Soft Law and Nanotechnology:
A Functional Perspective

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Abstract

Whether and how to regulate nanotechnology is debated widely. While *ad hoc* bits of regulation shuffle forward, a comprehensive response eludes us. Some advocate using new governance approaches, seeking to transform regulation from an agency-centric exercise to a collaborative undertaking by actors from multiple segments of society. One central aspect of this new governance is reliance upon "soft law" approaches to regulation. In the area of nanotechnology particularly, numerous commentators have proposed a variety of soft law mechanisms. Yet the concept of soft law is fuzzy in terms of its definition, specific functions and optimal uses. This article addresses that fuzziness in two ways. First, it provides a definition of soft law informed by the four functions soft law serves: the precursive, normative, directive and complementary functions. Second, it comments upon the usefulness of soft law with respect to each of those functions in the specific context of nanotechnology.

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Introduction. Nanotechnology is the latest challenge to our capacity for balancing technological progress with protection of human health and the environment. The scenario is a familiar one: a rapidly advancing technology offers tremendous potential for social good but presents substantial uncertainty regarding health and environmental harms. Tetra ethyl lead, nuclear power, biotechnology, cellular telephones, nanotechnology, synthetic biology; the cycle repeats. Even as engineers, chemists and others generate newer and more complex forms and uses of nanoparticles and nanostructures, toxicologists, environmental scientists and others struggle to develop the analytical tools, methods and models needed to understand and address potential hazards. In the face of this dynamic and uncertain environment, debates over whether and how to regulate nanotechnology continue in the literature and at conferences, meeting and hearings. *Ad hoc* bits of regulation shuffle forward, but a comprehensive response eludes us.

This policy debate coincides with renewed interest in regulatory reform. The conventional paradigm of prescriptive regulation—promulgated by a government agency following formal notice and comment procedures and followed by judicial review—has been under sustained attack from its very beginnings. But the classic market-based challengers of the 1980's and 1990's have been replaced by new governance approaches seeking to transform regulation from a agency-centric exercise in setting incentives to a collaborative undertaking by actors from multiple segments of society.[2] One central aspect of the new governance is reliance upon "soft law" approaches to regulation. In the area of nanotechnology particularly, numerous commentators have proposed a variety of soft law mechanisms. Yet the concept of soft law is fuzzy in terms of its definition, specific functions and optimal uses.[3] This article addresses that fuzziness in two ways. First, it provides a definition of soft law informed by the four functions soft law serves: the precursive, normative, directive and complementary functions. Second, it comments upon the usefulness of soft law with respect to each of those functions in the specific context of nanotechnology.

As with most regulatory concepts, soft law has no single standard definition. Those tackling the task of defining the term typically emphasize two features of soft law: it establishes standards of behavior and it is not legally binding.[4] Just how specific those standards of behavior are can vary considerably. Likewise, while formal legal sanctions are absent, a variety of other coercive tools may be deployed to secure compliance. Blurring the concept further, soft law can have multiple sources (including businesses, non-governmental organizations, governments, and various combinations of the three) and numerous forms (such as industry codes of conduct, product labeling regimes, or information clearinghouses.) Indeed, as some commentators note, it is more helpful to

[2] *See* Orley Lobel, *The Renew Deal: The Fall of Regulation and the Rise of Governance in Contemporary Legal Thought*, 89 Minn. L. Rev. 342 (2004) (providing a synthesis and evaluation of the new governance literature)..

[3] Timothy F. Malloy, Nanotechnology Regulation: A Study in Claims Making, 5 *ACSNano* 5 (2011).

[4] By "legally binding," commentators appear to be focusing primarily on direct government enforcement of rules either generated or embraced by the government. Presumably government enforcement of a contractual obligation through a damage award or injunctive relief would not prevent the underlying contract from falling within the scope of soft law.

focus on the relative "softness" of particular forms of governance rather than placing them in the dichotomous categories of soft or hard law.[5] That said, absent some organizing principle, assessing the usefulness of these diverse forms of softer law will be a largely *ad hoc* exercise. Focusing on the specific functions of soft law regimes rather than their form offers a more consistent, generally applicable basis for evaluation.

