YOU CAN’T PUT THE TOOTHPASTE BACK INTO THE TUBE: THE ADEQUACY OF FEDERAL REGULATORY OVERSIGHT TO PREVENT POTENTIAL ENVIRONMENTAL DAMAGE RESULTING FROM THE OPEN-FIELD TESTING OF TRANSGENIC CROPS

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FOREWORD

The Environmental Law Program (“ELP”) of the William S. Richardson School of Law is pleased to present the fourth issue of our occasional paper series, He Mau Mo’olelo Kānāwai o ka ‘Āina (“Stories of the Law of the Land”). Established through the generous support of the Pōhaku Fund of the Tides Foundation, the Mo’olelo series allows us to share with our friends and colleagues in the Hawai‘i, national, and international legal communities a selection of the best papers by our law students on environmental, land use, and indigenous peoples’ law issues.

This paper explores the cutting edge issue of the open field testing of transgenic crops, asserting that the current federal legal system fails to ensure that such crops will cause no long-lasting and irreversible effects on our food supply and on genetic diversity. In his paper, Mr. Paulson summarizes the scientific evidence regarding the potential costs and benefits of genetically modified crops. He found that development of transgenic crops can provide benefits such as insect and disease resistance and improved nutritional value, in addition to production of pharmaceutical proteins and industrial enzymes. However, he concludes that the research also shows that the long-term environmental and human health consequences of cultivating transgenic crops are unknown, warranting a more precautionary legal approach than the law currently provides.

After reviewing the scientific literature, Mr. Paulson analyzes the federal regulatory framework that surrounds open field testing of transgenic crops and finds it wanting. He reports on recent case law in the federal and state courts of Hawaii‘i that required public notification of open field testing sites. He asserts that federal Department of Agriculture (DOA) regulations requiring either agency notification or the issuance of a permit prior to the environmental release of a transgenic crop are inadequate to prevent potential ecological harm. Consequently, he proposes that the DOA modify its regulatory framework to oversee the release of transgenic plants under the Plant Protection Act and comply with the National Environmental Policy Act (“NEPA”) by completing an environmental impact statement (“EIS”) or an environmental assessment (“EA”) prior to the intentional environmental release of transgenic organisms.

We encourage you to take the time to review this important paper and to share it with interested colleagues. Please visit the ELP website at www.hawaii.edu/elp for more information about the Environmental Law Program and to read past issues of the He Mau Mo’olelo series, as well as our other excellent online publications.

Me ke aloha pumehana — with warm regards,

Professor Casey Jarman, Second-Year Seminar Instructor for Mr. Paulson
Professor Denise Antolini, Director Environmental Law Program
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I. INTRODUCTION

It was a cold November Thursday in Iowa when local farmers learned the United States
Department of Agriculture (“USDA”) would be confiscating and burning 155 acres of the state’s
corn fields. On November 14, 2002, the USDA announced that the corn fields were possibly
cross-pollinated by a genetically engineered (“transgenic”) corn species developed to produce a
“vaccine to prevent diarrhea in pigs.” If the Iowa corn fields had been fertilized by the transgenic
pollen, they too would likely produce the pig vaccine. These unapproved vaccine proteins could
then appear in our Nation’s food supply and be unknowingly consumed. Prior to the USDA
notification, the local farmers were unaware of the nearby open-field4 pharmaceutical test site.5
This ignorance stems from the deliberate site non-disclosure policy of the Animal and Plant Health
Inspection Service (“APHIS”), the Department within the USDA that regulates the open-air release
of transgenic crops and implements the policy to keep confidential the location of testing sites.6
APHIS discloses that an open-field test is occurring within the confines of a state’s borders, but its
regulations do not require it to release additional information that would allow the public to discern
the actual location of the test site.7

Plant-grown pharmaceuticals (“bio-pharmaceuticals”) had entered the U.S.’s food supply
prior to the vaccine-contaminated corn incident in Iowa. On November 13, 2002, just one day
prior to the news of the potential Iowa corn contamination, the USDA confiscated 500,000 bushels
of Nebraska soybeans because they were tainted by an undisclosed pharmaceutical protein.8
A transgenic corn pharmaceutical crop (“pharm-crop”) was previously field-tested where the
soybeans were cultivated. Some corn plants persisted and grew in the field among the soybeans
and were not removed before harvesting. This transgenic corn, which manufactured a confidential
pharmaceutical protein, was found in the grain elevator mixed with the harvested conventional
soybeans.9 According to a December 2002 New York Times article, ProdiGene, a private company
developing bio-pharmaceuticals, was held responsible by APHIS for both incidents of food crop
contamination.10 Although ProdiGene did not admit to any wrongdoing,11 the genetic pollution12
cost the company approximately $3 million in cleanup costs and fines to the U.S. Government.13

Scientific advancements in molecular biology and biotechnology are enabling the development
of custom-tailored transgenic plant species with widely varying phenotypes.14 Commonly grown
food crops, such as corn, oilseed rape (“canola”), papaya, soybeans, rice, sunflower, tomato, and
wheat15 have all been genetically “enhanced” for traits such as herbicide tolerance, insect and
disease resistance,16 improved nutritional value and shelf-life, and the production of pharmaceutical
proteins and industrial enzymes.17 Although such scientific and agricultural advancements may
potentially reap benefits to the farmer, the consumer, and the environment,18 the long-term
environmental and human health consequences of cultivating transgenic crops are unknown.19
The U.S. biotechnology (“biotech”) industry is currently developing transgenic plant species that
will produce a seemingly endless array of pharmaceutical and industrial products. These “second generation” transgenic organisms have intensified preexisting concerns about the safety of genetically engineering our Nation’s food crops.21

According to Stephen Nottingham, author of Genescapes: The Ecology of Genetic Engineering VII, these transgenic food and pharm crops are releasing genetically engineered DNA into the environment and may rapidly lead to herbicide and insecticide resistance among pests, genetic pollution in neighboring crops and wild weedy species, contamination of the U.S. food supply with unapproved medical and industrial products, and biodiversity loss.22

APHIS has authority under the Plant Protection Act of 2000 to regulate open-field testing of transgenic crops.23 Although APHIS regulations require either agency notification or the issuance of a permit prior to the environmental release of a transgenic crop, the existing regulations are inadequate to prevent potential ecological harm. Accordingly, this paper proposes that APHIS modify its regulatory framework to oversee more directly the release of transgenic plants under the Plant Protection Act, and suggests that APHIS comply with the National Environmental Policy Act (“NEPA”) by completing an environmental impact statement (“EIS”) or an environmental assessment (“EA”) prior to the intentional environmental release of any transgenic organisms.

As of 2005, biotech companies and research institutions had requested 11,278 open-field tests of transgenic crops nationwide.27 Of 1,823 requests to conduct field tests in Hawai‘i, APHIS has acknowledged or permitted 1,694.28 Shockingly, 1,606 of these Hawai‘i field tests proceeded under an expedited notification procedure, under which the companies proposing the tests provide APHIS a mere thirty-day review period.29 Although there have been no publicly disclosed cases of food crop contamination resulting from open-field testing in Hawai‘i, the risks inevitably increase as field tests on the islands become more numerous and second-generation transgenic crops produce more diverse and potentially toxic proteins.

Section II of this paper explains the application of recombinant DNA (“rDNA”) technology to develop transgenic plant species and describes the potential environmental benefits and risks resulting from their cultivation. Section II additionally describes the statutory and regulatory framework that controls the environmental release of transgenic plants. Section III proposes a more precautionary approach to the regulation of transgenic field releases, analyzes whether APHIS is bound by NEPA when deciding to permit the release of transgenic organisms, and addresses whether the Plant Protection Act requires a more rigorous regulatory regime than currently in force. Finally, Section IV proposes modifications to APHIS’s regulatory framework to ensure that potential environmental risks are more adequately assessed before transgenic organisms are intentionally released in Hawai‘i and nationwide.
II. BACKGROUND

Human genetic manipulation of plant and animal life is not a recent development. Man has utilized this technique for over 10,000 years to modify plant and animal species by selecting and propagating those organisms with desirable traits.\textsuperscript{30} The selection process has greatly modified the genetic makeup of domesticated species and resulted in the development of valuable cross-bred cultivated varieties.\textsuperscript{31}

The biology of sexual reproduction, however, places limits on the power of selection and cross-breeding. First, the cross-bred species must be sexually compatible.\textsuperscript{32} Second, all selected characteristics must be encoded in the genetic material of the parent species to be displayed by resulting progeny.\textsuperscript{33} Finally, it is nearly impossible to select for an individual trait without coincidently altering other non-target traits.\textsuperscript{34} For these reasons, traditional selection and cross-breeding methods have been described as “incremental, time-consuming, and imprecise.”\textsuperscript{35}

A. GENETIC ENGINEERING HAS VASTLY INCREASED MAN’S POWER TO ALTER PLANT CHARACTERISTICS

The recent development of molecular biology and biotechnology has vastly expanded the potential for modifying plant and animal life. Since the late 1980s, rDNA technology has enabled the insertion of genetic material from the genome of virtually any organism into the genome of a different organism.\textsuperscript{36} Whereas conventional cross-breeding is limited by the genetic material of the two sexually compatible parent organisms, rDNA technology enables the precise sharing of genetic material between sexually incompatible organisms.\textsuperscript{37}

