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Comments

Genetically Modified Organisms: Does the Current Regulatory System Compromise Consumer Health?

I. Introduction

There is a growing controversy in the United States and around the globe regarding the modification of agricultural crops through the use of genetic technology. This debate made national headlines over a year ago when a non-approved form of genetically modified corn was found in taco shells marketed by Kraft.[1] Since the story aired, there has been a great demand for improvement in the government's regulatory system.[2]

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1. *See* Neil D. Hamilton, *Legal Issues Shaping Society's Acceptance of Biotechnology and Genetically Modified Organisms (GMOs)*, American Agricultural Law Association Conference, St. Louis, October 21, 2000, D-1-1, D-1-3. Neil D. Hamilton is an Ellis and Nelle Levitt Distinguished Professor of Law, and Director of the Agricultural Law Center, Drake University Law School, Des Moines, Iowa (citing Marc Kaufman, *Test Detects Corn in Taco Shells*, DES MOINES REGISTER, Sept. 18, 2000, A1). In recent months, public concern surrounding a certain type of Bt (Bacillus thuringiensis) corn, called Starlink, has grown rapidly. Starlink has been approved for use in animal feeds, but not for human consumption because research indicates that a protein produced by Starlink may cause allergies in some people. When traces of Starlink were found in Kraft taco shells the products were pulled from grocery shelves. *See* Kaufman, *supra* note 1.

2. *See id.* (citing Marc Kaufman, *FDA Will Widen Probe of Biotech Corn Misuse*, WASHINGTON POST, Oct. 3, 2000, A13 and Andrew Pollack, *Labeling Genetically Altered Food is Thorny Issue*, NEW YORK TIMES, Sept. 26, 2000, A1). The issue of labeling

Proponents of the bioengineering of seeds and plants suggest that genetically modified foods are the next generation of agricultural technology.[3] A report created by the Asia-Pacific Economic Cooperation Organization states, "the availability of biotechnology may help offset the diminishing returns from traditional plant breeding programs and meet the rising demand for greater quantities of food from continuing world population growth and dietary upgrading."[4] Opponents of the genetic modification of crops, however, are concerned about the potential risks to humans[5] and the possible negative environmental impacts from the use of biotechnology.[6] A central issue surrounding the debate about genetically modified organisms (GMOs) is whether the regulatory system in the United States is adequate to protect consumers and the environment from the possible adverse effects of GMOs.

This comment will explore the current status of the regulation of GMOs in the United States and address the need to reform this fragmented system in an effort to protect the American consumer. Part II of this comment provides a background of the use of GMOs for agricultural purposes in the United States. Part III is a discussion of the three major federal agencies that currently play significant roles in the regulation of GMOs. Part IV provides an example of how the current

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genetically engineered foods has become an important part of the controversial debate over the use of GMO for agricultural purposes. Supporters of the labeling of genetically modified foods argue that consumers have a right to know whether the foods they buy contain genetically modified organisms. *See id.*

3. *See id.* at D-1-2. Proponents of the use of biotechnology for agricultural purposes have suggested that GMOs (genetically modified organisms) may be the necessary link in the effort to feed the world and end hunger.

4. Anthan George, *Many Countries Produce Biotech Food to Meet Shortages*, DES MOINES REGISTER, Dec. 15, 2000, B1. The article discussed the controversy that currently surrounds the safety of agricultural biotechnology, but explained that many countries are using genetically modified food to meet food shortages and the need for more diverse and nutritious diets. The report issued by Asian-Pacific Economic Cooperation organization (APEC) also states, "the availability of new biotech[nology] methods may offset the diminishing returns from traditional plant breeding programs." *Id.* APEC is comprised of 21 nation members including the United States of America. "Some estimate the world will need 40 percent more grain within two decades because of population increases and the demand for more meat by increasingly affluent people." *Id.*

5. *See* Hamilton, *supra* note 1, at D-1-10. A New York Times magazine cover story titled *Playing God in the Garden* by Michael Pollan brought national attention to the possible human health risks caused by GMOs. The article discussed the approval of Bt potatoes. Pollan specifically addressed the legitimacy of concerns about the potential of unknown human health risks associated with eating genetically modified foods, such as the New Leaf potato, which was featured in the story.

6. *See id.* at D-1-11 (citing Carol Kaesuk Yoon, *Biotech Corn Isn't Serious Threat to Monarchs, Draft U.S. Report Finds*, NEW YORK TIMES, Sept. 26, 2000, D4). Environmental concerns about the use of bio-pesticides received national attention in 1999 when sources reported the potentially harmful impact of Bt pollen on Monarch butterflies.

regulatory system threatens consumer safety. Part V of this comment describes the recent developments in the regulation of GMOs in the United States. This comment concludes that the regulation of GMOs in the United States is not adequate and direct action by the George W. Bush administration is needed to ensure that consumer health is not compromised by GMOs that have not been approved for human consumption.

II. Genetically Modified Organisms

Recent developments in biotechnology have changed many aspects of modern agriculture. Genetic engineering is the process by which scientists make modifications of the deoxyribonucleic acid (DNA) of an organism by uniting it with plant or animal genes with particular traits.[7] Recombinant DNA (rDNA) techniques are methods of molecular biology that permit scientists to identify specific genes, make copies of those genes, and introduce the gene copies into recipient organisms, such as a food crop.[8] Once the gene is introduced into the host genome, it functions like all other genes in the genome.[9] This process is called transformation, and it is commonly referred to as genetic engineering or gene splicing.[10] Scientists use rDNA techniques to copy the genes from which a potentially useful trait can be identified.[11]

"Genetically modified seeds may produce higher yields per unit area, lower pesticide use and costs, and result in crops that tolerate drought and salty soil."[12] Some of the genetically engineered crops that are already on the market include corn, potatoes, and cotton.[13] Further, according to 1999 industry estimates, genetically engineered crops cover

