Why the difference between risk and hazard matters for nanotechnology

Scientific progress is a balancing act: Weigh the empirical evidence and determine the appropriate balance between allowing new technologies and protecting public health.

Often, especially where there is little opportunity for sensationalizing the technology and its impact, risk analysts and managers can do their vital work in relative quiet and make sound and defensible decisions.

However, every now and then development is stymied by fear, which can overwhelm promising physical data. That was the story of the years-long public debate over agricultural biotechnology. In the wake of the FDA's recent public meetings on the regulation of nanotechnology, nanotech is now poised on the same knife's edge as biotech was in the last decade.

For several years, we have been hearing about nanotechnology's potential benefits. As with all new technologies, the bright promise of potential breakthroughs attracts investment and publicity at the same time that it is accompanied by a stream of warnings about the need for caution (or, in some quarters, precaution).

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In the United States the FDA held a broad-based public meeting for stakeholders in October 2006 to more closely examine the issue and to allow consumers, scientists, industry and other interested parties to weigh in. In January, it held an additional meeting and began soliciting input to develop priorities for environmental health and safety efforts.

The October meeting began with a series of well-presented speeches and testimony from a variety of stakeholders. The message from the scientists was unmistakable: The technology is a series of varied and remarkable applications that hold incalculable promise and which, like any applications, require appropriate partnerships between industry and government to determine risk.

But as the consumer activist community began its presentations, the message transmuted into one of fear and risk, focusing on the "lack of urgency and resources." The FDA's approach came out badly in comparison to the precautionary principle (unsafe unless proven safe, and conclusively) approach that characterizes the European Union's approach to regulation.

If this view holds, it will be a pity. Nanotechnology gives regulators the chance to get it right the first time, rather than succumb to the pressures to regulate based on an intellectually dishonest commingling of risk and hazard.

The FDA's efforts have been described as a logical next step in a continuum of efforts to ensure the consuming public – and the industries that will be offered more and more nanomaterials and nanoapplications for their finished products – that regulators understand the importance of "getting it right" and regulating based on realistic risk assessment.

This is in contrast to the troubling pattern of recent years where governments, bowing to concerns expressed by some activist groups, have conflated risk and hazard and stigmatized entire industries, preferring to use murky "precautionary principles" to regulate based on means of production, rather than on the safety of the product.

E. coli is a hazard to human life that must be eradicated. But nanomaterials should not be inappropriately classified as a similar hazard. If left unregulated, they could pose a risk, but if nanomaterials are managed carefully consumers can derive the tremendous benefits that accompany the understandable risk. There is a big difference, and the future depends on government's ability to understand it and to regulate and communicate accordingly.

There is no reason misunderstanding should occur. The United States has robust regulatory systems in place that allow each application to be evaluated and assessed on its own merits, though proper funding of those regulatory agencies would be of inestimable assistance.

The FDA has a golden opportunity to turn a bad trend on its head and show the world that regulation based on empirical data, rather than on fear, provides the best hope for a safe future. At the same time, it can bring home the truth that regulating the fruits of innovative technology based on uninformed fears imposes on society an unacceptable opportunity cost.

The message that ultimately emerges will influence what regulators around the world decide to do. An exercise of confident, sure-footed control by the FDA will go a long way toward building public confidence in an area where perceptions have yet to become rooted. ■