REGULATION OF NANOTECHNOLOGY AND NANOMATERIALS AT EPA AND AROUND THE WORLD: RECENT DEVELOPMENTS AND CONTEXT

MARK N. DUVALL
ALEXANDRA M. WYATT

FEBRUARY 18, 2011

Beveridge & Diamond, P.C.

1350 I Street, N.W., Suite 700

Washington, DC 20015

www.bdlaw.com

Executive Summary

This paper reviews key regulatory developments involving nanomaterials in the United States and elsewhere.

Nanotechnology is confronting regulators around the world with new technical, legal, and policy issues. Companies manufacturing, processing, or using nanomaterials for their revolutionary properties must navigate an uncertain, rapidly changing, and diverse regulatory environment. Strategies taken now may impact the market for products with nanomaterials far into the future. Tracking the most important of these developments and trends is therefore essential.

In the United States, the Environmental Protection Agency (EPA) is shifting from a voluntary to a mandatory approach to regulating and collecting information on the potentially novel risks from nanomaterials. Under the Toxic Substances Control Act (TSCA), in particular, EPA has reviewed more than 100 premanufacture notices for nanomaterials and has imposed restrictions on many of them. EPA is taking advantage of its current significant new use rule (SNUR) authority to impose restrictions and gather data on nanomaterials, with several SNURs for nanomaterials already on the books and a categorical SNUR for other nanomaterials in development. EPA is also developing a mandatory data submission rule and a testing rule for certain nanomaterials, and may be given more authority to regulate nanomaterials if TSCA legislation proceeds through Congress. EPA's efforts under TSCA are complemented by data gathering and regulatory measures under the Federal Insecticide, Fungicide, and Rodenticide Act, which regulates antimicrobial nanomaterials like nanosilver. A nanosilver active ingredient is in the process of potentially being conditionally registered, and EPA has also used nanosilver in a major draft case study. Other federal agencies and U.S. states and localities are also devoting attention to nanomaterials and in some cases imposing requirements.

Outside the United States, nanomaterial regulatory requirements are most prominent in the European Union, where nanomaterials are singled out for regulation under the Cosmetics Directive and where regulators are considering future alterations to the REACH Regulation and to the Restriction of Hazardous Substances (RoHS) Directive related to nanomaterials. Many other countries have also taken or are considering actions to regulate nanomaterials. Activities by other international agencies and organizations may have significant impacts on nanomaterial producers, processors, and users.

Contents

REGULATION OF NANOTECHNOLOGY AND NANOMATERIALS AT EPA AND AROUND THE WORLD: RECENT DEVELOPMENTS AND CONTEXT

Introduction

Nanotechnology, "the understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications,"[1] is a rapidly developing field with the potential to revolutionize many areas including electronics, medicine, energy production, and consumer products. However, regulators involved in these areas are struggling to deal with the novel issues and potential risks that nanotechnology may present. Nanomaterials are engineered materials approximately 1 to 100 nanometers (less than one one-thousandth of the width of a human hair) in at least one dimension. They can have unique properties that may not be adequately captured in current regulatory requirements, research standards, and risk assessment methods. The U.S. government is investing heavily in understanding the potential risks and benefits of nanomaterials; the President's 2012 Budget proposed $2.1 billion for the multi-agency National Nanotechnology Initiative -- a $201 million increase from the 2010 enacted level.[2] Stakeholders continue to debate whether nanomaterials are sufficiently similar to other scale materials to be regulated by the same methods, or whether more targeted approaches are needed.

The United States Environmental Protection Agency (EPA) has changed its approach to regulation of nanomaterials. Having previously sought to encourage nanomaterial manufacturers to provide information voluntarily through the Nanoscale Materials Stewardship Program (NMSP), EPA is shifting toward mandatory approaches, both to gather information and to impose standards on the manufacture, use, and disposal of nanomaterials. These changes at EPA are taking place along with and often in cooperation with actions at other agencies in the United States and around the world.

This document is intended to provide an overview of some of the most important recent developments relating to the regulation of nanotechnology, to project what this means for the future, and to show how these developments and trends are important for a wide range of industry sectors.

[1] National Nanotechnology Initiative, What Is Nanotechnology?, http://www.nano.gov/html/facts/whatIsNano.html.
[2] Office of Science and Technology Policy, Innovation, Education, and Infrastructure Science, Technology, STEM Education, and 21st Century Infrastructure in the 2012 Budget (2011), http://www.whitehouse.gov/sites/default/files/microsites/ostp/FY12-rd-fs.pdf.

I. Regulation of Nanomaterials at EPA

A. Toxic Substances Control Act

1. Background

The Toxic Substances Control Act (TSCA)[3] is the main statute under which industrial chemicals are regulated in the United States. TSCA provides EPA with authority to review new chemicals and certain new uses of chemicals before they enter the market, impose restrictions, and then add those new chemicals to the TSCA Inventory list of existing chemicals. Under TSCA, EPA may also require reporting, recordkeeping, and testing of chemicals that may pose an unreasonable risk to human health or the environment or that reach certain production or exposure levels. Certain substances are generally excluded from TSCA, including pesticides, food, drugs, and cosmetics.

At the outset, EPA's activities under TSCA should be viewed in light of the ongoing debate regarding legislative overhaul of TSCA. The ability of TSCA to adequately regulate new technologies such as nanomaterials has been a theme in the TSCA legislative discussion in Congress and among stakeholders. Of particular concern have been those nanomaterials which are nanoscale versions of chemicals already listed on the TSCA Inventory. To the extent such nanomaterials are deemed existing rather than new chemicals, some argue that EPA has less effective authority to review and regulate them. While this debate is ongoing, however, EPA has been engaging in increasingly aggressive regulatory efforts under TSCA's current provisions.

EPA's efforts under TSCA at first centered on voluntary industry efforts and research. It launched the Nanoscale Materials Stewardship Program (NMSP) in 2007, following several years of preparation and design.[4] The NMSP included a basic program for reporting available information as well as a more in-depth program to develop data, including testing, over a longer time frame. However, the NMSP concluded in 2009 with only limited success.[5] The information gathered by the NMSP has framed subsequent regulatory efforts under TSCA, which have turned away from this voluntary model. EPA also issued a Nanotechnology Research Strategy, [6] which is now being implemented.[7]

---

[3] 15 U.S.C. § 2601 et seq.

[4] *See* EPA, Nanoscale Materials Stewardship Program, http://www.epa.gov/opptintr/nano/stewardship.html.

[5] EPA issued an interim final report on the NMSP in 2009, http://www.epa.gov/opptintr/nano/nmsp-interim-report-final.pdf. No final report has been issued since then.

[6] EPA, Nanomaterial Research Strategy (2007), http://www.epa.gov/nanoscience/files/nanotech_research_strategy_final.pdf.

[7] For example, EPA announced recently the award of $5.5 million in grants to help researchers determine whether certain nanomaterials can leach out of products such as paints, plastics, and fabrics when they are used or disposed of and whether they could become toxic to people and the environment. EPA press release, EPA Awards $5.5 Million to Support Nanotechnology Research / Research to help determine whether health risks exist (Feb. 17, 2011), http://yosemite.epa.gov/opa/admpress.nsf/d0cf6618525a9efb85257359003fb69d/a9c35e55b54855a48525783a0066b29e!OpenDocument.

EPA issued a Nanotechnology White Paper in 2007, analyzing and providing recommendations relating to potential environmental benefits of nanotechnology, research needs associated with nanotechnology and risk assessment, and the relationship between nanotechnology and EPA's statutory mandates. In 2008, EPA built on the White Paper and the NMSP by issuing a guidance document, "TSCA Inventory Status of Nanoscale Substances – General Approach,"[8] which indicated that EPA would deem the nanoscale version of a macroscale substance listed on the TSCA Inventory, i.e., having the same molecular identity, to be an "existing" chemical substance. EPA under the Obama Administration subsequently undertook a review of that policy, due to doubts (partly inspired by the NMSP's limitations) that EPA could effectively regulate nanomaterials other than under the TSCA New Chemicals Program. EPA apparently resolved its review by planning several new rules governing nanomaterials.

Since 2005, EPA has received and reviewed more than one hundred premanufacture notices (PMNs) and low volume exemption applications for nanomaterials not on the TSCA Inventory, including carbon nanotubes and fullerenes, among others. EPA has permitted manufacture of these new nanomaterials under limited conditions, generally as provided in consent orders under section 5(e) of TSCA.[9] In 2010, EPA issued technical guidance for assessing screening level risks for nanomaterials, which guidance informs its review of nanomaterial PMNs.[10]

2. Recent and Upcoming Significant New Use Rules

a. Final Carbon Nanotube SNURs[11]

Under section 5 of TSCA, a manufacturer (defined to include an importer) must notify EPA through a PMN at least 90 days in advance of a new chemical's commercialization, to provide EPA an opportunity for review. (Low volume exemption applications allow a shorter review period.) There is no minimum data set required, but if EPA has concerns about a new chemical, it may enter into a consent order under section 5(e) with the manufacturer so that EPA allows the chemical to enter the market only under certain conditions, for example testing requirements or worker protections. Once the chemical is commercialized, it is listed on the TSCA Inventory (i.e., is "existing") and is no longer deemed "new." Thus, because the consent order only applies to the individual manufacturer who submitted the notice, other manufacturers could manufacture the chemical without submitting notices. To avoid this problem, section 5(a)

---

[8] EPA, Nanotechnology White Paper (2007), http://www.epa.gov/oppt/nano/nmsp-inventorypaper.pdf.

