Nano Risk Governance: Current Developments and Future Perspectives

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Abstract

As with many new technologies, developing a framework for making risk management decisions for nanotechnology is a challenge. Risk assessment has been proposed as the foundation for many regulatory frameworks for nanomaterials. Although the traditional risk assessment paradigm successfully used by the scientific community since the early 1980s may be generally applicable, its application to nanotechnology requires a significant information base. The authors' experience supporting federal agencies in the United States, Canada, and the European Union—as well as state agencies in Massachusetts and New York and cities such as Berkeley and Cambridge—suggests that nanomaterial regulatory frameworks could be built upon existing regulatory approaches with the addition of a more rigorous and transparent method for integrating technical information and expert judgment. The authors argue that the current focus on studying the amount of risk acceptable for a specific technology or material should be shifted toward comparative assessment of available alternatives, and the use of science and policy to identify alternative nanotechnologies and opportunities for risk reduction and innovation. This approach involves the use of both quantitative and qualitative decision analysis tools, offering roadmaps for assessing different information sources and making policy decisions. Two representative methods presented are the Alternatives Assessment method and the Multi-Criteria Decision Analysis method.

I. Introduction

Scientists and regulators use many experimental tests, computational models, and tools to assess toxicities and risks of chemicals in the environment; however, applying these tools to new substances or materials may be difficult. Traditional risk assessment essentially consists of

comparing measurable exposures associated with specific hazards to existing regulatory benchmarks that correspond to safe exposure levels. Although agencies have tried to apply this traditional risk assessment paradigm to emerging substances, its application to nanomaterials requires dealing with very large uncertainties in basic knowledge, while tools that are currently used for uncertainty analysis (*e.g.*, Monte-Carlo simulations) may not be easily applied. Integrating the heterogeneous and uncertain information in nanomaterial risk management therefore demands a systematic and understandable framework to organize the scarce technical information and required expert judgment.

This article begins with an assessment of trends in nanotechnology development and environmental health and safety ("EHS") data generation. Previous studies by the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars[1] and Hansen and co-authors[2] found that the emergence of nanotechnology products has occurred much faster than the generation of corresponding EHS data. This is partly related to the inherent challenges in the research underpinning EHS data generation for nanomaterials, such as the need for new analytic approaches, the requirement of standards for testing, the adaptation of existing test methods for nanomaterials, and the development of new sampling and monitoring equipment. The ability of regulatory agencies to use EHS data also lags due to resource limitations. Davies[3] and Taylor,[4] for example, estimate that the Environmental Protection Agency ("EPA") and the Food and Drug Administration ("FDA") have funding for about 50% of their workload. Additionally, until fiscal year 2009, the Consumer Product Safety Commission had no nano-specific budget at all. These constraints, coupled with the inherent challenges of the research, all contribute to the existence of a gap between data generation and agencies' ability to perform risk assessment. Our assessment of published papers confirms this trend and highlights the growing gap between nanotechnology development and nanomaterial EHS data generation.

We also discuss approaches for governing nanotechnology development and mitigating risk. The regulatory pyramid approach[5] and its modifications for the field of nanotechnology[6] were used to classify nanomaterial risk governance frameworks reported in the literature. Building on our previous review[7] and discussions at a 2008 NATO Workshop,[8] we summarize several regulatory approaches within the regulatory pyramid framework.

No matter which regulatory tools are implemented, the challenges associated with the acquisition of solid technical information in a rapidly evolving field are likely to persist. We believe that supplementing technical knowledge with formalized expert judgment is required for transparent and justifiable policy decision making. A risk-based governance approach persists as the best regulatory option. However, further development of risk assessment towards integration of decision analysis and other social science approaches may be required to bridge the nanotechnology EHS knowledge gap that will likely widen in the near future. We conclude with an assessment of the strengths and limitations of quantitative (*e.g.*, multi-criteria decision analysis) and qualitative (*e.g.*, alternatives assessment) tools available to support nanomaterial risk assessment with integration of expert judgment.

II. Nanotechnology: Industry Growth and EHS Data Generation

Our literature review of nanotechnology application and EHS data generation trends began with an analysis of the Science Citation Index (SCI) database available through the Web of Science,[9] focusing on the years 1995 though 2008. Figure 1 presents the number of articles published annually resulting from:

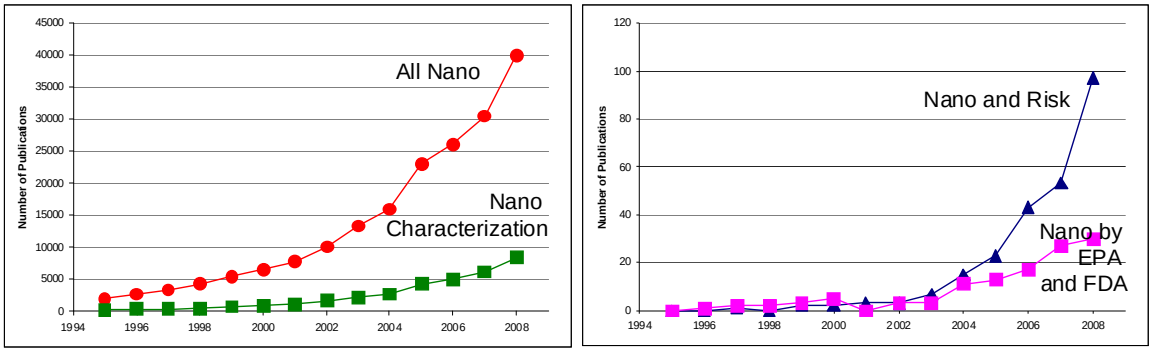
> **A search using the string**: "TS=(quantum dot OR nanostruc* OR nanopartic* OR nanotub* OR fulleren* OR nanomaterial* OR nanofib* OR nanotech* OR nanocryst* OR nanocomposit* OR nanohorn* OR nanowir* OR nanobel* OR nanopor* OR dendrimer* OR nanolith* OR nanoimp* OR nano-imp* OR dip-pen)"[10]

The total number of publications satisfying this search criterion increased from about 2,000 in 1995 to approximately 40,000 in 2008. This data is consistent with data reported by Lux Research for the span 1990-2006.[11]

The above results were then limited by adding the required search term Characteriz*. This search is designed to include publications which include nanomaterial characterization as part of the study. Figure 1 clearly shows that only a fraction of all papers report results of nanomaterial characterization. It is important to note that although the percentage of papers with characterization is steadily increasing (from about 10% in 1995 to over 20% in 2008), this does not mean that characterization of the tested nanomaterials is actually being reported, or that the quality of the characterization is sufficient to permit accurate identification of the hazardous properties of nanomaterials.[12]

Moreover, the number of papers satisfying the original search string that mention risk, as well as the number of papers co-authored by EPA or FDA scientists, was less than 10 through 2003. After this point we observe a rapid increase (from 7 in 2003 to almost 100 in 2008 alone). The number of papers co-authored by the EPA and FDA lags significantly (even though the papers in this category may be not necessarily risk or EHS-related; the agencies are also involved in nanomaterial technology development and publish technology-related papers), highlighting the challenges faced by agencies with tightly constrained funding.

