

EPA Approves Field Test of Altered Microbes

A new federal biotechnology committee is announced too, but the regulatory tangle remains

The federal government recently approved the first two field tests of genetically engineered organisms. The tests will be conducted by companies that already have run extensive greenhouse experiments and now want to observe the effects of an outdoor environment on their products. Agracetus of Middletown, Wisconsin, near Madison, will test tobacco plants that have been modified to resist disease. The company wants to determine whether the genetic engineering method used to alter the plant could serve as a model to introduce other changes to other types of plants, such as corn.

In the second experiment, Advanced Genetic Sciences of Oakland, California, will test bacteria that have been changed to prevent frost formation on strawberry plants. The unaltered bacteria are ubiquitous in nature and secrete a protein that acts as the nuclei to ice crystals. But by deleting a portion of a gene in the bacteria, the hope is that ice crystals cannot form. AGS plans to spray the modified bacteria on 2400 blossoming strawberry plants on a one-fifth acre plot located in Salinas Valley near Monterey.

It is the field test of the bacteria that has captured the most attention because Jeremy Rifkin, an author and activist, has challenged both the environmental safety of conducting an outdoor experiment with these bacteria and the federal review process that led to its authorization. On the day that the Environmental Protection Agency announced that it had sanctioned the field test, Rifkin filed suit to block the experiment, charging that EPA had failed to follow proper administrative procedure in its deliberations. (It is the second time that Rifkin has filed suit against the federal government to stop an experiment of this kind. Last year, he successfully obtained a court order that halted a similar experiment proposed by University of California researchers. Rifkin sued the National Institutes of Health, which has authority to approve the test because the university researchers receive federal funds.)

Rifkin's main objection to the test of the modified bacteria, which are *Pseudomonas syringae* and *P. fluorescens*, is that they may decrease rainfall. Unaltered *P. syringae* is important to rainfall because the microbes form the center of

droplets. Disrupting the balance of unaltered bacteria "may be highly significant" and change rainfall patterns, Rifkin says. He bases his contention on research conducted by Russell Schnell, a meteorologist at the National Oceanic and Atmospheric Administration in Boulder, Colorado.

But Schnell told *Science*, however, that there is "no proof" that decreasing the population of [unaltered *P. syringae*] on plants affects precipitation. There is circumstantial evidence that such a relationship might exist, but the science "is very loose and very shaky right now." Schnell said that he has "no concern" about this particular experiment given its



John Moore of EPA

"This is a pretty modest experiment."

small size. "What concerns me is spraying hundreds of square-mile plots. We need to do some better modeling."

EPA, anticipating a lawsuit by Rifkin, went out of its way to be thorough in its review. It took the unusual step of forming an ad hoc panel of outside scientists to peer review the AGS proposal. The 6-member committee included a microbiologist-toxicologist, a microbial ecologist, a plant pathologist, a soil microbiologist, a community ecologist, and a meteorologist. It advised EPA that "major questions and suggestions we raised during our review . . . have now been addressed." Although "some minor questions remain . . . on balance AGS has addressed the most important questions posed by the [committee] and EPA." The agency also called Schnell after Rif-

kin raised the potential rainfall problem.

Rifkin also contends that EPA has not established methods to predict the environmental consequences of the experiment. But AGS had to submit considerable data on the survivability of the bacteria, its host range, and competitiveness with other bacteria. The bacteria do not commonly cause disease in animals or humans. John Moore, assistant administrator for EPA's office for pesticides and toxic substances, said that the likelihood of an ecological disaster is "extremely remote. It's a pretty modest experiment." If AGS wants to conduct additional field tests, it will have to submit another application for permission.

Moore acknowledges that EPA has solicited grant proposals to develop ways to assess more precisely the environmental consequences of biotechnology products in general. The science of risk assessment of biotechnology products is evolving, he noted. In the meantime, there are sufficient data on the AGS experiment to give it the go-ahead.

The irony of these deliberations is that AGS has already conducted "very limited" field tests of naturally occurring mutants that prevent frost formation, according to John Bedbrook, AGS scientific director. "The results were encouraging." Pending the outcome of the lawsuit by Rifkin, AGS is also awaiting permission from a California state agency. The company hopes to begin the experiment as early as late December.

EPA's approval of the AGS experiment comes at a time when the administration is still trying to figure out how to regulate biotechnology. For the past 2 years, several regulatory agencies, the National Institutes of Health, and the Office of Science and Technology Policy have been sorting out jurisdiction and deliberating the need for a new federal group to review biotechnology matters.

OSTP has floated several proposals and the latest and final plan was published in the Federal Register on 14 November. The new committee, called the Biotechnology Science Coordinating Council, is a watered-down version of the original plan. Initially, OSTP proposed to set up a board that would have acted as a Supreme Court to advise agencies on regulatory and scientific is-

sues related to biotechnology. Scientists from outside government would have been included on the board.