[9] *See* Organisation for Economic Co-operation and Development (OECD), Current Developments/Activities on the Safety of Manufactured Nanomaterials (2010), ENV/JM/MONO(2010)42, at 60, http://www.oecd.org/officialdocuments/displaydocument/?cote=env/jm/mono(2010)42&doclanguage=en; Beveridge & Diamond, P.C., Developments in the Regulation of Carbon Nanotubes under TSCA (2010), http://www.bdlaw.com/assets/attachments/2010-12-14%20Client%20Alert%20re%20CNT%20SNUR%20and%20Docket.pdf.

[10] EPA, Interim Technical Guidance for Assessing Screening Level Environmental Fate and Transport of, and General Population, Consumer, and Environmental Exposure to Nanomaterials (2010), http://www.epa.gov/oppt/exposure/pubs/nanomaterial.pdf.

[11] *See generally* Beveridge & Diamond, P.C., Developments in the Regulation of Carbon Nanotubes Under TSCA (2010), http://www.bdlaw.com/assets/attachments/2010-12-14%20Client%20Alert%20re%20CNT%20SNUR%20and%20Docket.pdf.

authorizes EPA to issue significant new use rules (SNURs) essentially imposing the consent order requirements on all new uses of the chemical. However, complications have arisen when applying SNURs to nanomaterials, and specifically to carbon nanotubes (CNTs).

EPA considers CNTs to be different from carbon and graphite for purposes of the TSCA Inventory.[12] EPA has entered into consent orders with a number of PMN submitters for CNTs requiring, among other things, occupational protections and a 90-day inhalation test with laboratory rats. EPA issued direct final SNURs for two particular CNTs in 2009,[13] but withdrew and reissued the SNURs as a proposal after receiving notice that stakeholders were preparing to submit critical comments. The final SNURs, issued in September 2010,[14] deem the following activities significant new uses and require information submission by manufacturers or processors prior to beginning them:

- Any use of the CNTs without full-body chemical protective clothing to prevent dermal exposure and National Institute for Occupational Safety and Health (NIOSH)-approved respirators to prevent inhalation exposure;
- Any industrial, commercial, or consumer use other than allowed by the section 5(e) consent order;
- Aggregate manufacture and importation volume greater than that allowed by the section 5(e) consent order; or
- Any predictable or purposeful release of the substance, or a manufacturing stream associated with any use of the substance, into the waters of the United States.

The final SNURs for the two individual CNTs (and proposed SNURs for one other CNT[15]) provide important insights for nanomaterial manufacturers and users into EPA's approach to CNTs and other nanomaterials. The SNURs exempt CNTs that have been fully reacted or embedded in a polymer matrix, which will be important for the market for these materials. The European Commission thought the SNURs and other EPA nanotechnology regulations would be improved, and better harmonized with Europe's approach, if they included more exemptions for highly controlled circumstances of use where exposure criteria are met.[16] Some commenters have urged EPA to allow companies to test a representative sample of the materials they propose to manufacture, rather than each individual material.[17] Commenters on the SNURs also pushed back against the need for dermal exposure protections, and requested that the prohibition on releases to water include a de minimis limit; they were not successful in either case.

---

[12] 73 Fed. Reg. 64946 (Oct. 31, 2008).
[13] 74 Fed. Reg. 29982, 29990-91 (June 24, 2009).
[14] 75 Fed. Reg. 56880 (Sep. 17, 2010).
[15] 75 Fed. Reg. 5546 (Feb. 3, 2010) (proposed rule); 75 Fed. Reg. 44198 (Jul. 28, 2010) (reopening comment period).
[16] *See* Comments of the European Commission (2010), Docket EPA-HQ-OPPT-2008-0252, http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2008-0252-0122.1.
[17] *E.g.*, NanoSafety Consortium for Carbon, Correspondence with U.S. EPA, http://www.nanosafetyconsortium.com/keydocuments.html.

b. Upcoming Categorical SNUR

EPA is also planning to propose a categorical SNUR for existing nanomaterials.[18] EPA has predicted issuance of the proposed categorical SNUR by February 2011[19] and the final SNUR by the end of 2011.[20]

Section 26(c) of TSCA allows EPA to take any action allowable for a single chemical with respect to a "category" (a group of chemicals whose members are similar in some sense or "are in some other way suitable for classification as such"). The authors of this paper previously identified this rarely used approach as potentially useful to EPA in dealing with "existing" nanomaterials.[21] The categorical SNUR plan essentially resolves the debate over EPA's 2008 guidance document, TSCA Inventory Status of Nanoscale Substances – General Approach, by giving EPA roughly equal opportunities to impose controls on many nanomaterials under the new chemical and SNUR provisions of TSCA. The key difference is that with "existing" nanomaterials EPA must issue a SNUR through rulemaking, while with "new" nanomaterials EPA may issue a consent order.

According to EPA, the categorical SNUR for nanomaterials will be based on the category of "existing" nanomaterials (those with the same molecular identity as a macroscale substance listed on the Inventory).[22] EPA cannot regulate ongoing uses under its SNUR authority. It apparently plans to exclude uses of nanomaterials that are ongoing at the time of issuance of the proposal. The SNUR would apply broadly to any chemical for which more than 10% of its particle range is 1-100 nanometers, unless already subject to a SNUR. EPA's initial announcement indicated that the information required to be submitted by manufacturers or processors prior to engaging in the new uses would include chemical identification, material characterization, physical/chemical properties, commercial uses, production volume, exposure and fate data, and toxicity data. EPA has indicated that the SNUR will apply to processors as well as manufacturers. This could greatly extend the impact of the SNUR to industry sectors that use nanomaterials in their materials and products.

Even more than the consent order-based SNURs for individual CNTs, the categorical SNUR demonstrates that EPA is intent on gathering information about nanomaterials even at the expense of potentially slowing or limiting the expansion of markets and uses for nanomaterials. Many of the companies manufacturing nanomaterials are small startups on whom the SNUR requirements may be more burdensome. Larger companies that are considering purchasing or

---

[18] EPA, Control of Nanoscale Materials under the Toxic Substances Control Act, http://www.epa.gov/opptintr/nano/.
[19] EPA, Regulatory Agenda (December 20, 2010) at 262, http://www.regulations.gov/public/ContentViewer?objectId=0900006480bba9ef&disposition=attachment&contentType=pdf.
[20] EPA, Control of Nanoscale Materials under the Toxic Substances Control Act, http://www.epa.gov/oppt/nano/.
[21] Mark Duvall and Alexandra Wyatt, Using TSCA for "Existing" Nanomaterials: The Case for Significant New Use Rules, Bureau of National Affairs, Chemical Regulation Reporter, Vol. 33, No. 9, pp. 205-213 (2009), http://www.bdlaw.com/attachment/232/Using%20TSCA%20for%20'Existing'%20Nanomaterials%20-%20The%20Case%20for%20Significant%20New%20Use%20Rules.pdf.
[22] *See* Beveridge & Diamond, P.C., Update on Developments in EPA Regulation of Nanotechnology (Apr. 5, 2010), http://www.bdlaw.com/news-843.html.

using nanomaterials also need to be aware of the categorical SNUR so that they can work with suppliers to maintain compliance with applicable import, export, and reporting requirements.

3. Upcoming Information-Gathering Rules

EPA is proposing additional information-gathering rules under two other sections of TSCA. First, EPA is developing a mandatory information submission rule to require that nanomaterial manufacturers (including importers) notify EPA of certain information including production volume, methods of manufacture and processing, exposure and release information, and available health and safety data.[23] The scope of nanomaterials to which this rule would apply is currently unknown. Notably, the regulations for information submission rules allow for exemptions for R&D and small manufacturers and processors, unless the particular rule adds to, removes, or revises the default exemptions.[24]

Second, EPA is planning a test rule for other certain nanomaterials in commerce, particularly those not already being tested by other federal and international organizations.[25] EPA plans to focus on certain commercially relevant, high production volume single-walled and multi-walled CNTs, and on nanoscale clays and silica. The tests to be required are anticipated to include a two-year bioassay, chronic exposure, and environmental fate testing. The environmental fate testing will include leaching from landfills, weathering, incineration, and photolysis, since EPA is concerned about the potential for CNTs that are agglomerated or enmeshed in a polymer matrix to be freed at the end of life and be released into the environment.[26] According to EPA, "the results could also help to establish a correlation between the chemical/physical properties and the effects of the nanoscale materials."[27] EPA is projecting publication of a proposed reporting rule in February 2011 and a proposed test rule in April 2011,[28] with final rules for both issued by the end of 2011.[29]

While nanomaterial users who are not processors are not likely to be required by these rules to supply information to EPA, they may be asked for information by their suppliers, especially pertaining to use, exposure, and release data. Additionally, nanomaterial users may be impacted by these rules in terms of the market effects they may have on the development and production of both new and existing nanomaterials. The information gathered from these rules is also likely to feed into other nanotechnology regulatory efforts at EPA down the road.

