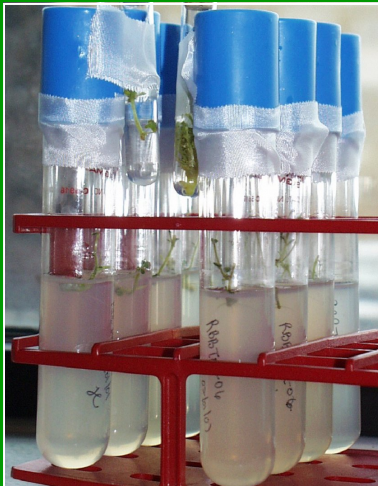


RAISING RISK



Field Testing of Genetically
Engineered Crops in the
United States

April 2005

U.S. PIRG Education Fund

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ACKNOWLEDGEMENTS

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The author would like to thank the Educational Foundation of America, John Merck Fund, Lillian Goldman Charitable Trust, and the Marisla Foundation for their support of our work on genetically engineered foods.

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EXECUTIVE SUMMARY

Although genetically engineered crops are still poorly understood, corporations and universities are growing them experimentally in the open environment with little oversight and public notification. Never before in the history of the planet have we been able to transfer genes across natural species barriers, creating unheard of combinations like tomatoes with fish genes, or even pigs with human genes. Contrary to assertions made by proponents of the technology, genetic engineering is not precise. Scientists cannot control where the gene is inserted into the host's genetic code, nor guarantee stable expression of the gene in the new genetically engineered organism. As a result, genetic engineering raises a host of ecological and human health risks, and these concerns have not been adequately addressed.

The biotechnology industry began field testing genetically engineered plants and crops in the 1980s. Field tests are supposed to determine the impact of the new crops on the environment and how well the plants function. The U.S. Department of Agriculture (USDA), however, failed to adequately regulate these field tests from the start, and its oversight has weakened over time. An analysis by the General Accounting Office (now the Government Accountability Office) in 1988 roundly criticized shortcomings in USDA's oversight, echoing calls by prominent microbiologists, ecologists, and others that certain regulatory decisions were "scientifically indefensible." USDA has continued to weaken its oversight of the technology despite little empirical evidence on which to base such decisions.

USDA's inadequate oversight of these field tests poses immediate risks. Nonnative organisms can invade and degrade ecosystems. Plants engineered to produce proteins with insecticidal properties may damage the soil or harm so-called

non-target species. Plants engineered to be virus resistant can cause new viral strains to evolve through recombination or make existing viruses more severe. And if field experiments are not properly monitored, genetic pollution can result, putting farmers' livelihoods, the environment, and human health at risk. In essence, our environment is serving as the laboratory for widespread experimentation of genetically engineered organisms with profound risks that can never be recalled once released.

Moreover, USDA has failed to require adequate data collection on field tests of genetically engineered crops, leaving the true impacts of these new creations still largely unknown. According to a review of the 85 most recent reports of field tests available in 1995, some of the most fundamental tests necessary to determine ecological effects, such as impacts on nontarget insects, were never even conducted. As the authors of the report concluded, this is a classic example of a "don't look, don't find" regulatory framework. Similarly, the National Academy of Sciences found serious shortcomings in USDA's oversight, saying the agency at times "lacked scientific rigor, balance, transparency" and chastising the agency for "inadequate expertise."

Key Report Findings

Raising Risk examines USDA data on field tests of genetically engineered crops in order to document the geographic breadth of these open air experiments and to demonstrate the implications of USDA's inadequate oversight. Key findings include:

- Between 1987 and 2004, USDA received 11,090 applications for field releases of

genetically engineered crops. USDA has approved 10,296 of these applications, allowing 18,608 field releases comprised of 47,219 field test sites. Overall, USDA has served as a rubber stamp for applications to conduct field tests, rejecting only 3.6% of all applications submitted.

- As of December 2004, 14 states and territories have hosted more than 1,000 field test sites. They are Hawaii (5,413), Illinois (5,092), Iowa (4,659), Puerto Rico (3,483), California (1,964), Nebraska (1,960), Pennsylvania (1,707), Minnesota (1,701), Texas (1,494), Indiana (1,489), Idaho (1,272), Wisconsin (1,246), Georgia (1,051), and Mississippi (1,008).

- Since 1991, USDA has received 240 requests for 418 field releases of crops engineered to produce pharmaceuticals, industrial chemicals, or other so-called biopharmaceuticals; the number of requested field releases of “biopharm” crops increased from 22 in 2003 to 55 in 2004.

- The ten crops authorized for the most field releases are corn, soybean, cotton, potato, tomato, wheat, creeping bentgrass, alfalfa, beet, and rice.

- USDA authorized field tests on several crops for the first time in 2003 and 2004, including American chestnut, American elm, avocado, banana, eucalyptus, marigold, safflower, sorghum, and sugarbeet.

- Between 1987 through 2004, Monsanto (or a wholly-owned subsidiary) submitted the most applications for field tests (4,279). The ten universities submitting the most requests to conduct field tests are Iowa State (129), University of Idaho (102), Rutgers (102), University of Kentucky (80), University of Florida (78), Oregon State (69), Stanford (63), Michigan

State (62), University of Arizona (55), and North Carolina State (52).

- The percentage of field tests conducted with genes considered Confidential Business Information and thus hidden from public scrutiny has increased dramatically, rising from 0% in 1987 to 70% in 2004.

Recommendations

Although USDA has authorized more than 47,000 field tests of genetically engineered organisms, USDA, the Environmental Protection Agency, and the Food and Drug Administration have not adequately answered fundamental questions about the human health, environmental, social, and ethical implications of this technology. Field tests of genetically engineered crops only should occur within a thorough and comprehensive ecological framework to assess their full impact.

In order to make progress toward this goal, we recommend a moratorium on the commercialization of genetically engineered foods and crops unless:

- independent safety testing demonstrates they have no harmful effects on human health or the environment;

- the public’s right to know about field tests is improved and any products commercialized are labeled; and

- the biotechnology corporations that manufacture them are held accountable for any harm they may cause.

INTRODUCTION

The technique of genetic engineering is radical and new. The first recombinant deoxyribonucleic acid (rDNA) molecules were generated at Stanford University in 1972.¹ Never before had scientists been able to isolate fragments of DNA from one organism and join it with DNA from a completely different organism. As scientists developed the techniques, they eventually created unheard of combinations such as tomatoes with fish genes, potatoes with mouse genes, apples with chicken genes, and even pigs with human genes.² Contrary to assertions made by proponents of the technology, genetic engineering is not precise. Scientists cannot control where the gene is inserted into the host's genetic code, determine how many copies of the gene are inserted, nor guarantee stable expression of the gene in the new genetically engineered organism. As a result, genetic engineering raises a host of ecological and human health concerns that thus far have not been adequately addressed.

In 1975, scientists from around the world gathered at a conference at the Asilomar Center in California to discuss genetic engineering and the risks involved. These scientists determined that self-regulation of genetic engineering research would be sufficient to mitigate the risks of this emerging technology.³ In fact, this was more the beginning of a public relations strategy than a scientific endeavor. Evidence unavailable to the public at the time shows that government researchers in 1976 decided to conduct a public relations campaign aimed at persuading the public that hazards of genetic engineering were exaggerated. One scientist, describing the misleading way scientists were communicating the risks of genetic engineering to the public, said the goal was to

make “this public thing go away... It's molecular politics, not molecular biology.”⁴

Despite early calls for precaution, a booming biotechnology industry soon turned its eyes to agriculture, and field experiments applying genetic engineering to plants began in the 1980s. Oversight of genetically engineered crops was largely in the hands of National Institutes of Health (NIH) through the first decade of development. As a result of a legal challenge from a public interest group,⁵ President Reagan's White House established an interagency task force in April 1984 to study and coordinate the government's regulatory policy for products of genetic engineering. Many agencies were involved,⁶ and the proposal for a Coordinated Framework for Regulation of Biotechnology was published on New Year's Eve 1984.⁷ The Framework outlined how government agencies with oversight over genetic engineering would work together, assigning several agencies complementary and often overlapping responsibilities for oversight of the technology.

Corporations, universities, and others conduct field tests of genetically engineered crops, mainly to determine how well they function in the open environment. Based on available data, this report documents the extent of field testing of genetically engineered crops across the United States, highlights the environmental risks, and details the lack of regulation. While other reports have addressed some of the shortcomings of the Framework with respect to the Environmental Protection Agency (EPA)⁸ and the Food and Drug Administration (FDA)⁹, this paper focuses on oversight at the Department of Agriculture (USDA) and how the agency has allowed an enormous amount of experimentation under its legal jurisdiction to occur with inadequate oversight.

USDA'S OVERSIGHT OF GENETIC ENGINEERING

Regulation of Genetic Engineering at USDA: 1984 Proposal

Regulation of genetically engineered crops at USDA was designed to support the biotechnology industry. In its 1984 proposal for the Coordinated Framework for Regulation of Biotechnology, the Office of Science and Technology Policy (OSTP) made the goals of the Framework clear: “[T]o enable a beneficial industry to proceed safely and efficiently...[it is] imperative that progress in biotechnology be encouraged.”¹⁰ The introduction emphasized that the U.S. is “committed to reducing barriers to trade in biotechnology.”¹¹ In order for the USDA (and all government agencies involved in the oversight of genetically engineered organisms) to accommodate the growth of this industry as a matter of policy, and defend it in matters of international trade, the U.S. government decided that no new laws or agencies were needed. The existing statutes, the policy stated, “seem adequate,” while the regulatory authorities in place “appear to accommodate these new products.”¹² Given the complexity of the science and the potential impacts of genetically engineered crops on human health, the environment, and the very structure of farming, one would have expected a great level of detail in oversight would be needed. Instead, USDA’s “Statement of U.S. Department of Agriculture Policy for Regulating Biotechnology Processes and Products” is a vague eight-page document.

USDA describes its mandate as follows: “the Department is chartered to develop new markets.”¹³ The agency also gives a two paragraph “Regulatory Philosophy,” in which it states “USDA anticipates that agriculture and forestry products developed by modern biotechnology will not differ fundamentally

from conventional products.” USDA’s philosophy of “substantial equivalence” makes it a simultaneous regulator and promoter of a powerful new technology. It would be 15 years before any Secretary of Agriculture would even acknowledge this problem.¹⁴

1986 Announcement of Policy

In 1986, USDA published its final statement of policy under the Framework. USDA proposed “not to regulate an organism or product merely because of the process by which it was produced,” thus exempting certain products from regulation.¹⁵ OSTP’s introduction to the Framework “anticipated” that products would soon receive “exemption from any federal review.”¹⁶ While only five field tests in 1987 and 16 in 1988 went through USDA’s permitting procedures, OSTP claimed that because “there is a substantial body of research indicating that such experiments are of low risk...not all experiments involving the environmental release of genetically engineered organisms require prior federal approval.”¹⁷ This claim, scientifically dubious at the time given the dearth of data, opened a huge loophole in oversight.

Several other exemptions were included in the Framework, including the transfer of foreign genetic material not believed to have an impact.¹⁸ OSTP also sought comment on exemptions of new organisms produced by exchanging genetic material within the same genera through genetic engineering as opposed to other methods.¹⁹ In sum, OSTP declared that “at the present time existing statutes seem adequate to deal with the emerging processes and products of modern biotechnology.”²⁰

USDA significantly changed its policy statement for the Framework from 1984 to 1986, making it more clear that the agency “considers products developed through biotechnological techniques as no different from those products resulting from research using conventional techniques,” assuming proper protocols.²¹ The agency assumes that in “most cases it is expected that they [genetically engineered crops] will be improved, and would therefore not pose any new threat to humans, other animal species, or to the environment.”²² Based on agency determinations, “genetically engineered organisms that are not plant pests or where there is no reason to believe such organisms are plant pests would not be regulated.”²³ There are also provisions for “certificates of exemption” for products of genetic engineering, exemptions for certain microorganisms,²⁴ and, as mentioned above, the agency sought comments on exempting certain new organisms produced by intragenetic exchange.²⁵

Knowing its regulations would “have a direct impact on the competitiveness of U.S. industry,” USDA stressed the need to avoid having “inconsistent or unnecessary procedures.”²⁶ USDA received 27 public comments on whether the existing framework could be applied to products of genetic engineering, and half disagreed with the judgment of the USDA. Undaunted, the agency responded that the “existing authority is considered adequate at this time.”²⁷ Only seven respondents discussed the issue of risk assessment or risk/benefit analysis of genetic engineering, including one who gave a warning against attempting to regulate the “hypothetical and imaginary ‘potential’ dangers” of recombinant DNA techniques.²⁸ In responding to comments on risk analysis, the agency mentions for the first and only time the need to consider ethical issues in agricultural biotechnology research. Many have questioned the commitment of USDA and others to a full

exploration of the ethical dimension of genetic engineering.²⁹

1986 Proposal on Plant Pests

On the same day USDA issued its revised Statement of Policy for the Coordinated Framework for Regulation of Biotechnology, USDA’s Animal and Plant Health Inspection Service (APHIS) issued a proposed rule focused on regulations for field tests of genetically engineered products.³⁰ Under the rule, monitoring requirements were inadequate and almost nonexistent. The rule did not require comprehensive ecological tests that would enable scientists to answer fundamental questions about the properties of genetically engineered organisms and discounted possible routes of gene escape such as genetically engineered plants interbreeding with wild relatives.

In the proposed rule, USDA laid out new requirements for permits for genetically engineered crops, including “that a written application for a permit should be submitted...at least 180 days in advance of the proposed introduction.”³¹ USDA later affirms its own guidelines by saying, “USDA believes that the 180 day time period required to process a permit application will not be an unreasonable delay in the marketing” of products produced through genetic engineering.³² Monitoring reports were to be submitted only “as deemed necessary by the Deputy Administrator in order for Plant Protection and Quarantine, under certain circumstances....”³³ USDA made this easier for industry and researchers by assuming that “[g]ene escape via a sexual transfer is not expected to occur and will not be considered.”³⁴

About 200 people responded to USDA in writing on its June 26, 1986 Federal Register notice, and the agency held one hearing in July and one in August on the proposed rule. Nearly all of the

speakers at the hearings were representatives of industry, including Pioneer Hi-Bred, Agracetus, Calgene, and the Industrial Biotechnology Association. As an example of industry's comments to the docket, Monsanto praised OSTP's failure to regulate products based on the production method, and the company urged expansions for certain exemptions.³⁵ In comments directed to EPA, Monsanto asked the agency to block public information-sharing by recommending "that public meetings of the biotechnology Science Advisory Committee be held only if the nature of the research program and potential product can be maintained confidential...[I]t must be recognized that individual companies can be harmed by disclosure of the nature of their research as well as by disclosure of data."³⁶

In comments directed at USDA, Monsanto asked the agency to deregulate all genetically engineered crops. The company declared that, "Logically, it would seem that the organisms produced by recombinant DNA methods should be exempted rather than those produced by classical techniques."³⁷ Monsanto criticized the agency for requiring too many experts to oversee the safety of research, claiming that committees "could soon result in an unwieldy size."³⁸ It also criticized the 180-day waiting period APHIS proposed before making a final decision on a regulated article, saying that it "is entirely too long in an age of rapid communication and electronic access to expertise worldwide. A maximum period of 45 days should be established."³⁹ Monsanto later states that:

With the exception of the 180-day period for APHIS review of plant pathogens, there is no clear definition of the time period required for review of proposals by the USDA. Such information is critical to timely research and development and seasonal field testing of agricultural biotechnology products. A time limit of 45 days should be incorporated into .407e, Review of Proposals.⁴⁰

1987 Final Rule on Plant Pests

On June 16, 1987, USDA published the final version of its changes to 7 CFR, Chapter III.⁴¹ The substance of the document did not change from the 1986 proposal, leaving the agency with an inadequate system of monitoring in place. In the rule, USDA capitulated to industry pressure and changed the time necessary to submit an application for release of a genetically engineered organism into the environment from 180 days in advance to 120.⁴² Many definitions, such as "classical genetics," "genetic manipulation," "mutagen," "pathogen," and "regulated article," were changed or dropped to be more favorable to industry's concerns.⁴³ As a result of concerns about the rule, the House Energy and Commerce Committee's Subcommittee on Oversight and Investigations asked the General Accounting Office (GAO, now the Government Accountability Office) to examine federal risk management policies and procedures applicable to field testing genetically engineered organisms. While USDA was proclaiming products of genetic engineering safe and barely regulating them, and industry was pushing them to do still less, GAO's report sharply criticized weaknesses in USDA's regulations.⁴⁴

GAO Report Criticizes USDA Oversight

GAO faulted USDA for failing to adequately regulate genetic engineering, emphasizing that the agency had based its regulations on insufficient data. As a result of the biotechnology framework, GAO pointed out, "Some organisms are not subject to regulation due to differences in legislative mandates and risk management policies. ...[Thus] USDA [is] exempting certain categories of organisms from regulatory scrutiny prior to developing scientific information on the behavior of these organisms in the environment."⁴⁵ Commenting

on a February 1, 1988 draft report, USDA wrote to GAO on March 18 that its exemptions were justified by their “limited nature.”⁴⁶ GAO’s response in June was clear: “the scientific basis for exempting from review certain genetically engineered organisms released into the environment has not yet been established.”⁴⁷ GAO’s methodology did not even examine the full range of flaws in USDA’s oversight. GAO points out, for example, that, “As scientists have recognized, the problems that might be associated with large-scale introductions of genetically engineered organisms may differ from those of small-scale testing, which was the focus of our review.”⁴⁸

In response to criticism by the GAO and others, USDA argued that it narrowed the scope of the exemptions for certain microorganisms in the final rule. This exemption was not a trivial one. One professor of microbiology, who testified on behalf of the American Society for Microbiology at congressional hearings, stated that the exemption was “scientifically indefensible.”⁴⁹ Regardless, USDA’s claims that its final rule narrows the exemption were not true. As GAO explained, “We find no evidence of a narrowing of the exemption in USDA’s final rule... [T]he scope of the exemption remained unchanged.”⁵⁰

The shortcomings of the USDA policy are only part of the picture. A more fundamental failure was the narrow focus on the evaluation of the genetically engineered organisms’ plant pest risk, rather than a more comprehensive approach to assessing all risks the plants posed. In so doing, “USDA is not requesting sufficient information from the applicant to assess an organism’s behavior in the environment and its potential ecological risk.”⁵¹ Or, as stated elsewhere, “no meaningful environmental data are being collected in the vast majority of the trials...The only questions being asked relate to the agronomic performance of the genetically modified plants, and the unwanted re-

emergence of engineered plants in the following seasons, so-called volunteer plants.”⁵² The agency responded by pointing out that an examination of environmental effects is required under the National Environmental Policy Act (NEPA). A few years later, USDA would propose excluding permitting and acknowledgement of notifications for field releases of genetically engineered organisms from the requirement to prepare environmental assessments or environmental impact statements under NEPA.⁵³

Changes in 1990s to USDA Oversight

In March 1993, after operating under a system of permits for less than six years, APHIS announced it was allowing certain crops to be grown without permitting, arguing that it had enough data to conclude these plants posed little or no ecological risk.⁵⁴ Instead, institutions simply notified APHIS of their intention to conduct a field test. APHIS exempted six plant species – corn, cotton, potato, soybean, tobacco, and tomato – as well as any “additional plant species that BBEP* has determined may be safely introduced.”⁵⁵ The streamlined notification application was carefully worded to only ask, for example, if the plant would “[e]ncode substances that are known or likely to be toxic to nontarget organisms known or likely to feed or live on the plant species.”⁵⁶ This wording ignores ecological impacts on species such as monarch larvae that feed on nearby species like milkweed, and it fails to examine impacts on the soil, which are only recently being adequately explored.⁵⁷ In addition, even beyond Monsanto’s hopes just a few years earlier,

* BBEP is the Biotechnology, Biologics, and Environmental Protection division of APHIS. They added “Environmental Protection” and dropped their old name (“Plant Protection and Quarantine”) in the same notice.

