BRS Factsheet

Biotechnology Regulatory Services

U.S. Department of Agriculture
Animal and Plant Health Inspection Service

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USDA Regulation of Biotechnology Field Tests in Hawaii

The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) regulates the field testing, interstate movement, and importation of genetically engineered (GE) organisms that are under development by biotech companies, universities, and other researchers. Because of Hawaii's tropical climate, which is favorable to agriculture and allows for a year–round growing season, the State has become an attractive location for field tests of a variety of biotech crops such as corn and soybeans. To ensure the safety of these field tests, APHIS, under the authority of the Plant Protection Act, thoroughly evaluates GE organisms to verify that they are just as safe for agriculture and the environment as traditionally bred crop varieties, which have been the cornerstone of American agriculture. In regulating biotechnology, APHIS' Biotechnology Regulatory Services (BRS) works in concert with the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA), which also play important roles in protecting food safety and the environment.

Before approving any permit, BRS consults with the Hawaii Department of Agriculture (HDOA) officials who play an important role in reviewing all proposed field trials.

As part of the Agency's review of all Hawaii biotech field tests, BRS biotechnologists consider the State's unique ecology, including the fact that the islands have more threatened and endangered species per square mile than any other place on earth. All permit conditions are designed to protect the surrounding environment and native flora and fauna. Since the 1980s, APHIS has overseen thousands of biotech field tests with no evidence of any adverse effects. Before approving any permit, BRS consults with the Hawaii Department of Agriculture (HDOA) officials who play an important role in reviewing all proposed field trials. Working together, BRS, its Federal partners and the HDOA protect the islands' native ecosystems, agriculture, and the food supply while allowing for the safe field testing of GE crops.

Importation and Movement

In addition to coordinating with States on field tests, BRS requires a permit and the concurrence of individual State Departments of Agriculture or other relevant agencies to import or ship any GE organisms that have the potential to be plant pests. This includes organisms imported into the United States as well as those shipped between States. Prior to approving these permit applications, BRS and HDOA officials inspect the receiving facilities to ensure the organisms will not be accidentally released into the environment. Inspectors also evaluate the personnel, security, and operational procedures of the laboratories, growth chambers, and greenhouses to ensure guidelines for good practices are being followed.

Field Testing

BRS oversees the field testing of GE plants through its notification and permit processes to ensure that GE organisms and their progeny do not escape or persist in the environment. Companies must submit all plans for field testing for review by BRS. The program only approves those applicants with the ability to adequately confine regulated articles within field test sites. To ensure compliance with permit conditions, field test sites are inspected and records are audited. BRS has never approved a field test permit over the objections of State counterparts or without accommodating additional permit conditions recommended by the States.

Depending on the nature of the GE crop field test, a researcher must file either a notification or a permit application. In general, most plants are field tested under the notification procedure, a more streamlined approval process that is used only for non–weedy crops with familiar traits considered to be low risk. Permitting is used for field tests of specialized GE plants with unfamiliar traits that do not qualify for notifications, such as plants producing pharmaceutical or industrial compounds.

Confinement measures are a set of rules that an applicant must follow to ensure that no viable genetic material escapes from the field test or persists beyond the duration of the trial.

Notifications

- Less restrictive than permits
- Used for low–risk crops—weeds and traits with higher risk are excluded
- BRS reviews the application for completeness, with up to 30 days to process
- Performance standards are established and applicant must comply with these for movement, planting, growing harvesting, and isolation
- Notifications are issued for GE plants only

Permits

- More restrictive than notifications used for field tests of specialized GE traits—examples include pharmaceutical and industrial crops
- Scientific review of conditions and confinement require up to 120 days to process application
- BRS authorizes procedures for field production and isolation
- Permitted pharmaceutical and industrial crop field tests are inspected multiple times before, during, and after the growing season
- Permits are issued for GE plants as well as for other types of GE organisms that have the potential to be plant pests, such as insects and microrganisms

When reviewing an application for field release, a team of BRS biotechnologists and other area experts check the application for completeness to ensure that all required information is provided. If more information is needed, BRS will request it from the applicant before proceeding. When applying for a permit, applicants must describe in the permit a system of confinement measures developed specifically for that field release. Confinement measures are a set of rules that an applicant must follow to ensure that no viable genetic material escapes from the field test or persists beyond the duration of the trial. These measures often include everything from washing and segregating farm equipment to the isolation distance of the field test site in relation to other crops in the area. In some instances, an applicant may be required to plant his or her test plot out of phase with surrounding crops so that when the test plants are fertile the surrounding crops are not (the time difference put in place between fertile and non–fertile crops is called temporal isolation) or even manually remove pollen–producing areas of the test plant. With pharmaceutical and industrial crop field tests, BRS may require redundant confinement measures as an additional precaution.