The biotech sector has focused heavily on the application of rDNA technology to agriculture. Transgenic technology was greeted enthusiastically by proponents, who believed it was “a means of increasing agricultural efficiency, decreasing world hunger, and ameliorating environmental damage caused by previous agricultural techniques.”\textsuperscript{38} The imminent biotech boom additionally produced skeptics who believed the environmental risks of this technology were not being adequately assessed.\textsuperscript{39}

I. Cultivation of Transgenic Crops May Benefit the Environment and the Consumer

Scientists claim that the cultivation of transgenic crops may likely result in environmental and consumer benefits, including increased crop yield, reduced pesticide use, and soil conservation.\textsuperscript{40} Additionally, genetic engineering may increase the nutritional content and shelf-life of food, improve taste, and enable the inexpensive production of pharmaceutical proteins and industrial products.\textsuperscript{41}

Transgenic crops engineered to be disease resistant or drought tolerant may also improve the productivity of the modern farm.\textsuperscript{42} Increased productivity of agricultural land may in turn reduce the need to develop additional farm land, thereby conserving natural habitats.\textsuperscript{43} Conservation of natural habitat is crucial to ensuring long-term species biodiversity and ecological health. Unfortunately, the available scientific data indicate that existing transgenic crops have not significantly outperformed their conventional counterparts.\textsuperscript{44}

Additionally, genetic engineering can incorporate insect resistance genes into crops, reducing the need for topical insecticide applications. The most common “natural pesticide” incorporated into plants is borrowed from the \textit{Bacillus thuringiensis} bacterium ("\textit{Bt}").\textsuperscript{45} Widely cultivated crops such as corn, cotton, and potato have been genetically engineered to encode \textit{Bt}\textsuperscript{46} and
synthesize the $Bt$ protein throughout plant tissues. Insects that consume the plant material die because the $Bt$ protein disrupts insect digestive processes. Insecticides containing the $Bt$ protein are considered environmentally friendly and are often utilized by organic farmers. Many other widely used insecticides are less environmentally benign. Insect resistant crops may therefore reduce a farmer’s dependence on environmentally damaging insecticidal sprays.

Furthermore, genetically engineered herbicide resistant plants may alter soil preparation practices, resulting in soil conservation. Because most herbicides are non-discriminatory killers of plant life, farmers traditionally apply herbicides to fields prior to crop planting. Herbicide resistant crops allow for post-emergent weed control, which may lead to less reliance on destructive soil tilling practices. Less soil disturbance decreases soil erosion and water loss while increasing beneficial soil organic matter. In a recent Monsanto publication, the biotech company highlights that 27.8 million acres of no-till soybeans were cultivated in 2001, compared to only 13.2 million acres in 1996. Unfortunately, because herbicide resistant crops are unaffected by the topical application of herbicides, a consequence of cultivating herbicide resistant crops can also be an overall increase in herbicide use.

Biotech companies are similarly touting the consumer benefits of transgenic crops. For example, the American Seed Trade Association predicts that transgenic crops “can contain fewer toxins, higher concentrations of nutrients, reduced concentrations of harmful substances[,] ... increased shelf lives, as well as improved flavor, texture, and appearance.” Although most consumers would welcome these traits, the benefits from biotechnology have been exaggerated on occasion. For example, the highly publicized “golden rice” was promoted by industry as the savior for populations with vitamin A deficiency induced blindness. The rice produces beta-carotene, a vitamin A precursor, but at extremely minute levels. Scientists have estimated that a person would need to consume up to nine kilograms of rice to receive the equivalent amount of beta-carotene contained in a few handfuls of green vegetables.

Transgenic crops currently in development push the limits of one’s imagination. The new transgenic crops have been “engineered as biological factories” to produce pharmaceutical and industrial products. One day, these pharm and industrial crops may grow pharmaceuticals, biologics, industrial chemicals, and research chemicals. Biotech companies have predicted these crops will lead to cheaper and faster production of pharmaceutical and industrial proteins, as well as avoid the ethical concerns of utilizing animals as bioreactors. These results may, in turn, lead to lower pharmaceutical prices, increased profits for farmers growing pharm-crops, and the development of orally administered fruit and vegetable vaccines.

2. The Environmental Release of Transgenic Crops During Open-field Tests May Lead to Environmental Degradation

Despite countless claims by the biotech industry that “GMOs are environmentally friendlier than conventional agrisystems,” scientists are unsure whether transgenic crops will harm the environment. Critics of agricultural biotechnology fear that transgenic and conventional plants may outcross and spread genetic pollution throughout the environment, thereby creating “superweeds” and reducing genetic biodiversity. Additionally, the cultivation of transgenic plants may select for weeds and insect pests resistant to popular control measures, requiring the use of harsher herbicides and insecticides, and having unintended consequences for non-target species. Finally, transgenic pharm-crops may contaminate the Nation’s food supply with pharmaceutical proteins or industrial products, exposing humans and animals to a seemingly limitless array of non-food contaminants.
A significant risk associated with the environmental release of transgenic plants is the spread of transgenic DNA to conventional crops and wild relatives.\textsuperscript{47} Pollen from transgenic plants may be dispersed long distances by wind or insect vectors, and may successfully share engineered genetic material with neighboring plants. For example, transgenic plants may outcross with weedy relatives and create hybrid superweed species.\textsuperscript{48} These superweeds could be resistant to insect pests or disease that naturally prevent a species from uncontrolled proliferation, or they could be herbicide tolerant and therefore immune to widely used herbicides. Furthermore, superweeds may have increased reproductive rates or be capable of rapid proliferation under new environmental conditions.

According to an October 1996 \textit{Science Magazine} article, Dr. Allison Snow, an evolutionary ecologist at Ohio State University, believes that biopharming over time will result in the transfer of an engineered gene creating a new weed or invigorating an old one.\textsuperscript{69} In 2002, \textit{Nature} magazine reported that, while studying the reproductive rate of a transgenic insect resistant sunflower, Dr. Snow preliminarily found the engineered organism had a significantly increased reproductive rate.\textsuperscript{70} Dr. Snow’s research team discovered that inserting the Bt gene into wild sunflowers increased seed production by 55\%.\textsuperscript{71} This finding indicates that some engineered organisms could out-compete neighboring plant species and disrupt ecological balance. The \textit{Nature} article reports that, after Dr. Snow revealed her preliminary data at an annual scientific meeting, the biotech companies that were funding the study and providing the test plants denied Dr. Snow further access to the engineered DNA or the seeds utilized in the preliminary study.\textsuperscript{72}

Although no superweeds have been documented, James L. White of APHIS has stated that “gene flow between crops and weeds has been known for over a century, and is not a unique characteristic of engineered plants.”\textsuperscript{73} Regardless of whether gene flow is unique to engineered plants, the potential harm of transgenic gene flow may be greater than previously believed. A recent discovery of genetically engineered DNA in some of Mexico’s native corn varieties surprised even researchers.\textsuperscript{74} Mexico has not approved the commercial cultivation of transgenic corn, so it is highly unlikely the genetically engineered DNA originated in Mexico. This posits the question of whether the Mexican maize could have been pollinated by U.S. transgenic corn. If corn pollen was viable for such a long distance, “crop genes might be able to spread across geographic areas and varieties more quickly than researchers had guessed.”\textsuperscript{75} According to a 2001 \textit{New York Times} article, Dr. Norman C. Ellstrand, an evolutionary biologist at the University of California at Riverside, fears that “other foreign genes — like pharmaceutical-producing genes being developed in crops — could also find their way quickly and unnoticed into distant food sources.”\textsuperscript{76} This genetic invasion may be silent, and long-term human health implications may be apparent only in the distant future.

Additionally, herbicide and insect resistant transgenic crops may rapidly select for pests tolerant to currently available control measures. Random genetic mutation will confer resistance to some individual pest organisms, identical to the development of antibiotic resistance among bacterial pathogens. When all organisms susceptible to a control measure are killed, only resistant individuals survive to propagate the localized population. For example, \textit{Bt} crops produce an insecticide within every cell of the plant. Insect pests living in these fields are thereby constantly exposed to lethal doses of \textit{Bt}, and it is only a matter of time before \textit{Bt}-resistant insects populate the fields.\textsuperscript{77}

The same selection process may create herbicide tolerant weed species. A Canadian study\textsuperscript{78} found a 50\% increase in herbicide use associated with the cultivation of herbicide tolerant crops. Ironically, farmers growing these transgenic crops rely on heavy applications of a single herbicide
because the engineered plant is typically immune to one herbicide. Such increased reliance on a single herbicide is similarly likely to select for herbicide tolerant weed species.

Furthermore, biotechnology may decrease biodiversity by depleting the available gene pool. Future genetic engineering depends on the availability of diverse genetic material. Unfortunately, the creation of transgenic plant species may likely “increase[e] genetic uniformity, [resulting in] a narrowing of the gene pool, and loss of the very genetic diversity that is so essential” to the biotech industry. Biotechnology critic Jeremy Rifkin has described this dilemma as the “massive catch-22 that lies at the heart of the new technology revolution.”

Although scientific study has not proven the safety of transgenic organisms, it has highlighted instances of lax APHIS regulatory oversight. For example, scientists reviewing the petition to deregulate and subsequently commercialize a disease resistant squash found that APHIS apparently relied on an industry “study [that] proved nothing.” Biotechnology critic Jeremy Rifkin cites Dr. Jane Rissler, senior staff scientist at the Union of Concerned Scientists as stating: “We don’t know very much about the risks and the benefits [of transgenic crops]. If we don’t know, why are we doing this?” Furthermore, Rifkin complained that “[y]ou cannot have governments telling us that the technology is safe when there is no science to judge it by.”