APHIS would now have only 30 days to respond to a notification for environmental release.⁵⁸

In a study produced in 1995, Joy Bergelson, an ecological geneticist at the University of Chicago, and Colin Purrington, now an evolutionary biologist at Swarthmore College, examined the seven genetically engineered crops approved by USDA for commercialization at that time. They concluded that USDA was basing its decisions on critically flawed data.⁵⁹ Moreover, they said the petitions relied in large part on unsupportable claims. Also in 1995, a report published in *Bio/Technology* surveyed all publicly available data from every field test.⁶⁰ In reviewing the 85 most recent reports of field trials, the authors note that none mentioned experiments to assess weediness, none of the reports on virus-resistant crops mentioned experiments measuring the production of new virus strains, and none of the reports on Bt crops mentioned experiments on the likelihood of adverse impacts on non-target insects.

Regardless, in 1995 USDA again proposed to “simplify procedures for the introduction of certain genetically engineered organisms.”⁶¹ USDA claimed that 87 percent of all field trials were already being conducted under the simplified regulatory requirements.⁶² The agency argued that “petitions can and should be reviewed in a more streamlined manner,”⁶³ and set a goal that “about 99 percent” of tests would be conducted under a simplified notification procedure that required even less study than before.⁶⁴ To do so, APHIS would deregulate a new set of crops. Because APHIS did not have a way to describe these new crops, the agency created a new term, “antecedent organism.”⁶⁵ This was an organism that had already received non-regulated status and thus would serve as a reference for comparison. This meant that as long as the new plant was “closely related,” a vague term not defined but described through one example, it was a candidate for non-regulated status.⁶⁶ USDA cited its experience at that time, having

“approved, in whole or in part, eight petitions for a determination of non-regulated status.”⁶⁷ This statement is inaccurate. According to USDA records, at the time 16 crops were no longer regulated.⁶⁸ Regardless, independent scientists criticized the extension of deregulation as “beyond all reason.”⁶⁹

The final rule, published on May 2, 1997, watered down field testing requirements, reduced oversight of virus-resistant plants, and simplified the procedures for further determinations of non-regulated status.⁷⁰ In responding to criticism that the agency had not yet obtained any hard data that would allow it to assess specific environmental impacts, USDA admitted that “it is true that the majority of field trials of regulated articles have been conducted in the last two years.”⁷¹ Regardless, USDA still concluded that “there has been no reason to believe that any hypothetical ‘long-term’ impacts have arisen or are likely or foreseeable as a consequence of the conduct of any field trial in accordance with this final rule.”⁷² So with very little data to support such a decision, the agency dismissed concerns and called two years of testing ‘long-term’.

With regard to virus resistant crops, USDA simultaneously concluded that more research was needed regarding the risks of virus resistant plants, yet admitted that it is highly unlikely that there will be any new viruses as a result of field testing.⁷³ The results were something of a *fait accompli*, as USDA wrote about the time when “eventually, approval is sought to grow the regulated articles under routine agricultural conditions...(i.e., when a petition is submitted to APHIS for a determination of nonregulated status).”⁷⁴

Responding to USDA’s 1995 notice, several people had recommended strengthening requirements for field tests, but the agency noted that “no evidence in support of such a view was provided.”⁷⁵ From the government’s perspective, to even “consider potential long

term environmental effects...would be an exercise in speculation.”⁷⁶ The lack of evidence about the safety of field tests reinforces the need for stricter testing requirements. A comprehensive literature review published in December 2000 on the potential impacts of genetically engineered crops concluded that key experiments are still lacking.⁷⁷

USDA’s regulations are a classic example of a “don’t look, don’t find” mentality. Between 1987 and 2004, USDA allowed more than 47,000 open air field experiments of genetically engineered organisms; regardless, because of the agency’s inadequate oversight, USDA has failed to undertake basic, fundamental explorations into the impact of genetically engineered organisms on human health, the environment, and a range of social and economic areas.

Recent Developments in USDA Oversight

In February 2002, the National Academy of Sciences released a new report that criticized USDA’s handling of the regulation of genetically engineered crops.⁷⁸ In part, the report undermined USDA’s deregulation decisions, stating that one “cannot presently judge whether extensive commercialization of transgenics... will significantly perturb agroecosystems because of major gaps in our knowledge of these systems.”⁷⁹ While USDA and biotechnology companies continue to state that this technology has not caused adverse environmental impacts, the National Academy calls that claim “nonscientific. There has been no environmental monitoring of these transgenic crops, so any effects that might have occurred could not have been detected.”⁸⁰

The report goes on to call USDA’s oversight at times “scientifically inadequate” and chastises the agency for “inadequate expertise.”⁸¹

Elsewhere it states that APHIS’s analysis “lacked scientific rigor, balance, and transparency.”⁸² The report faults the agency for allowing plants with allergenic properties to be grown under notification.⁸³ The report even makes it clear that USDA has no formal system in place to determine if results of small-scale field trials are at all applicable to large-scale commercial plantings.⁸⁴

Despite these scientists’ concerns, OSTP stated that existing field test requirements were adequate while admitting that the likelihood of contamination “may...increase.”⁸⁵ But instead of proposing a plan to prevent genetic pollution, OSTP has directed USDA to produce new rules that would allow contamination under the recently enacted Plant Protection Act, which supercedes the Plant Pest Act. Regulations under the Plant Pest Act, however, remain in effect until the agency proposes new regulations under its new authority.

In 2003, USDA proposed new rules for the field testing of plants engineered to produce pharmaceuticals or industrial compounds.⁸⁶ While the announcement does make some improvements, in itself an admission that oversight has been inadequate for some time, it falls short in many areas. The new rules increase the buffer zones to one-half mile for tassel-bagged and open-pollinated corn, but they still fail to prohibit the cultivation of food/feed crops on sites where biopharmaceutical plants were grown the previous year, leaving open the possibility of volunteer biopharm plants contaminating the food supply. The rules continue to allow biotechnology companies to use food crops for these experiments and do nothing to address the problem of extreme secrecy surrounding these tests. A coalition of environmental and consumer groups filed a 60 Day Notice Letter with USDA to address many of the shortcomings in its policy.⁸⁷ This rule has not yet been finalized.

In 2004, USDA announced its intention to change agency regulations by issuing an Environmental Impact Statement (EIS) evaluating its biotechnology regulations.⁸⁸ The agency held several meetings with interested stakeholders on a notice seeking comment on

the scope of the EIS, which indicated that the agency is seeking to tolerate contamination. The proposed EIS, which is to take into account public comments received as well as information learned in the meetings, has not yet been published.

RISKS ASSOCIATED WITH FIELD TESTING

Experts from around the globe have sounded alarms about releasing genetically engineered organisms into the environment without better understanding how they work and how they affect the environment and public health. The Ecological Society of America stated in its 2004 position paper on genetically engineered crops that “ecological and evolutionary consequences of crop-to-crop gene flow are just beginning to be investigated.”⁸⁹ In November 2004, the International Union for the Conservation of Nature (IUCN) voted to call for a moratorium on the further release of genetically engineered crops.⁹⁰ The IUCN consists of members from 140 countries, including 77 state governments, 114 government agencies, and 800-plus non-governmental organizations. More than 10,000 internationally-recognized scientists and experts from more than 180 countries volunteer their services to its six global commissions.⁹¹ Some of the numerous ecological concerns with the field testing of genetically engineered crops are detailed below.

Impacts on Beneficial Insects and Other Species

Research regarding the potential impacts of genetically engineered corn on monarch butterfly larvae is fairly well known as a result of media attention.⁹² John Losey and colleagues found higher mortality among monarch larvae feeding on Bt corn plants than on larvae eating conventional corn plants. Bt crops are engineered to produce a toxin derived from *Bacillus thuringiensis* (Bt) bacteria in every cell in an attempt to make them resistant to certain types of pests. When the article was published, proponents of genetic engineering had superficial data with which to counter the

findings. Monsanto had to admit that it had “not yet conducted its own research on Bt’s impact on monarch butterflies.”⁹³ This admission came despite years of field test experiments.

In response, biotechnology companies hastily convened a conference in November 1999⁹⁴ to argue that the risk to the monarch was minimal; many experts justifiably pilloried this conference as a “manipulation.”⁹⁵ Ultimately, additional research confirmed the findings of Losey et al. that pollen from Bt corn was toxic to monarchs.⁹⁶ This meant that regulatory agencies had approved a variety of genetically engineered corn toxic to monarchs under field conditions. The National Academy of Sciences later wrote that monarchs may not have been so lucky if the variety in question had proved more popular with farmers, stating that “the outcome for monarchs would have been substantially different.”⁹⁷

Despite the high media profile of Losey’s work, fewer people have heard about other research demonstrating adverse effects of genetically engineered crops on non-target species. Early in 2005, the results of a four year study in Britain revealed adverse impacts to wildlife from genetically engineered crops, including threats to wild flowers, butterflies, and bees.⁹⁸ Similarly, Giroux et al. reported that ladybugs, which prey on the Colorado potato beetle, consumed fewer potato beetle eggs when the potatoes had high levels of Bt toxin.⁹⁹ In work conducted at the Swiss Federal Research Station for Agroecology and Agriculture, Hilbeck et al. reported that lacewing larvae reared on prey that were fed Bt-producing corn took longer to develop and had a strikingly elevated mortality rate.¹⁰⁰ Other studies have produced similar results, including research in Ohio on genetically engineered potatoes, which

found natural enemies reduced to such low levels that aphid outbreaks occurred.¹⁰¹ The National Research Council asked in its 2000 report “whether such indirect effects will have a harmful effect on the agroecosystem.”¹⁰² Unfortunately, the question is being asked and studied far too late. As Hilbeck has stated: “We risk disrupting the regulatory mechanisms that naturally keep pests in check.”¹⁰³

Genetic Pollution

Genetic material engineered into a crop grown in an open field may travel by wind, insects, or animals into adjacent fields, polluting traditional crops with genetically engineered material. This genetic pollution poses risks to the environment, public health, and the nation’s farm economy.

When USDA designed its field testing regulations, the agency claimed that “plants show no evidence of mechanisms to transfer genetic material directly from one organism to another.”¹⁰⁴ Practical experience has proven this statement false. In 2000, for example, scientists discovered an herbicide-tolerant canola plant that cross-pollinates with a related weed.¹⁰⁵ Moreover, USDA has admitted that genetically engineered seeds may have moved outside of field test sites due to animal dispersal.¹⁰⁶ No published studies have examined the extent of the ecological consequences of this impact on natural populations.¹⁰⁷ Yet the potential for economic harm for farmers of genetic pollution are already real and severe.¹⁰⁸

According to APHIS regulations, an application for a permit to conduct a field test of a genetically engineered crop must include “a detailed description of the proposed procedures...which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations.”¹⁰⁹ This is particularly important since many crops being field tested have not

been approved for human consumption, and some never will, such as plants engineered to produce pharmaceutical proteins. Scientists reviewing these environmental assessments, however, found that APHIS has failed to ensure that contamination is not occurring. According to the authors of this study, APHIS concluded that cross-pollination of potato plants will not occur, yet “the nature or details of the documentation were not specified [and] no basis was given for the assurances of the applicant.” Trials on genetically engineered squash and cantaloupe, which generally outcross and are insect pollinated, contained no requirement that flowers be removed from plants. APHIS accepted environmental assessments citing data on adequate isolation distances that are contradicted by scientific literature. As a result, one environmental assessment suggested that 400 meters is an adequate isolation distance for field tests of squash, despite research confirming viable hybrid progeny of wild and cultivated squash separated by 1,300 meters. The authors state clearly: “APHIS does not require applicants to determine the extent and frequency of pollen movement nor the effectiveness of border rows in limiting the transmission of pollen during field tests.”¹¹⁰

Many farmers are relying more on non-engineered crops that require strict segregation to meet specific market demands that pay a premium price. The contamination of their conventional or organic crops by pollen flow or seed dispersal from engineered plants could have serious financial implications. Stewart Wells of the National Farmers Union of Canada, for example, has stated that it may soon be impossible to certify canola as organic because no one will be able to guarantee that it does not contain genetically-engineered seeds. “If this continues, once wheat, barley, lentils and other crops are genetically-engineered, I won't have anything left to grow. For organic farmers and the hundreds of thousands of consumers who choose organic food, this is an

extremely serious issue.”¹¹¹ In the United Kingdom, the government halted field experiments of genetically engineered corn for fear of genetic pollution of nearby organic farms.¹¹²

But the problem is far larger than for just organic growers. StarLink corn, for example, a variety approved only for animal feed and industrial use but not for human consumption, was nevertheless discovered in supermarket products.¹¹³ The corn was never approved for human consumption because the corn produced a protein that exhibited six characteristics of known allergens. Not all farmers followed planting requirements,¹¹⁴ resulting in contamination of the food supply. Abroad, harvested field tests of Monsanto’s genetically engineered sugar beet – not approved for human consumption – were mixed with other crops destined for food processing.¹¹⁵

Another startling example of genetic contamination was brought to light in the fall of 2001 in the journal *Nature*. Genetically engineered corn was discovered growing in Mexico despite a government moratorium on commercial planting.¹¹⁶ Contamination of Mexico’s crop could threaten corn’s greatest source of biodiversity.¹¹⁷ Sensing the seriousness of the issue, the biotechnology industry sought to suppress the information before it was released and discredit it afterwards. The director of a Mexican corporation offered one of the scientists who discovered the contamination a research post if he withheld his paper, then threatened the scientist by saying “he knew where to find his children.”¹¹⁸ *Nature* eventually published an editorial note claiming that the “evidence available is not sufficient to justify the publication of the original paper.”¹¹⁹ This retraction was the result of a concerted effort by a public relations firm that, among other tactics, had used phony names in Internet postings.¹²⁰

The most recent example of how field testing of genetically engineered crops can cause genetic pollution comes from creeping bentgrass. Monsanto and Scotts have sought to develop a strain of genetically engineered bentgrass for golf courses that is resistant to Monsanto’s Roundup herbicide. While tests by the companies had revealed some pollination at a distance of one mile from field tests, independent tests revealed that pollination could occur at distances as far as 13 miles.¹²¹ The Forest Service has stated that this genetically engineered grass “has the potential to adversely impact all 175 national forests and grasslands”; meanwhile, proponents have stated that it “would pose no new problems.”¹²²

Pest Resistance and “Superweeds”

Plants engineered to kill insects are likely to hasten the creation of pesticide-resistant species, already a major problem.¹²³ Bt crops are engineered to produce a toxin derived from *Bacillus thuringiensis* (Bt) bacteria in every cell in an attempt to make them resistant to certain types of pests. Bt is one of a limited number of tools that organic farmers have and can use as a natural pesticide. As a spray, Bt can be applied sparingly due to its reliable efficacy; because it breaks down very quickly, insects are exposed only sporadically. Sporadic exposure means little or no resistance develops. The continual exposure to Bt toxin in genetically engineered Bt plants raises the likelihood that insects will quickly develop resistance to Bt. Thus far, the strategy to slow development of resistance has been to rely on high-dose Bt crops planted with a small “refuge” of non-genetically engineered crops. High doses counteract somewhat the resistance-promoting effect of continual exposure by minimizing the number of Bt-resistant survivors. Even with high-dose plants, however, resistant pests will multiply over generations, making it necessary to interplant “refuges” of non-Bt plants with susceptible insects. Interbreeding between resistant and

susceptible “refuge” insects slows development of resistance in the general population.