Although BRS has ultimate authority for regulating biotech crops, the Agency coordinates closely with States on all biotech permits and notifications. Hawaii is one of the most active States when it comes to providing input on field test applications. HDOA officials can and do recommend additional permit conditions for field tests based on the islands' unique ecology. In fact, BRS and HDOA have worked together to develop a number of specially tailored permit conditions that apply to all biotech crop field tests in the State. For example, following the completion of a pharmaceutical field test, Hawaii requires that the field be tilled and irrigated to provide favorable conditions for the growth of any seeds, or other viable material that may remain from the field test. Any resulting plants are typically referred to as volunteer plants and must be destroyed. This process is required as part of a 30–day fallow period in which the field is closely monitored. After the first 30–day monitoring period is complete, the field is again tilled, irrigated, and monitored for a second 30–day period. This cycle is repeated until the field remains free of any volunteers for at least two 30–day cycles. Because Hawaii's cli-

mate allows for year–round planting, this specially tailored permit condition prevents commingling of biotech crops. As an added precaution, anytime biotech companies plant GE crops, they must also submit a written report to HDOA on the pollen movement and viability of the crop under the islands' climatic conditions to document that no traits were inadvertently transferred to plants outside of the field test.

HDOA also requires added recordkeeping. In conjunction with notifying BRS when field tests are planted, pollinated, and harvested, biotech companies must notify Hawaii agricultural officials as well. Any changes to field test sites, recommended conditions, unplanned releases or thefts of GE crops must also be reported to Hawaii officials. In addition to these standard field test conditions, HDOA officials review each and every notification and permit under consideration by BRS and can add additional planting requirements and restrictions on a case–by–case basis.

Depending on the location of the field test, BRS permit conditions may also require that the trial be monitored throughout the crop's growing cycle for the presence of threatened or endangered species designated in Hawaii under the authority of the U.S. Endangered Species Act. If any of these species are observed in the field and found to be consuming biotech seed, permittees are required to notify BRS immediately.

Compliance

To enforce permit conditions such as those outlined above, BRS has established an internal compliance unit dedicated to ensuring that companies and organizations maintain compliance with regulatory requirements. Compliance specialists use set criteria to thoroughly evaluate all potential compliance infractions. This approach is consistent with how other APHIS programs monitor and enforce regulations. BRS compliance specialists, as well as other APHIS inspectors, perform targeted inspections of field tests. Depending on whether the GE crop being tested is a pharmaceutical or industrial crop, a site may be inspected by APHIS up to seven times to ensure that the conditions set forth by BRS are carefully followed. In 2004, APHIS conducted 79 inspections of permitted field tests in Hawaii and 148 inspections of field tests approved through the notification process. The BRS compliance unit also works with companies and organizations to build self–reporting systems so that BRS is notified immediately when a compliance infraction occurs and can work directly with the responsible party to resolve the infraction and promptly reestablish compliance. Self reporting is especially applicable when an unexpected weather event, such as a wind or rainstorm occurs and affects a field test. While companies have no control over the weather, immediate notification is important in order to quickly implement any mitigation measures that might be necessary to confine the field test.

Based on a historical analysis of compliance with APHIS' biotech regulations, it's clear that companies, universities, and other researchers are adhering to the requirements set forth for GE crop field tests. During a 10–year period where enforcement data was analyzed, overall compliance rates exceeded 98 percent with less than 2 percent of all GE field tests resulting in compliance infractions. Nonetheless, BRS continues working to strengthen our oversight and inspection of GE field tests. Compliance is, and will always be, the highest priority. In addition, as the field of biotechnology progresses, BRS will develop any regulations necessary to meet the challenges posed by this new science while continuing to safeguard American agriculture, the food supply, and the environment.

The Future of USDA's Biotechnology Regulation

Experience has shown that the science of biotechnology is always changing requiring more tailored, complex, and risk–based regulations. BRS is considering broadening its regulatory scope beyond GE organisms that may pose a plant pest risk to include GE plants that may pose a noxious weed risk as well as GE organisms that may be used as biological control agents. Potential regulation changes

currently under review also include development of a risk–based, tiered permitting program, which would allow BRS to focus more time and resources on new or unfamiliar GE traits, such as pharmaceutical and industrial crops. BRS welcomes comments from the public, the industry, and stakeholders on its current regulations and potential regulation changes. The Agency also is committed to an open and transparent regulatory process that reflects the latest science, while continuing to protect America's agricultural and natural resources.

For More Information on USDA's Biotechnology Regulation

Contact the U.S. Department of Agriculture's Animal and Plant Health Inspection Service
http://www.aphis.usda.gov/brs/

Other Agencies Involved in Biotechnology Regulation

U.S. Environmental Protection Agency
http://www.epa.gov/pesticides/biopesticide
http://www.epa.gov/oppt/biotech/

U.S. Department of Health and Human Services' Food and Drug Administration
http://www.cfsan.fda.gov/~lrd/biotechm.html.

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