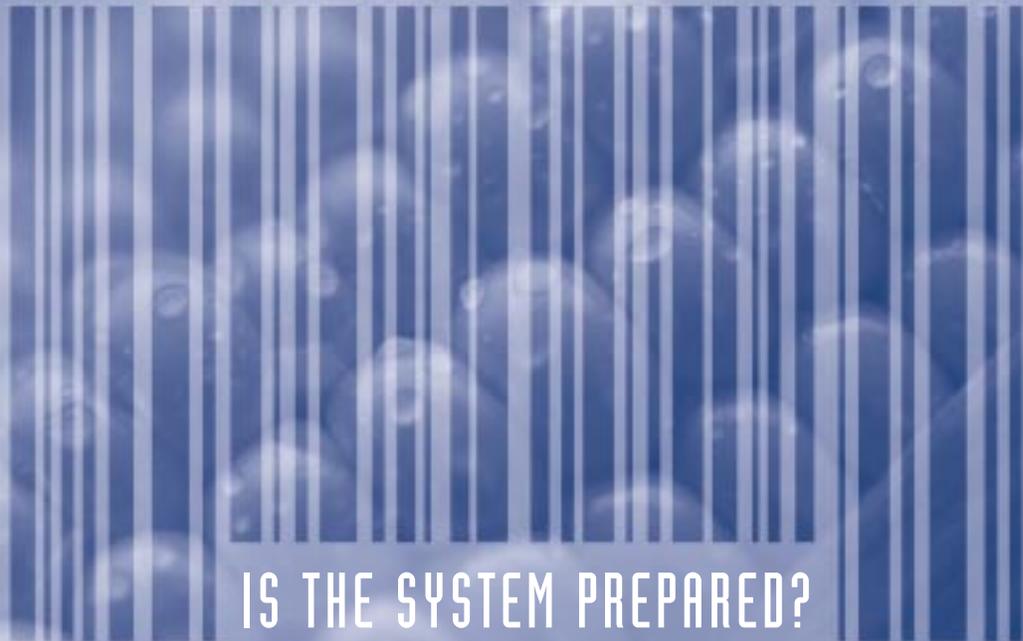




Post-Market Oversight of Biotech Foods



MICHAEL R. TAYLOR and JODY S. TICK

APRIL 2003

**A report commissioned by
the Pew Initiative on Food and Biotechnology
and prepared by
Resources for the Future**



Post-Market Oversight of Biotech Foods – Is the System Prepared?



Pew Initiative on Food and Biotechnology
1331 H Street, NW, Suite 900
Washington, DC 20005
TEL 202-347-9044
WEB www.pewagbiotech.org



Resources for the Future
1616 P Street, NW
Washington, D.C. 20036
TEL 202-328-5000
WEB www.rff.org

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Introduction

Rationale and Scope of the Report

In this report, we examine the postmarket regulatory oversight of genetically modified (GM) crops and foods by the U.S. Department of Agriculture (USDA), the U.S. Environmental Protection Agency (EPA), and the U.S. Food and Drug Administration (FDA), the three federal agencies that share responsibility for this task. As used in this report, the term “postmarket” refers to the presence of the crop or food in the environment, either released for precommercialization field trials or in the commercial marketplace. These agencies are also responsible for the premarket regulation of GM crops and foods, which includes oversight activities undertaken prior to environmental release or market entry. Both premarket and postmarket aspects of regulation are important to ensuring the safety of products for human health and the environment, and they are connected. Premarket regulation ensures that products have been adequately tested and determined to be safe under specified conditions of use before entering the environment or marketplace, whereas postmarket regulation ensures that products are used only under their authorized conditions and that any unforeseen problems are promptly detected and corrected.