Figure 1: Number of Journal Articles on Nanotechnology Topics by Year in Science Citation Index.



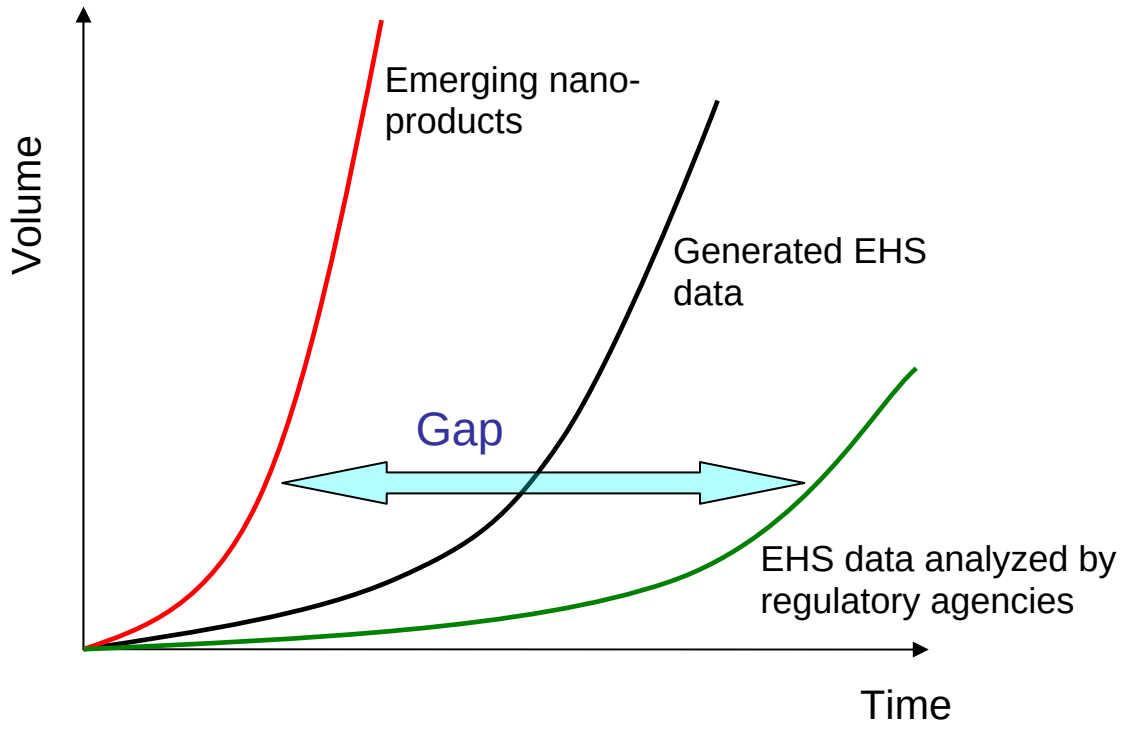
"All Nano" corresponds to all published papers returned by the Science Citation Index search string "TS=(quantum dot OR nanostruc OR nanopartic* OR nanotub* OR fulleren* OR nanomaterial* OR nanofib* OR nanotech* OR nanocryst* OR nanocomposit* OR nanohorn* OR nanowir* OR nanobel* OR nanopor* OR dendrimer* OR nanolith* OR nanoimp* OR nano-imp* OR dip-pen)" with document type = article. "Nano Characterization" and "Nano and Risk" are the subsets of papers returned by the original search string plus the refinements "characteriz*" or "risk." The final plot represents papers co-authored by scientists from FDA and EPA.*

Figure 1 shows that the emergence of nanotechnology products has occurred much faster than the generation of corresponding EHS data (*see* Figure 2). Moreover, there is currently a lag between the time EHS data is available and the time when regulatory agencies use this data. This lag exists because these agencies have limited resources and it takes time for them to adjust risk assessment procedures for application to nanomaterials. The precise extent to which a lag exists is unclear at this stage. A study by the European Environmental Agency ("EEA"), for example, analyzed fourteen cases where a lack of regulatory action following reports of harmful effects had costly and unpredicted consequences on human health and the environment.[13] In many of the cases, the time gap between the first report of harm and effective regulatory action was decades, and in some cases, even over a century.

In 1977, Lawless[14] and his team published the book *Technology and Social Shock*, which presented forty-five cases documenting a wide range of new technologies, including reproduction and genetics, food and medicine, and environmental problems. Lawless describes the episodes of public alarm or strong concern over various technologies and terms these cases "Social Shocks." A common theme identified by Lawless was that "social institutions grapple with the problem" for varying amounts of time while "papers on effects increased in the technical literature."[15] On average, this delay was one or two decades. Although the cases analyzed by the EEA and Lawless might not reflect all emerging technologies, they do represent plausible worst-case scenarios. Given that the "shelf life" of specific new nanotechnology products is likely to be short because of continuous technology improvements, the approaches to regulate these materials should be adjusted to the evolving nature of the field.

Figure 2: Schematic Representation of Emergence of Nanotechnology Products in Comparison to Generated EHS Data.[16]

This diagram is purely qualitative and is meant to illustrate the relative amount of time between the emergence of nano-products, the generation of EHS data, and the analysis of those EHS data by regulatory agencies.



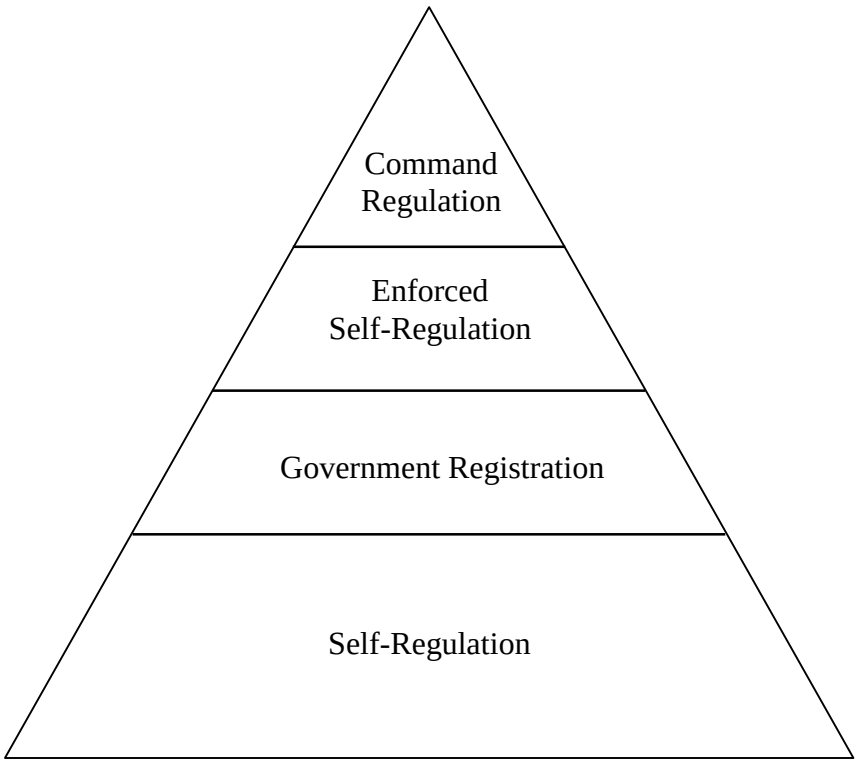
1. Available Regulatory Frameworks

A. Regulatory Pyramid Approach

Our review[17] identified multiple regulatory policy instruments (*e.g.*, voluntary programs, labeling, tax incentives, etc.) available for nanomaterial regulation. Fifteen documents[18] were specifically discussed by the Policy Working Group ("Group") at the 2008 NATO Workshop on Nanomaterial Risk Assessment.[19] The Group used a regulatory pyramid approach and responsive regulations[20] to provide a starting point for classifying these regulatory policy instruments and associated tools. The Group revised the original pyramid during the NATO Workshop (*see* Figure 3).

