



Regulation of Genetically Engineered Crops and Foods in the United States¹

Richard Caplan

U.S. Public Interest Research Group

Skip Spitzer

Pesticide Action Network North America

March 2001

Scientists have raised serious environmental and health concerns about genetically engineered (GE) crops and foods, including allergens and toxins in food, diminished nutritional quality of food, the development of antibiotic resistance, increased pesticide use, harm to wildlife, the development of newly invasive species, the creation of new or more virulent viruses, and the loss of agricultural biodiversity.² Other analysts have identified serious impacts on farmers, including loss of markets, falling commodity prices, genetic contamination (such as in the recent StarLink corn debacle), loss of natural bio-pesticides, and possible liability for harm caused by GE crops.³ Yet, the biotechnology and food companies that have created these products have tried to abdicate their responsibility for their impacts, claiming that the onus rests with federal regulators. In fact, Monsanto's Director of Corporate Communications Phil Angell said, "Monsanto should not have to vouchsafe the safety of biotech foods. Our interest is in selling as much of it as possible. Assuring its safety is the FDA's job."⁴

But does the regulatory system do an adequate job of protecting human and environmental welfare?

This paper assesses the current regulatory framework for genetically engineered crops and foods. It concludes that the regulatory scheme is seriously flawed, with shortcomings at each major agency involved, as well as key issues that no agency is adequately addressing.

Regulation of GE crops and foods also involves important international layers. For example, Codex Alimentarius (the standards-setting agency of the United Nations World Health Organization and Food and Agriculture Organization), the World Trade Organization, and the Biosafety Protocol all impact U.S. regulation. These topics, however, are beyond the scope of this paper.

¹ The authors would like to thank Jane Rissler of Union of Concerned Scientists and Joseph Mendelson of Center for Food Safety for their valuable assistance.

² See for example: Union of Concerned Scientists. "Risks of Genetic Engineering." Accessed from the Union of Concerned Scientists Web site at <<http://www.ucsusa.org/>> on 9 September 2000.

³ See for example: Midwest Sustainable Agriculture Working Group. "Position Paper On Genetic Engineering." 24 February 2000. Available at <<http://www.cfra.org/MSAWG-GE.htm>>.

⁴ Michael Pollan. "Playing God in the Garden." *New York Times*. 25 October 1998.

No new laws for biotechnology

The development of national biotechnology policy under Presidents Reagan and Bush set the stage for the current regulatory regime. The mid-1980's "Coordinated Framework for Regulation of Biotechnology" established that "existing statutes seem adequate to deal with the emerging processes and products of [genetic engineering]."⁵ Adding to the idea that biotechnology oversight requires nothing fundamentally new, Vice President Dan Quayle's Council on Competitiveness' 1991 report called for regulation of GE products based on their performance, not the processes by which they are produced.⁶ These directives resulted in a system in which the United States Department of Agriculture (USDA), Environmental Protection Agency (EPA), and Food and Drug Administration (FDA) regulate GE crops and foods under existing laws. Generally, the division of responsibility for regulation results in USDA's oversight over plants, EPA over pesticides, and FDA over foods.⁷

This arrangement was established well before any real investigation into the human and environmental impact of GE crops and foods. In fact, Dr. Charles Benbrook's review of pertinent research in this area concluded that "less than 10 percent of the total number of citations covering seven major areas of risk appeared before 1990."⁸ With the regulatory framework established before any comprehensive review of risk, it is not surprising that the current system of oversight has many failings.

FDA

The primary roles of FDA with respect to GE foods and crops are to ensure their safety for food and animal feed, as well as to determine labeling guidelines. With the exception of meat, poultry, and eggs, FDA has the authority under the Federal Food, Drug, and Cosmetic Act (FFDCA) to ensure the safety of all domestic and imported foods. The FFDCA requires pre-market safety testing of any food additive (defined as a substance intentionally added to food), unless a decision is made that the additive is Generally Recognized as Safe (GRAS). GRAS substances do not require testing of any kind. For instance, based on a long history of human use, corn has been determined to be GRAS, unless new evidence to the contrary is presented. FDA also requires that products be labeled to include information that would be "material" to consumers, a difficult to define concept that includes significant changes to taste or smell.

1992 policy: Genetically engineered foods are like conventional foods

The basis of FDA's policy regarding GE foods stems from a 1992 Statement of Policy in which the agency argues that genes added to common food substances via genetic engineering are GRAS because the new food is largely the same as its conventional counterpart.⁹ This idea has become known as "substantial equivalence." The questionable nature of substantial equivalence was demonstrated recently when new analysis of Roundup Ready soybeans revealed that they had more foreign DNA than Monsanto, or the government, thought.¹⁰ The result of automatically designating GE foods as GRAS is that these foods have never been subject to mandatory pre-market safety testing. FDA has encouraged institutions seeking to

⁵ Office of Science and Technology Policy. "Coordinated Framework for Regulation of Biotechnology." Federal Register. Vol. 51, No. 123. 26 June 1986. 23306.

⁶ Claire Cummings. Testimony at the California Senate Natural Resources Committee and Select Committee on Higher Education hearing on "The Environmental Implications of Genetic Engineering and the Corporatization of the University of California." 15 May 2000.

⁷ Other federal departments and agencies have some role or interest in genetic engineering. These include the National Institutes of Health (which plays a major role in oversight of human gene therapy), the National Research Council, the Department of Health and Human Service's Center for Biotechnology Information, the Department of State's Office of International Information Programs, the Patent and Trademark Office, the Department of Commerce, the Federal Trade Commission, the Office of the U.S. Trade Representative, and the Customs Service.

⁸ Claire Cummings. Testimony at the California Senate Natural Resources Committee and Select Committee on Higher Education hearing on "The Environmental Implications of Genetic Engineering and the Corporatization of the University of California." 15 May 2000.

⁹ Food and Drug Administration. "Statement of Policy: Foods Derived From New Plant Varieties." Federal Register. Vol. 57, No. 104. 29 May 1992. 22984.