Since the emergence of agricultural biotechnology in the 1980s, USDA, EPA, and FDA have devoted considerable effort to devising and implementing premarket regulatory programs. In 1986, the federal government issued the Coordinated Framework for Regulation of Biotechnology, which describes the legal and policy framework within which the regulatory agencies would make market-entry decisions about the products of biotechnology.¹ Since 1986, USDA, EPA, and FDA have each developed and implemented premarket regulatory systems for products under their jurisdictions. They devote significant resources to these programs, and issues concerning premarket regulation of biotechnology have been the subject of considerable public attention and debate.²

The Coordinated Framework does not address postmarket oversight, and the agencies have devoted much less of their attention and fewer resources to postmarket issues. This focus on premarket more than postmarket oversight is not unique to biotechnology but is common in the regulation of new food technologies and substances added to food, such as food additives, pesticides, and animal drugs. Standards for market entry of most such technologies are established by law, and under statutory mandate, government and industry pay considerable attention (and resources) to ensuring that these standards are met prior to marketing. By law, postmarket monitoring of such technologies is left to the discretion of the agencies and is relatively limited, based in part on the assumption that premarket oversight ensures the safety of the technology when used as intended. In addition, any extensive program of postmarket oversight of food-related technologies and their possible health and environmental impacts would consume significant agency resources,

1 OSTP 1986.

2 The National Academy of Sciences recently completed a study of USDA’s oversight program for field trials of biotech crops that calls for several improvements (NRC 2002). In 2001, FDA proposed important changes in its program in response to public concern about the degree of premarket control it provides (U.S. FDA 2001).

and any concerns in this area must compete for regulatory attention and resources with issues such as drug safety, farmworker health, and mad cow disease, which often are given higher priority on safety grounds.

On the basis of conclusions reached by the regulatory agencies and several expert bodies about the safety of the initial biotechnology products in food and animal feed, the products were assumed safe from the early stages.³ The Coordinated Framework initially focused on premarket

oversight issues because it was adopted before any biotech crops or foods had reached the market. The issues of greatest concern to the agencies, industry, and public in 1986 understandably involved market entry: what standards, testing, and regulatory

review process would ensure that products entering the market would be safe? Now, GM plants provide 68% of the nation's soybeans, 26% of its corn, and 69% of its cotton, and questions are being raised about how GM crops and foods are being managed in the marketplace.⁴

These postmarket issues were brought into sharp focus by the StarLink corn experience (see box, The StarLink Incident: A Challenge to the System), but scrutiny of postmarket regulatory issues would have been needed even without StarLink. Biotechnology is here to stay as a tool for farmers, and it is being developed for many other purposes beyond those underlying currently marketed products, including making higher-quality, more-nutritious foods for consumers and “growing” pharmaceuticals and industrial chemicals. Such products will raise their own challenging postmarket issues, some of which are different in kind from those posed by previous food production technologies. These issues make the nature and effectiveness of the regulatory system—premarket and postmarket—a legitimate public concern.

Layout of the Report

In the next section, Biotechnology and Its Challenges, we define what we mean by “biotechnology” for purposes of this report, describe some of the features of the technology to explain why it attracts so much public and regulatory attention, and provide a brief overview of the pipeline of biotechnology products under development—the products that will pose the postmarket regulatory issues of the future.

In the two subsequent sections, Objectives of Postmarket Oversight and Current Postmarket Oversight Regimes, we describe the purposes and status of postmarket oversight regimes at USDA, EPA, and FDA, focusing on the authority and potential reach of these regimes and the actual postmarket oversight activity in place today. Then, in Current Issues, we analyze five issues that relate to the preparedness and appropriateness of the government's postmarket oversight regime



GM plants provide 68% of the nation's soybeans, 26% of its corn, and 69% of its cotton

3 NRC 1987, 1989, 2000; WHO 1991; OECD 1993.

4 USDA NASS 2001.

for agricultural biotechnology: (1) the lack of systematic oversight by USDA of deregulated crops, (2) EPA’s approach to enforcing use restrictions on plant-incorporated protectants (like in StarLink), (3) the lack of an FDA compliance program for biotech foods, (4) the adventitious presence of genetic traits in plants for which they are not intended, and (5) identity preservation and the traceability of biotech foods. We conclude with a brief perspective on future issues.