7. *Seeds of Change: In the U.S. and Elsewhere the Food Supply is Being Genetically Altered. Here's why you should Care*, Sept. 1999 at 41. Many U.S. consumers are unaware of the debate over genetically modified foods. In a recent survey by the International Food Information Council, seventy-one percent of Americans surveyed rated themselves poorly informed about food biotechnology. One-third were aware that genetically engineered foods are available in the supermarket; half of those surveyed thought genetically engineered foods are not available in the supermarket; and the remainder of those asked didn't know or answer the question. *See id.*

8. James H. Maryanski, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, *FDA's Policy for Foods Developed by Biotechnology*, 605 AMERICAN CHEMICAL SOCIETY 12 (1995), http://www.cfsan.fda.gov/~lrd/biopolcy.html.

9. *See id.*

10. *See id.*

11. *See id.*

12. Julie Teel, Student Article, *Regulating Genetically Modified Products and Processes: An Overview of Approaches*, 8 N.Y.U. ENVTL. L. REV. 649, 652 (2000) (citing John H. Barton, *Biotechnology, the Environment, and International Agriculture Trade*, 9 GEO. INT'L ENVTL. L. REV. 95, 106 (1996).

13. *See Seeds of Change*, *supra* note 7, at 41.

one-fourth of U.S. cropland, which is more than ninety million acres.[14]

The development of genetic engineering has raised many questions regarding the safety of foods derived from these techniques. Specifically, the American public has expressed concern related to government regulation of GMOs. An analysis of the American approach to the regulation of GMOs requires an understanding of the eight fundamental features of U.S. policy on biotechnology and GMOs. The features are as follows:

American agriculture is historically technologically oriented and has been very successful relying on this approach;

GMOs are widely adopted by American farmers which is evidence of how well the technologies fit into the current structure and style of commodity production;

The U.S. views the technology as safe and believes there is no evidence supporting health concerns from eating or using GMOs and no evidence of environmental harm;

As a result the U.S. believes attacks on GMOs or even questions about their safety are based on other "non-scientific" objections or agendas;

The U.S. is a leader in biotechnology, essentially owning the science, and thus has a significant and valuable competitive advantage and opportunity;

The U.S. believes the various international trade agreements and protocols that support our position on using biotechnology will resist any efforts to effectively modify the rules to constrain GMOs, such as mandatory labeling;

The U.S. believes biotechnology will be important in "feeding the world" as reflected in the confidence placed in the next generation of products such as golden rice; and

The U.S. hopes the issue will go away over time and is essentially in a race to achieve this objective by facilitating the planting of GMOs here and in other grain producing nations with the effect of making it increasingly difficult for national and international policies on GMO use and labeling to be effectively reversed.[15]

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14. *See id.* The ninety million acres of genetically engineered crops represents more than thirty-five percent of all corn, almost fifty-five percent of all soybeans, and nearly half of all cotton. *Id.* "More than half of soybeans planted [in 1999] and 30 [percent] of the corn were made from biotech seeds, and through oils and sweeteners those products wind up in a huge number of processed products from corn chips and soft drinks." Melinda Fulmer, *Plan Seeks to Boost Oversight of Genetically Modified Foods Biotech: Firms Would Have to Notify the FDA Before Introducing New Gene-Altered Items, but Advocacy Groups Say it does Little for Consumers*, LOS ANGELES TIMES, May 4, 2000, C1.

15. Hamilton, *supra* note 1, at D-1-5. These fundamental issues are important in

III. The American Regulatory System

Regulation of GMOs in the United States is a fragmented system.[16] The three federal organizations that play significant roles in regulating genetically modified organisms include: the United States Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA).[17] The roles of various other organizations are described by the Coordinated Framework, which was developed by the Office of Science and Technology Policy (OSTP) in response to public concerns about the safety of biotechnology.[18] The Coordinated Framework has been highly criticized[19] for opting to resolve complex biotechnology issues through existing agencies rather than establishing a single agency to evaluate this evolving technology.[20] Each of the agencies is responsible for a different aspect of regulating GMOs, which raises many questions about the adequacy and efficiency of the system.

A. United States Department of Agriculture

The United States Department of Agriculture regulates GMOs pursuant to the Plant Protection Act of 2000.[21] The primary function of the USDA in the regulation of GMOs is the approval for testing genetically engineered plants and the commercialization of agricultural crops containing GMOs.[22] The primary method by which the USDA regulates GMOs is through the Animal Plant Health Inspection Service (APHIS).[23]

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understanding how U.S. policy positions have developed concerning biotechnology and the use of GMOs for agricultural purposes. The eight features also may indicate how U.S. regulation of GMOs may evolve in the future.

16. *See* Teel, *supra* note 12, at 649.

17. *See id.*

18. *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (1986). The central regulators within the Coordinated Framework for Regulation of Biotechnology include the National Institutes for Health (NIH), the Food and Drug Administration (FDA), the Department of Agriculture (USDA), and the Environmental Protection Agency (EPA).

19. *See* Gregary A. Jaffe, *Inadequacies in the Federal Regulation of Biotechnology*, 11 HARV. ENVTL. L. REV. 491, 528-43 (1987); Note, *Designer Genes That Don't Fit: A Tort Regime for Commercial Releases of Genetic Engineering Products*, 100 HARV. L. REV. 1086, 1087-92 (1987).

20. *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302. The current regulatory system provides for each agency to regulate a specific aspect of GMOs. The inadequacy of this fragmented structure is the lack of communication between the different agencies.

21. *See Pub. L. No. 106-224*, 114 Stat. 358 (2000).

22. *See* D.F., *Biotech Critics Watch the Watchdogs*, 286 NEW FOCUS 1662, 1664 (1999).

