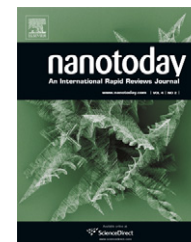




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NEWS AND OPINIONS

Should corporations contribute to nano-regulation?

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For the past several years there has been a flurry of debate over how to best regulate nanotechnology. The US Congress has conducted hearings.¹ The US EPA and FDA have been holding workshops.² The Royal Society and Royal

Academy of Engineering in the UK have been examining possible avenues.³ Environmental organizations and labor unions have been issuing press releases and pleading with governments to enact policies.⁴ And at the end of last year, the National Research Council criticized the US federal government's lack of progress toward regulation.⁵

Amidst all this debate, governments have taken a few steps toward regulation. One major focus has been on gathering data about what nanomaterials are being created and what is known about them. The City of Berkeley, California instituted the first nanoparticle regulation in the world in 2006, requiring facilities to report which engineered nanoparticles they are manufacturing or using as well as their current known toxicology.⁶ A handful of coun-

the October 2005 EPA workshop on Nanotechnology and the Environment: Applications and Implications [http://es.epa.gov/ncer/publications/workshop/pdf/10_26_05proceeding1.pdf].

³ <http://royalsociety.org/landing.asp?id=1210>.

⁴ See, for instance, the European Trade Union Confederation's 2008 resolution: <http://www.etuc.org/a/5159>.

⁵ See the report developed by the National Research Council's Committee for Review of the Federal Strategy to Address Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials: http://www.nap.edu/catalog.php?record_id=12559.

⁶ City of Berkeley Community Environmental Advisory Commission, "Manufactured Nanoparticle Health and Safety Disclosure" in: E. Fisher, C. Selin, J.M. Wetmore (eds.), *The Yearbook of Nanotechnology in Society, Volume 1: Presenting Futures*, Springer, 2008, pp. 201–206.

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¹ See, for example, the September 21, 2006 House Committee on Science and Technology Hearing on "Research on Environmental and Safety Impacts of Nanotechnology: What are the Federal Agencies Doing?" [http://science.house.gov/publications/hearings.markups_details.aspx?NewsID=1186] and the April 24, 2008 US Senate Committee on Commerce, Science & Transportation Hearing on the "National Nanotechnology Initiative: Charting the Course of Reauthorization" [http://commerce.senate.gov/public/index.cfm?FuseAction=Hearings.Hearing&Hearing_ID=5fdb60ea-8841-401c-9290-019eeb84e11c].

² E.g. the FDA's September 8, 2008 Nanotechnology Public Meeting in Rockville, MD [<http://www.fda.gov/nanotechnology2008/>] and

tries have adopted similar programs on a voluntary basis.⁷ The response to these voluntary programs has not been very high, however, and there is a push to make such programs mandatory, a switch that Canada is reported to make soon.⁸

The other major focus has been on determining whether existing regulations cover engineered nanomaterials. For instance the US EPA has announced that nanosilver falls under the regulations created by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) when used in products that claim antimicrobial properties.⁹ The US EPA is actively regulating nanosilver and has served their first fine to a computer peripheral company in California for making unsubstantiated claims that their nanosilver coated products can control germs and pathogens.¹⁰ Carbon nanotubes are now considered to be distinct from macroscale forms of carbon under the US Toxic Substances Control Act (TSCA) and require filing of pre-manufacturing notices which will be used to evaluate the health and safety measures necessary to protect workers and consumers from possible health hazards associated with nanotubes.¹¹

Although, local and national governing bodies are empowered to regulate materials, chemicals, and nano-enabled products, industry has also taken significant steps in developing regulatory frameworks. This may be surprising because traditionally industry is supposed to resist regulation, but many companies believe that the right regulations can provide enormous benefits. Corporations, like many others pushing for regulation of nanoscale materials and technologies, want to avoid exposing the general public to potentially harmful materials. Regulations can also limit risks to the corporation.

Corporations carefully plan for the future. To chart a successful roadmap they need to be able to understand the fiscal and regulatory environment within which they will be operating. Every new nano-enhanced product on the market poses a potential health or environmental hazard. And even if the hazards that nano-products pose are not as terribly different from other risks we accept on a daily basis, the public's perception of a "new and unknown risk" can still lead to new regulations and extensive litigation.

But when regulations are developed early with input from corporations, the risk of developing new products is mitigated by the boundaries of the regulations. It is significantly easier for companies to plan for the future when they know what the rules will be. Regulations also significantly bene-

fit corporations because they limit litigation. Corporations are expected to do more than simply meet the letter of the law, but those wishing to bring suit against them have a much more difficult time when the government has established basic guidelines for how companies should behave in a certain arena.

