

2003

The Academy Chokes on Food Biotech, Public Policy Suffocates

Henry I. Miller

Follow this and additional works at: <http://scholarship.richmond.edu/jolt>



Part of the [Food and Drug Law Commons](#)

Recommended Citation

Henry I. Miller, *The Academy Chokes on Food Biotech, Public Policy Suffocates*, 10 Rich. J.L. & Tech 1 (2003).

Available at: <http://scholarship.richmond.edu/jolt/vol10/iss1/5>

This Article is brought to you for free and open access by UR Scholarship Repository. It has been accepted for inclusion in Richmond Journal of Law and Technology by an authorized administrator of UR Scholarship Repository. For more information, please contact scholarshiprepository@richmond.edu.

THE ACADEMY CHOKES ON FOOD BIOTECH,
PUBLIC POLICY SUFFOCATES

By: HENRY I. MILLER, M.D.*

{1} The National Academy of Sciences, under its 1863 congressional charter, is supposed to be dedicated to “investigate, examine, experiment, and report upon any subject of science or art whenever called upon to do so by any department of the government.”¹ At least insofar as judging the scientific integrity of governmental regulation of biotechnology is concerned, however, two recent “expert” committees of the National Research Council (NRC), the research arm of the Academy, have been plagued by apparent bias, and their recommendations have been dubious.

{2} During the past two years, the Academy has placed its imprimatur on two questionable analyses of federal biotechnology regulatory policy toward field trials and commercialization of recombinant DNA-modified plants B the more recent on regulation by the U.S. Department of Agriculture (USDA), paid for by USDA,² and another earlier report concerning oversight by the Environmental Protection Agency (EPA).³

{3} The USDA has the legislative authority, primarily under the Plant Pest Act,⁴ to regulate the importation and interstate movement of plants, plant products, and other organisms that may introduce plant diseases or pests. For example, there has long been a permitting system for “plant pests,” defined as any organism “which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants.”⁵ The USDA’s Animal and Plant Health Inspection Service (APHIS) regulations incorporate an inclusive list of organisms that are or that harbor plant pests.⁶ This approach is essentially binary: a plant that an investigator might wish to introduce into the field is either on the proscribed, inclusive list of plants pests and therefore, requires a permit – or it is exempt. Further, the method is risk-based, in that the organisms that are required to undergo case-by-case governmental review are an enhanced-risk group, compared to plants not considered to be plant pests.

{4} For the past fifteen years, however, the USDA also has maintained a parallel regime focused exclusively on transgenic plants, or those that contain heterologous DNA introduced with molecular techniques.⁷ In order to establish this mechanism, in which the scope of what is regulated is essentially independent of risk, the APHIS tortured the original concept of a plant pest as something known to be harmful and crafted a new category – a “regulated article,” defined as “any . . . organism or product altered or produced through genetic engineering which the Administrator determines is a plant pest or has reason to believe is a plant pest.”⁸ The phrase “has reason to believe is a plant pest” has been broadly interpreted by the APHIS to include any organism that includes any amount of DNA from a plant pest,⁹ even a snippet of DNA that is incapable of conferring pathogenicity. Two such commonly-used DNA sequences are the cauliflower mosaic virus S35 promoter sequence and the T-DNA from *Agrobacterium tumefaciens*. The USDA’s case-by-case permitting process, costly field test design, and other requirements have made recombinant DNA-modified plants disproportionately expensive to develop and test. A field trial with a recombinant DNA-modified plant may be 100 times more expensive than the same experiment performed with a plant that has an identical phenotype but that was modified with less precise genetic techniques.¹⁰