While soft law's origins lie primarily in international commercial law[6] and public international law,[7] it has been discussed and applied in a variety of settings including congressional practices,[8] securities law,[9] health care reform,[10] and of course environmental law. Yet across these diverse settings, one can identify four common functions ascribed to soft law by commentators and policymakers: the precursive, normative, directive, and complementary functions. A particular soft law regime may serve multiple functions at once, or shift in function over time either organically or by design. The following sections describe each of the four functions and their interconnections, respectively, and provide examples from the world of nanotechnology and beyond. Each section also comments briefly upon the potential for various soft law instruments to fulfill these respective functions in the nanotechnology context.

The Precursive Function: Laying the Groundwork. The precursive function refers to the use of soft law to lay the groundwork for later hard law instruments. This often takes the form of voluntary programs aimed at collecting information needed to design conventional hard law programs.[11] A notable example is EPA's Nanoscale Materials Stewardship Program, a voluntary data collection program through which EPA encouraged companies to collect and submit hazard, exposure and risk management information. One of the primary goals of the program was to develop "a firmer scientific foundation for regulatory decisions by encouraging the development of key scientific information and appropriate risk management practices for nanoscale chemical substances."[12] The Voluntary Reporting Scheme for Engineered Nanoscale Materials run by the UK's Department of Environment, Food and Rural Affairs (DEFRA) is another

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[5]Margaret Chon, *Global Intellectual Property Governance (Under Construction)*, 12 Theoretical Inquiries in Law 349, 351 (2011) describing a ("regulatory matrix along a spectrum, rather than a binary between soft (often ignored) and hard (often over-emphasized"); Lobel, *supra* n. 2, at 389-90..

[6]It can be traced back dating back to the *lex mercatoria* of the Middle Ages through which merchants obtained swift, pragmatic justice unavailable in state courts. *See* Anna Di Robilant, *Genealogies of Soft Law*, 54 American Journal of Comparative Law 499 (2006)

[7] Some commentators ascribe authorship of the term to Lord McNair, although there is some dispute. *See* Jean d'Aspremont, *Softness in International Law: A Self-Serving Quest for New Legal Material*, 19 European J. Intl. L. 1075, 1081 (2008).

[8] Jacob Gerson and Eric Posner, *Soft Law: Lessons F\from Congressional Practice*, 61 Stanford Law Review 573 (2008).

[9] Roberta S. Karmel and Claire R. Kelly, *The Hardening of Soft Law in Securities Regulation*, 34 Brooklyn Journal of International Law 883 (2009).

[10] Louise G. Trubek, *New Governance and Soft Law in Health Care Reform*, 3 Indiana Health Law Review 137 (2006).

[11] Here the "standard of behavior" established by the soft law program would be the collection and submission of information, akin to mandatory information submission programs such as the Toxics Release Inventory program or the now-defunct Inventory Update Reporting rule under the Toxics Substances Control Act.

[12] 72 Fed. Reg. 38079, 38081 (July 12, 2007).

example of this type of program. DEFRA justified that program as providing assistance to the government in developing "appropriate controls in respect of any risks to the environment and human health from free engineered nanoscale materials... in the shortest time giving a predictable regulatory environment for all."[13]

Precursive soft law programs may also focus on taking potential regulatory approaches, methodologies or standards for a "test drive," hoping to inform or improve the design of the later mandatory program. At least in part, the DuPont-Environmental Defense Nano Risk Framework was intended to serve this purpose. That framework sets out a risk evaluation and management process for businesses using nanomaterials for industrial, chemical, manufacturing, and consumer applications. The Environmental Defense—DuPont Nano Partnership identified three goals of the framework: promoting responsible development of nanotechnology products, facilitating public acceptance, and supporting "the formulation of a practical model for reasonable government policy on nanotechnology safety."[14] Several activities of the National Institute for Occupational Health and Safety likewise fall within this category. Through voluntary partnerships with industry members and others, NIOSH has cultivated data and expertise needed to evaluate and manage workplace exposures, and used that knowledge to develop generic best practices and particle-specific recommended exposure levels (RELs) and mitigation approaches.[15] While NIOSH develops those practices and REL's in hope of directly influencing industry behavior, its work is also intended to support subsequent regulation by the Occupational Health and safety Administration (OSHA).[16]

Of course any type of soft law can sometimes "harden," such as when a voluntary program is codified into statute or regulation; that does not render all soft law precursive. The precursive function refers to a program designed and implemented with the expectation that it contribute to the development of conventional formal law. As I discuss below, this expectation that can significantly affect how the potential program participants respond to the program, particularly in those cases in which a regulatory agency is actively engaged in the program.

