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Sustainable Nanomaterials: Emerging Governance Systems

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ABSTRACT: Domestic and international laws, regulations, policies, and government and private-party governance programs are being carefully reviewed and revised to enhance their utility to nurture the commercialization of nanoscale materials. Whether existing laws are adequate to address potential risks from nanoscale materials and promote their sustainable use will inspire debate and governance initiatives for years to come.

KEYWORDS: *Nanoscale, Nanotechnology, Environmental health and safety, Nanoparticle, Green nano, Toxic substances control act, TSCA, Carbon nanotube, CNT, Initiatives*

This paper reviews existing domestic governance oversight systems, assesses regulatory initiatives addressing potential nanomaterial risks, and concludes that green nanotechnology is a concept that needs to be embedded and promoted in regulatory and voluntary initiatives to ensure nanotechnology's sustainable development. Particular attention is devoted to emerging regulatory approaches the U.S. Environmental Protection Agency (EPA) is taking under the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the two domestic chemical product laws responsible for ensuring the safety of chemical substances. It also concludes that the Sustainable Nanotechnology Organization's (SNO) reason for being is essential to the fulfillment of the goal of sustainable nanotechnology.[1]

BACKGROUND

Nanotechnology is now well recognized as the "understanding and control of matter at dimensions between approximately 1 and 100 nanometers (nm), where unique phenomena enable novel applications not feasible when working with bulk materials or even with single atoms or molecules."[2] Nanotechnology is viewed broadly as many technologies that, over time, are expected to generate many new products and applications. Lux Research, Inc., the New York-based nanotechnology research and advocacy firm, predicts that by 2015, revenue from nanomaterials will exceed $2.9 billion and that revenue from nanoenabled products will exceed $1960 billion.[3]

Stakeholders globally are focusing on nanotechnology for reasons beyond economic advancement. Because there continues to be a lack of complete understanding regarding the environmental, health, and safety (EHS) effects of exposure to engineered nanoscale materials, governments, industry, and other stakeholders are considering how best to address EHS issues while continuing to foster the sustainable commercialization of nanoscale materials.

It is generally believed that sufficient information exists about the toxicity of some nanoscale materials to suggest a need for caution. The small size of certain nanoparticles facilitates their uptake into cells and their movement through the body more readily than is the case with their conventionally sized counterparts.[4] Other factors contribute to a sense of uncertainty as to the biological and environmental implications of exposure to nanoscale materials. Size, shape, surface chemistry, and coating, for example, can all influence how these materials behave biologically and in the environment. The fact that nanoscale materials can have unusual properties, properties that do not conform to "conventional" physics and chemistry, may increase their commercial value and their potential for risk.

Federal agencies are reviewing nanotechnology applications and the EHS implications of nanotechnologies. These include EPA,[5] the Food and Drug Administration (FDA),[6] the Occupational Safety and Health Administration,[7] the National Institute for Occupational Safety and Health (NIOSH),[8] and the National Toxicology Program,[9] among other federal agencies and departments. Regulatory and health agencies globally are similarly engaged. EPA is involved in reviewing the EHS implications and funding research regarding the beneficial environmental applications of nanotechnologies.[10]

Nanoproducts are diverse and growing exponentially. According to the National Nanotechnology Initiative (NNI),

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nanoscale materials are used in electronics, pharmaceuticals, chemicals, energy, and biomedical, among other industries. Most experts agree that there is no "nanotechnology market" per se. Rather, there is a nanotechnology "value chain" that consists of nanomaterials, intermediate products with nanoscale features, and finished products and goods incorporating some aspect of nanotechnology. This is why nanotechnology is often referred to as an "enabling" technology that cuts across economic sectors. As of March 10, 2011, there are over 1317 manufacturer-identified nanoenabled consumer products currently on the market, produced by over 587 companies, located in 30 countries.[11] These products include paints, sporting goods, cosmetics, stain-resistant clothing, electronics, and surface coatings, among other applications.[11]

GREEN NANOTECHNOLOGY

Enter green nanotechnology, a conceptual approach to managing EHS risks potentially posed by nanoscale materials to ensure their responsible and sustainable development. There are two key aspects to green nanotechnology. The first involves nanoproducts that provide solutions to environmental challenges. These include environmental technologies to remediate hazardous waste sites and desalinate water, nanotechnology applications for improving food nutritional value, nanoproducts that facilitate sensing and monitoring technologies to detect hazardous pollutants, and other applications. The second involves producing nanomaterials and nanoenabled products in ways that minimize human and environmental harm. New nanomaterials can be made using well-established principles of green chemistry, thus avoiding dependence on processes that might result in pollutants.