{5} The EPA, which regulates pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), has contrived its own version of a regulated article. Under the statute, the EPA has long regulated field tests on areas greater than ten acres, the commercial use of pesticides, and substances that act as plant regulators, defoliants, desiccants and nitrogen stabilizers.¹¹ In 1994, the EPA proposed its “plant-pesticide” rule, which brought under the jurisdiction of FIFRA all the substances that mediate “host plant resistance” to pests, as well as the genetic material needed to direct the synthesis of these substances, but only if they are introduced with recombinant DNA techniques. In a final regulation published in 2001, seven years after the rule was first proposed, in place of “pesticide” the EPA coined the term “plant-incorporated protectants” (PIPs) to describe what it would regulate.¹² These PIPs are defined in a way that places them within the FIFRA definition of a pesticide, namely, a substance intended to prevent, repel or mitigate any pest, but only if the plant was constructed by recombinant DNA technology.¹³ Plants modified with “conventional breeding” are expressly exempted.¹⁴ The concept of a “regulated article” or “plant incorporated protectant” may be inventive, but it flies in the face of the disciplines of plant pathology and biology, as well conflicting with the risk-based mandate of the statutes. Moreover, the USDA’s and the EPA’s regulatory policies fail to acknowledge that genetic modification is a continuum – from crude, imprecise, traditional practices such as hybridization, intensive mutagenesis and somaclonal variation, to more precise and predictable recombinant DNA techniques.

{6} Likewise, they fail to take into consideration the extraordinary overall safety record of genetic modification in agricultural research throughout both the pre- and post-recombinant-DNA eras. Literally millions of genetically altered, but not recombinant DNA-modified, plants are field tested each year without governmental oversight or strictures: the average plant breeder of corn, soybean, wheat, or potato, for example, may put 50,000 discrete, new genetic variants per year into the field, many or all of which may be the product of “wide crosses” hybridization in which genetic material (including that from weedy or toxigenic plants) has been transferred across natural breeding barriers.¹⁵ The safety record of the tens of thousands of field trials of recombinant DNA-modified plants that have been performed worldwide, and of the hundreds of millions acres of cultivated commercial recombinant DNA-modified crops – virtually all of which have been performed with only the plant breeding practices standard for the parental crop has been stunning, and the results of risk-assessment experiments have been uniformly negative.¹⁶

{7} National and international scientific organizations including, repeatedly, the National Academy of Sciences and the National Research Council have addressed the question of whether there are unique risks associated with recombinant DNA-modified organisms with congruent conclusions. A 1987 white paper from the NAS concluded that there is no evidence of the existence of unique hazards, either in the use of recombinant DNA techniques or in the movement of genes between unrelated organisms.¹⁷ In 2000, an NRC report on the scientific basis of EPA’s regulation of recombinant plants concurred “that the *properties* of a genetically modified organism should be the focus of risk assessments, not the *process* by which it was produced.”¹⁸ Perhaps the most comprehensive and unequivocal analysis was the 1989 NRC report on the risks of recombinant plants and microorganisms, which concluded that “the same physical and biological laws govern the response of organisms modified by modern molecular and cellular methods and those produced by classical methods.”¹⁹ But this analysis went further, emphasizing that recombinant DNA techniques are more precise, circumscribed and predictable than other methods:

Recombinant DNA methodology makes it possible to introduce pieces of DNA, consisting of either single or multiple genes, that can be defined in function and even in nucleotide sequence. With classical techniques of gene transfer, a variable number of genes can be transferred, the number depending on the mechanism of transfer; but predicting the precise number or the traits that have been transferred is difficult, and we cannot always predict the phenotype that will result. With organisms modified by molecular methods, we are in a better, if not perfect, position to predict the phenotypic expression.²⁰

{8} In other words, recombinant technology is a refinement, or improvement, over older, less precise techniques, and its use generates less uncertainty, which led the committee to make the strong policy recommendation that “the nature of the process [of genetic modification] is not a useful criterion for determining whether the product requires less or more oversight.”²¹ So much for the discriminatory treatment of the USDA’s “regulated articles” and the EPA’s “plant-incorporated protectants,” the case-by-case review of which is triggered by the use of recombinant DNA techniques.