¹⁰ James Meikle. "Soya gene find fuels doubts on GM crops." *The Guardian (London)*. 31 May 2000.

commercialize GE foods to notify the agency of their intention to commercialize a GE product voluntarily, and has proposed to make the notification mandatory with a proposed rule discussed below.¹¹ In addition to long-standing pressure from public interest groups, major agribusiness corporations recently lobbied for this shift to a mandatory consultation as an attempt to quell public concern about lax oversight. However, a mandatory consultation is meaningless unless comprehensive testing is required, which is currently not the case and was not proposed under the new regime.

FDA has stated that labeling for genetically engineered foods is generally unnecessary because the agency has no evidence that GE foods are substantially different than other foods.¹² They do include the caveat, however, that their guidance “cannot identify all safety and nutritional questions that could arise in a given situation and, while comprehensive, should not be viewed as exhaustive.”¹³ There are limited situations in which a food would need to be labeled, particularly if it contains a known allergen. But the agency states in a footnote to their 1992 policy that there is no routine procedure to test for all allergens and thus if the donor gene has never been in foods before allergenicity is impossible to determine.¹⁴

1997 policy: Minor consultation

The agency’s most recent finalized guidance on consultation procedures for GE foods was issued in October 1997.¹⁵ The document did little to change FDA policy; it merely clarified the agency’s requirements. For example, the agency affirmed that, “FDA does not conduct a comprehensive scientific review of data generated by the developer [of a GE food].”¹⁶ Institutions seeking to commercialize a GE food are only required to submit a summary of their data to FDA. The summary is not technically required to include any information; the agency only asks that it “ordinarily” include things like the “expected” effect on the composition of the food or feed and an “estimate” of the concentration of any product encoded by the introduced genetic material. The agency makes clear that the institution seeking to commercialize a new GE crop is in charge, and not the agency. They state “the firm is in a position to conclude any ongoing consultation and inform FDA about its intention to initiate commercial distribution.”

Dissension within FDA

FDA’s position has been undermined by documents produced through an Alliance for Bio-Integrity legal challenge to the 1992 policy that indicate profound concerns of FDA scientists.¹⁷ For example, the documents indicate that one FDA compliance officer complained that the agency was “trying to fit a square peg into a round hole” by concluding “there is no difference between foods modified by genetic engineering and foods modified by traditional practices.” A member of FDA’s Microbiology Group stated, “There is a profound difference between the types of unexpected effects from traditional breeding and genetic engineering.” And FDA’s Division of Food Chemistry and Technology warned, “Undesirable effects such as the appearance of new, not previously identified toxicants...may escape breeders’ attention unless genetically engineered plants are evaluated specifically for these changes. Such evaluations should be performed on a case-by-case basis—every transformant should be evaluated before it enters the marketplace.” FDA ignored the concerns of these and other agency scientists—not to mention those of the broader scientific community.

¹¹ Department of Health and Human Services, Food and Drug Administration. “Premarket notice concerning bioengineered foods.” Federal Register. Vol. 66, No. 12. 18 January 2001. 4706.

¹² 57 FR 22991.

¹³ 57 FR 22991.

¹⁴ 57 FR 23000.

¹⁵ U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition. “Guidance on Consultation Procedures: Foods Derived from New Plant Varieties.” October 1997. Available at <<http://vm.cfsan.fda.gov/~1rd/consulpr.html>>.

¹⁶ *ibid.*

¹⁷ Alliance for Bio-Integrity, et al. v. Shalala, et al.

Health effects

Gene insertion is very imprecise, resulting in haphazard alterations to an organism's DNA.¹⁸ These "position effects" may result in the appearance of wholly new allergens and toxicants, an increase in the levels of known allergens and toxicants, or diminished levels of nutrients. There is a growing body of evidence supporting these concerns, which has led the British Medical Association to call for an indefinite moratorium on GE foods.¹⁹ One recent study published in the *Journal of Medicinal Food* found that levels of isoflavones, which may be involved in preventing some cancers, lowering cholesterol, increasing protection against osteoporosis, and relieving symptoms of menopause, were 12-14% lower in GE soybeans compared to conventional varieties.²⁰ Another experiment indicated that methylglyoxal, a highly toxic substance, was substantially increased in GE yeast strains as compared to controls. The researchers concluded that "the results presented may raise some questions regarding the safety and acceptability of genetically engineered food, and give some credence to the many consumers who are not yet prepared to accept food produced using gene engineering techniques."²¹

The consumer's right-to-know

Around the world, countries have instituted or are in the process of instituting mandatory labeling of GE foods. This includes Japan, Australia, New Zealand, South Korea, and the nations of the European Union, among others. Increasingly the U.S. stands alone in its intransigence to offer consumers information about how their food is produced. Health concerns about allergenicity alone merit a mandatory labeling regime. But other consumers have expressed additional concerns. Religious groups that want to avoid GE products because they interfere with their ability to practice their faith—for example Muslims avoiding a vegetable with a pork gene or the Eastern Orthodox Christian doctrine which objects to the use of viruses and pathogens to manipulate existing plants—cannot do so under current labeling rules. And consumers who are concerned about ecological impacts and that the way that GE crops perpetuate industrial, pesticide-based agriculture are unable to make informed purchasing decisions without labeling.

The biotechnology industry, however, has resisted labeling. In fact, an internal document from Monsanto equates a government labeling requirement with a ban.²² The hypocrisy of corporations that seek to avoid labeling because they claim their products are in certain ways identical to conventionally bred plants is highlighted by the intellectual property protection sought for GE plants.²³ The result is that manufacturers are telling one agency (FDA) that their products are the same and thus need no regulation, and telling another (the U.S. Patent Office) that they are wholly different and need a new form of treatment.

Recombinant Bovine Growth Hormone: A cautionary tale

Recombinant Bovine Growth Hormone (rBGH) is a genetically engineered hormone that is injected into cows to make them produce more milk. In 1990, FDA said rBGH was safe for human consumption.²⁴ Part

¹⁸ See for example: Michael Hansen. "Genetic Engineering Is Not An Extension of Conventional Plant Breeding: How Genetic Engineering Differs From Conventional Breeding, Hybridization, Wide Crosses and Horizontal Gene Transfer." Consumer Policy Institute/Consumers Union. January 2000.

¹⁹ British Medical Association. "The Impact of Genetic Modification on Agriculture, Food and Health," British Medical Association." May 1999.