In addition to the main report, we provide a chronology of events related to StarLink (Appendix A), a list of the people interviewed as part of our research (Appendix B), a list of the reviewers who provided feedback on early drafts of the report (Appendix C), a comprehensive list of references cited, and author biographies.

Biotechnology and Its Challenges

Agricultural Biotechnology

Biotechnology is nothing new, if we understand it as the harnessing of natural biological processes to meet human needs. Agriculture itself, going back to its prehistoric roots, is a form of biotechnology, as is conventional crossbreeding to improve food crops based on Mendel’s nineteenth-century insights on plant genetics.

The form of biotechnology addressed in this report is of more recent origin. It is based on the fundamental advances in molecular biology of the past half-century, including the discovery in the 1950s of the molecular structure of deoxyribonucleic acid (DNA) and the rapid development in recent decades of recombinant DNA (rDNA) technology. Using rDNA techniques, through the direct transfer of genetic material from one organism to another (even across species), scientists can directly alter a plant’s genome and, in turn, the plant’s composition and function. Plants modified using these techniques were first commercialized less than a decade ago, but GM soybean, corn, and cotton plants transformed to tolerate a popular herbicide or produce their own insecticide are now widely used.⁵

Such application of modern biotechnology to genetically transform plants is the “biotechnology” addressed in this report. The same techniques are being used to genetically modify animals for agricultural purposes, but the “agricultural biotechnology” addressed here includes only plants that have been genetically modified through these new rDNA techniques (referred to as GM or biotech plants) and the foods derived from those plants (referred to as GM or biotech foods). We recognize that plant varieties produced through conventional crossbreeding have also been genetically modified, often significantly, compared with their natural ancestors. These varieties are the products of biotechnology, in the sense that technological intervention is used to shape biological materials to human ends. The “GM” and “biotech” shorthand has become common

⁵ Monsanto’s Roundup Ready Soybeans were approved for sale in the United States in 1995 and first grown in 1996. Roundup Ready Cotton was first commercialized in the United States in 1997, and in 1998 DEKALB marketed the first Roundup Ready Corn (Monsanto Company 2001; Cornell Cooperative Extension 2002).

parlance, however, for describing plants that have been modified using the tools of modern biotechnology and thus are used in this report.

Practitioners and proponents of plant biotechnology often claim that, despite its novel techniques, it is just an extension of classical crossbreeding, with the advantage that it improves plants more precisely and predictably. On this basis, many contend that GM plants and GM foods raise no unique health or environmental concerns, a position that the National Academy of Sciences (NAS) and other expert bodies have generally supported as a scientific matter.⁶ This perspective influenced the basic approach the U.S. government took toward the regulation of biotechnology in 1986, which is that regulation would proceed within existing statutes and regulatory systems and that regulatory measures would be based on product-specific assessments of risk rather than the fact that the product was produced through biotechnology.⁷

What, then, is all the fuss about biotechnology? Why is it the cause of so much debate in scientific and public policy circles? Why is the examination of biotech plants and foods—specifically, the adequacy of the postmarket oversight—important? The answers lie partly in the public’s perspective on GM crops and foods, which makes determining the appropriate approach to pre- and postmarket regulation a particularly difficult task for policymakers.

Public Perspective on Biotech Crops and Foods

Although the practitioners and proponents of agricultural biotechnology claim that the technology is merely a logical extension of traditional methods, they also claim that it has the potential to transform agriculture and the food supply by making agriculture more efficient and environmentally sustainable and by providing less-expensive, more-nutritious, and higher-quality food for consumers.⁸ Some of these benefits would be achieved by meeting conventional goals, such as increased crop yields and disease resistance, with new techniques. Other potential benefits would result, however, from the unique capabilities of biotechnology; conventional methods of developing new plant varieties generally operate within species boundaries, whereas modern biotechnology can cross species lines and accomplish changes that nature cannot.