Green engineering principles are applicable as nanomaterials increasingly are incorporated into larger, more conventionally scaled products. Green engineering "embraces the concept that decisions to protect human health and the environment can have the greatest impact and cost effectiveness when applied early to the design and development phase of a process or product."[12] The most relevant time frame in the green engineering lifecycle of a nanomaterial is the design stage. Green engineering considers the full lifecycle of a product, from the extraction of the materials through manufacturing, product use, and end of life. Green nanotechnology's focus on the full lifecycle can better prepare users for recycling, reuse, or remanufacture of nanomaterials and nanoenabled products, thus minimizing generating new hazards through unintended consequences.

Nanomaterials can be designed to be sustainable. Nanomaterials can, for example, be coated so that they do not dissolve in water or enter biological cells. Some nanomaterials can be made from renewable ingredients or repurposing nontoxic biological waste products. Other nanomaterials can be considered to ensure no part of the product can be the source of harm to human or environmental health after gainful use and reclamation opportunities are exhausted.

A subset of greener production includes using nanomaterials to "green up" current processes. Catalysts are an important nanomaterial for this use. As a spherical particle gets smaller and smaller, it has more surface area proportional to its total volume. Catalyst reactions take place on the surface, so the more surface area and less volume the better. Nanomaterials used as catalysts have high surface areas making them more efficient and less wasteful, with potentially less polluting chemical reactions.

Nanoscale membranes are another illustration of green nanoapplications. In many chemical reactions, useful products must be separated from waste. These separations can be energy intensive, wasteful, or themselves polluting. Nanoscale membranes can minimize separation steps and energy use.

These examples are merely illustrative of a broad range of green nanoproducts and processes. While there is reason to be hopeful, there is also reason to be cautious when creating and managing these new, unique materials, and manufacturing processes.

EMERGING GOVERNANCE FRAMEWORKS

The lack of toxicological and ecological effects information on nanomaterials challenges regulatory agencies to oversee nanotechnology's commercialization. Governmental bodies and stakeholders alike have initiated actions to manage prudently nanotechnology's commercialization. The activities include regulatory initiatives, government-initiated voluntary/mandatory data gathering initiatives, standard-setting actions, business codes of conduct, and related private sector initiatives.

Adequacy of Existing Legal Authorities. An issue that has been long debated is whether existing legal authorities are adequate to address nanomaterial risks. The American Bar Association Section of Environment, Energy and Resources Nanotechnology Papers (available at http://www.abanet.nano) provided legal analyses of the core U.S. environmental statutes and the authority each conveys to EPA in addressing potential nanotechnology risks. Many believe, including EPA, that current laws are adequate and that no new laws are needed. Most would also agree, however, that the question of whether the government's statutory authorities are sufficient to address such risks does not say much about whether the regulatory implementation of those authorities, or its expertise, resources, or political will, are sufficient to manage nanotechnology risks effectively.

Federal Regulatory Initiatives. While the question of whether new laws are needed is unresolved, much nonlegislative work is ongoing. EPA's Office of Pollution Prevention and Toxics (OPPT) is developing a body of work under TSCA pertinent to nanoscale materials. Because TSCA is the federal law regulating chemicals, EPA has focused on using TSCA to regulate nanoscale substances, materials that are TSCA "chemical substances". On the regulatory front, EPA's OPPT's 2008 policy, *TSCA Inventory Status of Nanoscale Substances—General Approach*, assists manufacturers in determining whether TSCA Inventory requirements apply to nanoscale chemical substances. EPA has reviewed over 130 new chemical applications involving nanomaterials. While EPA's 2011 and earlier Regulatory Agendas included a TSCA Section 4 test rule for certain multiwall carbon nanotubes (CNTs), certain clays, and bentonite, alumina, and spray-applied nanomaterials, EPA's 2012 Regulatory Agenda no longer includes it.[13] EPA reportedly is preparing a proposed combined TSCA Section 8(a) recordkeeping and reporting rule and TSCA Section 5(a)(2) significant new use rule (SNUR) applicable to chemical substances when manufactured (defined by statute to include import) or processed as nanoscale materials.[14] The proposal has been snagged in the Office of Management and Budget (OMB) review since 2011.[15]