---

[23] EPA, Control of Nanoscale Materials under the Toxic Substances Control Act (citing TSCA section 8(a)), http://www.epa.gov/opptintr/nano/.
[24] 40 C.F.R. § 704.5.
[25] EPA, Control of Nanoscale Materials under the Toxic Substances Control Act (citing TSCA section 4), http://www.epa.gov/opptintr/nano/.
[26] *See* Beveridge & Diamond, P.C., Update on Developments in EPA Regulation of Nanotechnology (Apr. 5, 2010), http://www.bdlaw.com/news-843.html.
[27] EPA, Control of Nanoscale Materials under the Toxic Substances Control Act, http://www.epa.gov/opptintr/nano/.
[28] EPA, Regulatory Agenda (December 20, 2010) at 252, 257, http://www.regulations.gov/public/ContentViewer?objectId=0900006480bba9ef&disposition=attachment&contentType=pdf.
[29] EPA, Control of Nanoscale Materials under the Toxic Substances Control Act, http://www.epa.gov/opptintr/nano/

4. TSCA Modernization Legislation

The regulation of nanomaterials under TSCA has proven to be a hot topic as legislators and stakeholders debate legislation to overhaul TSCA.[30] The TSCA bills released by the Senate in April 2010, the Safe Chemicals Act of 2010, S. 3209, and by the House of Representatives in July 2010, the Toxic Chemicals Safety Act of 2010, H.R. 5820, included a number of important provisions singling out nanomaterials. The legislation proposed to allow EPA to deem all nanomaterials to be new chemicals, requiring submission of information before manufacture, import, or processing. The general provisions of the bills, too, would have dramatically impacted nanomaterials as well as other chemicals, by, among other elements, imposing a new and more stringent safety standard and extensive minimum data set for all chemicals.

TSCA legislation did not pass (even out of committee) before the end of the 111th Congress. Its progress now depends on its reintroduction, likely with substantial changes, in the more heavily Republican 112th Congress.[31] Prospects are uncertain, but there is still some chance that TSCA reform legislation will be enacted, depending in part on the action of stakeholders in promoting compromise.

B. Federal Insecticide, Fungicide, and Rodenticide Act

Chemicals, including nanomaterials, intended to prevent, destroy, repel, or mitigate pests, including microorganisms, are regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),[32] which gives EPA stronger information gathering and new product registration powers than does TSCA. Some nanomaterials, such as nanosilver, are potent antibacterial substances. Nanosilver is therefore one of the most prevalent engineered nanoparticles in consumer products, electronics, and medical devices.

As under TSCA, controversy has arisen whether nanoscale versions of already-reviewed substances should be considered new for regulatory purposes. The International Center for Technology Assessment (ICTA) and allied groups petitioned EPA in 2008 to classify nanosilver as a new pesticide under FIFRA,[33] and more recently filed a similar petition regarding nano-copper.[34] EPA is addressing nanoscale pesticides through its first proposed registration—a conditional one—of a known nanosilver pesticide and through development of a general reporting policy for nanomaterials. EPA is also proceeding with analytical efforts in support of ongoing and future nanopesticide risk assessments.

In 2010, the Government Accountability Office (GAO) recommended that EPA:

---

[30] *See* Beveridge & Diamond, P.C., Proposed TSCA Amendments Would Target Nanomaterials (2010), http://www.bdlaw.com/news-891.html; Beveridge & Diamond, P.C., House Discusses Potential Dramatic Changes to U.S. Chemicals Law (2010), http://www.bdlaw.com/news-938.html.

[31] *See* Beveridge & Diamond, P.C., Prospects for TSCA Legislation in the 112th Congress (2011), http://www.bdlaw.com/news-1049.html.

[32] 7 U.S.C. § 136 et seq.

[33] ICTA, Citizen Petition for Rulemaking to the United States Environmental Protection Agency (2008), http://www.nanoaction.org/nanoaction/doc/CTA_nano-silver%20petition__final_5_1_08.pdf.

[34] *See* ICTA, Letter to EPA Assistant Administrator Stephen A. Owens (Nov. 18, 2010), http://www.beyondpesticides.org/documents/ICTA%20Nano%20Copper%20Petition%20-%20Final.pdf.

- Modify FIFRA pesticide registration guidelines to require applicants to identify nanomaterial ingredients in pesticides.

- Complete its plan to clarify that nanoscale ingredients in already registered pesticides, as well as in those products for which registration is being sought, are to be reported to EPA and that EPA will consider nanoscale ingredients to be new.[35]

As explained below, EPA is in the process of implementing those recommendations.

1. Development of Nanoscale Ingredient Reporting Policy

EPA previously sent letters to the current registrants of all silver-based antimicrobial products informing them that they had a legal obligation under FIFRA section 6(a)(2) and its regulations, which dictate that pesticide registrants must submit any information concerning "unreasonable adverse effects" of their products, to identify for the Agency the presence of nanoscale ingredients in their products.[36] EPA is also preparing a Federal Register notice to (a) announce this interpretation of FIFRA section 6(a)(2) and its regulations, and (b) propose a new policy that when an active or inert ingredient contains a nanoscale material, it would be presumptively considered a new active or inert ingredient.[37] EPA plans to require additional data on all products with nanoscale materials, with the data need to be determined on a case-by-case basis according to the composition of the product and its intended use. EPA plans to issue the data call-in in 2011.[38] EPA submitted a notice on "Pesticide Products Containing Nanoscale Materials" in July 2010 for 90-day review by the Office of Management and Budget (OMB) under Executive Order 12866, but OMB extended that review, which is currently still pending.[39]

2. First Proposed Conditional Registration for Nanosilver

In January 2010, EPA's FIFRA Science Advisory Panel (SAP) recommended that EPA impose major additional data requirements for nanosilver pesticide product registrants and emphasized the importance of case-by-case review. These tiered data requirements, relating to product chemistry, toxicology, exposure, and environmental data, are in the process of being formalized in a proposed conditional registration of an antimicrobial nanosilver product, HeiQ AGS-20, a textile finishing powder.[40] Notably, the registration application originally claimed that HeiQ AGS-20 was similar to other currently registered silver-based antimicrobial pesticide

---

[35] GAO, Nanotechnology: Nanomaterials Are Widely Used in Commerce, but EPA Faces Challenges in Regulating Risk, GAO-10-549 (May 2010), http://www.gao.gov/new.items/d10549.pdf.

[36] William Jordan, Senior Policy Advisor, Office of Pesticide Programs, EPA, Pesticide Program Dialogue Committee Meeting (Apr.29, 2010), transcript at 29, http://www.epa.gov/pesticides/ppdc/2010/april2010/transcript.pdf.

[37] *Id.* at 33-36.

[38] Jennifer McLain, Deputy Director, Antimicrobials Division, Office of Pesticide Programs, EPA, PPDC Update - Pesticides Containing Nanoscale Materials (Dec. 14, 2010), http://www.epa.gov/pesticides/ppdc/2010/dec2010/session5-nano.pdf.

[39] *See* OMB, Executive Order Submissions Under Review, http://www.reginfo.gov/public/do/eoReviewSearch.

[40] *See* EPA, Proposed Decision Document for the Registration of HeiQ AGS-20 as a Materials Preservative in Textiles (Aug. 12, 2010), http://www.regulations.gov/search/Regs/contentStreamer?objectId=0900006480b2f27e&disposition=attachment&contentType=pdf.

products. Despite the delay in the formal release of the policy described in subsection 1 above, EPA determined that its nanosilver active ingredient was different from registered silver and therefore reclassified the application one involving a "New Active Ingredient Registration."

EPA proposed in August 2010 to grant a time-limited conditional registration, largely because the manufacturer would have had no time to comply with the SAP's data requirement recommendations, which were only finalized in the proposed conditional registration itself. The data developed during the four-year conditional registration period would determine whether the product could ultimately be registered. Despite this current lack of data, EPA proposed to decide that use of AGS-20 is in the public interest and would not cause unreasonable adverse effects during the conditional registration period, given label language and occupational and engineering control requirements. As another justification for the conditional registration, EPA stated that some products already registered for similar uses were later found to contain nanosilver, and EPA did not want to excessively disadvantage HeiQ relative to these other companies that did not have to submit the extensive data. EPA stated that it intends to require that similar data be developed to support the continued registration of these other nanoscale products as well, though it did not state how it plans to do so.

