

BRIEFING REPORT:

Deficiencies in Federal Regulatory Oversight of Genetically Engineered Crops¹

Those who question the appropriateness of local ordinances or state-level efforts to control the spread of genetically engineered (GE) crops often suggest that this technology is sufficiently well regulated by the federal government. But there is extensive evidence that federal oversight is not sufficient to protect farmers and the general public from the potential consequences of this technology. This briefing will attempt to address several salient questions:

- Does the federal government regulate genetically engineered crops?
- How does the USDA's oversight of GE crops in the field actually work?
- Is USDA oversight of GE crops adequate?
- How well do the EPA and FDA address environmental and food safety concerns?

We conclude that state and local jurisdictions should retain the power to address specific problems with GE crops that are not sufficiently addressed by federal regulators.

Does the federal government regulate genetically engineered crops?

No federal laws have been passed to specifically regulate genetically-engineered crops. Since 1986, responsibility for GE foods and crops has been divided among three federal agencies, based upon pre-existing statutes:

- The **U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA-APHIS)** was given authority to monitor field trials of new GE varieties and also to "deregulate" GE crops for commercial cultivation based on the Federal Plant Pest Act (1957) and the Federal Plant Quarantine Act (1912). In 2000, the Plant Pest Act was superseded by the Plant Protection Act, which also does not specifically address the genetic modification of plants.
- The **Environmental Protection Agency (EPA)** has authority over GE crops that produce pesticides, based on the Federal Insecticide, Fungicide, and Rodenticide Act of 1972 and the Food, Drug and Cosmetic Act of 1938.
- The **Food and Drug Administration (FDA)** offers voluntary consultations on other aspects of GE foods with companies that choose to consult with it, following its authority under the Food, Drug and Cosmetic Act, originally passed in 1938.

According to a 2004 peer-reviewed study by William Freese, policy analyst for Friends of the Earth and David Schubert of the renowned Salk Institute,² "claims regarding the safety of these crops ... are

¹ Prepared by Brian Tokar, Institute for Social Ecology Biotechnology Project, P.O. Box 93, Plainfield, Vermont 05667, with thanks to Britt Bailey, William Freese, Doug Gurian-Sherman, and Stephanie Weisenbach.

² William Freese and David Schubert, "Safety Testing and Regulation of Genetically Engineered Foods," *Biotechnology and Genetic Engineering Reviews*, Vol. 21, November 2004, pp. 299-324.

founded mostly on unpublished studies conducted by the crop developer.”³ Independent scientists are often denied access to proprietary plant material, and researchers who have identified significant problems with GE crop varieties have been subjected to ostracism and loss of academic standing. Thus, regulators are unusually beholden to the developers of GE crops for information regarding their potential consequences. According to Henry Miller, chief of biotechnology regulation at the FDA from 1979-1994, “In this area, the US government agencies have done exactly what big agribusiness has asked them to do and told them to do.”⁴

Because the USDA-APHIS has primary jurisdiction over genetically engineered seeds and plants in the field, this summary will focus mainly on this agency. Deficiencies in FDA and EPA oversight will be summarized in the final section.

How does the USDA oversight of GE crops actually work?

There are three components of USDA’s process with respect to GE crops: **Notification, Permitting and Deregulation:**

- Most new field tests of GE crops only require **notification** of the USDA. The company or researcher seeking to field test a new GE variety files a notice of intent and is obligated to submit summary data to the agency within six months after the field trial is completed. Some 10,000 such notifications have been filed for crop trials at over 40,000 sites since the early 1990s, covering 97 percent of all GMO field trials.⁵ The USDA is required to simply acknowledge these notifications within 30 days.
- Some experimental GE varieties require a **permit** from the USDA prior to conducting the field trial. These are varieties that are listed on a national registry of noxious weeds, are deemed genetically unstable, contain genes of unknown function, have toxic, infectious, or pharmaceutical properties, contain DNA from an animal or human pathogen, and/or are deemed to pose a risk of creating a new plant virus.⁶ The permit process takes up to 120 days.
- If and when a GE crop variety is deemed ready to be grown on a commercial scale, the producer applies for **deregulation**. Deregulation means that the particular crop variety is completely removed from further USDA oversight. No follow-up tests of any kind can be requested by the agency. As of April 2006, 70 transgenic varieties have been deregulated by USDA and five additional petitions are pending.⁷ Approximately a quarter of deregulatory petitions are withdrawn by the applicant; the vast majority of such petitions have been approved.⁸

³ *ibid.*, p. 299.