The underlying idea of responsive regulation is that the degree of regulatory intervention and supervision is based on a dynamic assessment of market conditions and regulated community performance rather than a 'one-size-fits-all' prescription.[21] Self regulation forms the base of the pyramid, representing the bulk of matters that can be handled informally without oversight by regulatory agencies. The regulatory approach becomes more prescriptive and punitive at the top of the pyramid. The regulatory response depends on the effectiveness of individual firms' self-regulation activities, as well as on how successfully they have responded to hazards and risks. Examples of regulatory tools from all levels are presented in the following sections.

Figure 3: Regulatory Pyramid based on Ayers & Braithwaite[22] and modified during discussions at 2008 NATO Workshop.



B. Self-regulation – A Partnership between Environmental Defense and DuPont

The base of the regulatory pyramid is self-regulation. In industry, one example is the Nano Risk Framework which was jointly released in early 2007 by Environmental Defense ("ED") and the DuPont Corporation.[23] This framework describes a process for "ensuring the responsible development of nanoscale materials."[24] The framework can be used freely by companies and other organizations. The intent of the framework "is to define a systematic process for identifying, managing, and reducing the potential environmental, health, and safety risks of engineered nanomaterials across all stages of a product's 'lifecycle'."[25] It is meant to offer a voluntary approach to facilitate the responsible development of nanomaterials by companies, as well as private and public research institutions.[26] The framework is designed to be used iteratively at different stages of development advancement including basic R&D, prototyping, pilot testing, test marketing, and finally full-scale commercial launch as well as when new information becomes available.[27]

The framework consists of six distinct steps:

1. Develop a general description of the nanomaterial and its intended uses, based on information already available, and identify analogous materials and applications that may help fill data gaps in this and other steps;[28]

2. Develop profiles of the nanomaterial's properties, inherent hazards, and associated exposures, considering all the elements of the nanomaterial's full lifecycle and also considering that a material's properties, hazards, and exposures may change during its lifecycle;[29]

3. Evaluate all of the information generated in the profiles and identify and characterize the nature, magnitude, and probability of risks of the nanomaterial and its application. Gaps in the lifecycle profiles should be prioritized and a decision should be made on how to address them;[30]

4. Evaluate the available risk management options and recommend a course of action, including engineering controls, protective equipment, risk communication, and product or process modifications;[31]

5. Decide alongside key stakeholders, experts, and decision-makers whether or not, or in what capacity, to continue development and production and document these decisions as well as their rationale, and share appropriate information with the relevant stakeholders;[32]

6. Update and re-execute the risk evaluation regularly or as necessary to ensure that risk management systems are working as expected and adapt in the face of new information or conditions; document and share appropriate information with relevant stakeholders.[33]

The author's clarify that, "[t]hrough these six steps, the framework seeks to guide a process for risk evaluation and management that is practical, comprehensive, transparent, and flexible."[34]

The ED-DuPont framework is further intended to guide users through information generation and help them update assumptions, decisions, and practices as new information becomes available. At various stages in the product-development process, the document provides a worksheet[35] to help participants: 1) organize, document, and communicate the information they have about their material; 2) acknowledge that information is incomplete; 3) explain how information gaps were addressed; and 4) explain the rationale behind the user's risk management decisions and actions.[36]

However, the amount of information required in the framework is directly related to the potential extent and degree of exposure of the specified application. ED and DuPont recommend that a broad range of stakeholders have access to the worksheet or summaries of it as products move into commercialization in order to facilitate ease of understanding.[37]

DuPont has made it clear that it fully supports this framework. In fact, DuPont has made the framework standard for its own operations involving nanomaterials.[38] In at least one instance, applying the framework indicated that a product's development should be halted.[39]

Similar to the ED-DuPont Nano Risk Framework, Davies[40] believes that the Responsible Care program of the American Chemistry Council ("ACC")[41] is also a useful example of self-regulation for the nanotechnology industry. Reponsible Care requires member companies to measure and publicly report performance as well as to obtain independent third-party verification that their operations are up to set standards.[42] Davies, however, notes that voluntary codes often suffer from a lack of participation, as well as lack of transparency and specificity.[43] Indeed, public opinion surveys reveal skepticism about self-regulatory programs alone.[44] That is, failures of self-regulation could damage public acceptance of nanotechnology. Thus, effective self-regulation with the threat of external pressure—enforced self-regulation—has been found to be more effective.[45]

2. Government Registration

Government registration moves one step beyond self regulation. While not directly regulating conduct, governments may require nanomaterial users within their jurisdiction to register their activities and provide some basic information about those activities. Berkeley, California, for example, issued a nanoparticle hazardous materials ordinance in December 2006.[46] This was the first time a city took such an approach in the United States.

Berkeley's ordinance states, "All facilities that manufacture or use manufactured nanoparticles shall submit a separate written disclosure of the current toxicology, to the extent known, and how the facility will safely handle, monitor, contain, dispose, track inventory, prevent release and mitigate such materials."[47] In the spring of 2007, Berkley published guidelines implementing the ordinance.[48] Berkeley's guidelines make it clear that the City only seeks *published* information and data.[49] Regarding toxicity, the City seeks five types of data: (i) inhalation, (ii) dermal, (iii) oral, (iv) mutagenicity/genotoxicity, and (v) reproductive.[50] While this comprehensive data does not exist for all materials, the Guidelines allow reporting businesses to indicate such "information is not available" in instances where none has been published.[51] At the same time, the City mandates a precautionary approach if toxicity data is unavailable.[52]

Javiera Barandiaran,[53] a researcher, criticized the "open-ended" question format used in the City's guidelines. She challenges that an "open" format is unlikely to produce useful data.[54] Barandiaran also believes that "[t]he type of information required by the ordinance fails to capture some key characteristics of nanomaterials considered to be important [for the] potential toxicity,"[55] such as surface to mass ratio, surface coatings, or surface characteristics and reactivity potential.[56] The author argues that while the information collected by the Berkeley ordinance fits well within the needs of a hazardous materials business plan, the debate on how to regulate nanomaterials would benefit more from the development of a reporting form that begins to get at the key factors of nano-toxicity.