{9} In addition to conflicting with scientific consensus, the USDA’s and the EPA’s regulation of recombinant DNA-modified plants is also incompatible with the two-decade-old part of the United States’ federal framework that is intended specifically to guide federal agencies’ regulatory approach to products derived from recombinant DNA-modified organisms. That guidance is contained in a 1992 statement of policy from the White House Office of Science and Technology Policy, “Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment,” which was specifically intended to circumscribe the scope of what should be subject to case by case review.²² It calls for:

[A] risk-based, scientifically sound approach to the oversight of planned introductions of biotechnology products into the environment that focuses on the characteristics of the . . . product and the environment into which it is being introduced, not the process by which the product is created. Exercise of oversight in the scope of discretion afforded by statute should be based on the risk posed by the introduction and should not turn on the fact that an organism has been modified by a particular process or technique.²³

{10} On the basis of the exegesis above and the recognition in the 2002 NRC report that government agencies are in the “difficult position of enforcing a higher environmental standard for transgenic plants than the standards currently used to regulate the impacts of other agricultural technologies and practices,”²⁴ one might logically have expected an endorsement and extension of the 1987 NAS white paper and 1989 NRC report, accompanied by a recommendation to rationalize the system and to regulate field trials of recombinant and conventional plants generally no differently, except for those plants with newly-introduced traits perceived to confer higher risk. Instead, the Academy committee recommends maintaining the current discriminatory, process-based regulatory system that focuses on plants modified by recombinant DNA technology.²⁵ It justifies this recommendation by invoking a variety of specious arguments.

{11} First, the committee invokes “a general assumption that the risks associated with the introduction of genetic novelty are related to the number of genetic changes and the origin of the novel genes.”²⁶ This author contends that there is no evidence to support these assumptions, but

if there were, one would expect to find intense concern about and recommendations for review of the widespread application of induced-mutation breeding, which has been in common use since the 1950's.²⁷ This technique involves exposing crop plants to ionizing radiation or toxic chemicals to induce random genetic mutations.²⁸ These treatments most often kill the plants or seeds or cause detrimental genetic changes, but on rare occasions, the result is a desirable mutation, for example, one producing a new trait in the plant that is agronomically useful, such as altered height, more seeds, or larger fruit.²⁹ In these cases, breeders lack detailed knowledge about the nature of the genetic mutation(s) that produced the useful trait, or about the large number of other mutations that inevitably have occurred in the plant.³⁰ Yet the more than 2200 mutation-bred plant varieties from a range of different species that have been marketed over the last half century have been and remain subject to no formal pre-market regulation.³¹

{12} Likewise, the committee's rationale makes it difficult to reconcile the exemption from regulatory review of wide crosses, hybridization in which embryo rescue or similar techniques are used to transfer what plant breeders call alien genes from one species or genus to another to create plants that would not exist in nature.³² Consider, for example, *Triticum agropyrotriticum*, a man-made "species" constructed by combining genes from bread wheat and a grass called quackgrass or couchgrass.³³ Possessing all the chromosomes of wheat and one extra whole genome from the quackgrass B thereby adding tens of thousands of genes – *T. agropyrotriticum* was independently produced via wide crosses in the former Soviet Union, Canada, United States, France, Germany, and China, where at various times it has been grown for both forage and grain.³⁴ These new genetic constructions are exempt from regulation (in spite of at least the theoretical possibility that the new gene products could make them more weedy, toxic or allergenic than parental wheat varieties), although the use of recombinant DNA techniques to add a *single* quackgrass gene to wheat would precipitate an extensive and expensive pre-market review from either the USDA or EPA, depending on whether the introduced gene conferred pesticidal properties.³⁵

{13} As to concerns about the origin of an introduced gene, the scientific consensus holds that the risk of an introduced gene is related primarily to its function, not its origin.³⁶ Moreover, the very concept of the "origin" of a gene has become murky with the accumulation and analysis of DNA sequencing data. Nearly identical DNA sequences and biochemical pathways are found across vast phylogenetic distances. Searching for homology to the *E. coli* genome using a high degree of stringency, for example, reveals gene sequences that are virtually identical in a variety of organisms, including other bacteria, plants, amphibia, insects and humans.³⁷ This broad conservation and sharing of gene sequences in nature weakens the argument that the origin, as opposed to the function – of newly introduced genetic material poses a safety concern (assuming that the introduced material is well-characterized).