23. *See* Teel, *supra* note 12, at 662.

The APHIS issues a permit for the "import, interstate movement, and field testing of genetically altered plants, microorganisms, and invertebrates."[24] The APHIS has relaxed the regulatory procedures for the introduction of genetically modified plants since the agency determined that genetically modified plants are generally safe.[25] The new APHIS regulations provide for most genetically engineered plants to be introduced under the "simplified notification procedure."[26] Prior to the amendments to the APHIS regulations, notification was only required for six crops: corn, cotton, potato, soybean, tobacco, and tomato.[27]

In addition, the APHIS regulations provide a process by which plants cease to continue to be regulated.[28] Once the APHIS has determined that a genetically engineered plant or organism will no longer be regulated by the agency, it prepares an Environmental Assessment and a Determination.[29] The purpose of the Environmental Assessment is to determine the potential environmental impact as a result of suspending the regulation of the plant or microorganism.[30] The Determination addresses whether a plant pest risk exists because of the genetically engineered plant or microorganism.[31]

B. Environmental Protection Agency

The Environmental Protection Agency becomes involved with GMOs if the product is a bio-pesticide. The EPA is responsible for regulating bio-engineered pesticides pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)[32] and the Federal Food, Drug, and Cosmetic Act (FDCA),[33] as amended by the Food Quality and Protection Act of 1996 (FQPA).[34] The EPA may determine that a pesticide is exempt from regulation because it will cause no harm to the public.[35] The EPA has authority under FIFRA to regulate the distribution, sale, and use of pesticides.[36] FIFRA also requires the

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24. Judith E. Beach, *No "Killer Tomatoes": Easing Federal Regulation of Genetically Engineered Plants*, 53 FOOD & DRUG L.J. 181, 182 (1998). Dr. Judith Beach is an Associate in the law firm of Hyman, Phelps, McNamara, P.C., Washington, D.C.

25. *See id.* at 183.

26. *Id.* (citing John H. Barton, *Biotechnology, the Environment, and International Agricultural Trade*, 9 GEO. INTN'L ENVTL. L. REV. 95, 106 (1996).

27. *See id.*

28. *See id.*

29. *See* Beach, *supra* note 24, at 184.

30. *See id.*

31. *See id.*

32. *See* 7 U.S.C. § 136-136(y) (1994).

33. *See* 21 U.S.C. §§ 301-395.

34. *See* Pub. L. No. 104-170, 110 Stat. 1489.

35. *See* 21 U.S.C. §§ 346a(c)(2)(A)(ii); *See* Beach, *supra* note 24, at 188.

36. *See* 7 U.S.C. § 136-136(y).

registration of pesticides before they are distributed or used.[37] Moreover, the field testing of pesticides cannot occur until Experimental Use Permits are acquired.[38]

C. Food and Drug Administration

The Food and Drug Administration regulates genetically modified foods in accordance with the FDCA[39] and the Public Health Service Act (PHSA).[40] The FDA has authority under the FDCA to ensure the safety of most domestic and imported foods in the U.S. market, except meat and poultry, which are regulated by the USDA.[41] The EPA primarily regulates the pesticides that are used in or on foods.[42]

The FDA regulates the safety of food, including foods genetically engineered under section 402(a)(1) of the FDCA.[43] The FDA uses the same provisions and regulations under the FDCA, which regulate traditional food products as they do to regulate genetically engineered foods and food ingredients.[44] Therefore, a food or food ingredient developed by genetic engineering is required to meet the same safety standards under the FDCA as other food products.

In 1992, the FDA determined that there is no substantive difference between genetically modified foods and those produced from traditional plant breeding methods.[45] As a result, the FDA has declared that no specific labeling or approval is necessary for most foods that contain GMOs.[46] The exception to this rule occurs when genetically engineered foods are comprised of known allergens.[47] In addition, the FDA does not perform safety tests involving feeding or consumption of the products.[48] Moreover, the FDA does not require the new GMO foods to have pre-market approval.[49]

Although the FDA has concluded that it is not necessary for the agency to conduct comprehensive scientific reviews of bio-engineered foods,[50] the agency has established a Biotechnology Evaluation Team

37. *See id.*
38. *See* 7 U.S.C. §136(c).
39. *See generally* 21 U.S.C §§ 301-395 (2000).
40. *See* 42 U.S.C. §§ 201-300 (2000).
41. *See* Maryanski, *supra* note 8, at 12.
42. *See id.*
43. *See* 21 U.S.C. § 342(a)(1).
44. *See* Maryanski, *supra* note 8, at 12.
45. *See* Hamilton, *supra* note 1, at D-1-13.
46. *See* 57 Fed. Reg. 22,984; *See* Beach, *supra* note 24, at 184-187.
47. *See* Hamilton, *supra* note 1, at D-1-14.
48. *See id.*
49. *See id.*
50. *See* Beach, *supra* note 24, at 185 (citing *Biotechnology of Food*, FDA BACKGROUNDER, May 18, 1994).

(BET).[51] The FDA encourages companies to provide scientific data regarding the safety and regulatory status of their products to the BET for evaluation; however, this process is completely voluntary.[52]

IV. StarLink Corn

The StarLink corn scare is a prime example of how the current regulatory system failed to protect the public consumer. In September 2000, a bio-engineered variety of corn, not approved for human consumption, was found in Kraft taco shells.[53] The corn, called StarLink, was genetically modified to contain a gene from the bacterium Bacillus thuringienis (Bt) that expresses an insecticidal protein, Cry9C.[54] The EPA approved the StarLink corn containing Cry9C only for domestic animal feed and non-food, industrial uses.[55] The agency had not approved Cry9C for human consumption due to concerns surrounding the potential for the protein to cause allergic reactions.[56]

"Although StarLink's developer, Aventis, was required to ensure that the bioengineered corn did not go into food, some became mingled with corn destined for human consumption."[57] The FDA launched an investigation into allegations that the taco shells contained StarLink corn and confirmed the presence of StarLink in the taco shells.[58] "Kraft foods, producers of the taco shells, initiated its own investigation and voluntarily recalled millions of taco shells as soon as an independent laboratory found that the shells contained [the] Cry9C gene."[59]

The StarLink scare made clear that as long as the government relies on developers of bio-engineered foods to test their own products, there is a danger that foods not approved for human consumption will find their way onto market shelves. This lends support for creation of an independent government regulatory system to ensure that consumers are not exposed to bio-engineered foods that have not been approved for human consumption.