StarLink corn is one good example. It and the other varieties of GM corn that produce their own insecticide do so because a gene from the bacterium *Bacillus thuringiensis* (Bt) is inserted into the corn; the plant then produces a Bt protein that is toxic to insects but not to humans. Genes from other bacteria have been inserted into tomatoes to delay ripening.⁹ This capability of biotechnology to cross species lines, coupled with the industry’s claims about its transforming potential, makes biotechnology different from conventional plant breeding and most other food-related technologies and naturally triggers press and public interest. It has long been possible for American consumers to keep agriculture and the technologies and methods used to produce food at arm’s

6 NRC 1987, 1989, 2000; WHO 1991; OECD 1993.

7 OSTP 1986.

8 Gianessi and Carpenter 1999; Persley et al. 1999.

9 Monsanto Company completed a consultation with FDA on such a product in 1995 (Rulis 1995).

length, but biotechnology, by virtue of the media attention it has received and its inherent capabilities, makes the process of creating food more immediate for consumers. The technology is no longer “out there,” something unseen and usually unknown. In some cases, the food itself is genetically modified. From that perspective, the food and the technology have become one.

This novel aspect of biotechnology may also explain why many consumers question the safety of biotech foods. Although public confidence in the safety of the American food supply is generally high,¹⁰ in a recent survey, 65% of respondents questioned the safety of biotech foods.¹¹ Most experts, including many who are critical of biotechnology on other grounds, consider the biotech foods on the market today to be safe. Many consumers, however, draw a distinction between conventional and biotech foods on safety grounds.

Agricultural biotechnology is further distinguished in the public mind from previous technologies by the wide range of values and interests it affects beyond safety. Some people oppose the genetic modification of plants on religious or ethical grounds.¹² Some are concerned that it perpetuates a large-scale, industrialized approach to agriculture that has detrimental effects on the environment and rural communities.¹³ Others are concerned that the ownership and extensive patenting of biotechnology by large companies place too much economic control over agriculture in a relatively few hands.¹⁴ Most of these values and interests are affected to some extent by aspects of American agriculture other than biotechnology, but biotechnology has heightened concern about them in some quarters and brought them more extensively to the attention of the public and of policymakers. The safety and other public concerns and perspectives surrounding biotechnology are not the subject of this report, but they drive public interest in the regulatory system for biotech crops and foods, and they provide context for the report’s analysis of postmarket oversight.

Regulatory Perspective on Biotech Crops and Foods

Biotech and conventional food and agricultural technologies (such as chemical pesticides, animal drugs, and food additives) have important differences for regulatory purposes. These differences were revealed in the StarLink case but may be even more important in future applications of agricultural biotechnology. The differences relate directly to the practical problem of post-market control.¹⁵

One of the core concepts underlying the regulation of conventional chemical pesticides and other chemicals used in food production and processing is that EPA and FDA evaluate and approve them as safe for specific uses and under specific conditions. The effectiveness of this regulatory approach is based on farmers and other users of such chemicals being able to control their use so

10 FMI 2002.

11 Pew Initiative 2001e.

12 Alliance for Bio-Integrity 1998–2001; Holland and Johnson 1998; Pew Initiative 2001a.

13 Ecostrat 2001; Goldberg 2001.

14 Ervin et al. 2000; ETC Group 2002.

15 This discussion appeared in a preliminary issue-identification paper prepared by the authors with support from the Pew Initiative for Food and Biotechnology (Taylor and Tick 2001).

that the regulated materials enter the environment and food chain only under circumstances that have been determined to be safe. This mode of regulation also assumes the ability of regulatory agencies to verify compliance with the approved conditions of use and to take effective action against violations.

For chemical pesticides, regulators have well-established tools for maintaining control over a product's use and verifying compliance with use restrictions. EPA prescribes in the product label how a farmer can use the chemical and generally sets a quantitative tolerance level, based on extensive testing, that reflects the maximum amount of residue that should be present in the food if the chemical has been used safely and in accordance with the label. The entry of the chemical into the environment and food supply is then controlled directly by the farmer, who has legal accountability (through the enforcement activities of the states) for the use of the product in a manner inconsistent with the label. FDA can test food to determine whether the tolerance has been exceeded and can remove from commerce commodities or food products containing violative residues. FDA has an established sampling and testing program for conventional pesticide residues in food.

