

RISK AND REGULATION: U.S. REGULATORY POLICY ON GENETICALLY MODIFIED FOOD AND AGRICULTURE

EMILY MARDEN*

Abstract: Since the 1980s, successive White House Administrations have shaped federal policy on genetically modified food and agriculture to (1) be product-based, (2) presume low risk from genetic modification, and (3) review GM products under existing federal standards. For two decades, the FDA, USDA, and EPA have erected a regulatory framework for GM products based on these three principles. This Article reviews the history and structure of this framework and the challenges that it has faced as more GM products have entered the market. The Article concludes that the three basic principles of federal GM policy may have to be reconsidered and redirected as genetic modification continues to grow as a force in world commerce.

INTRODUCTION

In February 2002, United States Trade Representative Robert Zoellick undertook a grand tour of Africa to stake out a position in the emerging trade war with Europe over genetically modified ("GM") foods.¹ Zoellick's mission was straightforward: he hoped to gain the support of African nations for the U.S. risk-based position on GM foods.² Zoellick has reportedly stated that he is "strongly consider-

* The author is an attorney at Sidley Austin Brown & Wood in New York. This Article was prepared in connection with a project on International GMO Regulatory Conflicts undertaken by the Center on Environmental and Land Use Law, New York University, with support from the Rockefeller Foundation. The support of the Center and the Rockefeller Foundation in the preparation of this Article is gratefully acknowledged. The author also wishes to recognize Dorothy Nelkin, Richard Stewart, Ed Levy, Oysim Chin, Roger A. Frie, and Marcy Katz for their contributions in the preparation of this Article.

¹ Neil King, Jr., *U.S. Official Courts African Allies for Brewing Biotech-Food Fight*, WALL ST. J., Feb. 22, 2002, at A24. Note that in this Article, I use the terminology "GM" foods or agriculture to refer collectively to plants/crops that have been modified using genetic engineering techniques. This terminology is used as an alternative to "genetically engineered foods," "Genetically Engineered Organisms" ("GEOs"), "Genetically Modified Organisms" ("GMOs"), or "agricultural biotechnology."

² *Id.* It is not clear that Zoellick was entirely successful in his mission. In late July 2002, Zimbabwe rejected thousands of tons of U.S. emergency food aid consisting of corn because the donations contained genetically modified varieties. According to the reports,

ing" filing a suit against the European Commission in the World Trade Organization for blocking the import of U.S. bioengineered seeds.³ U.S. corn farmers alone say they are losing more than \$200 million a year because of the closed European market, and that millions more are being lost on soy, cotton, potato and other products.

Zoellick and the U.S. government are ultimately hoping to demonstrate that the U.S. approach to the technology is the correct one and that alternative approaches should not be allowed to slow the industry or impede trade. Indeed, as Zoellick stated, the United States is willing to bring a suit before the World Trade Organization to stop other countries from unduly regulating GM products.⁴ The United States rejects restrictive regulations on GM products on grounds that they are not based on verifiable scientific risk. Instead, the United States takes the position that the product should be permitted to flourish in the marketplace in the absence of proven hazards.

The U.S. approach has three elements. First, the focus is exclusively on the end *product* of GM technology, rather than on the fact that the process of genetic modification is used. Second, U.S. policy holds that in the absence of verifiable "scientific risk," there is no reason to bar a technology from being introduced and integrated.⁵ Finally, the United States maintains that GM technology is on a continuum with other agricultural innovations, and that any risks are of the same kind as those of "traditionally" produced foods. On this ground, the United States has maintained that existing regulatory oversight is adequate to safeguard the public.⁶ It is important to note, however,

Zimbabwe was concerned that if some of the corn was used as seed it could contaminate the native crop, and make it unexportable to Europe. Rick Weiss, *Starved for Food, Zimbabwe Rejects U.S. Biotech Corn*, WASH. POST, July 31, 2002, at A12.

³ "I personally am of the view that we now need to bring a case," Zoellick said at a Jan. 9 press conference when asked about the ongoing conflict with the Europeans." *Zoellick Calls For WTO Case Against EU Biotechnology Moratorium*, INSIDE U.S. TRADE, Jan. 10, 2003.

⁴ As this Article went to press, the United States announced that it was filing a case in the World Trade Organization challenging the four-year-old moratorium by the European Union on authorizing GM crops. The United States is joined in its position by Argentina, Canada, and Egypt. Press Release, Office of the United States Trade Representative, U.S. and Cooperating Countries File WTO Case Against EU Moratorium on Biotech Foods and Crops (May 13, 2003), available at <http://www.ustr.gov/releases/2003/05/03-31.htm>.

⁵ See FDA, A DESCRIPTION OF THE U.S. FOOD SAFETY SYSTEM (2000), available at <http://www.fsis.usda.gov/OA/codex/system.htm>.

⁶ See generally Marsh Echols, *Food Safety Regulation in the European Union and the United States: Different Cultures, Different Laws*, 4 COLUM. J. EUR. L. 525 (1998). In her article, Marsh Echols explains the U.S. predilection for a risk-based approach as reflective of the national embrace of new technologies. She credits the European approach to the fact that food-safety laws are more reflective of local tradition.

that the nature of the scientific risks that could demonstrate risk or harm are not defined. Instead, the U.S. policy tends to minimize the existence of *any* risks associated with GM products, and directs the agencies to refrain from hypothesizing about or affirmatively searching for safety or environmental concerns.

This approach to regulating GM foods stands in contrast—in global politics—to an approach based on the precautionary principle. In its most general articulation, the precautionary principle states that where there is a lack of certainty about safety, a technology should be avoided or at least limited.⁷ In the global debate over GM foods, the European Commission has taken a precautionary approach toward the technology,⁸ and has permitted only limited varieties of GM species to be introduced in Europe. To support this approach, the Europeans focus on the fact that the GM process itself is new and therefore may have unintended hazardous consequences.

For its part, the U.S. approach to GM foods has helped the industry grow: the U.S. maintains dominance of the agricultural biotechnology industry worldwide, and the use of GM products continues to spread. At the same time, there have been costs associated with the U.S. policy. There are repeated complaints from non-governmental organizations (“NGOs”), consumer groups, and trade partners that safety, allergenicity, and environmental issues have not been adequately considered, even as the United States sees more and more GM products in development. In addition, these groups vociferously oppose the U.S. refusal to implement GM food labeling.

The aim of this Article is to review and assess the approach adopted by the U.S. government and its regulatory agencies. The U.S. perspective was initiated by the Reagan White House as the technology emerged in the 1980s, and was further developed by both the George H.W. Bush and Clinton Administrations. As GM products moved into the marketplace, the tenets of this perspective have been subject to questions. Already the focus on product, rather than process, has been adjusted to account for some of the concerns associated

⁷ See generally Katherine Barrett & Carolyn Raffensperger, *From Principle to Action: Applying the Precautionary Principle to Agricultural Biotechnology*, 4 INT'L J. BIOTECHNOLOGY 4 (2002); Richard B. Stewart, *Environmental Regulatory Decisionmaking Under Uncertainty*, 20 RES. L. & ECON. 71 (2002).

⁸ For a good general outline of the E.U. articulation of the Precautionary Principle, see EUR. ENV'TL. AGENCY, *LATE LESSONS FROM EARLY WARNINGS: THE PRECAUTIONARY PRINCIPLE 1896–2000* (2001), available at http://reports.eea.eu.int/environmental_issue_report_2001_22/en.

with genetic engineering of foods. It is also likely that the U.S. conception of "scientific risk" will need to be broadened so that concerns about allergenicity, safety, and environmental issues be considered. The United States may be forced to reconsider further elements of its policy as GM products continue to enter world commerce.

The Article begins with a brief review of the development of U.S. policy under the Reagan (1980–1988) and George H.W. Bush (1988–1992) Administrations.⁹ It then reviews the development and implementation of the regulatory framework through the three agencies that have primary responsibility for oversight of the technology: the Food and Drug Administration ("FDA"), the Department of Agriculture ("USDA"), and the Environmental Protection Agency ("EPA").

I. HISTORY

A. *Building a Framework*

GM food and agriculture products began reaching the commercialization stage in the 1980s. The first generation of products has included agricultural commodities, such as soy, cotton, corn, and canola. Most of these products have been modified to incorporate pesticidal elements within the plant itself (*e.g.*, *Bacillus thuringiensis* ("Bt") corn is modified to incorporate the pesticide *Bacillus thuringiensis*). The promise is that use of such plants can reduce the amounts of pesticide needed. Other plants have been introduced that have been modified for resistance to use of specific pesticides. For example, Roundup Ready soy is a Monsanto product that has resistance to the Roundup Ready herbicide incorporated into its genome. Therefore, the herbicide can be used on the soy without concern for damaging the soy plant itself.

Earlier genetic technologies had been the subject of regulatory controversy when they emerged. During the 1970s, the development of recombinant DNA ("rDNA") techniques sparked public concerns that mutant organisms might be released into the environment, causing serious damage. In response, communities such as Cambridge, Massachusetts banned genetic research within their boundaries and there were numerous protests of government discussions of the technology. To counter the threat of further local and national govern-

⁹ References to the Bush Administration are to that of President George H.W. Bush (1989–1993).

ment regulation of this technology, scientists opted to introduce responsible self-regulation.¹⁰

A group of scientists organized a conference at Asilomar in February 1975 and met there behind closed doors to reach a consensus on self-regulation of research involving rDNA techniques. The participants agreed on interim guidelines, which were then adopted by the National Institutes of Health ("NIH"), a research-funding arm of the U.S. government. In the absence of anything else, the guidelines became the de facto standard for private research. Until 1984, the NIH Recombinant DNA Advisory Committee was the primary federal entity that reviewed and monitored federally funded DNA research.¹¹ Ultimately, the apparent effectiveness of the Asilomar guidelines in ensuring the safety of research may have set the stage for declining public interest in novel genetic techniques. In addition, the lack of safety crises in subsequent years helped rDNA research gain respectability.

GM foods also raised safety and environmental concerns when their introduction appeared imminent in the 1980s. There were hearings in Congress on the technology and a movement to draft new laws specific to its application.¹² The United States, however, had developed its position as the world leader in biotechnology as a result of decades of well-funded basic research, and scientists, along with supporters in the Reagan Administration, were reluctant to relinquish this position.¹³ The White House therefore worked hard to ensure that U.S. dominance would continue, and thwarted legislative interference.¹⁴

¹⁰ For an excellent analysis of these events, see Dorothy Nelkin, *Threats and Promises: Negotiating the Control of Research*, DAEDELUS, Spring 1978. See also SHELDON KRIMSKY, *BIO-TECHNICS AND SOCIETY: THE RISE OF INDUSTRIAL GENETICS* (1991).

¹¹ On controversies over rDNA, see generally MICHAEL ROGERS, *BIOHAZARD* (1977); NICHOLAS WADE, *THE ULTIMATE EXPERIMENT: MAN-MADE EVOLUTION* (1977).

¹² See, e.g., *Planned Releases of Genetically-Altered Organisms: The Status of Government Research and Regulation: Hearing Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology*, 99th Cong. 72 (1985); *Biotechnology Regulation: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 98th Cong. 98-193 (1984); *Environmental Implications of Genetic Engineering: Hearing Before the Subcomm. on Investigations and Oversight and the Subcomm. on Science, Research and Technology of the House Comm. on Science and Technology*, 98th Cong. 2-3 (1983).

¹³ For a detailed discussion of these developments, see KRIMSKY, *supra* note 10.

¹⁴ See Jim Drinkard, *Biotechnology Predicted to Bring Big Farm Changes*, ASSOCIATED PRESS, Apr. 21, 1985 (quoting Dr. Bernadine Healy, Deputy Director of the Office of Science and Technology Policy worrying that Congressional hearings raised "concerns that biotechnology may . . . be an example of regulation stifling leadership").

Against the backdrop of an emerging U.S. lead in GM techniques, the Reagan and Bush Administrations took steps toward outlining a federal regulatory policy that would ensure safety.¹⁵ As with rDNA, the theory was that effective industry and scientific self-regulation could preclude burdensome or inhibitory legislation. Thus, through a series of working groups and policy statements begun in the mid 1980s, the Reagan and Bush Administrations developed three tenets of U.S. policy designed to ensure the development of the industry: (1) U.S. policy would focus on the product of GM techniques, not the process itself, (2) only regulation grounded in verifiable scientific risks would be tolerated, and (3) GM products are on a continuum with existing products and, therefore, existing statutes are sufficient to review the products. Within these tenets, industry would be encouraged to continue its rapid pace of development without regulatory impediments.

As an initial response to Congressional interest in legislating on the new technology, the Reagan Administration created an inter-agency working group within the White House Office of Science and Technology Policy ("OSTP"), which it charged with drafting an overall federal framework for food biotechnology.¹⁶ In 1984, the OSTP working group published the Coordinated Framework for Regulation of Biotechnology ("Coordinated Framework"), which proposed regulating genetically engineered products only according to measurable risks. The group expressly embraced an approach stating that products of biotechnology should be regulated in the same way as products of other technologies. In the legal context, therefore, the draft Coordinated Framework proposed that new biotechnology products be regulated under the existing web of federal statutory authority and regulation.¹⁷

After soliciting comments from the public, the OSTP working group finalized a version of the Coordinated Framework in 1986 similar to the draft version. This final policy document proclaimed again

¹⁵ SHELDON KRIMSKY & ROGER P. WRUBEL, *AGRICULTURAL BIOTECHNOLOGY AND THE ENVIRONMENT: SCIENCE, POLICY, AND SOCIAL ISSUE* 249-51 (1996).

¹⁶ Another impetus for the creation of this group may have been the legal challenge brought by biotechnology gadfly Jeremy Rifkin in 1984 against the National Institutes of Health that forced the Reagan Administration to consider and propose policies to guide activities of federal agencies responsible for reviewing biotechnology research and its products. See *Found. on Econ. Trends v. Heckler*, 587 F. Supp. 753, 754, 768-69 (D.D.C. 1984), *aff'd in part & vacated in part* by 756 F.2d 143 (D.C. Cir. 1985).

¹⁷ Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50,856 (proposed Dec. 31, 1984).

that "existing statutes seem adequate to deal with the emerging processes and products of [genetic engineering]."¹⁸ Ultimately, the Coordinated Framework sketched broad outlines of the jurisdiction of existing regulatory agencies over GM products.

The agency assignments outlined were consistent with existing federal exercise of jurisdiction. Thus, FDA was to have responsibility for regulating food and feeds modified via genetic engineering. USDA's Animal and Plant Health Inspection Service ("APHIS") would regulate importation, interstate movement, and environmental release of transgenic plants with an aim of protecting existing crops from hazards.¹⁹ APHIS thus had the responsibility for issuing the licenses for field testing of food crops prior to commercial release. Finally, the EPA would register certain pesticide products in transgenic plants prior to their distribution and sale and would establish pesticide tolerances for residues in foods.²⁰

The federal government²¹ outlined the division of responsibilities as follows:

Agency	Products Regulated	Reviews for Safety
FDA	Food, feed, food additives, veterinary drugs	Safe to eat
USDA	Plant pests, plants, veterinary biologic ²²	Safe to grow
EPA	Microbial/plant-pesticides, new uses of existing pesticides, novel microorganisms	Safe for the environment, safe new use of a companion herbicide

Following the publication of the Coordinated Framework, the federal agencies and the White House continued to work together on the specifics of how this division of authority would be exercised. The Biotechnology Science Coordinating Committee ("BSCC"), an inter-agency committee responsible for coordination of science policy, began working together with the agencies and the OSTP to define the

¹⁸ Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. 23,302 (proposed June 26, 1986).

