

Client Alert

An informational newsletter from Goodwin Procter LLP

Nanotechnology Risk Framework Spurs Controversy

One of the great unknowns in the developing area of nanotechnology is the potential health, safety and environmental risks of nanomaterials, and how best to address and manage those risks. Chemical company DuPont and Environmental Defense, a mainline Washington, D.C. environmental advocacy group with some 500,000 members, have recently circulated a draft "Framework" document that suggests an approach for dealing with those risks. Late last week, however, the AFL-CIO, the Natural Resources Defense Fund, Greenpeace and several other organizations released a letter attacking the DuPont/Environmental Defense Framework. This is unfortunate, because the DuPont/Environmental Defense proposal appears to be a promising approach for managing the risks presented by nanotechnology, and may serve as a starting point for government efforts to regulate this new area.

Background

A nanometer is one-billionth of a meter, roughly about one hundred thousand times smaller than the diameter of a human hair, a thousand times smaller than a red blood cell or half the size of the diameter of DNA. Nanotechnology is a broad term that has been defined in various ways, but most definitions encompass research and technology development at a length scale of approximately one to one hundred nanometers in any dimension. The only common characteristic of these so-called "nanomaterials" is their tiny dimensions. At that scale, many materials may exhibit novel properties and functions because of their small size. For example, nanoparticles of zinc oxide and titanium dioxide, which are used in sunscreens and cosmetics, are transparent, even though the larger particles of these same substances are opaque. Examples of other products in which nanomaterials are presently in use include various paints, lubricants and coatings; stain resistant and anti-bacterial clothing and pillows; and tennis rackets (reinforced with carbon nanotubes).

In the past few years, as the development, production and use of nanomaterials have increased, there have been concerns over the health and safety aspects of these materials. As explained in the July 2004 Report on Nanotechnology by the UK's Royal Society & Royal Academy of Engineering, although many of the materials themselves are not new, the smaller scale of these materials raises at least two concerns. First,

"nanomaterials have a relatively larger surface area when compared to the same mass of materials produced in a larger form. This can make materials more chemically reactive (in some cases materials that are inert in their larger form are reactive when produced in their nanoscale form), and affect their strength or electrical properties."

Second,

“quantum effects can begin to dominate the behaviour of matter at the nanoscale – particularly at the lower end – affecting the optical, electrical and magnetic behaviour of materials.”¹

Others have suggested that the unprecedented mobility of these small particles, both in the human body and in the environment, is another basis for concern.

These issues led the Royal Society to make several recommendations on the health and safety issues raised by nanomaterials, including that (i) “factories and research laboratories treat manufactured nanoparticles and nanotubes as if they were hazardous, and seek to reduce or remove them from waste streams”; (ii) the British Health & Safety Executive consider “setting lower occupational exposure levels for manufactured nanoparticles”; and (iii) for consumer products, “ingredients in the form of nanoparticles undergo a full safety assessment by the relevant scientific advisory body before they are permitted for use in products.” In the United States, while EPA and other government agencies have formed study groups, issued “white papers” and listed areas where further research is needed, there has been little concrete guidance to industry on how to address the health, safety and environmental risks of nanomaterials.

DuPont/Environmental Defense Nano Risk Framework

In February 2007, DuPont and Environmental Defense issued a 72-page draft Framework for evaluating and addressing the health, safety and environmental risks posed by the use of nanomaterials.² The expectation is that the draft Framework, which took about a year and a half to develop, will be revised and reissued after DuPont and Environmental Defense receive comments and suggestions from industry, government, environmentalists and others.

The Framework suggests six steps for evaluating and addressing the risks of nanomaterials. Steps 1 through 3 involve evaluation of the risks, while steps 4 through 6 are concerned with addressing those risks. While the Framework goes into considerable detail and contains an Appendix of worksheets for each step, the six steps are summarized briefly below.

Step 1: Describe Material and Its Applications. Step 1 involves developing a basic description of the nanomaterial and its proposed uses or applications. The point is to assemble all available information about the nanomaterial, from both laboratory and literature sources. With respect to proposed uses, Step 1 states that both intended and expected or possible applications or uses of the nanomaterial should be included, as well as any post-use management or disposal issues. As the Framework explains, Step 1 “allow[s] all interested stakeholders to become familiar with the material and its reasonably foreseeable applications.”

