Judge Halts Gene-Splicing Experiment

His ruling could hold up similar university experiments; those planned by private companies are unaffected

In a ruling that stunned most observers, Judge John J. Sirica on 16 May halted an experiment that would have involved the first deliberate release into the environment of organisms altered by gene splicing. The ruling has implications that extend well beyond that single experiment, for Sirica strongly suggested that he will hold up similar work until the National Institutes of Health (NIH) has conducted an exhaustive evaluation of the potential environmental impact of releasing genetically modified organisms.

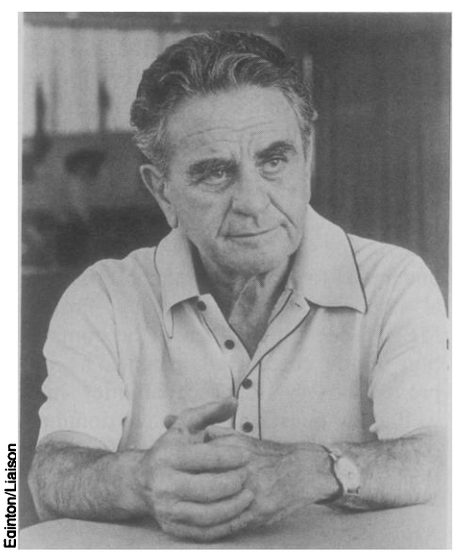
Sirica's ruling has a gaping loophole, however, for he explicitly exempted experiments conducted by private companies on the grounds that they are not covered by the same environmental laws. This, in theory at least, means that academic scientists may have to wait while company scientists can go ahead with similar experiments. Indeed, a company has already proposed an experiment virtually identical to the one halted by Sirica.

The decision brought immediate protests. "This is a very sad precedent," said Bernard Davis, a Harvard geneticist. "It will have a tremendous chilling effect," predicted Daniel Adams, president of Advanced Genetic Sciences, who also suggested that it will exacerbate "the drain of scientists from the universities into industry or out of the country."

The prime mover behind the ruling is Jeremy Rifkin, an author and social activist who heads the Washington, D.C.–based Foundation on Economic Trends. Last year, Rifkin sued NIH for approving three experiments involving environmental testing of organisms whose genetic makeup has been modified by recombinant DNA techniques. He contended that NIH had violated the National Environmental Policy Act (NEPA) by failing to publish a broad assessment of the environmental impact of such experiments before giving the testing a green light (*Science*, 30 September 1983, p. 1355).

One of the three experiments, involving the testing of genetically modified tomato and tobacco plants, has been abandoned following unpromising greenhouse trials. The second, a field test of corn plants to be conducted by Ronald Davis of Stanford University, is not yet ready to begin. But the third, proposed by a team headed by Steven Lindow of the University of California at Berkeley, was scheduled to start on 25 May. Rifkin thus went back to court in an attempt to block Lindow's experiment until his suit against NIH is disposed of (*Science*, 27 April, p. 371).

Lindow's experiment entails spraying a row of potato plants with a modified strain of *Pseudomonas syringae*, a bacterium that normally helps promote the formation of ice crystals. Lindow has found that if an area of the bacterium's genome is deleted, it loses the capacity to form a nucleus for ice crystals. In greenhouse tests, plants colonized with the modified strain are more tolerant to frost than those colonized by the wild strain, and Lindow now wants to test this capacity on potato plants growing in an open field. The experiment can only be done in the spring and fall, when the freezing conditions are right.



Edinton/Liaison

Judge Sirica

NIH did not follow correct procedure.

Sirica not only granted the motion to halt Lindow's experiment but he also strongly implied that he would rule in Rifkin's favor on the original suit. In the meantime, he told NIH not to approve any more experiments by academic researchers involving release of modified organisms. Sirica explicitly stated that he has "no desire, authority, or competence" to judge the possible hazards or benefits of the technology, but based his ruling strictly on the question of whether NIH had followed the correct procedures in approving the experiment.

The legal issues go back to 1976, when NIH issued guidelines governing research it funds involving recombinant DNA. The guidelines were aimed at containing modified organisms in the laboratory and expressly prohibited experiments entailing the deliberate release of recombinant DNA molecules into the environment. Two years later, however, then NIH director Donald S. Fredrickson approved changes to the guidelines that would permit experiments in the environment on a case-by-case basis.

The new guidelines require all such experiments performed with government funds to be reviewed and approved by the Recombinant DNA Advisory Committee (RAC), a committee of scientists established by NIH in the early 1970's to assess the hazards of recombinant DNA research. The committee approved the first three environmental release experiments last year.

Rifkin's suit contends that before permitting any of these experiments to go ahead, NIH should have produced an environmental impact statement analyzing the potential consequences of its change of policy. Although NIH published such a statement when it issued the original guidelines, it did not conduct a second analysis when it changed them 2 years later. In agreeing to halt the Lindow experiment until this suit is disposed of, Sirica said he believes Rifkin and his attorneys "have made a satisfactory showing that they are likely to succeed" in their claim that a second impact statement should have been produced.