3. Hawai‘i, the Open-field Test Capital of the World, Leads the Way in Piercing Agency Secrecy

The collapse of sugarcane in the Hawaiian Islands in the 1990s has left a large percentage of the State’s agricultural lands underutilized. This relatively sudden availability of land, coupled with a year-round growing season and local and state governments friendly to agriculture, has made Hawai‘i “a world leader in the open-field testing of transgenic crops.” As of February 3, 2003, APHIS had issued eighty-three Hawai‘i permits and acknowledged 1,337 notifications for open-field test releases statewide. Since April 2003, however, state and federal case law has drastically reduced the level of confidentiality available to companies seeking open-field testing in Hawai‘i.

The vast majority of Hawaiian field tests involve the cultivation of transgenic corn, yet tests have additionally involved other widely grown crops. Although the majority of field tests involve insect resistant and herbicide tolerant food crops, APHIS has issued at least nineteen permits to field test pharm-plants and industrial plants in Hawai‘i. At least twelve of these release permits involved either a confidential transgene or donor organism, and the majority utilized corn as the host plant.

In order to monitor for gene flow from test species, the sequence of the inserted transgene must be known. The widespread use of the Confidential Business Information (“CBI”) shield, which arises under the federal Freedom of Information Act (“FOIA”) and the Hawai‘i Uniform Information Practices Act (“UIPA”), has impeded independent scientific monitoring of genetic drift by keeping confidential the crucial information necessary to identify gene flow. Furthermore, APHIS has often withheld test site acreage information and generally has not disclosed test site locations. Accordingly, neither farmers nor private citizens have been privy to whether their neighbor is cultivating a genetically engineered organism, or whether the crop is growing a pharmaceutical or industrial protein. Although the USDA has not publicly documented incidents of genetic drift occurring from Hawaiian test sites, the widespread use of CBI has inspired little public confidence that minor incidents of contamination would be discovered or publicized. However, recently in Hawai‘i, for the first time in the U.S., the federal government was required to disclose the specific locations of field tests of genetically engineered crops to the public.
a. CFS's lawsuit against the HDOA

In 2003, the Center for Food Safety (“CFS”), \(^{100}\) represented by Earthjustice, brought two lawsuits attacking agency secrecy concerning test site locations at the state and national level. \(^{101}\) In the first lawsuit, CFS challenged the Hawai‘i Department of Agriculture’s (“HDOA”) denial of public access to records concerning pharm crop field tests. \(^{102}\) CFS sought to compel HDOA to comply with mandatory disclosure requirements under UIPA \(^{103}\) in releasing documents from the USDA related to open-air field testing. Specifically, CFS sought information on the nature of the field tests, their potential impacts in Honolulu, and their regulation by the federal and state authorities. \(^{104}\) The First Circuit Court in Honolulu ordered HDOA to provide its records concerning biopharming to the public and further ordered the agency to explain each item that was blacked out in its released records. HDOA produced this information on April 12, 2004. \(^{105}\)

b. CFS's lawsuit against the USDA

In the second lawsuit, filed in federal court in November 2003, CFS, KAHEA, \(^{106}\) and other Hawai‘i public interest groups \(^{107}\) sought to compel the USDA to comply with NEPA \(^{108}\) and the Endangered Species Act (“ESA”) \(^{109}\) in regulating and testing genetically engineered pharm crops. \(^{110}\) The plaintiffs requested that the Federal District Court of Hawai‘i order the USDA to “immediately terminate all open-air field tests of biopharmaceutical crops” \(^{111}\) until the department had: (1) consulted with the U.S. Fish and Wildlife Service to determine possible effects on endangered species; (2) prepared an Environmental Impact Statement that analyzes environmental impacts and alternatives to open-air trials; and (3) issued new regulations with the purpose of protecting the public and the environment from the adverse effects of pharm crops. \(^{112}\) According to an Earthjustice press release:

[CFS] sought information on the locations of these field tests in response to the government’s arguments that plaintiffs lacked standing to sue because they had not specified the precise locations of the field tests. Magistrate Judge Barry M. Kurren originally ordered discovery of the locations in April 2004, ruling that the mere locations of the field tests were not confidential business information. \(^{113}\)

District Court Judge David A. Ezra sided with CFS and against the USDA, and, on August 5, 2004, he ordered the USDA to disclose the locations of open-air field tests of biopharmaceutical crops in Hawai‘i. \(^{114}\) Rejecting the USDA’s “fears of potential ‘espionage,’ ‘vandalism,’ and ‘civil unrest,’” \(^{115}\) Judge Ezra found that the USDA and the biopharm industry had failed to demonstrate that disclosure of the locations of field tests would cause specific harm. \(^{116}\) Judge Ezra ruled that “the ‘isolated incidents’ raised by defendants failed to make a ‘particularized showing’ of harm.” \(^{117}\) After the court rejected the government’s final motion for a stay of disclosure, the USDA released the information on February 4, 2005. \(^{118}\)

According to an Earthjustice press release: “This [order] marks the first time the federal government has been forced to disclose the location of field tests of genetically engineered crops since it began systematically hiding these locations from the public.” \(^{119}\) However, the press release also stated that Judge Ezra “affirmed the ruling in August, but preliminarily limited disclosure to plaintiffs only, and allowed the government and industry 90 days to come up with better support for denying public access to the information.” \(^{120}\) According to the February 2005 press release, the biotech industry “submitted supplemental arguments, to which plaintiffs responded, but the court has not yet ruled on the public disclosure issue. Until then, plaintiffs cannot reveal the information to the public at large.” \(^{121}\)
Speculation exists over the impacts of this forced disclosure outside of Hawai‘i. Judge Ezra’s order may simply compel biotech companies to look outside of Hawai‘i to conduct tests, or it could set a nationwide standard for how states deal with open-air biotech testing.  

B. THE LEGAL FRAMEWORK TO REGULATE THE ENVIRONMENTAL RELEASE OF TRANSGENIC PLANTS

The U.S. approach to biotechnology regulation is a piecemeal system of shared jurisdiction among the USDA, the Environmental Protection Agency (“EPA”), and the Food and Drug Administration (“FDA”). Congress did not enact legislation to specifically regulate biotechnology, and agency jurisdiction was set up according to the Coordinated Framework for Regulation of Biotechnology (“Coordinated Framework”). The U.S. Office of Science and Technology, an executive agency formed during the Reagan Administration, created the Coordinated Framework. The Coordinated Framework was developed under the belief that “[t]here [was] no scientific basis for specific legislation for the implementation of rDNA technology and applications,” and it authorized biotechnology regulation under existing legislation. Consequently, the shared jurisdiction among federal agencies is exercised under several preexisting unrelated statutes with vastly varying missions and regulatory structures. Critics of the shared regulatory jurisdiction have described the system as “so convoluted and overlapping that it hinders an integrated regulatory approach.”

The USDA, EPA, and FDA oversee only those facets of the development, release, and cultivation of transgenic plants that would otherwise fall under their purview. Accordingly, the USDA, primarily through APHIS, regulates the transportation and environmental introduction of transgenic plants under authority of the Plant Protection Act of 2000 (“PPA”). The EPA ensures the safety of pesticidal substances and chemical substances produced by transgenic crops under authority of the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act. Finally, the FDA regulates the safety of food and feed products derived from transgenic plants under authority of the Federal Food, Drug, and Cosmetic Act. Because EPA and FDA regulatory involvement largely occurs after the initial environmental release of transgenic plants, and often after deregulation by APHIS, EPA and FDA statutory and regulatory frameworks are not discussed in this paper.

1. The Federal Plant Protection Act

The federal Plant Protection Act was enacted on June 20, 2000. Prior to the PPA, the Plant Quarantine Act and the Federal Plant Pest Act provided the USDA with regulatory authority for biotechnology oversight. The PPA presently provides authority to the USDA to prohibit or restrict the movement and environmental introduction of plants, plant pests, and noxious weeds.

The congressional findings section of the PPA illustrates the precautionary approach taken by Congress. When enacting the statute, Congress found that “the detection, control, eradication, suppression, prevention, or retardation of the spread of plant pests or noxious weeds is necessary for the protection of the agriculture, environment, and economy of the United States.” Furthermore, Congress found that “decisions affecting imports, exports, and interstate movement of products regulated under [the PPA] shall be based on sound science.”
The authority to regulate the environmental release of transgenic plants has been delegated to APHIS. APHIS does not have the statutory authority to regulate the movement of a transgenic plant solely because it has been genetically engineered. Rather, APHIS’s regulations prohibit or restrict the movement within the United States, or the environmental release, of any “regulated article,” defined as:

Any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent [is a listed plant pest], or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which the Administrator determines is a plant pest or has reason to believe is a plant pest.

Accordingly, a transgenic plant is a regulated article under the PPA if any part of the plant is a plant pest, an unclassified organism, or if the Administrator of APHIS believes the transgenic plant is a plant pest. A “plant pest” is defined to mean:

Any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants.

For any regulated plant pest, APHIS requires field testers to either obtain a permit or give agency notification prior to releasing the transgenic organism into the environment during an open-field test.

a. APHIS regulates the environmental release of transgenic plants by permit or by agency notification

Section 411 of the PPA prohibits the unauthorized movement of any plant pest and requires the issuance of a permit prior to the environmental release of a regulated article. If a regulated article meets all the requirements and performance standards set forth in sections 340.3(b) and (c) of APHIS’s regulations, the release does not require a permit but rather falls under the expedited notification procedure. A release permit is therefore required when: the transgenic plant is, or the inserted genetic material was derived from, a listed noxious weed; the plant produces a pharmaceutical protein or a viable vector agent; or the plant or any offspring may persist in the environment after the field release.