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51. *See* Beach, *supra* note 24, at 185 (citing CFSAN, FOOD AND DRUG ADMIN., GUIDANCE ON CONSULTATION PROCEDURES FOR FOOD DERIVED FROM NE PLANT VARIETIES, at 1 (Oct. 1997)).

52. *See* Beach, *supra* note 24, at 186.

53. Raymond Formanek Jr., *Proposed Rules Issued for Bioengineered Foods*, FDA CONSUMER MAGAZINE, MARCH-APRIL 2001, (last visited Dec. 27, 2001), http://www.fda.gov/fdac/features/2001/201_food.html.

54.*See id. See also StarLink History*, (last visited Dec. 27, 2001), http://www.starlinkcorn.com/History/What%20is%20StarLink%20corn.htm.

55. *See id.*

56. *See Formanek*, *supra* note 53.

57. *Id.*

58. *See id.*

59. *Id.*

V. Recent Developments in the Regulation of GMOs in the United States

Recent developments in the regulation of GMOs include independent review by federal agencies of their policies regarding agricultural genetic engineering, court cases involving the authority of federal agencies to regulate GMOs, legislative action strengthening governmental regulation, and international pressure pursuing greater measures to manage biotechnology.

A. Independent Review by Federal Agencies of Their Policies Pertaining to Genetically Modified Organisms

Federal agencies recently have taken steps to improve the regulation of genetically modified organisms in the United States. For example, the Secretary of Agriculture, Dan Glickman,[60] has appointed a thirty-seven member Biotechnology Advisory Committee to review the agency's policies including the procedures for testing and approval of new products.[61] Moreover, the EPA is reviewing its regulatory policies for genetically engineered foods.[62]

B. Recent Court Cases Involving the Regulation of Biotechnology

In addition to the initiatives taken by federal agencies, recent court cases have addressed developments in biotechnology. For example, a lawsuit filed by Greenpeace against the EPA for approving the use of Bacillus thuringiensis was recently dismissed.[63] Further, in a lawsuit against the FDA for approving the safety of GMOs without adequate testing, the United States District Court for the District of Columbia granted summary judgment for the government.[64]

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60. Dan Glickman, Remarks As Prepared for Delivery by Secretary of Agriculture before the National Press Club on New Crops, New Century, New Challenges: How Will Scientists, Farmers, And Consumers Learn to Love Biotechnology And What Happens If They Don't? (Washington, D.C.—July 13, 1999) (Release No. 0285.99. *available at* http://www.usda.gov/news/releases/1999/07/0285). Glickman said, "Agricultural biotechnology has enormous potential to help combat hunger. Genetically modified plants have the potential to resist killer weeds that are, literally, starving people in Africa and other parts of the developing world." *Id.*

61. *See* Hamilton, *supra* note 1, at D-1-22 (citing *USDA Advisory Committee on Agricultural Biotechnology*, 14 DIVERSITY, Nov. 4, 2000, 9).

62. *See* Fulmer, *supra* note 14.

63. *See Greenpeace Drops Bt Lawsuit*, AGBIOTECH REPORTER, Aug. 2000, 16. Greenpeace voluntarily dropped the lawsuit against the EPA.

64. *See* Alliance for Bio-Integrity v. Shalala, 116 F. Supp.2d 166 (D.C. Cir. 2000). The case was filed on May 27, 1998. The plaintiff challenged the FDA decision to permit the sale of GMO foods without mandatory labeling. The United States District Court for the District of Columbia held that the defendant (FDA) was not arbitrary and

On May 29, 1992, the FDA published a Statement of Policy: Foods Derived From New Plant Varieties (Statement of Policy).[65] In the Statement of Policy, the FDA announced that the agency would "presume that foods produced through the rDNA process were 'generally recognized as safe' (GRAS) under the Federal Food, Drug, and Cosmetic Act,[66] and therefore not subject to regulation as food additives."[67]

In *Alliance for Bio-Integrity v. Shalala*, plaintiffs challenged the FDA's policy on six different grounds:

> (1) the Statement was not properly subjected to notice and comment procedures; (2) the FDA did not comply with the National Environmental Protection Act (NEPA) by compiling an Environmental Assessment or Environmental Impact Statement; (3) the FDA's presumption that rDNA-developed foods are GRAS and therefore do not require food additive petitions under 21 U.S.C. § 321(s) is arbitrary and capricious; (4) the FDA's decision not to require labeling for rDNA-developed foods is arbitrary and capricious; (5) the FDA's decision not to regulate or require labeling for rDNA-developed foods violates the Free Exercise Clause; and (6) the FDA's decision not to regulate or require labeling for rDNA-developed foods violates the Religious Freedom Restoration Act.[68]

Plaintiffs argued that the Statement of Policy was invalid because it was not subjected to notice and comment proceedings, as required by the Administrative Procedure Act (APA).[69] The District Court for the District of Columbia reasoned that the Statement of Policy does not have a binding effect.[70] The court held that because the FDA Statement of Policy is a policy statement and announced only a GRAS presumption, the omission of formal notice and comment procedures did not violate the APA.[71]

Plaintiffs also claimed that the FDA violated the National Environmental Protection Act (NEPA)[72] because the FDA did not perform an Environmental Assessment (EA) or an Environmental Impact Statement (EIS).[73] NEPA requires "all federal agencies of the Federal

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capricious in its finding that it is not necessary to label genetically modified foods because they do not differ "materially" from non-modified foods under 21 U.S.C. § 321(n).