While this article is not intended to be a comprehensive evaluation of the efficacy or implications of soft law, some limited comments along those lines are in order. In the case of the precursive function as it relates to information generation, I start with the generally accepted notion that businesses typically have strong incentives to shield information regarding their operations generally and the health and safety implications of those operations particularly. Indeed, under the incentive structures created by the marketplace and the government policies, businesses may even avoid generating health

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[13] Department of Environment, Food and Rural Affairs, *UK Voluntary Reporting Scheme for Engineered Nanoscale Materials* (2006).

[14] Environmental Defense—DuPont Nano Partnership, NANO Risk Framework 11 (April 2007)

[15] *See* NIOSH, APPROACHES TO SAFE NANOTECHNOLOGY: MANAGING THE HEALTH AND SAFETY CONCERNS ASSOCIATED WITH ENGINEERED NANOMATERIALS, DHHS (NIOSH) Publication No. 2009–125 (2009)(NIOSH Nanotechnology Guidance); NIOSH, *Current Intelligence Bulletin 6:Occupational Exposure to Titanium Dioxide*, DHHS (NIOSH) Publication No. 2011–160 (2011).

[16] NIOSH, STRATEGIC PLAN FOR NIOSH NANOTECHNOLOGY RESEARCH AND GUIDANCE, DHHS 4 (NIOSH) Publication No. 2010–105 (2009); NIOSH, NIOSH Nanotechnology Guidance, *supra* n. 15.

and safety information in the first instance.[17] These effects are compounded by the fact that many firms developing and using nanotechnology are small start-ups lacking resources, technical experience and deeply ingrained focus on environmental, health and safety issues. Given these powerful forces, it is hardly surprising that voluntary information disclosure programs such as EPA's NMSP and DEFRA's voluntary program would produce lackluster results in the dynamic context of a rapidly emerging technology.

That said, two points are worth considering in assessing the value of precursive soft law information gathering. First, as with most things, details are quite important, and it may be that the volume and usefulness of data collected through such programs could be significantly improved by more attention to the specific design of the voluntary program. For example, it appears that NIOSH's approach of individualized site visits coupled with the offer of technical support has been fairly successful in generating useful data. The drawbacks of such an approach are painfully obvious, however; it requires substantial resources to develop information, and covers a fairly small sample of firms. Second, despite the limited substantive value of precursive information collection efforts, they may be a necessary part of the political and bureaucratic build-up to mandatory information disclosure. The history of environmental policy offers many examples of the slow escalation from consultation and voluntary initiatives to the deployment of coercive tools. Given the resource commitment and political capital required to extend formal regulation into new areas, it may be inevitable that regulators will first demonstrate to themselves and to other stakeholders that the softer route was unproductive.

The substantive dimension of precursive soft law may be more productive and valuable, particularly from the perspective of the regulator. Many conventional hard regulations use industrial best practices as the reference point for developing enforceable standards. This is the essence of the so-called "technology-based standard" that permeates our environmental policy. Such an approach necessarily requires some level of technologically mature management practices exist in the industry sectors of interest to the regulator. Soft law approaches can assist in the development and diffusion of those practices among a subset of firms, providing a sufficient empirical basis on which to base regulations. For these purposes, it is not necessary that the practices be used by all or even a majority of firms, only by enough to demonstrate the feasibility and effectiveness of the practices. Accordingly concerns about ensuring industry-wide compliance that arise in a fully-formed regulatory program are substantially less important.