An application for a release permit must be submitted to APHIS at least 120 days prior to the proposed environmental release to allow for review of any potential environmental impacts. Although detailed information regarding the molecular biology of the transgenic organism and field trial location must be submitted in the permit application, APHIS regulations allow the applicant to flag any trade secret or confidential business information (“CBI”). Any information marked as CBI is kept confidential by APHIS, and APHIS is not required by its own regulations to provide this information to a state department of agriculture for review. APHIS has issued 1,045 release permits nationwide, including eighty-eight permits for field trials in Hawai‘i. Surprisingly, APHIS has not yet denied a single release permit for a regulated transgenic crop.
Section 411 of the PPA additionally provides APHIS the authority to promulgate regulations to allow the movement of certain plant pests when the Secretary “finds that a permit… is not necessary.” Accordingly, if the regulated article meets the six requirements and six performance standards enumerated in sections 340.3(b) and (c), an applicant may proceed with an open-field trial of that organism by merely notifying APHIS thirty days prior to the intended release. The National Research Council, in its 2002 study on the scope and regulation of transgenic plants, found that “nearly 99% of all field tests” proceed under this expedited notification process.

b. The PPA provides authority to APHIS to deregulate transgenic plants after open-field testing

Finally, the PPA provides authority to APHIS to deregulate a transgenic plant for commercial sale and cultivation. A petition to deregulate a regulated article “must present a full statement explaining the factual grounds why the organism should not be regulated [by APHIS, including] copies of scientific literature, copies of unpublished studies,… and data from tests performed upon which to base a determination.” Before making its decision to deregulate, APHIS must publish a notice in the Federal Register and accept public comment. After APHIS deregulates a transgenic plant, it can no longer exercise any regulatory oversight over the movement of the species or its progeny. Accordingly, “separate deregulated lines can be mated with one another via conventional crossbreeding to bring together different transgenes in the same plant, and such plants are not subject to regulatory evaluation.” Furthermore, it is possible to move the engineered DNA from a deregulated organism to distantly related species through conventional crossbreeding, thereby creating a new transgenic organism that is not subject to any APHIS oversight.

To date, APHIS has not denied a single deregulation petition. APHIS has received ninety-seven deregulation petitions; sixty petitions were approved, five are pending a decision, and twenty-five were withdrawn by the petitioner. Although a deregulation petition requires the inclusion of “[r]elevant experimental data and publications,” APHIS “relies on data supplied primarily or exclusively by the applicant.”

Scientists reviewing deregulation petitions have been highly critical of the quality of the data supplied by the applicant, stating that APHIS “has frequently relied on unsupported claims and shoddy studies by the seed companies.” For example, a transgenic virus resistant squash produced by Asgrow Vegetable Seeds was deregulated in 1996. Because wild squash grows within the U.S. and could hybridize with the transgenic squash, the critical question for deregulation was whether viral infection naturally keeps the wild populations in check. Asgrow determined that virus infection was not the limiting factor by surveying fourteen wild squash plants in nine different locations. Because viral infection was not present in any surveyed plants, Asgrow concluded that viral infection does not naturally limit wild squash populations.

Based on the results of the survey, Asgrow determined that the spread of viral resistance from transgenic squash to wild squash would not create a superweed. When the Asgrow study was reviewed by environmental risk experts, they concluded that “the study proved nothing.”

Norman C. Ellstrand, an evolutionary biologist at the University of California at Riverside, explains:
What if we asked if the most important disease controlling human population sizes, malaria, was in fact an important disease… If you took 14 random individuals from around the world, the chances of picking one that has malaria would be relatively low, making the chance of getting a misleading result really high.186

Scientists at Asgrow acknowledged that the survey was not as thorough as it could have been.187 David Tricoli, the managing research scientist at Asgrow’s parent company, stated that “[t]his was a learning process for all of us… I’m a molecular biologist. I’m not an ecologist.”188 Because APHIS does not regularly seek outside scientific review on the quality of the scientific data contained in deregulation petitions, scientists report that “much of the data [relied upon by APHIS are] from critically flawed experiments.”189

2. The National Environmental Policy Act

The National Environmental Policy Act requires “to the fullest extent possible… [that] all agencies of the Federal Government” produce an environmental impact statement (“EIS”) for “major Federal actions significantly affecting the quality of the human environment.”190 Pursuant to the Council on Environmental Quality (“CEQ”) regulations, the purpose of NEPA is to “insure that environmental information is available to public officials and citizens before decisions are made and before actions are taken.”191 Accordingly, an EIS or an environmental assessment (“EA”) must be prepared unless the major federal action is categorically excluded.192

The PPA does not specifically require the preparation of an EA or an EIS prior to the environmental release of a transgenic crop,193 but the policy of the USDA is that “all… programs of the various USDA agencies shall be planned, developed, and implemented so as to achieve the goals and to follow the procedures declared by NEPA in order to assure responsible stewardship of the environment for present and future generations.”194 APHIS’s own NEPA regulations generally state that the approval and issuance of permits involving genetically engineered species are actions that normally require an EA.195 Contrary to this broad statement, however, the regulations then state that “permitting, or acknowledgment of notifications for, confined field releases of genetically engineered organisms and products” are actions categorically excluded from NEPA compliance.196 The regulations explain that this exclusion is appropriate because the means to avoid or minimize any adverse environmental impacts are “built right into the action[]” itself.197 Furthermore, the regulations provide an exception to the categorical exclusion for “action[s that] may have the potential to affect ‘significantly’ the quality of the ‘human environment.’”198 Therefore, APHIS ultimately accepts that it must prepare an EA or an EIS when the environmental release of a transgenic crop may significantly affect the quality of the human environment.199

CEQ’s NEPA regulations state that a determination of whether an action “significantly” affects the environment “requires considerations of both context and intensity.”200 Particularly, CEQ regulations indicate that the significance of a site-specific action, such as acknowledging or permitting the release of transgenic organisms, “would usually depend upon the effects in the locale rather than in the world as a whole.”201 To determine the significance of an action’s “intensity,” an agency must analyze the severity of an impact.202 Specifically, an agency should consider “[t]he degree to which the effects on the quality of the human environment are likely to be highly controversial[, and t]he degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks.”203
In the 1985 case, *Foundation on Economic Trends v. Heckler*, the D.C. Circuit Court of Appeals discussed the significance of environmental releases of transgenic organisms when determining the adequacy of an EA for the deliberate field release of a genetically engineered bacterium.\(^{204}\) The court affirmed an injunction to prevent the release of the ice-minus bacteria,\(^{205}\) even though the engineered bacteria occur in nature.\(^{206}\) The court stated that “the environmental consequences of dispersion of genetically engineered organisms are far from clear,”\(^{207}\) and that these unknown consequences therefore constituted a significant environmental concern requiring a detailed analysis in an EA.\(^{208}\)

APHIS has a spotty track record regarding NEPA compliance. APHIS has permitted 1,045 environmental releases to date, yet has prepared a mere twelve EAs for decisions to issue a release permit.\(^{209}\) The EAs all concluded with a finding of no significant impact (“FONSI”).\(^{210}\) APHIS’s online database provides no explanation regarding the criteria used to single out these twelve permit applications, or why all similar release permit applications did not receive the same level of environmental review.\(^{211}\)

The application of biotechnology to agriculture may offer both environmental and consumer benefits, but the scope of resulting environmental harm is currently unknown. The PPA provides authority to APHIS to regulate the movement and environmental release of transgenic organisms, yet the agency apparently does not adhere to a consistent NEPA review prior to acknowledging or permitting such an environmental release. Furthermore, the adequacy of APHIS’s regulatory framework under the PPA to prevent environmental degradation is questionable. Accordingly, a more precautionary regulatory approach may be required to comply with the purposes and policies of the PPA and NEPA.

### 3. Changes at APHIS

On October 17, 2003, the USDA created a “compliance and enforcement unit” within APHIS’s Biotechnology Regulatory Services (“BRS”) program; the program responsible for regulating the release of genetically engineered organisms.\(^{212}\) According to the USDA press release, the unit accompanies other changes in regulations, permit conditions, inspections, and auditing procedures designed to enhance compliance with APHIS’ biotechnology regulations.\(^{213}\)

On December 3, 2003, the USDA also established an “environmental and ecological analysis unit” within BRS.\(^{214}\) The stated purposes of the new unit are to assist with an anticipated increase in permit applications, to ensure compliance with environmental regulations, and to coordinate oversight of the BRS’s environmental impact statements.\(^{215}\)

On January 22, 2004, the USDA Secretary then in office, Ann M. Veneman, announced the USDA’s intention to “update and strengthen its biotechnology regulations for the importation, interstate movement and environmental release of certain genetically engineered organisms.”\(^{216}\) The anticipated changes include initiating a new multi-tiered, risk-based permitting system and enhancing the deregulation process, which, according to the USDA, “will be science and risk-based.”\(^{217}\) The next day, on January 23, 2004, APHIS issued a notice for public comment in the Federal Register on its intent to produce an EIS for its proposed regulation changes; the comment period ended in March 2004,\(^{218}\) then briefly reopened from March 29, 2004 until April 13, 2004.\(^{219}\)

As of November 2005, the BRS website states that BRS “will provide a notice in the Federal Register when the [EIS] draft is available and will also post information on this website at that time.”\(^{220}\)
III. ANALYSIS

Agricultural biotechnology offers many potential advantages over conventional farming. The highly unregulated “green revolution” has contributed to widespread environmental pollution and degradation. Agricultural biotechnology therefore presents the opportunity to decrease dependence on many of the negative practices associated with modern-day farming, such as extensive soil disruption, heavy utilization of increasingly scarce water, and large applications of insecticides, herbicides, and fertilizers.