²⁰ Marc Lappe, Britt Bailey, Chandra Childress, and Kenneth Setchell. "Alterations in Clinically Important Phytoestrogens in Genetically Modified, Herbicide-Tolerant Soybeans." *Journal of Medicinal Food*. Vol. 1, no. 4. 1 July 1999.

²¹ Tomoko Inose and Kousaku Murata. "Enhanced accumulation of toxic compound in yeast cells having high glycolytic activity: a case study on the safety of genetically engineered yeast." *International Journal of Food Science and Technology*. (1995) 30, 141-146.

²² Virginia V. Weldon. "Coehlo Talking Points for Espy Dinner," a memo on Monsanto company letterhead dated 21 September 1993, on file with U.S. PIRG.

²³ See for example: "The WTO's Impact on Emerging Health and Environmental Issues: Genetically Modified Organisms." In Lori Wallach and Michelle Sforza. Whose Trade Organization? Corporate Globalization and the Erosion of Democracy. Public Citizen. 1999.

²⁴ Judith C. Juskevich and C. Greg Guyer. "Bovine growth Hormone: Human Food Safety Evaluation." *Science*. 24 August 1990.

of its findings were based on 90-day rat feeding studies in which they reported that rBGH produced no toxicologically significant changes in rats administered rBGH orally. Based largely on this conclusion, FDA did not require human toxicological tests usually required for a veterinary drug. However, in April 1999, researchers from Health Canada, the Canadian equivalent to FDA, issued a report that contradicted FDA's findings.²⁵ Canadian researchers found studies showing that rats were absorbing rBGH after all. In fact, between 20 and 30% of the rats were developing distinct immunological reactions. Additionally, cysts formed in the thyroid of some male rats and infiltrated the prostate. According to Michael Hansen, a researcher with Consumer Policy Institute, a division of Consumers Union, "These are toxicologically significant changes in the rats and they should have triggered a full human health review, including assessment of potential carcinogenic and immunological effects."²⁶

In addition to the unresolved health issues regarding rBGH, FDA also issued labeling guidelines regarding the hormone that do not facilitate consumer choice and are a dangerous precedent for the agency's new guidelines to industry on GE foods. FDA did not require manufacturers to label their products as containing rBGH, despite many surveys that clearly indicated a consumer preference for such information.²⁷ The agency also encouraged milk sellers not to label their products as free of rBGH.²⁸ Monsanto sued two milk processors that labeled their milk as rBGH-free.²⁹ Although FDA's proposed guidelines on labeling of GE foods (discussed below) may allow manufacturers to label their products as GE free, the situation will be similar to that of rBGH. Companies will not voluntarily label their product as containing a GE ingredient, and those not using GE ingredients will essentially be forced to vouchsafe for non-GE counterparts through some type of disclaimer, such as the lengthy one that appears on Ben & Jerry's ice cream.³⁰ This arrangement is still a clear violation of the consumer's right to know about the food they are eating, and has been encouraged by manufacturers of GE products.

EPA

EPA's role in regulation of GE crops stems primarily from the FFDCA, as well as the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). These statutes limit EPA's oversight to only certain GE crops. Even within this narrow purview, however, its handling of GE products falls short.³¹

Regulation by pesticide registration

Most of EPA's involvement revolves around its authority to regulate pesticides under FIFRA, which mandates the agency to regulate plants (and microbes) producing pesticidal substances.³² This means that Bt crops, which are genetically engineered to produce a pesticide, must go through a pre-market registration (or approval) process to examine potential health and environmental effects.

Registrations of Bt crops, however, are subject to some of the same shortcomings as registration of conventional pesticides. For example, EPA generally relies on the use of research provided, and often conducted, by the applicant, potentially compromising its objectivity. Tainted industry research in pesticide

²⁵ Shiv Chopra et al. "rBST (Nutrilac) "Gaps Analysis" Report By rBST Internal Review Team." Health Protection Branch, Health Canada. 21 April 1998. Available at <www.nfu.ca/gapsreport.html>.

²⁶ Center for Food Safety Press Release. "Legal Challenge Filed with FDA to Remove Monsanto's rBGH from the Market." 15 December 1998. Available at <www.centerforfoodsafety.org/li/BGHpress1.html>.

²⁷ Peter Montague. "Hormones in Milk: No Right To Know." *Rachel's Environment and Health Weekly*. 17 March 1994.

²⁸ Keith Schneider. "FDA Warns the Dairy Industry Not to Label Milk Hormone-Free." *New York Times*. 8 February 1994.

²⁹ Keith Schneider. "Lines Drawn in a War Over a Milk Hormone." *New York Times*. 9 March 1994.

³⁰ "We oppose Recombinant Bovine Growth Hormone. The family farmers who supply our milk and cream pledge not to treat their cows with rBGH. The FDA has said no significant difference has been shown and no test can now distinguish between milk from rBGH treated and untreated cows. Not all the suppliers of our ingredients can promise that the milk they use comes from untreated cows."

³¹ Both of these laws have been amended by the Food Quality Protection Act of 1996 (FQPA).

³² Oversight of field testing of pesticide producing plants requires some coordination with the USDA.

registration has long been a problem.^{33 34 35} In the case of GE pesticides, a peer-reviewed report released by EcoStrat, an independent Swiss scientific assessment firm, indicated that the agency accepted inappropriate and scientifically questionable studies in approving the first Bt corn for U.S. growers.³⁶ In fact, the report states that studies submitted by Novartis and Mycogen to determine the effect of Bt corn on non-target insects were so poorly designed that there was virtually no chance that adverse effects would be observed.

Pesticide regulation entails other significant problems. Important tests are often not required,³⁷ and convenient assumptions about human toxicology are made.³⁸ There is also the problem of changing a pesticide's registration in the face of new evidence of harm, as the standard to justify regulatory reevaluation is extremely high.³⁹ These additional weaknesses of conventional pesticide regulation may impact the oversight of future GE pesticides, if not the current set of Bt crops.

Genetically engineered pesticides are different

GE pesticides also raise many issues outside the realm of conventional pesticides. Compared to conventional pesticides, GE pesticide plants make risk assessment much more complex. As living engineered organisms, they reproduce, spread their DNA, are extremely difficult to trace, and are impossible to recall. It can also be nearly impossible to fully identify how a crop has been modified, since gene insertion may result in unintended changes to an organism's DNA.