The Normative Function: Leveraging Social Norms. The normative function refers to the soft law program's capacity to support the formation and activation of norms of behavior among the targeted population of businesses. Unlike the precursive function, here the program has the specific substantive goal of affecting the manner in which firms and individuals use and manage nanotechnology. Such programs eschew formal law in

[17] *See* Wendy E. Wagner, *Commons Ignorance: The Failure of Environmental Law to Produce Needed Information on Health and the Environment*, 53 Duke Law Journal 1619, 1625-1710 (2004); Mary L. Lyndon, *Information Economics and Chemical Toxicity: Designing Laws to Produce and Use Data*, 87 Mich. L. Rev. 1795, 1810-1825 (1989)

pursuing that goal, relying instead upon the influence of social norms on behavior. For these purposes, a social norm is behavioral standard shared by a group that operates in the absence of formal legal sanctions. Researchers in social psychology, sociology, law and even economics have demonstrated the powerful role that social norms play in the behavior of individuals in a variety of circumstances, including the business setting. Such norms may be internalized by the individual and require no outside sanctions to secure compliance; feelings of obligation or guilt provide the incentive. Alternatively, social norms may be enforced through social sanctions imposed by other group members.[18] The critical point here is that where meaningful social norms regarding the appropriate health and safety practices exist, no legally enforceable regulation may be required.

Even so, one may still ask the question of whether some form of law—be it soft or hard—can serve to enhance the effect of social norms. One thread of the social norms literature deals with this question, and is particularly relevant to the normative function of soft law. That research identifies three mechanisms by which law can affect social norms: preference-shaping, preference-expression, and preference-informing. In preference shaping, the adoption of a law (and presumably even a soft law) can spread an existing norm or even support the creation of a new norm of behavior. Seat belt laws, pooper scooper ordinances, and smoking bans are examples of laws claimed to have changed social norms about what is appropriate behavior. In preference expression, the reflection of a particular norm in law emboldens individuals already holding that norm to express their dissatisfaction with those who violate the norm.[19] Thus, for example, a non-smoker may chastise someone smoking at the beach.

Preference-informing refers to a law's capacity to activate an existing norm by providing the individual with information. Where a law or regulation that bans or restricts some activity is enacted, it may signal to the population that the government or agency has credible information supporting the need for the intervention.[20] Consider a measure directed at minimizing exposure to secondary smoke. That law informs parents that the government takes the health risks seriously enough to take formal action, and may update the parents' view of the dangers that their smoking poses to children. Their behavior may change, not because the law creates a new norm, but because the information it transmits activates a pre-existing norm against doing harm to others.

There are numerous examples of soft law programs designed in whole or in part to serve the normative function. Two programs discussed above—the DuPont-ED NANO Risk Framework and the NIOSH best management practices guidances—expressly seek to play a normative role. The NANO Risk Framework centers upon preference-shaping, stating that it is designed to "promote responsible development of nanotechnology products."

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[18] Timothy F. Malloy, *Compliance, Regulation and the Firm*, 76 Temp. L. Rev. 451, 465 (2003)

[19] *See* Patricia Funk, *Is there an Expressive Function of Law? An Empirical Analysis of Voting Laws with Symbolic Fines*. 5 Am. L. and Econ. Rev. 135, 136 (2007). One may argue however, that the law does not actually shift preferences among individuals, but simply triggers a different norm of obeying the law. *See* Malloy, *Compliance*, *supra* n. 18, at 467-469.

[20] Dharmapala Dhammika and Richard McAdams, *The Condorcet Jury Theorem and the Expressive Function of Law: A Theory of Informative Law*, 5 American Law and Economics Review 1 (2003).

NIOSH emphasizes both preference-shaping and preference-informing mechanisms. For example, its guidance document for safe practices is explicitly intended to "make recommendations on occupational safety and health best practices in the production and use of nanomaterials" and to "raise awareness of the occupational safety and health issues involved with nanotechnology."[21]

Industry groups and non-governmental organizations, singly and in collaboration, have developed other soft law programs with normative functions. For example, the Swiss Retailer's Organisation (IG DHS), whose membership includes important businesses in Swiss retailing, issued its own voluntary Code of Conduct setting out general principles for retailers, suppliers and manufacturers in handling nanotechnology in consumer products.[22] Likewise, the Responsible Nano Code, the result of collaboration among an investment consulting company, the Royal Society, and the Nanotechnology Industries Association, establishes a set of seven general principles regarding accountability, environmental, health and safety concerns, stakeholder involvement and other issues. That code is meant to "establish a consensus of good practice in the research, production, retail and disposal of products using nanotechnologies and to provide guidance on what organizations can do to demonstrate responsible governance of this dynamic area of technology."[23]

