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## Ruling a slight setback for 'biopharm' growers

By [Jan TenBruggencate](#)  
Advertiser Science Writer

The U.S. Department of Agriculture violated federal environmental laws when it approved permits allowing companies to grow hundreds of acres of "biopharmaceutical" crops in Hawai'i — food crops with genetic modifications that cause them to produce drugs or other compounds, a federal judge ruled last week.

Federal district Judge Michael Seabright said the USDA was "arbitrary and capricious" in deciding to issue permits without conducting environmental studies, or at least saying why they were not being conducted. Seabright did not apply fines or order specific actions by government or industry. He has ordered a hearing Aug. 22 to determine what remedies should be ordered in the case.

The "biopharm" issue is one controversial aspect of the larger genetic engineering battle, which pits modern agricultural technology against those wary of a range of potential catastrophes that could arise from inserting genetic material into plants that could not get there through traditional breeding.

"The ruling is a clear victory for Hawai'i's environment. It will help protect the Islands from the illegal field-testing of genetically engineered, drug-producing crops," Joseph Mendelson, legal director of the Center for Food Safety, said in a prepared statement.

Industry representatives, however, said the ruling has no immediate effect because permits for all such experiments expired two years ago, and no biopharmaceutical crops are now being grown in Hawai'i. Also, it would allow such research to proceed once regulators have done the proper studies and paperwork.

"The Endangered Species Act and National Environmental Policy Act violations outlined by the court were procedural. The court did not rule that the issuance of these permits resulted in any harm to human health and safety or the environment," said Rick Klemm, director of a pro-industry group called Hawai'i Alliance for Responsible Health and Science.

Seabright's ruling arose from a lawsuit by environmental group Earthjustice on behalf of the Center for Food Safety, Friends of the Earth, Pesticide Action Network North America and the Hawaiian environmental alliance Kahea. The suit was over permits issued for Hawai'i field research by ProdiGene, Monsanto, HARC and Garst Seed Co. The permits were issued by the USDA's Animal and Plant Health Inspection Service.

Stephanie Whalen, president of the Hawaii Agricultural Research Center, which conducted some of the genetically engineered crop tests, said the ruling may delay work but eventually could make it safer.

"We'll be under tighter scrutiny in the future, and that's fine, because nobody wants it to get out," she said, referring to reproductive material from genetically engineered biopharmaceutical plants.

Whalen gave an example of a biopharm crop that her organization grew for a time. It was sugar cane that had been engineered to produce a human protein that could help cancer patients. She said federal inspectors visited the crop repeatedly, and the cane was not allowed to flower.

"The way the permit was written, there was no way for it to get into the environment. We had maybe six or seven inspections, and it was destroyed in front of them," she said. Ultimately, the experiment was not successful, since "we were unable to get a high enough concentration" of the material sought, she said.

Earthjustice attorney Paul Achitoff said in a prepared statement that Seabright's ruling is an indication that USDA inspection service control of the industry has not been sufficient.

"This decision shows that regulatory oversight of this out-of-control industry has been woefully inadequate. The agency entrusted with protecting human health and the environment from the impacts of genetic engineering experiments has been asleep at the wheel," Achitoff said.

The battle over biopharmaceuticals is far from over, said Andrew Kimbrell, executive director of the Center for Food Safety. "We will not rest until the federal government prohibits the irresponsible and hazardous field testing of drug-producing, genetically engineered crops," he said in a prepared statement.

Earthjustice reported that the inspection service permitted dozens of biopharm crop tests among the more than 5,000 tests of various genetically engineered crops allowed in Hawai'i from 1987 to 2004.

"Hawai'i is the nation's leading state for plantings of experimental, genetically engineered crops," Earthjustice said in a news release.

Reach Jan TenBruggencate at [jant@honoluluadvertiser.com](mailto:jant@honoluluadvertiser.com).

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