

/NEWS & COMMENTARY

EPA okays *Bt* corn; USDA eases plant testing

WASHINGTON, D.C.—In August, the U.S. Environmental Protection Agency (EPA, Washington, D.C.) approved full commercial use of insecticide-producing transgenic corn (maize) varieties developed by Mycogen (San Diego, CA) and by Ciba Seeds (Greenboro, NC), a division of Ciba-Geigy (Basel, Switzerland). Although the companies collaborated closely in developing the corn—Mycogen brought its *Bacillus thuringiensis* (*Bt*) technology under license to Ciba, and Ciba did much of the transgenic plant work-up—each has registered distinct hybrid lines.

Corn is not the first *Bt*-expressing transgenic plant that EPA has licensed for commercial growth and distribution. That was a potato from Monsanto (St. Louis, MO), approved by EPA in May of this year. Corn, however, is by far a larger and more important crop: In the U.S. alone, it is grown on some 60-70 million acres of land, and more than 9 billion bushels, worth

almost \$21 billion per year, are produced. The enormity of the market means that Ciba and Mycogen are unlikely to have it to themselves for long. Pioneer Hi-Bred International (Des Moines, IA), Monsanto, and Dekalb Genetics (Dekalb, IL) are all developing corn. Monsanto has granted a worldwide license to its *Bt* corn to Sandoz Seeds (Basel, Switzerland) and could have hybrid products ready for planting in 1996.

The Ciba and Mycogen efforts focused on a *Bt* protein that is active not only against the European corn borer but also the Southwestern corn borer, the lesser corn stalk borer, and the corn earworm. The activities of these major pests lead to an estimated \$800-900 million of losses per year, according to Richard Lotstein, director of regulatory affairs at Ciba Seeds.

Passage of the Mycogen and Ciba products through the U.S. federal review process at the U.S. Department of Agriculture (Washington,

D.C.) and the Environmental Protection Agency (EPA, Washington, D.C.) took less than one year. This acceleration was welcomed as a bright spot by industry watchers and as an important sign that transgenic products are finding a way to market. "The agency's review of *Bt* corn went relatively smoothly and rapidly," says Richard Godown of the Biotechnology Industry Organization (BIO, Washington, D.C.).

In another development in August affecting the same biotechnology sector, USDA further eased its system for overseeing field tests of transgenic plants, granting a broad exemption from the need for permits to test most crop species (see "Field testing following notification" and "Insect rules take shape"). Agricultural biotechnology is looking "very, very positive," says Godown. "Familiarity breeds acceptance where transgenic plants are concerned."

Industry representatives, federal

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Field testing following notification

In August, the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture (APHIS, Washington, D.C.) announced proposals that would allow field testing of most genetically engineered plants to occur following notification, rather than after the granting of a permit. According to APHIS estimates, this would save applicants approximately 95% of their administrative costs. Furthermore, the proposals would reduce the reporting requirements for field trials conducted under notification.

Currently, the regulations require that introductions of most plant species be done under permit from APHIS, with applications for permits evaluated on a case-by-case basis. Since 1987, APHIS has issued over 560 release permits and over 1280 movement permits, most of them for plants.

APHIS began the process of relaxing its requirement in April 1988, when it exempted the movement restrictions on certain microorganisms that contain plant pest sequences, and continued in December 1990, when movement of *Arabidopsis thaliana* was also exempted. These measures removed some of the red tape from the research community. Then, in March 1993, notification procedures were introduced for corn, cotton, potato, soybean, tobacco, and tomato. Since then, APHIS has reviewed over 900 notifications for these 6 species.

Now APHIS plans to extend that notification procedure to most other plants. The main exclusions from the procedure will be plants listed as weeds or parasitic plants. In addition, there will be some restrictions on the type of plant virus sequences that can be included in any constructs administered under the notification

scheme. To ensure that introduced genetic sequences do not pose a significant risk of the creation of any new plant virus, plant virus-derived sequences must be noncoding regulatory sequences of known function. Alternatively, they can be antigenic genetic constructs—derived from plant virus genes that are prevalent and endemic in the area where the introduction will occur—that infect plants of the same host species and that do not encode any functional noncapsid gene product responsible for cell-to-cell movement of the virus.

Based on trials to date, APHIS estimates that about 99% of all field trials could now be conducted under notification procedures if its current proposals are accepted. Any comments should be sent to APHIS on or before October 23, 1995.

— John Hodgson