EPA proposed TSCA Section 5(e) SNURs for seven CNTs and nine fullerene chemicals[16] and extended the comment period at the request of several labor unions.[17] EPA received in late 2012 TSCA Section 5(a)(1) premanufacture notices

(PMNs) for generic carbon nanostructures,[18] five different multiwalled CNTs, and a metallic nanoparticle solution.[19] EPA also in 2012 issued a direct final TSCA Section 5(e) SNUR for infused carbon nanostructures.[20]

Most recently, on February 25, 2013, EPA published proposed SNURs under TSCA for 37 chemical substances that were the subject of PMNs.[21] The proposed SNURs include 14 PMN substances whose reported chemical names contain the term CNT or carbon nanofibers. EPA states that, because of a lack of established nomenclature for CNTs, the TSCA Inventory names for CNTs are currently in generic form, *e.g.*, CNT, multiwalled CNT, double-walled CNT, or single-walled CNT. EPA uses the structural characteristics provided by the submitter to characterize the TSCA Inventory listing for a CNT. All submitters of new chemical notices for CNTs have claimed those specific structural characteristics as confidential business information (CBI). EPA states that it is publishing the generic chemical name along with the PMN number to identify that a distinct chemical substance was the subject of the PMN, without revealing the confidential chemical identity of the PMN substance.

Importantly, EPA has compiled a generic list of those structural characteristics entitled "Material Characterization of Carbon Nanotubes for Molecular Identity (MI) Determination & Nomenclature", which will be available at http://www.regulations.gov under Docket ID Number EPA-HQ-OPPT-2012-0727. If EPA develops a more specific generic chemical name for these materials, that name will be made publicly available.

On the pesticide side of EPA's Toxics Office, EPA announced in April 2010 that it intended to adopt a policy that would require any pesticide registrant that is aware that some constituent of a registered pesticide product is nanosized (i.e., has particles or structures with a diameter less than 100 nm) to submit the information to EPA pursuant to FIFRA Section 6(a)(2).[22] EPA regulations generally limit the obligation of a registrant to report information pursuant to FIFRA Section 6(a)(2) to information that concerns "adverse effects," so this expansion of EPA reporting requirements appears to be based on a premise that EPA regards the mere presence of any nanoscale materials to be "adverse". This approach sparked considerable industry opposition and the policy was never issued. More information about pesticide nanotechnology issues is available at EPA's Web site.[23]

EPA has been asked to consider at least four registration applications seeking registration of products containing nanosilver-based active ingredients. The nanosilver products would take the form of textile additives, polymers, coatings, and/or plastics and would be used to protect a treated product from microorganisms or to impart antimicrobial activity to a treated material. They would be used in the same manner as some of the currently registered silver products, including those used as material preservatives and antimicrobial pesticides.

EPA announced on December 1, 2011, that it is conditionally registering a pesticide product containing nanosilver as a new active ingredient. HeiQ AGS-20 is a silver-based antimicrobial pesticide product approved for use as a preservative for textiles.[24] As a condition of registration, EPA is requiring significant new data development requirements, including route-specific toxicity studies for occupational exposure scenarios and product characterization and stability tests to determine if nanosilver breaks away from HeiQ AGS-20.[25]

The Natural Resources Defense Council (NRDC) filed suit on January 26, 2012, in the U.S. Court of Appeals for the Ninth Circuit (California) challenging EPA's conditional registration of HeiQ AGS-20.[26] During oral arguments held on January 16, 2013, EPA maintained that NRDC lacks standing to challenge the conditional registration. According to NRDC, EPA should have used infants, who are more likely to chew on textiles and could have higher exposures. EPA responded that EPA has a long-standing practice of using three-year-olds in risk assessments with similar exposure patterns to AGS-20 and that its use of three-year-olds was supported by leaching studies.

