Briefing:

Biotech Guidelines Challenged by Rifkin

The Administration's proposed regulatory policy on biotechnology is the subject of a new lawsuit filed by activist Jeremy Rifkin and of a congressional hearing to be held on 23 July.

The policy, which was published in the *Federal Register* on 26 June, is now being circulated for public comment. The scientific basis of the policy is being challenged by Rifkin and will be examined at the hearing, which will be held jointly by three subcommittees of the House Science and Technology Committee. The detailed policy proposes how certain modified organisms will be regulated and says, for example, that a harmless microbe that has been modified by the addition of a noncoding regulatory sequence from a pathogenic organism will still be considered nonpathogenic (*Science*, 6 June, p. 1189).

Rifkin challenges this approach and, on 15 July, sued the federal government over the biotechnology guidelines. He alleges that the agencies involved failed to conduct an environmental impact statement of the policy and have not compiled an adequate record of its development as required by the Administrative Procedures Act. Rifkin has sued the federal government several times on similar grounds to oppose various actions involving field tests or product approvals and has scored some successes. This suit was filed against several regulatory agencies, the Office of Science and Technology Policy, the National Science Foundation, and the National Institutes of Health.

In the suit, Rifkin asks the U.S. District Court for the District of Columbia to halt federal approvals of field tests involving genetically engineered organisms, which would be regulated under the policy. Currently, however, there are few, if any, applications for field tests of genetically engineered organisms that are close to approval by the agencies. Ciba-Geigy on 30 June received approval by the U.S. Department of Agriculture to field test the first herbicide-resistant plant made by recombinant DNA methods. (Ciba will test tobacco plants made resistant to atrazine which is a major Ciba product and is used extensively to control weeds in corn crops. The experiment will take place in North Carolina.)

The biotechnology policy was discussed recently at the first public meeting of the newly established Biotechnology Science Coordinating Council, which includes the Environmental Protection Agency, the U.S. Department of Agriculture, the Food and Drug Administration, the National Science Foundation, and the Office of Science and Technology Policy. David Kingsbury, who is council chairman and an assistant director at the National Science Foundation, noted at the meeting held on 9 July that the comment period for the policy has been extended 30 days to 26 September.

The council also announced the formation of several subcommittees to examine biotechnology issues, including greenhouse containment, risk assessment, the training of scientists in biotechnology, the development of an agenda with the European Community that would include basic research topics such as environmental biology, and public information and education concerning genetic engineering.

The subcommittee on greenhouse containment plans to develop a set of guidelines by January and will also tackle issues related to the deliberate release of genetically engineered organisms into the environment. That subcommittee is headed by John Moore, EPA assistant administrator for pesticides and toxic substances, and Orville Bentley, USDA assistant secretary for science and education, and will include scientists from outside the agency, who have not yet been selected.

EPA is seeking nominations for a new science panel for biotechnology. The committee will comprise nine scientists from outside the agency and two lay persons. The agency is looking for a variety of scientists, including microbiologists and ecologists.

EPA has also added a biotech expert to its staff within the office of pesticides and toxic substances. Elizabeth Milewski is now special assistant for biotechnology at EPA. She is a molecular biologist and had been a veteran staff member at the National Institutes of Health office of recombinant DNA activities. ■ MARJORIE SUN

Hot Market for Biotech Stocks in 1986

In a remarkable turnaround, biotechnology companies have grossed more than $679 million from public stock offerings since December, more than 100 times the money invested in biotech stocks in the previous year.

For most of 1985, the investment community was cool to biotech stocks because few products made from the new biology were in sight, according to several analysts interviewed. Only Genentech, a leader in the industry, made a public offering, and it did well, raising $50 million.

Then several converging factors boosted confidence in genetic engineering companies, which in turn has led to a cascade of investment, say analysts Linda Miller of Paine Webber and Kathy Behrens of Robertson, Colman & Stephens. In general, interest rates dropped and investors began looking for places to put their money where it would grow, says Miller.

At the same time, biotech products began to show more promise as money-makers. Genentech, which is located in South San Francisco, won federal approval of human growth hormone made by recombinant DNA methods, and it quickly took hold in the market. Some companies also began selling medical diagnostics. In addition, researchers at the National Institutes of Health reported promising results involving two biotechnology products: interleukin-2 to fight cancer and tissue plasminogen activator to treat heart attacks. The news was widely publicized, heightening investors' interest, the analysts say.

Then two established companies bought biotechnology companies. Eli Lilly acquired Hybritech for about $300 million and Bristol-Myers purchased Genetic Systems for $294 million. The acquisitions "told investors that big companies had faith in biotechnology. It also validated current stock prices," Behrens says.

The first biotech company to take advantage of all these circumstances was Centocor of Malvern, Pennsylvania, which sold public shares in December and raised $38 million. Since then 25 companies have made public offerings, about half of them for the first time. Every month since December, at least one company and as many as nine have put forward new shares. Among the most successful, according to Behrens' data:

- Cetus of Oakland, California, added $50 million to its bank account in January;
- Amgen, Thousand Oaks, California, $39 million, March;
- California Biotechnology, Mountain View, California, $58 million, March;
- Genetics Institute, Cambridge, Massachusetts, $85 million, May; and,
- Chiron, Emeryville, California, $46 million, July.

Companies are using the money for a variety of purposes. Much of the cash is being funneled into additional research and clinical trials. They estimate that clinical testing of new chemical entities costs $70 million to $100 million; the testing of biologics runs $30 million to $50 million. Some of the larger companies, such as Genentech, Cetus, and Genetics Institute, are also putting their cash into new manufacturing facilities and distribution systems.

Most of the companies that have made