In Search of 'Zero Risk'

By Kathryn Kelly

Next week the House will consider legislation that would establish solid risk-assessment/cost-benefit criteria for environmental legislation. It's about time. The "acceptable risk" criterion on which much of the current environmental regulation is premised has no basis in scientific fact, has received no serious review, and was, in fact, "pulled out of a hat."

At issue is the so-called "one-in-a-million" standard of acceptable risk for environmental contaminants. This is a shorthand description of an increased lifetime chance of one in a million of developing cancer due to a certain substance. This standard guides the use of pesticides and food additives. It determines what emissions should be allowed from stacks, how a Superfund site should be cleaned up, and how much Alar to leave on apples.

What is the origin of this criterion, which has cost society billions of dollars? In 1991, my firm set out to solve this mystery. We contacted officials from the (Bush) White House, the Environmental Protection Agency, the Food and Drug Administration, the Congressional Office of Technology Assessment, and activist groups such as Greenpeace.

The result? No one—not even the very federal officials who currently use the one-in-a-million standard—knew what it is based on. A sample of the responses:

"My mind is a complete blank."

"My, what an interesting question!"

"It's an economic criterion."

"It's based on the chance of being hit by lighting, which is one in a million."

"It was a purely political decision made by several of the major agencies behind closed doors in the 1970s. I doubt very much you'll get anyone to talk to you about it."

And our personal favorite: "You really shouldn't be asking these questions"—this from one of the federal agencies.

So what is the origin of one-in-a-million? Return to Thanksgiving, 1959, when trace residues of a cancer-causing herbicide were found in cranberries, prompting the U.S. Department of Health, Education and Welfare to recommend against buying cranberries that year. This set off a panic that nearly devastated the cranberry industry.

Following the cranberry panic, the Eisenhower administration asked the National Cancer Institute to help establish which cancer-causing substances were "safe" and at what levels. The NCI researchers pointed out that to define these parameters, one must first come up with a definition of safety. For the purposes of discussion, they said, we'll assume "safe" is equal to one chance in 100 million of developing cancer.

When we asked the now eightysomething NCI researcher, Nathan Mantel, how he chose that number, he replied, "We just pulled it out of a hat."

The FDA appears to have been the first to have used the one-in-a-hundred-million criterion. In 1973, the FDA developed guidelines in response to the use of a drug called DES as a growth promoter in cattle. But by the time the final rule was issued in 1977, one-in-100 million apparently had turned out to be too high a threshold; so in an equally arbitrary manner, the FDA decided to adopt one-in-a-million as a definition of de minimis risk.

Other state and federal regulators quickly picked up the one-in-a-million standard. But along the way, the original standard—which was intended to define a level beyond which it was inefficient to regulate—had been translated into a maximum allowable level of risk, period. It soon became clear that there were serious drawbacks to interpreting the "zero risk" screening criterion as "maximum acceptable risk."

Cleaning up all hazardous waste sites to a one-in-a-million level is in some ways comparable to limiting highway traffic to 1 m.p.h.—the risks may be virtually eliminated, but the trip to get there can be costly and painfully slow.

What the federal government should do now is define a true de minimis risk below which it is agreed that the costs of achieving additional safety do not outweigh the benefits. This means doing away with a single, arbitrary threshold of "acceptable risk," which makes about as much sense as setting one speed limit for all terrains, vehicles, and driving conditions. Twenty m.p.h. is safe under some circumstances and extremely risky under others; and while 1 m.p.h. is safe under all conditions, the cost of enacting it is too high to pay.

Instead, standardize the process by which risks are assessed, and offer the regulatory agencies a range of risks within which each case may be decided on its merits, rather than on a single value. Base this range on known risks so that comparable risks can be compared with comparable risks, particularly for risks and benefits that cannot be well quantified.

Congress has a superb opportunity to achieve this goal as part of a broader risk-assessment/cost-benefit bill. Defining "acceptable" risk is a first step on the road toward more rational federal regulation.

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