DELIBERATE RELEASE

GUIDELINES DRAFTED, STILL NOT RELEASED

WASHINGTON, D.C.—To clarify how researchers should approach the field testing of genetically engineered organisms, U.S. Department of Agriculture (USDA) officials are devising options for implementing draft guidelines that were proposed earlier this year.

In the process, a focus on questions of safety and jurisdiction seems to have given way to renewed emphasis on the potential benefits of biotechnology, typified by the Vice President's recent policy statements on the topic (see "Quayle Likes Biotech, Not Regulation," this issue), as well as to the view that interagency coordination of regulatory activities is improving. A similar shift may be taking place within the Environmental Protection Agency (EPA), where the drafting of long-promised biotechnology-related regulations is nearing completion. Critics meanwhile assert that jurisdictional confusion is still a problem for federal regulators.

In February, USDA published its "Proposed USDA Guidelines for Research Involving the Planned Introduction in the Environment of Organisms With Deliberately Modified Hereditary Traits," with the title itself reflecting the language the Administration now favors for describing genetic engineering. The document, although intended for researchers whose efforts are funded by USDA, omits any reference to scope, jurisdiction, and how its proposals should be implemented.

Instead, the draft guidelines, which are "not mandatory," are presented as "points to consider to aid principal investigators and institutions." Noting that genetic changes can "increase, decrease, or result in no change in the level of safety," they describe an elaborate framework for assigning an unmodified organism to one of five levels of safety concern, assessing genetic changes made to that organism and their effects on safety, and setting an appropriate confinement level as well as the means for achieving it.

The current strategy for implementation is that research be reviewed principally at the local level before it is funded. The "ultimate goal," according to USDA officials, is "with the minimum workload...upon the investigator" to provide assurance to the public that research is safe. There is "keen interest" in setting up a flexible review process and perhaps in leaving it up to individual institutions to decide how best to follow USDA guidelines, says USDA's Maryln Cordle.

USDA guidelines or more formal regulatory activities under the Animal and Plant Health Inspection Service (APHIS) extend only so far, and then EPA responsibilities take over. EPA officials vowed early in 1990 to move the drafting of biotechnology-related regulations onto a "fast track" (*Bio/Technology* 8:187, Mar. '90). They now say that the rulemaking efforts are "nearing completion," and that the scope definitions and the more recent contributions of the Council on Competitiveness are "having a hand in contributing" to development of the rules.

Limits in the USDA proposals, restricted availability for outside scrutiny of deliberate release research proposals, and alleged confusion over agency jurisdiction continue to provoke criticisms. An incident involving follow-up use to a field where engineered strains of nitrogen-fixing bacteria had been tested by Bio-Technica International (BTI, Overland Park, KS) is a recent example where the degree of uncertainty varies according to who is describing the incident.

In 1989, BTI obtained a consent order from EPA to conduct a field test along with Gary Breitenbeck, the collaborating researcher at Louisiana State University (Baton Rouge). After the company completed its test, he sought guidance about what to do after EPA oversight and jurisdiction seemed to lapse. Further uncertainties about disposition of the test plot prompted inquiries from state officials, visits and memos from several federal officials, and considerable debate during a recent meeting of the USDA Agricultural Biotechnology Research Advisory Committee.

By mid-March, however, EPA was poised to send assurances to state officials and clarify the situation. Meanwhile, USDA officials agreed that follow-up jurisdiction resided with EPA until that agency relinquished it. Moreover, the situation was never hazardous, officials say, and the biggest question was whether extended monitoring was justified for its research value. Critics compare the incident to one last year involving a University of Wisconsin (Madison) research group (*Bio/Technology* 8:598, July '90) and conclude that the agencies are still "floundering."

—Jeffrey L. Fox