Step 2: Profile Lifecycle. This step involves assembling information on the nanomaterial’s properties, its potential hazards to human health and the environment, and the potential human and environmental exposures throughout the material’s lifecycle, all of which is needed to conduct the risk assessment in Step 3. For example, on the issue of potential hazards to human health, the Framework recommends assembling a “base set” of information on issues such as “short-term toxicity,” “skin sensitization,” “skin penetration,” and “genetic toxicity,” and also lists some additional

data to be developed “as needed,” such as “chronic (>1 year) inhalation/ingestion toxicity studies,” “developmental and reproductive toxicity studies,” “more extensive genotoxicity studies,” and “focused toxicity studies.” Similarly, with respect to potential hazards to the environment, Step 2 provides that the “base set” of information should include, depending on the anticipated routes of exposure, information on aquatic (fish, invertebrates and aquatic plants) and terrestrial (invertebrates and plants) toxicity. Again, possible additional sets of data to be developed are also suggested. With respect to potential human or environmental exposures, there is another listing of certain “base” information that should be gathered. This base information includes information on potential exposures during manufacture, use, distribution, storage and disposal.³

The Framework recognizes that in some cases, particularly at the early stages of product development, the data called for by Step 2 may not exist, and it may not be feasible to develop it. Because of the deep ignorance of the health and environmental effects of nanoparticles, this recognition is extremely important. In these circumstances, the Framework calls for the use of “reasonable worst-case values,” or “bridging data.” The Framework suggests that “reasonable worst-case values” can come from “data available on analogous bulk materials” or “nonengineered nanoparticles” or “from assignment to the highest-level tier in an existing classification system.” An example of this latter approach would be managing a material “as if it possessed characteristics of reproductive toxicity sufficient to classify it as a Category I substance,” that is, a “known or presumed human reproductive or developmental toxicant.” Use of “bridging data,” by contrast, involves filling data gaps for a nanomaterial by extrapolating or “bridging” from data for a similar material. As the Framework explains, the “strength” of the bridging strategy depends on having “robust” hazard data for the bridged material and “evidence that supports the relevance of the reference material to the new material, particularly with respect to its potential methods of toxicity.” While not as useful, obviously, as studies on the new material itself, the Framework states that “bridging” data can be useful as a “preliminary screen.”

Step 3: Evaluate Risks. This step involves taking all the data sets developed in Step 2 and estimating the nature, likelihood and magnitude of adverse effects from production or use of the nanomaterial on human health and the environment. The Framework acknowledges that, depending on the strength of the data gathered in Step 2, this assessment of the risk may be qualitative, semi-qualitative or quantitative. It stresses that the step should involve assembling a list of data gaps and prioritizing how to fill them. The Framework points out that, “as the material is nearing commercialization,” qualitative or semi-qualitative risk information “should no longer be relied upon”; instead, “adequate hazard or exposure profiles should be as complete as practically possible at that time.” The Framework also stresses that, where the absence of data results in a qualitative risk assessment, “it is extremely important that assumptions and default values be conservative,” that is, that all assumptions be a “reasonable worst case.”

Step 4: Assess Risk Management. This step uses the information on risks developed in Step 3 to formulate a plan to minimize or eliminate any adverse impacts on human health and the environment throughout the nanomaterial’s life cycle. The Framework stresses that this step should be addressed by a team made up of safety, occupational health and environmental science specialists, as well as business people familiar with the product or application under development. The members of the team should jointly assess how to minimize and control risks from the product, beginning with manufacture

of the product, and then moving to its use and, ultimately, its disposal. Methods to minimize risk include, for example, engineering controls, design changes, training of personnel, warnings to manufacturing workers and/or product users, and use of personal protective equipment in some situations. At the end of this step, this team should develop a formal, written plan for management of risks posed by the nanomaterial.

Step 5: Decide, Document and Act. This step involves formation of a “Review Team” which takes all the information developed in Steps 1-4 and decides what to do, such as whether and how to continue development of the nanomaterial or product. The Review Team may include, in addition to the health, safety, environmental and production personnel included in Step 4, financial, business and legal advisors. The Review Team should determine if additional data should be collected and the timetable for that collection, whether the risk management plan assembled in Step 4 is adequate and should be implemented, how compliance with that plan should be monitored and at what intervals health and safety issues connected with the material or product should be reviewed. The decisions of the Review Team should be well-documented, so that there is a written record demonstrating that the risk management decisions regarding the product were thorough and well thought through. The Framework urges as much transparency as possible in this step, with recognition, of course, of the need to protect confidential business information.

Step 6: Review & Adapt. This step is simply a process for both periodic and as-needed review of the decisions and actions taken in Step 5. The step recognizes that there is a need for periodic re-evaluation of these decisions made in Step 5, particularly as new information is developed but also on a regular basis. Thus, this step calls for both “regular” reviews and reviews “as needed” when new data or information comes to light.