Other regulatory initiatives include EPA's Office of Research and Development release in 2012 of a final case study examining nanoscale silver in disinfectant spray[27] and a draft case study examining and comparing multiwalled CNTs and decabromodiphenyl ether (decaBDE) flame-retardant coatings applied to upholstery.[28]

NIOSH announced its intent to conduct an exposure assessment and epidemiological study of U.S. workers exposed to CNTs and carbon nanofibers.[29] NIOSH also requested information and comment on silver nanoparticles.[30] NIOSH has initiated an evaluation of the scientific data on silver nanoparticles "to ascertain the potential health risks to workers and to identify gaps in knowledge so that appropriate laboratory and field research studies can be conducted".[30] The National Academy of Sciences (NAS) published recommendations for developing the science needed to address the EHS uncertainties of engineered nanomaterials,[31] and the U.S. Government Accountability Office (GAO) published recommendations for federal agencies to establish performance measures, targets, and timeframes for their nanotechnology EHS research.[32]

FDA issued draft guidance to industry on considerations for using nanomaterials in cosmetics[33] or as food ingredients or food contact substances.[34] The guidance documents reaffirm FDA's view that it regulates products not technologies, that the science of nanotechnology is expanding, and that its oversight of nanotechnology is iterative and adaptive. FDA reiterates, in both guidance documents, its willingness to meet with manufacturers before they take their products to market. The guidance documents will be useful to entities subject to FDA jurisdiction, and provide clarity on topics, including what is a "significant change" in a manufacturing process such that manufacturers should be mindful of the potential regulatory implications of such changes. The suit filed against FDA to compel action on a 2006 petition for rulemaking on nanomaterials was then voluntarily dismissed.[35]

State and Local Regulatory Initiatives. State and local governments are also beginning to focus on the regulation of nanoscale materials from a governance perspective. On December 12, 2006, the Berkeley, California, City Council unanimously approved a proposal to require businesses to report nanoparticles being used, provide available toxicological information, and outline measures for safe handling of the materials. All businesses that manufacture or use nanoparticles must submit a written report of the current toxicology of the nanomaterials reported, and methods for safely handling, monitoring, containing, disposing, and tracking the inventory.[36]

On January 8, 2007, the City Council of Cambridge, Massachusetts, asked the Cambridge Public Health Department to review the Berkeley ordinance and recommend a similar statute for Cambridge. The Cambridge Chamber of Commerce solicited the view of companies, laboratories, and other

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organizations active in the manufacture, research, and/or use of nanomaterials to ensure full industry participation in the City's review of the need for regulation and the possible development of statutes to that end. On July 28, 2008, the City Council voted to accept a set of recommendations for a municipal health and safety policy on nanomaterials. The recommendations were made in a report prepared by the Cambridge Public Health Department and the Cambridge Nanomaterials Advisory Committee.[37] Cambridge became the second city in the United States to take municipal action on nanomaterials.

The California Department of Toxic Substances Control (DTSC) has been obtaining information on nanoscale materials. In a 2009 letter to stakeholders, DTSC announced that it is requiring the submission of data "regarding analytical test methods, fate and transport in the environment, and other relevant information from manufacturers of carbon nanotubes". DTSC states that the term "manufacturers" includes persons and businesses that produce CNTs in California or import CNTs into California for sale.[38]

DTSC identified manufacturers that produce or import CNTs in California, including academic institutions doing CNT research and those manufacturers who are involved in producing or importing CNTs in their chemical form. The call-in "also includes companies outside California who may export carbon nanotubes into the State. Initially, we have not included manufacturers who import products containing carbon nanotubes; however, we may expand the list of manufacturers in the future to include product manufacturers."[38,39]

On January 25, 2010, DTSC posted responses from 17 companies who received a formal information request letter regarding CNTs on the DTSC Web site. DTSC also listed the companies who failed to respond by the January 22, 2010, due date on the DTSC Web site. DTSC issued follow-up letters to nine companies that reportedly failed to respond in a timely manner on February 16, 2010. DTSC also expressed interest in other nanomaterials. In 2010, DTSC stated that it will be focusing on other nanoscale materials, including nanometal oxides such as nano titanium dioxide and nano zinc oxide, and nanometals such as nanosilver and nano zerovalent iron.

Key Standard-Setting Initiatives. Efforts are underway to develop standards involving nanotechnology. The International Organization for Standardization Technical Committee 229 is preparing international consensus standards on several aspects of nanotechnology, including vocabulary, terms, and definitions; measurement and metrology; and EHS.[40]

ASTM International is working on a similar set of standards.[41] ASTM International Committee E 56 on Nanotechnology is developing standards and guidelines for nanotechnology, specifically including the following: terminology and nomenclature; characterization, environmental, and occupational safety and health; international law and intellectual property; liaison and international cooperation; and standards of care and product stewardship.

