

ENVIRONMENTAL RELEASE

AGBIOTECH PRODUCTS HIT REGULATORY SNAGS

NEW YORK—Biotechnology is front-page news once again. Three attempts to commercialize whole recombinant organisms have stumbled badly over regulatory obstacles.

Advanced Genetic Sciences. The U.S. Environmental Protection Agency disclosed that Advanced Genetic Sciences (Oakland, CA) performed unauthorized, open-air testing of its engineered bacteria. The company, which is developing recombinant *Pseudomonas fluorescens* and *P. syringae* as frost protection products, injected these "ice-minus" bacteria into trees growing on its roof as part of the pathogenicity tests reported in its experimental use permit (EUP) application. AGS told EPA that the tests were done indoors; EPA is seeking a total of \$20,000 in penalties (the maximum \$5,000 fine for each of four separate violations), and has suspended AGS's EUP until the tree tests are repeated under controlled (and, this time, contained) conditions. In addition, due to opposition by residents near AGS's planned test site in Salinas Valley, CA, the beleaguered company is considering relocating the trials.

Monsanto. On the heels of the AGS debacle, EPA announced that it expects to ask Monsanto (St. Louis, MO) for additional testing of the company's *P. fluorescens* pesticide, which contains and expresses the gene for *Bacillus thuringiensis* endotoxin. Previously, the agency had been concerned with the possibility of gene transfer to other microorganisms, and with possible toxic effects on non-target organisms. Now EPA is satisfied with Monsanto's evidence against gene transfer, but it planned to decide on April 22 whether flaws in Monsanto's testing will require the company to repeat dose studies on susceptible Lepidoptera, colonization studies of above ground insects, and non-target toxicity tests on honeybee larvae, mosquito larvae, milkweed bugs, and certain aquatic insects and crustaceans.

Biologics Corp. Also disclosed recently was the field-testing and marketing of a genetically altered virus that acts as a vaccine against pseudorabies in swine. Last fall, the U.S. Department of Agriculture (USDA) quietly granted Biologics Corp. (Omaha,

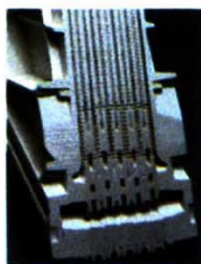
NE) approval to field-test the vaccine; the agency gave the marketing go-ahead in January. When Jeremy Rifkin and his Foundation on Economic Trends (Washington, D.C.) got wind of the approval—and the fact that USDA did not consult its Recombinant DNA Research Committee about the tests—USDA temporarily halted sales. The agency reported that it believes the approval procedures used were sound; by April 22 USDA was scheduled to have reviewed its approval process and have made another decision regarding allowing the vaccine on the market.

New efforts. Even in the current uncertain regulatory environment, the commercialization of genetic engineering marches on. In March, ARCO plant Cell Research Institute (Dublin, CA) submitted an application to USDA to field test genetically engineered alfalfa, cucumber, petunia, potato, and tomato plants. The company reports that the strains have been engineered to contain one or more of ten different plant genes that provide improved nutrition and other benefits. —Arthur Klausner

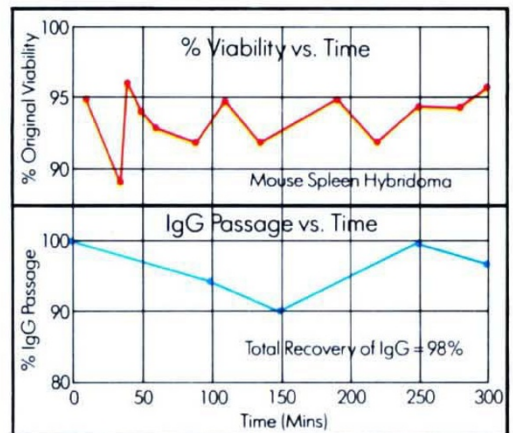
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