

Gene-Altered Crops Denounced

Environmental Groups Seek Moratorium on Open-Air Tests

By Rick Weiss Washington Post Staff Writer Wednesday, August 16, 2006; A03

Environmental groups yesterday called for a moratorium on open-air tests of crops genetically engineered to produce medicines and vaccines, citing a federal court's conclusion last week that the Agriculture Department repeatedly broke the law by allowing companies to plant such crops on hundred of acres in Hawaii.

In a toughly worded 52-page decision released without fanfare late last week, a U.S. District judge in Hawaii concluded that USDA's Animal and Plant Health Inspection Service (APHIS), which grants permits for the planting of genetically engineered crops, should have first investigated whether the plants posed a threat to any of that state's hundreds of endangered species.

The corn and sugar cane plants, already harvested because the experiments involving them were completed before the case was decided, had been modified to produce human hormones, drugs and ingredients for vaccines against AIDS and hepatitis B.

"APHIS's utter disregard for this simple investigation requirement, especially given the extraordinary number of endangered and threatened plants and animals in Hawaii, constitutes an unequivocal violation of a clear congressional mandate," wrote Judge J. Michael Seabright in his Aug. 10 decision.

The ruling is the first by a federal court on the controversial practice of "bio-pharming," in which crops are engineered to produce potentially therapeutic human proteins. But it is not the first damning federal critique of APHIS's oversight. A December 2005 audit by the Agriculture Department's Office of Inspector General found multiple failings in the agency's enforcement of research rules for gene-altered plants.

APHIS spokeswoman Rachel Iadicicco said yesterday that the agency had already corrected the major problems cited in the 2005 report and had recently made policy changes to satisfy the court's concerns, as well. In addition, she said, APHIS is crafting a sweeping "programmatic" environmental impact statement addressing larger, long-standing concerns about its oversight of biotech crops.

But opponents said they have heard such assurances before.

"We are asking the judge to enjoin the issuance of any biopharma permits anywhere in the country unless and until APHIS completes a programmatic analysis of their regulatory program," said Paul H. Achitoff, managing attorney for Earthjustice in Honolulu, which litigated the case with the Washington-based Center for Food Safety.

The judge has scheduled a hearing for Tuesday to decide what remedies to impose.

The court ruling is the latest in a decade-long struggle that has pitted biotech companies against an uneasy coalition of environmentalists and conventional food producers and

distributors.

Advocates believe that some drugs and vaccines may be produced more economically in crops than in the laboratory cultures that are commonly used today. Some even envision "edible vaccines," such as bananas laden with proteins that would boost blood levels of protective antibodies -- an attractive strategy for developing countries, where the refrigeration needed for many conventional vaccines is often not available.

But opponents fear that ordinary crops may become contaminated with drug-spiked versions grown in open fields, and that unwanted drug exposures from foods could trigger allergic reactions or other problems in people or animals.

Fears of admixture gained credence in 2002 when a Texas company was found to have broken rules in its cultivation of corn plants engineered to make a pig diarrhea vaccine. The error necessitated the destruction of 500,000 bushels of potentially contaminated soybeans, and left the now defunct company, ProdiGene, stuck with millions of dollars in cleanup costs.

"The use of food crops to produce materials not intended to be in the food supply must only proceed under systems proven to prevent any contamination or adulteration of the food supply," said Jeffrey Barach of the Food Products Association in Washington. "To date, effective control programs have not been demonstrated to our satisfaction."

The federal court decision responds to a 2003 lawsuit filed by several public interest groups. Taking a novel tack, the groups charged that APHIS failed to consider the potential impacts on endangered species when it approved four Hawaii field studies in the previous three years. The plants were produced by ProdiGene, Monsanto, the Hawaii Agriculture Research Center and Garst Seed of Slater, Iowa.

The plaintiffs -- including Friends of the Earth, Pesticide Action Network North America and Kahea, a Hawaiian environmental alliance -- noted that Hawaii is home to 329 endangered or threatened species, more than any other state, including many birds with easy access to test plots.

Seabright agreed with the groups that, although proof of harm is lacking, APHIS's issuance of the permits for 800 acres on four Hawaiian islands without consideration of those potential impacts was "arbitrary and capricious."

"This is probably the strongest message yet to USDA that they need to do a much better job at regulating all genetically engineered crop field trials," said Bill Freese of the Center for Food Safety, noting that about a dozen pharma permits are approved in a typical year. "They've been rubber-stamping for too long, and they need to get serious about these crops."

But the judge rejected the groups' broader claim that APHIS had broken its promise to improve its overall system of oversight.

"Although the Plaintiffs are understandably upset by the fact that this process has taken over three years, the court accepts APHIS's representations" that the delay is justified and progress is under way.

Stephanie A. Whalen, president of the Hawaii Agriculture Research Center, which ran the studies involving sugar cane engineered to make a human blood protein, said the ruling "looks backward" at problems already corrected.

"The idea that this has got the potential for harm has been all blown out of proportion," she said. "We're really proud of the work we do, and we know how important it is to safeguard the environment."

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