¹⁹ *Id.*

²⁰ For a good review of this early period of regulation, see generally Thomas O. McGarity, *Federal Regulation of Agricultural Biotechnologies*, 20 U. MICH. J.L. REFORM 1089 (1987).

²¹ See USDA, Regulatory Oversight in Biotechnology, Responsible Agencies, at <http://www.aphis.usda.gov/biotech/OECD/usregs.htm> (last visited Mar. 19, 2003).

²² A biologic is any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, applicable to the prevention, treatment, or cure of diseases or injuries to humans. Animal Virus, Serum and Toxin Act of 1913, 21 U.S.C. §§ 151–159 (2000) (amended 1985).

scope of organisms that would be subject to—and exempt from—federal biotechnology oversight. The BSCC, however, was ultimately unable to reach consensus on this issue.²³ The White House OSTP thus took the BSCC's working materials and forwarded them to the President's Council on Competitiveness, a group formed by the Bush Administration and led by Vice President Dan Quayle to promote U.S. industry. The Council on Competitiveness then established an Ad Hoc Committee on Scope. This group ultimately became responsible for defining the scope of federal biotechnology responsibility and included representatives of federal departments as well as other individuals.²⁴

As part of this effort, the Bush Administration's OSTP released a draft policy statement on GM foods titled "Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment" ("Proposed Scope") in 1992.²⁵ The document was to provide ongoing direction to federal agencies on the implementation of federal policy as outlined in the Coordinated Framework. It specifically stated that federal oversight under the Coordinated Framework should be limited to science-based risk assessment to "ensure the safety of planned introductions of organisms into the environment while not unduly inhibiting these introductions."²⁶ In another document, "Four Principles of Regulatory Review for Biotechnology" ("Principles of Regulatory Review"), the Bush Administration re-emphasized that the end product would be the focus of regulatory attention: Federal regulatory oversight should focus on the characteristics and risks of the biotechnology product—not the process by which it is created.

The stated rationale for this approach tied into the Administration's perspective on risk: "[P]roducts developed through biotechnology processes do not *per se* pose risks to human health and the environment; risk depends instead on the characteristics and use of the

²³ KRIMSKY, *supra* note 10, at 197, 204.

²⁴ Principles for Federal Oversight of Biotechnology: Planned Introduction Into the Environment of Organisms With Modified Hereditary Traits, 55 Fed. Reg. 31,118 (proposed July 31, 1990) [hereinafter Principles for Federal Oversight].

²⁵ Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment, 57 Fed. Reg. 6753 (proposed Feb. 27, 1992) [hereinafter Exercise of Federal Oversight].

²⁶ Principles for Federal Oversight, *supra* note 24. The final statement of principles was issued in Exercise of Federal Oversight, *supra* note 25, after a consideration of the comments. The final document retains and strengthens the fundamental risk-based approach articulated in the Proposed Scope document.

individual products."²⁷ The Principles of Regulatory Review goes on to outline the intended result of the government's approach. Thus, Principle Two states that when review is deemed necessary it should be "designed to minimize regulatory burden while assuring protection of public health and welfare."²⁸ Principle Three directs the government to "accommodate the rapid advances in biotechnology."²⁹

In a separate iteration of the risk-based approach, the President's Council on Competitiveness published the "Report on National Biotechnology Policy" ("Report") in February 1991. The Report characterized federal agencies as "gatekeepers" to the development and use of biotechnology. The document specified that in order to *not* inhibit growth, the government should presume that a product poses a minimal risk in the absence of any evidence to the contrary. On this basis the document indicated "[that the Administration would seek] to eliminate unneeded regulatory burdens on all phases of the development of new biotechnology products—laboratory and field experiments, products development, and eventual sales and use."³⁰ Ultimately, the Report went even further than prior statements regarding the minimal risks associated with GM technology by stating that the federal government should only implement new regulations on biotechnology for "those limited instances where private markets fail to provide adequate incentives to avoid unreasonable risks to health and the environment."³¹ According to a news report, Vice President Dan Quayle even promised the industry that the new policy was designed to provide regulatory relief for the fledgling industry so that it would remain a world leader.³²

In 1992, the Bush Administration's OSTP completed its deliberations on appropriate agency approaches to GM technology and published a Final Statement of Scope. This document reiterated the federal approach to regulation: "oversight will be exercised only where the risk posed by the introduction is unreasonable . . . when the value of the reduction in risk obtained by additional oversight is greater than the cost thereby imposed."³³ This document also explained that

²⁷ Exercise of Federal Oversight, *supra* note 25, at 6760.

²⁸ *Id.*

²⁹ *Id.*

³⁰ PRESIDENT'S COUNCIL ON COMPETITIVENESS, REPORT ON NATIONAL BIOTECHNOLOGY POLICY 11 (1991).

³¹ *Id.*

³² Warren E. Leary, *Cornucopia of New Foods Is Seen as Policy on Engineering Is Eased*, N.Y. TIMES, May 27, 1992, at A16.

³³ Exercise of Federal Oversight, *supra* note 25, at 6756.

this approach to risk was chosen because it "is scientifically sound, properly protects public health and the environment against risk, and avoids hindering safe innovations."³⁴

The scientific principles outlined in the Final Statement of Scope are the clearest statement of the Administration's tenets on GM foods. The five policy principles listed are:

1. The same physical and biological laws govern the response of organisms modified by modern molecular and cellular methods and those produced by classical methods;
2. Information about the process used to produce a GM organism is . . . not a useful criterion for determining whether the product requires less or more oversight;
3. No conceptual distinction exists between genetic modification of plants and microorganisms by classical methods or by molecular techniques. . . ;
4. Crops modified by molecular and cellular methods should pose risks no different from those modified by classical methods for similar traits . . . ; and
5. In many respects, molecular methods resemble the classical methods for modifying particular strains of microorganism, but [are even more useful than the classical methods.]³⁵

Neither the Final Statement on Scope nor the other documents outlines how to determine when measurable risks are present ("the scope principles do not dictate precisely how information on risk should be evaluated").³⁶ It was left to the agencies to implement these policy principles and to determine the degree of uncertainty acceptable under the Administration directives.

Although Administration policy statements have no formal authority over regulatory actions, they are important as guiding principles for agencies. During the Reagan and Bush Administrations, the three agencies involved were sympathetic to a pro-GM technology perspective. For example, Henry Miller, Commissioner of FDA during

³⁴ *Id.* at 6755.

³⁵ *Id.* This approach is sharply criticized by University of Minnesota ecologist Philip J. Regal in articles available on his Web site, biosci.umn.edu/~pregal/foodsafety.htm (last visited May 14, 2003). In his articles, Professor Regal traces the history of his doubts about the safety of GM foods and plants from a scientific perspective. Professor Regal's concerns stem from the pleiotropic effects that can result from gene insertions and he maintains that these concern were not and have not been adequately addressed by regulatory agencies.

³⁶ Exercise of Federal Oversight, *supra* note 25, at 6757.

the Reagan Administration, was openly supportive of GM technologies and averse to imposing any unjustified government burden. USDA was also eager to embrace the Administration's GM policies as part of its mission to promote U.S. agriculture, including GM crops. EPA was amenable as well, as its directive was simply to apply existing pesticide law to GM products.

The fundamental adherence to this policy continued under the Clinton Administration. By that time, the United States had established itself as the world leader in the GM arena, and government officials were eager to promote the U.S. position.

B. *The Social Context*

Perhaps as a result of the success of industry self-regulation of rDNA, there was very little public discussion of GM products in the 1980s and early 1990s. With the exception of biotechnology gadfly Jeremy Rifkin, consumer and environmental groups in the United States paid very little attention to the technology at the time of its initial introduction into the U.S. market.³⁷ Certainly, a number of scientists who participated in regulatory and international meetings on GM technologies did raise concerns about allergenicity, toxicity, and environmental issues. According to them, they trusted government scientist and regulator assurances that the agencies were aware of the risks and would ensure stringent safeguards.³⁸

Measurable public concern about the technology did not emerge in the United States until the late 1990s—well after varieties of soy, cotton, and corn had been introduced into American agriculture—and only after the issue had become a political force in Europe. Emergent opposition came from the agricultural sector, where there were concerns about economic and health implications of GM technologies.³⁹ In addition, natural food organizations began to take an interest in the implications of the technology for healthy food and organic

³⁷ See generally Paul S. Naik, *Biotechnology Through the Eyes of an Opponent: The Resistance of Activist Jeremy Rifkin*, 5 VA. J.L. & TECH. 5 (2000); Interview by PBS with Jeremy Rifkin, President, The Foundation on Economic Trends (Aug. 2000), at <http://www.pbs.org/wgbh/harvest/interviews/rifkin.html>.

³⁸ See generally Philip Regal, *Are Genetically Engineered Foods Safe? A Quest for Biosafety* (1999) (unpublished manuscript), available at <http://www.cbs.umn.edu/~pregal/foodsafety.htm>.

³⁹ Mothers for Natural Law, at <http://www.safe-food.org> (last visited May 14, 2003); The National Family Farm Coalition, *Farmer to Farmer Campaign on Genetic Engineering*, at <http://www.nffc.net/bio4.htm> (last visited May 14, 2003).

products.⁴⁰ Environmental groups also began to raise questions about long-term ecological and health consequences of GM products.⁴¹

Once focused on the issue, these voices became a force in agency decision making and responses. As discussed in detail below, consumer comments, petitions, and lawsuits have forced the agencies to address safety and labeling issues, and to be responsive to consumer and the public interest. Even in the face of such challenges, however, U.S. regulators have remained largely faithful to the three policy tenets laid out in the Coordinated Framework and associated Scope documents. Moreover, opposition groups have not slowed the flow of new products into the U.S. market.⁴²

The slow development of U.S. opposition to GM food and agriculture stands in marked contrast to the trajectory of the GM issue in Europe. There, the technology was the focus of intense public opposition even before it was introduced and the resulting debate has led to a moratorium on the introduction of GM products and stringent regulations on labeling. The reason for this difference has been much discussed but remains unclear.⁴³

Some hold that the threshold for European objection to a new food technology was much lower because of the rash of food scares there, including the Bovine spongiform encephelopathy ("BSE" or "mad cow disease") epidemic, and issues with dioxin-tainted products.⁴⁴ Others explain the European objection as a function of more enduring ties between urban populations and agriculture and food products.⁴⁵ Still others rationalize that the response to GM technology in Europe was simply an indirect route for rejecting American corpo-

⁴⁰ See Judy Schultz, *Genetically Altered Food Worries Consumers*, CALGARY HERALD, Sept. 2, 1999, available at http://www.gefoodalert.org/News/news.cfm?News_ID=604; *Advocacy Groups Launch Campaign Against Biotech Foods*, CBC NEWS, Sept. 8, 1999, available at http://www.gefoodalert.org/News/news.cfm?News_ID=592.

⁴¹ Alan Yonan, Jr. *Environmentalists Escalate Fight Against Altered Crops*, DOW JONES, Aug. 26, 1999, available at http://www.gefoodalert.org/News/news.cfm?News_ID=526; *Group Encourages Consumer Support for U.S. Ban on Genetically Altered Food*, Daily Rep. Executives (BNA) (Sept. 1, 1999), available at http://www.gefoodalert.org/News/news.cfm?News_ID=559.

⁴² On September 5, 2002, Monsanto announced a new line of GM corn. See *Fierce Biotech: the Biotech Industry's Daily Monitor*, at <http://www.fiercebiotech.com> (last visited May 14, 2003).

⁴³ See Lisette Alvarez, *Consumers in Europe Resist Gene Altered Foods*, N.Y. TIMES, Feb. 11, 2003, at A3.

⁴⁴ George Gaskell et al., *Worlds Apart? The Reception of Genetically Modified Foods in Europe and the U.S.*, 285 SCIENCE 384 (1999).

⁴⁵ See generally Echols, *supra* note 6.

rate arrogance.⁴⁶ Another view is that politicians with strong views on the propriety of GM technologies were able to find a voice in European governments as a result of the system of proportional representation, whereas such voices have been largely muted in the U.S. first-past-the-post political system.⁴⁷ It is likely that all of these factors are contributors to the distinct European reaction to GM technology.

II. ADMINISTRATIVE IMPLEMENTATION OF POLICY

The following sections outline the development of FDA, USDA and EPA regulation of GM products, and the impact of social criticism and international conflict on government positions. Following the Coordinated Framework and associated documents, each agency articulated a position encompassing the three tenets of U.S. policy. In this sense, each announced that existing statutory frameworks were adequate for regulation, emphasized the end-product rather than the process of GM technology, and made clear that regulation would not be made in the absence of measurable risks. As the technology has gained greater presence, pressures on the agencies have caused an evolution of these principles.

A. Food and Drug Administration

1. FDA's Framework for GM Products

FDA is the most central of the three agencies involved in oversight of GM products and is charged with ensuring the safety of human food and animal feeds. FDA's statutory framework for conventional foods is based on the approach that, in the absence of identifiable risks, a manufacturer may place a product on the market. Under the Federal Food, Drug and Cosmetic Act ("FFDCA"), the manufacturer bears responsibility for ensuring that a product is not adulterated or misbranded. Consistent with the Coordinated Framework, FDA applied this approach to GM foods.

In its initial informal statements following the publication of the Coordinated Framework, FDA stated that the safety of foods produced by new biotechnology would be ensured under existing general

⁴⁶ See generally Chaia Heller, *From Scientific Risk to Paysan Savoir-Faire: Peasant Expertise in the French and Global Debate Over GM Crops*, 11 *SCI. AS CULTURE* 7 (2002).

⁴⁷ This perspective has been articulated by Edwin Levy, Fellow, W. Maurice Young Centre for Applied Ethics at the University of British Columbia.

adulteration and food additive provisions of the FFDCA. The general food safety provisions of the FFDCA state that a food is adulterated if it "bears or contains any poisonous or deleterious substance which may render it injurious to health."⁴⁸ There are no pre-market reviews of approvals required of foods. Instead, manufacturers or distributors bear the burden of ensuring that any finished food placed on the market meets the safety levels implicit in the definition of adulterated foods. FDA is authorized to seek sanctions against foods that do not adhere to these standards through seizure, injunction, or criminal prosecution.⁴⁹

Novel ingredients or components of foods are subject to an additional layer of review. Ingredients added to conventional foods must be approved as food additives or must be generally recognized as safe ("GRAS"). Under 21 U.S.C. § 321(s), a food additive is defined as a substance, the use of which may "reasonably be expected to result, directly or indirectly, in its becoming a component" or "otherwise affecting the characteristics" of food. To gain approval of a substance as a new food additive, a manufacturer must submit a petition containing substantial scientific evidence of safety according to the tenets set out in 21 C.F.R. part 171. Before a food additive petition is approved, the fundamental safety standard requires that there be "reasonable certainty" that no harm will result from the proposed use of the additive.⁵⁰ The food additive approval process is very involved and must include extensive toxicity and feeding studies.