There is little doubt that group norms can have a powerful effect on behavior in the business setting. However, the operation of social norms is a complicated affair. Many factors affect their influence on behavior, including the impact of competing norms, the particular characteristics of the decision environment, and the specificity of the norm itself. For example, where an individual faces competing norms pointing to different courses of action, she will tend to harmonize the two rather than choose one over the other. In such cases, the less specific norm may be interpreted so as to conform with the more particular, competing norm. Such adaptive behavior is even more likely in a rapidly changing, high stress environment in which the individual faces adverse personal consequences.[24] Imagine the scenario in which strict implementation of a somewhat vague Code of Conduct principle regarding worker protection would place a firm's environmental manager in conflict with other firm managers, and significantly delay deployment of a new product. The critical point here is that reliance upon social norms as policy tools is a tricky business, and a cautious dose of skepticism is warranted.

Several other points regarding the normative function are relevant here. First the relationship between business and regulatory agencies is often adversarial, albeit to varying degrees in different industry sectors and contexts. The strategic nature of the firm's interaction with regulatory agencies could undermine the willingness of individuals within the firm to enthusiastically embrace norms proposed by regulatory agencies. Thus, soft law programs spearheaded exclusively or primarily by business organizations or neutral NGOs (or by non-regulatory agencies such as NIOSH) may be

[21] NIOSH Nanotechnology Guidance, *supra* n. 15, at 3.
[22] www.innovationsgesellschaft.ch/media/archive2/publikationen/CoC_Nanotechnologies_english.pdf (visited August 6, 2011).
[23] Insight Investments, *et al.*, *Information on the Responsible Nano Code Initiative* (May 2008).
[24] Malloy, *Compliance*, *supra* n. 18, at 474-75.

more successful at generating a normative influence than government-centric programs. Second, social norms depend heavily upon social sanctions from the relevant group for their influence over individuals within that group. Such sanctions will only occur where group members can observe each others' behavior, and thus depend heavily upon transparency to function. In many soft law programs such transparency is lacking as decisions regarding the management and use of nanotechnology may occur within the shadows of the firm. Third, the power of social norms to affect behavior appears to increase as the size of the group decreases. In a large, diverse community in which interactions among group members are impersonal or infrequent, the power of a social norm can be significantly diluted.[25]

One last note regarding the preference-expressing mechanism of the normative function is of particular interest in the context of firm behavior. A norm articulated by a credible source *outside* the firm can play an important role within the firm. Within the firm, environmental health and safety professionals must battle for attention and resources. Their influence can be enhanced where they can point to external, validating authorities within business and government as support for a particular course of action. In a sense, the normative assertions of soft law programs empower professionals within the firm. However, the non-binding nature of those pronouncements allows others in the firm to discount the importance of the normative principle, undermining the normative statement's impact on the power of the EH&S professional. This brings us to the directive function of soft law approaches.

The Directive Function: Trading Incentives. The directive function refers to those soft law instruments having a quasi-binding nature. Recall that one of the defining features of soft law is that it does not create legally binding obligations. In some situations, however, a soft law program may create opportunities for the firm to make commitments which, if met, give rise to desired benefits. There is, in a sense, a *quid pro quo* under which the participating firm will lose the benefits if it fails to comply with the standards demanded by the soft law program. Unlike soft law programs grounded in the normative function only, here once the firm commits, the soft law programs imposes obligations directly upon the firm.

Certification programs are the quintessential example of the directive function in action. Take the case of certification under ISO 14001, under which a firm obtains a third party certification that it uses an environmental management system complying with the standards set out in ISO 14001. To obtain certification, a facility must demonstrate that it has procedures to identify the environmental aspects of the facility's operations, to ensure proper management of hazardous materials, to engage with interested parties, and to comply with applicable law.[26] For various reasons, a firm may seek an ISO 14001 certification, perhaps to improve performance and reduce waste, to satisfy a customer's demand, or to mollify a shareholder group. Should the facility fail to maintain

[25] *See* Ann E. Carlson, *Recycling Norms*, 89 Cal. L. Rev. 1231, 1233-34 (2001) (discussing differences in operation of social norms as between small, homogenous groups and larger diverse groups).
[26] Charles J. Corbett and David A. Kirsch, International Diffusion of ISO 14000 Certification, 10 Production and Operations Management 327, 329 (2001).