The proposed conditional registration of HeiQ AGS-20, if finalized, would represent an important step for the use of nanosilver in consumer products. While the data generation will be costly, it will set the stage for future nanosilver and other nanopesticide registrations if EPA finds that the data meets FIFRA's standard of safety. EPA has also provided more certainty as to its data requirements for registration, which should benefit the market for nanosilver products. Despite these advantages, EPA received generally critical comments on the proposed conditional registration from several dozen individual citizens and a number of institutions, urging EPA to consider alleged known risks and potential unknown risks, especially to aquatic systems and wastewater treatment plants.[41]

3. Nanosilver Disinfectant Spray Case Study

In 2010, EPA released for public comment a review draft of a Nanomaterial Case Study on Nanoscale Silver in Disinfectant Spray.[42] The development of case studies was recommended in EPA's 2007 Nanotechnology White Paper in order to support risk assessment efforts for nanomaterials.[43] The draft case study was organized around a comprehensive environmental assessment framework, which encompasses the full product life cycle and direct and indirect effects. The draft case study also lists information gaps or possible research issues.

---

[41] *See* Docket EPA-HQ-OPP-2009-1012, http://www.regulations.gov/search/Regs/home.html#docketDetail?R=EPA-HQ-OPP-2009-1012.

[42] *See* EPA, Nanomaterial Case Study: Nanoscale Silver in Disinfectant Spray (External Review Draft, 2010), http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=226723.

[43] EPA Nanotechnology White Paper (2007), http://www.epa.gov/osa/nanotech.htm. The nanosilver case study follows an earlier nanotechnology case study, "Nanoscale Titanium Dioxide in Water Treatment and Topical Sunscreen," of which a review draft was released in July 2009.EPA, *Nanomaterial Case Studies: Nanoscale Titanium Dioxide in Water Treatment and Topical Sunscreen (External Review Draft)* (July 31, 2009), http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=210206.

In January 2011, EPA held a public information exchange meeting on the draft nanosilver case study, as well as a separate, longer workshop of invited participants to identify and prioritize research areas using the nanoscale silver case study, but no details from these meetings have been posted to the website or docket at the time of this writing. EPA predicts issuance of a final version by June 2011.[44]

C. Other EPA Statutes and Initiatives

In 2010, GAO released an extensive report to Congress on EPA's handling of nanomaterial issues.[45] The study analyzed nanotechnology's current and potential uses, its potential risks, the limitations on the current understanding of those potential risks, and EPA's approach in comparison to approaches taken by other regulatory authorities. The report noted some of the TSCA and FIFRA developments described above, and also analyzed EPA's authority under its other major environmental statutes, including the Clean Water Act, Clean Air Act, and Resource Conservation and Recovery Act.

The report stated that EPA considers that it has sufficient authority under statutes other than TSCA and FIFRA because the target chemicals are defined by their effects, rather than by their composition. According to GAO, however, EPA faces challenges attributable to volume-based thresholds and other special triggers, as nanomaterials may have impacts at smaller concentrations than other materials due to several factors, such as their greatly increased cumulative surface area. EPA has the authority to set lower thresholds for specific substances under some of its statutory authorities, but has not done so for nanomaterials. GAO also found that EPA faces technical challenges to enforcing its statutory authorities for nanomaterials, because they may be harder to detect in air, water, or waste.

EPA's Clean Water Act authority may be of special interest, because many of the concerns raised about both CNTs and nanosilver relate to water. In 2010, EPA indicated that it is considering altering its drinking water regulatory approach to focus on categories of contaminants, rather than its current pollutant-by-pollutant approach, in order to regulate more efficiently.[46] This approach, currently being implemented, could impact nanomaterials by allowing them to be regulated more easily, especially since individual manufacturers' nanomaterials can differ markedly in composition and properties. Processors and users, as well as manufacturers, should be on the lookout for possible new prevention and treatment requirements for releases of nanoscale materials to water.

---

[44] *See* EPA, Nanomaterial Case Study: Nanoscale Silver in Disinfectant Spray (External Review Draft, 2010), http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=226723.

[45] GAO, Nanotechnology: Nanomaterials Are Widely Used in Commerce, but EPA Faces Challenges in Regulating Risk, GAO-10-549 (2010), http://www.gao.gov/new.items/d10549.pdf.

[46] EPA, A New Approach to Protecting Drinking Water and Public Health (2010), http://www.epa.gov/ogwdw/sdwa/pdfs/Drinking_Water_Strategyfs.pdf.

II. Regulation of Nanomaterials in the United States – Outside EPA

A. Federal Agencies

EPA's struggles with regulating nanomaterials are shared by a number of other federal government agencies, which sometimes collaborate with EPA to share their knowledge and strategies.

The Food and Drug Administration (FDA) regulates nanomaterials that appear in drugs, medical devices, cosmetics, foods, and other categories of products—some of the most important potential applications of nanotechnology. FDA has already approved numerous nanotechnology-based products. FDA's aim also includes promotion of medical innovations, and its regulatory role must balance the risks and rewards of nanotechnology in ways that ensure safety. FDA is still considering how best to classify and distinguish nanomaterials and assign them for oversight by FDA's various Centers, which separately evaluate drugs, biologics, devices, and other categories of products under different standards and procedures. Nanotechnology blurs distinctions between "chemical," "mechanical," and "biological" activity, amplifying difficulties in the classification procedure for products that cross regulatory boundaries. As under TSCA and FIFRA, debate is ongoing as to whether nanoscale versions of other substances should all be deemed new and subject to higher levels of FDA scrutiny.

FDA held a public meeting on nanotechnology in 2006,[47] another in 2008,[48] and another, specifically on medical devices and nanotechnology, in 2010.[49] A key step forward was the 2007 report by an FDA Nanotechnology Task Force, which made numerous recommendations.[50] Since then, FDA has provided guidance for industry on the use of nanomaterials in food contact substances,[51] direct food additives,[52] and color additives,[53] and it plans to publish guidance on

[47] 71 Fed. Reg. 46,232 (Aug. 11, 2006).
[48] 73 Fed. Reg. 46,022 (Aug. 7, 2008).
[49] 75 Fed. Reg. 51,829 (Aug. 23, 2010).
[50] FDA, NANOTECHNOLOGY: REPORT OF THE U.S. FOOD AND DRUG ADMINISTRATION NANOTECHNOLOGY TASK FORCE (2007), http://www.fda.gov/nanotechnology/taskforce/report2007.pdf.
[51] FDA, Preparation of Premarket Submissions for Food Contact Substances: Chemistry Recommendations (2007), *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm081818.htm, §§ II.A.5 and II.C.
[52] FDA, Recommendations for Submission of Chemical and Technological Data for Direct Food Additive Petitions (revised 2009), *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm124917.htm, §§ III.A.7 and III.C.5.
[53] FDA, Guidance for Industry: Color Additive Petitions - FDA Recommendations for Submission of Chemical and Technological Data on Color Additives for Food, Drugs, Cosmetics, or Medical Devices (revised 2009), *available at* http://www.fda.gov/ForIndustry/ColorAdditives/GuidanceComplianceRegulatoryInformation/ucm171631.htm, § III.A.

the use of nanomaterials in cosmetics in 2011.[54] However, some of the recommendations of the Nanotechnology Task Force report remain to be implemented.[55]

The Consumer Product Safety Commission (CPSC) is also dealing with how to approach regulation of nanomaterials in consumer products. The agency's 2012 budget request outlined CPSC's ongoing Nanotechnology Initiative that includes ten activities related to nanomaterials in consumer products, including projects involving CNTs, nanosilver, and nanoscale titanium dioxide in consumer products.[56]

The Occupational Safety and Health Administration (OSHA) posted a compilation of current OSHA standards applicable to nanomaterials and other information.[57] It is not engaged in development of new nanotechnology-specific standards. OSHA's companion agency, the National Institute for Occupational Safety and Health (NIOSH, part of the Centers for Disease Control and Prevention), has sponsored conferences such as "Nanomaterials and Worker Health: Occupational Health Surveillance, Exposure Registries, and Epidemiological Research."[58] In addition, in 2010 NIOSH released for peer review a recommended exposure limit for CNTs and other nanofibers, proposing to set the voluntary standard at a daily average of 7 micrograms per cubic meter, the lowest concentration that can be effectively measured.[59]

For organic food products, in 2010 the U.S. Department of Agriculture's National Organic Standards Board passed a recommendation directing the USDA National Organic Program to prohibit engineered nanomaterials from certified organic products as expeditiously as possible.[60]

Federal research institutions and consortia have been heavily involved in nanotechnology research and assessment, which will assuredly feed into regulatory applications. The National Nanotechnology Initiative (NNI) is the most prominent federal program focusing on

---

[54] Department of Health and Human Services, Fiscal Year 2012 Food and Drug Administration Justification of Estimates for Appropriations Committees (Feb. 2011) at 120, *available at* http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM243370.pdf.