Ingredients that are determined to be GRAS are implicitly recognized as an exception to the food additive category and are exempt from the food additive petition process.⁵¹ GRAS ingredients include those substances demonstrated to be generally recognized as safe among the community of scientific experts knowledgeable about such substances. The GRAS exclusion has the effect of allowing substances for which there is widely available knowledge about safety to avoid the lengthy food additive review process.

FDA did not initially offer any guidance to industry as to how this framework would apply to GM products after the publication of the Coordinated Framework. The statutory framework itself only allowed a few alternatives. The substances added to (or altered in) food as a

⁴⁸ *Id.* § 342(a)(1) (2000).

⁴⁹ *See id.* §§ 331(b), 332, 333, 334.

⁵⁰ 21 C.F.R. § 170.3(i) (2003).

⁵¹ 21 U.S.C. § 321(s).

result of the GM process would be considered to be either food additives or GRAS. Thus, companies were faced with either submitting a food additive petition for each new GM variety, or determining them to be GRAS and therefore exempt from the food safety provisions.

In the aftermath of the Coordinated Framework, the agency received numerous inquiries from industry, government, academia, and the public for further information on which regulatory route would be required for GM foods.⁵² It was clear to all parties involved that this determination would have substantial bearing on the cost of bringing GM products to market.⁵³ In response to the inquiries, the agency issued its "Statement of Policy: Foods Derived From New Plant Varieties" ("1992 FDA Policy") to "clarify its interpretation of the [FFDCA] with respect to human foods and animal feeds derived from new plant varieties, including but not limited to plants developed by new methods of genetic modification."⁵⁴

The 1992 FDA Policy had two purposes. First, it outlined the agency's view that most GM products were presumed or likely to be GRAS, and therefore not subject to food additive review. In addition, it established a voluntary pre-market consultation process to reassure companies and the public that the food supply was being safeguarded. In internal documents, FDA made clear its intent to foster the biotechnology industry while simultaneously taking steps to allay any public concern about safety. Thus, a memorandum from FDA Commissioner David Kessler, M.D., to the Secretary of Health and Human Services, dated March 20, 1992, states, "The approach and provisions of the [1992 FDA Policy] are consistent with the general biotechnology policy established by the Office of the President in the recently published 'scope' document. It also responds to White House interest in assuring the safe, speedy development of the U.S. biotechnology industry."⁵⁵

An undated document titled "FDA Regulation of Food Products Derived from Genetically-Altered Plants: Point to Consider" similarly refers to the Final Statement on Scope in stating that "FDA's objectives in regulating the food products of biotechnology should be to assure safety and provide assurance to the public . . . while avoiding

⁵² Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984 (proposed May 29, 1992).

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ Memorandum from David Kessler, Commissioner of Food and Drugs, to the Secretary for Health and Human Services (Mar. 20, 1992).

'unnecessary' regulatory processes *i.e.*, ones that do not justify the resource burdens they place on FDA and industry."⁵⁶ The document goes on to balance the options for industry oversight between "satisfy[ing] the public that it is being protected" and "avoid[ing] the appearance of complete industry self-regulation."⁵⁷

Ultimately, the 1992 FDA Policy's GM definition facilitated the view that the risks associated with the technology were no different from those posed by traditionally produced foods. FDA explicitly positioned its policy in this context, stating that "genetic modification" included the "alteration of the genotype of a plant using any technique, new or traditional" (hybridization, etc.): "Modification" is used in a broad context to mean the alteration in the composition of food that results from adding, deleting or changing hereditary traits, irrespective of the method."⁵⁸ The agency re-emphasized that the approach was consistent with a product-based policy:

The method by which food is produced or developed may in some cases help to understand the safety or nutritional characteristics of the finished food. However, the key factors in reviewing safety concerns should be the characteristics of the food product, rather than the fact that the new methods are used.⁵⁹

FDA observed that with a few modest exceptions, food derived from new plant varieties—through traditional breeding techniques such as hybridization—are not routinely subjected to scientific tests for safety,⁶⁰ and it proposed to treat genetically modified plants in the same way.⁶¹

The essence of the 1992 FDA Policy was its presumption that genetic material inserted into existing plants was GRAS,⁶² and its expectation that most expression products would also be GRAS:

⁵⁶ FDA Regulation of Food Products Derived from Genetically-Altered Plants: Points to Consider, available at <http://www.bio-integrity.org/FDAdocs/21> (last visited May 14, 2003).

⁵⁷ *Id.*

⁵⁸ 57 Fed. Reg. 22,984 (proposed May 29, 1992).

⁵⁹ *Id.* at 22,984–85.

⁶⁰ *Id.* at 22,988.

⁶¹ *Id.* at 22,984. "The regulatory status of a food, irrespective of the method by which it is developed, is dependent upon the objective characteristics of the food and the intended use of the food." *Id.*

⁶² *Id.* at 22,990.

When the substance present in the food is one that is already present at generally comparable or greater levels in currently consumed foods, there is unlikely to be a safety question sufficient to call into question the presumed GRAS status of such naturally occurring substances and thus warrant formal premarket review and approval by FDA [M]inor molecular variations that do not affect safety would not ordinarily affect the GRAS status of the substances.⁶³

On its face, this presumption was logical.⁶⁴ In explicitly stating its GRAS presumption, however, the approach was different than FDA's approach to conventional food ingredients. There, the burden is always on the manufacturer, in the first instance, to establish that any altered ingredients remain GRAS (or are approved as food additives), and that the food as a whole meets the statutory safety standard. In this sense, prior to the introduction of GM foods, FDA had generally taken a conservative approach, and repeatedly made clear that companies should not presume that an ingredient is GRAS simply because it is present in the food supply in other countries or in different formats.⁶⁵

Even a component of food, such as phytosterols derived directly from vegetable oil, are not presumed to be GRAS. Instead, the manufacturer must demonstrate that the substance is GRAS at the levels and in the form provided. Though most new hybrids of standard fruits and vegetables will be determined to be GRAS by their producers, FDA has never issued a blanket presumption in this regard. Also, in making its general safety presumption, FDA did not address the issue of the complexity of the genome or the issue of unintended effects in modified foods.

In fact, FDA's GRAS presumption on GM foods is interesting because it is inconsistent with questions raised by some agency scientists themselves as the policy was being developed.⁶⁶ These statements sug-

⁶³ 57 Fed. Reg. 22,984, 22,990 (proposed May 29, 1992).

⁶⁴ It is also true, as FDA asserted, that all plants contain the nucleotides that comprise genetic material, and therefore that it has historically been part of the diet. *Id.*

⁶⁵ See, e.g., Warning Letter from John B. Foret, Director, Division of Programs and Enforcement Policy, FDA, to Robert Ehrlich, President, Robert's American Gourmet (Jan. 27, 2000); Warning Letter from John B. Foret, Director, Division of Programs and Enforcement Policy, FDA, to John Bello, CEO, South Beach Beverage Company (Feb. 1, 2000) (noting that ingredients such as chromium picolinate, lycopene, Echinacea, ginkgo biloba, guarana, St. John's Wort, and gotu kola are not GRAS for use in foods).

⁶⁶ Comments of certain members of the FDA staff on the 1992 Policy were revealed during the discovery process in *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166

gest that even while the agency as a whole adopted the Administration position, individual scientists questioned whether it corresponded accurately to the data available. Although dissent amongst scientists is not unusual, the comments made by agency scientists cast some doubt on whether GM foods were indeed *generally recognized as safe*.

In one document, a scientist in FDA's Office of Compliance communicated concerns about the agency's developing position to the FDA Biotechnology Coordinator, James Maryanski. The document questions equating GM products with traditional products, and notes the absence of data from which to draw such conclusions:

I believe that there are at least two situations relative to this document in which it is trying to fit a square peg into a round hole. The first square peg into a round hole is that the document is trying to force an ultimate conclusion that there is no difference between foods modified by genetic engineering and foods modified by traditional breeding practices. This is because of the mandate to regulate the product, not the process. . . . The second square peg in a round hole is that the approach of at least part of the document is to use a scientific analysis of the issues involved to develop the policy statement. In the first place, are we asking the scientific experts to generate the basis for this policy statement in the absence of any data? In the second place, I don't think that the scientific analysis as presented is complete.⁶⁷

Another agency scientist in FDA's Microbiology Group critiqued a draft of the 1992 FDA Policy:

The unintended effects cannot be written off so easily by just implying that they too occur in traditional breeding. There is a *profound difference* between the types of unexpected effects from traditional breeding and genetic engineering which is just glanced over in this document. This is not to say

(D.D.C. 2000). The Alliance for Bio-Integrity has since posted these documents on its Web site. Alliance for Bio-Integrity, Key FDA Documents Revealing (1) Hazards of Genetically Engineered Foods and (2) Flaws with How Agency Made Its Policy, at <http://www.bio-integrity.org/lists.html> (last visited May 14, 2003).

⁶⁷ Memorandum from Linda Kahl, FDA Compliance Officer, to James Maryanski, FDA Biotechnology Coordinator (Jan. 8, 1992) (on file with author).

that they are more dangerous, just quite different, and this difference should be and is not addressed.⁶⁸

The author of this statement added that several aspects of gene insertion "may be more hazardous" than traditional crossbreeding. Regarding the possible activation of "cryptic" pathways to generate unexpected toxins, the scientist wrote, "This situation IS different than that experienced by traditional breeding techniques."⁶⁹

The voluntary consultation program established by the 1992 FDA Policy was designed as a safeguard against erroneous GRAS presumptions. It established a process in which manufacturers and developers of GM food products had the opportunity to present data to the industry in a series of meetings prior to going to market.⁷⁰ FDA encouraged companies to participate in the program, given the novelty of the technology and mutual interest in ensuring safe food. The policy, however, was not mandatory, nor did it establish mandatory disclosure of information regarding GM foods. The only part of the process that would be transparent to the public was the letter that the agency sent "not objecting" to the voluntary consultation.

As the consultation program was implemented, FDA issued guidances on recommended information for a consultation. Thus, in a 1997 FDA document, "Guidance on Consultation Procedures for Foods Derived from New Plant Varieties," the agency outlined the types of information that agency scientists would want to see in a consultation proceeding. This list includes:

- (1) the name of the food and the crop from which it is derived;
- (2) a description of the applications or uses of the food;
- (3) information concerning the sources, identities and functions of introduced genetic material;
- (4) information on the purpose or intended technical effect of the modification and its expected effect on the food;

⁶⁸ FDA Memorandum On The Use Of Microorganisms And Plants As Whole Foods (Nov. 4, 1991).

⁶⁹ *Id.*

⁷⁰ According to FDA, the agency based its specific informational requests on the material examined in the Calgene Flavr-Savr tomato review. Calgene genetically modified a strain of tomato to reduce activity of a particular enzyme (polygalacturonase) that affects softening of outer tissue during ripening. Because the genetically modified tomato had less of this enzyme, it could remain longer on the vine prior to harvest, thereby enhancing its tomato flavor. 57 Fed. Reg. 22,984 (proposed May 29, 1992).

- (5) information concerning the identity and function of expression products encoded by the introduced genetic material;
- (6) information on any known or suspected allergenicity;
- (7) information comparing the GM food to that of natural or commonly consumed varieties;
- (8) a discussion of whether potential for allergic response has been altered by the genetic modification; and
- (9) any other information that is relevant to the safety of the GM food.⁷¹

The consultation would then involve a meeting with the agency and continued discussion on any outstanding issues.

Though the scope of information requested was broad, FDA's ability to obtain data it wanted may have been less than satisfactory. In January 2003, the Center for Science in the Public Interest ("CSPI") released a report based on its review of fourteen FDA GM product consultations obtained through a Freedom of Information Act request to the agency.⁷² According to CSPI, in six of the consultations, FDA requested additional information, and in three of those cases, the companies refused FDA's request.⁷³ For example, CSPI states that when Monsanto notified FDA of its intent to market two varieties of insect-resistant corn, it included data to show that the nutritional content of both genetically modified grains was not affected.⁷⁴ But for one of the varieties, Monsanto did not submit nutrient data for the rest of the corn plant, such as the stalks, which often go into animal feed.⁷⁵ When FDA requested that information, it was denied.⁷⁶ According to Monsanto, the information would have been supplied but the company did not go forward with the product.⁷⁷

CSPI also claims that FDA overlooked factual and scientific errors in documents that were submitted. For example, the developer of GM tomatoes and cantaloupes, Agitope Inc., claimed the products posed

⁷¹ See FDA, Guidance on Consultation Procedures for Foods Derived from New Plant Varieties (1997).

⁷² See generally DOUG GURIAN-SHERMAN, HOLES IN THE BIOTECH SAFETY NET: FDA POLICY DOES NOT ASSURE THE SAFETY OF GENETICALLY ENGINEERED FOODS (2003), available at http://www.cspinet.org/new/pdf/fda_report_final.pdf.

⁷³ See *id.* at ii, 4.

⁷⁴ See *id.* at 4.

⁷⁵ See *id.* at 4, 5.

⁷⁶ See *id.*

⁷⁷ Leila Aboud, *Modified-crop Makers Faulted on Safety Data Sent to FDA*, WALL ST. J., Jan. 7, 2003, at A3.

little risk because humans were already naturally exposed to the protein they were engineered to make.⁷⁸ According to CSPI, however, the scientific papers submitted to prove this point did not support it.⁷⁹ A company spokesperson said that FDA never raised the issue and that the product was dropped before going to market.⁸⁰

Through 2000, FDA processed approximately fifty consultations under the 1992 FDA Policy with fairly minimal public attention. As GM products assumed a greater presence on the market, however, questions about their safety and proliferation became more frequent. In part, this was probably due to the intense focus on the issue in Europe.⁸¹ The questions were also likely a response to the fact that by 1998, GM products represented thirty percent of the total soy acreage, twenty percent of the corn acreage, and over twenty-five percent of the cotton acreage in the United States.⁸²

By the late 1990s, public awareness of GM foods reached a critical level and a number of public interest groups emerged to focus on the issue. One of the early groups to focus on the issue was Mothers for Natural Law ("MFNL"), an Iowa-based organization that aimed to ban GM foods from the market. The group launched a national public awareness campaign on genetically engineered foods in July 1996.⁸³ In addition, it promoted an "initiative to secure rigorous pre-market safety testing, mandatory labeling and even a moratorium on these foods."⁸⁴

MFNL's campaign painted the specter of unsafe, untested infant formula and other family food products. Even now, the group's Web site asks, "Is genetic engineering safe for you and your family? Safe for the environment? Safe for the future of mankind? No long-term studies have been done. No one can answer these questions."⁸⁵ The group goes on to state, "If we don't engage the support of our government for serious caution, for rigorous safety testing, for a moratorium, ge-

⁷⁸ GURIAN-SHERMAN, *supra* note 72.

⁷⁹ *Id.*

⁸⁰ Aboud, *supra* note 77, at A3.

⁸¹ See generally Echols, *supra* note 6 (discussing the different responses to novel food technologies).