Unfortunately, the strategy is not being implemented properly, for several reasons. First, although the strategy is predicated on high-dose crops, USDA has approved applications by Mycogen, Novartis, and DeKalb (now owned by Monsanto) for crops that produce only moderate doses.¹²⁴ A study published in 1999 raises concern that insects may develop resistance to moderate dose Bt corn, potentially undercutting the high-dose-plus-refuge strategy.¹²⁵

Second, new research suggests that the original rules governing planting of Bt corn allow insects to develop resistance to Bt.¹²⁶ Thus the government has had to change its rules, stating that no more than 80% of a field can be planted in Bt corn varieties, and in cotton-growing areas no more than 50% can be planted in Bt corn varieties. While this announcement is a further admission of inadequacies in the initial oversight of the technology, farmers who use Bt can now only wait and see if irreparable damage has been done. A scientific advisory panel had recommended that EPA require refuge sizes of 50% for a recently approved variety of genetically engineered corn, but the agency ignored the panel’s advice and sided with Monsanto, which had pushed for 20%.¹²⁷ Moreover, not all growers are complying with the refuge requirements. Research conducted by the biotechnology industry confirms that nearly 15% of growers failed to comply with the rules in 2002; the numbers are even lower in the Corn Belt.¹²⁸

Another significant ecological concern posed by the introduction of genetically engineered crops is that genes designed to give crops a competitive advantage may be passed to related wild plants with which they interbreed, spawning new “superweeds.” In fact, the

current reliance on just a few broad-spectrum herbicides makes it likely that resistance will develop even faster. Already, canola weeds resistant to three herbicides have been found in a field in northern Alberta, Canada.¹²⁹ A recent scientific article reported that the physiological costs of this new trait are “negligible,” suggesting that it may persist and spawn more troublesome weeds.¹³⁰ The few studies of the relative fitness of hybrids between genetically engineered crops and wild relatives show that they are not necessarily less fit than their wild parent.¹³¹ Without regulatory oversight, genetically engineered plants will continue to hybridize with wild relatives and potentially create serious problems as invasive species. Already, the costs imposed on the United States by non-native species is estimated at \$123 billion annually.¹³²

Recent research has revealed that weeds are beginning to develop resistance to Monsanto’s Roundup herbicide. Weeds resistant to the herbicide already have been discovered in Delaware, Maryland, California, Tennessee, Ohio, Kentucky, and Indiana. Although Monsanto claims this is not a significant problem, some scientists have a different opinion. One academic was recently quoted saying, “Long term what’s going to have to happen is getting away from the continuous use of Roundup.”¹³³

Other Risks Associated with Genetically Engineered Crops

Damage to Soil Ecosystems

Experiments on genetically engineered crops present other serious ecological risks. One profound but largely unexplored area is the damage genetically engineered crops may cause to soil ecosystems. Work published by Saxena et al. demonstrated that Bt toxin is released into the rhizosphere soil in root exudates from Bt corn.¹³⁴ The authors concluded that “there may be a risk that non-

target insects and organisms in higher trophic levels could be affected by the toxin.” In response to Saxena et al.’s research, the Biotechnology Industry Organization claimed that it is “hard to find anything here that’s surprising.”¹³⁵

Saxena’s work is reinforced by Donegan and Seidler, who state that “pesticidal proteins produced in transgenic plants can persist in soil and that binding of the proteins to soil particles can protect them from biotic degradation. We also found that plant genomic DNA in transgenic plants can persist in a field environment for several months.”¹³⁶ The authors point out that “it is crucial that risk assessment studies on the environmental use of transgenic plants consider the impacts on microbial communities. Research in this area has been quite limited, however, as demonstrated by the few available references.” EPA admitted its lack of knowledge on this subject when it allowed Bt crops to continue to be grown but asked biotechnology companies to conduct studies on levels of the toxin in the soil.¹³⁷

One important analysis of corporate research provided to the USDA on the impact of genetically engineered crops on soil ecosystems found both problems with the methodology as well as troubling results that speak clearly to the need for more independent research. The author of the study noted that “the vast majority of toxicity studies reported in USDA petitions for deregulation relied on appallingly few replicates.”¹³⁸

Virus Resistance

Biotechnology companies also are engineering crops to be virus resistant, raising several ecological concerns. Three main concerns are that new viral strains may arise, viral host ranges may broaden, or that existing viral diseases may become more severe. Schoelz and Wintermantel¹³⁹ and Greene and Allison¹⁴⁰ have reported instances of viral recombination

involving viral DNA inserted into transgenic plants. Scientists also have raised concerns about the safety of one particular promoter – the cauliflower mosaic virus – used in nearly every genetically engineered plant either in commercialization or field trials. Scientists have noted that the cauliflower mosaic virus is prone to viral recombination and that its consumption carries risks for human health.¹⁴¹

Increased Chemical Use

Proponents of genetic engineering argue that the new technology reduces or eliminates the use of toxic farm chemicals, which are frequently manufactured by the same companies now touting genetically engineered crops. They claim that crops engineered for resistance to herbicides reduce the use of weed killers and that pesticide-producing plants such as Bt displace chemical insecticide use. The reality is that the technology may actually be used to perpetuate the pesticide era paradigm of agriculture rather than end it.

Among the most common genetically engineered crops on the market today are so-called Roundup Ready, meaning they are resistant to Monsanto’s Roundup herbicide. In an important analysis of Roundup Ready soybeans, the former Chair of the Board on Agriculture for the National Academy of Sciences found that genetically engineered soybeans “clearly require more herbicides than conventional soybeans, despite claims to the contrary.”¹⁴² The same report also notes that “Monsanto has manipulated comparative data on [Roundup Ready] and conventional soybean herbicide use in ways that fall between misleading and dishonest.” Similar research published in 2000 found farmers using two to five times more herbicide with Roundup Ready soybeans compared to other popular weed management systems.¹⁴³

Crops engineered to produce their own insecticides usually produce a toxin derived from *Bacillus thuringiensis*, or Bt. As described

above, Bt is one of a limited number of tools that organic farmers have and can use as a natural pesticide. It is also used by many conventional growers. As a spray, Bt can be applied sparingly because of its reliable efficacy; it then breaks down very quickly. Genetically engineered Bt plants maintain a high and constant killing dose, however, raising the likelihood that insects will quickly develop resistance to Bt. This would mean that not only

organic farmers, but all farmers would lose an effective tool for pest control.¹⁴⁴ The prospects for the long-term efficacy of Bt spray are further dimmed by the recent news concerning pests that actually adapt to use the insecticidal toxin in Bt crops as an energy source, a development that “radically undermines one of the key developments claimed for them” and “may be an even greater threat to organic farming than has been envisaged.”¹⁴⁵

REPORT FINDINGS

Raising Risk examines USDA data on field tests of genetically engineered crops in order to document the geographic breadth of these open air experiments and to demonstrate the implications of USDA's inadequate oversight. This data, spanning 1987 through the end of 2004, reveals how the agency has allowed an enormous amount of experimentation under its legal jurisdiction to occur with inadequate oversight.

Introduction

Currently, thousands of field tests of genetically engineered organisms are taking place all over the United States. The health and environmental risks of genetically engineered crops have not been thoroughly tested, and yet these experiments occur in the open environment in almost every state. Further, the current regulatory regime does not adequately address concerns related to widespread genetic pollution, impacts on non-target species, and the contamination of nearby crops. Field tests are supposed to determine whether or not the desired effects achieved in a laboratory setting are replicable when grown in the field and assess the potential environmental impacts of these crops. Yet we have allowed genetically engineered crops to be grown widely with almost no precautions.

The field testing of genetically engineered crops is generally overseen by the Animal and Plant Health Inspection Service (APHIS), a division of the USDA. The primary and almost exclusive role of APHIS with respect to genetically engineered crops is to determine whether they are "plant pests" under the federal Plant Pest Act. The act defines a plant pest as anything that poses a risk or a threat to a plant. Genetically engineered plants are

considered at risk of being plant pests if: (1) the donor organism from which the engineered gene comes from, (2) the recipient organism (usually a crop plant), or (3) the vector used for the genetic engineering is regulated. Thus, for example, if a gene from a group of organisms that are considered to be plant pests is introduced into a plant that is not considered a plant pest, APHIS would regulate the resulting plant as a potential plant pest. Based upon the results of field trials, those seeking to commercialize genetically engineered crops can petition for deregulation under the Plant Pest Act. The Department of Agriculture has never rejected a petition for deregulation.*

Two key concepts to understand in describing APHIS regulation of field experiments are "field releases" and "field test sites." When an institution petitions APHIS to conduct a field experiment of a genetically engineered crop, it can ask to conduct that experiment at one location only or at multiple locations. If the institution conducts experiments in multiple states, each state is considered a field release. If the institution conducts tests on the same crop at different field locations, even within one state, each experiment is called a field test site. Therefore, a single field release can contain several field test sites. For example, a request to conduct three field experiments on corn, two in California and one in Oregon, counts as one permit request, two field releases, and three field test sites.

* It is important to note the distinction between oversight in the field testing stage versus oversight of genetically engineered crops grown commercially. Institutions petition USDA for deregulation with information gathered from field tests when seeking to grow a food crop commercially. APHIS has never rejected a petition for deregulated status. The lack of oversight for commercial planting of genetically engineered crops is not the focus of this paper.

Field Test Sites

Between 1987 and 2004, APHIS received 11,090 applications for field releases of genetically engineered crops. APHIS approved 10,296 of these applications, allowing 18,608 field releases comprised of 47,219 field test sites.

Between 1987 and 1993, when we knew even less about genetic engineering, USDA did not reject a single permit application for a field test of a genetically engineered crop. The pattern of allowing nearly every request to go forward continues; through 2004, USDA denied only 3.6% of applications for permits and/or notifications (see Appendix A). According to APHIS, perhaps the only reason a submission is ever rejected is for minor paperwork violations, such as incomplete applications.¹⁴⁶ When asked to do so, USDA has ruled in every case that genetically engineered crops deserve a “Finding of No Significant Impact,” a determination that the plant will not have a significant impact on the quality of the human environment nor will the plant pose a risk of becoming a plant pest.¹⁴⁷

As of January 2005, 14 states and territories have hosted more than 1,000 field test sites (see Table 1 and Appendix B1).

Table 1. States and Territories with the Most Field Test Sites, 1987-2004

State	Number of Field Test Sites	State	Number of Field Test Sites
HI	5,413	MN	1,701
IL	5,092	TX	1,494
IA	4,659	IN	1,489
PR	3,483	ID	1,272
CA	1,964	WI	1,246
NE	1,960	GA	1,051
PA	1,707	MS	1,008

In 1987, USDA acknowledged five field test sites, and in 1993 there were 901. In 2003, USDA reported 2,946 field test sites, a three-fold increase over 10 years. Through 1992, USDA only allowed field releases of genetically engineered organisms under a permitting procedure, but that was changed to allow tests of certain species under a streamlined notification system in 1993. In 1993, after six years of conducting all field test sites under the permit system, USDA approved 36% (323) of the field test sites under the notification system. In 2004, USDA approved 95% of the field test sites under the notification system (see Table 2 and Appendix B2).

Table 2. Number of Field Test Sites Under Permit and Notification: 1987-2004

Year	Sites Under Permit	Sites Under Notification	Total Field Test Sites
1987	5	0	5
1988	16	0	16
1989	40	0	40
1990	81	0	81
1991	155	0	155
1992	381	0	381
1993	578	323	901
1994	232	1,699	1,931
1995	212	3,644	3,856
1996	324	2,674	2,998
1997	583	3,217	3,800
1998	43	5,049	5,092
1999	1,240	3,883	5,123
2000	1,065	3,474	4,539
2001	1,450	4,337	5,787
2002	250	4,886	5,136
2003	167	2,779	2,946
2004	213	4,210	4,423

The number of field test sites conducted under notification drops slightly after 1998 for several reasons, including an increase in the field testing of novel crops. But the primary reason is that USDA has encouraged certain

institutions field testing corn to apply under the permitting system rather than the notification system, because the agency claims to be familiar with the tests and can process a large number of them together with less paperwork.¹⁴⁸ Institutions can combine several requests for field tests into one “comprehensive permit.”

Field Releases of Genetically Engineered Crops

Between 1987 and 2004, APHIS approved applications for 18,608 field releases on 566,337 acres in 48 states and two territories. Certain crops have been tested far more than others because of various factors, including their economic importance as well as scientists’ familiarity with how they function. Between 1987 and 2004, USDA authorized the most field releases for corn (9,095), soybean (1,762), cotton (1,623), potato (1,366) and tomato (593), as shown in Table 3. USDA authorized the largest acreage of field tests for corn (215,682 acres), cotton (142,876 acres), potato (116,389 acres), and soybean (25,468 acres), as shown in Table 4. Refer to Appendix C for a detailed breakdown of field releases by state or territory and Appendix D for a list of crops and the acreage tested since 1987.

Table 3. Genetically Engineered Crops with More than 300 Field Releases, 1987-2004

Crop	Number of Field Releases
Corn	9,095
Soybean	1,762
Cotton	1,623
Potato	1,366
Tomato	593
Wheat	450
Creeping bentgrass	436
Alfalfa	363
Beet	355

Table 4. Crops with Most Acreage in Field Testing, 1987-2004

Crop	Acreage
Corn	215,682
Cotton	142,876
Potato	116,389
Soybean	25,468
Rapeseed	19,126
Alfalfa	17,011
Tobacco	10,855
Rice	4,990
Creeping bentgrass	4,431
Wheat	2,643
Beet	2,177
Tomato	1,250

While several crops have had limited testing in the field since 1987, such as coffee, eggplant, onion, and pineapple, USDA approved field tests in 2003 and 2004 for the first time for several crops, including American chestnut, American elm, avocado, banana, eucalyptus, marigold, safflower, sorghum, and sugarbeet. Field testing for these crops, which is taking place all over the country in New York, California, Florida, Ohio, Hawaii, and many other states, is the first step in bringing a crop to market. The fact that the biotechnology industry is testing new crops shows that it will continue to seek commercialization for new varieties of crops not currently available in a genetically engineered form.

“Biopharming”

Since 1991, USDA has been approving field trials for crops that are engineered to produce pharmaceuticals, industrial chemicals, and other compounds not intended to enter the food supply. These crops are often termed “biopharm” crops because they create a new bridge between farming for human consumption and the pharmaceutical industry. Since 1991, USDA has received 240 requests for 418 field releases of crops engineered to produce pharmaceuticals, industrial

chemicals, or other biopharmaceuticals; the number of requested field releases of “biopharm” crops increased from 22 in 2003 to 55 in 2004. Although most field releases of these crops contain genes categorized as Confidential Business Information, some known examples include a blood clotter, an anti-nutrient, blood thinners, an abortion-inducing compound, industrial enzymes, and vaccines.¹⁴⁹ Appendix E details the permit requests for field tests of “biopharm” crops since 1991.

Institutions Conducting Field Tests

From 1987 through 2004 inclusive, Monsanto (or a wholly-owned subsidiary) applied for the most permits and/or notifications every year. As shown in Table 5, the universities submitting the most requests for permits are Iowa State (129), University of Idaho (102), and Rutgers University (102). See Appendix F for a list of the institutions applying under the permit or notification procedures for field releases between 1987 and 2004.

Table 5. Institutions Submitting the Most Applications for Permits or Notifications, 1987-2004

Institution	Total, 1987-2004
Monsanto	4,279
Pioneer	685
AgrEvo	344
Du Pont	325
ARS	274
Seminis Vegetable Seeds	195
DeKalb	192
Calgene	176
Syngenta	168
Scotts	155
Aventis	136
Iowa State U	129
Dow	126
Rutgers U	102
U of Idaho	102

Since 1995, of the top 10 institutions applying for permits and/or notifications, seven have now merged into two companies: Monsanto and DuPont. The speed at which the industry has consolidated is evident from a closer examination of the major companies submitting requests for permits or notifications in 1995. In 1995, the institution submitting the largest number of requests was Monsanto, with 143. In 2000, Monsanto “merged” with Pharmacia & Upjohn to create a company called Pharmacia, with Monsanto remaining an autonomous subsidiary self-described as “one of the largest and fastest growing companies in the agricultural sector.”¹⁵⁰ Monsanto is currently the world’s second largest seed seller, and the world’s third largest seller of agrochemicals.¹⁵¹ Since 1995, Monsanto has bought the companies ranked 5th, 7th, 8th, and 9th in that year.¹⁵²

Also in 1995, DuPont, currently the world’s largest seed seller and the world’s fourth largest seller of agrochemicals, ranked 2nd with 98 requests.¹⁵³ In 1999, DuPont merged with Pioneer Hi-Bred, creating what the DuPont CEO called “the most powerful agricultural technology force in the world.”¹⁵⁴ Pioneer Hi-Bred was ranked 3rd in 1995 in terms of companies submitting requests. The National Academy of Sciences recently warned that the “kinds of hazards associated with concentration of the seed industry might be paralleled by the hazards that occurred during concentration of the fertilizer industry.”¹⁵⁵

Confidential Business Information

Between 1987 and 1989, all field tests of genetically engineered organisms in USDA’s database contain introduced genes that are all publicly disclosed. But from 1989 through 2004, the percentage of applications for field tests of crops containing genes declared “Confidential Business Information” increased dramatically, from 0% in 1989 to 70% in 2004

(see Appendix G). One example of a commercial permit from DuPont, #99-029-01, is for 18 release locations totaling more than 5,000 acres, yet several genes transferred to the host plant are not publicly available. It is not only private corporations that are failing to disclose critical information regarding field experiments. Universities also are shutting out the public from knowing what new creations are being introduced into the environment.

Violations of Field Testing Regulations

It is no secret that institutions conducting field tests have violated USDA's regulations. This is known in part because of a report from President Clinton's Council on Environmental Quality and Office of Science and Technology Policy, where it is noted that, "From 1995 through 2000, APHIS recorded a total of 63 such compliance infractions."¹⁵⁶ In order to determine the extent to which institutions are complying with regulations, APHIS can either rely on the companies to report themselves or conduct inspections. In response to a Freedom of Information Act (FOIA) request to obtain the data on inspections of field trials, USDA reported that no records on this subject were kept prior to the year 2000 but also failed to provide any data after 2000. We remain in dialogue with the agency to obtain these data, although the agency has refused several requests for the information.

