

Should States Regulate Biotechnology?

As the number of companies considering field trials of the fruits of recombinant DNA technology soars, states are asking whether federal regulators are doing an adequate job

EVENTS IN NORTH CAROLINA could set the stage for a major change in the way biotechnology is regulated in the United States. State legislators there are poised to pass a law that would require state permits for field experiments involving genetically engineered plants and microorganisms, adding yet another layer to the already cumbersome regulatory process.

To many biotech companies, the North Carolina legislature is creating a roadblock to progress, ironic for a state that has enthusiastically nurtured the new technology. Surprisingly, though, other companies argue that the state law would facilitate progress by clearly stating the rules of the local roads.

Among the skeptics, one chief concern is that the North Carolina action will stimulate other states to enact their own laws, creating a tangle of dissimilar laws that will impede research and slow the marketing of products. Regulations could conceivably vary so much, says Richard Godown, president of the Industrial Biotechnology Association, that federal and state agencies would reach different conclusions about the acceptability and safety of the same experiment.

That's not likely in North Carolina's case. The state-supported North Carolina Biotechnology Center assembled a 27-member panel made up of scientists, industry officials, environmentalists, and public servants who drafted a bill (H.B. 748) that requires researchers to submit to the state virtually the same information about an experiment that they must supply to the federal government. State regulators would have 90 days to decide whether to issue a permit.

But if the state requirements are virtually the same as the federal ones, why bother with a state statute? That's the argument of botanist Bruce D. Kohorn of Duke University in Durham, North Carolina, who contends that federal regulations are adequate to protect the public. Says Kohorn, who served on the panel that drafted the North Carolina bill, "It was largely written by people who are not biologists. All they wanted to do is to have some policy to placate the public." If the law is adopted, he

argues, it will take longer to get experiments approved and that will retard the pace of agricultural research.

Jerry Barnett, director of state government relations for Monsanto, agrees: "We are concerned about the precedent it may set." Companies such as Monsanto and Mycogen, which have invested heavily in developing new crop varieties and pest-fighting organisms based on recombinant DNA technology, fear a nightmarish future in which they would have to please 50 different state regulators as well as federal regulators. The last thing they need, they say, is a patchwork of state regulations. "It's like trying to build an interstate highway and having each state tell you where to put the road," says Jerry Caulder, president of Mycogen.

But these arguments are undermined by the fact that two multinational conglomerates, CIBA-GEIGY and ICI Americas, Inc., are begging for state regulation. Steven Dumford, director of new technology and research in CIBA-GEIGY's agricultural division, which has offices at Research Triangle Park, says accepting state regulation is smart business. "The only way to proceed with any kind of predictability is to know what the regulations will be," says Dumford.

Dumford's point is that by following clearly defined rules, companies would protect themselves from legal challenges. He maintains that his company was wide open to lawsuits when it conducted its first field experiment in 1987 of a tobacco plant that was engineered to be resistant to herbicides.

Dumford sees state legislation as minimally intrusive; what scares him is the possibility of locally imposed regulations. North Carolina's law would

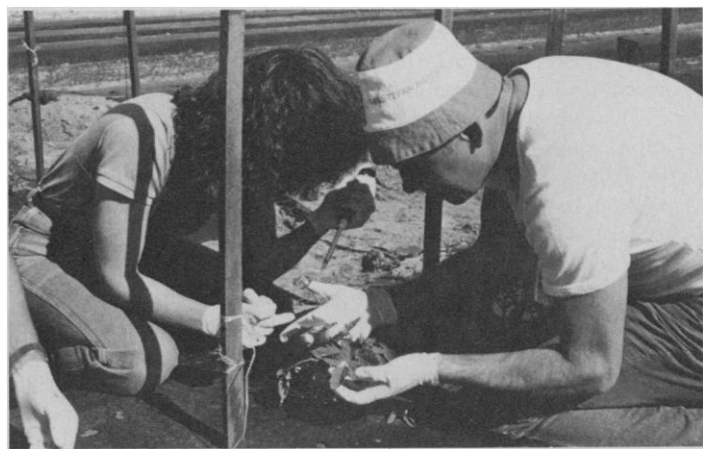
prohibit townships and counties from regulating biotechnology. That is not the case in some states, such as New Jersey, where there are no state laws to supersede local regulators. Dumford concludes that laws like North Carolina's give companies "some protection from unwarranted public debate."

But some states feel the federal government has not done enough to insure that the public's environmental concerns are being protected. Michael Cooper, an entomologist with the Tennessee Department of Agriculture, says many of his colleagues in other states are uncomfortable with the federal regulation. "There is some lack of faith in [federal] agencies like the Environmental Protection Agency and U.S. Department of Agriculture," he says.

This lack of trust prompted USDA to hold a conference of state regulators in North Carolina in June to assure officials like Cooper that the federal regulatory structure is adequate. "Our basic concern is having one uniform system for regulation," says Terry Medley, director of biotechnology at USDA Animal and Plant Health Inspection Service.

Whether other states will be satisfied with limiting their regulatory roles to participation in the federal review process is hard to say. Public interest and pressure to regulate are likely to grow as more companies seek permission to conduct field trials of genetically engineered organisms. Some 44 permits already have been issued by USDA for trials in 17 states, and EPA has approved another 41 experiments.

David Glass, vice president of regulatory affairs at Biotechnica Agriculture, Inc., in Kansas City, expects that many states will be deciding whether to regulate agricultural research experiments involving recombinant DNA technology. Says Glass of the North Carolina legislation, "This is the beginning of a trend that probably will not peak for a couple of years." ■ **MARK CRAWFORD**



Trials or tribulations? Should states regulate field tests like this one of Florida tomatoes?