Regarding the government registration approach, Suellen Keiner[57] suggests that action by states can spur action at the federal level. In her article, *Room at the Bottom? Potential State and Local Strategies for Managing the Risks and Benefits of Nanotechnology*, Keiner explains how certain federal laws allow states and municipalities to enact their own nanomaterial EHS laws, even if federal laws are later enacted.[58] She highlights examples where states have promulgated their own regulations concerning air,[59] waste,[60] water,[61] labeling,[62] and worker safety.[63] The author then

suggests four specific routes of possible state action concerning potential nano-related EHS concerns:

1. Require disclosure of potential health, safety, or environmental hazards (like Berkeley);

2. Adopt standards that are expert-driven by standard-setting bodies;

3. Stakeholders should pressure states to act; and

4. States may collaborate on joint regionally standards or approaches and also draft model laws, rules, and/or ordinances.[64]

While the author recognizes that these approaches may be made moot if the federal government chooses to regulate in this area, the author notes that it is still important for states to act because they can enact more restrictive regulations than the federal government.[65] The paper concludes that a lack of federal initiatives leaves plenty of room at the bottom for states and municipalities to regulate nanotechnology.[66]

3. Enforced Self-Regulation: The U.S. Stewardship Program and the NPPTAC Reporting Program

Selecting the appropriate regulatory tools for external pressure is crucial. Ayers and Braithwaite recommend engaging public interest groups in this process.[67] In *A New Approach to Risk Management for Nanotechnology*, Abbott, Marchant, and Sylvester expand this recommendation to include multiple stakeholder groups.[68] For any method selected, tools for information gathering should also be used to help build databases of nanomaterial properties as well as to facilitate the communication of risks and related information.

Indeed, information-based tools play an important role in applying external pressure. Two examples of programs that use this strategy in the U.S. are the Toxics Release Inventory (TRI) and California Proposition 65.[69] Under the TRI, companies that release more than *de minimis* amounts of potentially hazardous chemicals must inform the EPA, which then publicly releases the information.[70] In California, Proposition 65 established a state-maintained list of chemicals known to cause cancer, birth defects, or reproductive harm.[71] A product's label must declare if it contains any of the chemicals on the list.[72] Davies notes that the enforcement of these regulations is not always straightforward.[73] Nonetheless, the tools are conceptually simple, and they inform the public of a company's or chemical's behavior, applying pressure on companies to seek safer substitutes, as appropriate.

External pressure could also be applied in the form of economic incentives. Davies, in *Managing the Effects of Nanotechnology*, suggests, for example, tools such as tax breaks and tax penalties to promote adherence of companies to their industry code of conduct while penalizing those that fall behind.[74] Another economic tool is acceleration of the review and approval process for environmentally beneficial new products.[75] These actions would provide real incentive for companies in the nanotechnology industry to follow a code of conduct and act in an environmentally responsible manner. Davies is less enthusiastic about liability tools, since these require the enforcement of tort law and are applied only after some demonstrable environmental or health harm has been committed.[76]

One particular example of enforced self-regulation is the EPA's voluntary Nanoscale Material Stewardship Program ("NMSP").[77] The program's objectives are to help the agency assemble data, which encourages the development of data in particular, and to foster responsible nanomaterial development.[78] The scope of the NMSP includes nanomaterials that have been manufactured or

imported for commercial purposes or are soon to enter commerce.[79] Thus, the approaches are intended to be applicable to both "new" and "existing" chemical nanoscale materials, regardless of whether they qualify for various exemptions or fall below reporting or notification thresholds under the U.S. Toxic Substances Control Act ("TSCA").[80] The NMSP consists of two levels—one providing participants the opportunity to provide basic information (*i.e.*, EPA's Basic Program), and one providing them with the opportunity to generate and report in-depth information and implement more in-depth risk management practices (*i.e.*, EPA's In-Depth Program).[81] Participants would volunteer to provide information (although the specific information requirements are still to be determined) on one or more specific nanomaterials, but they need not volunteer all of their materials. The EPA would then make information relevant to understanding and addressing nanomaterial risk publicly available unless it is considered confidential business information.

In order to ensure broad participation, the EPA would require participants in the Basic Program to report existing material characteristics (such as chemical composition, physical form, solubility, etc.) as well as characterize hazard, use and exposure potential, and risk management practices.[82] Participants in the Basic Program are not required to fill in the gaps of knowledge about basic material characteristics or to implement basic risk management practices such as worker training, use of available engineering controls, product labeling, customer training, and waste management practices.[83] They are furthermore not required to describe their experiences in implementing the basic risk management practices and their degree of satisfaction with these.[84]

The In-Depth NMSP is aimed at organizations (or consortia) interested in going beyond the basic program.[85] These would be obligated to generate new information about the hazards and risks—including risk reduction—of specific nanomaterials, as well as identifying, implementing, and expanding risk management measures appropriate for a given lifecycle of the material, including monitoring workplaces, environmental releases, and worker health.[86] The NMSP is not time-limited and there is no mentioning of the EPA starting to develop regulations based on this program.

A basic concern is whether a sufficient number of manufacturers will choose to voluntarily participate in the NMSP. The EPA initially predicted that 120 out of an estimated 480 existing small nano-related business and 120 out of an estimated 240 existing large nano-related businesses would participate in the basic program over a three year period.[87] Further, depending on company interest and the resources dedicated to the program in the EPA Office of Pollution Prevention and Toxics, EPA expected to analyze 15 additional nanoscale substances through the in-depth program during this same period.[88] In mid-January 2009, EPA published an interim status report[89] regarding the NMSP. So far, information under the basic program has been submitted by 29 companies/associations, covering 123 nanoscale materials. Seven additional companies have also committed to submitting data under the basic program at a future date.[90] The in-depth program has commitments from four companies thus far. Additionally, the American Chemistry Council has expressed an interest in coordinating in-depth data submissions.[91]

A similar program in the United Kingdom[92] has faced similar hurdles. In the spring of 2008, the United Kingdom's Department for Environment, Food and Rural Affairs ("DEFRA") released its Sixth Quarterly Report concerning the response to its Voluntary Reporting Scheme for Manufactured Nanomaterials ("VRS").[93] The UK reported that no new submissions were received by DEFRA since its prior quarterly report in December 2007.[94] Consequently, the count for total submissions remained at nine, seven from industry and two from academia. DEFRA is still seeking submissions under the VRS, but it is recommending that the "objectives and data requirements for the scheme be more clearly articulated."[95]

4. Command Regulation: Registration, Evaluation and Authorization of Chemicals ("REACH") in Europe

Agencies, such at the EPA, practice risk assessment as a tool to evaluate risks associated with chemicals which have been in the environment for decades. The U.S. National Academy of Sciences formulated the risk assessment approaches and procedures[96] that were subsequently tailored to specific applications by the EPA[97] and other agencies in the US and worldwide. Risk management was initially separated from risk assessment; risk assessment was perceived as a scientific activity while risk management was dealt with in a policy framework. A risk assessment is generally constructed to have four components: hazard identification, toxicity assessment, exposure assessment, and risk characterization.[98] This traditional scientific risk assessment framework may then be used in support of developing command regulations for substances such as nanomaterials.