GE pesticide crops spur the development of pest resistance differently than conventional pesticides. Bt crops generally contain a toxin in every cell, throughout the life of the plant and beyond, regardless of actual need to control pests. Even proponents of genetic engineering acknowledge that this ever-present pesticide exposure will create resistant species in a relatively short period.⁴⁰ Despite this hazard, EPA began approving some Bt crops without requiring immediate implementation of resistance management plans.⁴¹ Under pressure from agency watchdogs, EPA eventually mandated management plans in which conventional crops are grown alongside Bt varieties as insect "refuges" to slow the development of resistance.⁴² While this strategy depends critically on grower compliance, EPA has yet to develop an effective compliance program. There is reason to believe that many growers create smaller-than-prescribed refuges, count their neighbor's land as part of their own refuge, or ignore the requirement altogether.⁴³

³³ E. Marshall. "Federal court finds IBT officials guilty of fraud." *Science* 222 (1983): 488.

³⁴ D. Fagin, M. Lavelle, and the Center for Public Integrity. *Toxic Deception: How the chemical industry manipulates science, bends the law, and endangers your health*. (Secaucus NJ: Carol Publishing Group, 1996).

³⁵ Pesticide Action Network North America. "More Pesticide Study Fraud?" *Global Pesticide Campaigner*. June 1991.

³⁶ Angelika Hilbeck, Matthias Meier and Andrea Raps. *Review on Non-Target Organisms and Transgenic Bt Plants*. April 2000.

³⁷ For example, tests for chronic neurotoxicity, effects on learned behaviors, and impacts on sperm production are generally not required. See for example: Caroline Cox. "No Guarantee of Safety." *Journal of Pesticide Reform*. Vol. 17, No. 2 (Summer 1997).

³⁸ For example, generally there is no consideration of exposure in combination of other pesticides (synergistic effects) and no consideration for impacts on non-average people (the sick, elderly, or chemically sensitive). See Cox 1997.

³⁹ In fact, EPA provides for a Special Review process, during which time the pesticide in question remains on the market. The average duration of this process is seven years. See Cox 1997. There is a distinct pattern of EPA inaction following receipt of data on adverse effects of specific pesticides (for example, metam-sodium, parathion, and aldicarb). See for example: Susan Cooper. "EPA and Pesticides: Lack of Leadership Cripples Decision-making." *Global Pesticide Campaigner*. February 1992.

⁴⁰ Les Levidow and Susan Carr. "Normalizing Novelty: Regulating Biotechnological Risk at the U.S. EPA." *Risk: Health, Safety & Environment*. Winter 2000.

⁴¹ Personal communication with Jane Rissler, Union of Concerned Scientists. 3 March 2000.

⁴² The idea is that in these conventional crop refuges, pests will not be exposed to the Bt toxin and will remain susceptible. These pests will mate with the exposed, resistant pests—"diluting" the passing of the resistance trait.

⁴³ Pollan 1998.

Moreover, even if these efforts were fully successful, they are only designed to delay the onset of resistance, not prevent it entirely.⁴⁴

Development of pest resistance is an all too accepted occurrence in modern, pesticide-based agriculture. Bt resistance, however, is of particular consequence. In its non-GE form, Bt toxin is an extremely valuable natural, low-impact pesticide and it would be a considerable loss to squander its effectiveness. In fact, Bt biopesticides are of great importance to organic growers, about 2/3 of which (in the U.S.) depend on it, at least as a tool of last recourse.⁴⁵ Bt resistance is thus a potential crisis for the burgeoning organic sector, now growing at about 20% annually. Yet Bt crops are registered without adequately assessing this potential impact.

Finally, pesticide crops may harm non-target insects and soil organisms in novel ways. Research suggests that pollen of Bt crops may harm lacewings and monarch butterflies.^{46 47 48} Most of this work indicates that more extensive research needs to be done. EPA's own Scientific Advisory Panel recently considered data requirements concerning the effect of these crops on "non-target" organisms, concluding that current requirements are not adequate.⁴⁹

GE pesticides in food

Under FFDCA, EPA sets tolerance limits ("safe" levels) for pesticides on and in food and feed, or establishes exemptions to tolerance requirements. While Bt pesticide food crops represent pesticides in food, they are routinely granted exemptions based on the relative safety of conventional Bt pesticides. For example, EPA deems Bt potatoes safe to eat, since conventional Bt pesticides are considered safe. Bt potatoes, however, may contain novel or altered proteins due to the imprecision of gene insertion and these may have serious health consequences.⁵⁰

Outside the realm of crops and pesticides, EPA also regulates commercial uses of GE microorganisms under authority of the Toxic Substances Control Act (TSCA).

USDA

The primary and almost exclusive role of USDA and their Animal and Plant Health Inspection Service (APHIS) with respect to GE 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. GE 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

⁴⁴ EPA Office of Pesticide Programs. "EPA and USDA Position Paper on Insect Resistance Management in Bt Crops." June 1999.

⁴⁵ Erica Walz. *Final Results of the Third Biennial National Organic Farmers Survey*. (Santa Cruz: Organic Farming Research Foundation, 1999).

⁴⁶ A. Hilbeck et al. "Effects of transgenic *Bacillus thuringiensis*-corn-fed prey on mortality and development time of immature *Chrysoperla carnea* (Neuroptera: Chrysopidae)." *Environmental Entomology* 27 (1998): 480-96.

⁴⁷ J.E. Losey, L.D. Rayor, and M.E. Carter. "Transgenic pollen harms monarch larvae." *Nature* 399 (1999) 214.

⁴⁸ L.C. Hansen and John J. Obrycki. "Field deposition of Bt transgenic corn pollen: lethal effects on the monarch butterfly." *Oecologia*. 19 August 2000.

⁴⁹ EPA Scientific Advisory Panel. "Report No. 99-06A: Scientific Advisory Panel Meeting, December 8, 1999, Session I - A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: Characterization and Non-Target Organism Data Requirements for Protein Plant-Pesticides." 4 February 2000. Accessed at <<http://www.epa.gov/scipoly/sap/1999/december/report.pdf>> on 28 December 2000.