Response of Labor and Certain Environmental Groups

On Thursday, April 12, the AFL-CIO, the Natural Resource Defense Council (“NRDC”), Greenpeace and several other labor and environmental organizations issued an “open letter” to the “International Nanotechnology Community at Large” denouncing the Framework “as fundamentally flawed.”⁴ It did not, however, critique any part of the Framework in detail; instead the signatories’ main complaint is that the government, rather than industry, should regulate nanotechnology. The letter states that “[w]e strongly object to any process in which broad public participation in government oversight of nanotech policy is usurped by industry and its allies” and continues:

“The history of other voluntary regulation proposals is bleak; voluntary regulations have often been used to delay or weaken rigorous regulation and should be seen as a tactic to delay needed regulation and forestall public involvement.”

The signatories also state that they did not participate in the formulation of the Framework “out of well-grounded concerns that our participation – even our skeptical participation – would be used to legitimize the proposed framework as a starting point or ending point for discussion of nanotechnology policy, oversight and risk analysis.”

Environmental Defense almost immediately posted a response on its website. It states that it “wholeheartedly agrees” that government regulation of the potential human health

and environmental risks from nanomaterials is needed, and that the Framework is not intended to “replace” government regulation or to “absolve[]” government from its duty to regulate. One of the reasons for the Framework is that the government has not acted. Environmental Defense concludes that the purpose of the Framework is “to speed the development of a meaningful and effective government policy” concerning nanomaterials, and to provide, “[i]n the interim,” “useful guidance” to companies “on how to address nanomaterials until government regulations are developed.”

Analysis

The labor and environmental groups’ position with respect to the Framework is consistent with the position that such groups have taken in letters to EPA and other government agencies concerning nanotechnology. In those letters, the AFL-CIO and others have complained that the government is not acting quickly and with enough resources with respect to the health, safety and environmental issues that have been raised with respect to nanomaterials. The labor federation has also complained about the “lengthy process” that EPA is recommending to gather information on these risks, and has advocated that EPA, acting under Section 4A of the Toxic Substance Control Act (“TSCA”), “require protective action immediately for all nanomaterials lacking comprehensive toxicological evidence of safety under foreseeable conditions of manufacture, use and disposal.”⁵

The attack of these groups on the DuPont/Environmental Defense Framework is unfortunate. Comprehensive governmental regulation of the health, safety and environmental issues raised by nanomaterials is not even on the distant horizon; there are too many variations in the materials and too much that remains unknown. The Framework is an attempt to allow the technology to move forward, where appropriate, but with systematic and documented attention along the way aimed at figuring out what is known about the risks, what data should be collected, how to handle gaps in information, how best to deal with the hazards, and mechanisms to reassess these decisions as time marches on. Any litigant or lawyer involved in toxic tort litigation can only wish that a similarly careful and painstaking approach had been followed by industry with respect to the development and use of “miracle” substances decades ago, such as asbestos fiber. Experience from asbestos and other toxic tort litigation demonstrates that industry cannot afford to wait for government regulation. As any first-year law student knows, a product manufacturer is charged with keeping abreast of the most up-to-date scientific and medical information available concerning its products and their components, regardless of whether the government has set safety standards or whether the manufacturer has complied with those standards.

The DuPont/Environmental Defense Framework is a responsible attempt to deal with the risks posed by nanomaterials. It provides a basic outline for companies trying to assess the risks of nanomaterials, and it may provide a basis for useful and reasonable government regulation in this area. It is to be hoped that others will give the Framework the serious consideration that it deserves, provide constructive criticism, and use it as a basis for making responsible public health and environmental decisions as this vibrant new technology advances. All manufacturers and users of nanomaterials will need to take the DuPont/Environmental Defense Framework into account in addressing the health, safety and environmental issues raised by nanotechnologies.

¹ The Royal Society & The Royal Academy of Engineering, “Nanoscience and Nanotechnologies: Opportunities and Uncertainties” (July 2004).

² The Framework is available at <http://www.nanoriskframework.com>.

³ These are just brief examples of the types of “base sets” of information delineated in Step 2; there is a great deal of detail in the Framework and Appendix concerning the type of information that needs to be gathered or developed on these three issues.

⁴ Other signatories to the letter include Beyond Pesticides, Brazilian Research Network in Nanotechnology, Society and Environment, Center for Environmental Health, Center for Food Safety, Corporate Watch, Edmonds Institute, ETC Group, Friends of the Earth Australia, Friends of the Earth Europe, Friends of the Earth United States, Institute for Agriculture and Trade Policy, International Center for Technology Assessment, International Union of Food, Agricultural, Hotel, Restaurant, Catering, Tobacco and Allied Workers’ Associations, Sciencecorps, Silicon Valley Toxics Coalition, Third World Network, and United Steelworkers of America.

⁵ *E.g.*, October 27, 2006 letter to EPA from AFL-CIO and others, regarding “Comments on risk management practices for nanomaterials, especially as it relates to exposure of workers per Federal Register notice 10/4/06 Vol. 71, No. 192, Pages 58601-03.”

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