⁴ *New York Times*, January 25, 2001, quoted in Freese and Schubert, *ibid.*

⁵ *Audit Report: Animal and Plant Health Inspection Service Controls Over Issuance of Genetically Engineered Organism Release Permits*, U.S. Department of Agriculture Office of the Inspector General, Southwest Region, Audit #50601-8-Te, December 2005, p. 2.

⁶ *ibid.*

⁷ http://www.aphis.usda.gov/brs/not_reg.html

⁸ Presentation by John Turner, USDA-APHIS Biotechnology Regulatory Services, Vermont Agency of Agriculture, Montpelier, Vermont, October 23, 2003.

Is USDA oversight of GE crops adequate?

Two independent scientific assessments have been commissioned to evaluate the efficacy of the USDA oversight process: a 2002 report by the National Research Council of the National Academy of Sciences,⁹ and an internal USDA Audit Report, published in 2005.¹⁰ Additionally, public interest organizations such as the Consumers Union, Union of Concerned Scientists, Friends of the Earth, and others have assessed various aspects of the USDA's oversight process for genetically engineered crops.

Concerns highlighted in these reports include:

Limits to USDA jurisdiction: The jurisdiction of APHIS is limited to potential plant pests, including noxious weeds. This generally requires “the presence of a previously identified plant pest or genes from a plant pest in the transformed plant.”¹¹ Other potential hazards from growing GE varieties do not fall under the agency's jurisdiction, including locally noxious effects that are not listed on the federal noxious weed registry.¹² In one instance, the USDA allowed the growing of corn engineered to produce a substance with known toxic properties under its simple 30-day notification process.¹³

The 2002 National Academy of Sciences report further addressed the lack of regulatory attention to the broad environmental consequences of genetically engineered plants: “There has been no environmental monitoring of these transgenic crops, so any effects that might have occurred could not have been detected. The absence of evidence of an effect is not evidence of absence of an effect.”¹⁴

Reliability of APHIS risk assessments: The National Academy of Sciences panel also concluded that the APHIS review process for GE crops was neither transparent nor scientifically rigorous. NAS experts pointed to a lack of scientific peer review and public input as well as applicants' failure to clearly present their data, methods, analyses and interpretations.¹⁵ APHIS does not rely sufficiently on independent scientific experts, especially in potentially precedent-setting decisions.¹⁶ Companies are allowed to hide vast amounts of data as Confidential Business Information (CBI); even the NAS Committee was hampered in its review by excessive CBI. In addition, APHIS is chronically understaffed in the area of ecological analysis.¹⁷ Unintended genetic or metabolic effects of the transgene on the host plant go unreported, unless they visibly alter the plant's weediness or fitness.¹⁸

The USDA's own Inspector General states that “weaknesses in APHIS regulations and internal management controls increase the risk that regulated genetically engineered organisms will inadvertently persist in the environment before they are deemed safe to grow without regulation,”¹⁹ and that “APHIS lacks basic information about the field test sites it approves and is responsible for

⁹ *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation*, Washington, DC: National Academy of Sciences Press, 2002

¹⁰ *Audit Report: Animal and Plant Health Inspection Service, op. cit.*

¹¹ *Environmental Effects of Transgenic Plants, op. cit.* p. 8.

¹² *Environmental Effects of Transgenic Plants, op. cit.* pp. 8-9, 178-179.

¹³ *ibid.*, pp. 181-182.

¹⁴ *ibid.*, p. 79.

¹⁵ *ibid.*, pp. 10-11, 168.

¹⁶ *ibid.*, pp. 171, 173.

¹⁷ *ibid.*, pp. 11-12, 177.

¹⁸ *ibid.*, p. 115.