Attorneys for the Justice Department and the University of California argued that the review given each experiment by RAC satisfies the legal requirement for assessing environmental impact. They pointed out that Lindow's experiment was twice described in the *Federal Register*, when public comments were invited, and that it was discussed at two open RAC meetings. Rifkin and his supporters did not participate in this review process, however.

If Sirica's ruling withstands an appeal—the University of California filed an appeal on 18 May, and the Justice Department is considering doing the same—NIH will almost certainly have to go through the lengthy and probably contentious process of analyzing all the potential consequences of releasing any genetically engineered organisms into the environment before approving any more university experiments in this area. It took NIH over a year to produce its environmental impact statement on the original guidelines, and NIH officials predict it will take them at least 18 months to do another analysis.

Sirica's ruling also sets up a double standard with respect to privately funded experiments. At present, the NIH guidelines apply only to researchers funded by the federal government, but private companies intending to conduct experiments in the environment are submitting their experiments to RAC on a voluntary basis. Sirica said in his decision that RAC can go on approving these private experiments because they are not covered by NEPA, but it must not approve any more federally funded work.

This could lead to a curious situation. At its next meeting on 1 June, RAC is scheduled to consider two experiments proposed by private companies. One, proposed by Cetus, involves a field test of a plant that has been genetically engineered to be disease-resistant. The other, proposed by Advanced Genetic Sciences, is almost identical to Lindow's experiment. This is not surprising because the company has been funding Lindow's research and now wants to test his modified bacteria on several different crops. (Lindow is required to seek RAC approval, even though NIH is not funding the work, because the university receives support from NIH.)

Immediately after Sirica's ruling, NIH officials said they assumed RAC would go ahead with its consideration of the two proposals. But there is speculation that the Justice Department may advise postponing action in view of the ruling.

Rifkin, who confessed to being surprised by Sirica's ruling, says he hopes it will stimulate a broad public debate on the technology. Even some scientists who are appalled that Lindow's experiment has been halted, say they hope the ruling will lead to a broader examination of the issues and a set of principles to guide RAC in considering deliberate release experiments. For example, Peter Raven, director of the Missouri Botanical Garden, says that although he filed an affidavit on NIH's behalf recommending that Lindow's experiment be allowed to proceed, he hopes the decision will focus attention on the ecological questions. "We need to work out our methodologies," he says. (Raven initially backed Rifkin's attempt to halt Lindow's experiment but changed his mind because he now feels it entails no risk.)

One indication of the need for general principles has come from RAC itself. A working group set up to consider environmental testing of genetically engineered plants will report to the 1 June RAC meeting that "the proposals so far submitted for . . . consideration have omitted information that is considered minimal and essential for their approval."

But Rifkin's actions are seen in a much more derogatory light by many scientists. Bernard Davis, for example, accuses him of being a Luddite who does not understand the technology. "He would have opposed the agricultural revolution," if he had been around at the time, scoffs Davis.—**COLIN NORMAN**

Europe to Boost Biotechnology?

London. Science and research ministers from the ten member countries of the European Economic Community (EEC) will be asked next week to endorse a 5-year, $134-million program of joint research, training, and other activities designed to create what the EEC's Commission in Brussels describes as the basis of a "Common Market in Biotechnology."

The explicit aim of the new program, which if approved would last from January 1985 to December 1989 and be jointly funded by the EEC and national governments, is to support a variety of actions that will help the European biotechnology industry to become competitive with those of Japan and the United States. These actions will range from research in key areas of "technical and scientific bottlenecks" which need to be resolved before large-scale applications of biotechnology can be reached, to support for common databases, perhaps jointly financed with the private sector.

In addition, however, the program has a number of political attractions which, its supporters inside and outside the Commission hope, will considerably increase its chances of being adopted. The first of these is that its heavy emphasis on research into the possible agricultural applications of biotechnology—for example, the improvement of high-value crop yields, or the processing of agricultural products—offers political leaders an opportunity to explore ways out of the problems caused by the EEC's current agricultural policies, and in particular its chronic overproduction of certain low-value products.

This aspect is said to have particularly appealed to the French government, which currently holds the presidency of the EEC and is keen to find a solution to the community's broader political problem, as well as to some of its domestic problems caused by the current agricultural policy.

The second attraction of the program is that it is a possible device for harmonizing the regulations of different countries on both biotechnology research and the diffusion of new products. This would be a step toward the creation of a unified European market which many leading biotechnology companies argue is essential for the growth of European industry.

"It is the size and accessibility of the home market which gives the U.S. the edge in biotechnology," Britain's Minister of State for Industry, Kenneth Baker, said in London last week in opening the Biotech 84 conference. "We must aim at lowering the barriers to trade and to aligning regulations between different countries; it is here that the European Commission has an important role to play."

The Commission itself would like to see the new biotechnology program supported as a counterpart to the recent $1.3-billion, 5-year research program into microelectronics (ESPRIT) approved by member states in February. So far, however, the member countries have been reluctant to commit funds of the same order of magnitude, and even approval for the relatively modest program now being proposed could be held up by their current differences on broader political issues.

Similar uncertainty hangs over another proposal to be discussed at next week's meeting, a $285-million, 4-year program of basic research in industrial technology, known as BRITE.—**DAVID DICKSON**