Nanotech under scrutiny, but tighter regulation remains distant

The nascent nanotech/nanobiotech industry is beginning to feel the heat of regulatory scrutiny. Both the US Environmental Protection Agency (EPA) and the US Food and Drug Administration (FDA) released position papers—FDA in July, EPA in February—and both called for more research to determine the human and environmental hazards of nanotech, although each declined to install special regulations to cover nanomaterials. FDA specifically declared that nanomaterials—classified as particles up to 100 nm or to 200 nm in diameter, depending on who you ask—can be covered by existing regulations.

That did not sit well with some watchdog groups, especially the nonprofit Friends of the Earth in San Francisco, which had called for special labeling of products containing nanoparticles. The organization is specifically concerned about sunscreens that contain nanoparticles of titanium dioxide and zinc oxide, which cause it to rub on clear instead of white. Friends of the Earth underscored its point by contacting more than 120 sunscreen manufacturers to inquire about their use of nanomaterials, but it reports that few responded to its request.

The Friends of the Earth campaign has raised some concerns that nanotech may elicit fear in the general populace, much as concerns about biotech led to some public and regulatory backlash in the 1970s and early 1980s. Early fears gradually dissipated before resurfacing in the late 1990s with respect to genetically modified crops. What's happening with nanotech "is very similar," says Khouane Ditthavong, an associate in the tort and environment practice at the law firm King & Spalding in Atlanta. "There's always the fear that a product will wreak havoc out there without any [controls]."

Although there have been no court cases over nanomaterials in the US, Ditthavong believes it's only a matter of time, with the most likely prospects being issues around worker health in manufacturing settings.

He says that the nanotech sector should learn from public perception issues surrounding genetically modified crops. "A lot of companies have learned the lesson, to become a bit more proactive and responsive to consumer concerns. The perception of harm from nanotech can really be disastrous. That could kill off an industry just as it's getting started."

In July, FDA's Nanotechnology Task Force issued a report outlining areas of research, but stopped short of recommending any new regulations. "What FDA is really saying is, 'We feel that the current system will capture any potential toxicity from nanomaterials. If you have data

Concerns over nanotech products in sunscreens have some calling for more stringent government oversight of the technology.

to show these things are toxic or harmful, they will be part of the analysis of whether they're acceptable for use," says Ditthavong. In fact, FDA states on its web site that "every degradable medical device or injectable pharmaceutical generates particulates that pass through this size range during the processes of their absorption and elimination by the body."

But Jennifer Sass, a senior scientist at the Natural Resources Defense Council (NRDC) in New York, views FDA's document as insubstantial. "They're getting involved in a lot of conversations that are appropriate, but they're running and hiding from actually demanding any kind of data, or even outlining what they believe their regulatory authorities are," she says, adding that FDA left "a lot of wiggle room on the definition of a nanomaterial. They didn't tie themselves strictly to a definition of under 100 nm." Some groups have argued that it should include nanoparticles up to 200 nm in size.

Sass points out that concerns over nanomaterials should not ignore the potential benefit. NRDC and Friends of the Earth object to their use in sunscreens, she says, but would be less adamant about restricting their use in medical devices or drug delivery. "The risk-benefit ratio is different than in a skin cream," she says.

The EPA also recognizes the potential environmental benefits of nanotech, including pollution remediation and prevention, but its report, published in February, laid out what is known about nanotech and potential toxicity issues, and set a research agenda to inform a future

regulatory framework. "The bulk of the report focused on what we need to understand about the health and environmental implications of nano-materials, and what sort of research we need to do to move into that area more robustly," says Jim Willis, who is the director of EPA's chemical control division. The report identified key research needs, including determining what physical properties are best used to characterize nanoparticles, such as particle size, surface area and surface charge. Other priorities include environmental detection methods, and studies of the environmental fate of nanoparticles.

Although both reports point to deficiencies in research on nanotech, most agree that regulation is still years away. In an effort to collect more data, EPA is poised to launch its Stewardship Program for Nanoscale Materials, which will call for companies working with nanomaterials that are based on existing chemicals to voluntarily submit the types of data required under EPA's New Chemicals Program, and to work with EPA to generate data to characterize the risks of nanomaterials. The results of the program should be published by the end of 2008.

EPA's program is modeled partly on a similar program in the UK, and Germany is also considering a similar effort, says Willis. In fact, Europe is ahead of the US when it comes to nanotech regulation, largely because of the REACH (Registration, Evaluation and Authorization of Chemicals) program. Enacted into law in June, REACH eliminated the distinction between existing chemicals and new chemicals, requiring every chemical to meet the same safety standards, even those already on the market.

REACH places the burden on the chemical manufacturer to provide safety data, embracing the 'precautionary principle' some want the US to adopt. Significantly, chemicals that are produced or imported in small quantities—less than one ton—are exempt, which allows for research use. In August, the European Commission recommended including nanomaterials in the EU's risk assessment guidelines, and these could be required as part of REACH registration, Ditthavong says.

Europe's precautionary approach encapsulates what Friends of the Earth would like to see in the US, says Ditthavong, but moving in that direction would "probably require a legislative change." But that doesn't mean some sort of regulatory scheme for nanotech isn't coming.

"We're probably talking years, not months," says Asimakis Iatridis, a partner at the law firm Berg Hill Greenleaf & Ruscitti in Boulder, Colorado.

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