⁵⁰ See for example: British Medical Association. "The Impact of Genetic Modification on Agriculture, Food and Health." May 1999. Available at <<http://web.bma.org.uk>>.

potential plant pest. Based upon the results of field trials, however, those seeking to commercialize GE crops can petition for deregulation under the Plant Pest Act.

Minimal oversight

Initial amendments by APHIS to their plant pest regulations were finalized in 1987.⁵¹ At that time, all GE organisms were regulated under procedures—still the fundamental framework applied by APHIS—that were criticized as inadequate by the General Accounting Office (GAO) in 1988, including calls that certain decisions by the agency were “scientifically indefensible.”⁵² All field trials were subject to permitting under the Plant Pest Act and the National Environmental Policy Act. After six years, APHIS allowed six crops species—corn, cotton, potato, soybean, tobacco, and tomato—to be grown without permitting. Instead, institutions simply notified APHIS of their intention to conduct a field test because APHIS felt they had enough data to conclude these plants posed little or no ecological risk.⁵³ In the last major change to their regulations, APHIS further simplified procedures for field testing GE crops, including reduced oversight for crops engineered to be virus-resistant.⁵⁴ APHIS summarily dismissed the existence and potential for long-term impacts from their actions.⁵⁵

Part of the process for commercialization of a GE crop is to receive deregulated status from APHIS under the Plant Pest Act. Institutions petition for deregulation with information gathered from field trials. APHIS has never rejected a petition for deregulated status, and in every case when asked to do so has found that GE crops do not have a significant impact on the environment.⁵⁶

Threats not addressed

Two independent analyses in 1995 seriously question decisions made by the agency in loosening their regulations in 1993 and again in 1997. Joy Bergelson, an ecological geneticist at the University of Chicago, and Colin Purrington, now an evolutionary biologist at Swarthmore College, examined the petitions approved by USDA at that time. Their conclusion was that many of the data upon which USDA was making its decisions were from critically flawed experiments.⁵⁷ They also said the petitions relied in large part on unsupported claims. Also in 1995, a report published in *Bio/Technology* surveyed all publicly available data from field tests.⁵⁸ In reviewing the 85 most recent reports of field trials, the authors noted that none mentioned experiments to assess weediness, zero (of the 19) reports on virus-resistant crops mentioned studies 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. Little has changed since GAO stated that “USDA is not requesting sufficient information from the applicant to assess an organism’s behavior in the environment and its potential ecological risk.”⁵⁹

Not only do these analyses seriously undermine the credence of APHIS’s claims that they had sufficient data to deregulate crops, but ecologists have stated that fundamental ecological tests are still not being performed. On the critical issue of virus-resistant crops, for example, these GE plants may cause development of new or worse viruses. While this is considered unlikely, the environmental consequences of such super-viruses could be far-reaching. Crops engineered for virus resistance can result in the creation

⁵¹ Federal Register. Vol. 52, No. 115. 16 June 1987. Pp.22908-22915.

⁵² General Accounting Office. “Biotechnology: Managing the Risks of Field Testing Genetically Engineered Organisms.” June 1988. GAO/RCED-88-27, at 48.

⁵³ Federal Register. Vol. 58, No. 60. March 31, 1993. Page 17056.

⁵⁴ Federal Register. Vol. 62, No. 85. May 2, 1997. Page 23945.

⁵⁵ 62 FR 23948.

⁵⁶ Carol Kaesuk Yoon. “Squash With Altered Genes Raises Fears of ‘Superweeds.’” *New York Times*. 3 November 1999.

⁵⁷ Colin Purrington and Joy Bergelson. “Assessing weediness of transgenic crops: industry plays plant ecologist.” *Trends in Evolution and Ecology*. Vol. 10, No. 8. 8 August 1995.

⁵⁸ Margaret Mellon and Jane Rissler. “Transgenic Crops: USDA Data on Small-Scale Tests Contribute Little to Commercial Risk Assessment.” *Bio/Technology*. 13 January 1995.

⁵⁹ GAO 1988, at 51.

of modified viruses that can infect a wider range of hosts, or have greater impact on them, than the parent viruses.⁶⁰

Part of the reason we know so little about the ecological impact of GE crops is due in part to premature regulatory laxity by USDA. In 1986 the agency stated that “[g]ene escape via a sexual transfer is not expected to occur and will not be considered.”⁶¹ But this is not necessarily the case. Already canola weeds resistant to three herbicides have been found in a field in northern Alberta, Canada.⁶² This finding demonstrates that genetic drift can quickly result in non-GE plants picking up traits from neighboring GE plants (here two of the three herbicide resistant plants were genetically engineered) and potentially creating serious ecological problems.

Genetic drift can result in biological pollution that is impossible to control. It was recently reported that the physiological costs to a plant of a GE trait can be “negligible,” suggesting the new trait could have an easy time persisting and thus spawning more troublesome weeds.⁶³ In fact the few studies of the relative fitness of crop-wild hybrids show that they are not necessarily less fit than their wild parent. With a strong push into international commercialization of these crops, the problem of genetic drift and its impact on biodiversity can easily be exacerbated. Without regulatory oversight, GE plants will continue to hybridize with wild relatives, and potentially create serious problems. The costs to the U.S. economy by non-native species are already estimated at \$138 billion annually.⁶⁴ And although the USDA has the authority under the Plant Quarantine Act to stop unlabeled and untested GE foods from entering the U.S., they have not exercised this authority.

USDA involvement in Terminator technology

Finally, instead of being a dispassionate regulator, USDA is actually invested in GE technology. USDA is the co-owner of a patent on the so-called “Terminator” technology, which causes plants to have sterile seeds and thus forces farmers to buy seeds every year instead of saving them, as is frequently the case. Despite international opposition to the development of this technology, USDA has continued with research and development and refused to unilaterally terminate its contractual agreement with co-patent holder Delta and Pine Land Seed Co., despite the fact that they have the legal option to do so.⁶⁵ And according to Delta and Pine Land, “We’ve continued right on with work on the [Terminator] Technology Protection System. We never really slowed down. We’re on target, moving ahead to commercialize it. We never really backed off.”⁶⁶

Dangers falling through the cracks

In addition to the shortcomings of the regulatory agencies discussed above, there are several important areas where regulation and oversight of GE products have not been adequately addressed by any agency detailed below. These include the following.