On the basis of the perception that traditional governance mechanisms, including statutory measures and traditional rulemakings, are inadequate for nanotechnology governance, the private sector is pursuing an unprecedented number of nanogovernance initiatives. These initiatives fall loosely into several categories, including EHS research, nomenclature/terminology, standard-setting initiatives, and product stewardship measures.

EHS research, nomenclature and terminology, and standard-setting measures are underway globally. No effort is made here to discuss each in detail. The work has been undertaken by government organizations; international organizations, including the International Organization for Standardization (ISO), ASTM International, and the Organization for Economic Cooperation and Development (OECD); public interest/research organizations, including Environment Defense Fund (EDF), Meridian Institute, Consumers Union, and the ETC Group, among others; and many private sector entities.

OECD has been energetic in this area. Two OECD Committees are relevant: the Chemicals Committee and its Working Party on Manufactured Nanomaterials (WPMN), and the Committee on Science and Technological Policy's Working Party on Nanotechnology, which focuses on creating supportive frameworks for innovation in nanotechnologies.

The WPMN is engaged in work on a variety of projects, each managed by a Steering Group (SG). The projects are the following: SG1 "Development of an OECD Database on EHS Research"; SG2 "EHS Research Strategies on Manufactured Nanomaterials"; SG3 "Safety Testing of Representative Set of Manufactured Nanomaterials"; SG4 "Manufactured Nanomaterials and Test Guidelines"; SG5 "Co-operation on Voluntary Schemes and Regulatory Programmes"; SG6 "Cooperation on Risk Assessment and Exposure Assessment"; SG7 "Role of Alternative Methods in Nanotechlogy"; SG8 "Cooperation on Exposure Measurement and Exposure Mitigation"; and SG9 "Environmental Sustainable Use of Manufactured Nanomaterials". These projects have commanded the international cooperation of an unprecedented number of OECD participants and others and are advancing the goals of each SG at a rapid pace. The output is expected to be historic at several levels and reflects unprecedented international cooperation. The point here is these activities reflect an internationalization of effort focusing on advancing the responsible development of nanotechnology that has commanded the time, attention, and commitment of global stakeholders unlike any other transnational challenge.

Other global initiatives are underway in the standard-setting arena. The ISO Technical Committee 229 on Nanotechnologies created three working groups: terminology and nomenclature, measurement and characterization, and health, safety, and environment. ASTM International Committee E56 on nanomaterials is also working on nanotechnology standards, and its Subcommittee E56.01 approved a standard on nanotechnology terminology, E2456-06, in 2007.

Key Private-Sector Stewardship Initiatives. In June 2007, EDF and DuPont formally announced the release of their joint effort, the *Nano Risk Framework*. The Framework is rapidly becoming the standard for measuring best management practices in the nano industry. The Framework defines "a systematic and disciplined process for identifying, managing, and reducing potential environmental, health, and safety risks of engineered nanomaterials across all stages of a product's 'lifecycle'—its full life from initial sourcing through manufacture, use, disposal or recycling, and ultimate fate".[42]

EDF and DuPont began their collaborative effort to develop the Framework in September 2005. They released a draft version to the public on February 26, 2007, and received comments from a diverse array of stakeholders—government, academia, public interest groups, and both large and small companies. In addition to considering the various comments, EDF and DuPont conducted pilot-testing on surface-treated, high-rutile phase titanium dioxide (TiO_2), single- and multi-walled CNTs, and nanosized zerovalent iron (nano-Fe^0) "to ensure that [the Framework] is flexible, practical, affordable, and effective."[43] The final document issued "offers guidance on the key questions an organization should consider in developing applications of [nanomaterials], and on the critical information needed to make sound risk evaluations and risk-management decisions".[44] The Framework is intended to support ongoing regulatory initiatives, not replace them.

EDF and DuPont believe that the Framework, aimed primarily at organizations, both private and public, that are actively working with nanomaterials and developing associated products and applications, will help users organize and evaluate currently available information; assess, prioritize, and address data needs; and communicate clearly how risks are being mitigated. Ultimately, EDF and DuPont "believe that the adoption of the Framework can promote responsible development of nanotechnology products, facilitate public acceptance, and support the formulation of a practical model for reasonable government policy on nanotechnology safety".[42]

The Framework consists of six steps and is intended to be used iteratively as stages of development advance and new information becomes available. The six steps are as follows:

Step 1: **Describe Material and Application**. The first step is to develop a general description of the nanomaterial and its intended uses, based on information in the possession of the developer or in the literature. The user also identifies analogous materials and applications that may help fill data gaps in this and other steps.

