Agricultural Genetics Goes to Court

Two lawsuits have focused public attention on the impending transition of a few areas of agricultural genetic engineering from laboratory experiments to large-scale testing. A coalition of environmental groups contends that this is an important transition because it will involve, for the first time, the deliberate release into the environment of organisms altered by gene splicing.

The coalition, led by Jeremy Rifkin of the Foundation on Economic Trends in Washington, D.C., filed suit against the National Institutes of Health (NIH) on 14 September, seeking to block experiments planned by Steven Lindow and his colleagues at the University of California, Berkeley, who want to test whether frost damage to plants can be decreased by spraying them with genetically engineered bacteria. The suit aims to prevent NIH from "authorizing the release of the first genetically engineered organisms into the environment," according to the legal brief.

Two days later, the same coalition was back in court seeking to force a public discussion of potential hazards associated with field tests planned by two private companies, Cetus Madison Corporation and BioTechnica International. Both companies have voluntarily sought NIH approval of their experiments, but want to keep the review process confidential in order to protect proprietary information. Cetus Madison is planning to field test genetically engineered plants that have shown disease resistance under greenhouse conditions, and BioTechnica wants to test a strain of *Rhizobium meliloti* that has been modified to enhance its nitrogen-fixing ability.

The suit involving the experiment planned by Lindow alleges that NIH has violated several federal laws, but the crux of these allegations is that NIH has failed to heed the National Environmental Policy Act. Thus, NIH is being sued for its failure to file either an environmental impact statement or to prepare an environmental assessment when the Guidelines for Research Involving Recombinant DNA Molecules were revised "to permit, rather than prohibit, the deliberate release into the environment of organisms containing recombinant DNA . . . ." And, specifically, NIH is being cited for approving Lindow's experiments, which Rifkin says "pose a potential danger to plant, animal and human health." He also says that the NIH Recombinant DNA Advisory Committee (RAC) "lacks the necessary scientific expertise to evaluate the risk of such experiments."

Just who possesses that expertise is difficult to say. The present Recombinant DNA Advisory Committee consists of scientists, lawyers, and "public representatives"; in the past it has included members of environmental groups. The NIH's approval of Lindow's experiment followed a procedure that has been in effect and often very much in the public eye since the RAC's inception. In this particular case, the first vote for approval in late 1982 was nearly evenly divided, leading NIH officials to reject RAC's recommendation. Lindow revised and resubmitted his proposal. Later, in April 1983, the RAC unanimously recommended that Lindow's new protocol be accepted, and NIH subsequently granted official approval. All of this activity was duly published in the Federal Register, and received wide publicity in the news media.

The lawsuit involving the Cetus Madison and BioTechnica experiments raises the tricky issue of how to balance the need for public discussion of potential risks against the need to protect proprietary information. Both companies submitted their proposals to RAC for approval, even though gene-splicing experiments by private companies are not technically covered by NIH's recombinant DNA guidelines. (The guidelines apply only to federally funded experiments.) One condition was that the proposals would not be discussed in public, and RAC duly scheduled a closed session of its 19 September meeting to evaluate them. The environmental coalition went to court to try to force RAC to open at least part of the discussion to the public, but the suit was thrown out of court by Judge John J. Sirica minutes before the meeting started and the session remained closed.

NIH staff will not disclose what RAC decided until Richard Krause, the senior NIH official who must okay it, has had a chance to review the recommendation. NIH is being particularly tight-lipped because it wants to encourage companies to submit their proposals voluntarily to RAC for review. Any release of proprietary information would certainly provide a major disincentive.

Rifkin and his coalition, in doubting the expertise of RAC and of NIH, have assembled their own ad hoc panel of scientific experts, some of whom submitted affidavits in support of the lawsuit involving the experiment planned by Lindow. At Rifkin's urging, these scientists, including ecologists, biochemists, and plant pathologists, now are voicing anxieties about potential problems that they claim have not been adequately addressed. For example, Cornell University entomologist David Pimentel points to various ecological problems, such as Dutch elm disease and the Japanese beetle infestations in the United States, that resulted from introducing organisms which "typically have explosively increased in the new environment." An analogous disaster occurring when genetically engineered microbes are introduced into the environment is no longer believed likely by the majority of molecular biologists who serve on the NIH committee.

The courts now may decide whether it is in the public interest to reconcile those different scientific views by methods other than those NIH has been employing. Beyond that, the lawsuit brought by the coalition of environmentalists is unusual in that it addresses matters over which NIH has no regulatory authority, but over which it has effectively exercised control since 1976 through its guidelines. Thus, the court is being asked to judge whether NIH's compliance with the National Environmental Policy Act has been adequate in the absence of any federal laws specifically governing recombinant DNA research. (In a previous ruling pertaining to high-level containment laboratories in Frederick, Maryland, NIH's environmental impact statement was judged adequate.) It also is being asked explicitly to judge whether there is anything special or peculiar about microbes whose genes have been changed by recombinant DNA methods that would warrant special attention under U.S. environmental statutes. NIH has no official comment on the suit.

—JEFFREY L. FOX and COLIN NORMAN