Unfortunately, the environmental harm resulting from previous technological revolutions was often discovered decades too late. Proceeding without a clear understanding of the consequences of new technologies has often permitted widespread ecological degradation. The utilization of agricultural biotechnology may contaminate the environment with one further type of pollution, genetic pollution. The true environmental risks of releasing transgenic organisms remain unknown, and there is no known conceivable method to clean-up or contain this pollution if deleterious effects are discovered. Accordingly, we need to proceed with caution until sound science can analyze the environmental ramifications of transgenic organism releases. The current regulatory regime is inconsistent with NEPA because it inadequately assesses the environmental effects of field releases. Furthermore, the regulatory regime is inconsistent with the purposes and policies of the PPA because the framework does not base decisions to release transgenic organisms on sound science.

A. UNKNOWN ENVIRONMENTAL EFFECTS RESULTING FROM THE RELEASE AND CULTIVATION OF TRANSGENIC ORGANISMS REQUIRE GREATER PRECAUTIONARY REGULATORY OVERSIGHT BY APHIS

An adequate assessment of the risks involved in releasing transgenic organisms requires a detailed ecological study of the possible direct and indirect effects of these organisms on the larger environment. Presently, the only clear fact is that science has not produced a body of evidence sufficient to prove that the release of transgenic organisms is either environmentally benign or destructive. Accordingly, scientific consensus about the likely ramifications of large and small-scale environmental releases is lacking both within the U.S and abroad.

Widespread use of CBI in publicly available documents creates a veil of secrecy that impedes independent scientific monitoring and public review. Even the National Research Council, which was asked by the USDA to complete a review of the adequacy of APHIS’s regulatory oversight, stated that “the committee often found it difficult to gather the information needed to write [its] report due to inaccessible CBI.” This excessive use of CBI erodes public confidence in the regulatory process, while simultaneously frustrating attempts to independently study the environmental effects of transgenic releases. Objective scientists cannot monitor for gene flow because, with a few exceptions, the location and content of field tests is kept confidential. The public is therefore completely dependent upon the regulatory oversight of APHIS to prevent the escape and dissemination of transgenic organisms in the environment.

Furthermore, the effects of incorporating novel traits into existing species may have profound unforeseen effects. If negative ecological consequences result from the release of genetically engineered organisms, existing technologies cannot effectively contain or eradicate the genetic pollution. A decision to release a transgenic crop is therefore a permanent one. This
decision should not be made hastily, and should require an assumption that significant adverse environmental effects may occur when genetically engineered organisms are released from the confines of the laboratory.

Environmental risk analysis often entails a cost-benefit analysis of the risk of a particular action and the cost society is willing to bear to prevent that risk. This traditional analysis is difficult, if not impossible, for the release of transgenic organisms because the risks are unknown. Furthermore, the risks may be irreversible, regardless of funds available to remedy any resulting genetic pollution. Accordingly, it is reasonable to require APHIS to decide to release transgenic organisms only after considering all potential environmental risks.

Given the scientific uncertainty of the risks posed by the release of transgenic organisms, the regulatory framework utilized by APHIS should ultimately be based on the precautionary principle. In essence, this principle states that the lack of scientific knowledge about a risk should not impede actions to reduce that risk. The precautionary principle, while rare in U.S. federal law, is increasingly included in international environmental agreements and declarations. If this principle were applied, APHIS would make decisions to release a transgenic plant based on a consideration of all possible environmental effects, not merely those with scientific proof.

B. NEPA REQUIRES THE PREPARATION OF AN EA PRIOR TO THE DECISION TO ACKNOWLEDGE OR PERMIT THE RELEASE OF TRANSGENIC ORGANISMS THAT MAY SIGNIFICANTLY AFFECT THE HUMAN ENVIRONMENT

NEPA imposes a duty on agencies to analyze the environmental impacts of major federal actions, yet this duty is not clear when the action is to acknowledge or permit open-field releases of transgenic crops. APHIS’s NEPA regulations indicate that the approval and issuance of a permit for a proposal involving a transgenic organism is an action that normally requires the preparation of an EA, but qualifies this broad statement by categorically excluding permitting and acknowledging the confined field release of transgenic crops. A quick read of this exclusion would lead one to believe that APHIS is not bound by NEPA when deciding whether to allow open-field releases of genetically modified crops. A further analysis of APHIS’s NEPA regulations, considering both the exceptions to the categorical exclusion and the rationale for the exclusion, indicate that the categorical exclusion is illogical. As explained below, this APHIS policy of avoiding NEPA evaluation of the environmental impacts of open-field releases violates the requirements of the PPA.

1. The Open-field Release of Many Transgenic Organisms May Potentially Have Significant Adverse Environmental Effects

Pursuant to APHIS’s NEPA regulations, an exception to the categorical exclusion occurs when the federal action “may have the potential to affect ‘significantly’ the quality of the ‘human environment.’” With regard to significance, CEQ regulations instruct all agencies to consider how controversial or unknown the potential adverse environmental effects may be, or whether the possible effects involve unique risks. When judged according to these standards, most open-field releases of transgenic crops may potentially have significant adverse environmental effects and therefore should require the preparation of an EA or EIS prior to their release.

The potential environmental effects of releasing genetically engineered organisms are highly controversial. The biotech industry and proponents of the technology claim that confined field releases have few if any potential adverse environmental effects and that these effects are similar
to those of traditional agricultural crops. Proponents tend to focus on the potential environmental and human health benefits of the large-scale cultivation of transgenic crops, downplaying any opposition as unfounded. Concerned scientists and NGOs paint a completely different scenario, highlighting the potential disastrous effects of gene flow and selection of resistance in pests. Such doomsday predictions may be exaggerated, but so too may be the industry predictions.

Regardless of the accuracy of either prediction, the environmental effects of releasing transgenic organisms are undoubtedly controversial. The industry has not performed the proper experiments to demonstrate the safety of its field tests, yet often inhibits objective research of the potential effects by denying access to regulated transgenic organisms early in the development process. APHIS relies on often-flawed industry data when determining the safety of these organisms under the assumption that no news is good news. The bottom line is that rDNA technology is still relatively new and the effects of its release cannot be predicted according to existing scientific knowledge.

Furthermore, the relevant case law on point agrees that the release of transgenic organisms may have significant adverse environmental effects. In Foundation on Economic Trends, the D.C. Circuit made this determination because “the environmental consequences of dispersion of genetically engineered organisms are far from clear.” Although this case is nearly twenty years old, the state of scientific knowledge regarding the effects of dispersion is largely unchanged. Scientists remain unable to predict these consequences. Therefore, in accordance with the letter and spirit of the CEQ’s NEPA regulations, an EA or EIS should be performed prior to the release of transgenic organisms until science can predict, with a high degree of confidence, the actual implications of the environmental release.

2. APHIS’s Categorical Exclusion Is Inappropriate Because of Lax Enforcement of the Environmental Safeguards Incorporated Into the Notification and Permit Procedures

APHIS justifies its categorical exclusion for open-field tests because, it asserts, the means to avoid adverse environmental impacts are incorporated into the permitting and notification processes. This justification is inappropriate because the incorporated environmental safeguards are only loosely followed by APHIS in its decisionmaking process. APHIS’s regulations allow the release of transgenic crops under the agency notification procedure if an individual can certify the organism meets enumerated requirements and performance standards. Because these standards are inherently not certifiable, the process should not be allowed to replace the preparation of an EA or EIS required by NEPA.

For example, biotech companies and research institutions must certify that “[t]here [is] no viable vector agent associated with the regulated article.” The regulations define vector to mean “[o]rganisms or objects used to transfer genetic material from the donor organism to the recipient organism.” Under this definition, pollen from a transgenic plant could be considered a vector. Indeed, pollen, used in the sexual reproduction of plants, functions precisely to transfer genetic material to a recipient organism. Although efforts can be taken to reduce the amount of viable pollen originating from an open-field test, it is impossible to certify as required by the regulation that there is “no viable vector.” Furthermore, the regulations require a certification that “[t]he regulated article will not persist in the environment, and [that n]o offspring can be produced that could persist in the environment.” This requirement is similarly impossible to certify. The only way to conform to this standard would be to require all transgenic organisms be sterile. This practice is not required by APHIS. Accordingly, APHIS is allowing 99% of field trials to proceed under regulatory requirements that are nearly impossible to meet.
If all of the performance standards could be certifiably met, APHIS would likely be correct that a NEPA-style environmental assessment would be duplicative and unnecessary. Field tests would be conducted in such a way that no risk of dissemination into the environment would be present. No risk of dissemination could indeed be comparable to a finding of no significant impact. Realistically, however, potentially significant environmental effects stemming from the release of transgenic crops exist, and the weak safeguards built into the current decisionmaking process do not replace the assessment required under NEPA.

Therefore, APHIS should be performing an EA prior to the decision to release most transgenic organisms. Even if many releases are considered routine by APHIS, the environmental effects remain unknown. The preparation of an EA would therefore highlight where further scientific research is required, and ultimately promote a better understanding of the ramifications of field releases.