We also filed a separate FOIA request to obtain information on the type of violations of the field testing regulations that have occurred and the agency's response. Now several years after the filing of this FOIA, USDA still has only responded with the records of two compliance infractions. In one instance, cattle ate some leaves of plants being field tested. USDA responded by calling the company and asking what the company planned to do to prevent such an act in the future. In the other instance, the company planted a genetically engineered crop before it actually had approval from USDA. The agency responded by sending a letter.¹⁵⁷

USDA has now set up a web site that is supposed to provide information on compliance infractions.¹⁵⁸ So far, the information on this site appears to be incomplete. For example, the press has reported that the biotechnology company Ventria violated its 2003 permit by growing biopharm rice too close to rice intended for human and animal feed,¹⁵⁹ but information about the violation is missing from USDA's page. It is also important to note that EPA, which does share some responsibility in oversight for the field testing of certain genetically engineered plants, recently fined Pioneer Hi-Bred International and Mycogen Seeds for violating permit conditions.¹⁶⁰ Among other violations, the former had planted crops at an unapproved location, and the latter failed to utilize trees as windbreaks.¹⁶¹

CONCLUSION AND RECOMMENDATIONS

The lax regulation of genetically engineered organisms at USDA is predicated upon the scientifically dubious notion that genetically engineered plants are no different than traditionally bred plants. Moreover, the agency has supported and encouraged the development of this technology with minimal oversight, thus acting as an outspoken proponent of a technology that it is supposed to regulate dispassionately and objectively. Damage caused by genetic engineering to the environment may already be severe, including disruption of soil communities, damage to non-target organisms, genetic pollution and biodiversity loss, and the perpetuation of heavy pesticide use by – in part – destroying the efficacy of Bt for use in farming and creating crops dependent on the application of synthetic chemicals. The impact of the technology on farmers and society in general has not been fully explored, nor has there been a full debate about the ethical dimension of genetic engineering. Other agencies, too, share part of the blame, and there needs to be a comprehensive restructuring of the regulations for genetically engineered foods and crops at all the major agencies involved in oversight. But as explained in this paper, USDA has rubber-stamped nearly every application for genetically engineered field tests without a full understanding of the risks involved nor a full exploration of alternatives.

Consumer awareness and concern about the issue of genetic engineering has been higher abroad than in the United States thus far. However, as a result of incidents like the StarLink debacle and increased attention from public interest groups and the media, attention and concern are on the rise among American consumers. As people learn more about the risks of genetically engineered foods, they look to the USDA and other agencies for sufficient

regulation and oversight to ensure a safe food supply with environmental protections. Thus far, by essentially automatically approving permits, USDA has not been playing an adequate regulatory role. The U.S. regulatory system must operate in a way that places public health and environmental protection as paramount considerations.

Accordingly, we recommend a moratorium on the commercialization of genetically engineered foods and crops unless:

- ♦ **Independent safety testing demonstrates they have no harmful effects on human health or the environment.**

U.S. regulators have not properly tested genetically engineered products for human health or environmental impacts, nor explored their social and ethical dimensions. USDA should allow field tests of genetically engineered crops only after establishing a thorough and comprehensive ecological framework to assess their full impact. The field tests conducted thus far have largely failed to answer basic, fundamental questions, and thus have largely served to only put the environment and farmers' livelihoods at risk. To continue to allow experimentation under the same lax regulations will continue to be of little value to anyone.

Genetic engineering is a new technology and carries with it new risks. USDA must immediately abandon the notion of substantial equivalence. This means that USDA and other agencies should assume that each new crop/gene combination is different and may present unique risks. USDA should not approve any new crops for field testing until long-term, independently reviewed studies assess the range of ecological risks, including protocols

for evaluating the risks of creating new plant viruses, the nontarget effects of plant-pesticides, as well as weediness potential and gene flow. USDA should not approve any open air planting of crops engineered to produce industrial chemicals or pharmaceutical proteins, nor should these types of combinations ever occur in food plants.

- ♦ **The public's right to know about field tests is improved and any products commercialized are labeled.**

USDA should make all information about field tests available to the public via the Internet in an easily navigable way. Currently, no information about tests conducted before June 1987 is available, and data about tests conducted since are parsimonious and organized in a way that is difficult to maneuver.

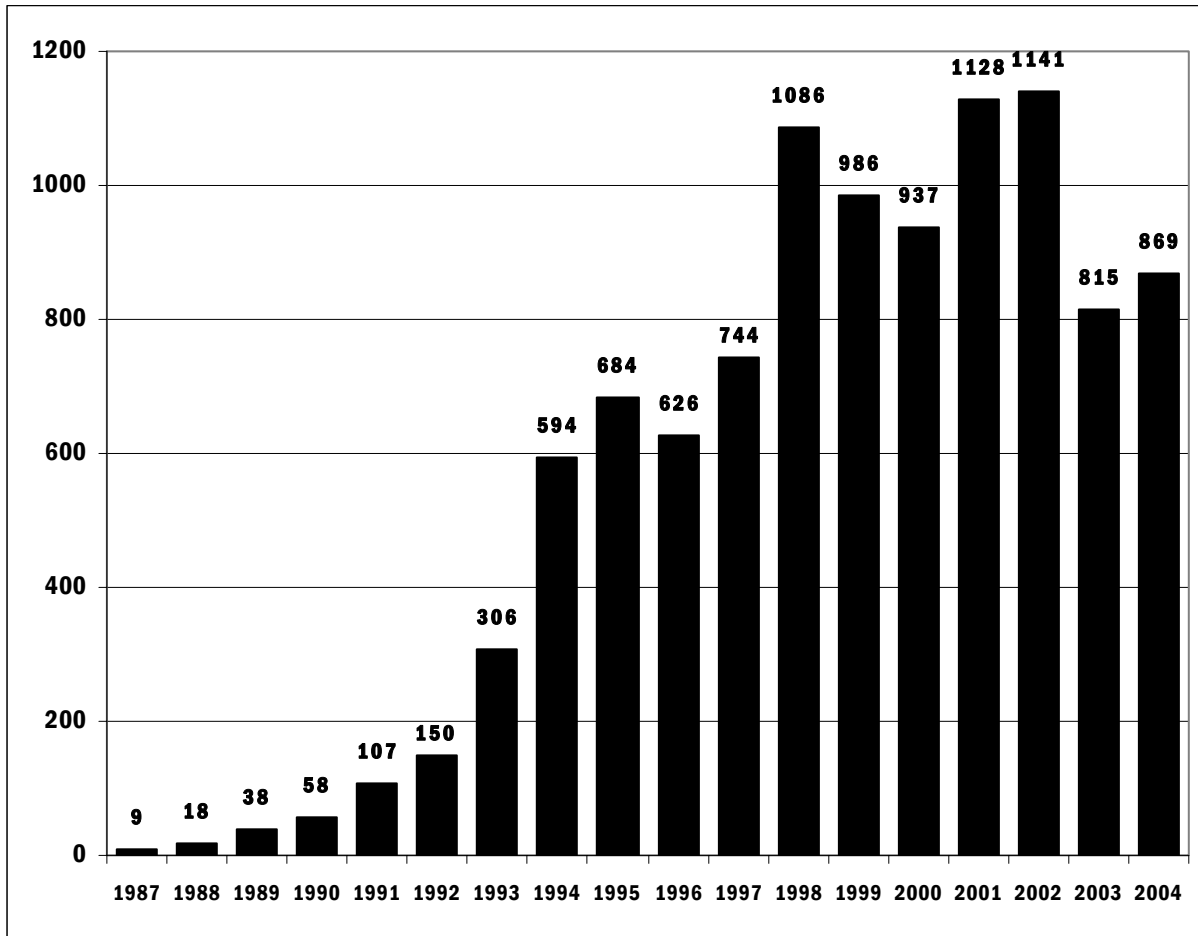
Data should include the locations and size of all field tests. Any products commercialized after rigorous safety testing should be clearly labeled so consumers have a choice about whether or not to purchase genetically engineered foods.

- ♦ **The biotechnology corporations that manufacture genetically engineered foods are held responsible for any harm.**

Regulators should hold the biotechnology companies that manufacture and test genetically engineered crops liable for adverse impacts caused by genetically engineered organisms, including impacts on the soil, nontarget organisms, other plants, the environment in general, and human health.

APPENDIX A:

1. Number of Approved Permits and Notifications by Year: 1987-2004



2. Total Permit Applications and Results (1987-2002)

Year	Received	Approved	Denied	Withdrawn	Voided	Pending
1987	9	9	0	0	0	0
1988	18	18	0	0	0	0
1989	38	38	0	0	0	0
1990	58	58	0	0	0	0
1991	107	107	0	0	0	0
1992	161	150	0	11	0	0
1993	374	306	0	68	0	0
1994	609	594	6	9	0	0
1995	709	684	2	18	5	0
1996	654	626	8	20	0	0
1997	808	744	33	28	3	0
1998	1,206	1,086	108	10	2	0
1999	1,062	986	47	23	6	0
2000	1,012	937	57	17	1	0
2001	1,189	1,128	39	20	2	0
2002	1,185	1,141	32	12	0	0
2003	867	815	30	19	2	1
2004	1,024	869	36	18	0	99
Total	11,090	10,296	398	273	21	100

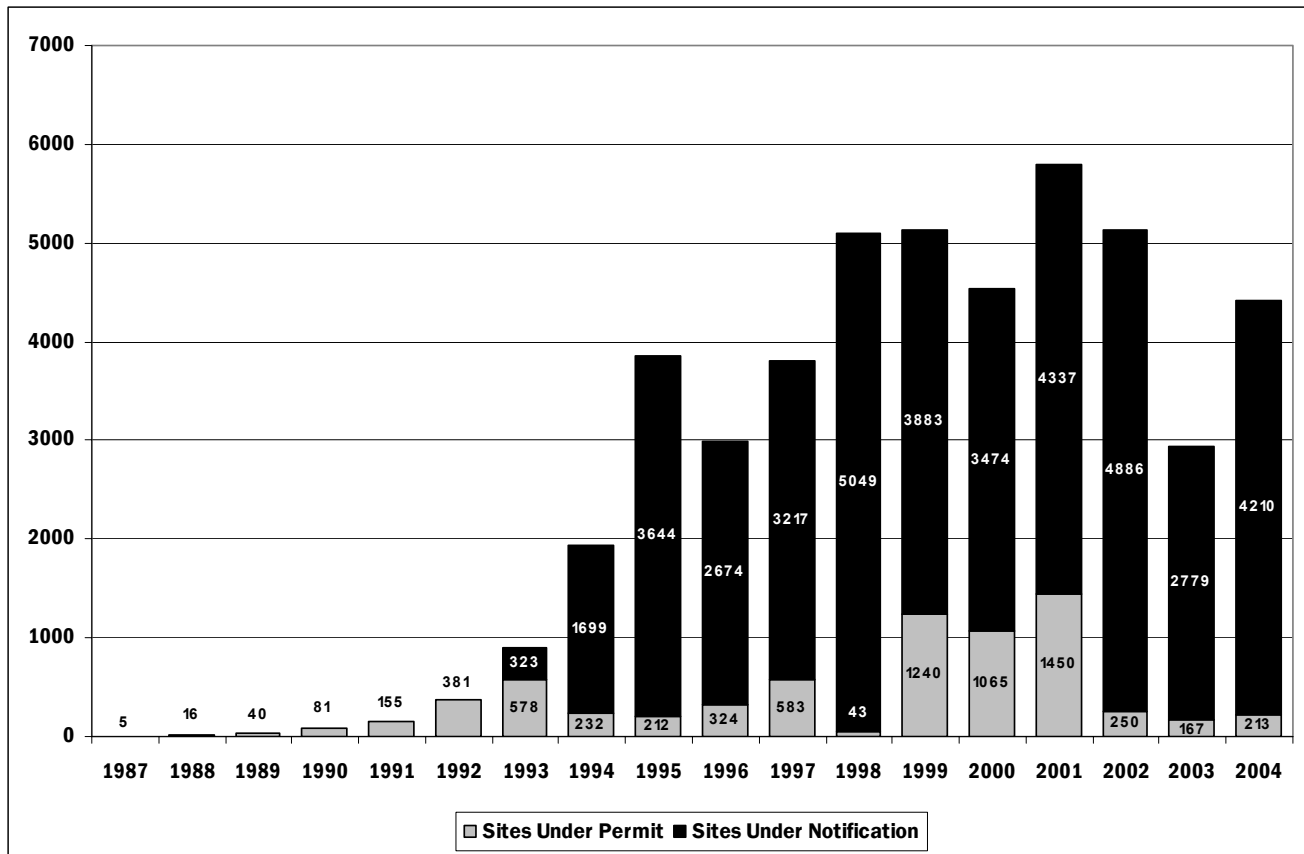
APPENDIX B:

1. Number of Field Test Sites, Ranked by State or Territory (1987-2004)

Rank	State	Number of Field Test Sites
1	Hawaii	5,413
2	Illinois	5,092
3	Iowa	4,659
4	Puerto Rico	3,483
5	California	1,964
6	Nebraska	1,960
7	Pennsylvania	1,707
8	Minnesota	1,701
9	Texas	1,494
10	Indiana	1,489
11	Idaho	1,272
12	Wisconsin	1,246
13	Georgia	1,051
14	Mississippi	1,008
15	Florida	896
16	North Carolina	781
17	North Dakota	759
18	Michigan	756
19	Kansas	730
20	Missouri	719
21	Arkansas	682
22	Louisiana	634
23	Oregon	627
24	Ohio	617
25	Washington	563
26	Tennessee	547
Total		

Rank	State	Number of Field Test Sites
27	Arizona	542
28	South Carolina	509
29	Maryland	474
30	Alabama	467
31	South Dakota	441
32	Delaware	392
33	Maine	375
34	New York	314
35	Colorado	311
36	Montana	297
37	Kentucky	273
38	Virginia	223
39	New Jersey	220
40	Connecticut	210
41	Oklahoma	120
42	Wyoming	52
43	Massachusetts	40
44	New Mexico	38
45	Utah	31
46	West Virginia	15
47	Alaska	8
47	Virgin Islands	8
49	Rhode Island	7
50	Nevada	2
51	New Hampshire	0
51	Vermont	0
		47,219

2. Field Test Sites Under Permit and Notification, 1987-2004



APPENDIX C:

Field Test Sites, Field Releases, and Crops Tested by State or Territory: 1987-2004

ALABAMA

Number of field releases 254

Number of field test sites 467

Plants Tested	Number of field releases
Alfalfa	1
Corn	49
Cotton	109
Creeping bentgrass	7
Kentucky bluegrass	3
Pea	1
Peanut	1
Poplar	1
Populus deltoides	2
Potato	8
Pseudomonas	3
Pseudomonas putida	1
Pseudomonas syringae	2
Rapeseed	8
Rice	1
Soybean	37
St. Augustine grass	4
Sweet potato	4
Tomato	5
Xanthomonas	6
Xanthomonas campestris	1

ALASKA

Number of field releases 6

Number of field test sites 8

Plants Tested	Number of field releases
Lettuce	1
Potato	4
Rice	1

ARIZONA

Number of field releases 278

Number of field test sites 542

Plants Tested	Number of field releases
Alfalfa	3
Beet	12
Corn	38
Cotton	137
Creeping bentgrass	5
Guayule	1
Lettuce	11
Melon	15
Pink bollworm	3
Rapeseed	21
Rice	1
Safflower	1
Squash	1
Sugarbeet	1
Tobacco	3
Tomato	1
Wheat	24

ARKANSAS

Number of field releases 289

Number of field test sites 682

Plants Tested	Number of field releases
Corn	31
Cotton	107
Kentucky bluegrass	1
Rice	39
Soybean	107
Wheat	4

CALIFORNIA

Number of field releases 1163

Number of field test sites 1964

Plants Tested	Number of field releases
Alfalfa	48
Apple	10
Avocado	1
Barley	3
Beet	27
Brassica	15
Brassica juncea	1
Brassica oleracea	13
Carrot	4
Chrysanthemum	1
Cichorium intybus	1
Corn	163
Cotton	79
Creeping bentgrass	13
Cucumber	10
Grape	20
Kentucky bluegrass	2
Lettuce	59
Melon	78
Onion	5
Pea	11
Pelargonium	3
Pepper	8
Persimmon	4
Petunia	6
Potato	40
Pseudomonas	1
Pseudomonas syringae	1
Rapeseed	60
Rice	78
Rubus idaeus	3
Soybean	2
Squash	24
St. Augustine grass	4
Strawberry	31
Sunflower	11
Tobacco	4
Tomato	283
Walnut	12
Watermelon	6
Wheat	18

COLORADO

Number of field releases 171

Number of field test sites 311

Plants Tested	Number of field releases
Alfalfa	10
Beet	31
Corn	55
Creeping bentgrass	5
Potato	26
Rapeseed	20
Sunflower	2
Wheat	22

CONNECTICUT

Number of field releases 230

Number of field test sites 210

Plants Tested	Number of field releases
Alfalfa	1
Corn	206
Creeping bentgrass	5
Cryphonectria parasitica	2
Kentucky bluegrass	2
Poplar	1
Populus deltoides	2
Potato	1
Rhododendron	7
Soybean	3

DELAWARE

Number of field releases 205

Number of field test sites 392

Plants Tested	Number of field releases
Corn	146
Cotton	1
Creeping bentgrass	5
Potato	3
Soybean	45
Squash	1
Tobacco	2
Tomato	2