{14} Second, the committee claims there is greater risk from recombinant DNA technology than other techniques because "a much broader array of phenotypic traits can potentially be incorporated into plants than was possible two decades ago."³⁸ But this is a second-order kind of concern: greater versatility is not the same as enhanced risk. The FDA emphasized this point in its 1992 policy on foods from "new plant varieties," which defined certain potentially hazardous characteristics of new foods, such as the presence of a substance new to the food supply, increased levels of an endogenous toxin, or the introduction of an allergen, that, if present, would require greater scrutiny by the agency and which could result in additional testing and labeling or the exclusion of the food from commerce.³⁹ During the past decade, under this policy thousands

of foods in U.S. supermarkets that contain byproducts of recombinant organisms have been marketed, irrespective of whether the plant arose from the application of recombinant DNA or traditional genetic engineering methods. Other risk-based approaches have been described for the oversight of field trials of recombinant plants.⁴⁰ However, in spite of the weight of scientific consensus and empirical evidence, in a particularly infelicitous circumlocution the panel concludes:

[T]hat the scientific justification for regulation of transgenic plants is not dependent on historically set precedents for not regulating conventionally modified plants. While there is a need to reevaluate the potential environmental effects of conventionally improved crops, for practical reasons, the committee does not recommend immediate regulation of conventional crops.⁴¹

{15} For practical reasons, indeed! Not a single conventional crop could meet the requirements being imposed by the USDA on recombinant DNA-modified plants. For a variety of reasons, conventional plant breeding would grind to a halt if it were subject to the USDA's regimen for gene-spliced plants.⁴² First, the mechanisms for enhancing host plant resistance for conventional plant breeding are largely unknown because this process uses far less precise and predictable methods than recombinant DNA.⁴³ Second, conventional plant breeding has led to the inadvertent introduction of undesirable traits into commercialized products.⁴⁴ On the basis of such scientifically unconvincing reasoning, the NAS panel recommends continued compulsory case-by-case oversight by the USDA of the field trials of all recombinant DNA-modified plants.⁴⁵

{16} Perhaps one such scientifically indefensible, internally inconsistent report could be dismissed as an anomaly, but the NRC's previous report on a parallel subject, namely the EPA's oversight of recombinant DNA-modified plants, was similarly flawed.⁴⁶ The committee that produced the EPA report chose to ignore crucial aspects of its charge.⁴⁷ Specifically, the committee failed "to examine the existing and proposed regulations to qualitatively assess their consequences for research, development, and commercialization of [recombinant plants modified to enhance pest-resistance]."⁴⁸ The committee also failed to "provide recommendations to address the identified risk/benefits, and, if warranted, for the existing and proposed regulation of [recombinant plants modified to enhance pest-resistance]."⁴⁹ This point is essential because most other analyses have found the EPA's existing and proposed regulation to be unscientific, illogical and potentially damaging to agricultural research.

{17} Both the 1987 and 1989 NAS/NRC analyses and the analyses of other academic groups arrived at conclusions incompatible with the EPA approach. The EPA approach circumscribes only recombinant DNA-manipulated plants for repeated, redundant case-by-case reviews of field trials and subjects each gene product and the requisite transgenic DNA to onerous pesticide registration procedures.⁵⁰ A large segment of the scientific community has unequivocally condemned this approach. A 1996 report by eleven scientific societies, representing 80,000 biologists and food professionals, excoriated the EPA's approach and warned of a number of negative consequences for agriculture and consumers in the event of the implementation of the policy of the EPA.⁵¹ This report predicted that it would:

[D]iscourage the development of new pest-resistant crops, thereby prolonging the use of synthetic chemical pesticides; [i]ncrease the regulatory burden for those developing pest-resistant varieties of crops, while also increasing federal and state bureaucracy; [l]imit the

use of biotechnology for the development of pest-resistant plants to those developers that can pay the increased costs associated with additional regulation..., [h]andicap the United States in competition for international markets because of U.S. government policy that new pest-resistant varieties, or products from these varieties, be identified as containing their own 'pesticides;' and [l]imit the use of valuable genetic resources and new technologies to improve crop protection from pests and diseases.⁵²

