Status of Biotech Field Trial Activity

1,606 distinct APHIS notifications submitted (1,513 acknowledged; 84 denied/withdrawn/void; 150 currently in effect)

102 distinct APHIS permit applications submitted (88 issued; 13 denied/withdrawn/void; 7 currently in effect)

15 APHIS permits issued for varieties of corn, rice, and sugarcane engineered to produce compounds for pharmaceutical production

No APHIS notifications or permit applications submitted for crops engineered to produce compounds for industrial applications

18 crops total for which APHIS notifications and/or permit applications were submitted

Most APHIS notification and permit applications submitted for biotech varieties of corn

Other crops include: barley, coffee, cotton, lettuce, papaya, peanuts, pineapples, potatoes, rice, soybeans, sugarcane, sunflowers, tobacco, tomatoes, and wheat
Biotech Activity and Legislative Status

Biotech Activity and Interest

Biotechnology research is a major component of Hawaii’s agricultural economy. Hawaii leads the country in the number of APHIS-authorized field trials, including the largest number of permits issued for pharma crops.446 This reflects Hawaii’s reputation as having conditions conducive for the testing and growing of biotech crops, including a year-round growing season.447

At the same time, an organic producer group representative commented in response to the survey that “Hawaii has a very fragile ecosystem” and “biotech companies are ... planting biopharmaceuticals possibly too close to seed corn grown for the entire U.S.” One focus of attention in Hawaii today is a lawsuit brought by Earthjustice on behalf of the Center for Food Safety against the Hawaii Department of Agriculture to compel the department under Hawaii’s open records law to release information about pharma crop field trials in the state.448 A second lawsuit is being pursued in Honolulu against the USDA by Earthjustice, on behalf of the Center for Food Safety, KAHEA – the Hawaiian Environmental Alliance, Friends of the Earth, and the Pesticide Action Network of North America, seeking a halt to all “open-air” field testing of pharma crops until USDA performs assessments of the environmental and public health risks.449 Since a large number of those field trials take place in Hawaii, the conclusions of the case are important to the state (see Section IV. for the vignette titled, “Confidential Business Information and State Oversight of Biotech Crops: Hawaii Litigation Airs the Debate,” for more details).

Regulatory Legislation

Although Hawaii does not have a comprehensive statute addressing the regulation of biotech crops and foods, state law requires that anyone who submits an application to a federal agency “for any permit for or approval of any bioproduct, field testing of genetically modified organisms, or environmental impact assessment of genetically modified organisms,” simultaneously submit a copy of the application to the Hawaii Department of Health (19 Haw. Rev. Stat. § 321-11.6 et seq. (2003)).

Legislative activity addressing regulatory aspects of agricultural biotechnology issues in Hawaii is high. Many bills that would appropriate funds to assess the long-term effects of growing biotech crops in Hawaii have been introduced over the last three years. In 2001 and 2002, a number of bills calling for the labeling of genetically modified foods, or the labeling of nongenetically modified foods, died in the legislature. However, the labeling of both foods and seeds is addressed by a set of bills introduced in 2003

446 Information Systems for Biotechnology 2004(f).
448 Center for Food Safety v. Department of Agriculture, Hawaii, Civil No. 03-1-1509-07, 2003.
and carried over into 2004, the second year of this legislative session, that require conventional farmers to be notified of nearby biotech crops and that discuss liability issues concerning cross-pollination between biotech crops and nonbiotech crops (HB1281, HB1033, SB601). Bills requiring the reporting to Hawaii’s legislature of research dealing with genetic modification and establishing permits for the release of specific genetically modified organisms have also been introduced.