⁸² Peter A. Riley et al., *U.S. Farmers are Rapidly Adopting Biotech Crops*, AGRIC. OUTLOOK (USDA, Washington, D.C.), Aug. 1998, at 21, available at <http://jan.mannlib.cornell.edu/reports/erssor/economics/ao-bb/1998/ao253.pdf>.

⁸³ Mothers for Natural Law, About Mothers for Natural Law, at <http://www.safe-food.org/~campaign/about.html> (last visited Apr. 7, 2003).

⁸⁴ *Id.*

⁸⁵ Mothers for Natural Law, *supra* note 39.

netically engineered foods will become the norm, labeling will be redundant and our children will live in a world where real food, natural food, is no longer available."⁸⁶ In 1998 and 1999, MFNL undertook a grassroots petition drive to call for labeling of GM products and generated nearly 500,000 signatures.⁸⁷ This petition was distributed through health food stores, regional coordinators and on university campuses, as well as tens of thousands of signature gatherers all over the country.⁸⁸

The Union of Concerned Scientists ("UCS"), an alliance of 60,000 citizens and scientists, has been another prominent voice on the issue.⁸⁹ UCS relies on its scientific expertise and publicly questions the basis for FDA's regulatory process. UCS has urged FDA to require safety testing—on the level of food additive petitions—prior to allowing GM foods on the market and has also consistently urged the agency to require labeling of its products. As the pace of GM products entering the market increased in the 1990s, UCS became a vocal critic of what it saw as the agency's collusion with industry and failure fully to take account of allergenicity and other safety issues.

The Center for Food Safety ("CFS"), a public interest organization dedicated to strict regulation of GM foods, organics, and other novel technologies, is also a prominent voice on the issue. In 2000, CFS filed a citizen petition with FDA outlining safety concerns associated with GM foods.⁹⁰ Signers of the CFS petition included a range of NGOs, from environmental organizations to health food concerns to representatives of traditional family farms. Collectively, the signers accused FDA of a too permissive position on GM foods and asked that the agency institute mandatory food additive petitions for these products.

On the legislative front, the Campaign to Label Genetically Engineered Foods became a persistent critic of FDA. The organization was launched in March 1999 as a response to the "growing acreage of un-

⁸⁶ Mothers for Natural Law, *supra* note 83.

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ Union for Concerned Scientists, About UCS, at <http://www.ucsusa.org/ucs/about> (last visited Apr. 7, 2003).

⁹⁰ Center for Food Safety, Citizen Petition Before the United States Food and Drug Administration, Petition Seeking the Establishment of Mandatory Pre-Market Safety Testing, Pre-Market Environmental Review, & Labeling for all Genetically Engineered Foods, available at <http://www.centerforfoodsafety.org/li/BigFDAPetition9.html> (last visited May 14, 2003).

labeled and inadequately tested genetically engineered crops."⁹¹ The group focuses on lobbying Congress and has been instrumental in getting Congressman Dennis Kucinich, a Democrat from Ohio, to become the primary sponsor of legislation that would require labeling on GM foods.⁹² Kucinich also introduced legislation to require food additive review for each GM product.⁹³ If passed, this bill would amend the FFDCA to include GM products in the definition of "food additive."⁹⁴ In addition, it would provide for citizen suits as a means of consumer enforcement of the provision.

On May 27, 1998, FDA faced the strongest legal challenge over the legitimacy of its 1992 policy to date. In *Alliance for Bio-Integrity v. Shalala*, a group of concerned citizens sued the agency over its position on GM foods.⁹⁵ The plaintiffs challenged FDA's presumption that genetically modified foods should be considered safe unless they contain substances that are allergens or change the character of the food. The plaintiffs identified a range of secondary changes that could occur in products as a result of genetic modification, including unwanted, unpredictable new toxins and/or carcinogens or degradation of nutritional quality.

The suit further claimed that in drafting the 1992 FDA Policy the agency failed to abide by the public notice-and-comment procedures of the Administrative Procedures Act, and that FDA's refusal to require labeling and safety testing for GM foods raised health and environmental concerns. The suit identified thirty-six GM foods that were likely being eaten by U.S. consumers without their knowledge.⁹⁶ Ultimately, the *Alliance for Bio-Integrity* plaintiffs asked the court to compel the agency to carry out the same testing and safety evaluations conducted for food additives under 21 U.S.C. § 409, and to require labeling of these foods on grounds that they had been "materially" changed.⁹⁷

⁹¹ See The Campaign to Label Genetically Engineered Foods, About Us, at <http://www.thecampaign.org/aboutus.php> (last visited May 14, 2003).

⁹² The Genetically Engineered Foods Right to Know Act, H.R. 3377, 106th Cong. (1999). A companion bill was introduced in the Senate by Senator Boxer in 2000. See S. 2080, 106th Cong. (2000).

⁹³ Genetically Engineered Food Safety Act, H.R. 4813, 107th Cong. (2002).

⁹⁴ See generally *id.*

⁹⁵ 116 F. Supp. 2d 166 (D.D.C. 2000).

⁹⁶ The Religious Freedom Restoration Act of 1993, Pub. L. 103-141, 107 Stat. 1488. This act requires that federal laws or regulations not impede the free exercise of religion.

⁹⁷ 116 F. Supp. 2d at 178. The debate over labeling is discussed further below.

The U.S. District Court of the District of Columbia rejected each of the plaintiffs' arguments and granted the government's motion for summary judgement.⁹⁸ The court disagreed that the 1992 FDA Policy had been improperly promulgated, and noted that a policy, as opposed to a formal agency action, is not subject to the notice-and-comment requirements.⁹⁹ On substantive issues, the court deferred to FDA's presumption in its 1992 policy statement that GM foods are GRAS.¹⁰⁰ The court noted that scientific applications of statutory law were within FDA's expertise, and that well-established principles of administrative law prevented the court from second-guessing the agency.¹⁰¹

The court was similarly deferential to FDA's judgement with respect to labeling. The relevant statute states that FDA can take action for the misbranding of a food if the labeling "fails to reveal facts . . . material with respect to consequences which may result from use of the article."¹⁰² The court stated that FDA had determined that changes to foods resulting from genetic modification were not "material," and it therefore did not require labeling.¹⁰³ The court declined to challenge the agency's expert conclusion on the effects of GM on foods.

Ultimately, this decision made clear that critics of FDA's policy had very little legal ground on which to stand. The case, however, did heighten public awareness of GM foods and added to the perception that the government was not regulating these products. Even more, documents released by FDA during the discovery process showed that agency scientists themselves had doubts about the risk assessment process and the government's position.¹⁰⁴ The net result was to put the issue in the spotlight and to force FDA to defend its policies more publicly.

In light of the heightened focus on GM products, the agency announced a series of public hearings in 1999.¹⁰⁵ These hearings were

⁹⁸ *Id.* at 181.

⁹⁹ *Id.* at 170, 172.

¹⁰⁰ *Id.* at 177, 178.

¹⁰¹ *Id.*

¹⁰² 21 U.S.C. § 321(n) (2000).

¹⁰³ *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 178.

¹⁰⁴ In dismissing the case, the court noted that the internal FDA dissent revealed by a few of the estimated 44,000 pages of documents released was insufficient to lead the court to challenge agency discretion. *Id.* at 177.

¹⁰⁵ Press Release, U.S. Department of Health and Human Services, FDA Announces Public Meetings on Bioengineered Foods (Oct. 18, 1999).

held in Oakland, California, Chicago, and Washington, D.C. and attracted a large amount of public attention. According to FDA's own estimates, over 50,000 written comments were submitted to FDA in the context of the hearings.¹⁰⁶ The meetings were colorful affairs: demonstrators gathered outside dressed in costumes with signs and banners. Companies such as Monsanto were concerned enough about the impact of the meetings that they bussed in GM supporters to stand off against the demonstrators. Inside, the meetings were equally lively. Most commentators represented consumers, the public interest, or other anti-GM groups and articulated their comments in kind.¹⁰⁷

According to the agency's summary, comments revolved around three major themes.¹⁰⁸ The first, generally from representatives of industry, was that there was no information that raised questions about the safety of GM foods then being marketed.¹⁰⁹ The second focused on whether FDA's current regulatory regime was adequate to ensure safety given the range of unknowns.¹¹⁰ The third focused on whether labeling GM products should be required.¹¹¹

In January 2001, FDA responded to the comments by proposing a new rule that would *require* manufacturers of "plant-derived, bioengineered foods and animal feeds" (GM foods) to notify FDA at least 120 days before the products are marketed in a "Premarket Biotechnology Notice" ("PBN").¹¹² In essence, FDA's proposed rule would make the 1992 voluntary consultation process mandatory.¹¹³ FDA was careful to state that its proposal did not reflect any new safety concerns about the products.¹¹⁴ The agency characterized the proposed rule as simply a proactive measure to ensure that FDA stayed current

¹⁰⁶ Center for Food Safety and Applied Nutrition, FDA, Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or have Not Been Developed Using Bioengineering (Jan. 2001) (draft) [hereinafter Guidance for Industry], available at <http://vm.cfsan.fda.gov/~dms/biolabgu.html>.

¹⁰⁷ See FDA Transcripts of Public Meetings on Bioengineered Foods (on file with FDA). For more information on the meetings, see generally <http://www.fda.gov/oc/biotech/default.htm> (last visited May 14, 2003).

¹⁰⁸ Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4708 (proposed Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192, 592).

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² *Id.* at 4707.

¹¹³ 66 Fed. Reg. at 4707.

¹¹⁴ Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4709 (proposed Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192, 592).

with developing technology as GM products became more widespread and complex. FDA restated its belief that GM products are safe.¹¹⁵

In justifying its proposal, FDA stated that as the pace of development of GM products increased, it made sense for the agency to ensure that it retained "the *opportunity* to discuss safety and other regulatory issues . . . before new bioengineered foods go on the market."¹¹⁶ The PBN rule would require the submission of data and information about the substance, as well as a narrative interpretation of this information.¹¹⁷ To satisfy the public demand for information, FDA stated that it would make the existence of the PBN, as well as the agency's evaluation and response to the notice, accessible to the public, though any informal consultations with the agency would be kept confidential.¹¹⁸

The proposal met with mixed reviews. Companies involved in the production of GM foods applauded the agency for making its progress more rigorous and confirming to the outside world that GM products were tightly regulated by the agency. Critics of the agency were less generous. While many congratulated FDA for making the process mandatory, critics complained that the process was not transparent enough and that FDA had still failed to articulate clear standards on what would need to be shown for the agency to not object to a product.¹¹⁹ Moreover, critics maintained that by continuing to rely on a presumption that GM foods were GRAS, the agency was essentially giving a wide range of products free reign, without investigating how small changes in plant genetic matter can have unexpected effects. Critics reiterated their view that nothing short of holding these products to a food additive review standard would satisfy them that FDA was adequately protecting the public.¹²⁰ Despite the continued support of industry for the proposal, FDA has not yet finalized the rule.¹²¹

¹¹⁵ *Id.*

¹¹⁶ *Id.* (emphasis added).

¹¹⁷ *Id.* at 4725.

¹¹⁸ *Id.* Specifically, FDA states that it will publish the fact of the notification and the agency's response in an accessible place. To obtain copies of the actual submissions, however, minus confidential information, a Freedom of Information request would need to be filed.

¹¹⁹ See Consumers Union, Consumers Union Comments on Docket No. 00N-1396, Premarket Notice Concerning Bioengineered Foods (May 1, 2001), available at <http://consumersunion.org/food/biocpi501.htm>.

¹²⁰ *Id.*

¹²¹ *Industry Presses FDA for Premarket Biotech Notification*, FOOD CHEM. NEWS, Dec. 5, 2002, at 5.

2. Labeling

FDA's perspective on labeling also reflects its embrace of a product-based, rather than process-based approach. To date, the agency has declined to require mandatory labeling of GM products. Moreover, FDA permits voluntary labeling of GM products only if such statements are carefully structured to avoid "misleading" consumers into the belief that such products differ in any material way from their conventionally produced counterparts.

The foundations of FDA's labeling policy are (1) 21 U.S.C. § 343(a)(1), which states that a food is misbranded if "its labeling is false or misleading in any particular;" and (2) 21 U.S.C. § 321(n), which states that labeling is misleading if it "fails to reveal all facts that are material in light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates." Ultimately, the statutory language makes clear that labeling which omits material facts may be deemed misleading by FDA, and thereby subject to enforcement action.

Neither the statute nor the legislative history of the FFDCA offers any further explication of when information is material for purposes of labeling, or when information can or cannot be required. In the past, FDA has interpreted these sections of the FFDCA to require special labeling in cases where the absence of such information may

- (1) pose health or environmental risks (*e.g.*, a warning on protein products used in very low calorie diets);
- (2) mislead the consumer in light of other statements on the label (*e.g.*, requirement for quantitative nutrient information when certain nutrient content claims (*i.e.* low calorie) are made about a product); or
- (3) mislead the consumer to assume that because of its similarity to another food, a product has certain specific nutritional characteristics.¹²²

In FDA's opinion, none of these scenarios apply to the GM context. Indeed, under its product-based approach, FDA takes the position that GM food is "substantially similar" to its conventional counterpart, and therefore there are no material differences that could

¹²² See, *e.g.*, *Hearing Before the Subcomm. on Health, Education, Labor, and Pensions*, 107th Cong. (Sept. 26, 2000) (statement of Joseph A. Levitt, Director, Center for Food Safety and Applied Nutrition), available at <http://vm.cfsan.fda.gov/~lrd/stbioeng.html>.

form the basis of special labeling.¹²³ Based on this position, the 1992 FDA Policy specifically states that any labeling that a food is "GM-free" or "GMO-free" would be considered misleading under 21 U.S.C. § 343.¹²⁴ FDA has further stated that there is no precedent for requiring disclosure of a manufacturing process based simply on consumer desire to know.¹²⁵

Even as the agency articulated this policy and published it in a policy statement in 1995,¹²⁶ consumer demand for labeling was growing. A consumer survey conducted in 1997 by Novartis found that ninety-three percent of Americans wanted FDA to require labeling of genetically engineered foods.¹²⁷ In addition, a Time Magazine poll conducted in 1999 found that eighty-one percent of those polled wanted bioengineered foods to be labeled. A poll conducted by the Center for Science in the Public Interest in 2001 helps put the intensity of consumer desire into context. In that poll, for example, sixty-two percent of those surveyed agreed that labels should include information on whether ingredients came from GM crops. Within the context of attributes that could or should be disclosed (e.g., pesticide use, use of plant hormones), the fact of being genetically engineered was deemed the second most important piece of information, after use of pesticides. Those surveyed also indicated that labeling was most important if the whole food (e.g., a tomato) was modified, slightly less important if a major ingredient (e.g., the wheat in Wheaties) was modified, and still less important if a minor ingredient in a processed food was modified.¹²⁸

¹²³ FDA requires special labeling for foods if they pose special safety or usage issues. In the example FDA often gives, if a food had a new protein introduced into it to which people were allergic, FDA would require the label to reveal that information. In its 1992 policy statement, the agency noted that labeling would be required if genes were introduced from foods that were commonly allergenic, unless the developer could scientifically demonstrate that the protein was not responsible for the allergenicity of the original foods.