¹⁹ *Audit Report: Animal and Plant Health Inspection Service, op. cit.*, p. i.

monitoring, including where and how the crops are being grown, and what becomes of them at the end of the field test.”²⁰ For instance, USDA inspectors found that companies frequently only listed their business address, failing to specify the locations of the field trials. The auditors recommended that applicants be required to submit basic field trial protocols to ensure gene containment, and make these available to USDA inspectors, a recommendation that was rejected by APHIS officials.²¹ By refusing to require submission of these protocols, the auditors concluded that “APHIS is relinquishing its regulatory responsibility in favor of self-certification by the notification applicants.”²² In many instances, this may represent a significant risk to public health and the environment.

Lack of post-commercialization testing and monitoring: APHIS considers deregulation to be “absolute,” according to the National Academy of Sciences study. Environmental effects, however, are more likely to appear at the scale of a commercial planting as compared to a test plot.²³ Many such effects are scale-dependent, including harm to locally important plants and wildlife, and are not considered in the standard application process.²⁴ The National Academy panel proposed a program of ongoing environmental monitoring to assess unanticipated or long-term environmental impacts, as well as “any potential impacts of transgenic plants on regional farming practices or systems in its deregulation assessments.”²⁵ This recommendation has not been implemented by USDA. APHIS also does not require holders of permits to grow crops that are engineered to produce pharmaceutical and industrial chemicals to report on the final disposition of these potentially hazardous materials.²⁶ For instance, over two tons of crop material containing plant-produced pharmaceuticals were stored at two locations for over a year without the knowledge of APHIS, much less inspection of the storage facilities or approval of handling procedures.

Weaknesses in inspection and enforcement: The USDA’s inspectors reported a lack of coordination between the agency that oversees inspection of permitted field test sites, and the agency that actually carries out inspections. Of the field trials reviewed by the auditors, barely half of the required inspections took place – just 23 of 60 for high-risk pharmaceutical crop field trials. Sites are not selected for inspection based on systematic risk assessment criteria, and violations are often not reported in time to address problems. Of 11 field trial violations found by the auditors, none had been recorded, and USDA’s Biotechnology Regulatory Services had taken enforcement action on only one.²⁷ Companies are not held financially responsible for the consequences of unauthorized releases of regulated GMOs, and crops are often allowed to lie in fields for months after harvest, without regard to potential effects on wildlife or human passersby.²⁸

Additional concerns raised by critics of the USDA permitting processes include:

- “[A] company can get a single permit number that covers a number of genes, phenotypes and test locations.” For example a permit issued to Pioneer Hi-Bred in 2003 for genetically engineered soybeans “covers 42 different genes comprised of 10 phenotype categories, with field tests

²⁰ *ibid.*

²¹ *ibid.*, p. v.

²² *ibid.*, pp. v-vi.

²³ *Environmental Effects of Transgenic Plants, op. cit.*, p. 13.

²⁴ *ibid.*, p. 189.

²⁵ *ibid.*, p. 15.

²⁶ *Audit Report: Animal and Plant Health Inspection Service, op. cit.*, p. ii.

²⁷ *ibid.*, p. iii.

²⁸ *ibid.*, pp. iii, iv.

occurring in 13 states plus Puerto Rico.”²⁹ This practice appears to be routine under APHIS’ stripped-down notification procedures.

- Genetically engineered traits can be classified under the generic category “novel protein,” which in effect allows companies to withhold all information about the properties, and even the general nature, of these proteins, including potential toxicity to humans or wildlife.³⁰
- USDA-APHIS Environmental Assessments for experimental GMO varieties that require a full permit are often fraught with internal inconsistencies; for example a rice variety engineered to produce a human protein with antimicrobial properties (human lactoferrin) was reported as having no possible effect on wildlife due to rapid digestion, and at the same time advertised as a potential nutritional supplement, which could only succeed if the protein resisted digestion.³¹
- “USDA does not consider economic consequences in its regulatory decisions, relegating those to ‘the market.’ Thus field trials or deregulations that could have significant economic impact can be approved, leaving farmers unable to protect their livelihoods in the absence of local authority.”³²
- “APHIS pays little or no attention to the potential negative effects of [transgenic] proteins on wildlife or insects. For instance, in 1998 Limagrain obtained permits to conduct four field trials of corn ... The four virtually identical EAs written by APHIS contain the same two-sentence section on non-target organism impacts: ‘There is *no reason to believe* that the novel gene products expressed by these plants would have a significant impact on non-target organisms, including vertebrate or invertebrate species. Neither of the novel gene products *is known to be* toxic to organisms’ (USDA EA 98-117-01 to 04, 1998, emphasis added).”³³ Such language is purely speculative, and represents a “failure to conduct any pertinent studies whatsoever, or even search the [scientific] literature.”³⁴ The National Academy of Sciences committee also criticized such “no evidence of harm” statements as falsely implying that rigorous tests had come up negative, rather than a lack of evidence due to lack of testing, which is often case.³⁵