65. *See id.* at 170 (citing 57 Fed. Reg. 22,984 (1992)).
66. 21 U.S.C. § 321(s).
67. *Alliance for Bio-Integrity*, 116 F. Supp.2d. at 170.
68. *See id.* at 166.
69. See id. at 172. *See also* 5 U.S.C. § 553 (2000).
70. *See id.*
71. *See id.* at 173.
72. *See* 42 U.S.C. § 4321 (2000).
73. *See Alliance for Bio-Integrity*, 116 F. Supp.2d. at 173.

Government . . . [to] include in every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment, a detailed statement by the responsible official on the environmental impact of the proposed action."[74] The critical dispute was over the definition of "major federal action."[75] The statute states that "major federal action" includes "actions with effects that may be major and which are potentially subject to Federal control and responsibility."[76]

The court concluded that the FDA's declaration that foods produced through rDNA technology are GRAS was not a final determination that any particular food would be allowed into the environment, nor a particular regulatory action that could affect the environment.[77] Moreover, the court decided that the preparation of an EIS was not necessary because the FDA had neither taken nor prepared to take irreversible action because the FDA's presumption is not binding.[78] In addition, the court found that the FDA's decision maintained the substantive status quo and therefore did not constitute a major federal action under NEPA.[79]

Moreover, plaintiffs contended that the FDA's Statement of Policy is in violation of NEPA because the agency failed to regulate genetically modified foods, and that failure produces environmental consequences.[80] The court held that NEPA applies only to agency actions, "even if inaction has environmental consequences."[81] Finally, the court held that because the FDA's Statement of Policy "[was] reversible, maintaine[d] the substantive status quo, and [took] no overt action, the Statement of Policy [did] not constitute a major federal action under NEPA."[82] Therefore, the FDA was not required to prepare an Environmental Assessment or Environmental Impact Statement in conjunction with the Statement of Policy.[83] As a result, the court held that the FDA did not violate NEPA.[84]

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74. 42 U.S.C. § 4332(2)(c)(i) (2000).

75. *Alliance for Bio-Integrity*, 116 F. Supp.2d. at 173.

76. 40 U.S.C. § 1508.18 (2000).

77. *See Alliance for Bio-Integrity*, 116 F. Supp.2d. at 174.

78. *See id. See also Wyoming Outdoor Council v. U.S. Forest Service*, 165 F.3d. 43, 49 (D.C. Cir. 1999).

79. *See id.* at 174. *See also* Fund for Animals v. Thomas, 127 F.3d 80, 84 (D.C. Cir. 1997); Committee for Auto Responsibility v. Solomon, 603 F.2d 992, 1002-03 (D.C. Cir. 1979).

80. *See id.* at 174-175.

81. *Id.* (citing Defenders of Wildlife v. Andrus, 627 F.2d 1238, 1243 (D.C. Cir. 1980). The *Defenders of Wildlife* court reasoned that Congress did not intend for federal agencies to prepare environmental studies when the agencies were not acting.

82. *Alliance for Bio-Integrity*, 116 F. Supp.2d. at 175.

83. *See id.*

84. *See id.*

Plaintiffs also claimed that the Statement of Policy's presumption that rDNA-engineered foods are GRAS violates the GRAS requirements of the Federal Food, Drug, and Cosmetic Act,[85] and is therefore arbitrary and capricious.[86] The FDA states that any substance which may "becom[e] a component or otherwise affect[] the characteristics of any food" shall be deemed a food additive.[87] The FDA must approve a petition for the production of food additives unless the additive is "generally recognized [by qualified experts]... as having been adequately shown through scientific procedures... to be safe under the conditions of its intended use."[88]

In the Statement of Policy, the FDA indicated that the intended or expected introduction of a substance into food makes the substance potentially subject to food additive regulation under § 321(s).[89] Therefore, in the case of genetically modified foods the "genetic material and the intended expression product or products... could be subject to food additive regulation, if such material or expression products are not GRAS."[90] The FDA reasoned that the substances added to genetically modified foods are nucleic acid proteins, which are "not only generally recognized as safe but also necessary for survival."[91] Therefore, the FDA concluded that genetically modified foods should be considered GRAS until there is evidence to the contrary.[92]

The court referred to the Supreme Court decision in *Chevron v. Natural Resources Defense Council*[93], to address plaintiff's arbitrary and capricious claim. The court first considered the plain language of the statute[94] by determining whether Congress spoke directly to the issue.[95]

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85. 21 U.S.C. § 321(s).
86. *See Alliance for Bio-Integrity*, 116 F. Supp.2d. at 175.
87. 21 U.S.C. § 321(s).
88. *Id.*
89. *See Alliance for Bio-Integrity*, 116 F. Supp.2d. at 176.
90. *Id.* (citing 57 Fed. Reg. at 22,990 (2000)).
91. *Alliance for Bio-Integrity*, 116 F. Supp.2d. at 176.
92. *See id.*
93. Chevron v. Natural Resources Defense Council, 467 U.S. 837 (1984).
94. *See Alliance for Bio-Integrity,* 116 F.Supp.2d. at 176. *See also* Butler v. West, 164 F.3d 634, 639 (D.C. Cir. 1999); Pennsylvania Dep't of Pub. Welfare v. Davenport, 495 U.S. 552, 557-58 (1990).
95. *See Alliance for Bio-Integrity*, 116 F. Supp.2d. at 176. Determining whether Congress has spoken to the directly to the issue at hand is commonly known as *Chevron* step one. If Congress answers the question in the affirmative, using "traditional tools of statutory construction," *Natural Resources Defense Council v. Browner*, 57 F.3d 1122, 1125 (D.C. Cir. 1995), then "that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron*, 427 U.S. at 842-43.