FLORIDA

Number of field releases 654

Number of field test sites 896

Plants Tested	Number of field releases
Banana	1
Begonia semperflorens	1
Carrot	4
Chrysanthemum	2
Citrus viroid III	2
Corn	222
Cotton	34
Creeping bentgrass	4
Eucalyptus camaldulensis	2
Eucalyptus grandis	15
Grape	1
Grapefruit	1
Kentucky bluegrass	1
Lettuce	4
Melon	7
Metaseiulus occidentalis	1
Papaya	5
Paspalum notatum	3
Pea	2
Peanut	2
Pelargonium	1
Pepper	4
Petunia	9
Poplar	2
Potato	89
Rapeseed	7
Rice	5
Soybean	22
Squash	3
St. Augustine grass	9
Strawberry	1
Sugarcane	12
TMV	2
Tobacco	10
Tomato	153
Watermelon	3
Wheat	1
Xanthomonas	4
Xanthomonas campestris	2
Xanthomonas campestris pv. vesicatoria	1

GEORGIA

Number of field releases 373

Number of field test sites 1051

Plants Tested	Number of field releases
Alfalfa	3
Bermudagrass	4
Corn	57
Cotton	110
Creeping bentgrass	6
Cucumber	9
Fusarium moniliforme	1
Fusarium verticillioides	1
Lettuce	3
Melon	25
Pea	23
Peanut	23
Poplar	1
Potato	2
Rapeseed	26
Soybean	30
Squash	18
St. Augustine grass	4
Sweet potato	1
Sweetgum	5
Tobacco	9
Tomato	11
Watermelon	1

HAWAII

Number of field releases 1685

Number of field test sites 5413

Plants Tested	Number of field releases
Anthurium andreanum	1
Apple	2
Barley	2
Coffee	3
Corn	1545
Cotton	13
Dendrobium	3
Lettuce	1
Papaya	12
Pea	1
Peanut	1
Pine	2
Pineapple	2
Potato	1
Rice	23
Soybean	33
Sugarcane	1
Sunflower	6
Tobacco	11
Tomato	4
Wheat	18

IDAHO

Number of field releases 525

Number of field test sites 1272

Plants Tested	Number of field releases
Alfalfa	43
Barley	15
Beet	42
Carrot	1
Corn	55
Creeping bentgrass	6
Kentucky bluegrass	2
Pea	15
Potato	272
Rapeseed	20
Tomato	1
Wheat	53

ILLINOIS

Number of field releases	1584
Number of field test sites	5092
Plants Tested	Number of field releases
Alfalfa	8
Arab. thaliana	9
Arabidopsis	1
Barley	3
Beet	1
Belladonna	6
Carrot	2
Clavibacter	1
Corn	1217
Cotton	5
Creeping bentgrass	14
Fusarium graminearum	8
Fusarium moniliforme	1
Fusarium sporotrichioides	1
Kentucky bluegrass	4
Melon	1
Pelargonium	1
Petunia	3
Potato	5
Rapeseed	7
Rice	2
Soybean	219
Squash	1
Sunflower	1
Tobacco	18
Tomato	23
Wheat	19
Xanthomonas	1
Xanthomonas campestris	1
Xanthomonas campestris pv. vesicatoria	1

INDIANA

Number of field releases	680
Number of field test sites	1489
Plants Tested	Number of field releases
Alfalfa	18
Corn	475
Creeping bentgrass	8
Festuca arundinacea	2
Fusarium graminearum	4
Kentucky bluegrass	2
Pepper	1
Peppermint	1
Poplar	1
Populus deltoides	1
Potato	3
Rapeseed	1
Rice	1
Soybean	116
Sunflower	3
Tomato	31
Wheat	12

IOWA

Number of field releases	1225
Number of field test sites	4659
Plants Tested	Number of field releases
Alfalfa	35
Barley	3
Beet	2
Clavibacter	1
Clavibacter xyli	1
Corn	959
Creeping bentgrass	8
Fusarium moniliforme	1
Kentucky bluegrass	3
Oat	1
Poplar	2
Pseudomonas	1
Pseudomonas syringae	1
Rapeseed	2
Soybean	199
Sunflower	2
Tobacco	4

KANSAS

Number of field releases 293

Number of field test sites 730

Plants Tested	Number of field releases
Alfalfa	4
Corn	214
Cotton	2
Creeping bentgrass	8
Sorghum	1
Soybean	48
Tobacco	1
Wheat	15

KENTUCKY

Number of field releases 170

Number of field test sites 273

Plants Tested	Number of field releases
Alfalfa	5
Corn	41
Creeping bentgrass	11
Kentucky bluegrass	2
Perennial ryegrass	2
Poplar	2
Potato	1
Soybean	31
TEV	1
TMV	7
Tobacco	66
Tomato	1

LOUISIANA

Number of field releases 246

Number of field test sites 634

Plants Tested	Number of field releases
Aspergillus flavus	5
Corn	19
Cotton	97
Petunia	1
Potato	1
Rice	67
Soybean	23
St. Augustine grass	3
Strawberry	3
Sugarcane	21
Sweet potato	1
Tobacco	4
Wheat	1

MAINE

Number of field releases 143

Number of field test sites 375

Plants Tested	Number of field releases
Cotton	1
Potato	142

MARYLAND

Number of field releases 310

Number of field test sites 474

Plants Tested	Number of field releases
Clavibacter	7
Clavibacter xyli	1
Corn	174
Cotton	3
Creeping bentgrass	11
Gladiolus	3
Potato	9
Soybean	90
Squash	3
Tobacco	2
Tomato	7

MASSACHUSETTS

Number of field releases 17

Number of field test sites 40

Plants Tested	Number of field releases
Corn	1
Creeping bentgrass	10
Kentucky bluegrass	2
Potato	4

MICHIGAN

Number of field releases 324

Number of field test sites 756

Plants Tested	Number of field releases
Alfalfa	3
Amelanchier laevis	1
Arab. thaliana	1
Beet	21
Carrot	1
Corn	123
Creeping bentgrass	13
Cucumber	8
Kentucky bluegrass	3
Melon	24
Poplar	3
Potato	66
Rapeseed	11
Soybean	29
Squash	9
Tomato	6
Watermelon	2

MINNESOTA

Number of field releases 597

Number of field test sites 1701

Plants Tested	Number of field releases
Alfalfa	13
Barley	4
Beet	46
CBI	1
Clavibacter	1
Corn	364
Creeping bentgrass	5
Pea	2
Petunia	1
Poplar	3
Potato	50
Rapeseed	27
Soybean	38
Sunflower	3
Wheat	39

MISSISSIPPI

Number of field releases 434

Number of field test sites 1008

Plants Tested	Number of field releases
Alfalfa	2
Aspergillus flavus	5
Corn	53
Cotton	260
Kentucky bluegrass	2
Poplar	2
Rice	21
Soybean	77
St. Augustine grass	4
Strawberry	3
Tobacco	5

MISSOURI

Number of field releases 365

Number of field test sites 719

Plants Tested	Number of field releases
Alfalfa	6
Arab. thaliana	1
Corn	226
Cotton	37
Creeping bentgrass	9
Kentucky bluegrass	2
Poplar	1
Populus deltoides	1
Potato	4
Rice	9
Soybean	65
Tobacco	1
Tomato	3

NEBRASKA

Number of field releases 635

Number of field test sites 1960

Plants Tested	Number of field releases
Alfalfa	8
Beet	21
Clavibacter	4
Clavibacter xyli	1
Corn	467
Creeping bentgrass	11
Kentucky bluegrass	2
Melon	1
Potato	26
Rapeseed	1
Soybean	55
Squash	1
St. Augustine grass	4
Sunflower	2
Triticum	1
Wheat	30

MONTANA

Number of field releases 131

Number of field test sites 297

Plants Tested	Number of field releases
Alfalfa	7
Barley	2
Beet	17
Corn	1
Creeping bentgrass	4
Potato	34
Rapeseed	5
Wheat	61

NEVADA

Number of field releases 2

Number of field test sites 2

Plants Tested	Number of field releases
Creeping bentgrass	1
Safflower	1

NEW JERSEY

Number of field releases 180

Number of field test sites 220

Plants Tested	Number of field releases
Bermudagrass	9
Corn	17
Creeping bentgrass	96
Eggplant	7
Heterorhabditis bacteriophora	1
Kentucky bluegrass	22
Lettuce	1
Perennial ryegrass	3
Poa pratensis X Poa arachnifera	2
Poplar	1
Potato	9
Soybean	6
Squash	3
Tobacco	3

NEW MEXICO

Number of field releases 32

Number of field test sites 38

Plants Tested	Number of field releases
Alfalfa	1
Corn	6
Cotton	8
Onion	1
Potato	14
Soybean	2

NEW YORK

Number of field releases 232

Number of field test sites 314

Plants Tested	Number of field releases
Alfalfa	10
American Chestnut	2
American elm	2
Apple	12
Barley	1
Begonia semperflorens	1
Brassica	4
Brassica oleracea	4
Corn	49
Creeping bentgrass	14
Cucumber	3
Cucurbita texana	2
Grape	20
Kentucky bluegrass	1
Melon	13
Papaya	1
Pelargonium	1
Petunia	7
Poplar	3
Populus deltoides	1
Potato	46
Rosa hybrida	2
Squash	11
Tomato	20
Wheat	2

NORTH CAROLINA

Number of field releases 348

Number of field test sites 781

Plants Tested	Number of field releases
Arab. thaliana	5
Brassica	3
Brassica rapa	3
Clary	2
Corn	112
Cotton	96
Creeping bentgrass	6
Festuca arundinacea	4
Kentucky bluegrass	2
Poplar	1
Potato	8
Rapeseed	3
Soybean	24
Squash	5
St. Augustine grass	4
TMV	3
Tobacco	60
Tomato	4
Wheat	3

NORTH DAKOTA

Number of field releases 269

Number of field test sites 759

Plants Tested	Number of field releases
Alfalfa	7
Barley	8
Beet	43
Corn	30
Cotton	1
Potato	81
Rapeseed	31
Safflower	2
Soybean	5
Sunflower	11
Wheat	50

OHIO

Number of field releases 351

Number of field test sites 617

Plants Tested	Number of field releases
Alfalfa	3
Arab. thaliana	1
Beet	1
Begonia semperflorens	3
Corn	187
Creeping bentgrass	45
Kentucky bluegrass	20
Marigold	2
Melon	1
Pelargonium	4
Petunia	15
Poa pratensis X Poa arachnifera	2
Potato	9
Soybean	39
Squash	1
St. Augustine grass	10
Tomato	8

OKLAHOMA

Number of field releases 90

Number of field test sites 120

Plants Tested	Number of field releases
Alfalfa	12
Corn	23
Cotton	23
Festuca arundinacea	9
Italian ryegrass	2
Pea	4
Peanut	4
Perennial ryegrass	1
Potato	1
Russian wildrye	4
Soybean	2
Squash	1
Tobacco	2
Wheat	2

OREGON

Number of field releases 325

Number of field test sites 627

Plants Tested	Number of field releases
Alfalfa	6
Apple	8
Barley	1
Beet	57
Corn	12
Creeping bentgrass	42
Erwinia spp.	1
Kentucky bluegrass	18
Melon	14
Pea	3
Pear	3
Petunia	1
Poa pratensis X Poa arachnifera	2
Poplar	34
Potato	81
Rapeseed	2
Rubus idaeus	8
Squash	1
St. Augustine grass	1
Strawberry	7
Sugarbeet	4
Tomato	10
Wheat	9

PUERTO RICO

Number of field releases 1330

Number of field test sites 3483

Plants Tested	Number of field releases
Corn	944
Cotton	99
Papaya	1
Rice	15
Soybean	262
Tobacco	1
Tomato	8

RHODE ISLAND

Number of field releases 8

Number of field test sites 7

Plants Tested	Number of field releases
Corn	1
Creeping bentgrass	4
Potato	2
Velvet bentgrass	1

PENNSYLVANIA

Number of field releases 188

Number of field test sites 1707

Plants Tested	Number of field releases
Alfalfa	14
Corn	125
Creeping bentgrass	10
Kentucky bluegrass	8
Poa pratensis X Poa arachnifera	3
Potato	8
Soybean	13
Squash	1
Tobacco	6

SOUTH CAROLINA

Number of field releases 266

Number of field test sites 509

Plants Tested	Number of field releases
Arab. thaliana	1
Chrysanthemum	1
Corn	1
Cotton	92
Creeping bentgrass	4
Eucalyptus camaldulensis	4
Eucalyptus grandis	12
Kentucky bluegrass	2
Pine	48
Plum	1
Poplar	25
Populus deltoides	9
Potato	5
Rapeseed	8
Soybean	12
Squash	3
St. Augustine grass	5
Sweet potato	3
Sweetgum	19
Tobacco	10
Tomato	1

SOUTH DAKOTA

Number of field releases 188

Number of field test sites 441

Plants Tested	Number of field releases
Alfalfa	2
Barley	1
Beet	1
Corn	140
Potato	1
Rapeseed	2
Soybean	13
Sunflower	3
Wheat	25

TENNESSEE

Number of field releases 272

Number of field test sites 547

Plants Tested	Number of field releases
Alfalfa	3
Corn	139
Cotton	70
Creeping bentgrass	2
Kentucky bluegrass	2
Poplar	2
Populus deltoides	1
Rapeseed	4
Rice	1
Soybean	41
Squash	1
Tobacco	6

TEXAS

Number of field releases 454

Number of field test sites 1494

Plants Tested	Number of field releases
Alfalfa	13
Beet	3
Brassica	2
Brassica oleracea	2
Carrot	1
Citrus sinensis X Poncirus trifoliata	1
Corn	117
Cotton	217
Grape	4
Grapefruit	4
Kentucky bluegrass	2
Melon	9
Onion	1
Potato	6
Rapeseed	3
Rice	27
Soybean	15
Squash	6
St. Augustine grass	7
Sugarcane	11
Tobacco	2
Tomato	1

UTAH

Number of field releases 24

Number of field test sites 31

Plants Tested	Number of field releases
Alfalfa	4
Beet	1
Creeping bentgrass	2
Kentucky bluegrass	9
Nicotiana attenuata	5
Poa pratensis X Poa arachnifera	3

VIRGIN ISLANDS

Number of field releases 10

Number of field test sites 8

Plants Tested	Number of field releases
Cassava	4
Papaya	4
Potato	1
Sweet potato	1

VIRGINIA

Number of field releases 127

Number of field test sites 223

Plants Tested	Number of field releases
Alfalfa	1
Beet	1
Corn	26
Cotton	14
Creeping bentgrass	9
Kentucky bluegrass	3
Pea	1
Peanut	1
Poplar	4
Potato	16
Soybean	15
Squash	3
Tobacco	29
Tomato	4

WASHINGTON

Number of field releases 281

Number of field test sites 563

Plants Tested	Number of field releases
Alfalfa	18
Apple	12
Barley	17
Beet	7
Cephalosporium gramineum	2
Corn	11
Creeping bentgrass	19
Grape	9
Kentucky bluegrass	2
Pea	8
Pear	3
Pepper	2
Peppermint	2
Poplar	8
Potato	109
Rapeseed	6
Rubus idaeus	5
Tobacco	1
Wheat	40

WEST VIRGINIA

Number of field releases 16

Number of field test sites 15

Plants Tested	Number of field releases
Alfalfa	1
Apple	2
Cryphonectria parasitica	3
Pea	2
Pear	2
Plum	3
Poplar	1
Potato	2

WISCONSIN

Number of field releases 599

Number of field test sites 1246

Plants Tested	Number of field releases
Alfalfa	48
Barrelclover	1
Beet	3
Corn	249
Cotton	8
Cranberry	1
Creeping bentgrass	13
Kentucky bluegrass	2
Onion	1
Poplar	3
Potato	176
Pseudomonas	13
Pseudomonas syringae	10
Rapeseed	7
Rhizobium	4
Rhizobium etli	2
Rhizobium fredii	1
Rhizobium leguminosarum	3
Soybean	44
Spruce	1
Tobacco	3
Tomato	6

WYOMING

Number of field releases 26

Number of field test sites 52

Plants Tested	Number of field releases
Alfalfa	2
Beet	18
Corn	2
Creeping bentgrass	1
Rapeseed	1
Wheat	2

NATIONAL TOTALS

Number of field releases 18,608

Number of field test sites 47,219

Total estimated acreage 566,337

Plants Tested	Number of field releases
Alfalfa	363
Amelanchier laevis	1
American Chestnut	2
American elm	2
Anthurium andreaeanum	1
Apple	46
Arab. thaliana	18
Arabidopsis	1
Aspergillus flavus	10
Avocado	1
Banana	1
Barley	60
Barrelclover	1
Beet	355
Begonia semperflorens	5
Belladonna	6
Bermudagrass	13
Brassica	24
Brassica juncea	1
Brassica oleracea	19
Brassica rapa	3
Bt	0
Carrot	13
Cassava	4
CBI	1
Cephalosporium gramineum	2
Chrysanthemum	4
Cichorium intybus	1
Citrus sinensis X Poncirus trifoliata	1
Citrus viroid III	2
Clary	2
Clavibacter	14
Clavibacter xyli	3
Coffee	3
Corn	9095
Cotton	1623
Cranberry	1
Creeping bentgrass	436
Cryphonectria parasitica	5

National Totals, continued

Plants Tested	Number of field releases
Cucumber	30
Cucurbita texana	2
Dendrobium	3
E. coli	0
Eggplant	7
Erwinia spp.	1
Eucalyptus camaldulensis	6
Eucalyptus grandis	27
Festuca arundinacea	15
Fusarium graminearum	12
Fusarium moniliforme	3
Fusarium sporotrichioides	1
Fusarium verticillioides	1
Gladiolus	3
Grape	54
Grapefruit	5
Guayule	1
Heterorhabditis bacteriophora	1
Italian ryegrass	2
Kentucky bluegrass	126
Lettuce	80
Lime	0
Marigold	2
Melon	188
Metaseiulus occidentalis	1
Nicotiana attenuata	5
Oat	1
Onion	8
Papaya	23
Paspalum notatum	3
Pea	73
Peanut	32
Pear	8
Pelargonium	10
Pepper	15
Peppermint	3
Perennial ryegrass	6
Persimmon	4
Petunia	43
Pine	50
Pineapple	2
Pink bollworm	3