One of the most significant attempts by a corporation to contribute to the discussion of nano-regulation is the DuPont–Environmental Defense Fund (EDF) partnership to create a "Framework for Responsible Nanotechnology."¹² DuPont worked to develop this partnership in 2005 at least in part because it had made investments in nano-related materials, but faced uncertainties about the potential health and environmental impact as well as the public expectations of such products. If anything went wrong with the industry in general it, as a wealthy corporation, would likely be subject to numerous lawsuits. Without solid government regulation in sight, DuPont partnered with EDF and the two organizations took steps to find common ground between corporate and public opinion about what should be expected of corporations as they develop nano-enabled technologies. As US government agencies typically do, Dupont–EDF both solicited and, in a bold gesture of transparency, posted on their website comments from the general public as well as organizations particularly concerned about the future of nanotechnology. Ultimately they published their framework for cataloguing, evaluating, and reporting nanomaterials; began to use it in their own work; and encouraged other companies to do so as well. Their hope is that the Framework will be used to collect important data and accelerate regulation in a manner that is amenable to corporations so they can move forward with nano-enabled products with an acceptable amount of financial, environmental, and health risk.¹³

Corporate executives have also begun to realize that more than broad frameworks are needed. There are basic questions about toxicity, environmental exposure, and genetic risk that we simply do not know the answers to. Partially in an effort to fill these gaps in knowledge, large companies like DuPont have entire labs dedicated to understanding the health and environmental impact of the products they produce.¹⁴ Other corporations invest in organizations like the Semiconductor Research Corporation (SRC) which has begun funding universities to do some of the basic research needed to better understand the potential risks of emerging nano-related semiconductor manufacturing techniques.¹⁵ These companies recognize the need to better understand the impact of engineered nanomaterials and are promoting research in order to protect themselves,

⁷ See, for example, the US EPA Nanoscale Materials Stewardship Program [<http://www.epa.gov/oppt/nano/stewardship.htm>], the UK DEFRA Voluntary Reporting Scheme (VRS) for Manufactured Nanomaterials [<http://www.defra.gov.uk/ENVIRONMENT/nanotech/policy/>], and Canada's New Substance Program [http://www.ec.gc.ca/substances/nsb/eng/a200706_e.shtml].

⁸ <http://www.nanotechproject.org/news/archive/7061/>.

⁹ <http://www.epa.gov/opp00001/about/intheworks/nanotechnology.htm>.

¹⁰ <http://yosemite.epa.gov/opa/admpress.nsf/dc57b08b5acd42-bc852573c90044a9c4/16a190492f2f25d585257403005c2851!OpenDocument>.

¹¹ EPA, "Toxic Substances Control Act Inventory Status of Carbon Nanotubes," *Federal Register* 73(212), Oct 31, 2008, pp. 64946–64947. [<http://edocket.access.gpo.gov/2008/E8-26026.htm>].

¹² The name of the framework has subsequently been changed to the "Nano-Risk Framework." See S. Walsh, T. Medley, "A Framework for Responsible Nanotechnology," in: E. Fisher, C. Selin, J. Wetmore (Eds.), *The Yearbook of Nanotechnology in Society: Volume 1*, Presenting Futures, Springer, 2008, pp. 207–213 and <http://www.nanoriskframework.com>.

¹³ <http://nanoriskframework.com/content.cfm?contentID=6556>.

¹⁴ E.g. the DuPont Haskell Laboratory for Health and Environmental Sciences.

¹⁵ Engineering Research Center (ERC) for Environmentally Benign Semiconductor Manufacturing.

their workers, the environment, and the public, as well as improve regulations. While the DuPont–EDF Framework may pave the way for near-term general regulations, the SRC funded projects may improve the formulation of more specific regulations in the future.

There are drawbacks to extensive corporate involvement in the development of nano-regulations. Corporations do not want just any nano-regulation. Most companies contend they have a responsibility to first act in their shareholders' best interests and not those of the general public. As such, the allure of near term profits can trump long-term vision and there can be a temptation to push for self-serving regulations. For instance, large corporations are more likely to have the financial resources to deal with the paperwork and reporting that often accompanies regulations. This can raise inequities with new start-up companies and leave the major share of opportunities and profits to the established companies most likely to have the resources to be involved in debates about regulation in the first place.

Having corporations play a major role in developing regulations can also limit some important voices and ideas. It is not likely that corporations would favor approaches like the precautionary principle—the idea that when the worst case scenarios are especially bad we should require specific new materials to be proven safe before they can be put on the market. Such ideas are popular among some environmental organizations, but would significantly slow the development of products (and their accompanying profits). Because of concerns such as these a number of environmental and labor organizations refused to participate in the Framework.¹⁶ They argued that a corporation creating a pre-regulatory framework was a conflict of interest that could undermine the federal government's authority.

Despite these drawbacks, the US government has traditionally enlisted the help of corporations in the development of regulations. It is logical to draw on the investments companies have made and the expertise of the scientists and engineers working most closely with the products that will eventually find their way to market. Regulations are never imposed with complete understanding of the risks. But without the knowledge embodied in the corporate world, we will be even farther from developing the background we need to make sound decisions about nano-regulation. Corporations should be encouraged to actively participate in the discussions on new regulations while remembering that ultimately they must carefully look out for the well being of the general public.

We all want to avoid another asbestos. Or do we? At a recent conference, independent lawyers recommended that

corporations take a protectionist stance, suggesting that they resist contributions to voluntary reporting programs like US EPA's Stewardship program.¹⁷ Although this may serve lawyers who seek out litigation or the short-term goal of corporations to escape liability, it will not help us anticipate threats to health and the environment, avoid litigation due to chronic exposure to nano-hazards, do better science, regulate the dangerous nanotechnologies, or prosper from the harmless nano-enabled products that the nano-revolution has promised.



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¹⁶ See the April 2007 open letter signed by over 20 organizations: http://www.etcgroup.org/en/materials/publications.html?pub_id=610.

¹⁷ See Rick Weiss's "The Big Business of Nano Litigation: Attorneys Are Hard at Work Protecting Nanotech Makers—What About Consumers?" on the 2nd Annual Conference on Nanotechnology Law, Regulation and Policy, February 18–19, 2009. Washington DC: <http://www.scienceprogress.org/2009/02/the-big-business-of-nano-litigation/>.