JAPAN ROUNDUP

Scientists at Hasegawa Koryo Inc., working in collaboration with Hiroshi Orui at Tohoku University, have developed a method for the complete chemical synthesis of the AIDS therapeutic AZT (azidothymidine). Currently, AZT is synthesized from deoxythymidine isolated from DNA, an expensive starting material. In contrast, the new method begins with D-xylose, an inexpensive sugar, cutting the cost of AZT synthesis by 50 percent. Hasegawa Koryo, a top perfume manufacturer located in Tokyo, has not yet decided whether it will begin commercial production of AZT using the new synthetic method.

Researchers at Nikken Chemicals Co., Ltd. in Tokyo, working in collaboration with the Japanese General Food Research Institute, have developed a bioreactor for producing large quantities of the low-calorie sweetener erythritol. A four-carbon-containing polyalcohol which is synthesized from glucose by certain strains of yeast, the white powder is similar to sucrose and is about 80 percent as

sweet. Nikken's new bioreactor allows the reuse of the special yeast cells developed by the company, thereby increasing the efficiency of production to a level that can bring the product's end cost to about three times the cost of table sugar.

Mitsubishi Gas Chemical Co., Ltd.'s first medical diagnostic product will be an assay kit for measuring serum levels of thrombomodulin, according to company officials who expect to receive Japanese governmental approval to sell the kit by June 1989. Thrombomodulin plays an important regulatory role in clot formation and dissolution; however until now, there was no convenient method for quantifying this protein. The new assay uses a sandwich-type enzyme-linked immunoassay with two monoclonal antibodies that recognize different epitopes of thrombomodulin. Clinical tests of the new assay's performance in determining serum and urine levels of thrombomodulin in various diseases should be completed by the end

of the year, and Mitsubishi analysts expect that within two years annual sales will amount to 10,000 kits or nearly \$30 million.

Scientists at the Research Foundation for Chemical and Immunological Therapies in Kumamoto, working in collaboration with the Diamond Scientific Company in Des Moines, Iowa, have developed the first vaccine effective in preventing porcine diarrhea caused by pathogenic *Escherichia coli*. This type of diarrhea affects approximately 10 percent of juvenile pigs, killing many of them within weeks of onset. Although antibiotics are effective against the *E. coli*, such treatment is expensive and cumbersome since pigs must be treated individually. The new vaccine prevents diarrhea in pigs born to vaccinated mothers.

Prepared by Hal Plotkin and Ken Coleman, Biotechnology in Japan News-service. Japan Pacific Associates (Palo Alto, CA).

EPA MEETING

RELEASE REGULATORS REFINING THEIR ROLES

WASHINGTON, D.C.—The smooth operation of the Environmental Protection Agency (EPA) is essential for all groups seeking U.S. approval of experiments to deliberately release genetically engineered microorganisms. And at its May meeting, EPA's Biotechnology Science Advisory Committee (BSAC) examined how efficient the agency's review process has become and considered how it might be refined further. Although agency officials are unlikely to move quickly away from the current case-by-case approach, BSAC eventually may help steer them in that direction.

Altogether, EPA has considered about two dozen deliberate release proposals and has approved about half of them so far. All the proposals reviewed within the Office of Toxic Substances have been conducted "case-by-case, but we're speeding up the review," says EPA's Ron Evans. "It's difficult to say if there are any common themes yet." Nonetheless, Rita Colwell of the University of Maryland (College Park, MD), who chairs BSAC, gently urged EPA to be alert for "common themes" that might generate a "unified set of rec-

ommendations in the future."

One past stumbling block in the review process—namely the need for cooperation between federal agencies—apparently is being overcome, according to BSAC member James Tiedje from Michigan State University (East Lansing, MI). In evaluating and tentatively approving a proposal from Crop Genetics International Corp. (Dorsey, MD) to test a microbial pesticide in corn, the joint review procedures between EPA and the U.S. Department of Agriculture "worked very effectively," he says. And the go-ahead decision was made easier because the scale of the proposed test is so small, and thus its risk is considered minimal, he notes.

BSAC is now contemplating whether larger-scale tests will require special review procedures. There are four critical "categories of difference" between small- and large-scale deliberate release tests, according to BSAC member Douglas Rouse from the University of Wisconsin (Madison): the persistence of microbes; their dissemination; the greater possibility of horizontal gene transfer; and the potentially increased scope of health,

environmental, and financial consequences of a test. Jay Hair of the National Wildlife Federation (Washington, DC) urges fellow committee members to "review current procedures and identify any concerns...for different oversight for large-scale testing."

Perhaps the most difficult issue before BSAC—one that is still far from being resolved—is how EPA should evaluate claims by companies that information they submit must be kept confidential. Currently, BSAC members are divided on this issue—cognizant that some claims for confidentiality are essential but uncertain where the threshold ought to be set.

A proposal now before BSAC would attempt to make as much information public as possible, and would make this decision as early in a product's development as possible. Industry representatives such as Randy Schumacher of the Chemical Manufacturers Association (Washington, DC) warn that such an approach would be a "burden" to industry and hurt the international competitiveness of U.S. firms.

—Jeffrey L. Fox