

Modified seeds reach European market first

European agbiotech firms are winning marketing approval for modified seeds, while their U.S. counterparts are being held up by bottlenecks in the U.S. approval process.

OXFORD—Europe's reputation for entangling biotechnology's development may not be wholly justified. In fact, European agbiotech companies have begun to get marketing approval for genetically modified seeds, while their U.S. counterparts are being held up by bottlenecks in the U.S. approval process. Ironically, the lead products in both the U.S. and Europe are seeds that have been modified to tolerate the Rhône-Poulenc Agrochimie (Lyon, France) weed killer, bromoxynil.

In Europe, Rhône-Poulenc has been given the green light by the European Commission (Brussels) to market bromoxynil-tolerant tobacco seeds anywhere in the 12 member states of the European Union (EU), if it so wishes. Yet Rhône-Poulenc has no plans to put its modified tobacco seed on the European market, though it says that European marketing approval will allow it to conduct more extensive European field tests of the seed without regulatory hassles. The approval shows, moreover, that the European regulatory approach of a

company first winning marketing approval of an agbiotech product in one EU member state, before winning almost automatic marketing approval of the product throughout the remaining EU member states, does work. Indeed, once one EU member state approves an agbiotech product, the remaining 11 member states have about 3 months to object to a blanket approval of the product. Rhône-Poulenc, for its part, first won approval of its bromoxynil-tolerant tobacco seed in France.

In the U.S., Rhône-Poulenc is working with Calgene (Davis, CA) to develop bromoxynil-tolerant seeds for several crops. The two firms are awaiting marketing approval from the Environmental Protection Agency (EPA, Washington, DC) for bromoxynil-tolerant cotton seeds, even though the seeds have already received approval from the Department of Agriculture (Washington, DC). The delay with the EPA is due to the fact that the EPA has yet to approve the use of bromoxynil—a killer of broad-leaf weeds—on cotton. Bromoxynil,

though, is currently used by U.S. farmers to kill weeds colonizing corn and small grains. The EPA is not expected to approve the bromoxynil-tolerant cotton seed for this growing season.

The most likely candidate to become Europe's first modified seed to be both approved and actually marketed is an oilseed rape modified by Plant Genetic Systems (PGS, Ghent, Belgium) to tolerate AgrEvo's (Frankfurt) weed killer, phosphotricin. PGS has been granted marketing approval for modified oilseed rape by the U.K. Advisory Committee on Releases to the Environment (ACRE, London). This potentially opens the door for PGS to get EU-wide marketing approval for the product.

The environmentalist group, Greenpeace (London), is disappointed by ACRE's decision and alleges that it could have disastrous implications for the environment. Greenpeace contends that seeds made tolerant to herbicides will result in the overapplication of those herbicides. —Mike Ward

Can EPA handle commercial-release requests?

WASHINGTON, D.C.—In an exercise that they hope will not continue to be Sisyphean, officials of the Environmental Protection Agency (EPA, Washington, DC) recently submitted revised draft rules for regulating genetically engineered microorganisms for review by the White House Office of Management and Budget (OMB, Washington, DC). Although hints from Clinton administration officials are raising hopes at the EPA that the OMB will allow the proposed rules under the Toxic Substances Control Act (TSCA) to move forward this summer, the proposal still faces a round of public comments and potential changes before this eight-year, rule-making effort can become a *fait accompli*.

Even as the draft TSCA rules are being evaluated, EPA officials are facing the first application under which those rules would be applied to an open-field, commercial-scale release of a genetically engineered

microorganism. Research Seeds (St. Joseph, MO) recently submitted a formal request to the EPA seeking to commercialize a genetically improved strain of *Rhizobium meliloti*, a bacterium that forms nodules along the roots of plants—in this case, the legume alfalfa—to capture atmospheric nitrogen for use as a nutrient. EPA officials are expected to respond to the request by Research Seeds before October.

Since 1986, when Reagan administration officials declared that new laws were not necessary for regulating biotechnology and that federal agencies should apply current statutes to such regulation, EPA officials have written, and revised, several drafts of proposals for applying TSCA to genetically engineered microorganisms. TSCA, one of several federal statutes overseen by the EPA, was originally written with synthetic chemicals in mind. Much of the controversy over biotechnology

rule-making for TSCA revolves around the scope of the rules, particularly as they pertain to microorganisms being studied for research and development (R&D) purposes. The EPA, however, has always maintained that TSCA applies to microorganisms being developed with "commercial intent."

According to David Giamporcuro, section chief of the EPA's TSCA Biotechnology Program, the new draft proposal will contain several regulatory exemptions. For instance, because *R. meliloti* has been extensively field tested, the proposal calls for it, and similar nitrogen-fixing microbes, to be exempt for R&D-testing purposes. The proposal also outlines a means for other classes of microorganisms to be granted similar exempt status. Yet when environmental releases are contemplated, even for R&D purposes, engineered organisms that contain genes from intergeneric exchange-