remains undeveloped due to a variety of technical, institutional, economic, and perceptual barriers." In particular, funding is "insufficient and comparatively unstable." Some 60 new training programs at 49 institutions are helping to meet those needs, albeit with support from dwindling federal training budgets.

In other respects, traditional federal programs supporting basic research are healthy and continue to contribute to biotechnology. OTA reports that federal agencies spent about $2.7 billion in fiscal year 1987 for research and development programs in biotechnology-related areas. The largest share of that spending comes from the National Institutes of Health, whose biotechnology-related budget of $2.3 billion accounts for 84 percent. The Department of Defense, the National Science Foundation, the Department of Agriculture, and the Department of Energy are next in line with substantive programs.

Besides the long-standing effort within federal agencies, some 33 states now support biotechnology development in one form or another. The aggregate budget figure for state programs was $147 million in fiscal year 1987—with New Jersey, Pennsylvania, Florida, North Carolina, and Maryland being among the top spenders. Although some or perhaps all the high investment rates may not be "sustainable" (since they probably represent start-up costs), the state-run programs "could lead all levels of government in the design of applied research programs," the OTA report notes.

Moreover, such programs may "succeed in areas where the federal government will not." According to OTA study director Kathi Hanna, state governments can force academic and industrial parties into forming useful collaborations. "The state governments give real scrutiny to the economic potential of a project, and can probably achieve more than a federal review group could," she says.

—Jeffrey L. Fox

The OTA report, "U.S. Investment in Biotechnology", GPO stock number 052-003-01115-8, is available from the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, for $13.00 per copy. The 296-page report cost $165,000 to produce over a 2-year period.

NEWS ANALYSIS

MANEUVERING TO BREAK (PROPOSED) EPA RULES

WASHINGTON, D.C.—Summers in the capital are nasty, brutish, but long. In the withering heat of 1988, a lengthy set of biotechnology rules proposed by the Environmental Protection Agency (EPA) got badly scorched. This instance of classic Washington-style maneuvering has agency officials obviously upset, watching the overdue proposals practically eclipsed before ever seeing the light of day in the Federal Register. While some critics claim that EPA should go back to the drawing board, agency officials are inclined to simply amend the proposals for the time being.

The proposed rules, drafted under authority of the Toxic Substances Control Act, are intended to clarify how the agency will review commercial activities involving microorganisms. The proposed rules have two major components. One embodies review of experiments in which microorganisms are released into the environment during commercial research and development efforts.

The other component is a proposal that "significant new use notices" be submitted to the agency before release for commercial use of any naturally occurring or genetically altered microorganisms that are not specifically excluded from such treatment. Academic research without "immediate or eventual commercial purpose," for example, will be exempt from such requirements. In addition, an inventory of exempt microbes will eventually be compiled.

Although the draft rules were completed in the spring, publication has been held up by a reiterative review process, involving the Biotechnology Science Coordinating Committee, the Office of Management and Budget, and other federal-level interagency reviewers. During this prolonged and admittedly contentious review period, the draft rules have become virtually a public document. As such, they also have been subjected to a detailed but still unofficial barrage of criticisms from outside the federal sphere.

On the public side, the Association of Biotechnology Companies (ABC, Washington, DC) has led the pack of critics. ABC contends that, if the EPA rules were to be made official, they "would profoundly stunt the ability of the United States to research, develop, and market many types of biotech-derived products." The proposed rules are too complex, ABC officials say, calling them "a bewildering matrix and a perplexing set of definitions." ABC also says that the proposal is "scientifically flawed," that it "imposes a costly and unreasonable regulatory burden, endangers proprietary information, [and] increases the likelihood of litigation."

Criticism is also coming from other quarters. For instance, Barton Gilbert of General Environmental Science Corporation (Cleveland, OH) is worried that the new rules could put too many companies under the same regulatory umbrella. His company assembles proprietary mixes of natural bacteria isolated from soil samples, supplying the microbes to waste-water treatment plants. "We don't create the same kinds of concerns as gene splicers," he says, arguing that it's "not fair for us to fall under the same regulations." His company, in business for 14 years "without any problem whatsoever," has never been subject to EPA regulations. With few employees, it would be burdensome and expensive to "comply with the federal bureaucracy," he says.

The National Association of State and Land Grant Colleges (Washington, DC) also has misgivings about the EPA proposals, albeit for different reasons. "Without even looking at one word, merely knowing what the [proposals] deal with, I'm full of apprehensions," says Jerry Roschwalb of the Association. Tampering with biotechnology efforts on campuses makes him "nervous," he says. Those efforts have a great deal of creative momentum, and the field has blurred traditional distinctions between pure and applied research. Thus, although EPA's proposed rules exempt noncommercial research activities, he believes the two categories of research are not so readily distinguished. "It's a big problem," he says. "I don't want to see [biotechnology at universities] bureaucratized to death."

Meanwhile, the rules themselves have been bouncing around the federal establishment. An alternative proposal also is being drafted outside EPA, and it calls for a narrowing rather than a broadening of the agency's jurisdiction over microorganisms. EPA officials appear frustrated over the maneuvering. "I think the utility of the review process has been exhausted," says John Moore, who is Assistant Administrator for Pesticides and Toxic Substances at EPA. "The rules should be promulgated, so we can get public comment before anything else happens. That's this agency's intention."

—JLF