

New technologies seen outpacing regulation

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Despite a spate of publicity about nanotechnology, a regulatory regime is not yet in place, Mark Mansour, a partner in the Washington law firm Foley & Lardner, told a March 4 forum on new technologies sponsored by the American Society of International Law.

"The pace of change far exceeds the ability to keep up," Mansour said. "There's no impartial arbiter out there except for government. Consumer organizations don't have the mantle of officialdom. How do you imbue government agencies with the ability to manage change?"

Mansour noted that, unlike biotech, regulators could see nanotech coming. "There's no excuse [for inaction]," he said, citing potential squeamishness on the part of consumers, little understanding of output traits and "controversy swirling around it."

Regulators are "trying to get their arms around" nanotechnology, Mansour continued, praising the National Institute for Occupational Safety and Health (NIOSH) for doing the best job, especially regarding aircraft production. "FDA and EPA are woefully under-resourced; FDA can't deal with the problems it already has. I don't think nano is a major issue for food production, except for packaging," he added.

Industry understood the need for self-regulation, Mansour said, noting that DuPont has worked with Environmental Defense on the issue. The European Union has also been proactive, engaging with the Woodrow Wilson Center for Scholars and others "to avoid what happened with biotech."

Stressing that the most important use of nanotechnology is military, Mansour said worker safety regimes are needed. "Still, there are lots of imponderables," he said. "You can't complete a safety regime because it's a bunch of industries. These are retail regulatory regimes, and principles are needed to guide the flow of products.

"Industry would like to give government the tools to do the job," he concluded. "They don't want to go the way of biotech and see consumer confidence go down the drain."

"Seamless transition" for animal cloning?

Sharon Bomer Lauritsen, vice president for food and agriculture at the Biotechnology Industry Organization, forecast a "smooth and seamless transition" of food from the offspring of clones into the food supply. "There are no unique health risks to animals from cloning. When people understand the technology, they accept it," she said.

Lauritsen said it would be three to five years before food from the offspring of clones enters the food supply, adding, "There's a built-in transition into the marketplace for the technology."

Acknowledging that USDA's Foreign Agricultural Service needs to educate foreign governments on cloning technology, she concluded, "The science is clear; the technology is safe; foods will enter the food supply in the next few years."

Speaking as an individual, Wolf-Martin Maier, counselor on food safety, health and consumer affairs in the European Commission's Washington delegation, was less optimistic. He warned that the European Union is more receptive than the United States to "labeling to inform consumers of the presence of material giving rise to ethical concerns," and he noted that Denmark has prohibited cloning of animals for food purposes.

"The science of cloning is far from clear," Maier said. "It works, but no one knows how. The biology is not understood. There are syndromes such as stillbirth, and there's no way to predict them. I don't feel so happy about it."

Offering a consumer viewpoint, Greg Jaffe, biotechnology director at the Center for Science in the Public Interest, asked, "Why should we embrace these technologies? I haven't seen any evidence of healthier animals or better food [from animal cloning]."

Noting that U.S. regulators dismiss ethical and social concerns as relatively unimportant, Jaffe said CSPI doesn't address them either, "but they are important to people. Government needs forums to address them. They get masked as safety concerns."

Legal scholar Michael T. Roberts posed 20 questions about the new technologies, including the following:

- * What are the international institutions and instruments relevant to the regulation of animal cloning and nanotechnology?
- * Given that these technologies, especially nanotechnology, may evolve in a number of distinct phases - each progressing with its own legal, regulatory, social and political issues - should international standards be developed now or should they be delayed?
- * Would the WTO Sanitary and Phytosanitary Agreement and the Technical Barriers to Trade Agreement apply to measures regulating trade in animal cloning and nanotechnology?
- * Can or should the WTO and SPS/TBT construct respond to the political, ethical and moral nuances raised in animal cloning and nanotechnology?
- * What should be the role of consumer concerns in connection with these emerging technologies in a world where consumers increasingly view themselves as purchasing not only products but also shares of responsibility in the moral and ecological economy that produces them?
- * What will and should be the role of private standards in the international regulation of cloning and nanotechnology?
- * Will a sharp public divide over these emerging issues, coupled by ignoring consumer concerns, provide further impetus to legal pluralism in the global food sector, effectively bolstering the role of private standards at the expense of a vibrant public international food law scheme?

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