On January 1, 2007, the European Parliament regulation, termed Registration, Evaluation and Authorization of Chemicals ("REACH"), went into effect.[99] REACH is a new chemical legislation regarding the manufacturing and commercialization of chemical substances in the European market. The regulation establishes an authorizing system that requires the registration and evaluation of existing and new chemical substances.[100] A chemical substance is defined as "a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition[.]"[101] In theory, the broad definition of a chemical substance under REACH includes nanoscale substances.[102]

While the REACH definition may cover nanoscale substances, REACH does have at least two major potential limitations in regard to nanoparticles. First, registration is based on chemical composition—and not, for instance, properties, which might be a better descriptor for the risks of nanoparticles such as particle size or surface area.[103] This means that C_{60} and carbon nanotubes could in theory be registered under the same registration as carbon black,[104] and nano-sized TiO_2 could be registered under the same registration as micron-sized TiO_2.[105]

Second, although REACH obliges producers or importers to provide toxicological data and assess environmental exposure, requirements are based on mass thresholds.[106] Hence, data sets are not required until production or imported volumes are above the threshold of 1 ton/year of a substance per producers.[107] For many nanoparticles, this threshold would likely not be reached in the short term.[108] Furthermore, the usually low concentration of nanoparticles in the final article is likely to exclude many nanoengineered articles from the REACH legislation, since no registration is required when the concentrations of a substance is lower than 0.1% w/w.[109]

5. In Search of Solutions

There is no doubt that risk assessment is key to developing nanotechnology governance; however, its application to nanomaterials is impaired by significant uncertainty and variability in available data. Most of the uncertainty analysis methods developed for chemicals and other stressors (*e.g.*, probabilistic assessment, Bayesian analysis, and multivariate statistical analysis) can be generally characterized as data-intensive. A clear deficiency, if not a practical impossibility, of these types of methods when applied to nanomaterials risk assessment is their rigid data quality requirements. Implementation of these methods is currently not achievable for most studied nanomaterials.

Several decision support methods and tools have been proposed for how to best govern nanomaterial development in the face of heterogeneous information, uncertainty, and risk. The proposed application frameworks clearly acknowledge the need to integrate expert judgment with

multiple other factors to support the risk assessment and decision-making process. They advocate a change from the current focus of studying risk to investigating solutions. Rather than focusing on how much risk is acceptable for specific nanomaterials, these approaches could use science and policy to identify alternative nanotechnologies and opportunities for risk reduction and innovation.

One group of decision tools includes qualitative policy instruments that offer roadmaps for assessing different information sources and making policy decisions, often through several analysis tiers or steps. At each tier, specific decision points are assessed. Even though quantitative tools could be applied within such methods, their use is limited to traditional statistical and mathematical analysis of technical and scientific information while judgment is integrated qualitatively. A second group of methods quantitatively integrate expert judgment of the utility of heterogeneous technical information with societal value calls. Two representative methods that the authors have experience with are Alternatives Assessment,[110] corresponding to the first group, and multi-criteria decision analysis ("MCDA"),[111] corresponding to the second group.

Alternatives Assessment is a common-sense approach whereby a wide range of alternatives (*e.g.*, technologies, processes, social changes) to potentially hazardous activities are examined at the time risks are identified.[112] The key elements of Alternatives Assessment include performing a broad appraisal, opening up of a range of options (change phrasing), and looking for risk-superior alternatives and avoidance of risk-risk tradeoffs.[113]

Generally, Alternatives Assessment consists of six steps: (1) identify target(s) for action, (2) characterize and prioritize end uses, (3) identify alternatives, (4) evaluate and compare alternatives, (5) select preferred alternative(s), and (6) review selection.[114] Alternatives Assessment does not only involve, for example, substituting a hazardous chemical with a less hazardous one; rather, it mandates that society examines the service and function that it requires as opposed to just examining the chemical under question. Alternatives in this instance need not simply be nanomaterials, but may include the process or administrative changes that reduce the need for the materials in the first place.[115] The main limitation of Alternatives Assessment is that the evaluation and comparison of alternatives is a complex and challenging process so that, generally, no one method exists which can compare environmental, health, technical, economical, and social trade-offs.[116]

The **Alternatives Assessment** approach consists of six steps:
(1) identify target(s) for action,
(2) characterize and prioritize end uses,
(3) identify alternatives,
(4) evaluate and compare alternatives,
(5) select preferred alternative(s), and
(6) review selection.

The **Multi-Criteria Decision Analysis** process consists of four steps:
(1) structuring the problem by identifying stakeholders and criteria (*e.g.*, nanomaterial properties) relevant to the decision at hand,
(2) eliciting the parameters of the mathematical model (*e.g.*, weights, thresholds, etc.) and assigning measurements for each alternative (*e.g.*, nanomaterial risk group),
(3) executing the model through software, and
(4) interpreting the results of the model and possibly re-iterating the process from step 1 or 2.

MCDA tools have recently been attracting attention as a way to structure fragmented information for application in environmental management.[117] MCDA refers to a group of methods used to impart structure to the decision-making process.[118] Generally, the MCDA process consists of four steps: (1) structuring the problem by identifying stakeholders and criteria (*e.g.*, nanomaterial properties) relevant to the decision at hand, (2) eliciting the parameters of the mathematical model (*e.g.*, weights, thresholds, etc.) and assigning measurements for each alternative (*e.g.*, nanomaterial risk group), (3) executing the model through software, and (4) interpreting the results of the model and possibly re-iterating the process from step 1 or 2.[119] The goal of the MCDA process is not to select a single best alternative, but to rank or group alternatives through a structured process. In *Multiple Criteria Decision Analysis: An Integrated Approach*, Belton and Stewart[120] present a detailed analysis of the theoretical foundations for different MCDA methods and their comparative strengths and weaknesses. Linkov et al.[121] present a review of MCDA applications to environmental management. Researchers have also reported examples of MCDA application for use with nanomaterials.[122]

The advantage of using MCDA techniques over other less-structured decision-making methods is in its clear and transparent methodology for combining information from disparate sources. MCDA algorithms provide the ability to clearly explain and quantify technical judgment and values. Moreover, MCDA software can provide useful graphical techniques and visualization methods to express the gathered information in understandable formats. When changes occur in the requirements or the decision process, decision analysis tools can repeat the analysis by reprocessing and iterating with the new inputs. MCDA has been recommended as one of the most promising risk governance tools.[123] The main limitations of MCDA are the need for quantification of multiple criteria and measures developed as part of a decision model. Additionally, implementation of different MCDA theories may lead to potentially different solutions.

Decision analysis tools (both qualitative and quantitative) can help to generate and map technical data as well as individual judgments into organized structures that can be linked with other technical tools from risk analysis, modeling, monitoring, as well as cost estimation. Such an integration of decision, scientific and engineering tools provides users with a valuable decision-making framework without attempting to apply either type of tool beyond its intended scope. Both qualitative and quantitative tools have strengths and limitations.