¹²⁴ Food Labeling: Foods Derived From New Plant Varieties, 58 Fed. Reg. 25,837 (proposed Apr. 28, 1993). Note that FDA issued a new policy on the use of these terms in 2001, as discussed below.

¹²⁵ The court in *Alliance for Bio-Integrity* supported this position.

¹²⁶ CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, FDA'S POLICY FOR FOODS DEVELOPED BY BIOTECHNOLOGY (1995), available at <http://vm.cfsan.fda.gov/~lrd/biopolcy.html>.

¹²⁷ The Center for Food Safety, Citizen Petition Before the United States Food and Drug Administration (2000) (received Mar. 21, 2000).

¹²⁸ Center for Science in the Public Interest, National Opinion Poll on Labeling of Genetically Modified Foods (Mar. 30-Apr. 1, 2001), at http://www.cspinet.org/new/poll_gefoods.html. The CSPI survey also revealed a certain amount of confusion or ambivalence about the GM process. For example, equal numbers stated that they would buy

During the public meetings that FDA held in 1999, a large number of the more than 50,000 written comments received by the agency related to labeling.¹²⁹ According to the agency, most of those comments requested mandatory disclosure of the fact that a food or its ingredients was GM or was produced from GM foods.¹³⁰ The rationale for such comments varied and included the desire to safeguard the purity of the food, prevent potential allergic reactions, avoid a process that interferes with religion or moral views, and promote traditional farming. In addition, many of the comments expressed concern about possible long-term consequences from unknowingly consuming GM food.¹³¹

In response to the 1999 meetings and public concerns, FDA published "Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering," explaining its position and outlining the parameters for voluntary labeling of GM foods.¹³² In this document, FDA reaffirmed the position that most GM foods were substantially equivalent to their conventional counterparts. The agency also made clear that the process of genetic modification was not itself a material difference in the food:

The agency is still not aware of any data or other information that would form a basis for concluding that the fact that a food or its ingredients was produced using bioengineering is a material fact that must be disclosed under sections 403(a) [343(a)] and 201(n) [321(n)] of the act. FDA is therefore reaffirming its decision to not require special labeling of all bioengineered foods.¹³³

The agency went on to suggest that because of the strongly divergent views on labeling, manufacturers could consider providing more information about GM foods as long as this information was "truthful and not misleading."¹³⁴ The agency reiterated that, in its view, statements such as "GM free" or "biotech free" were potentially "false and

GM fruits or vegetables (or processed foods) as those who stated they would buy products made from cross-bred corn. Fifty-five percent of those surveyed stated that they were not very familiar or not at all familiar with GM foods.

¹²⁹ Guidance for Industry, *supra* note 106.

¹³⁰ *Id.*

¹³¹ *See id.*

¹³² *Id.*

¹³³ *Id.*

¹³⁴ Guidance for Industry, *supra* note 106.

misleading," based on the fact that (1) there are no established threshold levels of bioengineered constituents or ingredients in foods, and (2) there is no evidence that GM foods are inferior in any way to their conventional counterparts.¹³⁵

Ultimately, FDA did acknowledge a limited role for labeling in the context of GM foods. Labeling would be mandatory if a GM product differed from its conventional counterpart so that the common or usual name of the item no longer applied; for example, if a GM soybean oil no longer had the same nutritional or functional properties as non-GM soybean oil. FDA also acknowledged that if the product differed in safety (i.e. allergenicity) profile, labeling would be required.¹³⁶

In addition, FDA identified the range of voluntary labeling statements that manufacturers could use. These include: "This product contains cornmeal that was produced using biotechnology;" "These tomatoes were genetically engineered to improve texture;" or "Some of our growers plant tomato seeds that were developed through biotechnology to increase crop yield."¹³⁷ For FDA, these statements are not misleading because they are informative without implying that GM foods are better or worse than conventional foods.

Critics of this latest policy statement have called it disingenuous. They point to the proposed labeling of irradiated foods as an example of providing process-based label information to consumers. FDA approved the use of irradiation on certain foodstuffs based on its conclusion that this form of processing does not result in any material difference in the foods. Despite this, FDA requires disclosure that this process has been used on labels of treated foods.¹³⁸ In its rule making on the subject, FDA stated:

¹³⁵ *Id.* It is worth noting that FDA identified the term "genetically modified" itself as confusing and potentially misleading. According to the agency, genetic modification occurs in all plants regardless of human agency and the goal of traditional plant breeding is genetic modification. FDA concludes that

while it is accurate to say that a bioengineered food was "genetically modified," it likely would be inaccurate to state that a food that had not been produced using biotechnology was "not genetically modified" without clearly providing a context so that the consumer can understand that the statement applies to bioengineering.

Id.

¹³⁶ *Id.*

¹³⁷ *Id.*

¹³⁸ FDA's position may be overturned. The Farm Security and Rural Investment Act of 2002, H.R. 2646, 107th Cong., directed FDA to review its labeling regulation for irradiated

[I]n the absence of a statement that a food has been irradiated, the implied representation to consumers is that the food has not been processed Whether information is material under [321(n)] . . . depends not on the abstract worth of the information but on whether consumers view such information as important and whether the omission of label information may mislead a consumer.¹³⁹

Supporters of GM food labeling point to this reasoning as analogous to their own request and have questioned repeatedly why it does not apply in the GM context. These critics take the view that the absence of an affirmative statement that a food had been genetically modified would be viewed as an implied representation to consumers that it has been grown by traditional means. Despite the logic of this position, FDA has not explained the seemingly inconsistent reasoning.

Despite the criticism and repeated calls for mandatory labeling, FDA's approach to GM labeling has been upheld by the courts. In *Alliance for Bio-Integrity*, one of the key plaintiff demands was that FDA institute mandatory labeling of GM foods on grounds that genetic alteration made material changes (i.e. safety, allergenicity risks) to foods, meriting labeling. Plaintiffs took the position that the process of being genetically modified was itself a material fact. As noted, however, the court rejected both of these arguments and affirmed FDA's position. In a manner seemingly inconsistent with the irradiated-food labeling regulations, the court stated that consumer demand itself was not a basis for mandatory labeling.¹⁴⁰

food, and until the review is done, to allow companies to seek permission to change the labeling for specific irradiated products. Companies are seeking to use language less alarming to consumers, such as "Cold Pasteurized." These proposals remain controversial.

¹³⁹ Irradiation in the Production, Processing, and Handling of Food, 51 Fed. Reg. 13,376 (Apr. 18, 1986) (to be codified at 21 C.F.R. pt. 179). For further discussion, see Frederick Degnan, *Food Labeling and the Right-to-Know*, 52 FOOD & DRUG L.J. 49 (1997).

¹⁴⁰ *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 178. Courts have also taken this position in cases dealing with the related issue of mandatory labeling for milk produced from cows treated with recombinant Bovine Growth Hormone ("rBGH"), a bioengineered version of growth hormone injected into cows to increase the rate of lactation. The first such case, *Stauber v. Shalala*, 895 F. Supp. 1178 (W.D. Wis. 1995), involved a challenge to FDA's determination that it would not require labeling disclosing that dairy products came from rBGH-treated cows. The court granted summary judgement against the plaintiffs on this point, deferring instead to FDA's finding that there was no difference between dairy products from rBGH-treated or non-treated cows. *Id.* at 1193.

The second case, *International Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67 (2d Cir. 1996), involved an industry challenge to a Vermont law mandating disclosure of rBGH use in the

3. Containment

The issue of containment poses the latest challenge to FDA, and may result in the agency having to move away from its product-based approach and perhaps even reliance on existing statutory law. Containment refers to the effort to contain GM plants/seeds from cross-fertilizing neighboring crops or contaminating non-GM foods. From the first discussions of GM foods, scientists have pointed to the potential risks from altered genomes spreading into other plants and the environment. FDA has not, however, explicitly addressed the issue or to what degree contamination of food products by unapproved GM products will be tolerated. Nonetheless, contamination issues are occurring with greater frequency both in the United States and internationally, and it appears that FDA is on the verge of issuing a guidance document on the subject.

At present, FDA reviews GM products that are intended for food uses only under its consultation program. Containment issues could mean that the agency would need to consider potential food presence of GM products that were not intended for use as foods. As such, the agency would be forced to move beyond its product-based approach.

The questions posed by containment became a reality for FDA in April 2002, when Monsanto notified FDA that a GM canola oil marketed by the company *could* potentially be contaminated with small amounts of a different strain of GM canola oil that had not been subject to agency review for food uses.¹⁴¹ According to news reports, Monsanto sent the FDA a letter detailing the possibility of contamination of its RT73 canola oil¹⁴² with the unreviewed GT 2000 strain, in order to avoid legal challenges and recalls of the type experienced following the StarLink crisis. In discussing the incident with Wall

production of milk. The U.S. Court of Appeals for the Second Circuit struck down the Vermont law on grounds that "consumer curiosity" was not "substantial" enough to justify the intrusion on commercial free speech under the First Amendment. *Id.* at 74.

For further discussion of rBGH and these cases, see Emily Marden, *Recombinant Bovine Growth Hormone and the Courts: In Search of Justice*, 46 *DRAKE L. REV.* 617 (1998).

¹⁴¹ Scott Kilman & Jill Carroll, *Leading the News: Monsanto Admits Unapproved Seed May Be in Crops*, *WALL ST. J.*, Apr. 15, 2002, at A3.

¹⁴² Monsanto's RT73 Canola Oil was submitted for review under the agency's 1992 notification policy on April 5, 1995. On September 26, 1995, FDA responded that it had no objection to Monsanto's conclusion that this product was "not materially different in composition, safety or any other relevant parameter from canola varieties currently on the market and it would not raise issues that would require premarket review or approval by FDA." Letter from Alan M. Rulis, Ph.D., Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition, to Monsanto Company (Sept. 26, 1995).

Street Journal reporter Michael Phillips, an industry observer acknowledged, "As we see more and more varieties come out . . . you might find trace amounts [of bioengineered ingredients] in food that didn't go through the full regulatory measure."¹⁴³

In this instance, FDA opted to address Monsanto's problem within the confines of its consultation program. That is, the agency decided to interpret Monsanto's letter as a voluntary consultation on the unreviewed strain of canola, even though it was not clear that the variety was intended for human food uses. On April 16, 2002, a news source announced that FDA was "[nearing completion] of its voluntary review of the canola" and said it would be sending Monsanto a letter stating the canola is "safe to eat and will not require mandatory FDA approval to be sold."¹⁴⁴

FDA was able to fit the second canola strain in its existing framework only because Monsanto detected the contamination and brought safety information to FDA's attention. In drafting its 2001 proposed rule, however, FDA recognized that most contamination challenges would not be detected before they were a part of the food supply. In the proposed rule, FDA therefore urged companies developing non-food GM products to consult with the agency in the expectation that contamination would or could result.¹⁴⁵ FDA's aim is to preclude the chance of a contamination crisis, where unreviewed products enter the food supply and the agency has no information about their safety.

More recently, a notice published by the OSTP directed FDA, as well as EPA and USDA, to outline specific containment policies. This August 2, 2002 publication, "Proposed Federal Actions to Update Field Test Requirements for Biotechnology Derived Plants and To Establish Early Food Safety Assessments for New Proteins Produced by

¹⁴³ Kilman & Carroll, *supra* note 141 (quoting Michael P. Phillips of the Biotechnology Industry Organization, an industry trade group).

¹⁴⁴ Jill Carroll, *FDA Says Monsanto Canola Doesn't Appear to Pose Risks*, WALL ST. J., Apr. 16, 2002.

¹⁴⁵ Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4714 (proposed Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192, 592). FDA states that it

encourages developers of [GM products] that are not intended for use in food or feed, but that theoretically could enter the food or feed supply, to participate in the consultation program described This participation would ensure that developers have given careful consideration to the procedures needed to ensure that their products do not inappropriately get into the food supply, and are aware of the legal implications if their products do.

Such Plants,"¹⁴⁶ acknowledges that as the number of new GM agricultural products being tested increases, there is a likelihood that small amounts of these new products will contaminate existing crops.¹⁴⁷ The notice states, "This could result in intermittent, low levels of biotechnology-derived genes, and gene products occurring in commerce that have not gone through all applicable regulatory reviews."¹⁴⁸ In response, OSTP states that each of the three relevant regulatory agencies will issue guidances and/or update regulations to reflect the reality of GM contamination.

With respect to FDA, the notice states that the agency will issue a guidance establishing procedures under which developers may provide FDA with safety information on GM foods/feeds that have not previously been evaluated by FDA and are new to the food crop into which they are engineered.¹⁴⁹ As suggested by the proposed rule, FDA is to review GM crops that are *not* intended for food uses because such products may enter the food supply through cross fertilization or other contamination. The notice directs FDA to review this additional information to assess potential toxicity and allergenicity, to ensure food safety even if there are containment problems.¹⁵⁰ Consistent with existing practices, FDA would issue a written response after any consultations and post this information on its Web site.¹⁵¹

If FDA issues such a guidance, it will be a marked step away from its product-based approach. Indeed, FDA will be in the position of reviewing all new crops for GRAS status based solely on the process by which they have been developed. Further, such reviews would stretch the traditional interpretation of the applicable statutes. Under 21

¹⁴⁶ 67 Fed. Reg. 50,578 (Aug. 2, 2002).

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*

¹⁴⁹ *Id.* at 50,579

¹⁵⁰ *Id.*

¹⁵¹ Containment is also becoming more prominent as plants producing pharmaceuticals become a reality. The risk is that ordinary food crops could be contaminated with pharmaceuticals. FDA and USDA recently issued a draft guidance on this issue. USDA & FDA, Guidance for Industry: Drug, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals (Sept. 2002) (draft), available at <http://www.fda.gov/cber/gdlns/bioplant.htm>. An example of the risk was revealed when regulators discovered that a biotech corn variety engineered to produce an experimental type of insulin had contaminated a neighboring soybean field in Nebraska. The responsible company, ProdiGene, a Texas-based biotechnology company, has since been fined by the authorities. Press Release, USDA, USDA Investigates Biotech Company for Possible Permit Violations (Nov. 13, 2002), available at <http://www.aphis.usda.gov/lpa/news/2002/11/prodigene.html>.

U.S.C. § 348, only ingredients intended for *food uses* are subject to the food additive or GRAS safety review. As outlined by OSTP, however, FDA would essentially be applying its GRAS review to all GM products, regardless of whether or not they are intended to be used as human or animal foods.

Industry touted the OSTP move as further indicative of the will of government to protect the public. The New York Times reported the Biotechnology Industry Organization as welcoming the new proposals: "For consumers, this enhancement adds yet another layer of assurance to the existing regulatory review of agricultural crops."¹⁵² Critics have maintained that the containment issue is far greater than the government acknowledges and warn that contamination could result in unsafe foods, or even unintended pharmaceuticals, in daily products.¹⁵³

B. U.S. Department of Agriculture

Both USDA and EPA share significant authority over GM foods with FDA. Like FDA, each of these agencies focuses its policies on the three-part approach developed by the White House and OSTP. Yet, USDA and EPA have responded to the three regulatory principles in different ways. Thus, although USDA explicitly stated that it agreed that existing statutory frameworks and risk-based regulation were priorities, it initially took a more precautionary approach to the technology. It extended its pre-introduction permit requirement to *any* GM product that was deemed to have the potential to spread or cause injury in other plants. Only after several years of experience did USDA conform to OSTP policy and presume minimal levels of risk.