> The second step of the Chevron review relates to the is "rooted in statutory analysis and is focused on discerning the boundaries of Congress' delegation of authority to the agency." Arent v. Shalala, 70 F.3d 610, 615 (D.C. Cir. 1995).

The court concluded that when Congress passed the Food Additives Amendment in 1958, "it obviously could not account for the late twentieth-century technologies that would permit genetic modification of food."[96] Nonetheless, the statute exempts from regulation as additives, substances that are "generally recognized . . . to be safe under the conditions of its intended use."[97] In order for a substance to be generally regarded as safe, it must meet two criteria: (1) it must have technical evidence of safety, usually in published scientific studies, and (2) this technical evidence must be generally known and accepted in the scientific community.[98] The court held that Plaintiffs failed to provide sufficient evidence that the GRAS presumption was inconsistent with the statutory requirements.[99]

Plaintiffs further challenged the Statement of Policy's failure to require the labeling of genetically engineered foods based on the presumption that the ingredients in genetically modified food are generally recognized as safe.[100] Plaintiffs argued that the FDA should have considered consumer interest and special concerns of religious groups and persons with allergies when they decided not to require the labeling of genetically modified foods.[101]

The FDA has authority to require the labeling of products pursuant to the FDCA.[102] Under the statute, foods will be considered misbranded if their labeling "fails to reveal facts . . . material with respect to consequences which may result from the use of the article to which the labeling . . . relates under the conditions of use prescribed in the labeling . . . or under such conditions of use as are customary or

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In order to resolve the issue before the court, "the question . . . is whether the agency's construction of the statute is faithful to the plain meaning, or, if the statute has no plain meaning, whether the agency's interpretation 'is based on the permissible construction of the statute.'" *Id.* If the court concludes the agency's interpretation is "reasonable and consistent with the statutory scheme and legislative history." Cleveland v. United States Nuclear Regulatory Comm'n, 68 F.3d 1361, 1367 (D.C. Cir. 1995), then the court must pay deference to the agency.

96. *Id.* at 177. The "object and policy" of the food additive amendments, Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1067 (D.C. Cir. 1998), is to "require the processor who wants to add a new and unproven additive to accept the responsibility . . . of first proving it to be safe for ingestion by human beings." S. Rep. No. 85-2422, at 2 (1958). The plain language of § 321(s) states in reference to food additives that "any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and. . . . any source of radiation intended for such use." 21 U.S.C. § 321(s).

97. *Id.*

98. *See id.* at 177. *See* 21 C.F.R. § 170.30(a-b); 62 Fed. Reg. 18,940 (1997).

99. *See id.* at 177-178.

100. *See Alliance for Bio-Integrity*, 116 F. Supp.2d. at 178.

101. *See id.*

102. *See* 21 U.S.C. § 321(n).

usual."[103] The dispute was over the FDA's interpretation of the term "material."[104]

The court determined that Congress did not speak directly to the issue of whether "materially" includes consumer interest.[105] As a result, the court gave deference to the agency's interpretation.[106] The FDA concluded that under § 321(n), no material change had occurred in the rDNA derived foods.[107] Moreover, the FDA determined that § 321(n) does not authorize labeling requirements "absent unique risks to consumer health or uniform changes to food derived through rDNA technology."[108] In addition, the FDA concluded that § 136(n) does not authorize labeling requirements solely because of consumer demand.[109] The court held that the FDA's exclusion of consumer interest from the determination of whether a change is material constitutes a reasonable interpretation of the statute.[110] Moreover, the court held that the FDA's interpretation of § 321(n) was not arbitrary and capricious.[111]

Plaintiffs further claimed that the Statement of Policy unconstitutionally violates their right to the free exercise of religion by allowing unlabeled genetically modified foods to be on the market.[112] The court dismissed plaintiff's Free Exercise Claim because it was undisputed that the Statement of Policy was neutral and generally applicable.[113]

Finally, plaintiffs claimed that the FDA's Statement of Policy was

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103. *Id.*

104. *Alliance for Bio-Integrity*, 116 F. Supp.2d. at 178.

105. *See id.*

106. *See id.* When Congress does not speak directly to the issue, the court must determine whether the agency's interpretation of the statute is reasonable. *See Chevron*, 467 U.S. at 864. Accordingly, the interpretation of § 136(n)'s language is left to the discretion of the agency. "[T]he relatively unspecific nature of the labeling standard which Congress has prescribed . . . suggests that this is an area in which courts must give great deference of the Secretary[of Agriculture]'s judgements." Community Nutrition Inst. v. Block, 749 F.2d 50,54 (D.C. Cir. 1984). Moreover, an agency's interpretations receive substantial deference when the agency is interpreting a statute that is charged with administering. *See* Rust v. Sullivan, 500 U.S. 173, 184 (1991).

107. *See id.*

108. *Id.* at 179.

