UNCERTAIN FATE

USDA EASES FIELD-TESTING RULES

WASHINGTON, D.C.—Several strategic steps to ease regulations affecting genetically engineered plants have been taken by the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS), with the centerpiece being a proposed move to a notice-based rather than a permit-based system. How these general efforts will play out remains uncertain because of odd timing and political change, as the proposed rules were made public for comments just days after the November election.

In a related development, APHIS officials took one specific step that does seem clear-cut from a regulatory standpoint. They decided during the fall that Calgene's (Davis, CA) Flavr Savr tomatoes could be grown and shipped throughout the U.S. without further need of permits or approvals from the agency.

Calgene's Flavr Savr

Calgene company officials praise the APHIS decision, saying it will enable them to scale up field production in anticipation of a commercial launch of the product next summer. Whether that target will be met, however, still depends on the tomatoes clearing at least one more regulatory hurdle at the Food and Drug Administration (FDA, Bethesda, MD). Moreover, activist Jeremy Rifkin, his Foundation on Economic Trends (Washington, DC), and a coalition of chefs have vowed to organize a boycott of this and all other genetically engineered food products. Nonetheless, USDA's early action now leaves these other forces to play catch up with the advancing Calgene tomato.

Meanwhile, the fate of the far more sweeping APHIS deregulatory proposals seems less assured. There are two key features to the proposals. The first would lift current permit requirements for entering certain categories of transgenic plants into open-field trials, replacing them with far-simpler notification procedures. The first plants recommended for such notification procedures include corn, cotton, potato, soybean, tobacco, and tomato. The second proposed feature is to offer a means for specific transgenic-plant species to be exempted from regulatory scrutiny by the agency.

Although these proposals represent a compromise among conflicting forces, the dust appears not to have fully settled. Events trace back to late in the summer when representatives from the biotechnology industry and environmental organizations met with White House officials to negotiate a compromise over the APHIS regulations. At the time, officials were considering a proposal from academic researchers to do away with the APHIS biotechnology-regulatory procedures, which critics from that community consider confusing, burdensome, and unduly inhibitory for many university-based researchers.

Unsettled dust

The subsequent compromise, embodied in the November *Federal Register* notice from APHIS, falls short of satisfying some members of the academic community but pleases most industry representatives. For instance, Industrial Biotechnology Association (Washington, DC) president Richard Godown, who helped negotiate the compromise, welcomes the results. "The new APHIS regulations will dramatically cut the costs, time, and resources involved in the development of new genetically enhanced agricultural products," he says. "USDA has managed to ease the regulatory burden while maintaining government oversight. The new regulatory scheme will benefit industrial and academic researchers alike."

However, the published proposals have renewed doubts among some environmentalists, who are wondering whether essential elements of the summer compromise were lost on the way to the *Federal Register*. "We're not very satisfied with what's proposed," says Rebecca Goldburg of the Environmental Defense Fund (EDF, Washington, DC), who also met with White House officials during the summer. "The USDA folks have gone too far, and there are not enough safeguards."

Goldburg objects to several features in the proposals, including the call for simultaneous rather than advance notice by researchers to USDA and also the resurrected proposal to use review boards at individual institutions rather than USDA. Moreover, she says that the proposals do not deal adequately with certain kinds of transgenic plants, particularly those that will be engineered to produce pharmaceutical products.

—Jeffrey L. Fox

FUTILITY AND BOREDOM

MEANINGLESS REPORT?

WASHINGTON, D.C.—When members of the National Biotechnology Policy Board (NBPB, Washington, DC) met recently, a sense of futility and boredom cropped up more than once among participants. They convened to revise a draft policy report to be delivered to the President and Congress. In doing so, the board members left most of the draft's recommendations intact but softened its tone.

With sweeping changes expected throughout the federal establishment following the November election, however, the NBPB report will likely have even less impact than its discouraged authors anticipated for it. The reasons for the apparent frustrations underlying this peculiar effort are several, ranging from election outcomes to the make-up of the board itself.

NBPB was established in 1989 by the National Institutes of Health (NIH, Bethesda, MD) to fulfill a legislative mandate from Congress. However, the real impetus for NIH to establish the board came from former Senator Lawton Chiles (D-FL), who left the Congress in 1990. No successor emerged during the next two years to follow up his particular interests. Moreover, from the outset, critics faulted the narrow composition of the board, arguing that it lacked representation from consumer and environmental groups, as well as certain key government agencies.

Deregulatory moves

"A lot of people will be affected by this technology, and there needs to be some recognition of the legitimacy of the views of these people," notes one critic. Another critic questions whether "so much of the report should be devoted to regulatory policy when the board received comments on a wide variety of topics. Also, it fails to provide adequate support for the strong positions it takes in both its regulatory and economic analysis."

Nonetheless, recommendations embodied in the final report center on policy issues that, even if viewed in a different light by appointees of President-elect Bill Clinton, will require attention from federal officials. "Whether the recommendations represent a bipartisan view, I don't know," admits one insider, who says that the board has fulfilled its mandate and that the final draft of the report is making its way through channels. In it, the board recommends several deregulatory moves that seem more in keeping with policies of the outgoing administration of President George Bush than what may be anticipated from a Clinton administration.

For instance, echoing a general theme from recent years, NBPB recommends that the degree of regulatory oversight be "tailored to product risk," once again