[55] *See, e.g.*, FDA, Center for Drug Evaluation and Research, *Manual of Policies and Procedures*, MAPP 5015.9, "Reporting Format for Nanotechnology-Related Information in CMC Review" (June 3, 2010), http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ManualofPoliciesProcedures/UCM214304.pdf.

[56] CPSC, 2012 Performance Budget Request (Feb. 2011) at 30-33, http://search.cpsc.gov/cs.html?url=http%3A//www.cpsc.gov/CPSCPUB/PUBS/REPORTS/2012plan.pdf&charset=iso-8859-1&qt=nanotechnology&col=&n=2&la=en.

[57] *See* OSHA, Safety and Health Topics: Nanotechnology, *available at* http://www.osha.gov/dsg/nanotechnology/nanotechnology.html.

[58] Conference: Nanomaterials and Worker Health: Medical Surveillance, Exposure Registries, and Epidemiologic Research (Jul. 21-23, 2010), http://www.cdc.gov/niosh/topics/nanotech/keystone2010/; *see also* NIOSH, 5th International Conference Scheduled for August 2011, http://www.cdc.gov/niosh/topics/nanotech/news.html#5intl (describing International Conference on Nanotechnology-Occupational and Environmental Health, to be held in August 2011 in Boston).

[59] CDC-NIOSH, Peer Review – Occupational Exposure to Carbon Nanotubes and Nanofibers (Dec. 2, 2010), http://www.cdc.gov/niosh/review/peer/HISA/nano-pr.html. NIOSH is accepting public comments until February 18, 2011 and held public meeting on this topic for February 3, 2010 in Cincinnati, Ohio. *Id.*

[60] NOSB, Guidance Document - Engineered Nanomaterials in Organic Production, Processing and Packaging (Oct. 28, 2010), http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5087795&acct=nosb.

nanomaterials, established in 2001 to coordinate federal agencies' nanotechnology research and development.[61] The NNI "creates a framework for a comprehensive nanotechnology R&D program by establishing shared goals, priorities, and strategies, and it provides avenues for each individual agency to leverage the resources of all participating agencies," which include the Departments of State, Defense, Homeland Security, Energy, Transportation, and Education, as well as EPA, FDA, CPSC, OSHA, NIOSH, and others. The White House Office of Science and Technology Policy has released its 2011 National Nanotechnology Initiative Strategic Plan,[62] and solicited comments on the Draft National Nanotechnology Initiative Strategy for Nanotechnology-Related Environmental, Health, and Safety Research during December 2010.[63] President Obama's proposed 2012 budget would increase spending by the NNI by more than 10%.[64]

B. Congress

By the close of the 111th Congress in December 2010, several bills (besides the TSCA reform legislation discussed above) directly relating to nanotechnology had been introduced, but none enacted. The NNI reauthorization bill passed the House (H.R. 554 and H.R. 5116) but not the Senate (S. 1482). The House of Representatives also saw little progress on the Nanotechnology Advancement and New Opportunities Act, H.R. 820, or the Nanotechnology Education Act, H.R. 4502, both to promote nanotechnology. The Safe Cosmetics Act, H.R. 5786, would have encouraged labeling of nanomaterials in cosmetics.[65] In the Senate, the Nanotechnology Safety Act of 2010, S. 2942, would have amended the Federal Food, Drug, and Cosmetic Act to establish a nanotechnology program. The Promote Nanotechnology in Schools Act, S. 3117, also did not make it out of committee.

Even though none of these bills passed, they show that nanotechnology's benefits and risks are on the radar of at least some legislators. Control of the House of Representatives in the 112th Congress is in the hands of Republicans, and it remains to be seen whether nanotechnology-related bills will progress further under their leadership. Only one nanotechnology-related bill, a Senate tax break for small businesses engaged in "high technology trade or business" including, among other topics, nanotechnology, has been introduced in the 112th Congress so far.[66]

Nanotechnology received several mentions in the House Committee on Oversight and Government Reform's preliminary staff report on "Assessing Regulatory Impediments to Job Creation,"[67] part of the House Republicans' efforts to roll back EPA regulatory initiatives. The

---

[61] *See* NNI, http://www.nano.gov/html/about/home_about.html.
[62] NNI, Strategic Plan (Feb. 2011), http://www.nano.gov/nnistrategicplan211.pdf.
[63] 75 Fed. Reg. 75707 (Dec. 6, 2010).
[64] National Science Foundation, FY 2012 Budget Request to Congress (Feb. 14, 2011) at 6, http://www.nsf.gov/about/budget/fy2012/pdf/fy2012_rollup.pdf?WT.mc_id=USNSF_124.
[65] *See* Beveridge & Diamond, P.C., Cosmetics Safety Bill Would Incorporate TSCA Bill Provisions (2010), http://www.bdlaw.com/assets/attachments/Cosmetics%20Safety%20Bill.pdf.
[66] S. 256, A bill to amend the Internal Revenue Code of 1986 to allow a credit against income tax for equity investments in small business concerns, introduced Feb. 2, 2011 by Sen. Mark Pryor.
[67] U.S. House of Representatives, Committee on Oversight and Government Reform (Darrell Issa (R-CA), Chairman), Preliminary Staff Report: Assessing Regulatory Impediments to Job Creation (Feb. 9, 2011),

report cast a skeptical eye toward the TSCA and FIFRA rulemakings and policies discussed above.

C. States and Localities

In the absence of federal TSCA reform, states and localities have become major players in the regulation of chemicals, particularly chemicals in consumer products. According to a recent analysis by two NGOs, over the past 8 years, 18 states have passed more than 70 laws of varying levels of comprehensiveness to restrict allegedly toxic chemicals in consumer products.[68] These laws have been passing at an increasing pace, and often with substantial bipartisan support. In 2011, according to the National Caucus of Environmental Legislators and the Safer Chemicals, Healthy Families Coalition, various chemicals management-related bills will be introduced in at least thirty states and the District of Columbia, although it is unknown at this point how many, if any, would directly address or substantially impact nanotechnology.[69]

California has taken the lead in this arena. The California Department of Toxic Substances Control (DTSC) continues to work to refine and finalize its Proposed Safer Alternatives for Consumer Products Regulations under the state's Green Chemistry Initiative.[70] These regulations would significantly impact any manufacturer, importer, distributor, or retailer of consumer products in California. Responsible entities, primarily manufacturers, would have to submit extensive information on chemicals and perform alternatives assessments on products containing chemicals deemed priorities by DTSC. In the latest iteration of the proposed regulation,[71] DTSC removed a number of references in earlier versions[72] to nanotechnology, including a proposed definition of "nanomaterial," proposed inclusion of nanoscale properties as factors in prioritization, and the proposed exclusion of nanomaterials from the de minimis exemption.

---

http://oversight.house.gov/images/stories/Reports/Preliminary_Staff_Report__Regulatory_Impediments_to_Job_Creation.pdfA.pdf.

[68] Safer Chemicals Healthy Families and Safer States, Protecting Families from Toxic Chemicals While Congress Lags Behind (Nov. 2010), http://www.saferchemicals.org/PDF/reports/HealthyStates.pdf.

[69] *See* Beveridge & Diamond, P.C., Update on State Efforts to Regulate Chemicals (Feb. 2, 2011), http://www.bdlaw.com/assets/attachments/Update%20on%20State%20Efforts%20to%20Regulate%20Chemicals.pdf.

[70] *See* Beveridge & Diamond, P.C., California Announces It Will Not Adopt Green Chemistry Safer Alternatives Regulations for Consumer Products by the January 1, 2011 Statutory Deadline (Dec. 30, 2010), http://www.bdlaw.com/news-1036.html; Beveridge & Diamond, P.C., California Revises Proposed Green Chemistry Safer Alternatives Regulations for Consumer Products; State on Track to Finalize Regulations By Year End (Nov. 22, 2010), http://www.bdlaw.com/assets/attachments/California%20Revises%20Proposed%20Green%20Chemistry%20Safer%20Alternatives%20Regulations.pdf; Beveridge & Diamond, P.C., Formal Rulemaking Begins for California's Green Chemistry Regulations on Safer Alternatives for Priority Consumer Products (Sept. 23, 2010), http://www.bdlaw.com/news-959.html (citing DTSC, Chemical Information Call-In, http://www.dtsc.ca.gov/PollutionPrevention/Chemical_Call_In.cfm).

[71] DTSC, Safer Consumer Product Alternatives, Proposed Regulations, R-2010-05 (Nov. 2010), http://www.dtsc.ca.gov/LawsRegsPolicies/upload/SCPA_Regs_15Day_Revisions_COURTESYCLEAN.pdf.