²⁹ “Comments of Consumers Union on Docket No. 03-031-1: Field Testing of Plants Engineered to Produce Pharmaceutical and Industrial Compounds,” at www.consumersunion.org/pub/2003/06/000198print.html.

³⁰ *ibid.*

³¹ “Consumers Union’s Comments on USDA Animal Plant Health Inspection Service (APHIS) Environmental Assessment for Field Test of Permit of Ventria Bioscience rice genetically engineered to express human lactoferrin USDA/APHIS Docket No. 05-006-1,” at www.consumersunion.org/pub/2005/03/002090print.html

³² Comment of Dr. Doug Gurian-Sherman, Senior Scientist, Center for Food Safety, Washington, DC, personal communication, May 24, 2006.

³³ *Manufacturing Drugs and Chemicals in Crops: Biopharming Poses New Threats to Consumers, Farmers, Food Companies and the Environment*, by Bill Freese, Policy Analyst, Friends of the Earth, Washington, DC, July 2002.

³⁴ *ibid.*

³⁵ *Environmental Effects of Transgenic Plants*, *op. cit.* p. 79. A typical quote concludes the “Limits to USDA jurisdiction” section, above.

How well do the EPA and FDA address environmental and food safety concerns?

The Environmental Protection Agency (EPA) has jurisdiction over plants that are genetically engineered to produce pesticides, most notably the family of toxin proteins derived from the bacterium *Bacillus thuringiensis* (Bt). The Agency disavows authority over any aspects of GE plants other than these incorporated pesticides and the pesticides that are sprayed on GE crops. As with the USDA's oversight process, the EPA relies almost entirely on company data, and does not require an approved set of laboratory tests to help assure meaningful results. For example, studies of the potential consequences of Bt toxins for non-target insects (*e.g.*, honeybees) were carried out for only a few days, far from sufficient to detect any possible medium- to long-term health and behavioral effects.³⁶

Meanwhile, the EPA has used its authority under the Federal Food, Drug and Cosmetic Act to exempt the pesticides currently produced by GE plants from any limit on human exposure. At the same time, the agency has agreed to raise the allowable tolerance levels of chemical herbicide residues on crops that are engineered to tolerate exposure to herbicides, thus permitting higher levels of chemical weed killers in our foods. Finally, the EPA does not require any medium or long-term feeding studies with GE products on test animals, as recommended by many experts.

The biotech industry often claims that the safety of their products for human consumption has been certified through a rigorous approval process carried out by the Food and Drug Administration (FDA). The FDA's actual role, however, is far different from this. Whereas chemical food additives regulated under the federal Food, Drug and Cosmetic Act do undergo pre-market review and approval, GE crops are only subject to "voluntary consultations" with companies that choose to consult with the agency about their products. Because the consultations are voluntary, FDA does not specify a required list of studies or test methods, but instead accepts superficial in-house summaries of whatever testing the company has chosen to do. FDA requests for additional data sometimes go unfulfilled.

The result is a system in which companies essentially "self-certify" their GE crops as safe. This is well-illustrated by the letter FDA sends companies after a consultation is complete, a typical example of which reads as follows:

*"...it is our understanding that Monsanto has concluded that corn products derived from this new variety are not materially different ... from corn currently on the market, and that the genetically modified corn does not raise issues that would require pre-market review or approval by FDA ... as you are aware, it is Monsanto's responsibility to ensure that foods marketed by the firm are safe, wholesome, and in compliance with all applicable legal and regulatory requirements."*³⁷

FDA political appointees and other officials essentially ignored the recommendations of agency scientists, who proposed a mandatory system involving required tests for toxicity and other unintended health effects.³⁸ The FDA has likewise ignored numerous recommendations from independent scientists to require rigorous testing of GE foods for mutagenic effects, toxicity, altered nutritional composition, reproductive effects and allergenic properties. Instead, the FDA's consultative process allows for chronic abuses, including: test protocols designed to hide potential problems; substitution of "surrogate

³⁶ Freese and Schubert, *op. cit.* 1, p. 303.

