THE ENVIRONMENT

The EPA's war on bioremediation

Henry Miller

A 1994 headline in *Nature* proclaimed success at bioremediation, or biological cleanup, of the Exxon Valdez oil spill, which had occurred five years earlier. Bacteria were degrading the oil! My elation turned to disappointment, however, when I realized that the effects were modest and the techniques used—dumping fertilizer on the beach to stimulate the growth of any indigenous bacteria—were throwbacks to the 19th century.

The 1980s brought great expectations for modern biotechnology applied to biological cleanup. William Reilly, the US Environmental Protection Agency (EPA; Washington, DC) administrator at the time of the Exxon Valdez accident, later recalled "[W]hen I saw the full scale of the disaster in Prince William Sound in Alaska. . .my first thought was: Where are the exotic new technologies, the products of genetic engineering, that can help us clean this up?"

The answer was simple: Although technically feasible, the needed research and biotechnological innovations were blocked by a decade-long "interim regulation" from the EPA under the Toxic Substances Control Act (TSCA).

The TSCA regulation was aimed directly at limiting the use of our most sophisticated new genetic engineering techniques. On April 11, 1997, in a final rule containing 52,000 words of impenetrable bureaucratese, the EPA finalized that regulation. It institutionalizes potent disincentives to R&D, ensuring that researchers will continue to be intimidated by regulatory barriers.

Before the interim regulation, under TSCA all organisms were assumed to be "natural" and therefore exempt from any review, either during testing or at the time of commercialization. In 1986, the EPA eliminated the exemption for microorganisms containing DNA from different sources (the EPA's "code" for gene-spliced products). This captured for the EPA's comprehensive review virtually all early-stage field trials of microorganisms that were crafted with new biotechnology techniques and that eventually could have commercial value. In effect, the EPA thereby defined recombinant DNA-manipulated organisms as "new," even though that is doubly inaccurate: Many recombinant organisms are not fundamentally novel in any material sense, whereas other genetic techniques can give rise to new organisms, whether or not heterologous DNAs are recombined. (Recall the oil-eating Chakrabarty *Pseudomonas*, for example, which was the subject of the first patent for a live organism.)

For the EPA, "newness" is synonymous with risk, and because gene-splicing techniques can easily be used to create new gene combinations, these techniques therefore "have the greatest potential to pose risks to people or the environment." (That's like arguing that newer, safer, and more comfortable automobiles are actually more dangerous, because people are likely to drive them longer distances.)

Characteristically, in the April 11 rule, the EPA comes to its conclusions via bizarre circumlocutions. "EPA concluded that microorganisms found in nature could also be considered not new because they occur naturally, without human intervention, and therefore, 'naturally occurring microorganisms' are automatically. . .not subject to this rule." In this way, the EPA defines virtually all organisms, except gene-spliced ones, as "natural," or "not new," and exempts them from review.

But "new" is not synonymous with "harmful." Both science and common sense dictate that it is not the origin of a snippet of DNA that matters, but its function. The obvious kinds of questions that should be part of a risk analysis for any new organism include: How hazardous is the organism you started with? (Is it a harmless, ubiquitous organism found in garden soil, or one that causes bubonic plague?) Does the genetic change merely make the organism able to degrade oil more efficiently, or able to grow in new ecosystems and difficult to control?

The EPA's reasoning is incompatible with long-standing, widely held scientific consensus that the risks associated with the products of the biotechnology are fundamentally the same as for other products. The US National Academy of Sciences has said there is no evidence that novel hazards attend the movement of genes between unrelated organisms. The US National Research Council has observed that use of the newest biotechnology techniques lowers even further the already minimal risk associated with field testing. It is now possible to introduce pieces of DNA that contain one or a few well-characterized genes, in contrast with older genetic techniques that transfer or modify a variable number of genes haphazardly. That means users of the new techniques can be more certain about the traits they introduce into organisms.

As well as being at odds with scientific consensus, the EPA's biotechnology policy conflicts with an official federal policy (developed with the EPA's formal agreement and published in 1992) that regulation of biotechnology products should be "risk-based," "scientifically sound," and focused on "the characteristics of the biotechnology product and the environment into which it is being introduced, not the process by which the product is created."

The regulations mandate comprehensive and costly case-by-case government review of virtually all small-scale field trials of gene-spliced microorganisms. Tests of similar organisms—even those with identical properties introduced by less precise, older genetic techniques—are exempt. Naturally occurring organisms are exempt, even if they might foul waterways or pose other serious environmental or public health risks. (Moreover, the EPA continues to exempt from review all small-scale field trials of chemicals, including those similar to DDT and sarin).

While the EPA's earlier approach can hardly be said to be risk-based, as it exempted both low-risk and high-risk organisms (and chemicals) alike, there is a certain logic: Small-scale experiments seldom pose significant safety concerns. Under the exemption for small-scale trials, R&D has been performed safely for more than a century with thousands of strains of microorganisms for purposes as varied as pest control, frost prevention, artificial snowmaking, promoting the growth of plants, mining, oil recovery, bioremediation, and sewage treatment. (And let us not forget the unremarkable, "incidental" releases that occur continuously from research laboratories and fermentation facilities.)

The power of regulatory disincentives is potent. the EPA's misapplication of TSCA (leaving aside FIFRA, the pesticide statute) has discouraged the application of recombinant DNA techniques to both industrial R&D and the precommercial research performed at major research universities. Researchers know that experiments using biotechnology will meet a wall of red tape, intraagency politics, and vast expense.

The EPA's now-final policy, based on willful misapprehensions of biotechnology, has already left a legacy of reduced US competitiveness, continued reliance on dated techniques for bioremediation, and environmental damage. It ensures that cleanup crews will continue futilely to slop fertilizer on the beach instead of putting high technology to work. ///

Henry Miller is a senior research fellow at the Hoover Institution and a consulting professor at Stanford University's Institute for International Studies. He is the author of Policy Controversy in Biotechnology: An Insider's View, *Academic Press, 1997.*