Two bills that were introduced in 2003 and carried over to the 2004 legislative session would require companies to disclose the location of biotech field trials as well as contract with organizations to conduct safety evaluations (SB1640 and SB1436). Additional legislation that was introduced in 2003 included a set of three resolutions mandating the study of biotechnology in the context of sharing genetic resources and preserving biological diversity, and a similar bill that was carried over into the 2004 session (SB643). One other bill would impose a moratorium on planting biotech kona coffee while the consequences of introducing this coffee into Hawaii are evaluated and a permitting process is set up (HB99). Two pieces of legislation that did not get past the 2003 session would have requested a task force to recommend statutory and regulatory frameworks for GM organisms in Hawaii, while another would have established a working group to assess the ethical, health, ecological, and agricultural consequences of GM organisms in Hawaii.

**Nonregulatory Legislation**

The Hawaii legislature has created a Hawaii technology investment program that allows individual investors to contribute to a venture capital fund whose monies are invested in technologies, including biotechnology (13 Haw. Rev. Stat. § 221F-51 et seq. (2003)). The state also exempts from excise taxes the proceeds from any research, development, sale, or production of agricultural biotechnology and other biotechnology products (13 Haw. Rev. Stat. § 209EF-11 (2003)).

In Hawaii’s General Assembly, a few nonregulatory bills addressing biotechnology that failed in recent years include two bills to address the liability of manufacturers of genetically modified organisms and a bill to include transgenic produce in the definition of “fresh fruits, fresh vegetables, and coffee.” As in many other states, however, an anti-crop-destruction bill did pass in the 2001 legislative session holding vandals liable for double the damage they cause (SB640).

A significant volume of legislation related to agricultural biotechnology research and education, as well as economic growth and development, has been introduced in Hawaii since 2003. An array of bills were introduced

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450 Pew Initiative on Food and Biotechnology 2004(c).
451 Pew Initiative on Food and Biotechnology 2004(c).
452 Pew Initiative on Food and Biotechnology 2004(c).
to appropriate funds or set up working groups surrounding this topic, although only two of these pieces were passed or adopted in 2003. One set up a group to develop a strategic plan for workforce development for industries, including the biotechnology industry (SB837), and the other, a legislative resolution, urged the promotion of careers in areas of economic development, including biotechnology (HCR185). Most of the 25 bills introduced in 2003 were carried over to 2004.

### REGULATORY AUTHORITY, AGENCIES, AND RESOURCES

#### RELEVANT STATUTORY AUTHORITY

<table>
<thead>
<tr>
<th>Biotech-Specific Regulatory Statutes</th>
<th>Other Potential Statutory Authority Over Biotech Field Trials</th>
<th>Other Potential Statutory Authority Over PIPs</th>
<th>Other Potential Statutory Authority Over Biotech Food Safety</th>
</tr>
</thead>
</table>

#### AGENCIES WITH CURRENT OR POTENTIAL BIOTECH ROLES

<table>
<thead>
<tr>
<th>Biotech-Specific</th>
<th>Plant Health</th>
<th>Pesticides</th>
<th>Food Safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>Hawaii Depart-ment of Agriculture – Plant Industry Division, Plant Quarantine Branch</td>
<td>Hawaii Depart-ment of Agriculture – Plant Industry Division, Pesticides Branch</td>
<td>Hawaii Depart-ment of Health – Food &amp; Drug Branch and Sanitation Branch</td>
</tr>
</tbody>
</table>

#### RESOURCES

Hawaii Department of Agriculture budget: FY 04 $12,500,000
Budget for plant health protection: FY 04 $4,360,000

Narrative description of budget for biotech crops and foods component: The Hawaii Department of Agriculture, at this point in time, does not have a position dedicated solely to biotechnology issues. For resources allocated to biotechnology activities, the breakdown is: Plant Special, one individual, approximately 40% of time for permit reviews, field inspections and related activities; two Plant Quarantine inspectors, Maui and Kauai, approximately 10% of time to assist USDA, APHIS in field inspections; Plant Quarantine Program Manager, approximately 20% of time; Plant Industry Administrator, approximately 10% of time; and other program staff in Plant Industry participate in biotechnology issues to some extent, but the activities overall are not a significant part of the FTE.

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453 Pew Initiative on Food and Biotechnology 2004(c).