[72] For the September 2010 version, see http://www.dtsc.ca.gov/LawsRegsPolicies/upload/SCPA-Regs_APA-format-9-07-10-rev-9-12.pdf. To see changes in the November 2010 version from the September 2010 version, see http://www.dtsc.ca.gov/LawsRegsPolicies/upload/SCPA_Regs_15Day_Revisions_11162010.pdf.

California has also issued a mandatory data call-in for carbon nanotubes and subsequently for several kinds of nanometal oxides.[73] The information and experience gathered from California's initiatives may be used by other states and EPA in the development of future regulatory approaches to nanomaterials.

Other states and localities have targeted nanotechnology for regulation and policy analysis as well. In Berkeley, California, the only city in the U.S. that currently regulates nanotechnology, "[a]ll facilities [in Berkeley or certain parts of Oakland] that manufacture or use manufactured nanoparticles shall submit a separate written disclosure of the current toxicology of the materials reported, to the extent known, and how the facility will safely handle, monitor, contain, dispose, track inventory, prevent releases and mitigate such materials."[74] Cambridge, Massachusetts considered and rejected similar regulation; however, the state's Office of Technical Assistance and Technology (OTA) released a guidance document on "Nanotechnology – Considerations for Safe Development" in 2010.[75] The Wisconsin State Legislative Council Special Committee on Nanotechnology is also developing recommendations for nanotechnology legislation and policy.[76] According to the Environmental Council of the States, Washington, Pennsylvania, and South Carolina have also identified nanoparticles as contaminants of concern.[77]

The key takeaway from these and other state and local developments in nanotechnology regulation is that experimentation with nanotechnology policy is likely to continue into the future in the absence of a modernized federal TSCA. This could lead to a patchwork of disparate policies, some intended to encourage nanotechnology business development but others intended to reduce real or perceived risks by imposing burdens on nanomaterials manufacturers and users. These developments also entail the need for broad-focused attention from company compliance officials.

III. Nanotechnology Developments Around the World

This section provides an overview of some of the more significant developments related to regulation of nanotechnology outside the United States.[78]

---

[73] *See* Beveridge & Diamond, P.C., California Targets Nanometal Oxides, Nanosilver, and Zerovalent Iron in Possible Second Mandatory Data Call-In for Nanomaterials (2009), http://www.bdlaw.com/news-597.html; DTSC, Chemical Information Call-In: Nano Metals, Nano Metal Oxides, and Quantum Dots, http://www.dtsc.ca.gov/TechnologyDevelopment/Nanotechnology/nanometalcallin.cfm (linking to Round Two Call-In Request Letter sent December 21, 2010).

[74] Berkeley, CA, Code § 15.12.040-050 (as revised in 2007).

[75] Massachusetts OTA, OTA Technology Guidance Document: Nanotechnology — Considerations for Safe Development (2010), http://www.mass.gov/Eoeea/docs/eea/ota/tech_reports/ota_nanotech_guidance.pdf.

[76] Wisconsin State Legislature, Legislative Council, Special Committee on Nanotechnology, http://legis.wisconsin.gov/lc/committees/study/2010/NANO/index.html.

[77] Environmental Council of the States. State Experiences with Emerging Contaminants: Recommendations for Federal Action (2010), http://www.ecos.org/files/3959_file_January_2010_ECOS_Green_Report.pdf.

[78] For a concise review of recent governmental activity by 15 countries in addition to the European Commission, see OECD, Current Developments/Activities on the Safety of Nanomaterials, Tour de Table at the 7th Meeting of the

A. Europe

Nanotechnology regulation is anticipated to develop at a relatively quick pace in Europe in 2011. However, currently, only one European Union-wide law specifically regulates nanomaterials. The Cosmetics Directive was recast in 2009 as a regulation to consolidate and amend the provisions. Under the Cosmetics Regulation, six months prior to placing a cosmetic product on the market, manufacturers, importers, or certain distributors must notify the European Commission of nanomaterials in the product, the nanomaterials' specifications, toxicology and safety data, and reasonably foreseeable exposure conditions.[79] In addition, ingredients in the form of nanomaterials must be clearly indicated on the label's list of ingredients.[80]

Chemicals management in the European Union is mainly under the REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) Regulation,[81] and the related Regulation 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures (CLP).[82] Nanomaterials are not currently singled out under either regulation, but they are chemical substances and therefore subject to the laws' classification, registration, reporting, and other requirements. The European Chemicals Agency (ECHA) has published a number of guidance documents on the application of REACH and CLP to nanomaterials.[83] The European Commission's REACH Implementation Projects on Nanomaterials (RIPoNs) are ongoing to advise ECHA on ways to further incorporate nanomaterials into guidance documents.[84]

Modification of REACH to more directly address nanomaterials has often been discussed. In 2009, the European Parliament adopted a resolution asking the European Commission to consider revisions to legislation to address the safety of nanomaterials.[85] In response, the Commission has undertaken such a review, to be completed by the end of 2011.[86] A broader review of REACH, scheduled for 2012, will incorporate the results of the nanomaterials-focused review.[87] In 2010, the Belgian Minister for Energy, Environment,

---

Working Party on Manufactured Nanomaterials, ENV/JM/MONO(2010)42 (2010), http://www.oecd.org/officialdocuments/displaydocument/?cote=env/jm/mono(2010)42&doclanguage=en.

[79] European Regulation (EC) No 1223/2009 (OJ L342, 22/12/09), Art. 13, 16.

[80] *Id.*, Art. 19.

[81] European Regulation (EC) No 1907/2006, as amended, http://ec.europa.eu/environment/chemicals/reach/pdf/consolidated%20REACH.pdf.

[82] European Regulation (EC) No 1272/2008.

[83] *See* European Commission, REACH and Nanomaterials, http://ec.europa.eu/enterprise/sectors/chemicals/reach/nanomaterials/index_en.htm; ECHA, Nanomaterials in IUCLID 5.2 User Manual, http://iuclid.eu/download/documents/usermanual/IUCLID_User_Manual_Nanomaterials_v1.0.pdf.

[84] *See* Franz M. Christensen et al., European Commission, Introduction to and Mandate of the RIP-oNs, Presentation at the Early Harvest of Research Results on Nanosafety Joint Workshop in Ispra Italy (Apr. 14-15, 2010), http://ihcp.jrc.ec.europa.eu/docs/nbs_enpra/presentations_nano_workshop.pdf.

[85] European Parliament, INI/2008/2208: Regulatory aspects of nanomaterials (2009), http://www.europarl.europa.eu/oeil/FindByProcnum.do?lang=en&procnum=INI/2008/2208.

[86] *See, e.g.*, speech by Stavros Dimas, European Commissioner for the Environment, Nanotechnologies ... Challenges for the Future (2009), SPEECH/09/460, http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/09/460&format=HTML&aged=1&language=EN&guiLanguage=en.

[87] European Commission, Review of the Scope of Reach, http://ec.europa.eu/environment/chemicals/reach/review_scope_en.htm.

Sustainable Development and Consumer Protection, Paul Magnette, proposed that REACH should add a new registry specific to nanomaterials to ensure their traceability in commerce, and should regulate nano labeling.[88] The European Commission recently solicited comment on an overarching definition of the term "nanomaterial" for use in EU legislation and policy.[89] Publication of the regulatory definition is expected in early 2011 and will likely be highly influential elsewhere.

There has also been debate over the regulation of nanotechnology under the Restriction of Hazardous Substances (RoHS) Directive,[90] which currently restricts lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, and polybrominated diphenyl ether (PBDE) in electronic and electrical equipment. A recast of this Directive, which has been approved by the European Parliament[91] and must be formally adopted by EU Council of Ministers, will expand the scope of covered equipment from items on a list to an "open scope" of all electronic and electrical equipment unless otherwise excluded (after approval, this will take full effect in 8 years). Earlier committee-level versions of the recast would have "called for a ban on nanosilver and long multi-walled carbon nanotubes, and said other electrical and electronic material containing nanomaterials should be labelled, and that the manufacturers should be obliged to provide safety data to the European Commission."[92] Under the recently approved compromise, the European Commission will review the negative list three years after the recast Directive has been published in the Official Journal, and the planned list of priority substances to be assessed for possible prohibition has replaced by a set of non-binding declarations making nanomaterials priorities for future review.[93]

---

[88] *See* Belgian Presidency of the Council of the European Union, "Regulation of products containing nanomaterial: Traceability, a pre-condition to acceptability" (Sept. 14, 2010), http://www.eutrio.be/pressrelease/regulation-products-containing-nanomaterial-traceability-pre-condition-acceptability.

[89] European Commission, Consultations: Proposal for a definition of the term "nanomaterial" that the European Commission intends to use as an overarching, broadly applicable reference term for any European Union communication or legislation addressing nanomaterials (2010), http://ec.europa.eu/environment/consultations/nanomaterials.htm. It recommended defining a "nanomaterial" as a material that meets at least one of the following criteria: (1) consists of particles, with one or more external dimensions in the size range 1 nm - 100 nm for more than 1% of their number size distribution; (2) has internal or surface structures in one or more dimensions in the size range 1 nm - 100 nm; or (3) has a specific surface area by volume greater than 60 m^2/cm^3, excluding materials consisting of particles with a size lower than 1 nm. "Particle" would be defined as "a minute piece of matter with defined physical boundaries," using the definition from ISO 146446:2007.

