# Rifkin and NIH Win in Court Ruling

A federal appeals court has ruled that experiments involving the release of genetically altered organisms into the environment can proceed, provided that their potential ecological effects have been properly evaluated. The opponents in the lawsuit—author and activist Jeremy Rifkin and the National Institutes of Health (NIH)—immediately proclaimed victory, and, in a sense, they were both right.

The ruling, however, does not immediately clear the way for the first deliberate release experiment to actually proceed. Since Rifkin filed his suit, the Environmental Protection Agency (EPA) has decided to exercise authority over some types of field tests and, as a result, some research groups are awaiting clearance from EPA as well as NIH before they can start their experiments.

The ruling by the appeals court was the latest turn of events in a lawsuit filed in 1983 by Rifkin against NIH, which claimed that the agency had failed to evaluate adequately the environmental impact of deliberate release experiments. Specifically, he charged that NIH violated the National Environmental Policy Act by failing to conduct two kinds of analyses: an environmental assessment and a much more in-depth evaluation called an environmental impact statement. NIH has argued that review of the experiments by its recombinant DNA advisory committee constituted an adequate environmental analysis.

In May 1984, Federal District Judge John Sirica sided with Rifkin and, in effect, put a moratorium on all field tests of genetically modified microbes. His decision halted what would have been the first deliberate release experiment, a University of California test involving bacteria designed to prevent frost formation on plants. Subsequently, NIH and the University of California appealed the decision.

On 27 February the U.S. Court of Appeals for the District of Columbia in a unanimous decision upheld part of Sirica's decision and overturned another part. In a point for Rifkin, the court ruled that NIH must conduct an environmental assessment of the California experiment and warned that it should do so for other experiments. (NIH, in fact, conceded part of the suit in December and submitted an environmental assessment of the California experiment. The court, however, did not acknowledge the document in its opinion.)

In NIH's favor, the court lifted the preliminary injunction that barred the agency from approving all other deliberate release experiments as long as environmental assessments are completed. In addition, the court stopped short of saying that NIH must conduct a full-scale environmental impact statement of all deliberate release experiments as Rifkin had hoped. NIH was worried that the court might mandate an environmental impact statement because the process of developing the document is lengthy and bureaucratically burdensome, according to Bernard Talbot, who is deputy director of the National Institute for Allergy and Infectious Diseases and oversees the activities of the recombinant DNA advisory committee. Second, NIH contends the experiments vary too widely to be considered generically, making a comprehensive evaluation of them impractical and meaningless.

The court decision, which was written by Judge J. Skelly Wright, had some harsh words for NIH. "We emphatically agree with the district court's conclusion that NIH has not yet displayed the rigorous attention to environmental concerns demanded by law, and that the deficiency rests in NIH's complete failure to consider the possibility of various environmental effects." In particular, the court said, "the most glaring deficiency" is that NIH did not sufficiently analyze the potential for the bacteria to be used in the California experiment to disperse or to survive in the environment.

In a practical sense, Talbot said, the ruling by the appeals court means that it is now "likely" that, in the future, researchers submitting proposals to NIH to field test genetically altered organisms also will have to include an environmental assessment report.

The court, however, hedged on whether NIH must complete a comprehensive environmental impact statement on deliberate release experiments in general and said that the agency "should at least consider whether a programmatic EIS is required. . . ." J. Carol Williams, the Justice Department attorney who represented NIH, interpreted the court's decision to mean that "NIH has to sit down and decide whether it has to do a programmatic impact statement and if it thinks not, then it has to have good reasons and articulate them."

It is unclear when the California experiment can start. NIH and Justice Department lawyers are now deciding whether they need to go back to Sirica to have the injunction lifted. Rifkin's attorney, Edward Lee Rogers, has already suggested that they may challenge the adequacy of NIH's environmental assessment of the California experiment, which would add further delay. University of California researchers have also submitted their proposal to EPA for review and are still awaiting clearance.

In the meantime, Advanced Genetic Sciences, which has obtained approval from the NIH advisory committee to conduct an experiment similar to the California test, has withdrawn its application from NIH and taken it to the EPA for evaluation. Although only federally funded researchers are required to submit proposals for experiments to NIH, companies traditionally have done so as well. Now that EPA and other federal agencies are developing their own policies on how to regulate biotechnology products, some companies are deciding simply to go directly to the agencies for review rather than NIH.

In a letter obtained by *Science,* EPA has requested Advanced Genetic Sciences to submit more information about its experiment and to obtain a permit before starting the test. The letter said that although the test "would seem to pose only a very low [ecological] risk," the agency wants more information. University of California reasearchers are likely to have to obtain a permit too.

The bottom line seems to be that academic researchers, in order to field test genetically altered organisms, now have to pass two hurdles before proceeding—NIH and a regulatory agency such as EPA. Companies are opting to apply straight to the regulatory agency. Harvey Price, director of the Industrial Biotechnology Association, said, "There's not yet enough confidence that NIH won't be a roadblock" to experiments planned by companies.

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