{18} The report also offered general principles and recommendations for the oversight of new plant varieties, including that federal oversight should be based on scientific principles, that it "should focus on high-probability risk rather than hypothetical or unrecognizable risk," and that "the level of risk of a plant variety to the environment or human safety is determined by the characteristics of the plant, not by the method by which a gene for pest defense is transferred."⁵³

{19} In 1998 the Council on Agricultural Science and Technology (CAST), an international consortium of thirty-six scientific and professional groups, reiterated the criticisms of the eleven societies' report, characterizing the EPA's approach as "scientifically indefensible" and stating that treating gene-spliced plants as pesticides would "undermine public confidence in the food supply."⁵⁴

{20} Therefore, it was extraordinary to find in the 2000 report from the Academy that "the committee has chosen to take EPA's proposed rule and the overarching [federal governmental] coordinated framework as given."⁵⁵ This critical decision enabled the committee to produce a report which accepted a policy that had been censured repeatedly. The EPA's calls into question the long, distinguished history of breeding pest resistance into plants that have yielded enormous improvements in food production and safety, worldwide. This is a policy that if applied to other, less precise technologies would have thwarted the Green Revolution, which has been, literally, life-giving to hundreds of millions of starving people in developing countries.

{21} The NRC's 2000 analysis of the EPA's regulatory approach contains language that reflects and endorses the scientific consensus on the nature of risk: "the committee agrees that the *properties* of a genetically modified organisms should be the focus of risk assessments, not the *process* by which it was produced."⁵⁶ This only emphasizes the logical inconsistency of choosing to ignore the flawed, central, fundamental tenet of the EPA's approach to regulation; namely, that the use of recombinant DNA techniques is the trigger to regulation. This tenet violates the regulatory principle that the degree of scrutiny should be commensurate with risk.

{22} How could the esteemed National Academy of Sciences twice have gone so far wrong in its assessment of the scientific basis for federal regulatory policy? The game was "fixed." The USDA committee was stacked with members known to harbor antagonism or skepticism toward biotechnology; moreover, unlike the 1987 and 1989 NRC committees, it contained few fellows of the Academy. Of the twelve members on the committee, only two were Academy fellows. The EPA committee contained no Academy fellows, save the chairman.

{23} The committee members and invited reviewers for the EPA report were selected with disregard for apparent conflicts of interest and bias. Stanley Abramson, Fred Betz and Morris Levin, three members of the twelve-person committee, are former EPA staff who helped to craft and defend a variety of process-based regulatory policies at the agency. Another member, Rebecca Goldberg, has produced a succession of anti-biotechnology tracts over the past decade

and a half. Moreover, during the formal review process, the document was reviewed by another former senior EPA official, Lynn Goldman, who had been instrumental in crafting and defending the policy in question, and by Jane Rissler, an intractable anti-biotechnology activist. Three members of the USDA committee, Chairman Fred Gould, David Andow and Norman Ellstrand, are long-time skeptics about the safety of recombinant plants and have consistently advocated process-based regulation. Another USDA committee member, Ignacio Chapela, is the author of a discredited article on supposed contamination of the teosinte gene pool by transgenes from Bt-maize banned in Mexico.⁵⁷

{24} The report on EPA oversight had the desired result.⁵⁸ After seven years of opposition from the scientific community to the unscientific proposed rule, the Academy report offered sufficient cover for the EPA to issue a final rule.⁵⁹ The prestige of the Academy attached to the report on the USDA's regulation, virtually assuring the permanence of stultifying, process-based regulation at the USDA that will unnecessarily inflate the costs of research and the commercialization of new plant varieties.

