

Recombinant DNA

Watch on human experiments

Washington

THE Recombinant DNA Advisory Committee (RAC) in the United States last week reaffirmed its intention to review any experiments involving human subjects or the release of recombinant organisms into the environment. Under rule changes adopted overwhelmingly by the committee, any proposal to transfer recombinant DNA into human subjects would have to be cleared by the full RAC.

Although the rules are legally binding only upon recipients of federal research money, industry and all government agencies have agreed voluntarily to follow the RAC procedures.

RAC's decision formally to require a review of human genetic engineering experiments was prompted largely by the demise last year of the President's Commission on Bioethics and the resulting concern that no group was monitoring developments in this field. RAC also decided to establish a nine-member working group, made up of scientists, lawyers and ethicists, to look at any human genetic engineering proposals. This move parallels a legislative proposal by Representative Albert Gore (Democrat, Tennessee) that would create a human genetic engineering commission with similarly broad representation. That proposal passed the House last year, but was never enacted into law. RAC itself is dominated by scientists and physicians.

In a related discussion of the scope of RAC's oversight, RAC appeared committed to continuing to review deliberate environmental release experiments and industrial activities. The Food and Drug Administration and the Department of Agriculture offered strong support for RAC's role in these areas; the Environmental Protection Agency (EPA), which has announced its intention eventually to regulate deliberate release of recombinant organisms under the Toxic Substances Control Act, said at last week's RAC meeting that it supported RAC's handling these areas at least until EPA's regulations are issued. A report released last week by the staff of Representative Gore's subcommittee questioned whether RAC has the expertise or the administrative capacity to handle a large flow of proposals from industry.

Anti-genetic-engineering activist Jeremy Rifkin was much in evidence at last week's meeting, notably for obtaining a court order barring RAC from holding a closed session to discuss a deliberate-release experiment proposed by Advanced Genetic Systems, Inc (AGS). The company is the sponsor of the planned release of frost-resistant bacteria by Steven Lindow of the University of California, Berkeley, currently tied up in other litigation initiated by Rifkin. AGS decided to submit to RAC its own proposal to conduct a similar

experiment. In accordance with standard procedures for dealing with proprietary information, RAC announced a closed session to review the proposal.

At the behest of several RAC members, a decision was later made to open as much of the discussion as possible. Rifkin argued in his lawsuit that RAC did not have sufficient grounds to close any of its discussions of the proposal and that the subsequent decision to open part of it was not announced 30 days in advance in the Federal Register, as required for public meetings. A US Court of Appeals panel, acting on the technicalities of Rifkin's complaint rather than its substance, ordered RAC not to hold its discussion until it had published proper advance notice and had it explained why any portion of the discussion should be closed to the public.

Rifkin also appeared at the meeting to protest against a proposal from researchers at Uniformed Services University of the Health Sciences to lower the containment required for a previously-approved experiment aimed at cloning the gene of a bacterial toxin responsible for dysentery. Rifkin, claiming the support of several prominent arms-control experts, said the experiments should not commence until an "Arms Control Impact Statement" was prepared on the research. The Arms Control and Disarmament Agency is charged by Congress with preparing such a statement on any government research with potential military applications.

Rifkin said these experiments could be used to create biological warfare agents, and that RAC members "would be personally liable under international law and the principles enunciated at Nuremberg in aiding the commission of crimes against humanity" should the work lead to biological weapon development.

Paul Warnke, former SALT negotiator and the first name on the list of supporters claimed by Rifkin, said in an interview that he had not endorsed Rifkin's remarks, but had only told Rifkin in a telephone conversation that he believed an impact statement would be important in judging the implications of the research. He said that he neither supported nor opposed the actual research.

Proponents of the experiment, which was approved by RAC last year at P4 containment, said the research was vital to the development of a vaccine against the leading cause of dysentery. RAC approved the request to lower the containment requirement to P2 by a 9 to 5 vote with 4 abstentions. The director of the National Institute of Allergy and Infectious Diseases, to whom RAC reports, has generally declined to accept recommendations made on split votes such as this one.

Stephen Budiansky

Australian technology

Tax perks to stimulate

Canberra

AUSTRALIAN investors and technology companies are likely to benefit from the Management and Investment Companies Act that comes into force at the beginning of this year. The act embodies a tax-deductible venture capital scheme designed to bring sophisticated investors, innovative small business management and investment companies (MICs). A licensing board, appointed by Mr Barry Jones, Minister for Science and Technology, is to select about eight applicants and to approve the amount of free capital each can raise.

The MICs will choose several small, high-technology businesses which they believe can sustain an annual sales growth rate higher than 20 per cent over the next three years. They will supply the businesses with long-term equity, loan capital and entrepreneurial advice, especially marketing and finance. The source of venture capital supply to the MICs will be investors who may claim 100 per cent deduction on the capital subscribed in the year of the investment.

Like Britain, Australia has done poorly in bringing technological innovation to commercial success: the technologists blame the businessman's conservatism and financiers blame the inventor's lack of management skill. The MIC scheme is based on recommendations of the Espie committee, set up by the previous government to investigate ways of financing high-technology enterprise in Australia. The committee perceived a gap at the high-risk, high-return end of the Australian capital market. The scheme may go some way towards plugging it. As if to fend off the possible jibe that a business with sales expanding at more than 20 per cent a year needs no special assistance and that the plan is merely the embodiment of Australian lack of self-confidence, Mr Jones recently echoed the Espie committee's remark that it "knew of no country which had succeeded in establishing a climate for investment in high technology without the government taking positive action".

The first MIC licences are expected to be granted in April. Over the first five-year period of phased capital injections into the ventures, \$A200 million will be licensed for subscription to the MICs, at an estimated tax revenue loss of \$A100 million.

On 24 January, the Treasury altered the proposed tax-incentive schedule for investors to promote long-term "patient" equity investment in the MICs and to inhibit abuse of the scheme. Investment for less than two years now attracts no net deduction; for the full, 100 per cent deduction, a four-year investment is necessary.

Jeffrey Seligman