C. APHIS’S WEAK REGULATORY OVERSIGHT IS INCONSISTENT WITH THE PURPOSE AND POLICIES OF THE PPA

The PPA does not precisely specify how USDA should regulate the environmental release and dissemination of plant pests, but contains a congressional findings section that represents the purposes and policies of the Act. Although these findings are not legally binding, they indicate the intent with which the PPA should be read and interpreted. Because the statute authorizes USDA to promulgate regulations to control the environmental release and dissemination of plant pests, these findings should additionally be evident in the purposes and policies of any resulting regulations.

One such finding is that “decisions affecting imports, exports, and interstate movement of products regulated under [the PPA] shall be based on sound science.” Accordingly, Congress intended USDA to utilize sound scientific data when deciding whether to permit the movement, or environmental release, of a regulated article. The term “sound science” is not statutorily defined, but its meaning can be inferred by combining the definitions of each individual word. The *Oxford English Dictionary* defines “sound” to mean “[i]n full accordance with fact, reason, or good sense; founded on true or well-established grounds; free from error, fallacy, or logical defect; good, strong, valid.” The *Oxford English Dictionary* defines “science” to mean “[k]nowledge acquired by study.” Accordingly, “sound science” can be defined as knowledge derived from experiments that are designed and performed without error or logical defect.

Furthermore, Jane Rissler, senior staff scientist at the Union of Concerned Scientists, has identified four conditions that “must be met” for data to be considered “sound science” for biotech regulation: (1) “the science must exist”; (2) “the government must carefully and rigorously evaluate the experiments, monitoring methods, and data”; (3) “the quality of the experiments … must be high[, and] the work must meet generally accepted standards… set or agreed to by nonindustry scientists”; and (4) “the science… must be known to the public.”

Rissler’s first condition, that the science must exist, is oftentimes not met for transgenic testing. Concerned scientists have repeatedly stated that the proper experiments are not being performed for crop releases. Furthermore, scientists who have reviewed permit applications for open-field tests concluded that APHIS “has frequently relied on unsupported claims and shoddy studies by the seed companies.” Therefore, Rissler’s third condition is additionally not met. Finally, the condition that science be publicly available is often made impossible by APHIS itself. The widespread use of CBI and heavy reliance on unpublished data impede efforts by the public to understand the basis on which APHIS is making its decisions.
Accordingly, any claim that APHIS utilizes “sound science” when deciding whether to permit the environmental release of transgenic plants is somewhat comedic. This reliance on unsound science is not in accordance with the congressional findings in the PPA and should be rectified to require adequate consideration of potentially adverse environmental effects.

IV. RECOMMENDED MODIFICATIONS TO APHIS’S REGULATION OF TRANSGENIC CROP RELEASES

Biotechnology offers seemingly unlimited opportunities to improve agricultural efficiency and reduce the adverse environmental impacts of food production. The research and development of rDNA technology therefore needs to continue without undue regulatory burden. Simultaneously, current scientific knowledge cannot predict the actual ramifications of the intentional release of genetically engineered organisms. Because genetic pollution is impossible to contain or eradicate, decisions regarding intentional releases must be made with utmost care and caution. The following proposed modifications to APHIS’s regulatory oversight would reduce the risk of permitting the intentional release of organisms with adverse environmental effects by increasing the scrutiny of permit applications and release notifications prior to the initial release.²⁶⁷

A. APHIS SHOULD UTILIZE “SOUND SCIENCE” AND SEEK PEER REVIEW OF RELEASE REQUESTS WHEN DECIDING TO ALLOW THE RELEASE OF TRANSGENIC ORGANISMS

To ensure that APHIS’s decisions are based on sound science and to increase public confidence in agency oversight, APHIS should actively seek independent scientific review of all notification and permit applications. Objective peer review would test the rigor of the scientific data provided by biotech companies and help insure that only sound science was relied upon in the APHIS decisionmaking process. The National Research Council, after completing its review of the APHIS regulatory process in 2002, recommended instituting such a peer review process.²⁶⁸ According to the Council, “[e]ven if the APHIS staff were larger and more balanced in expertise, an external scientific peer review process would still likely raise and address issues that would be missed by the staff.”²⁶⁹

Implementing the sound science requirement and peer review process would require changes to APHIS’s PPA regulations.²⁷⁰ Presently, there is little mention of the quality of scientific data required in notification requests and permit applications, and there is no required or permitted peer review process. These changes to the regulatory process would likely require extending the thirty-day review period for notifications as well as the 120-day review period for permit requests. This additional delay would not be unduly burdensome to the biotech industry. The review period would be extended only by the time necessary for proper scrutiny of scientific methods utilized and data presented to APHIS. Furthermore, objective peer review of scientific methods and data is common practice in the scientific community. Respected journals require this review process prior to publishing any articles. It is reasonable to hold scientific data relied upon by APHIS to the same level of scrutiny because public health and environmental protection depend upon responsible and careful decisions.
B. APHIS SHOULD PERFORM AN EA/EIS FOR ALL RELEASES THAT MAY POTENTIALLY HAVE SIGNIFICANT ENVIRONMENTAL EFFECTS

APHIS’s NEPA regulations require the preparation of an EA or an EIS prior to the acknowledged or permitted release of any transgenic organism that may potentially have significant environmental effects. Currently, APHIS apparently operates under the assumption that decisions to release transgenic organisms during field trials have no significant environmental effects. Because the state of scientific knowledge does not support this assumption, APHIS’s categorical exclusion for open-field releases should be repealed. Field releases should be exempt from NEPA requirements only when scientific consensus indicates there is no potential for significant environmental effects. Reversing the default assumption would better safeguard the environment from hasty decisions to permit the release of organisms that may have significant adverse environmental effects.

This recommendation requires changes to APHIS’s NEPA regulations. Although requiring the preparation of an EA/EIS would be more burdensome to APHIS, this imposition is reasonable because the agency has been delegated authority to regulate such releases to prevent the dissemination of regulated articles. Avoiding increased agency burden should not be an acceptable excuse to disregard NEPA mandates.

C. APHIS SHOULD DISCLOSE TEST SITE LOCATIONS AS WELL AS THE MOLECULAR BIOLOGY OF TEST ORGANISMS

Presently, the APHIS regulatory process is cloaked in unnecessary secrecy. APHIS should disclose all test site locations as well as the molecular biology of test organisms in order to enable independent scientific monitoring of the effects of releasing transgenic organisms. Currently, APHIS’s regulatory framework regarding open-field testing caters to the interests of the biotechnology industry. Other than recent court-ordered releases of biopharmaceutical crop information in Hawai‘i, APHIS keeps confidential all open-field test locations and often keeps confidential even acreage information in order to prevent the public from discovering the locations of open-field tests. The only logical explanation for this cloak of secrecy is to protect the economic interests of the biotech companies. This practice prevents competing biotech companies from discovering which transgenic crops are involved in the research and development stage and additionally protects the test site from vandalism.

Simultaneously, this non-disclosure practice places the crops of conventional and organic farmers at risk of contamination due to genetic drift. Presently, a farmer has no way of knowing whether a neighbor’s field contains a conventional or a transgenic crop and has no way to monitor for genetic contamination. Contamination from gene flow could be devastating to the economic interests of conventional and organic farmers. Organic farmers risk losing their organic status, and all farmers risk losing a market for their crop if contaminated by genetically modified DNA.

Ultimately, the non-disclosure policy indicates that the economic interests of powerful biotech companies are considered by APHIS to be more important than the economic interests of farmers. It is difficult to believe that biotech companies truly fear competing companies entering a test field to steal research and development data. The most logical explanation is that biotech companies fear vandalism of test sites. The non-disclosure policy places at risk individuals that neither assumed nor caused the risk. If biotech companies fear vandalism of test sites, it should be their responsibility to pay for necessary security. A policy of disclosing both test sites and test subjects would return the economic burden to the rightful owner.
V. Conclusion

We are at a juncture, potentially embarking on a path to rectify many environmental harms associated with the modern-day farm. Alternatively, history could be repeating itself, and transgenic crops may be spreading a new form of pollution throughout the environment. Until science can demonstrate upon which path we are currently traveling, we should make precautionary decisions by assuming that at least some of the potential environmental threats may be accurate. While the proposed changes in APHIS oversight of biotechnology as well as recent trends in Hawai‘i case law may suggest a more protective regulatory framework for transgenic crop technology, the danger that is inherent in open-field testing of transgenic crops must not be overlooked.

The USDA has already permitted widespread commercial cultivation of first generation transgenic crops, yet we have the option to proceed at a slower pace with the next generation. We can no longer afford to proceed under the guise that “no news is good news.” Accordingly, APHIS should more strictly scrutinize notification requests and permit applications for transgenic crops until the myriad of disconcerting scientific questions are publicly answered.
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2 An organism is “transgenic” when a gene has been inserted into its genome through genetic engineering. STEPHEN NOTTINGHAM, GENESCAPES: THE ECOLOGY OF GENETIC ENGINEERING VII (Zed Books 2002) (defining “transgene” and “transgenic plant”).


4 The term “open-field” refers to the cultivation of crops in an open field, as opposed to in a contained environment.


6 TESTS CONDUCTED, supra note 5.


8 U.S. Investigating, supra note 1, at C7.

9 Id.

10 Gene-Altered Pharmaceutical Corn, supra note 3, at A15.


12 The term “genetic pollution” refers to “the unplanned spread of genetically modified organisms… and the transfer of transgenes to unmodified organisms.” NOTTINGHAM, supra note 2, at 62.