Impacts on soil

Recent studies have cast doubt on the rigor with which the government has studied the threat that GE crops may cause to soil ecosystems. In 1996, an APHIS determination on deregulated status for a Monsanto

⁶⁰ Union of Concerned Scientists. “Risks of Genetic Engineering.” Accessed from the Union of Concerned Scientists Web site at <<http://www.ucsusa.org/>> on 9 September 2000.

⁶¹ 51 FR 23385.

⁶² Mary MacArthur. “Triple-resistant canola weeds found in Alta.” *Western Producer*. 10 February 2000.

⁶³ Snow, A. A., B. Andersen, and R. B. Jørgensen. “Costs of transgenic herbicide resistance introgressed from *Brassica napus* into weedy *Brassica rapa*.” *Molecular Ecology*, 8(4) April 1999.

⁶⁴ David Pimentel, Lori Lach, Rodolfo Zuniga, and Doug Morrison. “Environmental and Economic Costs Associated with Non-Indigenous Species in the United States.” Cornell University. 12 June 1999. Accessed at <<http://www.news.cornell.edu/releases/Jan99/species/costs.html>> on 9 September 2000.

⁶⁵ Rural Advancement Foundation International. “USDA Refuses to Abandon Terminator Technology.” 28 July 2000. Accessed at <www.rafi.org> on 22 February 2001.

⁶⁶ Rural Advancement Foundation International. “Suicide Seeds on the Fast Track.” 25 February 2000. Accessed at <www.rafi.org> on 28 December 2000.

insect and herbicide resistant variety stated that, “environmental fate studies cited in the petition indicate that the CryIA(b) protein [a Bt toxin] present in crop residues will lose bioactivity quickly upon incorporation into the soil, and the rate of dissipation is comparable to that observed with previously registered microbial (non-GM) Bt products.”⁶⁷ But work published in December 1999 demonstrated that Bt toxin is released into the soil through the roots of Bt corn.⁶⁸ 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.” This news is reinforced by another key study which states that “pesticidal proteins [i.e., Bt toxin] 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.”⁶⁹ 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.”

Loss of biodiversity

Biodiversity, the variety of living things, is vitally important to healthy ecosystems. It is also important in agriculture.⁷⁰ The more diverse an agricultural region, the more that region is able to accommodate challenges from pests, disease, or climate change. GE crops accelerate the already grave loss of biodiversity by fostering the widespread adoption of a small number of commercially successful varieties.⁷¹ Genetic engineering also has the potential to undermine biodiversity by creating invasive species that out-compete native ones. In the United States, 42% of the species that are threatened or endangered are at risk primarily due to non-indigenous species.⁷²

Industrial materials

The federal government has not yet decided which agency will regulate crop plants engineered to produce industrial materials such as plastics precursors or those engineered to absorb and detoxify industrial wastes. According to James Alwood, EPA’s biotech coordinator for the Toxic Substances Control Act, “Everybody is looking around saying someone needs to look at these plants in some way.”⁷³

GE animals

GE animals pose human health risks to consumers, and environmental risks as new and potentially invasive species. For example, one company, A/F Protein, is currently requesting approval from FDA to market a transgenic fish. Although FDA has expertise in the area of food safety, it is not an environmental agency, and thus concerns about the ecological impacts of transgenic fish would likely be being handled by the wrong agency. Instead of the coordinated, multi-agency framework necessary to properly handle the introduction of transgenic fish—which, according to a paper in the *Proceedings of National Academy of Sciences* in December 1999, could quickly drive native fish populations to extinction⁷⁴—current oversight

⁶⁷ Determination of Nonregulated Status for Insect-Resistant/Glyphosate-Tolerant Corn Line MON 802. Petition Number: 96-317-01p.

⁶⁸ Deepak Saxena, Saul Flores, and G. Stotzky. “Insecticidal toxin in root exudates from *Bt* corn.” *Nature*. Vol. 402. 2 December 1999.

⁶⁹ Katherine K. Donegan and Ramon J. Seidler. “Effects of transgenic plants on soil and plant microorganisms.” *Recent Research and Developments in Microbiology*, 3 (1999): 415-424.

⁷⁰ See for example: John Tuxill. “Nature’s Cornucopia: Our Stake in Plant Diversity.” *Worldwatch Paper* 148. September 1999.

⁷¹ The UN Food and Agricultural Organization estimates that 75% of the world’s agricultural genetic diversity has been lost since the beginning of this century. See for example: Food and Agriculture Organization. “Crop Genetic Resources.” In *Biodiversity for food and agriculture* (Rome: Food and Agriculture Organization).

⁷² USDA Press release. “President Clinton Expands Federal effort to Combat Invasive Species.” 3 February 1999.

⁷³ Bette Hileman. “Biotech Regulation Under Attack.” *Chemical and Engineering News*. 22 May 2000.

⁷⁴ Matt Walker. “Extinction point.” *New Scientist*. 4 December 1999.

is inadequate. Another regulatory hole is the disposal of animals engineered to produce drugs. USDA may allow them to be used as food and feed ingredients after they can no longer be used to generate drugs.⁷⁵

Loss of natural biopesticides

As discussed above, the development of pest resistance to Bt crops would undermine the efficacy of the relatively benign natural Bt-based biopesticides on which large numbers of conventional and organic growers depend. Yet Bt crops are registered without full consideration of this critical issue. Given the dire need to advance sustainable agricultural practices and farming systems, the question of current and future impact of GE crops on biopesticides must be comprehensively addressed.