³⁷ Letter from Alan M. Rulis, Office of Premarket Approval, Center for Food Safety and Applied Nutrition, FDA to Dr. Kent Croon, Regulatory Affairs Manager, Monsanto Company, Sept 25, 1996. See Letter for BNF No. 34 at <http://www.cfsan.fda.gov/~lrd/biocon.html>, or *ibid.*, pp. 304-305.

³⁸ Documented in a collection of 24 government memos, indexed at <http://biointegrity.org/list.html>.

proteins,” derived from genetically engineered bacteria, for the proteins actually produced by a GE plant; and flouting of widely accepted scientific protocols, such as those recommended by the World Health Organization to identify potential human allergens.³⁹ The FDA does not recommend, much less require, that companies carry out animal feeding trials with the intact GE crop.

Conclusion

In a public statement announcing the comprehensive, peer-reviewed study of federal regulation of GMOs (co-authored with William Freese, policy analyst for Friends of the Earth), Dr. David Schubert of the renowned Salk Institute described the disturbing conclusion of their evaluations:

“One thing that surprised us is that U.S. regulators rely almost exclusively on information provided by the biotech crop developer, and those data are not published in journals or subjected to peer review... The picture that emerges from our study of U.S. regulation of GM foods is a rubber-stamp ‘approval process’ designed to increase public confidence in, but not ensure the safety of, genetically engineered foods.”⁴⁰

This and numerous other careful studies conclude that present federal oversight is insufficient to address the potential environmental, human health, and economic consequences of experimental genetically engineered crops.

In the absence of sufficient federal oversight, local jurisdictions should retain the ability to monitor genetically engineered plantings, address possible unforeseen consequences, and respond to any emergency conditions that may arise. Local jurisdictions are better able to respond to matters involving local residents’ health, safety, and welfare. Thus there should be no new laws limiting the capacity of local jurisdictions to control the use of genetically engineered seeds or crops.

³⁹ Freese and Schubert, *op. cit.* 1, pp. 305-310.

⁴⁰ Friends of the Earth Media Advisory, November 16, 2004, Washington, DC.

**Addendum to Briefing Report:
Deficiencies in Federal Regulatory Oversight of Genetically Engineered Crops**

— Brian Tokar, Institute for Social Ecology Biotechnology Project, June 29, 2006

In June 2006, the Food and Drug Administration released a new set of guidelines for the evaluation of experimental genetically engineered (GE) crop varieties. This was a response to widespread public concern that the food supply could become contaminated with pharmaceutical ingredients engineered into food crops undergoing field trials, along with other experimental GE proteins that have not yet been evaluated in any regulatory proceeding.

This new FDA document, “Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use,” merely extends the process of “voluntary consultation” that is already applied to new GE food varieties, and allows companies to apply for an “early evaluation” of experimental proteins that could become part of the food supply. It does not provide the additional protections that various public interest organizations requested to prevent the contamination of our food with pharmaceuticals and other experimental substances.

The FDA guidance states right at the outset what many critics of the agency have been pointing out for several years, “FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities.” “Early evaluation” of experimental GE crop varieties is “suggested or recommended, but not required.” Ignoring the basic biochemical fact that even small modifications in the structure of a protein can drastically alter its biological activity, the guidance states, “In most cases, the [new] proteins ... will be the same or quite similar to proteins commonly found in food.”

As with conventional consultations with the FDA for new GE food ingredients, the FDA only requests “a synopsis of the safety data” on these new proteins and a report on the company’s own conclusions as to their safety. The agency requests that the application focus on potential allergenicity or toxicity, and lists some of the specific information it would like to receive. The FDA allows itself 120 days to respond to these submissions.

It is clear that these guidelines offer no new substantive protections to those who may be exposed to experimental genetically engineered substances. They simply allow companies to continue submitting cursory data, and receive a rubber stamp from the agency saying that their data has been evaluated and found to raise no new concerns. This policy only reinforces the need for local jurisdictions to retain the right to address the potential hazards of GE crops grown in their regions.