EPA, in contrast, has remained largely consistent in its approach. EPA made clear that the relevant statutory framework was written broadly enough to include GM products, and that its existing product-based approach would apply. In recent years, this perspective has been subject to criticism in response to growing concerns that EPA has not fully considered environmental risks and lacks the capacity to monitor them.

¹⁵² Andrew Pollack, *Earlier Safety Reviews Proposed for Gene-Altered Crops*, N.Y. TIMES, Aug. 2, 2002, at C3.

¹⁵³ See, e.g., The Campaign to Label Genetically Engineered Foods, GMO Contamination, at <http://www.thecampaign.org/analysis/analysis100501.htm> (last visited May 14, 2003).

The Coordinated Framework directed USDA to oversee the introduction of GM plants into agriculture as well as the transport of such products around the United States. In response, USDA stated that such oversight would be conducted under the then existing statute, the Federal Plant Pest Act ("FPPA"),¹⁵⁴ which directed the agency to monitor the introduction and transport of new agricultural organisms. The FPPA specifically empowered USDA to regulate imports and the movement of items deemed to be "plant pests" (e.g., microorganisms, plants, or insects) and authorized USDA to seize, quarantine, destroy, or apply other remedial measures to articles that infested or were infected by or contained a plant pest.¹⁵⁵ The aim was to maintain the health and sustainability of U.S. agriculture. Before the arrival of GM products, USDA had used this authority to establish a permit regime for the introduction of all organisms that could potentially injure or cause disease or damage in any plants.¹⁵⁶

In a sharp divergence from FDA, USDA initially chose to take a precautionary approach under this existing statutory regime. Instead of presuming that existing regulations were adequate to apply also to GM products, USDA proposed and promulgated regulations specific to GM products. These regulations made clear that not all GM products would be subject to the FPPA, but went on to state that those GM products that *could* be considered "plant pests" under the existing definition would be subject to a mandatory pre-release permitting process.¹⁵⁷ As of 1999, USDA had completed more than 6,700 permits for more than 20,000 locations under this system.¹⁵⁸

In the regulation, "plant pest" is defined as "[a]ny living stage of [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."¹⁵⁹ Those GM products that would be subject to the FPPA regulations would be those that had

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

¹⁵⁵ *Id.* § 150dd.

¹⁵⁶ *Id.* § 150aa(c).

¹⁵⁷ Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There is Reason to Believe Are Plant Pests, 52 Fed. Reg. 22,908 (June 16, 1987) (to be codified at C.F.R. pts. 330, 560).

¹⁵⁸ See CHAIRMAN NICK SMITH, SUBCOMM. ON BASIC RESEARCH OF THE COMM. ON SCIENCE, 106TH CONG., SEEDS OF OPPORTUNITY: AN ASSESSMENT OF THE BENEFITS, SAFETY, AND OVERSIGHT OF PLANT GENOMICS AND AGRICULTURAL BIOTECHNOLOGY 26 (Comm. Print 2000) (citing Sally McCammon, USDA), available at <http://www.house.gov/science/smithreport041300.pdf>.

¹⁵⁹ 7 C.F.R. § 340.1 (2003).

been "altered or produced through genetic engineering, if the donor organism, recipient organisms, or vector agent belongs to any genera or tax designated in §340.2 and meets the definition of plant pest."¹⁶⁰

It appears, therefore, that the regulation applies to GM plants simply because they have been produced via the *process* of genetic engineering. In this sense, USDA's approach is a deviation from the OSTP policy that regulation should be product-based, and not process-based. USDA attempts to deny its divergence in both the preamble to the proposed rules and the final rules. Its reasoning, however, is unconvincing. USDA states that the rule is consistent with the Coordinated Framework because it applies to "only genetically engineered organisms or products which are plant pests or for which there is reason to believe are plant pests, and not to . . . an organism or product merely because of the process by which it was produced."¹⁶¹ Nevertheless, the language of the regulation makes clear that the trigger is the GM process, as well as meeting the plant-pesticide definition.

As USDA gained experience with GM plants, it modified its regulations to make them more consistent with the policy of minimal regulation in the absence of measurable risk. USDA, however, never moved away from its initial process-based approach. In 1992, the agency proposed a notification process by which certain organisms would not be subject to the pre-introduction permitting process.¹⁶² This process allowed plants that met certain criteria to avoid the detailed informational requirements established in the permit rule. Notification also streamlined the process, permitting applicants to introduce their plant varieties without waiting for a lengthy agency review. The six criteria used to determine eligibility for the less detailed petition process were:

- (1) whether the plant is corn, cotton, potato, soybean, tobacco or tomato;
- (2) whether the genetic material is integrated in a stable manner;
- (3) whether the function of the introduced genetic material is known and does not result in a plant disease;

¹⁶⁰ *Id.*

¹⁶¹ Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which there is Reason to Believe are Plant Pests, 52 Fed. Reg. 22,892 (July 16, 1987) (to be codified at 2 C.F.R. pts. 330, 340).

¹⁶² Genetically Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status, 57 Fed. Reg. 53,036 (proposed Nov. 6, 1992) (to be codified at 7 C.F.R. pt. 340).

- (4) whether the genetic material does not encode infectious, toxic or pharmaceutical substances;
- (5) whether the genetic material does not pose the risk of a new plant virus; and
- (6) whether the plant does not include genetic material from a known animal or human pathogen.¹⁶³

Under the notification requirement, the manufacturer or importer has the responsibility of certifying to the agency that the plant meets the six requirements.¹⁶⁴ In addition, the notifying party must inform USDA of its intention to conduct field tests thirty days in advance of such tests, and to provide information about the plant, time and place of the test.¹⁶⁵

USDA has explicitly highlighted its goal of being consistent with the OSTP and White House policy statements with the introduction of its notification system. The preamble to the proposed rule states:

This proposed rule is consistent with the overall Federal policy for the regulation of the products of biotechnology. The proposed rule would reduce regulatory constraints on certain introductions to achieve the Federal policy goal of oversight commensurate with the risk (Office of Science and Technology Policy's biotechnology oversight policy document (February 27, 1992; 57 Fed. Reg. 6753); the President's regulatory review initiative of January 28, 1992; and the Department's request for comments (February 25, 1992; 57 Fed. Reg. 6483-6484)). The proposed rule would also achieve the Federal policy goal of performance-based regulatory principles as outlined in the President's Council on Competitiveness "Report on National Biotechnology Policy" (February 1991).¹⁶⁶

In promulgating the regulation, USDA also made clear that its aim was to manage an introduced regulated article so that it or its offspring would not persist in the environment. The agency, however,

¹⁶³ See 7 C.F.R. § 340.3(b); *see also* USDA, USER'S GUIDE FOR INTRODUCING GENETICALLY ENGINEERED PLANTS AND MICROORGANISMS, TECH. BULL. NO. 1783 § IV (rev. ed. 1997), available at <http://www.aphis.usda.gov/bbep/bp/usergd.html>.

¹⁶⁴ 7 C.F.R. § 340.3(d)(2)(v) (2003).

¹⁶⁵ *Id.* § 340.3(d)(2).

¹⁶⁶ See 57 Fed. Reg. 53,036 (Nov. 6, 1992) (to be codified at 7 C.F.R. pt. 340).

stated that its experience showed that it was unnecessary for certain products to be subject to the lengthy permit process.¹⁶⁷

Industry generally supported USDA's decision to streamline the process.¹⁶⁸ Critics, however, complained that the notification process would effectively shield the release of GM plants from the public. In addition, critics charged that the move to a notification system was premature and not based on convincing data.¹⁶⁹ USDA disagreed with both of these comments, noting that the agency had a history of public involvement in decision making and that the agency was confident that the nonregulated plants did not pose a risk.¹⁷⁰

USDA amended its regulations again in 1997 to open the notification process to *any* plant species—not just the six listed—meeting the six requirements, as long as those species had similar “low risk” characteristics.¹⁷¹ In its preamble to this proposed rule, USDA revealed its enthusiasm for the technology by predicting that eventually eighty to ninety percent of all GM plants would be introduced under the simplified procedure.¹⁷² Eventually, the agency stated that it expects that as many as ninety-nine percent of all crops could be introduced by notification.¹⁷³

At the time the notification system was proposed in 1992, USDA also introduced a petition process by which parties could establish that GM products should be exempt from either the permitting or notification process. USDA uses the term “nonregulated” to refer to such plants. The petition process thus gave applicants a route for establishing that their GM products were not “plant pests” and thus

¹⁶⁷ *See id.*

¹⁶⁸ *See* 58 Fed. Reg. 17,044 (Mar. 31, 1993) (to be codified at 7 C.F.R. pt. 340).

¹⁶⁹ *Id.*

¹⁷⁰ *Id.*

¹⁷¹ Genetically Engineered Organisms and Products; Simplification of Requirements and Procedures for Genetically Engineered Organism, 62 Fed. Reg. 23,945 (May 2, 1997) (codified at 7 C.F.R. §§ 340.0, 340.3).

¹⁷² Judith E. Beach, Ph.D., *No “Killer Tomatoes”: Easing Federal Regulation of Genetically Engineered Plants*, 53 FOOD DRUG L.J. 181, 183 (1998). USDA describes the notification program in an industry guideline as being “the simplest way to obtain APHIS permission to import, move, field test a genetically engineered plant . . . applicable in the vast majority of cases.” USDA, Permitting, Notification, and Deregulation, at <http://www.aphis.usda.gov/ppq/biotech/> (last visited May 14, 2003).

¹⁷³ Beach, *supra* note 172, at 183. At the same time, it should be noted that the USDA has been working on new rules for the review of GM crops to account for the availability of GM crops, since the United States Congress updated a major plant law. *USDA: Federal GM Reviewers are ‘superficial’ and protective of big business, says report*, JUST-FOOD, Feb. 22, 2002, available at http://www.just-food.com/news_details.asp?art=47999.

were not subject to other FPPA or USDA regulations.¹⁷⁴ A successful petition for nonregulated status would be one that demonstrated that a GM product did not pose a greater plant pest risk than the unmodified organism from which it was derived.¹⁷⁵

USDA's 1997 modifications to its regulations also expanded the class of potentially nonregulated organisms. USDA stated that nonregulated status would be extended to GM plants that were "closely related" to a GM plant that had been granted nonregulated status under a petition.¹⁷⁶ Thus, once a GM plant had been granted nonregulated status under a petition, all "closely related" plants would also be exempt.¹⁷⁷ A party simply had to certify to USDA that an article was "closely related."¹⁷⁸

USDA stated that it had taken this measure to streamline further the regulatory process based on risk principles.¹⁷⁹ In its comments, the agency took the position that any such extensions of nonregulated status would be based on clear scientific evidence.¹⁸⁰ It is worth noting, however, that USDA offered no clear definition of what level of similarity would demonstrate "closely related" status or how the agency would assess whether specific gene insertions create unreasonable levels of risk.¹⁸¹ Even as USDA has implemented this provision, these standards have remained unclear.

Each of USDA's successive moves was accompanied by great agency confidence in its capacity to ensure safety even while streamlining requirements. With respect to the 1997 modifications, the deputy director for biotechnology at APHIS confidently stated that there was "no scientific evidence that genetically engineered plants present health and safety risk for humans."¹⁸² He added that "[t]he more time goes by, the more information comes in to validate ... APHIS."¹⁸³

Critics, however, have sharply criticized the 1997 modifications as opening a "huge loophole ... under which risk assessments of poten-

¹⁷⁴ 7 C.F.R. § 340.6 (2003).

¹⁷⁵ *Id.*

¹⁷⁶ 62 Fed. Reg. 23,945, 23,952 (May 2, 1997) (to be codified at 7 C.F.R. pt. 340).

¹⁷⁷ *Id.*

¹⁷⁸ *Id.*

¹⁷⁹ *Id.*

¹⁸⁰ *Id.*

¹⁸¹ 62 Fed. Reg. at 23,952.

¹⁸² *EU/US Perspectives on Labeling Genetically Engineered Foods*, FOOD CHEMICAL NEWS, June 1998, at 19 [hereinafter *EU/US Perspectives*].

¹⁸³ *Id.* (quoting Arnold Foudin, deputy director for biotechnology, APHIS).

tially dangerous new varieties would not be made."¹⁸⁴ Critics pointed out that the lack of clarity as to what organisms would be considered "closely related" opened the nonregulated status petition process to potential abuses.¹⁸⁵ At the time the rule was finalized, USDA responded that safety was ensured whether the GM organism was under a permit or a notification, or was nonregulated. USDA pointed out that any company introducing a GM product has obligations to certify that the plant or organism meets regulatory safety standards and these obligations ensure that companies will remain in compliance.¹⁸⁶ USDA further noted that it conducts inspections at various intervals of time, again ensuring compliance.¹⁸⁷

In fact, USDA's actions on GM products have been the subject of extensive criticism. Many have pointed out that the agency has an internal conflict of interest on the regulation of GM products, as it does for all newly introduced plants. Indeed, USDA's APHIS unit is responsible for issuing regulations and reviewing releases of GM organisms in the environment.¹⁸⁸ At the same time, the Agricultural Research Service ("ARS") and Agricultural Marketing Service ("AMS") of USDA are geared toward developing and promoting agricultural biotechnology in the United States and internationally. ARS, for example, is partially responsible for developing and promoting the controversial "Terminator" technology.¹⁸⁹ A division of the Food Safety Inspection Service ("FSIS") advocates the U.S. position on regulation of GM products in international fora such as Codex Alimentarius. The U.S. Codex Commission, housed in FSIS, has consistently taken a strong position that GM products pose no novel risks and should not be the subject of extensive process-based regulations.

An example of this internal conflict was on display in a speech given by Secretary of Agriculture Ann M. Veneman at the United Nations Food and Agriculture Organization's ("FAO") 31st Confer-

¹⁸⁴ 62 Fed. Reg. 23,945, 23,952 (May 2, 1997) (to be codified at 7 C.F.R. pt. 340).

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

¹⁸⁷ *Id.* at 23,953.

¹⁸⁸ See *EU/US Perspective*, *supra* note 182, at 20.

¹⁸⁹ "Terminator" technology is the popular name used to describe genetic seed sterilization, which USDA developed and patented in 1998 together with Delta & Pine Land, the world's largest cotton company. The technology is used to make the seeds of a plant sterile, so that they cannot be used for a new generation of plants. Seed sterilization was developed to allow seed companies to protect their patents on novel varieties: with the technology in place, a seed company ensures that purchasers cannot make second generation uses of the patented seeds it sells.

ence.¹⁹⁰ Secretary Veneman touted the benefits of GM crops and went so far as to promote American products: "[B]iotechnology . . . will reinvigorate productivity growth in food and agriculture production and . . . make agriculture more environmentally sustainable. Agricultural biotechnology . . . also promises much more, such as drought resistant crop varieties for Africa."¹⁹¹ To critics, such statements prove that USDA has no interest in upholding stringent regulations on the GM industry.