14 The term “phenotype” refers to “[t]he detectable outward manifestations of a specific [genetic makeup].” ANTHONY J. F. GRIFFITHS ET AL., AN INTRODUCTION TO GENETIC ANALYSIS 872 (W.H. Freeman & Co. 1996).


16 NOTTINGHAM, supra note 2, at 33-47.

17 Id. at 47-53.


20 NOTTINGHAM, supra note 2, at 47. Nottingham states:

Transgenic crops released to date have been referred to as “first generation” crops. They have been modified for a limited set of agronomic benefits. A ‘second generation’ of transgenic crops is being developed. They will have a much wider range of modifications and offer potentially greater benefits to society at large.

Id.
21 See generally id.
22 See generally id.
25 Id. § 340.4 (requiring a permit when the transgene or transgenic plant is a known plant pest, or when the transgenic plant does not meet the enumerated requirements and performance standards in 7 C.F.R. § 340.3).
27 FIELD TEST RELEASES, supra note 15.
28 Id. (searching the database by “location” = Hawai‘i). Because some trial requests are either pending, were withdrawn, or denied, the total number of field trials that have been permitted in Hawai‘i as of February 12, 2005 is 1,694. Id.
29 Id.
30 NOTTINGHAM, supra note 2, at 1.
31 Saigo, supra note 18, at 782.
32 NOTTINGHAM, supra note 2, at 4.
33 Id.
34 Saigo, supra note 18, at 782.
35 Id.
36 COMM. ON ENVTL. IMPACTS ASSOCIATED WITH COMMERCIALIZATION OF TRANSGENIC PLANTS, NAT’L RESEARCH COUNCIL, ENVIRONMENTAL EFFECTS OF TRANSGENIC PLANTS: THE SCOPE AND ADEQUACY OF REGULATION 18 (National Academy Press 2002) [hereinafter COMM. ON ENVTL. IMPACTS].
37 To create a transgenic plant, the gene(s) of interest must first be isolated from the donor organism. To insert the gene(s) into the host organism, the genetic material must either be physically injected or shot into the cell, or introduced via bacteria or viral infection. A marker gene within the transgene construct is utilized in order to determine if the transgene has been successfully integrated into the host genome. Oftentimes, this marker gene encodes for antibiotic resistance. Therefore, all resulting progeny cells that are resistant to the specific antibiotic additionally express the protein encoded by the transgene. See generally GRIFFITHS, supra note 14.
38 COMM. ON ENVTL. IMPACTS, supra note 36, at 18.
39 See id.
42 WIECZOREK, supra note 40.
43 Phifer & Wolfengarger, supra note 19, at 2091.
45 Saigo, supra note 18, at 785.
46 WEICZOREK, supra note 40, at 2.
48 Id.
49 For example, the application of active pesticide ingredients decreased by 8.2 million pounds between 1997 and 1998. Phifer & Wolfenbarger, supra note 19, at 2090 (citing ECON. RESEARCH SERV., U.S. DEP’T OF AGRIC., GENETICALLY ENGINEERED CROPS: HAS ADOPTION REDUCED PESTICIDE USE?, at http://www.ers.usda.gov/publications/agoutlook/aug2000/ao273f.pdf (last visited Mar. 31, 2005)). This 3.5% nationwide reduction in pesticide use corresponded to an increase in the cultivation of transgenic crops. Id. After the figures are standardized for annual variations in pesticide use, it is estimated that the cultivation of transgenic crops resulted in a 2.5 million pound decrease in pesticide application. Id.
50 Id. at 2091.
51 Saigo, supra note 18, at 786.
52 Phifer & Wolfenbarger, supra note 19, at 2091 (citing R. Q. Cannell & J. D. Hawes, Trends in Tillage Practices in Relation to Sustainable Crop Production with Special Reference to Temperate Climates, 30 SOIL TILL. RES. 245 (1994)).
53 Id.
55 See Phifer & Wolfenbarger, supra note 19, at 2091 (usage of herbicides increased in 1998, but in fewer applications). See also NOTTINGHAM, supra note 2, at 33-34. Biotech companies likely intended this result, as transgenic herbicide resistant crops are engineered to be resistant only to the company’s herbicide. Id. Because the plant is nearly impervious to the herbicide, farmers can apply greater quantities without fearing harm to the crop. Id. This results in greater sales of a company’s herbicide. Id.
56 Saigo, supra note 18, at 787-88 (citations omitted).
58 ENVTL. NEWS NETWORK, supra note 57. See also Marion Nestle, Genetically Engineered “Golden” Rice is Unlikely to Overcome Vitamin A Deficiency, 101 J. AM. DIETIC ASS’N 288 (2001). When scientists at the International Rice Research Institute were questioned about the low levels of beta-carotene, “[t]hey confirmed that the currently available golden rice produces very low levels of beta-carotene, and that higher amounts of this provitamin A would be needed to correct nutritional deficiencies.” Id.
59 UNION OF CONCERNED SCIENTISTS, supra note 41, at 1-2.
60 The term “biologics” refers to “complex biological products such as antibodies, vaccines, and blood products used in human and veterinary medicine.” Id. at 3.
61 Id. at 2-4.
62 Id. at 4-5.
63 Id. See also Andrew Pollack, Vaccines Delivered by Fork, Not Needle, N.Y. TIMES, May 14, 2000, at I26.
64 Hails, supra note 19, at 654. “Although there is plenty of evidence that modern farming methods have reduced biodiversity in many countries, a report by the British government’s advisers on GM releases expresses a widely held view when it says that researchers do not yet know whether the planting of genetically modified crops will make things better or worse.” Id.
65 The term “conventional” refers to non-transgenic organisms.
The term “superweed” has been coined to describe the herbicide, insect, or disease resistant hybrid weed resulting from the outcrossing of a transgenic cultivated species and a wild weedy relative. James Kling, *Could Transgenic Supercrops One Day Breed Superweeds?*, 274 SCIENCE 180 (1996).


“[T]he seed firms say that they no longer want to continue the research because they do not plan to seek permission from the US government to sell transgenic sunflower seeds.” *Id.*


> There are many examples of hybridization and introgression between domesticated plants and their wild relatives. Many of these involve hybridization that has been implicated in weed evolution. One of the best examples is Johnsongrass (*Sorghum halepense*) which arose from the hybridization of cultivated sorghum (*S. Bicolor*) and the wild *S. Propinquum*. Some of the ecological traits thought to have been acquired from the crop include earlier flowering, greater seed production, larger individual seed weight, and earlier emergence, traits that are often associated with weediness.

*Id.*


Claire Hope Cummings, *Genetic Engineering in the Garden of Eden: Basic Information About Agricultural Biotechnology for Hawai’i*, at http://kahea.org/gmo/pdf/GMO_Background_HI.pdf (last visited Mar. 31, 2005). “Eight species of insects have developed some level of resistance to Bt. . . . As a result of rapidly developing resistance, both Bt sprays and Bt crops are rapidly becoming ineffective.” *Id.*


See *Squash with Altered Genes, supra* note 68, at A1.

*Id.* (paraphrasing experts in environmental risk). To determine that populations of wild weedy squash relatives were not kept in check by disease, the biotech company looked for disease in 14 plants from 9 locations. *Id.*

*Gene-Altered Crop Studies, supra* note 83, at A1 (referring to the release of transgenic crops into the ecosystem).


FIELD TEST RELEASES, supra note 15 (searching database by location).

See infra Section II.A.3.a-b.

FIELD TEST RELEASES, supra note 15 (searching database by location and organism). Additional crops include anthurium, barley, coffee, cotton, dendrobium, papaya, pineapple, potato, rice, soybean, sugarcane, sunflower, tobacco, tomato, and wheat. Id.

Id. (searching permit database by location and phenotype).

See generally ANIMAL AND PLANT HEALTH INSPECTION SERV., U.S. DEP’T OF AGRIC., INSTRUCTIONS FOR SUBMITTING CONFIDENTIAL BUSINESS INFORMATION (CBI) AND CBI-DELETED INFORMATION, at http://www.aphis.usda.gov/brs/cbinfo.html (last visited Mar. 21, 2005). “Financial or commercial information the applicant does not want disclosed for competitive reasons can be claimed as confidential business information. Applicants must submit a written justification to support each claim…. ‘trade secrets’ (information relating to the production process, such as formulas, processes, quality control tests and data, and research methodology) may be claimed as CBI. This information must be (1) commercially valuable, (2) used in the applicant’s business, and (3) maintained in secrecy.” Id.


See infra Section II.A.3.a-b.

FIELD TEST RELEASES, supra note 15. See also supra note 5.


Haw. Dep’t of Agric., Civ. No. 03-1-1509.

Government Forced to Disclose, supra note 99.

“KAHEA is a community-based organization working to improve the quality of life for Hawai’i’s people and future generations through the revitalization and protection of Hawai’i’s unique natural and cultural resource. We advocate for the proper stewardship of our resources and for social responsibility by promoting multi-cultural understanding and environmental justice.” KAHEA: The Hawaiian-Environmental Alliance, at http://www.kahea.org (last visited Mar. 21, 2005).


Government Forced to Disclose, supra note 99.


Government Forced to Disclose, supra note 99.


Rebecca Bratspies, The Illusion of Care: Regulation, Uncertainty, and Genetically Modified Food Crops, 10 N.Y.U. ENVTL. L.J. 297 (2002). The Plant Protection Act, which presently provides the USDA with authority to regulate transgenic field tests, repealed the Federal Plant Pest Act and the Plant Quarantine Act. Id. at 310-12.


