INTERCONTINENTAL REGULATION

U.S. AND EUROPE FINDING COMMON GROUND

WASHINGTON, D.C.—Government and industry officials from the United States and Europe, brought together for a panel discussion at the Biotech USA conference held here late last year, seemed like old friends. Each side warmly admired the progress of the other toward harmonization, seeming to find the grass a little greener. "Reconciling the Regulations," the panel's theme, seemed almost within reach, with participants agreeing on the desirability of science-based regulations and frequent bilateral contacts across the Atlantic to promote free trade of biotechnology products.

Panel chairman Gregory C. Simon, staff director and counsel of the U.S. House of Representative's Science, Space, and Technology Subcommittee on Investigation and Oversight, applauded European Community (EC) progress towards a unified regulatory scheme. In trying to coordinate 12 nations, eight or nine different languages, and disparate cultures, "they may have had an easier row to hoe because their obstacles were so visible," he said. "Over here we have to try to figure out some way to get the agencies to speak to each other in one language."

Mark Cantley, director of the EC's Concertation Unit for Biotechnology in Europe (CUBE), agreed that the need to create a new coordinated framework has helped: "In some cases, what the U.S. Administration has chosen not to legislate, we have had to legislate if we were going to create any sort of common market at all." Creating new laws rather than shoe-horning new technologies into existing ones has allowed European regulations to be more science based, he said.

Cantley praised the frequent bilateral contacts between U.S. agencies and their near-equivalent European Directorates General (DG); for example, between the U.S. Environmental Protection Agency and the EC's Environment and Consumer Protection DG, in which the two counterparts recently set up a permanent technical working group.

Presenting a U.S. view was Pep Fuller, director of chemicals and advanced technology policy in the Office of the U.S. Trade Representative. Fuller echoed Cantley's call for a transparent, science-based international regulatory structure and encouraged industry to "do its best to ensure that the best science and the best data go forward on a continuing

basis to the regulators—whether in the U.S. or the EC—because, in the end, that's going to improve the regulatory process."

Pamela Bridgen, executive director of the Association of Biotechnology Companies (ABC, Washington, DC) brought up the question of the "fourth hurdle" issue facing Europe as one that U.S. regulators would do well to keep an eye on. The fourth hurdle refers to the suggestion that socio-economic effects should be considered in the review of biological products. Although in Europe a recent proposal to ban veterinary growth promoters on these grounds

was voted down, Bridgen says, "It's still potential in other areas, and the companies that I represent have almost unanimously told me that they have a big concern about it."

Clearly, the regulations passed on one continent can be expected to go beyond its shores. For that reason, the U.S. and Europe devoutly wish each other success in harmonizing their policies. As Fuller pointed out, "We really are living in a global economy...it would be very shortsighted for the U.S. not to find problems with a situation in which Europe was not conducive to the growth of biotechnology."

—Pamela Knight

JAPAN ROUNDUP

A collaboration between the National Institute of Agrobiological Resources of the Ministry of Agriculture, Fisheries and Forestry and Joachim Messing's group at Waksman Institute, Rutgers University has resulted in the development of a shuttle vector for use in plants, as announced at the annual meeting of the Japan Molecular Biology Society.

The new vector is derived from a wheat virus, WDV. Genes responsible for the virus's replication have been isolated and connected with both a marker gene and genes needed for replication in *Escherichia coli*. This is the first shuttle vector for plants which can be manipulated in *E. coli* to insert foreign genes and then transfer them into plant cells. The vector multiplies in the plant cell, producing higher foreign-gene expression than conventional methods.

Mitsubishi Petrochemical Co., Ltd. (Tokyo) has discovered a plasmid stabilizing factor from a strain of *Brevibacterium* (MJ238) used for industrial production of amino acids. The new factor is approximately 600 base pairs long, and can be inserted into a plasmid to confer stability.

When the factor was inserted into a plasmid that had shown a retention rate of less than five percent over 25 generations, the improved plasmid conferred stability for up to 100 generations.

Starting in the coming fiscal year, the Ministry of International Trade and Industry will launch an eight-year R&D project for hydrogen production. Hydrogen—vital for petroleum and chemical processing—is currently produced by heat degradation of petroleum, consuming a vast amount

of energy and producing a large quantity of CO₂. The project will therefore focus on using algae and photosynthetic bacteria to produce the gas at high efficiency.

An autoclavable serum-free culture medium may become a reality. Researchers from Ajinomoto's Central Research Laboratory (Tokyo) have succeeded in developing heat-resistant culture medium technologies for animal cells. The medium can be bulk-heated and requires no sterilization by filtration.

Kirin Brewery (Tokyo) has developed a new radial-flow bioreactor system for protein mass-production. In experiments with an erythropoietin (EPO) production system using Chinese hamster ovary cells, the new bioreactor has proven stable up to 100 days, with 1,000-fold higher production efficiency than conventional methods.

The radial-flow bioreactor utilizes multi-pore glass beads as a substrate for cell fixation. The beads—carrying cells at a density of 1.3×10^8 cells per ml—are packed in the core of the cylindrical tube. Culture medium flows from the outer side of the cylinder into the core (thus the medium flows in the reverse-radial direction). This system attains the highest known cell density with stable oxygen and nutrient supplies, resulting in high efficiency and stability. The company aims to use this system to mass-produce EPO and other substances with important physiological activities.

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