{25} The excessive regulation acts as a market-entry barrier to smaller competitors unable to bear inflated regulatory costs. In contrast, the handful of large agribusiness companies currently involved in agricultural biotechnology will actually benefit from such extensive and expensive EPA and USDA regulatory regimes. Academic researchers, the ultimate engine for innovation, are the most severely affected victims of excessive, ill-conceived regulation. Operating on small budgets, their ability to perform field trials of recombinant plants and microorganisms is markedly restricted.

{26} The late DeWitt "Hans" Stetten, an esteemed NIH researcher and administrator, once wrote that "[s]cience cannot tolerate the man who takes lightly his moral obligation to report strictly what is true."⁶⁰ It appears, however, that on certain high-profile, politically-charged subjects, the National Academy of Sciences lately has chosen to exempt itself from that axiom.

* Dr. Henry I. Miller is an academic researcher, author and consultant. He graduated from the Massachusetts Institute of Technology with a Bachelor of Science degree in Life Sciences and attended the University of California, San Diego, receiving the M.S. (Molecular Biology) and M.D. degrees. After completing his clinical training in internal medicine as a Clinical Fellow in Medicine at Harvard Medical School, Dr. Miller spent almost three years as a Research Associate at the National Institutes of Health, using and helping to refine the recombinant DNA ("gene-splicing") techniques that were then emerging. Dr. Miller is currently at Stanford University, where he is a fellow at the Hoover Institution.

¹ National Academies of Science, *About the NAS*, at [http://www4.nationalacademies.org/nas/nashome.nsf/\(leftnav\)/AboutTheNAS_History?OpenDocument](http://www4.nationalacademies.org/nas/nashome.nsf/(leftnav)/AboutTheNAS_History?OpenDocument) (quoting the NAS's Act of Incorporation) (2003).

² NAT'L RES. COUNCIL ET AL., *ENVIRONMENTAL EFFECTS OF TRANSGENIC PLANTS: THE SCOPE AND ADEQUACY OF REGULATION* (2001), available at <http://www.nap.edu/books/0309082633/html/> (last visited Sept. 15, 2003).

³ NAT'L RES. COUNCIL ET AL., *GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION* (2000), available at <http://www.nap.edu/books/0309069300/html/> (last visited Sept. 15, 2003).

⁴ 7 U.S.C. § 150aa-jj (repealed 2000).

⁵ Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or

HENRY I. MILLER, M.D. - THE ACADEMY CHOKES ON FOOD BIOTECH

Which There is Reason to Believe are Plant Pests, 7 C.F.R. § 340.1 (2003).

⁶ *Id.* § 340.2 (2003)

⁷ *Id.* § 340 (2003).

⁸ *Id.* § 340.1 (2003).

⁹ S.L. Huttner, et al., *U.S. Agricultural Biotechnology: Status and Prospects*, 50 *TECH. FORECASTING & SOC. CHANGE* 25, 30 (1995).

¹⁰ *Id.*

¹¹ Pesticide Registration and Clarification Procedures, 40 C.F.R. § 152.3 (2001).

¹² *Id.*

¹³ *Id.*

¹⁴ Environmental Protection Agency, *Questions & Answers, Biotechnology: Final Plant-Pesticide/Plant Incorporated Protectant (PIPs) Rules*, at <http://www.epa.gov/scipoly/qanda.pdf> (July 19, 2001).

¹⁵ NAT'L RES. COUNCIL ET AL., *FIELD TESTING GENETICALLY MODIFIED ORGANISMS: FRAMEWORK FOR DECISIONS 66* (1989), available at <http://books.nap.edu/books/0309040760/html/66.html#pagetop> (last visited Sept. 15, 2003).

¹⁶ See generally L.L. Wolfenbarger & P.R. Phifer, *The Ecological Risks and Benefits of Genetically Engineered Plants*, 90 *Sci.* 2088 (2000).

¹⁷ NAT'L RES. COUNCIL ET AL., *INTRODUCTION OF RECOMBINANT DNA-ENGINEERED ORGANISMS INTO THE ENVIRONMENT: KEY ISSUES 22* (1987).

