EDITOR

Douglas K. McCormick

RESEARCH EDITOR

Harvey Bialy

SENIOR EDITOR

Jennifer Van Brunt

ASSOCIATE EDITOR

Arthur Klausner

CONTRIBUTING EDITOR

Bernard Dixon

EDITORIAL ASSISTANT

Clair Berg

ART DIRECTOR

Dorothy E. Schloerb

PRODUCTION MANAGER

Donna Zuckerman

PUBLISHER

Gary M. Rekestad

ADVERTISING SALES MANAGER

Marion Delaney

EUROPEAN ADVERTISING

SALES MANAGER

Andy Sutherland

CIRCULATION DIRECTOR

Paul Siman

EDITORIAL CORRESPONDENCE:

BIO/TECHNOLOGY, 65 Bleecker St., New York, NY 10012. Telephone: (212) 477-9600. Telex: 668497UW. BIO/TECHNOLOGY, 4 Little Essex Street, London WC2R 3LF. Telephone: (01) 836 6633. Telex: 262024.

SCIENTIFIC ADVISORY BOARD

CHAIRMAN

George Poste, Smith Kline & French Pharmaceutical Development

Mary-Dell Chilton, CIBA-Geigy Plant Molecular Biology

Carlo Croce, Wistar Institute Monoclonal Antibodies

Arnold Demain, MIT Secondary Metabolism and Fermentation

Stanley Falkow, Stanford Medicine and Vaccine Development

David Goeddel, Genentech Recombinant DNA Products

Benjamin Hall, Univ. of Washington Yeast Genetics

Ernest Jaworski, Monsanto Plant Biotechnology

Ephraim Katchalski-Katzir Tel Aviv University Immobilized Enzymes and Polymers

Allen Laskin, N.J. Center for Advanced Biotechnology and Medicine Hydrocarbons and Polysaccharides

Malcolm Lilly, University College, London Biochemical Engineering

David Mount, University of Arizona Computer Applications

Carl-Gustaf Rosen, Alfa-Laval Biochemical Engineering

Yukio Sugino, Takeda Cancer Chemotherapy

Lemuel B. Wingard, University of Pittsburgh

Enzyme Engineering and Biosensors

To supplement coverage of Japanese developments, BIO/TECHNOLOGY has an editorial liaison with the editorial staff of Japan Chemical Daily, Ltd. and Japan Chemical Week.

THE FIRST WORD

ENTERPRISES TURNED AWRY

So. It is done. Not wisely or well, perhaps, but it is done: While industrialists and regulators have soliloquized earnestly over the last year or so—groping towards valid principles for regulating the free release of recombinant organisms into the environment—a genetically engineered live-virus vaccine has been in field-tests under the auspices of the U.S. Department of Agriculture. It was even, *mirabile dictu*, sold legally on the open market. At least, it was on the market from January until Jeremy Rifkin found out and started shouting about it.

What is one to make of this whole episode? It appears (through news reports) that the manufacturer, Biologics Corporation of Omaha, submitted its applications in a responsible way to the USDA's Animal and Plant Health Inspection Service. It similarly appears that the Service's scientists evaluated the application fairly—according to conventional standards—and duly approved it. Trials began last year. And in January USDA approved sale of the vaccine, so on the market it went, offering a weapon against porcine pseudorabies, an expanding problem which costs hog farmers tens of millions of dollars each year.

Seen in isolation, USDA's actions appear a triumph of reason over bureaucratic dithering. The genetically engineered product faced exactly the same tests of efficacy and clinical safety that thousands of other products have faced. Treated as just another vaccine, it passed with flying colors. Genetic engineering undoubtedly can produce new strains with strange properties otherwise impossible to attain; today's genetically engineered organisms are, however, no different in essence or performance from their naturally bred cousins. And they are much better characterized—one might say better bred—than the graduates of chemostats and irradiation chambers.

Some substantive issues remain. Bob Nicholas, of Blum, Nash, and Railsback, sums up the three significant questions in all of this:

- Is the first release of a recombinant organism a significant governmental action? Probably. If so, then USDA had two choices under the National Environmental Policy Act (NEPA). It could have compiled an environmental impact statement or published a finding of "no significant impact." The agency did neither.

- Did USDA actually compile the data it would have needed to support a finding of "no significant impact"? That is open to question.

- Did USDA's own policies require review by the National Institutes of Health's Recombinant DNA Advisory Committee (NIHRAC), the Agriculture Recombinant DNA Advisory Committee, or some other body? Doubtful.

USDA officials have publicly said that the department should have taken the field-test proposal for outside, expert review. That would have caused delay in itself and might have been an open invitation to outside interference. Nothing in the USDA's stated policies (*Federal Register* 49:50899, Dec. 31, '84) requires any such review. The only (indirect) reference to the NIHRAC is a requirement that producers comply with NIH guidelines for recombinant research.

Still, even discounting possible NEPA violations, the whole affair is a colossal gaffe. USDA completely ignored a widespread and nearly unprecedented cooperation among industry, environmentalists, and regulators—all aimed at building consistent and workable principles for biotechnology regulation. In giving its approval without public notice or outside scientific review, USDA's regulatory process invites suspicion and fear. In general, the agency seems to have acted narrowly, parochially, without considering public opinion or the long-term effects of a frightened backlash on the industry's ability to bring the benefits of biotechnology to agriculture.

Things may change rapidly in the near future. But right now, Jeremy Rifkin seems to be setting out tables for a public-opinion bake sale and choosing up sides for a three-legged race to the Supreme Court. He's getting ready to have himself a field day.

So, after years of waiting impatiently, we are relieved that someone has finally used a recombinant organism, used it for the general welfare, and used it in the vast world beyond laboratories and fermentors. At the same time, we are deeply troubled that this important step has been taken so shortsightedly.

—Douglas McCormick