III. Conclusion

In summary, we believe that nanomaterial regulatory frameworks could be built on the existing risk assessment and management approaches with the addition of rigorous and transparent methods for integrating technical information and expert judgment that are offered by decision analysis tools. The use of these tools does not replace information collection and application of quantitative risk assessment methods; rather it provides a quantitative and adaptive framework under which expert judgment and technical data can be congruently managed to arrive at potential solutions. This increasingly important function is underscored by the existence of a potentially widening data/knowledge gap in the field of nanomaterial risk management and provides additional rigor for the interim period prior to acquisition of definitive technical data.

ENDNOTES

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[1] *See* Woodrow Wilson Int'l Ctr for Scholars, Project on Emerging Nanotechnologies: A Nanotechnology Consumer Product Inventory, http://www.nanotechproject.org/44 (last visited April 6, 2009).

[2] *See* Steffen Foss Hansen et al., *Categorization Framework to Aid Exposure Assessment of Nanomaterials in Consumer Products*, 17 ECOTOXICOLOGY 438 (2008); Steffen Foss Hansen & Joel A. Tickner, *The Challenges of Adopting Voluntary Health, Safety and Environment Measures for Manufactured Nanomaterials: Lessons from the Past for More Effective Adoption in the Future*, 4 NANOTECH. L. & BUS. 341 (2007).

[3] *See* J. Clarence Davies, *Managing the Effects of Nanotechnology*, WOODROW WILSON INT'L CTR. FOR SCHOLARS: PROJECT ON EMERGING NANOTECH. (2006) [hereinafter Davies 2006], *available at* http://www.nanotechproject.org/process/files/2708/30_pen2_mngeffects.pdf.

[4] Michael R. Taylor, *Regulating the Products of Nanotechnology: Does FDA Have the Tools It Needs?* WOODROW WILSON INT'L CTR. FOR SCHOLARS: PROJECT ON EMERGING NANOTECH. 46-47 (2006), *available at* http://www.nanotechproject.org/process/assets/files/2705/110_pen5_fda.pdf.

[5] *See* IAN AYRES & JOHN BRAITHWAITE, RESPONSIVE REG.: TRANSCENDING THE DEREGULATION DEBATE (1992).

[6] *See e.g.*, Graeme A. Hodge & Diana M. Bowman, *Engaging in Small Talk: Nanotechnology Policy & Dialogue Processes in the UK & Australia*, 66 AUSTL. JOURNAL OF PUBLIC ADMIN. 223 (2007); KENNETH W. ABBOTT, GARY E. MARCHANT, & DOUGLAS J. SYLVESTER, A NEW APPROACH TO RISK MANAGEMENT FOR NANOTECHNOLOGY (2007).

[7] *See* Igor Linkov & F. Kyle Satterstrom, *Nanomaterial Risk Assessment and Risk Management: Review of Regulatory Frameworks*, REAL TIME AND DELIBERATIVE DECISION MAKING (Igor Linkov et al. eds.) (2008).

[8] *See* Igor Linkov et al., *Emerging Methods and Tools for Environmental Risk Assessment, Decision-Making, & Policy for Nanomaterials: Summary of NATO Advanced Research Workshop*, 11 JOURNAL OF NANOPARTICLE RES. 513 (2009).

[9] *See* Thomson Reuters, Web of Science Overview, http://thomsonreuters.com/products_services/scientific/Web_of_Science (last visited April 6, 2009).

[10] Search string adopted from Lux Research. *See* Lux Research, *Small Stuff in Search of the Big Bucks: Nanotechnology Commercialization Activities by Sector*, Presentation to IEEE San Francisco Bay Area Nanotechnology Council on Dec. 18, 2007.

[11] *See id*.

[12] *See* Hansen et al., *supra* note 2.

[13] *See* EUR. ENV'T AGENCY, LATE LESSONS FROM EARLY WARNINGS: THE PRECAUTIONARY PRINCIPLE 1896–2000, ENVTL. ISSUE REPORT (2001), *available at* http://www.eea.europa.eu/publications/environmental_issue_report_2001_22/ Issue_Report_No_22.pdf.

[14] EDWARD W. LAWLESS, TECHNOLOGY & SOCIAL SHOCK (1977).

[15] *Id*.

[16] Break-out Group Meeting, Canadian Workshop, Edmonton 2008 (on file with author).

[17] *See* Linkov & Satterstrom, *supra* note 7.

[18] *See* ENVTL. PROTECTION AGENCY ("EPA") OFFICE OF THE SCIENCE ADVISOR, NANOTECHNOLOGY WHITE PAPER (2007), *available at*, http://www.epa.gov/OSA/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf; FOOD & DRUG ADMIN., NANOTECH.: A REPORT OF THE U.S. FOOD & DRUG ADMIN. NANOTECH. TASK FORCE (2007), *available at* http://www.fda.gov/nanotechnology/taskforce/report2007.pdf; Davies, *supra* note 3; Envtl. Defense – DuPont Nano P'hip, Nano Risk Framework (2007) [hereinafter DuPont], *available at* http://www.edf.org/documents/ 6496_Nano%20Risk%20Framework.pdf; Québec Comm. de L'éthique de la Science et de la Technologie, Position Statement: Ethics and Nanotechnology: A Basis for Action (2006), *available at* http://www.ethique.gouv.qc.ca/IMG/pdf/Avis-anglaisfinal-2.pdf; The Royal Soc'y & Royal Acad. of Eng'g, Nanosci. & Nanotechnologies: Opportunities & Uncertainties, http://www.nanotec.org.uk/finalReport.htm (last visited April 10, 2009); *See* U.K. DEPT. FOR ENV'T, FOOD & RURAL AFFAIRS, CHARACTERIZING THE POTENTIAL RISKS POSED BY ENGINEERED NANOPARTICLES: UK GOV'T RESEARCH – A PROGRESS REPORT (2008), *available at* http://www.defra.gov.uk/environment/nanotech/research/pdf/nanoparticles-progressreport.pdf; The Royal Soc'y, Workshop Report: How Can Business Respond to the Technical, Social & Commercial Uncertainties of Nanotechnology? (2006), *available at* http://www.responsiblenanocode.org/documents/Workshop-Report_07112006.pdf; Eur. Comm. Health & Consumer Protection Scientific Committee on Emerging & Newly-Identified Health Risks, *Opinion on the Appropriateness of the Risk Assessment Methodology in Accordance with the Technical Guidance Documents for New & Existing Substances for Assessing the Risks of Nanomaterials* (2007) [hereinafter EC SCENIHR], *available at* http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_010.pdf; *Communication from the Commission to the Council, the European Parliament and the Economic & Social Committee: Nanosciences & Nanotechnologies: An Action Plan for Europe 2005-2009* (2005), *available at* http://ec.europa.eu/research/ industrial_technologies/pdf/nano_action_plan_en.pdf; Int'l Risk Governance Council ("IRGC"), White Paper on Risk Governance: Towards an Integrative Approach (2005), *available at* http://www.irgc.org/IMG/pdf/ IRGC_WP_No_1_Risk_Governance__reprinted_version_.pdf; IRGC, WHITE PAPER ON NANOTECH. RISK GOVERNANCE (2006), *available at* http://www.irgc.org/IMG/pdf/IRGC_white_paper_2_PDF_final_version-2.pdf; IRGC, POLICY BRIEF: NANOTECH. RISK GOVERNANCE: RECOMMENDATIONS FOR A GLOBAL, COORDINATED APPROACH TO THE GOVERNANCE OF POTENTIAL RISKS (2007), *available at* http://www.irgc.org/IMG/pdf/ PB_nanoFINAL2_2_.pdf; NAT'L NANOTECH. INITIATIVE NAT'L SCI. & TECH. COUNCIL, ENVTL., HEALTH, & SAFETY RES. NEEDS FOR ENGINEERED NANOSCALE MATERIALS (2006), *available at* http://www.nano.gov/NNI_EHS_research_needs.pdf; *See* Commission Regulation 1907/2006, Concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, 2006 O.J. (L 396) 1 [hereinafter REACH Reg.], *available at* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=oj:l:2006:396:0001:0849:en:pdf.