¹⁸ NAT'L RES. COUNCIL ET AL., *GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION* (2000), available at <http://www.nap.edu/books/0309069300/html/> (last visited Sept. 15, 2003).

¹⁹ NATIONAL RESEARCH COUNCIL, *supra* note 15, at 15.

²⁰ NATIONAL RESEARCH COUNCIL, *supra* note 15, at 13-14.

²¹ NATIONAL RESEARCH COUNCIL, *supra* note 15, at 15.

²² Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment, 57 *Fed. Reg.* 6753 (Feb. 27, 1992).

²³ *Id.*

²⁴ NATIONAL RESEARCH COUNCIL, *supra* note 2, at 3.

²⁵ NATIONAL RESEARCH COUNCIL, *supra* note 2, at 9.

²⁶ NATIONAL RESEARCH COUNCIL, *supra* note 2, at 4.

²⁷ Henry I. Miller & Gregory Conko, *Precaution (of a Sort) Without Principle*, 13 *PRIORITIES FOR HEALTH* 3, ¶ 22 (2001), available at <http://www.cei.org/gencon/019,02243.cfm> (last visited Sept. 15, 2003).

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

³² See Robert M. Goodman et al., *Gene Transfer in Crop Improvement*, 236 Sci. 48, 48 (1987) (describing gene transfer systems based on recombinant DNA).

³³ Miller, *supra* note 27, at ¶ 20.

³⁴ *Id.*

³⁵ *Id.*

³⁶ See NATIONAL RESEARCH COUNCIL, *supra* note 17, at 14-15.

³⁷ See generally Takeshi Itoh et al., *Construction and Analysis of Escherichia Coli Genome Database*, at <http://citeseer.nj.nec.com/cachedpage/116462/1>.

³⁸ NATIONAL RESEARCH COUNCIL, *supra* note 2, at 14.

³⁹ Statement of Policy, *Foods Derived From New Plant Varieties*, 57 Fed. Reg. 22,984 (May 29, 1992).

⁴⁰ See Henry I. Miller et al., *Risk-Based Oversight of Experiments in the Environment*, 250 Sci. 490 (1990).

⁴¹ NATIONAL RESEARCH COUNCIL, *supra* note 2, at 5.

⁴² NATIONAL RESEARCH COUNCIL, *supra* note 15, at 54-64.

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ *Id.* at 76.

⁴⁶ NATIONAL RESEARCH COUNCIL, *supra* note 3.

⁴⁷ *Id.*

⁴⁸ *Id.* at 11.

⁴⁹ *Id.*

⁵⁰ Pesticide Registration and Clarification Procedures, 40 C.F.R. § 152.3 (2001).

⁵¹ See generally Institute for Food Technology, *Appropriate Oversight for Plants with Inherited Traits for Resistance to Pests* (1996) (on file with Richmond Journal of Law & Technology).

⁵² *Id.* at 3-4.

⁵³ *Id.* at 29.

⁵⁴ Council for Agricultural Science and Technology, *The Proposed EPA Plant Pesticide Rule* (Oct. 1998), at http://www.cast-science.org/cast-science.lh/epar_ip.htm.

⁵⁵ NATIONAL RESEARCH COUNCIL, *supra* note 3, at 11.

⁵⁶ *Id.* at 6.

⁵⁷ See Editorial Note, 416 NATURE 600 (2000) (explaining why the original paper was not published for lack of sufficient evidence).

⁵⁸ See generally NATIONAL RESEARCH COUNCIL, *supra* note 3 (indicating that the Board on Agriculture and Natural Resources charged a committee to investigate the risks and benefits of Genetically Modified Pest-Protected Plants and the regulatory body governing the use of these plants).

⁵⁹ See generally Procedures and Requirements for Plant-Incorporated Protectants, 40 C.F.R. § 174 (2001) (explaining that the report's conclusions were supported in the final rules adopted by the EPA).

⁶⁰ DeWitt Stetten, Jr., *Reported Laboratory Frauds in Biomedical Sciences*, 226 Sci. 1375, 1376 (1984).