Step 2: **Profile Lifecycle(s)**. Step 2 defines a process to develop three sets of profiles—the nanomaterial's properties, its inherent hazards, and associated exposures throughout the lifecycle. The user considers the nanomaterial's full lifecycle, from material sourcing, through production and use, to end-of-life disposal or recycling. The user considers how the material's properties, hazards, and exposures may change during that lifecycle.

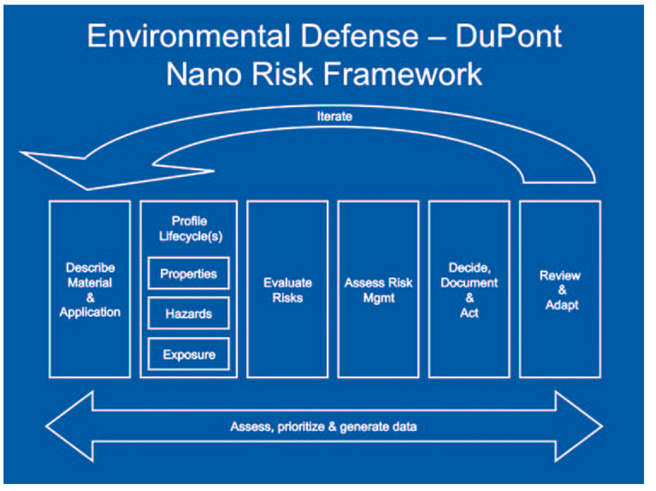
Step 3: **Evaluate Risks**. In this step, all of the information generated in the profiles is reviewed to identify and characterize the nature, magnitude, and probability of risks presented by the nanomaterial and its anticipated application. The user considers gaps in the lifecycle profiles, prioritizes those gaps, and determines how to address them—either by generating data or by using, in place of such data, "reasonable worst case" assumptions or values.

Step 4: **Assess Risk Management**. In the fourth step, the user evaluates the available options for managing the risks identified in step 3 and recommends a course of action. Options include engineering controls, personal protective equipment, risk communication, and product or process modifications.

Step 5: **Decide, Document, and Act**. In step 5, the user consults with the appropriate review team and decides whether or in what capacity to continue development and production. Consistent with transparent decision-making, the user documents those decisions and their rationale and shares appropriate information with the relevant internal and external stakeholders. A worksheet is provided in the appendix for documenting information, assumptions, and decisions.[45]

Step 6: **Review and Adapt**. Through regularly scheduled and triggered reviews, the user updates and re-executes the risk evaluation, ensures that risk management systems are working as expected, and adapts those systems in the face of new information or new conditions. Reviews may be prompted by development milestones, changes in production or use, or new hazard or exposure data. As in step 5, the user not only documents changes, decisions, and actions but also shares appropriate information with relevant stakeholders.

Below is a schematic setting forth the six steps. (Reprinted with permission from ref 42, p 3. Copyright 2007 Dupont).



Another private sector initiative is the GoodNanoGuide, a collaboration platform designed to enhance the ability of experts to exchange ideas on how best to manage nanomaterials in occupational settings. The GoodNanoGuide's beta sponsors include the National Institute for Occupational Safety and Health, International Council on Nanotechnology, Nanotech BC, Nano Alberta, Health Canada, Nano Quebec, and IRSST (a scientific research organization in Quebec).[46] The GoodNanoGuide has three goals: develop and launch a protected Internet site on occupational practices for the safe handling of nanomaterials using a Wiki-software platform; create a process wherein multiple stakeholders within the international community contribute, share, and discuss information related to occupational safety; and establish a modern, interactive forum that fills the need for up-to-date information and remains current as new practices develop.

While the GoodNanoGuide reflects the global dialogue underway regarding the effect nanotechnologies may have on human health, the environment, and society in general, the GoodNanoGuide is not meant to address or resolve such issues. Instead, according to ICON, it "is a collaboration platform designed to enhance the ability of experts to exchange ideas on how best to handle nanomaterials in an occupational setting".[46]

Finally, the GoodNanoGuide is open for everyone to review. To ensure the dependability of the good practices reported, the GoodNanoGuide is a protected site in which contributions are limited to those individuals that have become GoodNanoGuide members.