[19] *See* Linkov et al., *supra* note 7.

[20] *See* AYRES & BRAITHWAITE, *supra* note 5.

[21] *See* Linkov et al., *supra* note 7.

[22] *See* AYRES & BRAITHWAITE, *supra* note 5.

[23] *See* DUPONT, *supra* note 18.

[24] *See id*. at 1.

[25] *See id*. at 12.

[26] *See id*. at 12-14.

[27] *See id*. at 8-15.

[28] *See id*. at 8.

[29] *See id.* at 8.

[30] *See id*. at 9.

[31] *See id*. at 9.

[32] *See id*. at 9.

[33] *See id*. at 10.

[34] *Id*.

[35] *See id*. at 8.

[36] *See id*. at 87-100.

[37] *See id*. at 9.

[38] *See e.g.*, DuPont, Nanomaterial Risk Assessment Worksheet (2007), *available at* http://www.edf.org/documents/6554_nZVI_Summary.pdf.

[39] *See* Linda Fisher, Envtl. Defense & DuPont to Jointly Launch Risk Framework. June 21 2007, *available at* http://www.wilsoncenter.org/ondemand/index.cfm?fuseaction=home.play&mediaid=A3F4AE5D-B21E-8EBB-069B78254ED2E9C4.

[40] J. Clarence Davies, *EPA and Nanotechnology: Oversight for the 21st Century*, WOODROW WILSON INT'L CTR. FOR SCHOLARS PROJECT ON EMERGING NANOTECH. 35-36 (2007) [hereinafter Davies 2007], *available at* http://www.nanotechproject.org/file_download/files/Nano&EPA_PEN9.pdf.

[41] *See* Am. Chem. Council, Responsible Care, http://www.americanchemistry.com/s_responsiblecare/sec.asp?CID=1298&DID=4841 (last visited April 10, 2009).

[42] *See id*.

[43] *See* Davies 2007, *supra* note 40 at 36.

[44] *See* Jane Macoubrie, *Informed Public Perceptions of Nanotechnology & Trust in Government*, WOODROW WILSON INT'L CTR. FOR SCHOLARS PROJECT ON EMERGING NANOTECH. (2005), *available at* http://www.nanotechproject.org/process/files/2662/informed_public_perceptions_of_nanotechnology_and_trust_in_government.pdf.

[45] *See* NEIL GUNNINGHAM & PETER GRABOSKY, SMART REGULATION: DESIGNING ENVIRONMENTAL REGULATION (1998).

[46] *See* CITY OF BERKLEY, CAL., ORDINANCE 6960-NS (2006) (modifying Municipal Code §§ 15.12.040, 15.12.050), *available at* http://www.cityofberkeley.info/citycouncil/2006citycouncil/packet/121206/2006-12-12%20Item%2003%20-%20Ord%20-%20Nanoparticles.pdf

[47] CITY OF BERKLEY, CAL., MUNICIPAL CODE §§ 15.12.040(I) (2006), *available at* http://www.ci.berkeley.ca.us/bmc/berkeley_municipal_code/Title_15/12/040.html

[48] *See* City of Berkeley, Cal., *Intro. to Manufactured Nanoscale Material Health & Safety Disclosure for the Reporting Period of June 1, 2007-June 2, 2008* (2007) [hereinafter Berkeley Guidelines], *available at* http://www.ci.berkeley.ca.us/uploadedFiles/Planning_(new_site_map_walk-through)/Level_3_-_General/Manuffactured%20Nanoscale%20Materials.pdf. *See also* City of Berkley, Cal., Community Envtl. Advisory Comm'n Meeting Minutes (2006), *available at* http://www.ci.berkeley.ca.us/citycouncil/2006citycouncil/packet/120506/2006-12-05%20Item%2013%20Manufactured%20Nanoparticle%20Health%20and%20Safety%20Disclosure-Supp.pdf.

[49] *See* Berkeley Guidelines.

[50] *See* Berkeley Guidelines.

[51] *See* Berkeley Guidelines.

[52] *See* Berkeley Guidelines.

53 Javiera Barandiaran, *The City of Berkeley Ordinance on Nanotechnology: Shortcomings, Improvements, and Implications for Risk Governance*, UC BERKELEY GOLDMAN SCHOOL OF PUBLIC POLICY, SCI. TECH. & ENG'G WHITE PAPER COMPETITION (2007), *available at* http://step.berkeley.edu/White_Paper/Barandiaran.pdf.

54 *Id*. at 5.

55 *Id*. at 5.

56 *Id*.

57 *See* Suellen Keiner, *Room at the Bottom? Potential State and Local Strategies for Managing the Risks and Benefits of Nanotechnology*, Woodrow Wilson Int'l Ctr. for Scholars Project on Emerging Nanotech. (2008), *available at* http://www.nanotechproject.org/process/assets/files/6112/pen11_keiner.pdf.

58 *See id*. at 17-19.

59 *See id.* at 22-23 (discussing the Clean Air Act and stricter laws in states including California).

60 *See id.* at 22-23 (discussing the Resource Conservation and Recovery Act and the Comprehensive Environmental Response, Compensation and Liability Act /Superfund and stricter laws in both Colorado and California).

61 *See id.* at 26-27 (discussing the Clean Water Act and stricter laws in states including Idaho, Minnesota, Missouri, Montana, Nebraska, New Jersey, and New York).

62 *See id.* at 27-29 ("California is unique among the states in requiring that consumer products be labeled with warnings about any toxic chemicals they contain. Neither EPA nor the Consumer Products Safety Commission has the authority to require labels on consumer products that contain toxic ingredients.").

63 *See id.* at 29 (noting that "OSHA has approved plans for 21 states (plus Puerto Rico) that apply federal safety standards to workers in private industry, and at least some of those states may be able to adopt requirements for ensuring the safety of workers in nanobusinesses.").

64 *See id*. at 8-9.

65 *See id.* at 9.

66 *See id*.

67 *See* AYRES & BRAITHWAITE, *supra* note 5.

68 *See* ABBOTT ET AL., *supra* note 6.

69 *See* Davies 2007, *supra* note 40 at 34.

70 *See id*.

71 *See id*. *See also* Cal. Office of Envtl. Health Hazard Assessment, Proposition 65, http://www.oehha.ca.gov/prop65.html (last visited April 10, 2009) [hereinafter CA OEHHA].