National Totals, continued

Plants Tested	Number of field releases
Plum	4
Poa pratensis X Poa arachnifera	12
Poplar	101
Populus deltoides	17
Potato	1366
Pseudomonas	18
Pseudomonas putida	1
Pseudomonas syringae	14
Rapeseed	283
Rhizobium	4
Rhizobium etli	2
Rhizobium fredii	1
Rhizobium leguminosarum	3
Rhizobium meliloti	0
Rhododendron	7
Rice	291
Rosa hybrida	2
Rubus idaeus	16
Russian wildrye	4
Safflower	4
Sorghum	1
Soybean	1762
Spruce	1
Squash	97
St. Augustine grass	59
Strawberry	45
Sugarbeet	5
Sugarcane	45
Sunflower	44
Sweet potato	10
Sweetgum	24
TEV	1
TMV	12
Tobacco	263
Tomato	593
Triticum	1
Velvet bentgrass	1
Walnut	12
Watermelon	12
Wheat	450
Xanthomonas	11
Xanthomonas campestris	4
Xanthomonas campestris pv. vesicatoria	2

APPENDIX D:

Acreage of Crops Field Tested, 1987-2004

Crop	Acreage
Alfalfa	17,011.1
American elm	1.3
Anthurium andreanum	1.0
Apple	103.1
Arab. thaliana	2.7
Avocado	0.5
Banana	1.3
Barley	44.0
Barrelclover	4.0
Beet	2,176.7
Begonia semperflorens	10.0
Belladonna	1.0
Bermudagrass	6.3
Brassica	131.4
Brassica juncea	0.3
Brassica oleracea	10.1
Brassica rapa	1.0
Carrot	6.3
Cassava	1.1
CBI	1.0
Chrysanthemum	4.0
Citrus sinensis X Poncirus trifoliata	0.3
Citrus viroid III	21.0
Clary	0.3
Corn	215,682.2

Crop	Acreage
Cotton	142,875.9
Creeping bentgrass	4,430.9
Cryphonectria parasitica	2.0
Cucumber	69.4
Cucurbita texana	1.0
Dendrobium	3.0
Eggplant	1.5
Eucalyptus camaldulensis	17.9
Eucalyptus grandis	30.2
Festuca arundinacea	4.5
Gladiolus	1.3
Grape	194.9
Grapefruit	1.2
Guayule	0.5
Italian ryegrass	0.6
Kentucky bluegrass	787.9
Lettuce	166.0
Marigold	4.0
Melon	340.9
Metaseiulus occidentalis	34.0
Nicotania attenuata	3.0
Oat	0.1
Onion	11.0
Papaya	15.3
Paspalum notatum	2.5

Crop	Acreage
Pea	75.7
Peanut	17.8
Pear	16.5
Pelargonium	14.0
Pepper	2.2
Peppermint	0.2
Perennial ryegrass	3.7
Persimmon	4.0
Petunia	63.5
Pine	44.8
Pineapple	2.0
Pink bollworm	3.0
Plum	1.0
Poa pratensis X Poa arachnifera	140.0
Poplar	126.7
Populus deltoides	27.7
Potato	116,388.9
Pseudomonas	9.2
Pseudomonas syringae	9.2
Rapeseed	19,126.3
Rhododendron	0.9
Rice	4,990.1
Rosa hybrida	4.0
Rubus idaeus	4.6
Russian wildrye	0.6

Crop	Acreage
Safflower	28.0
Sorghum	0.5
Soybean	25,467.9
Squash	118.3
St. Augustine grass	193.0
Strawberry	12.6
Sugarbeet	85.0
Sugarcane	37.1
Sunflower	201.6
Sweet potato	11.8
Sweetgum	25.4
TEV	0.3
TMV	70.0
Tobacco	10,854.8
Tomato	1,249.8
Triticum	1.0
Velvet bentgrass	1.0
Walnut	15.0
Watermelon	19.7
Wheat	2,642.9
Xanthomonas	1.2
Xanthomonas campestris	1.2
Xanthomonas campestris pv. vesicatoria	1.2
Total	566,337

APPENDIX E:

Applications for Field Releases of “Biopharm” Crops: 1987-2004

Institution	Crop/ Organism	Application Received	Application Status	Issued	Effective	Phenotype(s)	Release Location(s)	Acreage	Begin Release	End Release
Biosource	TMV	01/07/91	Issued	05/01/91		Pharmaceutical proteins produced	NC			
Noble Foundation	Alfalfa	07/01/92	Issued	10/10/92		Pharmaceutical proteins produced	OK			
U of Wisconsin	Alfalfa	03/29/93	Issued	06/04/93		Industrial enzyme produced	WI			
Agracetus	Soybean	11/17/93	Acknowledged		12/17/93	Industrial enzyme produced	PR	0.1	01/01/94	03/31/94
Cargill	Rapeseed	02/17/93	Issued	05/04/93		Industrial enzymes produced	CO, IL			
Agracetus	Soybean	09/14/94	Acknowledged		10/14/94	Antibody produced	AR, MD, PR	5	10/16/94	10/16/96
Agracetus	Soybean	10/06/94	Acknowledged		11/05/94	Antibody produced	AR, MD, PR	0.5	11/10/94	11/10/96
Agracetus	Corn	10/06/94	Acknowledged		11/05/94	Antibody produced	PR, WI	0.3	11/10/94	11/10/96
Agracetus	Soybean	05/16/94	Acknowledged		06/15/94	Industrial enzyme produced	MD	0.5	06/01/94	12/01/94
U of Wisconsin	Alfalfa	12/28/94	Issued	04/12/95		Industrial enzyme produced	OR, WI			
Agracetus	Soybean	03/15/95	Acknowledged		04/14/95	Antibody produced	WI	0.1	04/10/95	04/10/96
Agracetus	Soybean	03/15/95	Acknowledged		04/14/95	Antibody produced	WI	0.1	04/10/95	04/10/96
Agracetus	Soybean	04/03/95	Acknowledged		05/03/95	Antibody produced	WI	1	05/01/95	12/01/95
Agracetus	Soybean	04/03/95	Acknowledged		05/03/95	Antibody produced	WI	1	05/01/95	12/01/95
Agracetus	Corn	04/03/95	Acknowledged		05/03/95	Antibody produced	WI	1	05/01/95	12/01/95
Agracetus	Corn	04/03/95	Acknowledged		05/03/95	Antibody produced	IA, MI, WI	3	05/01/95	12/01/95
Agracetus	Soybean	04/11/95	Acknowledged		05/11/95	Antibody produced	WI	1	05/01/95	12/01/95
Agracetus	Corn	09/13/95	Acknowledged		10/13/95	Antibody produced	PR	2	10/15/95	10/15/96
Agracetus	Soybean	09/26/95	Acknowledged		10/26/95	Antibody produced	PR	1	10/25/95	10/25/96
Agracetus	Corn	12/06/95	Acknowledged		01/05/96	Antibody produced	HI	1	01/08/95	01/08/96
Agracetus	Soybean	01/19/95	Acknowledged		02/18/95	Industrial enzyme produced	PR	0.1	02/01/95	02/01/97
Pioneer	Corn	01/26/95	Acknowledged		02/25/95	Novel protein produced	HI	22.5	03/01/95	06/01/95
Pioneer	Corn	01/26/95	Acknowledged		02/25/95	Novel protein produced	TX	2	03/01/95	07/01/95
Pioneer	Corn	01/26/95	Acknowledged		02/25/95	Novel protein produced	IL	2	05/01/95	09/01/95
Pioneer	Corn	01/26/95	Acknowledged		02/25/95	Novel protein produced	NE	2	05/01/95	09/01/95
Pioneer	Corn	01/26/95	Acknowledged		02/25/95	Novel protein produced	IA	24	05/01/95	09/01/95
Pioneer	Corn	10/11/95	Acknowledged		11/10/95	Novel protein produced	HI	6	11/01/95	09/28/96

Institution	Crop/ Organism	Application Received	Application Status	Issued	Effective	Phenotype(s)	Release Location(s)	Acreage	Begin Release	End Release
Pioneer	Corn	12/01/95	Acknowledged		12/31/95	Novel protein produced	PR	6	01/01/96	03/15/96
R J Reynolds	TMV	02/10/95	Issued	06/09/95		Pharmaceutical proteins produced	NC			
Agracetus	Corn	04/04/96	Acknowledged		05/04/96	Antibody produced	IA, MD, WI	14	05/01/96	05/01/97
Agracetus	Corn	04/04/96	Acknowledged		05/04/96	Antibody produced	WI	1	05/01/96	05/01/97
Agracetus	Soybean	04/22/96	Acknowledged		05/22/96	Antibody produced	AR, IL, MD	0.3	05/20/96	05/20/97
Agracetus	Soybean	04/22/96	Acknowledged		05/22/96	Antibody produced	MD	0.1	05/20/96	05/20/97
Agracetus	Soybean	06/20/96	Acknowledged		07/20/96	Antibody produced	PR	1	07/18/96	07/18/97
Agracetus	Corn	11/12/96	Acknowledged		12/12/96	Antibody produced	PR	3	12/15/96	12/12/97
Agracetus	Corn	11/12/96	Acknowledged		12/12/96	Antibody produced	PR	3	12/15/96	12/15/97
Agracetus	Soybean	07/16/96	Acknowledged		08/15/96	Antibody produced; Novel protein produced	WI	0.1	08/15/96	08/16/97
Agracetus	Soybean	10/03/96	Acknowledged		11/02/96	Industrial enzyme produced	WI	0.2	11/04/96	11/04/97
Agracetus	Soybean	04/22/96	Acknowledged		05/22/96	Industrial enzyme produced	AR, IL, MD, WI	0.3	05/20/96	05/20/97
Agracetus	Soybean	07/16/96	Acknowledged		08/15/96	Industrial enzyme produced	WI	0.1	08/15/96	08/15/97
Pioneer	Corn	03/19/96	Acknowledged		04/18/96	Novel protein produced	IL	3	04/25/96	09/20/96
Pioneer	Corn	03/19/96	Acknowledged		04/18/96	Novel protein produced	WA	3	04/20/96	08/25/96
Pioneer	Corn	03/19/96	Acknowledged		04/18/96	Novel protein produced	IA	3	05/01/96	09/15/96
Biosource	Tobacco	07/02/96	Acknowledged		08/01/96	Novel protein produced	KY	20	07/27/96	10/31/01
Biosource	TMV	02/20/96	Issued	06/04/96		Pharmaceutical proteins produced	KY			
Pioneer	Rapeseed	08/02/96	Issued	09/17/96		Pharmaceutical proteins produced	CA			
Applied Phytologics	Rice	12/20/96	Issued	03/31/97		Pharmaceutical proteins produced	CA			
Monsanto	Rapeseed	03/01/96	Issued	04/16/96		Polymer produced	ND			
Monsanto	Soybean	03/26/96	Acknowledged		04/25/96	Polymer produced	IL	2	05/01/96	05/01/97
Agracetus	Corn	04/23/97	Acknowledged		05/23/97	Antibody produced	IA, IN, WI	5.25	05/22/97	05/22/98
Agracetus	Corn	05/28/97	Acknowledged		06/27/97	Antibody produced	IN, KS, MO, OH, OK	5	06/23/97	06/23/98
Agracetus	Corn	06/13/97	Acknowledged		07/13/97	Antibody produced	TX	1	07/11/97	07/11/98
ProdiGene	Corn	04/08/97	Acknowledged		05/08/97	Novel protein produced	NE	5	05/01/97	10/31/97
ProdiGene	Corn	09/10/97	Acknowledged		10/10/97	Novel protein produced	PR	0.2	10/09/97	03/01/98
Biosource	TMV	02/14/97	Issued	04/22/97		Pharmaceutical proteins produced	KY	6		
Limagrain	Corn	04/16/97	Denied		05/16/97	Pharmaceutical proteins produced	IN		05/16/97	05/16/98
Biosource	TMV	10/24/97	Issued	11/18/97		Pharmaceutical proteins produced	FL	1.5		
ProdiGene	Tomato	10/28/97	Issued	01/29/98		Pharmaceutical proteins produced	TX	1		
Applied Phytologics	Rice	12/29/97	Issued	02/25/98		Pharmaceutical proteins produced	CA			

Institution	Crop/ Organism	Application Received	Application Status	Issued	Effective	Phenotype(s)	Release Location(s)	Acreage	Begin Release	End Release
Monsanto	Rapeseed	09/23/97	Denied		10/23/97	Polymer produced	CA	1	10/22/97	10/22/98
Monsanto	Rapeseed	09/30/97	Denied		10/30/97	Polymer produced	CA	2	10/27/97	10/27/98
Monsanto	Rapeseed	10/10/97	Withdrawn		11/09/97	Polymer produced	CA	2	10/27/97	10/27/98
U of Wisconsin/Madison	Alfalfa	02/21/97	Issued	04/23/97		PQ - Industrial enzymes produced	WI			
Monsanto	Corn	03/09/98	Acknowledged		04/08/98	Antibody produced	IA, ID, IN, KS, NE, OH, WI	204	04/10/98	04/10/99
Monsanto	Corn	03/09/98	Acknowledged		04/08/98	Antibody produced	HI	6	04/10/98	04/10/99
Monsanto	Corn	03/09/98	Withdrawn		04/08/98	Antibody produced	MN	12	04/10/98	04/10/99
ProdiGene	Corn	03/26/98	Acknowledged		04/25/98	Novel protein produced	NE	4	05/01/98	10/15/98
ProdiGene	Corn	09/30/98	Acknowledged		10/30/98	Novel protein produced	PR	0.35	11/01/98	04/30/98
ProdiGene	Corn	09/30/98	Acknowledged		10/30/98	Novel protein produced	PR	0.35	11/01/98	04/30/99
ProdiGene	Corn	12/22/98	Acknowledged		01/21/99	Novel protein produced	PR	0.1	02/20/99	05/15/99
Applied Phytologics	Rice	01/08/98	Issued	02/25/98		Pharmaceutical proteins produced	CA			
Biosource	TMV	03/01/98	Issued	04/24/98		Pharmaceutical proteins produced	KY	30		
ProdiGene	Corn	09/14/98	Issued	11/25/98		Pharmaceutical proteins produced	PR			
Limagrain	Corn	04/27/98	Issued	06/12/98		Pharmaceutical proteins produced	IL	0.25		
Limagrain	Corn	04/27/98	Issued	06/12/98		Pharmaceutical proteins produced	IN	0.2		
Limagrain	Corn	04/27/98	Issued	06/10/98		Pharmaceutical proteins produced	IA, IL	0.5		
Limagrain	Corn	04/27/98	Issued	06/12/98		Pharmaceutical proteins produced	IN	0.5		
Biosource	TEV	04/30/98	Issued	07/15/98		Pharmaceutical proteins produced	KY	0.25		
Monsanto	Corn	10/01/98	Issued	02/04/99		Pharmaceutical proteins produced	HI	1		
Monsanto	Corn	10/01/98	Issued	02/03/99		Pharmaceutical proteins produced	FL, TX	10		
Pioneer	Corn	10/21/99	Acknowledged		11/20/99	Novel protein produced; Phosphinothricin tolerant; Visual marker	PR	10	11/20/99	11/20/00
Pioneer	Corn	10/21/99	Acknowledged		11/20/99	Novel protein produced; Visual marker; Phosphinothricin tolerant	HI		11/20/99	11/20/00
ProdiGene	Corn	09/28/99	Acknowledged		10/28/99	Antibody produced	PR	0.33	11/15/99	03/20/00
ProdiGene	Corn	12/06/99	Acknowledged		01/05/00	Antibody produced	HI	0.13	01/06/00	03/31/00
Monsanto	Soybean	03/15/99	Acknowledged		04/14/99	Industrial enzyme produced	AR, MD, WI	6	04/01/99	04/01/00
Monsanto	Soybean	05/27/99	Withdrawn		06/26/99	Industrial enzyme produced	AR, WI	10	06/15/99	06/15/00
ProdiGene	Corn	02/03/99	Issued	03/03/99		Novel protein produced	IA			
ProdiGene	Corn	02/24/99	Acknowledged		03/26/99	Novel protein produced	NE	0.2	05/01/99	10/15/99
ProdiGene	Corn	02/24/99	Acknowledged		03/26/99	Novel protein produced	NE	0.2	05/01/99	10/15/99
ProdiGene	Corn	02/24/99	Acknowledged		03/26/99	Novel protein produced	IA, NE	4	05/01/99	10/15/99