Id. § 7712. “The term ‘plant’ means any plant (including any plant part) for or capable of propagation, including a tree, a tissue culture, a plantlet culture, pollen, a shrub, a vine, a cutting, a graft, a scion, a bud, a bulb, a root, and a seed.” Id. § 7702(13).

Id. § 7711. The term “plant pest” is statutorily defined to mean:

any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: (A) A protozoan; (B) A nonhuman animal; (C) A parasitic plant; (D) A bacterium; (E) A fungus; (F) A virus or viroid; (G) An infectious agent or other pathogen; or (H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs.

Id. § 7702(14).
The term “noxious weed” is statutorily defined to mean “any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment.” Id. § 7702(10).

Id. § 7701. See 7 U.S.C. §§ 7711-12 (providing authority to regulate only the movement of plant pests, plants, plant products, biological control organisms, noxious weeds, articles, and means of conveyance).


Section 340.3(b) enumerates six requirements for notification of release:

(1) The regulated article is any plant species that is not listed as a noxious weed . . . and when being considered for release into the environment, the regulated article is not considered by the Administrator to be a weed in the area of release into the environment[;] (2) The introduced genetic material is “stably integrated” in the plant genome[;] (3) The function of the genetic material is known and its expression in the regulated article does not result in plant disease[;] (4) The introduced genetic material does not: (i) Cause the production of an infectious entity, or (ii) Encode substances that are known or likely to be toxic to nontarget organisms known or likely to feed or live on the plant species, or (iii) Encode products intended for pharmaceutical use[;] (5) To ensure that the introduced genetic sequences do not pose a significant risk of the creation of any new plant virus, plant virus-derived sequences must be: (i) Noncoding regulatory sequences of known function, or (ii) Sense or antisense genetic constructs derived from viral genes from plant viruses that are prevalent and endemic in the area where the introduction will occur and that infect plants of the same host species, and that do not encode a functional noncapsid gene product responsible for cell-to-cell movement of the virus[; and] (6) The plant has not been modified to contain the following genetic material from animal or human pathogens: (i) Any nucleic acid sequence derived from an animal or human virus, or (ii) Coding sequences whose products are known or likely causal agents of disease in animals or humans.

Id.

Section 340.3(c) sets the following performance standards:

(1) If the plants or plant material are shipped, they must be shipped in such a way that the viable plant material is unlikely to be disseminated while in transit and must be maintained at the destination facility in such a way that there is no release into the environment[;] (2) When the introduction is an environmental release, the regulated article must be planted in such a way that they are not inadvertently mixed with non-regulated plant materials of any species which are not part of the environmental release[;] (3) The plants and plant parts must be maintained in such a way that the identity of all material is known while it is in use, and the plant parts must be contained or devitalized when no longer in use[;] (4) There must be no viable vector agent associated with the regulated article[;] (5) The field trial must be conducted such that: (i) The regulated article will not persist in the environment, and (ii) No offspring can be produced that could persist in the environment[; and] (6) Upon termination of the field test: (i) No viable material shall remain which is likely to volunteer in subsequent seasons, or (ii) Volunteers shall be managed to prevent persistence in the environment.

Id. (emphases added).
§ 340.3(c)(4).

§ 340.3(c)(5)(i), (ii).

§ 340.4(b). See also id. § 340.4(b) n.7 (stating that the 120-day review period may be extended if an EIS must be prepared).

Id.

§ 340.4(a).

Id. Under APHIS regulations, two copies of the permit application must be submitted to APHIS. Id. One copy of the permit application may omit trade secrets by designating trade secrets as “CBI,” while the other copy must contain the trade secrets, noted as “CBI.” Id. After APHIS’s initial review of the permit, APHIS must submit a copy of the initial review and the permit application with the omitted CBI to the State Department of Agriculture for “notification and review.” Id. § 340.3(b).

See generally INFO. SYS. FOR BIOTECH., supra note 15 (searching “release permits only” by “status”).

Id.


§ 340.3(b), (c). See supra text accompanying notes 152 & 153.

§ 340.3(d)(3).

COMM. ON ENVTL. IMPACTS, supra note 36, at 107.

§ 7 U.S.C. § 7711(c)(2). The deregulation process is the “sole route for commercialization of transgenic plants.” COMM. ON ENVTL. IMPACTS, supra note 36, at 111.

§ 340.6(b).

§ 340.6(d)(2).

COMM. ON ENVTL. IMPACTS, supra note 36, at 111.

Id. at 112.

Id.


Id.

Id. In addition to the approved, pending, and withdrawn petitions, one petition was determined to be incomplete, and another was deemed void. Id.


COMM. ON ENVTL. IMPACTS, supra note 36, at 112 (emphasis added).

Squash with Altered Genes, supra note 68, at A1.

CHECK THE STATUS OF AN APPLICATION, supra note 175.

Squash with Altered Genes, supra note 68, at A1.
42 U.S.C. § 4332(C) (2000). The Council on Environmental Quality regulations state that “[t]he phrase ‘to the fullest extent possible’... means that each agency of the Federal Government shall comply with that section unless existing law applicable to the agency’s operations expressly prohibits or makes compliance impossible.” 40 C.F.R. § 1500.6 (2003).

40 C.F.R. § 1500.1(b) (2003).

Id. §§ 1501.4(a), (b). The CEQ regulations define a “categorical exclusion” as:

a category of actions which do not individually or cumulatively have a significant effect on the human environment and which have been found to have no such effect in procedures adopted by a Federal agency in implementation of these regulations (§ 1507.3) and for which, therefore, neither an environmental assessment nor an environmental impact statement is required.


7 C.F.R. § 1b.2 (2003).

Id. § 372.5(b)(4).

Id. § 372.5(c)(3)(ii).

Id. § 372.5(c).

Id. § 372.5(d).

An enumerated exception to a categorically excluded action is “when a confined field release of genetically engineered organisms or products involves new species or organisms or novel modifications that raise new issues.” Id. § 372.5(d)(4).

40 C.F.R. § 1508.27 (2003).

Id. § 1508.27(a).

Id. § 1508.27(b).

Id. §§ 1508.27(b)(4), (5).

756 F.2d 143 (D.C. Cir. 1985).

Id. at 158. The bacterium was engineered to prevent frost damage in food crops. Id.

Id. at 152.

Id. at 147.

Id. at 154. The court held “[a]n [EA] that fails to address a significant environmental concern can hardly be deemed adequate for a reasoned determination that an EIS is not appropriate.” Id. (citing Vermont Yankee Nuclear Power Corp. v. NRDC, 435 U.S. 519, 553 (1978)).

See generally FIELD TEST RELEASES, supra note 15 (searching “release permits only” by “status,” and viewing “full record”). APHIS has not prepared any EISs. Id.

Id. When viewing the “full record,” release permits with a completed EA contain a hyperlink to the EA. Id.

Id.


Id.


Id.


Id.


220 Id.

221 The term “green revolution” refers to technical changes in farming techniques such as: growing large monocrops; heavily using fertilizers and pesticides; and extensive watering “to increase crop yields to feed existing and growing populations.” COMM. ON ENVTL. IMPACTS, supra note 36, at 34-35.

222 See supra Section II.A.1.

223 See supra Section II.A.2.

224 Hails, supra note 19, at 685. “Risk assessment of GM plants has been divided traditionally into direct and indirect impacts. Direct impacts arise from the presence of the transgenic plant itself, or the consequences of transgene of the transgene into wild relatives. Indirect impacts arise from the management practices associated with the transgenic crop.” Id.

225 See generally Phifer & Wolfenbarger, supra note 19; Hails, supra note 19.

226 COMM. ON ENVTL. IMPACTS, supra note 36, at 11.

227 See id. at 177.

228 See supra Section II.B.3.

229 See supra Section II.A.2.


231 See supra Section II.A.


233 See id.

234 Stone, supra note 230, at 10790.

235 See supra Section II.B.2.


237 Id. § 372.5(d).

238 Id. § 372.5(c).

239 Id. § 372.5(d).


241 See supra Section II.A.

242 See supra Section II.A.1.

243 See supra Section II.A.2.

244 See generally Hails, supra note 19.

245 See Dalton, supra note 70, at 655.

246 See supra Section II.A.2.

247 See Found. on Econ. Trends v. Heckler, 756 F.2d 143, 154 (D.C. Cir. 1985) (finding the EA for the release of a genetically engineered bacterium insufficient).

248 Id. at 147.

249 7 C.F.R. § 372.5(c) (2003).

250 Id. § 340.3.

251 Id. § 340.3(c)(4).

252 Id. § 340.1.

253 Id. § 340.3(c)(4) (emphasis added).

254 Id. § 340.3(c)(5).
See COMM. ON ENVTL. IMPACTS, supra note 36, at 107.

See supra Section II.B.1.


One statutory definition of “movement” is “to release into the environment.” Id. § 7702(9)(E).


Squash with Altered Genes, supra note 68, at A1.

Although there are additional areas of biotechnology regulatory oversight that could be improved, they occur after the initial release of transgenic organisms and are therefore outside the scope of this paper.

COMM. ON ENVTL. IMPACTS, supra note 36, at 188.


See supra Section III.B.

This statement was inferred by the author because APHIS has completed a mere eleven EAs for thousands of permitted releases.


See id. pt 372.

See supra Section II.B.1.

Government Forced to Disclose, supra note 99.

See supra Section II.A.2.