Contamination of conventional and organic crops

GE crops entail possible contamination of non-GE crops and commodities through pollen and co-mingling of seed or produce, yet the regulatory framework does not seek to address this issue in a comprehensive manner. Farmers growing non-genetically engineered crops are losing markets as a result of the international community's reluctance to accept either genetically engineered crops or crops that may have been contaminated through pollen or co-mingling. In 1996, the first year of significant commercial plantings of corn and soybeans, exports to Europe amounted to about \$3 billion; by 1999 it had dropped to \$1 billion.⁷⁶ The much-reported StarLink corn case, in which GE corn approved in the U.S. only for animal consumption widely contaminated corn in the food supply, highlights some of the far-reaching impacts of such contamination. Foreign markets for U.S. corn are tightening, growers who planted StarLink or who have StarLink-contaminated corn have had difficulty getting rid of it, and growers who have conventional corn are increasingly having to pay the costs of segregation and certification that their crops are StarLink-free. (This is an serious burden, as the use of planters, combines, augers, grain elevators, trucks, mills, storage bins and facilities for both GE and non-GE crops makes real segregation extremely difficult.⁷⁷)

For organic farmers, contamination is a particularly alarming problem. Terra Prima, a company that manufactures organic tortilla chips, lost \$87,000 worth of merchandise when it was discovered that their product had become contaminated.⁷⁸ Testing revealed that, as a result of genetic drift, one organic farmer selling corn to Terra Prima had his crop contaminated by a neighboring farmer who had planted GE corn, and thus the chips tested positive for GE content.⁷⁹ Contamination could make it impossible for organic farmers to retain their certification—the basis of their livelihoods. And growers also face possible liability for harm caused by GE crops.⁸⁰

The taxpayer burden

While doubts continue to grow about the wisdom of applying genetic engineering to crops and food production, it is worth noting that taxpayers are carrying part of the bill. Moreover, the taxpayer burden for this technology cannot even be accurately measured. The Congressional Research Service reported that, “The Administration does not track federal food and agricultural biotechnology funding of research as a line item in federal budget analyses. Consequently, the total amount of public funding for this research is unclear.”⁸¹ Thus American taxpayers have subsidized a technology of questionable merit in an unaccountable way.

⁷⁵ Hileman 2000.

⁷⁶ David Barboza. “In the Heartland, Genetic Promises.” *New York Times*. 17 March 2000.

⁷⁷ Wayne Beck, VP of Pioneer Hi-Bred International, put it bluntly: “Everyone has to realize that no one can guarantee 100% [GE]-free grain.” “Genetically Modified Crops: Questions and Answers.” American Corn Grower Association Web site. <<http://www.acga.org/GMOBrochure/05.htm>> on 16 November 2000.

⁷⁸ Michael Passoff. “Genetically-Engineered Food: Threats to Shareholder Value.” *GeneWatch*. September 2000.

⁷⁹ Personal communication with Melodi Nelson, co-owner of Terra Prima. September 2000.

⁸⁰ Skip Spitzer. “Riding the Bullet Train: The Impact of GE Crops on U.S. Farmers.” *Global Pesticide Campaigner*. December 2000.

⁸¹ Donna U. Vogt and Mickey Parish. “Food Biotechnology in the United States: Science, Regulation, and Issues.” Congressional Research Service. 2 June 1999.

Given these areas of outright regulatory neglect, as well as the lax oversight of areas the regulatory agencies do consider, there is a fundamental danger: our health and safety are not being protected under the current regulatory regime. The public is being exposed to a new and largely untested technology before an adequate evaluation of the environmental and human health impacts has been conducted.

Civil groups take legal action

Given the inadequacy of current regulatory oversight, it is not surprising that civil society organizations have taken legal action. In May 1998, an unprecedented coalition of scientists, religious leaders, health professionals, consumers and chefs filed suit against FDA to obtain mandatory safety testing and labeling of GE foods. The suit alleged that current FDA policy, which permits such altered foods to be marketed without testing and labels, violates the agency's statutory mandate to protect public health and provide consumers with relevant information about the foods they eat. The suit, filed in federal district court, also alleged that FDA policy is a violation of religious freedom. Through this case, FDA produced over 44,000 pages of documents during discovery. These documents, excerpts of which are included above in the FDA section, reveal for the first time that despite their public pronouncements to the contrary, the agency's own scientists expressed serious reservations about grouping GE foods with foods produced through conventional means. In October 2000, a federal court held that FDA's 1992 policy on GE foods "does not have a binding effect" on food producers. In so doing, the court equated FDA policy to agency inaction and therefore found it immune from challenge under a number of statutes.

In February 1999 (amended March 1999), a coalition of environmentalists, farmers, and consumers filed a lawsuit against EPA to cancel the registration of all plants engineered to produce Bt toxin because of concerns that its widespread use will hasten insect resistance to the toxin and eliminate the efficacy of conventional Bt biopesticides. The legal action called on the agency to cease the approval process for any new registrations of all Bt crops, and immediately perform a programmatic environmental impact assessment under the National Environmental Policy Act to analyze the cumulative impacts of all Bt plant registrations. EPA was forced to respond to the pre-litigation petition for rulemaking in April 2000 with a 107-page document. The lawsuit was voluntarily withdrawn in July 2000 as part of a broader legal strategy.

In December 1999, six farmers filed a class action lawsuit alleging that Monsanto and other biotechnology companies formed a global cartel through which they have fixed prices on GE seeds, and conspired to restrain trade in the GE corn and soybean seed markets (Higginbotham, et al. v. Monsanto). The suit also alleges that Monsanto failed to adequately test GE seeds and crops for human health and environmental safety prior to marketing them, and that Monsanto and others made deceptive statements or omissions concerning the testing and approval of GE foods and crops. Recently, the lawsuit has been transferred to the Federal District Court for the Southern District of Illinois, where it is being consolidated with another lawsuit pending there on similar grounds (Blades, et al. v. Monsanto). Monsanto has moved to dismiss both cases but no decision has been made. A trial date has been set in the Blades case for July 2001.

Finally, in December 1998, a legal challenge by the Center for Food Safety (CFS) was filed with FDA to remove Monsanto's rBGH from the market. A legal petition filed in January 1999 by CFS and two dozen other public interest organizations followed the challenge. The petition calls for the withdrawal of the approval of Monsanto's rBGH.

Special interests

The failings of USDA, EPA and FDA in the regulation of GE crops and foods are in part due to influence of the biotechnology industry. While a full examination of this is beyond the scope of this paper, it is worth noting some of the channels by which industry interests are expressed.

One key avenue of influence is the so-called "revolving door" between agency and industry personnel. There is no shortage of such cases. For example, Terry Medley, who presided over the hearings USDA held in 1986 on new directions in agency policy and was APHIS Administrator when the agency issued its last substantive rule change in 1997, became director of regulatory and external affairs for DuPont, a major biotechnology player. A study by the Environmental Working Group revealed that 2/3 of those who have held the highest-ranking positions in EPA's pesticide program now receive at least part of their paycheck

from pesticide interests actively fighting EPA regulatory efforts.⁸² Margaret Miller, former chemical lab chief at Monsanto, became an FDA deputy director.⁸³ Michael Taylor worked at FDA in the late 1970s and early 1980s, then worked as an attorney for Monsanto, went back to work for FDA, and then returned again to work as an attorney for Monsanto.

