Unauthorized environmental release cleared by NIH

Washington

IN a report issued last week, the US National Institutes of Health (NIH) concludes that Gary Strobel, the Montana State University researcher who last summer conducted an unauthorized field experiment using genetically altered bacteria, did not violate any rules governing experimentation with recombinant DNA. A ten-member committee of NIH scientists, formed by director James D. Wyngaarden to investigate the incident, decided that the experiment did not involve recombinant DNA, and therefore did not fall under NIH's voluntary rules.

Strobel injected 14 elm trees with a strain of *Pseudomonas syringae* that produced an anti-mycotic agent, to see if the bacteria would protect the trees against Dutch Elm disease. To trace the movement of the bacteria, Strobel combined the *P. syringae* with a strain of *Escherichia coli* that contained a recombinant plasmid carrying a transposon coding for kanamycin resistance. Because the *E. coli* transferred the gene for kanamycin resistance to the *P. syringae* by normal bacterial conjugation, and because no other part of the recombinant plasmid remained in the *P. syringae* after integration of the transposon, the NIH committee reasoned that according to its rules the bacteria did

not contain recombinant DNA.

The committee agreed that the experiment did constitute a deliberate release of genetically altered bacteria into the environment, but this does not fall under NIH jurisdiction. Strobel received sanctions from the US Environmental Protection Agency for the release, and must find a 'responsible party' to co-sponsor any further research he undertakes. The NIH committee recommended that the definition of recombinant DNA be clarified.

The Strobel incident caused a flurry of activity in Washington, and prompted an assessment by the General Accounting Office (GAO) of the effectiveness of the NIH's institutional biosafety committees. The GAO concluded in a report, also released last week, that the majority of biosafety committees have complied with NIH guidelines, but that they contain too many members with backgrounds in genetic engineering and too few specialists in physical containment, epidemiology, ecology and large-scale fermentation techniques. Committee chairmen also confessed to ignorance of the rules governing biotechnology in the GAO study; 75 per cent had not reviewed the Coordinated Framework for the Regulation of Biotechnology, published in June of 1986.

Carol Ezzell

Vaccine project is scrapped

Sydney

THE problems of academic scientists collaborating with industry are underlined by events at the Division of Animal Health of the Commonwealth Scientific and Industrial Organization (CSIRO).

For a number of years, CSIRO scientists have been trying to create a vaccine against two sheep parasites, *Trichostrongylus columbriformis* and *Haemonchus contortus*, otherwise known as barber's pole worm. The incident has its roots in 1984 when the Division of Animal Health received a grant for this research from the Department of Industry, Trade and Commerce. The grant came with the condition that a commercial partner must be involved, so the company Biotechnology Australia was given a share in the grant and given exclusive rights to any vaccine developed against either of the parasites at the CSIRO — even though the company made no financial contribution to the work.

Things started to go awry when Dr Edward Munn, of the Institute of Animal Physiology and Genetics Research at Babraham Hall, Cambridge, England, visited the Division of Animal Health's McMaster Laboratory last year to give a seminar on his work on antigens and in particular one from the barber's pole worm which might eventually form the basis of a vaccine.

CSIRO scientists Dr Barry Wagland and Dr Warwick Grant were sufficiently impressed to want to try Munn's antigen made from Australian worms in Australian sheep. According to the then chief of division, Dr John Dineen, he approached Biotechnology Australia but the company said it was not interested in the work.

Dineen — since retired — gave the go-ahead for a purely in-house evaluation of Munn's antigen with the stipulation that if the work were to go any further it would mean negotiating with and receiving approval from Biotechnology Australia.

In October last year, Biotechnology Australia became aware that experiments and discussions with Munn were still going on; claiming that it was prejudicial to its commercial interests, Biotechnology Australia demanded that the work be stopped and that all the experimental results be destroyed.

Had Munn's antigen eventually led to a vaccine, the intellectual property rights would have been contaminated by Munn's input and Biotechnology Australia would not be entitled to exclusive patents. According to its agreement with CSIRO, it was well within its rights. As it demanded, the CSIRO's relationship with Munn was terminated.

Charles Morgan

Initial sales of Genentech's TPA set new records

Washington

THE clot-dissolving drug TPA (tissue plasminogen activator) is well on the way to becoming the \$1,000 million money-earner that its manufacturer, Genentech, had hoped for. At the Hambrecht & Quist health care conference in California last week, Genentech announced that sales of TPA, trade-named Activase, had reached \$58 million in the last six weeks of 1987, following the drug's approval in the second week of November.

But now that public clamour to approve the drug has subsided, some critics are asking if the drug's price, ten times that of streptokinase, is really justified. Genentech's chief executive officer, Robert Swanson, lauded the sales figures, saying TPA was "the most successful new drug ever launched in the United States".

Huge publicity and high expectations have surrounded TPA from the beginning. Swanson assembled a large marketing and sales team early in the drug approval process, and representatives armed with lap-top computers were in the field, extolling the virtues of TPA to physicians

even as the US Food and Drug Administration debated potential side effects.

TPA was a magic name on Wall Street last year; the prices of Genentech and other biotechnology stocks oscillated according to rumours of its impending approval. Even hospitals have tried to cash in by advertising that they use TPA.

Although skeptics are hard to find, some worry that, because Genentech has convinced top cardiologists (many of whom have stock in the company) of the drug's superiority, doctors from rural areas and non-specialists without time to scrutinize the literature will prescribe TPA whether or not it is the best treatment for their patients.

Despite the wave of support that carried TPA into 1988, sales are likely to taper off as users acquire inventories of the drug. Stuart Weisbrod, an analyst with Prudential-Bache, attributes 75 per cent of the initial sales to "filling of the Activase pipeline", and warns that investors should not expect sales to continue at the present level. He expects 1988 TPA sales to be some \$160 million.

Carol Ezzell