At the end of the Clinton Administration, then-USDA Secretary Dan Glickman acknowledged the institutional conflict of interest, and announced measures to combat its effects in decision making.¹⁹² Among the measures proposed were independent scientific reviews of USDA's biotechnology approval process, a reinforced line between agency regulatory functions and promotions of trade, and the convening of a panel of representatives from industry, farm, consumer and environmental groups to advice on issues related to GM foods.¹⁹³ With the change in Administrations, however, this proposal does not appear to have gone forward. As a result, it is not clear whether the proposal would have placated critics.

USDA has also been criticized for lax oversight on the permit applications and notification petitions it does receive. Currently, APHIS receives approximately 1,000 notifications each year from biotechnology companies wishing to field-test new transgenic plants or petitioning to have a plant deregulated altogether.¹⁹⁴ Field-testing of the vast majority of transgenic plants is conducted under the notification process introduced in the 1992 modification to the regulation.¹⁹⁵

The National Academy of Sciences ("NAS"), a nonprofit society of scholars in scientific and engineering fields, published a report in 2002 sharply criticizing USDA oversight.¹⁹⁶ The report was intended to investigate how the government evaluates the potential environ-

¹⁹⁰ Secretary of Agriculture Ann M. Veneman, Remarks at the U.N. Food and Agriculture Organization 31st Conference Plenary Session: State of Food and Agriculture, Rome, Italy (Nov. 5, 2001), available at <http://www.usda.gov/news/releases/2001/11/0222.htm>.

¹⁹¹ *Id.*

¹⁹² Bette Hileman, *News of the Week*, CHEMICAL & ENGINEERING NEWS, July 19, 1999; Secretary of Agriculture Dan Glickman, Remarks to the National Press Club (July 13, 1999), available at <http://www.usda.gov/news/releases/1999/07/0285>.

¹⁹³ Glickman, *supra* note 192.

¹⁹⁴ Press Release, National Academy of Sciences, Regulations of Transgenic Plants Should be Reinforced; Field Monitoring for Environmental Effects is Needed (Feb. 21, 2002).

¹⁹⁵ *Id.*

¹⁹⁶ *Id.*

mental risks posed by GM crops. After a detailed examination of the USDA regulatory framework, the report concluded that reviews of permit applications and notifications were "generally superficial" and that the review process "should be made significantly more transparent and rigorous," with more input from the public and external scientific experts.¹⁹⁷

Specifically, the NAS report identified an instance in which a variety of corn producing a protein with insecticidal properties was grown commercially, following a notification, without any thorough consideration by the manufacturer or the agency of the impacts of the insecticide on the environment.¹⁹⁸ In addition, NAS found fault with the fact that once USDA accepts a petition for nonregulated status, it does not conduct post-commercialization monitoring for environmental effects.¹⁹⁹ According to NAS, without such systematic monitoring, there is no way to ensure that nonregulated status is appropriate and that environmental damage has not occurred.²⁰⁰ The report also noted that the amount of information kept secret by USDA "hampers external review and transparency of the decision-making process."²⁰¹ Ultimately, NAS did not advise doing away with the notification process, but rather recommended more thorough screening of submissions so that careful reviews are conducted where merited.²⁰² At this time, it is unclear what effect, if any, the report will have on USDA procedures.

The process for petitioning for nonregulated status, introduced in 1997, has also been the subject of extensive criticism. The Natural Resources Defense Council ("NRDC"), an environmental organization, filed a petition with USDA in April 2000 to demand that the agency undertake a notice-and-comment rule-making process to establish prescriptive requirements for field testing and for supporting information necessary to support petitions for nonregulated status.²⁰³ NRDC pointed to two instances in which USDA granted petitions for nonregulated status of two varieties of virally resistant squash without

¹⁹⁷ *Id.*

¹⁹⁸ *Id.*

¹⁹⁹ Press Release, *supra* note 194.

²⁰⁰ *Id.*

²⁰¹ Jill Carroll, *Reviews of Crops Altered by Genetics Are "Superficial"*, WALL. ST. J., Feb. 21, 2002.

²⁰² *Id.*

²⁰³ Press Release, Natural Resources Defense Council, NRDC-Led Coalition Calls for USDA to Stop Environmentally Harmful Release of Genetically Engineered Crops (Apr. 26, 2000).

adequate consideration of environmental issues.²⁰⁴ In NRDC's view, nonregulated status was being granted on an ad hoc basis, without any external requirements as to the specific information that must form the basis of any agency decision making.²⁰⁵ The group accused USDA of relying on qualitative rationalizations and incomplete field studies and expressed concern that USDA's grant of nonregulated status to a variety of plants could have irreversible harmful effects on genetic diversity and on the plants' traditional counterparts.²⁰⁶ There has been no response from USDA on this matter.

Like FDA, USDA regulations have shifted as greater numbers of GM products have entered the market. The evolution of USDA's position, however, has been converse to the changes instituted by FDA. USDA began with a position that was more precautionary than the Coordinated Framework and associated policy statements, but the agency has steadily shifted to a more risk-based policy. Ultimately, this shift has meant a smaller regulatory burden for companies moving forward with GM products.

C. *Environmental Protection Agency*

EPA is the third agency with major responsibility for oversight of GM products. EPA has authority to ensure that any such products are safe for the environment and safe for human uses. Following the Coordinated Framework, EPA took the position that its existing statutory and regulatory framework under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") would be adequate for GM products.²⁰⁷

Under FIFRA, "pesticide" is defined broadly to include any substance "intended for preventing, destroying, repelling, or mitigating any pest" or "intended for use as a plant regulator, defoliant, or desiccant."²⁰⁸ To register a pesticide, the registrant must demonstrate that when used in accordance with widespread and commonly recognized practice, the pesticide will not generally cause unreasonable adverse impacts on the environment.²⁰⁹ In general, this standard requires the registrant to submit extensive information on the pesticide, as well as

²⁰⁴ *Id.*

²⁰⁵ *Id.*

²⁰⁶ *Id.*

²⁰⁷ 7 U.S.C. § 136 (2000).

²⁰⁸ *Id.* § 136(u).

²⁰⁹ *Id.* § 136c(d).

its environmental fate, potential toxicity to humans and other animals, and its potential for ecological disruption.²¹⁰

EPA has additional authority under the FFDCA, as amended by the 1996 Food Quality Protection Act, to set "tolerances"—or permissible levels—of pesticide residues on food.²¹¹ EPA is directed by statute to set a tolerance such that there is "reasonably certainty that no harm will result" from aggregate exposure to the pesticide over a lifetime.²¹² The FFDCA states that a food is adulterated if it contains a pesticide residue, unless the amount of residue is within an established tolerance.²¹³

Following the publication of the Coordinated Framework, EPA made clear that it would rely on existing regulations promulgated under FIFRA to ensure the safety of GM plants with pesticidal properties. Beyond this, EPA did not issue any further outline detailing its approach to GM products. After receiving numerous inquiries as to the data required under FIFRA for registration of GM plants, however, EPA issued a proposed policy statement in 1994.²¹⁴ The aim of the statement was to clarify the status of EPA regulations under FIFRA and FFDCA as GM plants became a market reality.²¹⁵

In the proposed policy, EPA coined the term "plant-pesticide" to refer to GM products under EPA authority. By definition, a "plant-pesticide" was a "pesticidal substance that is produced in a living plant and the genetic material necessary for the product of the pesticidal substance, where the pesticidal substance is intended for use in the living plant."²¹⁶ EPA also made clear that it considered its existing review and risk assessment procedures adequate for GM products. Like FDA, EPA stated that its approach would be product-based: "EPA indicates that it proposes to focus its regulatory attention on the plant-pesticide and not on the plant per se."²¹⁷

²¹⁰ 40 C.F.R. §§ 158.165, 158.170, 162.163 (2003).

²¹¹ 21 U.S.C. § 346(a) (2000).

²¹² *Id.* § 346(c) (2).

²¹³ In May 1997, EPA published a Supplemental Notice of Proposed Rulemaking to elicit public comments on its evaluation of the requirements imposed by the Food Quality Protection Act. Plant-Pesticide: Supplemental Notice and Proposed Rulemaking, 62 Fed. Reg. 27,132 (proposed May 16, 1997) (to be codified at 40 C.F.R. pt. 180).

²¹⁴ Proposed Policy; Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug and Cosmetic Act, 59 Fed. Reg. 60,496 (Nov. 23, 1994).

²¹⁵ *Id.*

²¹⁶ *Id.* at 60,500;

²¹⁷ *Id.* at 60,498.

To focus the agency's resources where there was greater risk, EPA's 1994 proposed policy identified a number of products that would be exempt because the risks were deemed negligible.²¹⁸ Exemptions included plants that already contained some level of the incorporated pesticide, plants that were sexually compatible with another plant containing some level of the incorporated pesticide, and those modifications that only affected the plant itself.²¹⁹ The agency's rationale was that "[i]f a plant normally produces a pesticidal substance, organisms that normally come in contact with the plant have likely been exposed to that substance in the past."²²⁰ In a further justification, the agency acknowledged that genetic modification designed to increase the levels of previously existing pesticidal proteins in plants posed the greatest risk to non-target species. Even so, the agency reflected that any such increases were not likely to result in overall significantly different exposures of the non-target organisms to the public and thus did not need to be targeted by regulation.²²¹ In addition, EPA reasoned that transfers between closely related species would not likely result in levels of toxic proteins that greatly exceeded the normal range, and that there are limits to which toxic protein can be increased without unwanted effects on other desirable characteristics of the plant.²²² Thus, EPA concluded that most plants with altered levels of plant-pesticides would not require registration.

Traditional pesticides subject to FIFRA must undergo an extensive pre-market testing regime laid out in regulations.²²³ These tests are designed to establish environmental and ecological impacts of pesticides, and predate GM technology. As written, the rules do not require testing on GM plant-specific issues such as the potential travel of the genotype into other plants or wider potential ecological effects on the food chain. Despite EPA's acknowledgement of these issues in the agency's 1994 proposed policy, the agency has never formally ad-

²¹⁸ *Id.* at 60,501.

²¹⁹ 59 Fed. Reg. at 60,502-03.

²²⁰ Proposed Policy; Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug and Cosmetic Act, 59 Fed. Reg. 60,496, 60,502 (Nov. 23, 1994).

²²¹ *Id.*

²²² *Id.* at 60,503.

²²³ Pesticide Registration Procedures; Pesticide Data Requirements, 53 Fed. Reg. 15,982 (May 4, 1988) (to be codified at 40 C.F.R. pt. 158).

dressed what kind of testing would be appropriate for plant-pesticides.²²⁴

Instead, the agency has stated that it will negotiate applicable testing requirements with manufacturers on a case by case basis.²²⁵ Thus, EPA encourages prospective plant-pesticide registrants to consult the agency on the types of information relevant to evaluating the product, though unlike FDA there is no written policy to this effect.²²⁶ The agency then assesses the health and environmental risks posed by the plant-pesticides and, where appropriate, issues a registration under FIFRA. All FIFRA registrations contain the built in safety provision that registrations issued are temporary. Thus, each registrant must apply for re-registration at periodic intervals, allowing EPA an opportunity to reevaluate the product.

In 2001, EPA published a rule finalizing elements of the 1994 publication. Inter alia, the final rule changed the name of the regulated element from "plant-pesticide" to "plant incorporated protectant."²²⁷ The nomenclature change clarified that a regulated GM plant was one *intended* to have pesticidal properties: "Plant incorporated protectant means a pesticidal substance that is intended to be produced and used in a living plant, or in the produce thereof, and the genetic material necessary for production of such a pesticidal substance."²²⁸ Thus, the definition excludes plants with chance pesticidal modifications. The 2001 rule also affirmed the exemptions contained

²²⁴ The 1994 policy promised to issue data requirements for plant-pesticides at some future date and to solicit comments from the public. *Hearing on Plant Genome Science, Subcomm. on Basic Research of the House Comm. on Science*, 106th Cong. (Oct. 19, 1999) (testimony of Janet L. Andersen, Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, EPA) [hereinafter Testimony of Janet L. Andersen], available at http://commdocs.house.gov/committees/science/hwy215140.000/hwy215140_1.htm. So far, however, this has not taken place.

²²⁵ *Id.* (reflecting that EPA works with each company to determine the appropriate data requirements).

²²⁶ 59 Fed. Reg. 60,496, 60,511 (Nov. 23, 1994). The agency also assesses the need for environmental and ecological risk data on a case by case basis. Each environmental risk assessment is based on an analysis of the properties of the engineered organism and its target environment. The degree of EPA scrutiny depends on the type of gene product and the intended mode of action. Sharlene Matten, *EPA Regulation of Plant-Pesticides and Bt Plant-Pesticide Resistance Management*, in *AGRICULTURAL BIOTECHNOLOGY AND ENVIRONMENTAL QUALITY: GENE ESCAPE AND PEST RESISTANCE* 105 (Nat'l Agric. Biotechnology Council Report No. 10, 1998), available at http://www.cals.cornell.edu/extension/nabc/pubs/nabc_10.pdf.

²²⁷ Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants, 66 Fed. Reg. 37,772 (July 19, 2001) (to be codified at 40 C.F.R. pts. 152, 174).

²²⁸ 40 C.F.R. § 152.3 (2003).

in the 1994 proposal and reiterated EPA's focus on the pesticidal aspects of the plant and not on the plant itself, remaining consistent with White House policy.

As of 1999, EPA had registered twelve plant-pesticide GM products under FIFRA.²²⁹ Because these registrations were not open to the public, the range of data reviewed by EPA is not known. As of 1999, EPA had exempted all plant-pesticides registered for food from the FFDCA tolerance requirement. The agency's justification in each case was that the pesticidal proteins originated from sources not known to be food allergens, and that the plant-pesticides were therefore not expected to be food allergens.

EPA's position on plant-incorporated pesticides came under heavy fire in 1999, after the release of a study suggesting that pollen from GM corn dusted on the leaves of milkweed killed forty-four percent of the caterpillars that fed on it. Monarch caterpillars feed exclusively on milkweed and the study appeared to show that there were significant ecological impacts that had not been considered by EPA.²³⁰ This laboratory study was later discredited for not accurately reflecting the behavior of Bt corn pollen in the field. Nevertheless, it triggered widespread focus on EPA for not recognizing the range of actual risks presented by GM technologies and not adequately monitoring compliance.²³¹

The monarch butterfly quickly became the motif of protests against the introduction of GM foods. At the 1999 hearings held by FDA, for example, protesters dressed as monarch butterflies paraded outside the hearing sites. In June 1999, the Environmental Defense Fund ("EDF") called on EPA to require sixty-foot buffer zones around fields planted with GM corn to protect butterflies.²³² According to EDF, such borders would dramatically reduce the flow of corn pollen.

In response to the monarch study, EPA scientists said that they were aware that the Bt pollen could kill insects, but did not believe the butterflies would be exposed to the toxin.²³³ EPA stated that the subsequent discrediting of the study validated its approach. Nonetheless, in January 2000, EPA issued new planting restrictions on GM

²²⁹ Testimony of Janet L. Andersen, *supra* note 224.

²³⁰ John E. Losey et al., *Transgenic Pollen Harms Monarch Larvae*, NATURE, May 20, 1999.