Industry also influences regulation through political representation. Both Congress and the White House impact agency decision-making and there is very strong evidence of undue industry influence in these branches of government.^{84 85 86 87 88}

Current Regulatory Issues

In the January 18, 2001 Federal Register, FDA published a proposed rule related to pre-market notification on GE foods, as well as proposed guidance on voluntary labeling. The documents are a reaffirmation of the failed status quo regarding regulatory oversight. FDA will require no comprehensive, mandatory pre-market safety testing, nor will GE foods be labeled, despite the fact that the majority of the American public commented in support of such information. The documents stand in sharp contrast to the oversight sought by the public interest community, as outlined in a legal petition filed 21 March 2000.⁸⁹ These new documents are supported by industry and trade groups like the Grocery Manufacturers of America, the National Food Processors Association, and the Biotechnology Industry Organization, and unanimously opposed by public interest groups such as the Genetically Engineered Food Alert coalition. Public comments will be accepted for 60 days on the labeling guidance, and 75 days on the pre-market notification rule.

EPA's proposed rule regarding the regulation of GE plants, published in 1994, has never been finalized, although the agency has been implementing its essential elements in registration actions taken since 1995. The National Research Council published a report in April that highlighted several shortcomings in EPA's oversight.⁹⁰ EPA has given no indication publicly regarding their timetable for finalizing the rule. Also outstanding at EPA is a petition from Aventis CropScience to grant StarLink corn, which was illegally sold in products intended for human consumption, an exemption from the requirement of a tolerance. EPA convened a Scientific Advisory Panel regarding this issue on 28 November 2000, and the Panel issued their report on 1 December 2000. A final decision from EPA could come at any time.

USDA has announced no plans to alter in any fundamental way the inadequacies regarding its oversight of GE foods and crops. There are three major areas where the agency will continue to receive input about their regulations. First, the agency appointed members to an Advisory Committee on Agricultural Biotechnology (ACAB) on January 21, 2000 that held three meetings during the year. In September, eleven members of the ACAB sent a letter to Agriculture Secretary Dan Glickman urging him to abandon government

⁸² Emily Headen. *From Bureaucrats to Fat Cats* (Washington: Environmental Working Group, 1999).

⁸³ Organization for Competitive Markets. "FDA's revolving door: Part II." *Organization for Competitive Markets Newsletter*. February 2000. Accessed from the Organization for Competitive Markets Web site at <<http://www.competitivemarkets.com/>> on 6 July 2000.

⁸⁴ D. Fagin, M. Lavelle, and the Center for Public Integrity. *Toxic Deception: How the chemical industry manipulates science, bends the law, and endangers your health*. (Secaucus NJ: Carol Publishing Group, 1996).

⁸⁵ Brian Tokar. *Earth for Sale: Reclaiming Ecology in the Age of Corporate Greenwash* (Boston: South End Press, 1997)

⁸⁶ "The Bromide Barons." Report by the Political Ecology Group and the Transnational Resource and Action Center. May 1997

⁸⁷ "Unreasonable Risk." Report in the Congress and the People series by the Center for Public Integrity. 1998

⁸⁸ G. William Domhoff. *The Powers That Be* (New York: Vintage Books, 1978)

⁸⁹ See: <http://www.centerforfoodsafety.org/li/FDApetition.html>.

⁹⁰ National Research Council. "Genetically Modified Pest-Protected Plants: Science and Regulation." National Academy Press. Washington, DC. 2000.

involvement with Terminator seeds.⁹¹ But the outcome of the letter, and the ACAB in general, are very much in doubt. According to Keith Pitts, a USDA special assistant, “The ACAB is not congressionally mandated, so it would be up to the next secretary to decide if the committee should continue.”⁹² Second, USDA has sponsored a Standing Committee on Biotechnology, Food and Fiber Production, and the Environment at the National Research Council (NRC). The Committee held its first meeting in May 2000. In addition to the Standing Committee, the NRC will be undertaking other studies, including one that deals with the environmental impacts associated with the commercialization of transgenic crops. Two other studies relate to the health effects of genetically engineered foods and intellectual property issues associated with seeds. The third area where USDA will receive input is from a recent request for public comments on issues related to identity preservation and product segregation.⁹³ The public comment period on the request ends 28 February 2001.

Conclusion

Genetically engineered foods have been rushed to commercialization before adequate regulation has been put in place, for which both government and industry are culpable. The government has not adequately protected human health and the environment, and industry has failed to demonstrate the safety of their products. The information necessary to make an adequate determination of safety for human health and the environment for these products is not currently sufficient.

In light of these circumstances, precaution is warranted. That is, until adequate information is gathered about the impacts of GE foods and crops on people and the environment, some of which are completely irreversible, they should not be commercialized. One campaign based on this principle is that of the Genetically Engineered Food Alert, a national coalition of more than 200 scientists, physicians, religious leaders and chefs, as well as agricultural, consumer, environmental and public health organizations. Genetically Engineered Food Alert calls for a moratorium on the commercialization of GE crops and foods unless three basic conditions have been met. First, GE crops must be demonstrated to be safe for human health and the environment. Second, liability for any damage posed by these crops must be clearly established as lying with the manufacturers. And third, the consumer’s right to know about what he or she is buying must be respected through clear product labeling for all GE products.

⁹¹ National Coalition Against the Misuse of Pesticides. “Eleven on Biotech Panel Call for USDA to Dump Terminator.” Technical Report, Vol. 15, No. 10. October 2000.

⁹² Mary Scott. “The ACAB: USDA’s Sincere Gesture or Stalling Technique?” Organic Farming Research Foundation Information Bulletin, Number 8. Summer 2000.

⁹³ USDA Agricultural Marketing Service. “Request for Public Comments on How USDA Can Best Facilitate the Marketing of Grains, Oilseeds, Fruits, Vegetables, and Nuts in Today’s Evolving Marketplace.” Federal Register, Vol. 65, No. 231. 30 November 2000. 71272.