72 *See id*. at Frequently Asked Questions: As a Business, How Do I Know if I Need to Provide a Proposition 65 warning?, at http://www.oehha.ca.gov/prop65/p65faq.html.

73 *See* Davies 2007, *supra* note 40 at 34.

74 *See* Davies 2006, *supra* note 3 at 25-6.

75 *See id*. at 20.

76 *See* Davies 2007, *supra* note 40 at 40.

77 *See generally* EPA, Nanoscale Materials Stewardship Program, http://www.epa.gov/oppt/nano/stewardship.htm (last visited April 10, 2009) [hereinafter EPA Stewardship].

78 *See id*.

79 *See id*. at More on the Basic Program.

[80] *See generally* EPA, Nanotechnology Under the Toxic Substances Control Act, http://www.epa.gov/oppt/nano/ (last visited April 10, 2009) [hereinafter EPA TSCA].

[81] *See* EPA Stewardship, *supra* note 74.

[82] *See id*. at Under the Basic Program, More on the Basic Program.

[83] *See id*.

[84] *See* NAT'L POLLUTION PREVENTION & TOXICS ADVISORY COMM. TO THE EPA, OVERVIEW DOC. ON NANOSCALE MATERIALS, Doc. ID: EPA-HQ-OPPT-2002-0001-0073 (2006).

[85] *See* EPA Stewardship, *supra* note 74.

[86] *See id*. at Under the In-Depth Program, More on the In-Depth Program.

[87] *See* EPA, Supporting Statement for an Information Request, Information Collection in Support of EPA's Stewardship Program for Nanoscale Materials, EPA ICR No.: 2250.01, OMB Control No. 2070-new, 15 (2007) (on file with author).

[88] *See id*.

[89] EPA OFFICE OF POLLUTION PREVENTION & TOXICS, NANOSCALE MATERIALS STEWARDSHIP PROGRAM, INTERIM REPORT (2009), *available at* http://www.epa.gov/oppt/nano/nmsp-interim-report-final.pdf.

[90] *See id*. at 9, fn. 1.

[91] *See id*. at 11.

[92] *See* U.K. DEPT. FOR ENV'T, FOOD & RURAL AFFAIRS, *supra* note 18.

[93] *See* U.K. DEPT. FOR ENV'T, FOOD & RURAL AFFAIRS, UK VOLUNTARY REPORTING SCHEME FOR ENGINEERED NANOSCALE MATERIALS: SIXTH QUARTERLY REPORT (2008) (on file with author).

[94] *See id*.

[95] *Id*.

[96] NAT'L ACAD. OF SCI., RISK ASSESSMENT IN THE FED. GOV'T: MANAGING THE PROCESS (1983), *available at* http://www.nap.edu/openbook.php?isbn=0309033497.

[97] *See e.g.*, EPA OFFICE OF EMERGENCY & REMEDIAL RESPONSE, RISK ASSESSMENT GUIDANCE FOR SUPERFUND, VOL. I, HUMAN HEALTH EVALUATION MANUAL (PART A), EPA/540/1-89/002 (1989), *available at* http://www.epa.gov/oswer/riskassessment/ragsa/index.htm; EPA, GUIDELINES FOR ECOLOGICAL RISK ASSESSMENT, EPA/630/R095/002F (1998), *available at* http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=12460.

[98] *See generally* JOHN BURKE SULLIVAN & GARY R. KRIEGER, CLINICAL ENVIRONMENTAL HEALTH & TOXIC EXPOSURES 78 (2001).

[99] *See* REACH Reg., *supra* note 18.

[100] *See id*. at ¶ 19-20.

[101] *See id* at Ch. 2, Art. 3.

[102] *See* Diana Bowman & Geert van Calster, *Reflecting on REACH: Global Implications of the European Union's Chemicals Regulation*, NANOTECH. L. & BUS. 375 (2007).

[103] *See* EC SCENIHR, *supra* note 18.

[104] *See* Antonio Franco et al., *Limits and Prospects of the "Incremental Approach" & the European Legislation on the Management of Risks Related to Nanomaterials*, 48 REGULATORY TOXICOLOGY & PHARMACOLOGY 175-77 (2007).

[105] *See* Quasim Chaudhry et al., *A Scoping Study to Identify Gaps in Environmental Regulation for the Products and Applications of Nanotechnologies*, U.K. DEPT. FOR ENV'T, FOOD & RURAL AFFAIRS (2006).

[106] *See e.g.*, REACH Reg., *supra* note 91 at ¶ 25, 64; Ch. 25, Art. 24.

[107] *See id*. at Ch. 3, Art. 28.

[108] *See e.g.*, Bowman & van Calsterm, *supra* note 94; Franco et al., *supra* note 96 at 177-78.

[109] *See* Franco et al., *supra* note 96 at 177-78.

[110] *See* Mark Rossi, Joel Tickner & Ken Geiser, *Alternatives Assessment Framework Version 1.0*, LOWELL CTR. FOR SUSTAINABLE PRODUCTION (2006), *available at* http://www.chemicalspolicy.org/downloads/FinalAltsAssess06_000.pdf.

[111] *See e.g.*, JOSE FIGUEIRA, SALVATORE GRECO & MATTHIAS EHRGOTT, MULTIPLE CRITERIA DECISION ANALYSIS: STATE OF THE ART SURVEYS (2005).

[112] *See id*. at 5.

[113] *See id*. at 4. *See also* Hansen & Tickner, *supra* note 2.

[114] *See e.g.*, Rossi, *supra* note 102 at 12.

[115] *See id*. at 15.

[116] *See id*. at 16-17.

[117] *See e.g.*, FIGUEIRA, *supra* note 103; Tommi Tervonen & Risto Lahdelma, *Implementing Stochastic Multicriteria Acceptability Analysis*, 178 EUR. JOURNAL OF OPERATIONAL RES. 500 (2007).

[118] *See generally* FIGUEIRA, *supra* note 103.

[119] *See id*.

[120] VALERIE BELTON & THEODOR J. STEWART, MULTIPLE CRITERIA DECISION ANALYSIS: AN INTEGRATED APPROACH (2002).

[121] *See* Igor Linkov et al., *From Comparative Risk Assessment to Multi-Criteria Decision Analysis and Adaptive Management: Recent Developments and Applications*, 32 ENV'T INT'L 1072 (2006).

[122] *See e.g.*, Igor Linkov et al., *Multi-Criteria Decision Analysis & Environmental Risk Assessment for Nanomaterials*, 9 JOURNAL OF NANOPARTICLE RES. 543 (2007); Tommi Tervonen et al., *Risk-based Classification System of Nanomaterials*, 11 JOURNAL OF NANOPARTICLE RES. 757 (2009); Thomas P. Seager & Igor Linkov, *Coupling Multi-Criteria Decision Analysis & Life Cycle Assessment for Nanomaterials*, 12 JOURNAL OF INDUSTRIAL ECOLOGY 282 (2008).

[123] *See e.g.*, Mihail C. Roco, *Possibilities for Global Governance of Converging Technologies*, 10 JOURNAL OF NANOPARTICLE RES. 11 (2008).