compliance with the ISO 14001 standards, it faces decertification.[27] The Sustainable Forestry Initiative (SFI) likewise provides certification for those firms that demonstrate and maintain compliance with the specific standards of tha program.[28] In the nanotechnology area, the CENARIOS nanotechnology certification program, created by a consulting firm and a technical services firm, serves the directive function.[29] Marchant and his colleagues have proposed a nanotechnology certification program in which firms would receive certification by meeting certain standards regarding disclosure, testing, risk management and surveillance standards.[30]

Of the four soft law functions, the directive function is perhaps the closest in operation to hard law. Although the behavioral standard is not legally enforceable, in theory failure to comply with it carries consequences significant enough to influence the actions of the participating firm. Moreover, for many programs incorporating the directive function, the behavioral standards are more specific than those typically found in soft law instruments grounded in the normative function. Given that specificity and the potential consequences of noncompliance, one would expect that soft law programs embracing the directive function would be more effective than normatively driven programs. One recent meta-analysis of voluntary environmental programs (VEPs) provides some limited support for that expectation, concluding that "participation in certified VEPs is associated with greater improvements in environmental performance than participation in self-monitored VEPs." (Even so, on average the environmental performance of firms participating in certified VEPs was only marginally better than that of firms that did not participate in VEPs at all.[31])

The directive function could also enhance the empowerment of EH&S professionals within a firm. Unlike the situation in which soft law programs rely on the normative function, in directive programs the behavioral standard may carry weight within the firm more akin to that of mandatory legal obligations. If the directive soft law standard is violated, the firm could suffer a clear, meaningful detriment—loss of certification.

As with the percursive function, the specific details of directive approaches can vary a great deal, with potential impacts on program effectiveness. A comparison of ISO 14001 certification and certification under the Sustainable Forestry Initiative (SFI) is a case in point. ISO 14001 certified facilities are not required under that standard to disclose the results of periodic compliance audits. Moreover, decertification for noncompliance with ISO 14001 is relatively rare. In contrast, in the

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[27] Martí Casadesús , *et al.*, *ISO 14001 Diffusion After the Success of the ISO 9001 Model*, 16 Journal of Cleaner Production 1741, 1750 (2008).
[28] Nicole Darnall and Stephen Sides, *Assessing the Performance of Voluntary Environmental Programs: Does Certification Matter*, 36 Policy Studies Journal 95, 111 (2008).
[29] http://www.innovationsgesellschaft.ch/images/publikationen/Factsheet_CENARIOS_english_arial2.pdf (visited August 7, 2011).
[30] Gary E. Marchant, *et al.*, *A New Soft Law Approach to Nanotechnology Oversight: A Voluntary Product Certification Scheme*, 28 UCLA J. Envtl. L. & Pol'y 123 (2010).
[31] Darnall and Sides, *supra* n.28 at 109.

SFI decertification is a commonly used response to noncompliance, and the compliance records of certified firms are publicly disclosed.[32]

The Complementary Function: Integrating Hard and Soft Law. The complementary function links hard law and soft law together. Here soft law serves to assist in the implementation of existing hard law. One widely-used soft law tool used for this purpose is the informal guidance document, issued by an agency to clarify its interpretation of a statute or regulation.[33] Such guidance is typically not legally binding, often promulgated without formal notice and comment. Yet it provides some level of predictability in the implementation of the hard law, and can serve as a focal point for engagement among the agency and interested parties. Likewise, technical assistance programs more generally in the form of training, workshops and site visits are all forms of soft law advancing the complementary function. Such efforts would likewise serve a valuable function with respect to hard law instruments that may be established for nanotechnology in the future.

There is clearly an important role for soft law in the management of nanotechnology. While its substantive role in information generation will likely continue to be marginal, soft law is already playing a constructive role in the eventual development of hard law through efforts such as the DuPont-ED NANO Risk framework and NIOSH's best practices activities. Design issues and inherent limitations of the normative function in this context will likely limit the impact of normatively grounded codes of conduct, while careful designed directive-centered programs may yet serve an important interim role in securing meaningful management of nanotechnology applications.

[32] *Id.* at 111.
[33] Lobel, *supra* n. 2 at 390-91.