[90] Directive 2002/95/EC, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:EN:PDF.

[91] European Commission, Press Release: EU set to revise law on hazardous substances in electrical and electronic equipment (Nov. 24, 2010), http://europa.eu/rapid/pressReleasesAction.do?reference=IP/10/1596.

[92] *See* European Parliament Committee on Environment, Public Health and Food Safety, Press Release: MEPs flag potentially hazardous substances in electrical and electronic equipment (June 2, 2010), http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+IM-PRESS+20100531IPR75278+0+DOC+XML+V0//EN&language=EN.

[93] *See* European Parliament legislative resolution of 24 November 2010 on the proposal for a directive of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast) (COM(2008)0809 – C6-0471/2008 – 2008/0240(COD)), Annex, http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P7-TA-2010-0431.

In addition to these and other actions at the EU level, individual member states have also been addressing the potential risks and rewards of nanotechnology through domestic legislation and policy. In France, for example, the Grenelle II Act adopted in 2010 is instituting a mandatory nanoparticle reporting and tracking scheme, which will need to be implemented by future regulatory text.[94] A public consultation on implementation of this scheme recently ended.[95] The government of Austria adopted a Nanotechnology Action Plan in 2010, recommending a number of measures to promote both the nanotechnology industry and the safety of nanomaterials through Austrian law.[96] The goal is to implement the recommendations by the end of 2012. Other European countries with calls by government entities, feasibility studies, or actual plans to establish mandatory reporting schemes or databases for nanotechnology include Italy,[97] Belgium,[98] the Netherlands,[99] Norway[100] (a member state of the European Economic Area but not of the EU), and Germany.[101] In addition, in 2010 Switzerland published guidelines for producing safety data sheets for synthetic nanomaterials.[102] Companies may want to closely monitor these developments, as they may shape the markets for nanomaterials in these countries and also precipitate similar actions by other European countries or the EU itself.

---

[94] Le Grenelle Environnement, Presentation de la loi Grenelle 2, http://www.legrenelle-environnement.fr/Presentation-de-la-loi-Grenelle-2.html. Article 185 provides (as translated):

> Persons who manufacture, import or distribute nanoparticulate substances, in the form of nanoparticles or contained in unbounded mixtures, or materials designed to discharge such substances under normal or reasonably expected conditions of use, shall periodical declare to the administrative authority, for the purposes of traceability and public information, the identity, quantities and applications of these substances, as well as the identity of the professional users to whom they have been sold either for payment or free of charge.

[95] *See* Nanotechnology Industries Association (NIA), French Regulation of Nanomaterials (Jan, 28, 2011), http://www.nanotechia.org/global-news/french-regulation-of-nanomaterials---public-consultation-open-for-a-short-time (linking to French-language materials).

[96] Austrian Nanotechnology Action Plan (2009) (in English), http://www.umweltnet.at/filemanager/download/60006/ .

[97] *See* Belgian Presidency of the EU, Conclusions of the High Level Event, Towards a Regulatory Framework for Nanomaterials' Traceability (Sept. 14, 2010), http://www.health.belgium.be/filestore/19064475_FR/fr_12129319.pdf ("national compulsory declaration measures are being taken in France and are examined in Italy, Belgium and the Netherlands").

[98] *See id.*

[99] *See id.; see also* OECD, Current Developments/Activities on the Safety of Manufactured Nanomaterials: Tour de Table at the 6th Meeting of the Working Party on Manufactured Nanomaterials, (ENV/JM/MONO(2010)4) (2010), at 49, *available at* http://www.oecd.org/dataoecd/49/49/44947758.pdf (describing motions regarding regulation of nanotechnology in Netherlands' Lower House of Parliament, and the Dutch Action Plan Nanotechnology).

[100] Norwegian Board of Technology (Teknologirådet), "Businesses asked to declare use of nanomaterials" (2009), http://www.teknologiradet.no/FullStory.aspx?m=3&amid=7830.

[101] BMU (Federal Ministry for the Environment, Nature Conservation and Nuclear Safety), Rechtliche Machbarkeitsstudie zu einem Nanoproduktregister (Legal feasibility study on a nano product register: Final report) (May 2010), www.bmu.de/gesundheit_und_umwelt/downloads/doc/46240.php; BMU, Press Release, "Nano-Kommission presents its final report" (Feb. 2, 2011), http://www.bmu.de/english/current_press_releases/pm/pdf/47004.pdf.

[102] State Secretariat for Economic Affairs, Swiss Confederation, Safety data sheet (SDS): Guidelines for synthetic nanomaterials (Dec. 21, 2010), http://www.seco.admin.ch/themen/00385/02071/index.html?lang=de&download=NHzLpZeg7t,lnp6I0NTU042l2Z6ln1acy4Zn4Z2qZpnO2Yuq2Z6gpJCFeoN_fWym162epYbg2c_JjKbNoKSn6A--.

B. The Americas

The United States' neighbors in the Western Hemisphere have also addressed nanotechnology. In Latin America, the focus is primarily on technology promotion rather than safety regulation.[103] However, Canada has reportedly been developing a nanomaterials reporting scheme for several years. Presently, Canada's Acts and Regulations have no explicit reference to nanomaterials, although Environment Canada released a policy statement and an analysis of possible regulatory frameworks in 2007 on the New Substances Notification Regulations' application to nanomaterials.[104] In 2010, Health Canada solicited comment on its Interim Policy Statement on its Working Definition for Nanomaterials.[105] Canada's regulatory choices are, of course, especially likely to strongly impact and be impacted by those of the United States.

C. Asia-Pacific

Asian nations are investing significant resources in nanotechnology promotion and safety regulation. In Japan, for example, the Ministry of Economy, Trade and Industry (METI) published the results of its voluntary information gathering on nanotechnology industry activities in 2010.[106] The Ministry of Health, Labour, and Welfare (MHLW) launched a six-year (2009-2014) research program on the potential hazards of nanomaterials, focusing on carcinogenicity. MHLW and the Ministry of the Environment (MOE) have both instituted a number of other important reports and surveys on nanomaterials safety research and best practices.[107] The National Institute of Advanced Industrial Science and Technology (AIST) published interim risk assessment reports on nanomaterials generally and on fullerenes, CNTs, and titanium dioxides in 2009.[108]

In Thailand, the National Nanotechnology Center (NANOTEC) has driven several regulatory and policy initiatives, including the "Nano Q" standard nanomark for selected Thai nano-products to identify types, sizes, and properties of nano-particles, and a National Nano-

---

[103] *See, e.g.*, Ministério da Ciência e Tecnologia, Programa para Nanotecnologia, http://www.mct.gov.br/index.php/content/view/77609.html (Brazil); Jimena Ramos, UNITAR Presentation: Assessment of the Development, Manufacture and Use of Nanomaterials in Mexico (Mar. 12, 2010), http://www2.unitar.org/cwm/publications/event/Nano/Kingston_12_Mar_10/14_Mexico.pdf.

[104] *See* Environment Canada, Evaluating New Substances: Nanomaterials (2007), http://www.ec.gc.ca/subsnouvelles-newsubs/default.asp?lang=En&n=D179F162-1.

[105] Environment Canada, Interim Policy Statement on Health Canada's Working Definition for Nanomaterials (Feb. 11, 2010), http://www.hc-sc.gc.ca/sr-sr/consult/_2010/nanomater/draft-ebauche-eng.php.

[106] *See* OECD, Current Developments/Activities on the Safety of Manufactured Nanomaterials: Tour de Table at the 7th Meeting of the Working Party on Manufactured Nanomaterials (ENV/JM/MONO(2010)42 (Sept. 22, 2010), at 43, http://www.oecd.org/officialdocuments/displaydocumentpdf?cote=env/jm/mono(2010)42&doc language=en (citing Japanese report http://www.meti.go.jp/policy/chemical_management/other/nano.html).