²³¹ See generally Thomas McGarity & Patricia Hansen, *Breeding Distrust: An Assessment And Recommendations For Improving The Regulation Of Plant Derived Genetically Modified Foods* (Jan. 11, 2001), http://www.biotech-info.net/Breeding_Distrust.html.

²³² *Buffers Urged Around Bt Corn Fields*, ENVTL. NEWS NETWORK, July 14, 1999.

²³³ *U.S. Places Restrictions on Biotech Corn*, ENVTL. NEWS NETWORK, Jan. 17, 2000.

corn which would require that the crops be mixed with conventional varieties, in part as a response to the type of concerns raised in the monarch study. Mixing GM and conventional varieties was to prevent insects from becoming resistant to the Bt toxin and to reduce exposure to other organisms, such as the monarch butterfly. The new restrictions, which EPA drafted jointly with industry, require farmers to plant at least twenty percent conventional corn in most regions, and fifty percent where cotton is grown. Seed companies are also required to expand field monitoring for signs of where insect resistance may be occurring.²³⁴

Further criticism of the agency's review practices arose after the NAS published a report in April 2000 titled "Genetically Modified Pest-Protected Plants: Science and Regulation."²³⁵ Although generally positive, the NAS report pointed out that EPA and other agencies needed to coordinate their regulatory authority over GM plant-pesticides to ensure that there were no adverse effects on human health and the environment.²³⁶ The NAS report took issue with exemptions for certain transgenic plant-pesticides in EPA's 1994 Proposed Rule and urged EPA to reconsider potential environmental impacts of these varieties.²³⁷ For example, the NAS raised the question of whether an exemption for introduction of a gene from a sexually compatible plant was advisable, given the lack of understanding of expression products.²³⁸ In addition, the NAS recommended the development of a strategy for monitoring long-term impacts of plant-protectant pesticides on human and environmental health.²³⁹

With the emergence of the StarLink corn "crisis," even more pressing questions were raised about EPA's ability to recognize risks and to monitor compliance appropriately.²⁴⁰ To critics, the StarLink episode conclusively demonstrated that EPA's approach had failed and that the agency had not adequately understood the unique risks posed by a GM product—as opposed to a conventional pesticide—in

²³⁴ *Id.*

²³⁵ See generally COMM. ON GENETICALLY MODIFIED PEST-PROTECTED PLANTS, NAT'L ACAD. OF SCI., *GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION* (2000).

²³⁶ See *id.* at 37–38.

²³⁷ *Id.*

²³⁸ *Id.*

²³⁹ *Id.* at 63.

²⁴⁰ For a detailed discussion of the development and impact of the StarLink crisis, see Dorothy Nelkin & Emily Marden, *The Starlink Controversy: The Competing Frames of Risk Disputes*, INT'L J. BIOTECHNOLOGY (forthcoming 2003).

its FIFRA review. In EPA's eyes, the episode simply represented a bad judgement that has no bearing on overall regulatory structure.

StarLink is the trade name for GM corn hybrids produced by Aventis Crop Science of Research Triangle Park, North Carolina. StarLink hybrids contain a plant-pesticide protein (Cry9C) derived from the common soil microbe *Bacillus thuringiensis* ("Bt"), which kills certain destructive pests of corn such as the European corn borer.²⁴¹ In May 1998, the originator of the technology, Plant Genetic Systems Inc. registered StarLink corn under FIFRA with EPA. The registration was subsequently transferred to AgrEvo USA and then to Aventis. At the time of the registration, Plant Genetic Systems had presented health and safety tests that it believed indicated that the Cry9C protein contained in StarLink did not resemble any known allergens. But the science of identifying potential allergens is inexact, and despite the company's protestations, EPA's Scientific Advisory Panel concluded that results did not rule out the potential for allergenicity. The agency identified two particular concerns: one test showed that Cry9C protein could survive cooking or processing and another test determined that Cry9C is hard to digest.²⁴²

Despite the uncertain data, EPA took the unusual step of issuing a "split registration," which limited use of the product to animal feed or industrial purposes—and restricted it from human use.²⁴³ The split registration required that systems be in place to prevent StarLink from entering the human food supply. Thus, growers had to agree that the corn would not be sold for food and that they would adopt practices to preserve the identity of the crop and prevent cross polli-

²⁴¹ There are several chronologies of this dispute. Information is available at the Aventis Web site, <http://www.aventis.com>, and on the Greenpeace Web site, <http://www.greenpeace.org>.

²⁴² See *Allergenicity Assessment of Cry9C BT Corn Plant Pesticide*, 64 Fed. Reg. 71,452 (Dec. 21, 1999) (discussing the history of the allergenicity assessment).

²⁴³ Issuing a split registration is a fairly common practice by EPA with conventional pesticides, as each registration specifies the crops on which the pesticide can be used. The typical split registration, before StarLink, might allow pesticide use on corn, but not on soy, for example. Split registrations had not, however, been previously used for a GM product and the agency failed to recognize the possible risk of contamination. It is worth noting that AgrEvo and then Aventis (the patent changed hands several times) asked EPA in 1999 and again in late 2000 to re-evaluate the evidence and consider registering StarLink for human uses as well. In each case, EPA's Scientific Advisory Panel noted that the data was insufficient to rule out potential allergenicity issues. See generally CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, *FDA EVALUATIONS OF CONSUMER COMPLAINTS LINKED TO FOODS ALLEGEDLY CONTAINING STARLINK CORN* (2001), available at <http://www.epa.gov/scipoly/sap/2001/july/fda.pdf>.

nation with other hybrids.²⁴⁴ In some ways, EPA appears to have issued the split registration in disregard of the ability of farmers to track their varieties and the risks of containment. From the outset, the 660-foot buffer between corn grown for human versus animal uses appeared to many to be naively insufficient.²⁴⁵

At its peak, StarLink corn was only grown on a small portion of the nation's corn acreage, and did not attract much attention. Thus, it was a surprise to consumers, regulators, and farmers alike when, in September 2000, a coalition of consumer and environmental groups called Genetic Engineering Food Alert hired Genetic ID, an independent testing laboratory, to test samples of corn products. The lab found traces of StarLink in Kraft taco shells that were widely sold under the brand name Taco Bell. As publicity mounted, StarLink continued to be detected in a range of other food products in the United States and Japan. FDA and USDA recalled contaminated food products and offered to buy remaining StarLink products from farmers. Ultimately, under pressure of negative publicity, the company voluntarily withdrew its registration so that StarLink would no longer be authorized for commercial use.

The StarLink crisis created a public challenge to the adequacy of EPA's approach to GM products. In issuing a split registration for StarLink, the agency had stated that it was acting in response to the lack of identified risks associated with the product. But this approach was implemented without consideration of whether planting restrictions would be adequately communicated to farmers, and whether agency enforcement was available. Many pointed out that contamination was inevitable given the lack of enforcement capacity at EPA.²⁴⁶ The incident resulted in public calls for validated testing procedures and mandatory pre-market reviews by experts *outside* the government.²⁴⁷

Within EPA itself, the application of the FIFRA regime has not changed. When the StarLink crisis broke, EPA was in the midst of a

²⁴⁴ Neil Harl et al., *The StarLink Situation* (July 30, 2001) (unpublished manuscript).

²⁴⁵ See, e.g., Andrew Pollack, *1999 Survey on Genetically Altered Corn Disclosed Some Improper Uses*, N.Y. TIMES, Sept. 4, 2001 (revealing that EPA was aware of containment problems with StarLink as early as 1999, just a year after the product was first commercialized).

²⁴⁶ McGarity, *supra* note 20, at 108.

²⁴⁷ ALEJANDRO E. SEGARRA & JEAN M. RAWSON, *STARLINK CORN CONTROVERSY: BACKGROUND* (Cong. Research Serv. Report No. RS20732, Jan. 10, 2001), available at <http://www.ncseonline.org/NLE/CRSreports/Agriculture/ag-101.pdf>.

reassessment of several unrelated Bt Corn and cotton products²⁴⁸ for re-registration purposes.²⁴⁹ The Bt products under consideration had not, like StarLink, been subject to split registrations. Many critics, however, had hoped that the StarLink incident would lead the agency to take a more precautionary approach to GM products of all types.

In October 2001, EPA announced that the review had confirmed that the agency's existing regulation and risk strategies were sufficient to ensure safety to the environment. The agency therefore re-registered these substances and authorized continued commercial planting for seven more years.²⁵⁰

EPA has not shifted its approach, even as challenges to the agency have emerged. EPA viewed plant-incorporated pesticides as merely an additional variety of pesticide covered under FIFRA, and takes essentially the same position today. In this sense, the EPA approach is perhaps the most accurate reflection of the vision of the drafters of the Coordinated Framework and associated policy documents.

CONCLUSION

U.S. regulatory policy on GM food and crops, as exercised by FDA, USDA, and EPA, was developed according to three basic principles adopted by successive Administrations. These principles included (1) a product-based approach, (2) treatment of GM products as being on a continuum with other agricultural innovations, and (3) the position that regulatory action should be based on demonstrable "scientific risk" rather than precaution.

For the most part, the agencies continue to adhere explicitly to these three principles. In fact, however, as the presence of GM products has increased, each agency's policy has been subject to criticism and challenges and thus been forced to evolve. FDA, for example, initially took a strong position that all regulation would be product-

²⁴⁸ This re-review did not include StarLink. As noted, the registration for this product had been voluntarily withdrawn by the company.

²⁴⁹ The reassessment was announced by EPA in Time Extension for B.t. Corn and B.t. Cotton Plant-Pesticides Expiring Registrations, 65 Fed. Reg. 48,701 (Aug. 9, 2000), and was a response to an initiative by the Clinton Administration to review policies on food biotechnology. See also Announcement of Public meeting; Opportunity to Comment on Implications of Revised Bt Crops Reassessment for Regulatory Decisions Affecting These Products, and on Potential Elements of Regulatory Options, 66 Fed. Reg. 37,227 (July 17, 2001).

²⁵⁰ See, e.g., 65 Fed. Reg. at 48,701.

based, and that the risks posed by GM products were no different than risks posed by foods produced from traditional methods. In asserting this position, FDA went so far as to presume the safety of most GM products, based on their substantial equivalence to existing products. FDA also declined to recognize asserted safety risks—such as allergenicity—in the absence of demonstrable harms. Consistent with these positions, FDA declined to embrace mandatory labeling of GM products.

As the agency responsible for ensuring the safety of the food supply, FDA's approach was subject to thoroughgoing criticism from the outset. In part as a result of these challenges, FDA has moved away from the three principles outlined by the Administration while denying any such movement. In fact, the agency continues to take a product-based approach. Based on the increasing number of GM products being developed, however, FDA has introduced a mandatory pre-market consultation program specifically for products created through bioengineering. In introducing this change, FDA was careful to insist that it has not changed its risk strategy, and that there is still no evidence that GM products are harmful. In addition, FDA now permits voluntary labeling regarding GM content, though it continues to insist that any language suggesting that GM products are different or less safe is false and misleading.

Like FDA, USDA insisted that its approach would adhere to the White House principles as GM products began to near market readiness. Despite these assurances, however, USDA initially implemented a precautionary approach for GM products, according to which it subjected them to a permit requirement. As its experience with GM products grew, USDA moved away from the precautionary approach. The department now explicitly states that it hopes to free most GM products from burdensome pre-market requirements based on the lack of risk connected to the technology. USDA has, however, retained its process-based regulatory framework and continues to rely on a permitting and notification system specifically for GM products.

For its part, EPA has remained consistently committed to the White House approach, though it too is subject to increasing pressure for change. At the time the Coordinated Framework was developed, EPA's existing regulatory framework appeared consistent with White House principles: the definition of "pesticide" contained in FIFRA was written broadly enough to include GM products without question and already had a product-based approach. Moreover, existing regulations under FIFRA were designed to regulate according to verifiable risks, consistent with the Coordinated Framework. EPA continues to ap-

proach GM products from this perspective. The Monarch butterfly and StarLink episodes, however, have raised questions about the agency's ability to consider adequately and then monitor environmental risks unique to GM products.

Ultimately, it is likely that the regulatory framework will continue to evolve. The changing nature of the technology itself, however, makes it difficult to predict the direction of future regulation. The first generation of GM products has focused primarily on improving agronomic traits for the producer, such as herbicide resistance or pest resistance. A second generation of GM products is, however, emerging. These products aim at improving food attributes such as nutritional values, color, texture, flavor, or processing properties. Products that have been promised include rice with high vitamin A content, potatoes that are less fat-absorbing during frying, and tomatoes with increased levels of flavonols. The shifting nature of these products could open the door to greater consumer receptiveness for GM products. Alternatively, if concerns about safety, labeling, or contamination are not resolved, these second generation products may not reach the commercialization stage.

In addition, ongoing conflicts in the international arena will likely impact the domestic regulatory environment. At present, groups including the Convention on Biological Diversity ("CBD"), the World Trade Organization, Codex Alimentarius, G8, the Organization for Economic Development, the World Bank, and the United Nations provide for a debate on the application and regulation of GM technology in foods and agriculture.²⁵¹

Consistent with domestic policies, the United States has thus far taken a strong position in opposition to any efforts to regulate GM technology based on the development process, or on grounds of *potential* health or environmental risks. In discussions of the Codex Alimentarius Commission ("Codex"), a joint venture of the World Health Organization and the Food and Agriculture Organization of the UN, the United States has consistently sparred with Europeans over the incorporation of the Precautionary Principle into regulation of GM technology.²⁵² In addition, the United States and its allies in the so-called "Miami Group" stood firm against efforts by the Euro-

²⁵¹ For discussion of the roles of these various groups, see George E.C. York, *Global Foods, Local Tastes and Biotechnology: The New Legal Architecture of International Agriculture Trade*, 7 COLUM. J. EUR. L. 423, 428, 454-65 (2001).

²⁵² E.g. FDA Public Meeting on the Codex Ad Hoc Intergovernmental Task Force on Food Derived from Biotechnology (Dec. 15, 1999) (memorandum on file with author).

pean Commission and others negotiating the CBD to permit non-scientific base measures to justify exclusion of GM products from entry into a country.²⁵³

With respect to labeling, the United States has warned other countries that it will consider trade sanctions in response to labeling frameworks that it regards as non-scientific based and exclusionary. The European Parliament voted in favor of mandatory labels on a food or food product containing 0.5% of a GM ingredient in July 2002,²⁵⁴ and the United States stated that the action could "seriously impair trade in agricultural biotech products."²⁵⁵

The trajectory of these conflicts is not clear. To the degree that international bodies endorse regulatory frameworks for GM products that conflict with the United States, however, there will be domestic impacts. Regulatory assurances alone cannot sell products.

²⁵³ See York, *supra* note 251.

²⁵⁴ EUR. PARL. DOC.(COM (2001) 182-C5-0380/01-2001/0180 (COD)) (2002); *see also* Press Release, Seed Quest, European Parliament Votes on Traceability and Labelling of GMOs (July 3, 2002), available at <http://www.seedquest.com/News/releases/2002/july/4622.htm>. The current E.U. labeling threshold is one percent. Brandon Mitchener, *EU Nears Stricter GMO Food Labels*, WALL ST. J., July 5, 2002, at A8. The vote was only the second step in a legislative process that could take until next year to complete.

²⁵⁵ Mitchener, *supra* note 254, at A8.