Now, according to Robert Rabin of OSTP, the new committee will only comprise government officials from agencies including EPA, NIH, the U.S. Department of Agriculture, and the Food and Drug Administration, and will limit its attention to generic scientific questions. It will be formed under the auspices of an obscure federal committee called the Federal Coordinating Council for Science, Engineering and Technology. The sense is that the committee won't be doing much, according to several gov-

ernment officials and observers. Senator Albert Gore (D-Tenn.) said at a hearing recently, "I'm concerned that the council is toothless and just a kind of discussion group."

The one problem that companies have been concerned about is where to get approval for their products. But after 2 years, the regulatory waters are still muddy. Neither the biotechnology council nor its parent committee resolves the confusion about jurisdictional control, remarked Harvey Price, director of the Industrial Biotechnology Association.

The council does take away some of the pressure from NIH's recombinant

DNA advisory committee, which has been the main forum for discussing general biotechnology matters. On the other hand, it is not clear yet what role USDA is going to play in reviewing biotechnology products. The tobacco plant experiment planned by Agracetus was approved by NIH, but officials there hope that in the future, such applications will go to USDA, so it can turn its full attention to reviewing biomedical proposals. The General Accounting Office is currently conducting a study to evaluate what USDA's regulatory role should be in biotechnology.

—MARJORIE SUN

Gandhi Shakes Up Indian Science

Government R&D programs are being critically evaluated and links with Western science are being encouraged

New Delhi. India's scientific enterprise is in the midst of a shake-up, thanks to policies adopted by Prime Minister Rajiv Gandhi and a small group of close associates. Government departments are being told to conduct a thorough assessment of their scientific programs, with the aim of speeding up high-priority projects and weeding out those deemed unproductive. Greater internationalism in science is also being encouraged. Not surprisingly, these changes are being viewed with mixed feelings in India's scientific community.

Like his mother, Indira Gandhi, and his grandfather, Jawaharlal Nehru, the country's first postindependence prime minister, Rajiv Gandhi has staked out a strong personal role in shaping India's science policy. He is also emphasizing his commitment to science and is promising to use high technology to propel India into the 21st century.

In his first Independence Day speech, for example, which was delivered in August from the ramparts of Delhi's famous Red Fort, he explicitly identified India's postcolonial support for science and technology as the key to its economic and social progress over the past 38 years, "while many other developing countries have fallen by the wayside." Perhaps even more significant, in a major cabinet reshuffle in September, science and technology was one of five portfolios that Gandhi decided to retain for himself. He had previously held responsibility for 13.

This top-level interest does not mean

that bigger budgets are on the way. In recent years, science and technology have done well by the government. During the past 5 years, for example, government funding for research and development has almost doubled. "We have been in a privileged position," admits one senior administrator with the Council of Scientific and Industrial Research (CSIR). Few pretend that such a growth rate can be maintained, and funding for R&D will not increase significantly in the Seventh Five Year Plan, which officially started this year but was not approved until early November.

But money alone does not reveal the whole picture. Other government policies could have an equal, if not greater, impact on the conduct of government-funded research. One of the most important is the new accent that Gandhi and his finance minister, Vishwanath Pratap Singh, are placing on the need for greater accountability in all levels of government, including its research community.

For the first time, for example, the Department of Science and Technology has been asked to carry out a top-to-bottom peer review of all the research it supports in both government laboratories and universities. Ringing in the ears of administrators as they organize this effort are Gandhi's instructions, given while opening a new defense laboratory in July, that research projects found to be yielding important results should be completed speedily and their benefits fully utilized; in contrast, projects not shown to be producing results should be

"identified quickly and discarded."

Also being recalled is a statement the new prime minister made to the CSIR directors that, whereas "chasing other countries" might have been adequate when the agency was born in the period immediately following independence, "now we should choose some areas and aim at being the foremost in the world." Consequently, "we are using a zero-based budget approach, looking at total resources and the totality of our requirements," says CSIR Director-General S. Varadarajan.

The second aspect of the new government's science policy that seems to mark a significant shift from the past is a far greater willingness to accept the need to import both technology and science from abroad in some situations. The concept of "self-reliance" frequently applied by Indira Gandhi and Nehru to science and technology was usually interpreted as the ability to generate indigenous activities broadly comparable to similar programs in the advanced nations. Today, it is being interpreted more as the ability to adapt the most advanced technology from elsewhere.

The former approach to self-reliance is epitomized by India's success in space technology—a new, totally Indian telecommunications satellite, Insat-II, is to be launched from an Indian rocket in the 1990's—and in developing an indigenous nuclear capability. In contrast, the areas in which the new approach can be most clearly seen are those such as microelectronics, materials research, advanced