■ FOSTERING AND PROMOTING GREEN NANOTECHNOLOGY

Emerging governance strategies and mechanisms demonstrate a global concerted effort to ensure effective oversight mechanisms are in place to foster the responsible development of sustainable nanotechnology. Many of the EHS concerns associated with nanotechnology could be addressed through more extensive application of green nanotechnology practices. By ensuring nanoscale materials are engineered with an eye on sustainability, their use in applications to further sustainability are unlikely to invite the kinds of EHS concerns that have been the subject of much discussion over the past several years. To foster the development of green nanotechnology, these are specific actions stakeholders should consider embracing and promoting.

Develop a Life-Cycle Assessment Appropriate for Green Nanoproducts. Before a product or production process can be considered green, the product's EHS implications must be assessed using an appropriately tailored life-cycle assessment (LCA) that is capable of identifying and quantifying nanotechnology EHS implications and gauging the trade-offs that arise in the context of their applications. An LCA is a comprehensive management tool that is used to evaluate how a material and/or a product, from the status of production through end-of-life, affects ecosystems and human health.

Establish Performance and Branding Standards for Green Nanotechnology. Too little is known about green nanotechnology, and the terms—green nanotechnology—are not well understood or consistently interpreted. Stakeholders should consider establishing specific standards that products would need to meet to be considered green. If these standards are met, stakeholders should consider the criteria to apply in branding products as "green nano".

Provide Tax and Related Business Incentives to Innovators to Encourage Application of Green Nanotechnology. Among the many challenges nano-innovators face is the cost of commercializing a product and the shortage of investment capital to do so. To the extent government funding is available, it should be made available first to nano-innovators who embrace green nanotechnology. Similarly, much could be done to incentivize green nano by offering greater tax benefits and other forms of tax relief for those who practice green nanotechnology.

Increase Patent Term Protection for Green Nanoproducts. Innovators whose products reflect the principles of green nano should be rewarded by extended patent term protection or other form of intellectual property protection.

Establish a DfE Green Nano Category. EPA's Design for the Environment (DfE) recognizes and rewards innovative product design that reflects sustainability. The program could develop a green nano category that promotes nanoproducts that are the result of green nanotechnology.

Provide Greater Funding for Green Nano Research. Research dollars are always in short supply in the nano area. Enhanced research funding could be made available to green nano research.

Convene a Forum to Develop and Implement Green Nano Principles in a Systematic Way. While there are many ongoing dialogues focusing on controlling risks from nanomaterials, there remains a paucity of fora that address risk prevention through the design of safer and more environmentally benign nanomaterials and the processes that make them. The creation of a forum intended chiefly to address green nano principles would provide great value.

Actively Promote Green Nano in Regulatory and Voluntary Initiatives. Stakeholders should actively promote and advocate principles of given nano in all initiatives—regulatory and voluntary—to ensure a cohesive set of principles emerges and is embedded in pesticides initiatives. Stakeholders should seek to engage EPA in developing such principles as part of the new chemical review process.

CONCLUSION

As with other commercial, legal, and governance issues, businesses engaged in the production and use of nanoscale materials must look to existing laws and regulations, voluntary and stewardship initiatives, and best industry practices to avoid liability. At the same time, these entities must discover new ways to proceed in an arena where the state of knowledge is still catching up to entrepreneurial initiatives. Joining and actively supporting the SNO is one way stakeholders can achieve the goals of sustainable nanotechnology as SNO's primary reason for being is to promote and achieve sustainable nanotechnology.