109. *See id.*

110. *See Alliance for Bio-Integrity*, 116 F. Supp.2d at 179. The court explained that Plaintiffs "failed to understand the limitation on the FDA's power to consider consumer demand when making labeling decisions because [Plaintiffs] fail to recognize that the determination that a product differs materially from the type of product it purports to be is a factual predicate to the requirement of labeling." *Id.* Because the FDA already determined that, in general, rDNA modification does not materially alter foods, "the FDA lacks a basis upon which it can legally mandate labeling, regardless of the level of consumer demand." *Id.*

111. *See id.*

112. *See id.*

113. *See id.* at 179-180.

in violation of the Religious Freedom Restoration Act (RFRA),[114] because it burdened their religion. The focus of plaintiff's argument was that without the labeling they were unable to know whether the foods they consumed contained genetically modified foods or not.[115] RFRA's test for compelling interest provides that "Government shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability . . . [unless the rule is] (1) in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest."[116] The court held that the plaintiffs were not entitled to relief under RFRA because the Policy Statement "does not place 'substantial pressure' on any of the plaintiffs, nor does it force them to abandon their religious beliefs or practices."[117]

The United States District Court for the District of Columbia concluded that the FDA's 1992 Statement Policy did not violate the Administrative Procedures Act, the National Environmental Policy Act, or the procedures mandated by the Federal Food, Drug and Cosmetic Act and FDA regulations.[118] Moreover, the FDA was not arbitrary and capricious in deciding that genetically modified foods do not need to be labeled because they do not materially differ from the non-modified foods under 21 U.S.C. § 321(n).[119] Finally, the court found that the FDA's Policy Statement does not violate the First Amendment Free

114. *See* 42 U.S.C. § 2000bb-2000bb-4 (2000). Congress enacted RFRA in reaction to the Supreme Court's decision in Employment Div. v. Smith, 494 U.S. 872 (1990), in order to "restore the compelling interest test" for Free Exercise issues. § 2000bb(b). In *Employment Div. v. Smith*, the Supreme Court held that neutral laws of general applicability do not violate the Free Exercise Clause, even if the laws incidentally burden religion.

115. *See Alliance for Bio-Integrity*, 116 F. Supp.2d. at 180. The plaintiffs argued that the government does have some obligation to facilitate the practice of religion. The plaintiffs cited several cases involving prisoners, in which the government was "required to provide nutritional information and alternative diets for inmates whose religious beliefs required dietary restrictions." *Id.*

116. 42 U.S.C. § 2000bb-2000bb(4). This test is not to be "construed more stringently or more leniently than it was prior to *Smith*." H.R. Rep. No. 103-88, at 7 (1993). The court noted that although the Supreme Court overruled the portions of RFRA applicable to state governments on the grounds that Congress exceeded its authority under the Fourteenth Amendment. *See* City of Boerne v. Flores, 521 U.S. 507 (1997). The court's holding does not affect RFRA's applicability to the federal government. *See Alaska Airlines v. Brock*, 480 U.S. 678, 684 (1987). "A court should refrain from invalidating more of the statute than is necessary." *Id.*

117. *Alliance for Bio-Integrity*, 116 F. Supp.2d. at 181. *See also Branch Ministries v. Rossotti*, 40 F. Supp.2d 15 (D.D.C. 1999)(citing Thomas v. Review Bd. Of Indiana Employment Sec. Div., 450 U.S. 707, 718 (1981) and Sherbert v. Verner, 374 U.S. 398, 404 (1963)).

118. *See id.*

119. *See id.*

Exercise Clause or RFRA.[120] Accordingly, the court denied plaintiff's motion for summary judgment.[121]

C. *Legislative Action to Strengthen Governmental Regulation of Genetic Engineering*

Although the decision by the United States District Court for the District of Columbia in *Alliance for Bio-Integrity v. Shalala* gave deference to the FDA, U.S. legislators have become increasingly involved in the controversy surrounding the use of agricultural biotechnology in an effort to provide greater governmental regulation. Most importantly, United States Senator Richard J. Durbin, a Democrat from Illinois, recently introduced the Genetically Engineered Foods Act to ensure the safety of biotech foods and assure American consumers that the U.S. government is adequately regulating GMOs.[122]

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120. *See id.* at 181.

121. *See Alliance for Bio-Integrity*, 116 F. Supp.2d. at 181.

122. *See* Richard J. Durbin, *Biotech Foods: Put the FDA in Charge*, BUS. WK., Dec. 11, 2000, 21. Senator Durbin introduced S.3184 on October 11, 2000. The official title as introduced was "A bill to amend the Federal Food, Drug, and Cosmetic Act to require pre-market consultation and approval with respect to genetically engineered foods, and for other purposes." The short title of the bill as introduced was "Genetically Engineered Foods Act." The current status of the bill is that it was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry. *Bill Summary & Status for the 106th Congress*, (last visited Dec. 21, 2000) http://thomas.loc.gov/cgi-bin/bdquery/z?d106: SN03184:@@@L&summ2=m&.Richard J. Durbin was elected to the U.S. Senate on November 5, 1996. In addition to the Appropriations Committee, Senator Durbin is a member of the Senate Governmental Affairs, Budget and Ethics Committees in the 106th Congress. Senator Durbin spent 12 years of his 14 years in the U.S. House of Representatives as a member of the House Appropriations Committee, rising to chairman of the Subcommittee on Agriculture and Rural Development.

> Consumer protection is high priority for Senator Durbin. He has become a national leader in the effort to modernize the nation's food safety inspection system. His legislation to create a single, independent food safety agency out of the dozen agencies currently involved in the process has gained the support of major consumer and public health groups. *Biography of Senator Richard J. Durbin* (last visited Dec. 21, 2000) http://www.senate.gov/~durbin/ Biography/index.htm.
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> > Moreover, legislation has been introduced requiring the labeling of genetically engineered foods. The Genetically Engineered Right to Know Act (HR3377) introduced by Ohio Democratic Representative Dennis Kucinich, has 58 cosponsors. The official title of the bill as introduced was "to amend the Federal Food, Drug, and Cosmetic Act, the Federal Meat Inspection Act, and the Poultry Products Inspection Act to require that food that contains a genetically engineered material, or that is produced with a genetically engineered material, be labeled accordingly." The current status of the bill is that it has been referred to the Subcommittee on Health and Environment. *Bill Summary & Status for the 106th Congress* (last visited Jan. 9, 2001)