[107] *Id.*

[108] *Id.* (citing AIST, Risk Assessment Documents for Manufactured Nanomaterials (2009) (English language summaries, http://www.aist-riss.jp/main/modules/product/nano_rad.html?ml_lang=en).

safety Guideline.[109] NANOTEC is also pursuing a broader nanosafety strategy that may include greater regulation and labeling requirements.[110]

Korea is, among other actions, examining application of its current regulations to nanomaterials and nanotechnology as well.[111] Korea has also instituted a decade-long "master plan" for chemicals management that singles out nanomaterials as targets for "enhanced" management.[112]

In Australia, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), essentially a counterpart to TSCA, is implementing regulatory reform in stages following stakeholder consultation. NICNAS recently announced "Adjustments to NICNAS New Chemicals Process" for notifying new "Industrial Nanomaterials."[113] Effective January 1, 2011, new chemicals that fall under the policy's working definition of "industrial nanomaterial" must include additional information with their notification forms and will not be permitted under exemption categories where any human or environmental exposure can reasonably be anticipated, i.e., the low volume exemptions and the low concentration non-hazardous cosmetic exemption. The agency Safe Work Australia is also implementing an extensive Nanotechnology Work Health and Safety Program, with research projects, policy guidance, and regulatory analysis.[114] An Australian agency has also completed a review of scientific literature on the environmental fate of nanomaterials.[115]

D. International Agencies and Organizations

Major international bodies also have focused attention on nanotechnology risks and benefits. The OECD, which has 33 member countries and extensive contacts with dozens of non-member countries, founded its Working Party on Manufactured Nanomaterials (WPMN) in

---

[109] *Id.* at 53-54.

[110] *See* NIA, Thailand's First Steps Toward Nano-Regulation (2011), http://www.nanotechia.org/global-news/thailand-is-making-first-steps-towards-nano-regulation; NANOTEC, Public hearing on Nanosafety Strategic Plan at NanoThailand 2010 (2010), http://www.nanotec.or.th/en/?p=957.

[111] *See* OECD, Current Developments/Activities on the Safety of Manufactured Nanomaterials: Tour de Table at the 7th Meeting of the Working Party on Manufactured Nanomaterials (ENV/JM/MONO(2010)42 (Sept. 22, 2010), at 46-47, http://www.oecd.org/officialdocuments/displaydocumentpdf?cote=env/jm/mono(2010)42&doc language=en.

[112] Republic of Korea, Ministry of Environment, "Ministries set a master plan for chemicals management" (Jan. 18, 2011), http://eng.me.go.kr/board.do?method=view&docSeq=9055&bbsCode=new_news.

[113] NICNAS, Guidance on New Chemical Requirements for Notification of Industrial Nanomaterials (2009), http://www.nicnas.gov.au/current_issues/Nanotechnology/Guidance%20on%20New%20Chemical%20Requirements%20for%20Notification%20of%20Industrial%20Nanomaterials.pdf; NICNAS, Adjustments to NICNAS new chemicals processes for industrial nanomaterials (Dec. 2010), http://www.nicnas.gov.au/Current_Issues/Nanotechnology/FAQs_Nano_Adjustments_for_New_Chemicals_Processes_Dec_2010.pdf.

[114] Safe Work Australia, Nanotechnology and Work Health and Safety, http://www.safeworkaustralia.gov.au/AboutSafeWorkAustralia/WhatWeDo/Research/Nanotechnology/Pages/Nanotechnology.aspx.

[115] Australian Department of the Environment, Water, Heritage and the Arts, Fate of manufactured nanomaterials in the Australian Environment (Mar. 2010), http://www.environment.gov.au/settlements/biotechnology/publications/pubs/manufactured-nanomaterials.pdf.

2006 within the Chemicals Committee,[116] and its Working Party on Nanotechnology (WPN) in 2007 within the Committee for Scientific and Technological Policy.[117] The latter focuses on monitoring nanotechnology developments and promoting nanotechnology cooperation and innovation, while the former focuses on health-related and environmental safety-related aspects of manufactured nanomaterials. The WPMN has a number of major projects now being implemented, including a database on environmental health and safety research activities and results; a set of commitments by a number of countries (including the United States) to test a representative set of 13 manufactured nanomaterials for a list of enumerated endpoints; a review of existing OECD Test Guidelines for adequacy in addressing manufactured nanomaterials; development of a report on voluntary schemes and regulatory regimes; and other reports and cooperative endeavors.[118] Some of these initiatives are supported by public-private partnerships, like the PROSPECT project providing test methods and data on nano-CeO2 and nano-ZnO, two of the OECD "representative" nanomaterials.[119] The OECD recently issued a summary of the activities of the WPMN and WPN over the last five years.[120]

The International Agency for Research on Cancer (IARC), which operates under the auspices of the World Health Organization, designated CNTs in 2008 as a high priority for future (2010-2014) IARC Monographs.[121] The Monographs categorize the subject substances as either carcinogenic to humans, probably carcinogenic to humans, possibly carcinogenic to humans, not classifiable, or probably not carcinogenic to humans. These classifications have far-ranging regulatory, legal, and business consequences, and could tarnish the reputation and market prospects of CNTs if the data collected for the Monograph were determined to possibly show carcinogenicity.

Standard-setting bodies have also been analyzing nanotechnology, with important results for nanotechnology producers, users, and regulators alike. The powerful International Organization for Standardization (ISO), a collection of national standards organizations, created Technical Committee (TC) 229 on Nanotechnologies in 2005. ISO TC 229 has already published 11 standards relating to nanomaterial characterization, classification, testing, and vocabulary, and has 33 more in development stages.[122] ASTM International (ASTM), a now-worldwide organization originally known as the American Society for Testing And Materials, is also working to develop standardized terminology, test methods, and occupational safety

---

[116] OECD, Safety of Manufactured Nanomaterials, http://www.oecd.org/about/0,3347,en_2649_37015404_1_1_1_1_1,00.html.
[117] OECD, Science and Technology Policy: Nanomaterials, http://www.oecd.org/site/0,3407,en_21571361_41212117_1_1_1_1_1,00.html.
[118] *See* OECD, List of Manufactured Nanomaterials and List of Endpoints for Phase One of the Sponsorship Programme for the Testing of Manufactured Nanomaterials; Revision, ENV/JM/MONO(2010)46 (Dec. 1, 2010), http://www.oecd.org/officialdocuments/displaydocument/?cote=env/jm/mono(2010)46&doclanguage=en.
[119] *See generally,* NIA Prospect, http://www.nanotechia-prospect.org/.
[120] OECD, Nanosafety at the OECD: The First Five Years 2006-2010 (Jan. 2011), http://www.oecd.org/dataoecd/6/25/47104296.pdf.
[121] IARC, Report of the Advisory Group to Recommend Priorities for IARC Monographs during 2010-2014, pp. 18-19 (2008), http://monographs.iarc.fr/ENG/Publications/internrep/08-001.pdf; Vincent Cogliano et al., IARC, Future priorities for IARC Monographs, 9 Lancet Oncology 8: 708 (2008).
[122] ISO, Technical Committees – TC 229, http://www.iso.org/iso/iso_technical_committee?commid=381983 and http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_tc_browse.htm?commid=381983&development=on.

guidance relating to nanomaterials through its Committee E56 on Nanotechnology. This Committee recently launched a new subcommittee to develop standards relating to Nano-Enabled Consumer Products.[123] These bodies may have significant influence in setting definitions and important scientific protocols.

Conclusion

The many scientific, legal, policy, and regulatory developments highlighted herein are only a subset of the changes facing nanomaterial manufacturers, processors, and users. However, they represent a general trend toward increased regulatory attention on nanomaterial safety and shifts in a number of areas from voluntary to mandatory approaches to data gathering and health and safety protections. Current and potential manufacturers, processors, and users of various nanomaterials face hurdles in interpreting and dealing with this rapidly changing environment.

In particular, processors and downstream users of nanomaterials may have more incentive than with other materials to become involved in various levels of compliance assurance and product stewardship, including testing. Regulatory actions are happening at all levels of government, in the United States and in countries and regions around the world. There is a large amount of information to track and process. Manufacturers of nanomaterials are often small companies with fewer resources for such demanding compliance monitoring. Processors and users of nanomaterials, meanwhile, may be blindsided by compliance issues if they are relying on manufacturers to manage most compliance assurance. Processors and downstream users may also be impacted by mandatory data gathering schemes; they should pay close attention to the confidentiality provisions of any such proposals. In addition, both regulatory proposals and market conditions are driven by the level of confidence that governments, consumers, and others have in the safety of nanomaterials. Thus, direct contributions to the knowledge base on nanomaterial safety across all stages of a product's life cycle can help companies using nanotechnology and its products to assure a better regulatory and market environment.

Nanotechnology offers great promise for wide range of applications, but only if development of the industry is not hampered by health and safety concerns and overly burdensome governmental restrictions. Companies hoping to take advantage of the many benefits of nanomaterials have growing regulatory burdens to navigate.

For more information, please contact Mark N. Duvall, (202) 789-6090, mduvall@bdlaw.com, or Alexandra M. Wyatt, (202) 789-6086, awyatt@bdlaw.com.

1396593v9 Washington 009250

[123] ASTM International, Technical Committee E56, http://www.astm.org/COMMIT/COMMITTEE/E56.htm; ASTM International news release, ASTM Nanotechnology Committee Creates Subcommittee on Nano-Enabled Consumer Products (Sept. 2010), http://www.astmnewsroom.org/default.aspx?pageid=2270&year=2010&category=Standards%2fTechnical+Committee+News.