

# Larger Public Sector Role Sought on Biotech

*Controversy stirred up by initial field test plans worries industry, triggers demand for broader government action*

**P**UBLIC outcries over proposals to conduct outdoor tests of genetically modified organisms have shaken the biotechnology industry. Companies are concerned that product introductions could be delayed by a regulatory crisis. This uncertainty also is prompting industry leaders to step up pressure for federal and state governments to fashion a regulatory apparatus to ensure that agricultural biotechnology experiments can go forward.

"The real question is whether there will be overreaction," says Richard D. Godown, executive director of the Industrial Biotechnology Association, who fears biotechnology's critics will demand "wholesale regulation." To lay the ground for rational regulation, industry and government officials have begun suggesting that the federal government take a more active role to assure that basic research is conducted to identify biotechnology's risks and regulatory needs. There also is a push for the government to provide giant facilities for testing modified organisms as an intermediate step between greenhouse experiments and open-air trials.

Relatively few products for agriculture are expected to come forth in the next couple of years. But within 5 years the number of bacterial, viral, and plant products engineered for agriculture is expected to soar. In addition to the need to allay public concern about safety, industry executives want a comprehensive regulatory structure up and running before regulators are inundated with field test applications. For both small and large companies, which are sinking millions into research, a regulatory bottleneck that unnecessarily delays product introduction could be financially disastrous.

The debate over federal regulation has intensified in part because of the controversy created by Advanced Genetic Sciences' outdoor testing of genetically altered bacteria—*Pseudomonas syringae* and *P. fluorescens*. When stripped of part of their genetic code, the bacteria cease to produce proteins that aid the formation of damaging frost on crops such as strawberries. In a test of the product, the company injected the bacteria into the bark of trees located on the roof of its Oakland, California, laboratory, thinking it was in compliance with Environmental

Protection Agency regulations (*Science*, 14 March, p. 1242).

EPA officials, however, have taken exception to the company's procedure, stating that the experiment should have been conducted within the confines of a greenhouse. AGS's efforts to field test this product also have been stalled by the company's failure to plainly explain the experiment to Monterey County residents. In January, the company was forced to delay plans for its field test in the wake of local concerns.

The depth of the industry's worry was made clear 11 March in New York at a *Business Week* conference on biotechnology attended by 200 industry executives. Ralph W. F. Hardy, deputy chairman of BioTech-

nica International, Inc., of Cambridge, Massachusetts, noted that "after the events in the press over the last few weeks, regulation is a key issue at this stage."

The concept of federally supported test facilities to fill the gap between greenhouse research and field tests has been kicked around by Executive Branch agencies for some time. But Hardy says that federal regulators have acted too slowly. "The public sector has to move forward," he says, "and play a major role in field research as far as evaluation of the benefits and the risks attendant in biotechnology products."

David Kingsbury, assistant director for biological sciences at the National Science Foundation, says "There is no question that [regulation] is getting to be a very critical issue." No consensus, however, has been reached within the Administration on the type of intermediate facilities, or the classes of agricultural products that should be routed through them. Similarly, the industry has yet to formally make its own determination about the nature of standards and facilities that are needed.

There are signs, however, that substantive action will be forthcoming. The industry's

## EPA Suspends Biotech Permit

The Environmental Protection Agency has suspended a permit issued to a California biotechnology company to conduct a field test of genetically engineered bacteria. The microorganisms are designed to stop frost from forming on crops.

On 24 March, EPA announced that Advanced Genetic Sciences of Oakland, California, had violated agency's rules, asserting that the company had conducted an outdoor test of the modified microbes without permission and falsified part of the scientific data submitted to the agency. EPA fined the company \$20,000, the maximum penalty possible.

The federal action is the latest development in a regulatory saga involving the company. Advanced Genetic Sciences won EPA approval to conduct the test last year, but encountered stiff local opposition (*Science*, 14 February, p. 667). Then it was disclosed that a year ago the company, without EPA's knowledge, had injected the altered bacteria into trees located on the rooftop of the company building to analyze plant pathogenicity.

The outdoor test violated agency rules, EPA said in a letter to the company. EPA also said that the company had "falsified" data by claiming in its permit application that the tree test had been done at specific ranges of humidity and temperature. An agency investigation this month concluded that the company did not record these conditions during the experiment. Agency officials told *Science*, however, that the trees did not develop any disease linked with the altered bacteria in these tests.

EPA says that the company may repeat the tests in the greenhouse and apply again for a permit, which the firm says it will do. The company has also invited a scientist of EPA's choosing to monitor the experiment.

Although the altered bacteria are widely regarded by scientists and regulators as harmless, EPA's action against Advanced Genetic Sciences signals that the agency will enforce its regulatory policy regarding biotechnology experiments. Agency official John Moore said, "EPA is not going to tolerate any infraction of its regulations" governing biotech. ■ **MARJORIE SUN**