The purpose of the bill is to strengthen the FDA's role in the regulation of GMOs.[123] The Genetically Engineered Foods Act modifies the current FDA voluntary review process and makes pre-market approval mandatory.[124] In addition, the bill requires that the FDA initiate a testing program to screen supermarket products and to minimize the likelihood of contamination by unapproved genetically engineered ingredients.[125] Moreover, the Genetically Engineered Foods Act provides for a more transparent review process, allowing legislators and the public to become more actively involved in the review process.[126]

D. International Pressure on the U.S. to Improve the Regulation of Genetically Modified Organisms

In 2000, a panel was formed at the request of President Clinton and European Commission president Romano Prodi to make recommendations concerning genetically engineered foods.[127] The panel, called the U.S.—EU Biotechnology Consultative Forum, included representatives of consumer groups, academia, and industry from the U.S. and the European Union.[128] In a report released in December 2000,

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http://thomas.loc.gov/cgi-bin/bdquery/z?d106:HR03377:@@@L &summ2=m&.

In addition, Senator Barbara Boxer, a Democrat from California, introduced a similar bill (S.2080) in the United States Senate to mandate the labeling of genetically engineered foods. Amy Martinez Starke, *The Biotech Food Fight: To Label or Not to Label?*, Portland Oregonian, May 30, 2000, FD01.

The official title of the bill as it was introduced on February 2, 2000 was "a bill to amend the Federal Food, Drug, and Cosmetic Act to require that food that contains a genetically engineered material or that is produced with a genetically engineered material, must be labeled accordingly, and for other purposes. The current status of the bill is that it was read twice and has been referred to the Committee on Agriculture, Nutrition, and Forestry. *Bill Summary & Status for the 106th Congress* (last visited Jan. 9, 2001) http://thomas.loc.gov/cgi-bin/bdquery/z?d106: SN02080:@@@L&summ2=m&.

123. *See* Durbin, *supra* note 122. "[FDA] officials said several months ago that they will start requiring biotech companies to notify the agency before they market new products. The FDA, however, has yet to complete its requirements, and companies currently consult the agency voluntarily. But the FDA has stopped short of establishing mandatory food labeling." Sarah Lueck and Scott Kilman, *Gene-Altered Food Needs Labels, Safety Reviews, Committee Says*, WALL ST. J., Dec. 19, 2000, B6.

Consumers groups have placed pressure on the FDA to require the labeling of foods that contain genetically modified material. Whether the labeling of GMOs will become a reality is uncertain. Agriculture Secretary Dan Glickman said, "[m]any observers, including me, believe that some type of informational labeling is likely to happen." Starke, *supra* note 111.

124. *See id.*

125. *See id.*

126. *See id.*

127. *See* Lueck and Kilman, *supra* note 123.

128. *See id.*

the committee recommended safety reviews and mandatory labeling for GMOs.[129] Although the recommendations are not binding, they could increase pressure on the U.S. to improve governmental regulation of biotechnology.[130]

VI. Conclusion

Recently, a panel of the National Academy of Sciences concluded that although genetically engineered food is basically safe, the potential exists for undesirable effects such as allergic reactions and higher toxicity.[131] Advances in biotechnology are occurring so rapidly that increased research and close regulation of genetically modified foods are required to ensure that the GMOs are safe for human consumption and will not harm the environment.[132] Although there have been recent developments in the regulation of GMOs, it is clear that the current regulatory system is insufficient to protect American consumers and the environment from the possible adverse effects of genetically engineered foods.[133] The fragmented regulatory system that delegates specific responsibilities to various federal agencies has failed to adequately determine the effects of GMOs on humans and the environment. Moreover, the decision by the FDA to not require the labeling of genetically modified foods leaves consumers in the dark.

It is uncertain how President George W. Bush and the officials in his administration will view genetically modified foods. Some opponents of biotechnology fear that the administration will fail to successfully address issues surrounding the agricultural use of genetic modification.[134] "We're going into an administration that's not likely to be very sympathetic to the consumer perspective on biotech issues . . . This puts regulation, particularly consumer-driven regulation, in a trade context," said Margaret Mellon, director of the food and agriculture program at the Union of Concerned Scientists.[135]

One suggestion for the improvement of the regulation of GMOs is to increase cooperation among federal agencies and provide greater resources devoted to the research of GMOs. Cliff Gabriel, a deputy director of the Clinton administration's Office of Science and Technology Policy, said, "we need better coordination between the three

129. *See id.* The U.S.—EU Biotechnology Consultative Forum's report states, "[c]onsumers should have the right of informed choice regarding the selection of what they want to consume." *Id.*

130. *See id.*

131. *See* Lueck and Kilman, *supra* note 123.

132. *See id.*

133. *See* Hamilton, *supra* note 1.

134. *See* Fulmer, *supra* note 14.

135. Fulmer, *supra* note 14.

agencies [USDA, EPA, and FDA], and we need to make sure they [are] adequately funded so they can get research done."[136] Gabriel's approach is a plausible solution to the problem. However, it is apparent that the current regulatory system, which delegates specific responsibilities to various agencies, is not working. Therefore, this comment advocates a new approach.

In contrast to Gabriel's position, this comment proposes a position that many others have adopted. The area of GMOs is extremely scientific and complex, which requires the specific attention of an independent federal agency. The creation of an independent federal agency that has the exclusive responsibility of regulating GMOs would be more successful in regulating the rapidly growing technological developments related to genetically modified food. Moreover, this comment recommends that the George W. Bush administration devote immediate attention to the improvement of the U.S. regulation of GMOs. Such direct action is necessary to ensure that consumer health and the environment are not compromised by genetically modified foods.

Heather N. Ellison

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136. *Id.*