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Notes

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(17) Proposed Significant New Use Rules on Certain Chemical Substances. Reopening of Comment Period. *Fed. Regist.* **2012**, *77*, 4947; to be codified at 40 C.F.R. pt. 721; reopening of comment period.
(18) Notice, Certain New Chemicals; Receipt and Status Information. *Fed. Regist.* **2012**, *77*, 64984.
(19) Notice, Certain New Chemicals; Receipt and Status Information. *Fed. Regist.***2012**, *77*, 5092. Notice, Certain New Chemicals; Receipt and Status Information. *Fed. Regist.* **2012**, *77* 48514.
(20) Significant New Use Rules on Certain Chemical Substances. *Fed. Regist.* **2012**, *77*, 20296, 20299; to be codified at 40 C.F.R. § 721.10287.
(21) *Fed. Regist.* **2013**, *78*, 12684.
(22) See Jordan, W. Nanotechnology and Pesticides. *Presentation to the Pesticide Program Dialogue Committee*, Arlington, VA, Apr 29, 2010; http://www.epa.gov/pesticides/ppdc/2010/april2010/session1-nanotec.pdf.
(23) EPA. Regulating Pesticides that Use Nanotechnology. http://www.epa.gov/pesticides/regulating/nanotechnology.html (accessed May 2013).
(24) EPA. Pesticide News Story: EPA Announces Conditional Registration of Nanosilver Pesticide Product. http://www.epa.gov/oppfead1/cb/csb_page/updates/2011/nanosilver.html (accessed May 2013).
(25) EPA's Decision Document: Conditional Registration of HeiQ AGS-20 as a Materials Preservative in Textiles. http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-1012-0064 (accessed May 2013). The data requirements are set forth in Appendix A.
(26) A recording of the oral arguments is available at http://www.ca9.uscourts.gov/media/view.php?pk_id=0000010249 (accessed May 2013).
(27) EPA. Nanomaterial Case Study: Nanoscale Silver in Disinfectant Spray (Final Report). http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=241665 (accessed May 2013).
(28) Notice; Nanomaterial Case Study: A Comparison of Multi-walled Carbon Nanotubes and Decabromodiphenyl Ether Flame-Retardant Coatings Applied to Upholstery Textiles. *Fed. Regist.* **2012**, *77*, 39236.
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(30) Notice; Silver Nanoparticles (AgNPs); Information and Comment Request. *Fed. Regist.* **2012**, *77*, 75169.
(31) National Academy of Sciences. *A Research Strategy for Environmental, Health, and Safety Aspects of Engineered Nanomaterials*; National Academies Press: Washington, D.C., 2012; available at http://www.nap.edu/catalog.php?record_id=13347.
(32) U.S. Government Accountability Office. *Nanotechnology: Improved Performance Information Needed for Environmental, Health, and Safety Research*, 2012; report GAO-12-427; available at http://www.gao.gov/products/GAO-12-427.
(33) Notice, Draft Guidance for Industry: Safety of Nanomaterials in Cosmetic Products; Availability. *Fed. Regist.* **2012**, *77*, 24722.
(34) Notice, Draft Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients That Are Color Additives; Availability. *Fed. Regist.* **2012**, *77*, 24722.
(35) *International Center for Technology Assessment v. Hamburg*, No. 3:11-cv-06592-MEJ; California Northern District Court; dismissal entered May 14, 2012.
(36) The amendment is available at http://www.ci.berkeley.ca.us/citycouncil/ordinances/2006/6960.pdf (accessed Mar 2013).
(37) *Recommendations for a Municipal Health & Safety Policy for Nanomaterials: A Report to the Cambridge City Manager*; Cambridge Public Health Department: Cambridge, MA, 2008; available at http://www.cambridgepublichealth.org/publications/July_17_08_Nano_Recommendations.pdf. The recommendations call for Cambridge to take the following steps: establish an inventory of facilities that manufacture, process, handle, or store engineered nanoscale materials; offer technical assistance to help firms and institutions evaluate their existing health and safety plans; offer up-to-date health information to residents on products containing nanomaterials; track rapidly changing developments in research; track the evolving status of regulations and best practices concerning engineered nanoscale materials; and report back to the City Council every other year on the changing regulatory and safety landscape.
(38) The letter is available at http://www.dtsc.ca.gov/TechnologyDevelopment/Nanotechnology/upload/Formal_AB289_Call_In_Letter_CNTs.pdf (accessed May 2013).
(39) DTSC's current list of manufacturers is available on the Internet at http://www.dtsc.ca.gov/TechnologyDevelopment/Nanotechnology/upload/AB289_CNT_Contact_List.pdf (accessed May 2013).
(40) http://www.iso.org/iso/home/store/catalogue_tc/catalogue_tc_browse.htm?commid=381983=on=true (accessed June 2013).
(41) http://www.astm.org (accessed May 2013).
(42) A complete copy of the Framework and other related information are available at http://www.nanoriskframework.com/download-framework/ (accessed June 2013).
(43) http://nanoriskframework.com, p 12.
(44) http://nanoriskframework.com, p 7.
(45) Completed worksheets for the three DuPont demonstration projects—TiO_2, CNTs, and nano-Fe^0—are available at http://www.nanoriskframework.com/case-studies/ (accessed May 2013).
(46) The GoodNanoGuide is available at http://www.goodnanoguide.org (accessed May 2013).