Institution	Crop/ Organism	Application Received	Application Status	Issued	Effective	Phenotype(s)	Release Location(s)	Acreage	Begin Release	End Release
ProdiGene	Corn	02/24/99	Acknowledged		03/26/99	Novel protein produced	NE	2	05/01/99	10/15/99
ProdiGene	Corn	02/24/99	Acknowledged		03/26/99	Novel protein produced	NE	0.05	05/01/99	10/15/99
ProdiGene	Corn	02/24/99	Acknowledged		03/26/99	Novel protein produced	PR	0.6	03/12/99	06/25/99
Iowa State U	Corn	04/16/99	Acknowledged		05/16/99	Novel protein produced	IA		06/06/99	03/01/00
ProdiGene	Corn	05/25/99	Acknowledged		06/24/99	Novel protein produced	TX	15	06/15/99	11/30/99
ProdiGene	Corn	09/28/99	Acknowledged		10/28/99	Novel protein produced	PR	0.16	11/25/99	03/20/00
ProdiGene	Corn	09/28/99	Acknowledged		10/28/99	Novel protein produced	PR	0.013	11/25/99	03/20/00
ProdiGene	Corn	09/28/99	Acknowledged		10/28/99	Novel protein produced	PR	0.28	11/25/99	03/20/00
ProdiGene	Corn	10/01/99	Acknowledged		10/31/99	Novel protein produced	PR	0.35	11/25/99	03/20/00
ProdiGene	Corn	10/05/99	Acknowledged		11/04/99	Novel protein produced	HI	0.25	11/01/99	03/01/00
ProdiGene	Corn	10/29/99	Acknowledged		11/28/99	Novel protein produced	FL	20	11/18/99	03/30/00
ProdiGene	Corn	11/03/99	Withdrawn		12/03/99	Novel protein produced	FL	20	11/18/99	03/30/00
ProdiGene	Corn	12/06/99	Acknowledged		01/05/00	Novel protein produced	HI	12.2	03/01/00	07/15/00
Agracetus	Corn	02/19/99	Issued	04/14/99		Pharmaceutical proteins produced	IA, IN, WI	24		
ProdiGene	Corn	02/03/99	Issued	03/04/99		Pharmaceutical proteins produced	IA			
ProdiGene	Corn	02/03/99	Issued	03/03/99		Pharmaceutical proteins produced	IA			
CropTech	Tobacco	02/10/99	Issued	03/08/99		Pharmaceutical proteins produced	VA	0.4		
CropTech	Tobacco	02/10/99	Issued	03/08/99		Pharmaceutical proteins produced	VA	0.4		
Biosource	TMV	02/17/99	Issued	04/30/99		Pharmaceutical proteins produced	KY	32		
Applied Phytologics	Rice	09/29/99	Issued	10/28/99		Pharmaceutical proteins produced	HI			
Applied Phytologics	Rice	09/29/99	Issued	10/28/99		Pharmaceutical proteins produced	HI			
ProdiGene	Corn	10/06/99	Issued	11/18/99		Pharmaceutical proteins produced	PR	0.2		
ProdiGene	Corn	10/06/99	Issued	11/18/99		Pharmaceutical proteins produced	PR			
ProdiGene	Corn	11/03/99	Issued	11/18/99		Pharmaceutical proteins produced	FL			
ProdiGene	Corn	12/09/99	Issued	02/22/00		Pharmaceutical proteins produced	HI			
ProdiGene	Corn	02/24/99	Acknowledged		03/26/99	Novel protein produced	NE	12	05/01/99	10/15/99
Pioneer	Corn	01/21/00	Issued	03/31/00		Altered maturing; Yield increased; Ear mold resistant; Smut resistant; Cyanamide tolerance; Phosphinothricin tolerant; Coleopteran resistant; Lepidopteran resistant; Novel protein produced; Animal feed quality improved; Fumonisin degradation; Grain processing improved	CA, DE, GA, HI, IA, IL, IN, KS, MD, MI, MN, MO, NC, ND, NE, PA, PR, SD, TN, TX, WI			

Institution	Crop/ Organism	Application Received	Application Status	Issued	Effective	Phenotype(s)	Release Location(s)	Acreage	Begin Release	End Release
Pioneer	Corn	01/21/00	Issued	03/30/00		Altered maturing; Yield increased; Ear mold resistant; Smut resistant; Cyanamide tolerant; Phosphinothricin tolerant; Coleopteran resistant; Lepidopteran resistant; Novel protein produced; Animal feed quality improved; Fumonisin degradation; Grain processing improved	HI			
Pioneer	Soybean	01/21/00	Issued	03/30/00		Altered maturing; Yield increased; Ear mold resistant; Cyanamide tolerant; Phosphinothricin tolerant; Coleopteran resistant; Lepidopteran resistant; Novel protein produced; Animal feed quality improved; Fumonisin degradation; Grain processing improved	HI			
ProdiGene	Corn	02/29/00	Denied		03/30/00	Antibody produced	NE	0.16	05/07/00	10/15/00
ProdiGene	Corn	02/18/00	Acknowledged		03/19/00	Novel protein produced	TX	2	03/15/00	07/20/00
ProdiGene	Corn	02/18/00	Acknowledged		03/19/00	Novel protein produced	TX	25	01/25/00	02/05/00
ProdiGene	Corn	02/29/00	Acknowledged		03/30/00	Novel protein produced	NE	1.46	05/07/00	10/15/00
ProdiGene	Corn	03/07/00	Acknowledged		04/06/00	Novel protein produced	NE	4.12	05/07/00	10/15/00
ProdiGene	Corn	03/07/00	Acknowledged		04/06/00	Novel protein produced	NE	21.2	05/07/00	10/15/00
ProdiGene	Corn	03/07/00	Acknowledged			Novel protein produced	NE	0.1	05/07/00	10/15/00
ProdiGene	Corn	04/18/00	Acknowledged		05/18/00	Novel protein produced	NE	10	05/20/00	10/15/00
ProdiGene	Corn	05/01/00	Acknowledged		05/31/00	Novel protein produced	HI	0.15	07/25/00	11/30/00
ProdiGene	Corn	07/10/00	Acknowledged		08/09/00	Novel protein produced	FL	13	09/01/00	03/15/01
ProdiGene	Corn	07/13/00	Issued	08/23/00		Novel protein produced	FL	0.5		
Applied Phytologics	Rice	08/04/00	Issued	10/06/00		Novel protein produced	HI			
ProdiGene	Corn	08/08/00	Acknowledged		09/07/00	Novel protein produced	HI	1	10/01/00	09/30/01
ProdiGene	Corn	08/11/00	Acknowledged		09/10/00	Novel protein produced	PR	0.33	11/15/00	03/30/01
Applied Phytologics	Wheat	08/15/00	Issued	10/10/00		Novel protein produced	HI			
Applied Phytologics	Barley	08/15/00	Issued	10/10/00		Novel protein produced	HI			
ProdiGene	Corn	08/15/00	Acknowledged		09/14/00	Novel protein produced	PR	0.06	11/15/00	03/30/01
ProdiGene	Corn	08/15/00	Acknowledged		09/14/00	Novel protein produced	FL	0.25	10/01/00	04/15/01
ProdiGene	Corn	08/15/00	Acknowledged		09/14/00	Novel protein produced	PR	0.06	11/15/00	03/30/01
ProdiGene	Corn	08/15/00	Acknowledged		09/14/00	Novel protein produced	PR	0.07	11/15/00	03/30/01
Applied Phytologics	Wheat	02/28/00	Issued	05/04/00		Novel protein produced; Nutritional quality altered	ID	3		

Institution	Crop/ Organism	Application Received	Application Status	Issued	Effective	Phenotype(s)	Release Location(s)	Acreage	Begin Release	End Release
Large Scale Biology	TMV	02/18/00	Issued	05/01/00		Pharmaceutical proteins produced	KY			
ProdiGene	Corn	03/07/00	Issued	05/01/00		Pharmaceutical proteins produced	IA	40		
ProdiGene	Corn	03/07/00	Issued	04/26/00		Pharmaceutical proteins produced	NE			
CropTech	Tobacco	03/10/00	Issued	04/19/00		Pharmaceutical proteins produced	VA			
CropTech	Tobacco	03/10/00	Issued	04/19/00		Pharmaceutical proteins produced	VA			
ProdiGene	Corn	03/13/00	Issued	05/26/00		Pharmaceutical proteins produced	NE	2		
ProdiGene	Corn	05/01/00	Issued	07/14/00		Pharmaceutical proteins produced	HI			
Monsanto	Corn	07/21/00	Issued	11/03/00		Pharmaceutical proteins produced	FL, PR	15		
Monsanto	Corn	07/21/00	Issued	11/03/00		Pharmaceutical proteins produced	FL, PR	15		
Monsanto	Corn	07/21/00	Issued	11/03/00		Pharmaceutical proteins produced	HI	15		
ProdiGene	Corn	07/21/00	Issued	10/13/00		Pharmaceutical proteins produced	HI	0.1		
Monsanto	Corn	07/25/00	Issued	12/01/00		Pharmaceutical proteins produced	HI	15		
ProdiGene	Corn	08/08/00	Issued	11/03/00		Pharmaceutical proteins produced	PR			
Washington State U	Barley	11/29/00	Issued	03/22/01		Pharmaceutical proteins produced	WA	3		
Monsanto	Corn	12/28/00	Issued	03/21/01		Pharmaceutical proteins produced	CA, MO, WA, WI	32		
Monsanto	Corn	12/28/00	Issued	03/21/01		Pharmaceutical proteins produced	CA, MO, WA, WI	33.4		
Applied Phytologics	Rice	03/09/00	Issued	05/15/00		Pharmaceutical proteins produced; Novel protein produced	CA	7		
Applied Phytologics	Barley	02/23/00	Issued	04/18/00		Novel protein produced	ID	3		
Pioneer	Corn	01/22/01	Issued	04/13/01		Altered maturing; Fertility altered; Fumonisin degradation; Increased stalk strength; Yield increased; Ear mold resistant; Phosphinothricin tolerant; Lepidopteran resistant; Novel protein produced; Animal feed quality improved; Grain processing improved	AL, CA, CO, DE, FL, GA, IA, IL, IN, KS, KY, LA, MD, MI, MN, MO, NC, ND, NE, OH, OK, PA, PR, SD, TN, TX, WI			
Pioneer	Corn	01/22/01	Issued	04/13/01		Yield increased; Ear mold resistant; Phosphinothricin tolerant; Coleopteran resistant; Lepidopteran resistant; Novel protein produced; Visual marker; Animal feed quality improved; Grain processing improved	HI			
ProdiGene	Corn	07/09/01	Acknowledged		08/08/01	Industrial enzyme produced	FL		09/01/01	04/30/02
ProdiGene	Corn	01/12/01	Acknowledged		02/11/01	Novel protein produced	MN	1	04/15/01	10/31/01
ProdiGene	Corn	01/12/01	Acknowledged		02/11/01	Novel protein produced	MN	1	04/15/01	10/31/01
ProdiGene	Corn	02/01/01	Acknowledged		03/03/01	Novel protein produced	TX	0.5	03/15/01	07/20/01
ProdiGene	Corn	02/14/01	Acknowledged		03/16/01	Novel protein produced	NE	0.15	05/10/01	10/15/01
ProdiGene	Corn	02/14/01	Acknowledged		03/16/01	Novel protein produced	NE	0.75	05/10/01	10/15/01

Institution	Crop/ Organism	Application Received	Application Status	Issued	Effective	Phenotype(s)	Release Location(s)	Acreage	Begin Release	End Release
ProdiGene	Corn	02/14/01	Acknowledged		03/16/01	Novel protein produced	NE	0.36	05/10/01	10/15/01
ProdiGene	Corn	02/14/01	Acknowledged		03/16/01	Novel protein produced	NE	0.54	05/10/01	10/15/01
ProdiGene	Corn	02/14/01	Acknowledged		03/16/01	Novel protein produced	NE	0.06	05/10/01	10/15/01
ProdiGene	Corn	02/14/01	Acknowledged		03/16/01	Novel protein produced	NE	0.12	05/10/01	10/15/01
ProdiGene	Corn	02/14/01	Acknowledged		03/16/01	Novel protein produced	NE	0.12	05/10/01	10/15/01
ProdiGene	Corn	07/12/01	Acknowledged		07/22/01	Novel protein produced	FL		08/20/01	08/19/02
ProdiGene	Corn	07/13/01	Acknowledged		08/12/01	Novel protein produced	HI		11/15/01	03/20/02
ProdiGene	Corn	07/13/01	Acknowledged		08/12/01	Novel protein produced	HI		11/15/01	03/20/02
ProdiGene	Corn	07/13/01	Acknowledged		08/12/01	Novel protein produced	HI		11/15/01	03/20/02
ProdiGene	Corn	08/17/01	Acknowledged		09/16/01	Novel protein produced	FL		09/01/01	04/30/02
ProdiGene	Corn	11/20/01	Acknowledged		12/20/01	Novel protein produced	HI		12/26/01	04/30/02
Applied Phytologics	Rice	07/25/01	Issued			Novel protein produced; Pharmaceutical proteins produced	HI			
ProdiGene	Corn	01/16/01	Issued	04/17/01		Pharmaceutical proteins produced	IA, KS, TX	10		
ProdiGene	Corn	01/16/01	Issued	04/19/01		Pharmaceutical proteins produced	NE	0.7		
ProdiGene	Corn	01/16/01	Issued	04/19/01		Pharmaceutical proteins produced	NE	0.25		
ProdiGene	Corn	01/23/01	Issued	05/08/01		Pharmaceutical proteins produced	NE	53.5		
ProdiGene	Corn	01/23/01	Issued	05/08/01		Pharmaceutical proteins produced	NE	0.25		
CropTech	Tobacco	03/15/01	Issued	05/11/01		Pharmaceutical proteins produced	VA			
CropTech	Tobacco	03/15/01	Issued	05/11/01		Pharmaceutical proteins produced	VA			
Horan Bros. Agri. Enterprises	Corn	02/26/01	Issued	04/25/01		Pharmaceutical proteins produced	IA	33.2		
Large Scale Biology	TMV	02/27/01	Issued	04/25/01		Pharmaceutical proteins produced	KY			
ProdiGene	Corn	04/24/01	Issued	07/12/01		Pharmaceutical proteins produced	HI	1		
Iowa State U	Corn	05/02/01	Issued	06/14/01		Pharmaceutical proteins produced	IA	0.2		
ProdiGene	Corn	07/06/01	Issued	11/13/01		Pharmaceutical proteins produced	HI	0.4		
ProdiGene	Corn	07/09/01	Issued	10/05/01		Pharmaceutical proteins produced	FL			
Dow	Corn	07/31/01	Issued	10/23/01		Pharmaceutical proteins produced	HI	7.9		
Monsanto	Corn	09/14/01	Issued	01/11/02		Pharmaceutical proteins produced	HI	20.8		
Hawaii Agriculture Research Ce	Sugarcane	11/02/01	Issued	01/11/02		Pharmaceutical proteins produced	HI	0.5		
Applied Phytologics	Rice	01/29/01	Issued	04/19/01		Pharmaceutical proteins produced; Gene expression altered; Novel protein produced; Storage protein altered	CA	100		
U of Hawaii	Corn	05/30/01	Acknowledged		06/29/01	Polymer produced	HI	1	04/01/01	03/30/02

Institution	Crop/ Organism	Application Received	Application Status	Issued	Effective	Phenotype(s)	Release Location(s)	Acreage	Begin Release	End Release
Pioneer	Corn	01/23/02	Issued	04/10/02		Altered maturing; Fertility altered; Increased stalk strength; Ear mold resistant; Phosphinothricin tolerant; - Coleopteran resistant; Lepidopteran resistant; Visual marker; Increased transformation frequency; Industrial enzyme produced; Novel protein produced; Animal feed quality improved; Fumonisin degradation improved	CA, DE, GA, IA, IL, IN, KS, MD, MI, MN, MO, NC, ND, NE, NY, OH, PA, PR, SD, TN, TX, WI	508		
Pioneer	Soybean	01/23/02	Issued	04/10/02		Fungal susceptibility; Sclerotinia resistant; Increased transformation frequency; Novel protein produced; Animal feed quality improved; Yield increased	DE, IA, IL, MD, MI, MN, OH, PR	182		
ProdiGene	Corn	03/22/02	Acknowledged		04/21/02	Industrial enzyme produced	IL, NE, SD		04/23/02	04/15/03
ProdiGene	Corn	04/23/02	Acknowledged		05/23/02	Industrial enzyme produced	NE	5	04/23/02	04/15/03
ProdiGene	Corn	03/22/02	Acknowledged		04/21/02	Novel protein produced	IL, NE		04/23/02	12/31/02
ProdiGene	Corn	03/22/02	Denied		04/21/02	Novel protein produced	IL, NE		04/23/02	12/31/02
ProdiGene	Corn	03/22/02	Acknowledged		04/21/02	Novel protein produced	IL, NE		04/23/02	12/31/03
ProdiGene	Corn	03/22/02	Acknowledged		04/21/02	Novel protein produced	IL, MN, NE, TX		04/23/02	04/15/03
ProdiGene	Corn	03/22/02	Acknowledged		04/21/02	Novel protein produced	NE		04/23/02	12/31/02
Enlay and Associates	Safflower	04/09/02	Acknowledged		05/09/02	Novel protein produced	ND	1	05/03/02	09/30/02
Dow	Corn	03/12/02	Issued	06/07/02		Pharmaceutical proteins produced	AZ, CA			
CropTech	Tobacco	03/21/02	Issued	05/07/02		Pharmaceutical proteins produced	VA, SC	0.5		
Meristem Therapeutics	Corn	04/18/02	Issued	05/21/02		Pharmaceutical proteins produced	VA	5		
Meristem Therapeutics	Corn	05/21/02	Issued	06/05/02		Pharmaceutical proteins produced	KY	1		
Ventria Bioscience	Rice	12/27/02	Issued	04/14/03		Value added protein for human consumption	CA	93		
Pioneer	Soybean	01/22/03	Issued	04/15/03		Yield increased; Fusarium resistant; Sclerotinia resistant; Glyphosate tolerant; Phosphinothricin tolerant; CBI; Fungal susceptibility; Increased transformation frequency; Novel protein produced; Animal feed quality improved	AR, DE, IA, IL, IN, KS, MD, MN, MO, NE, OH, PR, TX, WI	520		
Pioneer	Soybean	01/22/03	Issued	05/01/03		Yield increased; Sclerotinia resistant; Glyphosate tolerant; Phosphinothricin tolerant; Fungal susceptibility; Increased transformation frequency; Novel protein produced; Animal feed quality improved; Nutritional quality improved; Oil quality altered	HI	80		

