STATES NOTICING FIELD RELEASES

by David J. Glass and Elizabeth D. Owens

The newest biotechnology "growth industry" may be state government regulation. While state notice requirements serve public interest, a regulatory scheme that duplicates the federal government would be both cumbersome and ineffectual.

Perhaps two dozen states in recent years have adopted or considered adopting new legislation or regulations specifically to oversee biotechnology field tests and other environmental uses. Recent meetings on this subject, including the U.S. Department of Agriculture's July 1990 conference in Sacramento, CA, have been well attended. This growing interest arises from concerns over the adequacy of federal government regulation, yet this trend raises serious questions about whether state regulation will affect development of agricultural biotechnology products.

California—where the earliest field tests were done without adequately addressing the public's need to be informed—was the first to adopt a formal state regulatory framework. While subsequent field tests were not as controversial, the notoriety of the early cases enhanced the public's awareness of all biotech field tests. As a result, seven states (Florida, Hawaii, Illinois, Minnesota, North Carolina, Wisconsin, and Oklahoma) have adopted new legislation specifically to review biotech field tests. Is this the tip of the iceberg?

Minnesota and North Carolina require a state permit for any "deliberate release." Although the state permit process would run concurrently with any federal review, additional regulatory requirements might be imposed. Florida modified its plant pest law to clarify its biotech authority. The Oklahoma law, passed this year, requires permits only for activities not regulated by the federal government. Hawaii, Illinois, and Wisconsin require only that the state be notified of any proposed field test, formalizing the current practice by which federal regulators consult with the state.

Many people distrust the federal government: state involvement can play an important role in reassuring the public that research and manufacturing practices are safe and adequately regulated. State involvement allows citizens the opportunity for greater input into the regulatory process; it can also bring local environmental concerns to the attention of federal regulators. Properly executed, the federal-state partnership can be an effective approach to regulation and risk communication.

Nevertheless, most biotech observers have tangible concerns about this growing state involvement. The greatest concern is over the possible duplication of the federal regulatory framework. Few, if any, states have the financial resources or the access to scientific expertise to carry out the kind of regulatory review routinely done by federal agencies. Duplicate reviews would increase the cost of regulatory compliance, particularly for early-stage research, which historically has not been regulated. Of longer-term concern is whether a patchwork of differing state requirements will make it far more difficult and costly for companies to comply with applicable regulations.

We agree that state or local regulation of *contained* research and manufacturing can provide beneficial regulatory stability. Local ordinances mandating compliance with the NIH Guidelines are a potentially stabilizing influence because they create a reasonable, risk-based regulatory scheme *in the absence* of federal regulation. A predictable regulatory scheme is a prerequisite for the large capital investments required for labs or manufacturing plants. These ordinances require little bureaucracy, can be managed by municipal health departments, and are generally a proper and acceptable exercise of local government authority.

But for environmental applications, federal authority over field tests and commercial activity already exists. Since this regulation requires or promotes state involvement, it generally serves the purpose of providing the desired local input without the need for a separate state regulatory process.

We therefore strongly dispute the contention that state field test regulation benefits biotechnology companies by providing regulatory stability. Contained research guidelines affect a company at one or a small number of sites, while state environmental regulations could create different requirements for multiple field locations, or for products sold in interstate commerce. Field tests at a given site do not require as substantial an investment in equipment or personnel as does the construction of a manufacturing plant. Regulatory predictability is therefore less needed for these smaller, more mobile financial commitments.

For these reasons, new state permit schemes for field tests place an unnecessary burden on agbiotech research. States have other avenues for involvement. Existing state laws and regulations (e.g., plant pest laws, pesticide regulations) can give states authority for field test oversight. An interagency task force might review existing authority before creating new regulations, a strategy endorsed in the consensus report of the Sacramento meeting. If a given state believes that new legislation is necessary (e.g., to respond to public concern), the favored role is a notification scheme to formalize and enhance the federal-state partnership.

This trend towards state regulation ironically comes at a time when federal agencies are gaining more experience and becoming more comfortable with the issues raised by small-scale field tests. Federal regulation of these tests is becoming more routine and less stringent, particularly for "repeat" field trials of previously reviewed organisms. In fact, the recently published "scope" guidelines suggest abandoning the current policy that all outdoor uses of engineered organisms must be regulated, no matter how small the scale.

We therefore hope that states avoid the rigidity inherent in new legislation, and instead adopt flexible policies that allow them to focus resources on cases truly needing oversight, rather than on low-risk experiments.

David J. Glass is vice president, government and regulatory affairs, and Elizabeth D. Owens is manager, commercial development and regulatory affairs, BioTechnica Agriculture, 85 Bolton Street, Cambridge, MA 02140. These opinions are the authors' own, and do not necessarily reflect those of *Bio/Technology*.