcome could completely undermine the credibility and appeal of the program. However, any oversight system, including the most rigorous traditional regulatory program, inherently runs the risk of such a failure, and that has never been a compelling reason not to attempt any form of oversight. What remains within the control of the program's designers is to make the certification requirements as effective as possible, thus reducing the risk of system failure.

VI.
CONCLUSION

A voluntary, government supervised safety testing certification program can help fill the gap in government oversight of nanotechnology until sufficient data are available to support traditional regulation. As Bowman and Hodge have recently argued, no single soft law program will be capable of completely filling the oversight gap; rather, a menu of soft law options and initiatives will be necessary.[88] The voluntary certification scheme proposed in this Article would be a useful addition to this menu of choices.

88. Bowman & Hodge, *supra* note 29, at 479.