Institution	Crop/ Organism	Application Received	Application Status	Issued	Effective	Phenotype(s)	Release Location(s)	Acreage	Begin Release	End Release
Enlay and Associates	Safflower	03/12/03	Issued	06/03/03		Industrial enzymes produced; Pharmaceutical proteins produced	ND, NV	11		
Chlorogen, Inc.	Tobacco	03/04/03	Issued	05/15/03		Pharmaceutical proteins produced	SC	0.1		
Large Scale Biology	TMV	05/26/03	Issued	12/23/03		Pharmaceutical proteins produced	FL			
Meristem Therapeutics	Corn	03/27/03	Issued	06/05/03		Pharmaceutical proteins produced	CO			
Garst	Corn	05/23/03	Issued	10/14/03		Pharmaceutical proteins produced	HI	36		
Ventria Bioscience	Rice	12/31/03	Issued	05/13/04		Value added protein for human consumption	CA	1		
Pioneer	Corn	01/20/04	Issued	04/20/04		Altered maturing; Fertility altered; Increased stalk strength; Yield increased; Ear mold resistant; Phosphinothricin tolerant; Increased transformation frequency; Novel protein produced; Animal feed quality improved; Fumonisin degradation; Grain processing improved	CA, CO, DE, GA, IA, IL, IN, KS, MD, MI, MN, MO, ND, NE, OH, PA, PR, SD, TN, TX, WA, WI	7475		
Pioneer	Corn	01/20/04	Issued	04/20/04		Altered maturing; Fertility altered; Increased stalk strength; Yield increased; Ear mold resistant; Phosphinothricin tolerant; Increased transformation frequency; Novel protein produced; Animal feed quality improved; Fumonisin degradation; Grain processing improved	HI	3200		
Pioneer	Soybean	01/20/04	Issued	04/15/04		Longer stems; Shorter stems; Yield increased; Sclerotinia resistant; Glyphosate tolerant; Phosphinothricin tolerant; CBI; Fungal susceptibility; Novel protein produced; Transformation frequency increased; Animal feed quality improved	HI	100		
ARS	Brassica juncea	01/09/04	Issued	03/30/04		Salt tolerance increased; Industrial enzyme produced	CA	0.3		
Pioneer	Soybean	01/20/04	Issued	04/13/04		Yield increased; Sclerotinia resistant; Glyphosate tolerant; Phosphinothricin tolerant; CBI; Fungal susceptibility; Novel protein produced; Transformation frequency increased; Animal feed quality improved; Longer stems; Shorter stems	AR, DE, IA, IL, MD, MN, OH, PR	410		
ProdiGene	Corn	04/30/04	Issued	07/02/04		Novel antigen produced	TX			
Large Scale Biology	TMV	11/04/04	Issued	02/08/05		Novel protein produced	FL			
ProdiGene	Corn	02/09/04	Issued	04/28/04		Pharmaceutical proteins produced	NE			
Planet Biotechnology	Tobacco	02/13/04	Issued	04/28/04		Pharmaceutical proteins produced	KY	2		

Institution	Crop/ Organism	Application Received	Application Status	Issued	Effective	Phenotype(s)	Release Location(s)	Acreage	Begin Release	End Release
Washington State U	Barley	03/03/04	Withdrawn	07/10/04		Pharmaceutical proteins produced	WA	0.01		
Iowa State U	Corn	03/05/04	Withdrawn	09/07/04		Pharmaceutical proteins produced	IA	0.25		
Chlorogen, Inc.	Tobacco	03/17/04	Withdrawn	07/27/04		Pharmaceutical proteins produced	KY, MO, SC	3		
Chlorogen, Inc.	Tobacco	04/23/04	Issued	05/25/04		Pharmaceutical proteins produced	KY, MO, SC	1		
Iowa State U	Corn	05/10/04	Issued	06/01/04		Pharmaceutical proteins produced	CO	0.25		
Chlorogen, Inc.	Tobacco	12/20/04	Pending			Pharmaceutical proteins produced	KY, MO, SC	12.5		
Ventria Bioscience	Barley	04/13/04	Issued	06/01/04		Value added protein for human consumption	IA	0.05		
Ventria Bioscience	Rice	10/28/04	Pending			Value added protein for human consumption	MO	100		
Large Scale Biology	TMV	02/13/04	Issued	06/01/04		Value added protein produced	KY			
ProdiGene	Corn	04/23/04	Withdrawn	08/25/04		Value added protein produced	TX			
ProdiGene	Corn	04/30/04	Withdrawn	08/25/04		Value added protein produced	TX			
Washington State U	Barley	03/23/04	Acknowledged		04/22/04	Novel protein produced	WA	1	03/01/04	12/31/04

APPENDIX F:

Institutions Submitting Applications for Permits or Notifications, 1987-2004

Institution	Total, 1987-2004
Monsanto	4,279
Pioneer	685
AgrEvo	344
Du Pont	325
ARS	274
Seminis Vegetable Seeds	195
DeKalb	192
Calgene	176
Syngenta	168
Scotts	155
Aventis	136
Iowa State U	129
Dow	126
Rutgers U	102
U of Idaho	102
ProdiGene	98
ArborGen	94
DNA Plant Tech	91
Stine Biotechnology	90
Northrup King	88
Betaseed	87
Upjohn	85
Asgrow	81
U of Kentucky	80
Novartis Seeds	79
U of Florida	78
Cargill	71
Oregon State U	69
Harris Moran	66
Agracetus	63
Stanford U	63
Michigan State U	62
Agritope	60
Frito Lay	58

Institution	Total, 1987-2004
Zeneca	58
U of Arizona	55
North Carolina State U	52
PetoSeed	51
U of Nebraska/Lincoln	47
Ciba-Geigy	46
Plant Genetic Systems	46
Mycogen	45
Louisiana State U	44
BHN Research	43
Cornell U	41
Delta and Pine Land	41
Purdue U	41
U of Georgia	41
U of California/Davis	40
Bayer CropScience	38
Holdens	38
Limagrain	37
U of Minnesota	36
Biogemma	35
CBI	35
U of Wisconsin	35
Washington State U	34
Westvaco	34
U of California	33
BASF	32
Rhone-Poulenc	31
U of Chicago	31
Noble Foundation	30
Texas Tech U	30
Montana State U	29
Vector Tobacco	28
U of Illinois	24
Applied Phytologics	22

Institution	Total, 1987-2004
Garst	21
New York State Exp Stn	19
Southern Illinois U	19
U of California/Berkeley	19
U of Hawaii	19
Texas A&M	18
ExSeed Genetics	17
GenApps	17
CropTech	16
NC+ Hybrids	16
ICI	15
U of Wisconsin/Madison	15
Campbell	14
Golden Harvest Seeds	14
Great Lakes Hybrids	14
Hawaii Agriculture Research Center	14
Pennsylvania State U	14
Rogers	13
Cook C Rutgers U	12
Hunt-Wesson	12
New Mexico State U	12
Ohio State U	12
AgReliant Genetics	11
American Cyanamid	11
Boyce Thompson Institute	11
Dairyland Seeds	11
Ventria Bioscience	11
Auburn U	10
Biosource	10
U of Connecticut	10
U of North Carolina	10
WyFFels Hybrids	10
Arcadia Biosciences	9
Forage Genetics International	9

Institution	Total, 1987-2004
Kansas State U	9
New York State U/Geneseo	9
North Dakota State U	9
U of Hawaii/Manoa	9
U of Missouri	9
United States Sugar	9
R J Reynolds	8
Tuskegee U	8
U of Virgin Islands	8
American Takii	7
APHIS	7
Crop Genetics	7
Dry Creek	7
Heinz	7
Hoechst-Roussel	7
Max Planck Ins Chem Ecology	7
Targeted Growth, Inc.	7
Virginia Tech	7
Applied PhytoGenetics, Inc.	6
Emlay and Associates	6
InterMountain Canola	6
Interstate Payco Seed	6
M.S. Technologies, LLC	6
New York State U/Albany	6
PanAmerican Seed	6
Sandoz	6
Shoffner Farm Research, Inc.	6
Texas Agricultural Exp Stn	6
U of Rhode Island	6
U of Tennessee	6
AgriPro	5
AgriVitis	5
Amer Crystal Sugar	5
BioTechnica	5

Institution	Total, 1987-2004
Colorado State U	5
Duke U	5
J. R. Simplot Company	5
Jacob Hartz	5
Large Scale Biology	5
Michigan Tech U	5
New York State U	5
Plant Genetics	5
Research for Hire	5
Rogers NK	5
Stine Seeds	5
Sunseeds	5
Union Camp	5
United Agri Products	5
VanderHave	5
Amoco	4
Becks Superior Hybrids	4
Cal West Seeds	4
Chlorogen, Inc.	4
Coors Brewing	4
FFR Cooperative	4
ICI Garst	4
Lipton	4
Plant Sciences	4
Sanford Scientific	4
Southern Piedmont AREC	4
U of California/San Diego	4
U of Nebraska	4
AgraTech Seeds	3
AgriGenetics	3
Connecticut Ag Exp Stn	3
Exelixis	3
Genetic Enterprises	3
Goertzen Seed Research	3

Institution	Total, 1987-2004
International Paper	3
Meristem Therapeutics	3
Miles	3
Mississippi State U	3
Pure Seed Testing	3
Rohm and Haas	3
SemBioSys Inc.	3
W-L Research	3
Abbott and Cobb	2
Advanced Genetic Science	2
All-Tex Seed	2
Anton Caratan & Son	2
Boswell	2
Clemson U	2
Crows	2
Demegen	2
Fort Valley State University	2
Gargiulo	2
Hilleshog	2
Integrated Plant Genetics	2
Interstate	2
Land O Lakes	2
Mendel Biotechnology	2
Oklahoma State U	2
Plant Science Research	2
PlantGenix, Inc.	2
RiceTec, Inc.	2
SemBioSys Genetics	2
U of Washington	2
West Virginia U	2
WestBred LLC	2
Western Ag Research	2
Advanta North America	1
Applied Starch Tech	1

Institution	Total, 1987-2004
Athenix Corporation	1
Ball Helix	1
Barham Seeds	1
Bejo	1
BioKyowa	1
Bowdoin C	1
Brownfield Seed	1
Canners Seed	1
Chembred	1
Cold Spring Harbor Lab	1
Dunn	1
Edenspace Systems Corporation	1
Genetic Resources Inc.	1
Horan Bros. Agri. Enterprises	1
HybriGene, LLC	1
Illinois U	1
Midwest Oilseeds	1
National Starch & Chemical	1
Nestle	1
North Carolina Dept of Agr	1

Institution	Total, 1987-2004
Pebble Ridge Vineyards	1
Planet Biotechnology	1
Seedco	1
Thermo Trilogy	1
Tilak Raj Sawheny	1
U of Arkansas	1
U of California/ Kearney	1
U of California/ Riverside	1
U of Delaware	1
U of Michigan	1
U of Puerto Rico	1
U of South Carolina	1
Van den Bergh Foods	1
Washington U	1
Weyerhaeuser	1
Williams Seed	1
Wilson Genetics	1
Wright State U	1
Yoder Brothers	1

APPENDIX G:

Approved Applications for Testing of Crops Containing Confidential Business Information (CBI): 1987-2004

Year	Number of Permits/Notifications Approved	Number with CBI	% Containing CBI
pre-1987	3	0	0%
1987	9	0	0%
1988	18	0	0%
1989	38	0	0%
1990	58	7	12%
1991	107	16	15%
1992	150	49	33%
1993	306	133	43%
1994	594	222	37%
1995	684	251	37%
1996	626	250	40%
1997	744	387	52%
1998	1,086	673	62%
1999	986	643	65%
2000	937	623	66%
2001	1,128	752	67%
2002	1,141	781	68%
2003	815	542	67%
2004	869	606	70%
Total	10,299	5,935	58%

END NOTES

- ¹ Desmond S.T. Nicholl, *An introduction to genetic engineering*, Cambridge University Press, 1994.
- ² See for example: Richard Caplan and Ellen Hickey, *Weird Science: The Brave New World of Genetic Engineering*, October 31, 2000.
- ³ General Accounting Office (GAO), "Biotechnology: Managing the Risks of Field Testing Genetically Engineered Organisms," June 1988, GAO/RCED-88-27, at 24.
- ⁴ Susan Wright, "Splicing Away Regulations: Down on the Animal Pharm," *The Nation*, March 11, 1996.
- ⁵ *Foundation on Economic Trends v. Heckler*, 587 F. Supp 753 (D.C. 1984) 756 F.2d 143 (D.C. 1985).
- ⁶ Departments of Interior, Justice, State, Agriculture, Commerce, Defense, Energy, Health and Human Services, and Labor; EPA; Council of Economic Advisors; OMB; Office of Policy Development; the National Science Foundation; USTR; and the Office of Science and Technology Policy.
- ⁷ Office of Science and Technology Policy. "Proposal for a Coordinated Framework for Regulation of Biotechnology." Federal Register. December 31, 1984. Vol. 49, No. 252. 50855.
- ⁸ Public Employees for Environmental Responsibility, "Genetic Genie: The Premature Commercial Release of Genetically Engineered Bacteria," September 21, 1995 (re-issued January 25, 2000); Les Levidow and Susan Carr, "Normalizing Novelty: Regulating Biotechnological Risk at the U.S. EPA." *Risk: Health, Safety & Environment*, Winter 2000.
- ⁹ See official FDA rulemaking docket # 00P-1211/CP1; also see Jeff Kamen, "Formula for Disaster," *Penthouse*, March 1999.
- ¹⁰ 49 FR 50856.
- ¹¹ 49 FR 50857.
- ¹² 49 FR 50858.
- ¹³ 49 FR 50898.
- ¹⁴ Dan Glickman, "New Crops, New Century, New Challenges: How Will Scientists, Farmers, And Consumers Learn to Love Biotechnology And What Happens If They Don't?" Remarks given at National Press Club speech, July 13, 1999, USDA Release No. 0285.99, noting that, "A few years ago, we created a food safety agency separate and distinct from any and all marketing functions to ensure that no commercial interests have even the appearance of influence on our decisions regarding food safety. It needs to be the same with biotechnology."
- ¹⁵ Office of Science and Technology Policy. "Coordinated Framework for Regulation of Biotechnology." Federal Register. Vol. 51, No. 123. June 26, 1986. 23302; 51 FR 23355.
- ¹⁶ 51 FR 23303.
- ¹⁷ 51 FR 23305.
- ¹⁸ 51 FR 23307.
- ¹⁹ 51 FR 23308.
- ²⁰ 51 FR 23306.
- ²¹ 51 FR 23338.
- ²² 51 FR 23339.
- ²³ 51 FR 23342.
- ²⁴ 51 FR 23343.
- ²⁵ 51 FR 23308.
- ²⁶ 51 FR 23344.
- ²⁷ 51 FR 23345.
- ²⁸ 51 FR 23346.
- ²⁹ See for example: H. Lehman and J.F. Hurnik, "Concerns about the ethics of genetic modification," presented at the Fifth World Congress on Genetics Applied to Livestock Production, August 7-12, 1994, Proceedings Volume 20; and Jonathan Robinson, "Ethics and transgenic crops: a review," *Electronic Journal of Biotechnology*, Vol. 2, No.2., August 15, 1999.
- ³⁰ 51 FR 23352.
- ³¹ 51 FR 23355.
- ³² 51 FR 23360.
- ³³ 51 FR 23357; also 51 FR 23364 (§340.3(c)(9)).
- ³⁴ 51 FR 23385.
- ³⁵ Robert L. Harness, Director, Environmental Affairs for Monsanto Agricultural Company. Comments to docket for "Coordinated Framework for Regulation of Biotechnology" published in the June 2, 1986 Federal Register. September 26, 1986.
- ³⁶ Robert L. Harness, Director, Environmental Affairs for Monsanto Agricultural Company. Comments to docket for "Coordinated Framework for Regulation of Biotechnology" published in the June 2, 1986 Federal Register. September 26, 1986, at 4.
- ³⁷ Robert L. Harness, Director, Environmental Affairs for Monsanto Agricultural Company. Comments to docket for "Coordinated Framework for Regulation of Biotechnology" published in the June 2, 1986 Federal Register. September 26, 1986, at 6.
- ³⁸ Robert L. Harness, Director, Environmental Affairs for Monsanto Agricultural Company. Comments to docket for "Coordinated Framework for Regulation of Biotechnology" published in the June 2, 1986 Federal Register. September 26, 1986, at 7.
- ³⁹ Robert L. Harness, Director, Environmental Affairs for Monsanto Agricultural Company. Comments to docket for "Coordinated Framework for Regulation of Biotechnology" published in the June 2, 1986 Federal Register. September 26, 1986, at 6-7.
- ⁴⁰ Robert L. Harness, Director, Environmental Affairs for Monsanto Agricultural Company. Comments to docket for "Coordinated Framework for Regulation of Biotechnology" published in the June 2, 1986 Federal Register. September 26, 1986, at 7.
- ⁴¹ USDA Animal and Plant Health Inspection Service. "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason To Believe Are Plant Pests." Federal Register. Vol. 52, No. 115. June 16, 1987, p22892.
- ⁴² 52 FR 22911.
- ⁴³ 52 FR 22898.
- ⁴⁴ General Accounting Office, "Biotechnology: Managing the Risks of Field Testing Genetically Engineered Organisms," June 1988, GAO/RCED-88-27.
- ⁴⁵ General Accounting Office, "Biotechnology: Managing the Risks of Field Testing Genetically Engineered Organisms," June 1988, GAO/RCED-88-27, at 3.
- ⁴⁶ General Accounting Office, "Biotechnology: Managing the Risks of Field Testing Genetically Engineered Organisms," June 1988, GAO/RCED-88-27, at 91.
- ⁴⁷ General Accounting Office, "Biotechnology: Managing the Risks of Field Testing Genetically Engineered Organisms," June 1988, GAO/RCED-88-27, at 5.

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- ⁴⁸ General Accounting Office, "Biotechnology: Managing the Risks of Field Testing Genetically Engineered Organisms," June 1988, GAO/RCED-88-27, at 21.
- ⁴⁹ General Accounting Office, "Biotechnology: Managing the Risks of Field Testing Genetically Engineered Organisms," June 1988, GAO/RCED-88-27, at 48.
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