Crops genetically modified to contain the Bt toxin are subject to most of the same basic regulatory principles as chemical pesticides,¹⁶ but the practical task of monitoring and controlling how the pesticide enters the environment and food supply is different. The pesticide is not applied externally to the plant by a farmer who is legally obligated to follow a label; rather, it is incorporated into the plant itself as an inherent part of a living organism. This raises the possibility that, through the spread of pollen to nearby fields, the pesticidal trait might unintentionally be transferred (or "outcrossed") to other crops for which it is not approved and whose owner may unknowingly sell the crop for unapproved purposes. Outcrossing of pesticidal and other traits (such as herbicide resistance) may also have environmental consequences that merit control of how the biotech crop is used in the field. Airborne drift of chemical pesticides poses similar concerns, but the practical control problem is different because externally applied chemicals tend to wash off or degrade and do not reproduce, whereas traits incorporated into and outcrossing from a living plant can potentially spread and persist in the environment indefinitely, well beyond the farmer's control. Thus, for farmers and regulators, the outcrossing potential of plants with pesticidal traits presents control challenges quite different from those posed by conventional pesticides.

The difficulty of postmarket control of GM crops is also affected by the commingling of commodity crops. Commingling results from the nature of how most corn, soybeans, and other commodity crops are produced and traded.¹⁷ Although a portion of the crop may be segregated to meet specific commercial needs of customers, most of the production is commingled through a bulk commodity trading system that is not set up to segregate one portion of the crop from another on the basis of variety, whether it was produced from GM seed, or for regulatory purposes.

¹⁶ The primary exception is that seeds containing plant-incorporated protectants (such as the Bt toxin), inserted into crops through genetic modification, are not considered pesticides when sold to farmers and thus do not bear a label that farmers are obligated to follow.

¹⁷ Persley et al. 1999; Shipman 2002.

es, such as to distinguish corn approved only for animal use from corn intended for human consumption. The farmer—the one person in the distribution chain who knows for sure what was planted and under what regulatory restrictions—controls only his or her practices and the first sale of the crop. After that, the grain trade passes each lot of a commodity along, commingling it with others without regard to regulatory distinctions among various lots. Even in this high-volume, highly efficient bulk commodity system, well-established chemical detection methods and other measures are available to government and industry to ensure that violative levels of conventional chemical pesticides rarely reach consumers. The StarLink case revealed that the government lacks ready access to some of the detection methods required to provide similar assurance for biotech crops.

The ability to control how biotech crops are grown in the field and distributed through the food chain promises to become an even more compelling issue, partly because of the divergence in regulatory approaches and in consumer acceptance of products between the United States and some of its trading partners, such as Europe and Japan. An increasing number of crops lawfully grown and sold in the United States cannot be sold into some foreign markets due to regulatory or commercial obstacles. The regulatory system and the marketplace need to be able to differentiate products and ensure that only products approved for sale in the receiving countries are exported there.

The very nature of biotechnology and its capabilities, however, are most likely to drive heightened interest in postmarket control of GM crops and plants, whether through regulatory or market mechanisms. As explained in the next section, scientists are developing plant biotechnology for a wide range of purposes. New agronomic traits include drought and disease resistance, which may confer competitive advantages on GM plants that could pose new environmental questions that require postmarket controls on use. Improvements to the food itself include an improved nutritional profile, longer shelf life, or other benefits to consumers. Preserving the distinct identity of such foods will be necessary for regulatory and commercial reasons: to avoid unlawful misbranding of the food and to realize the food's commercial value, producers will have to be able to tell consumers what they are getting in a verifiable way.

Scientists also envision modifying crops to produce pharmaceutical or other substances that have industrial nonfood uses. At the approval stage, regulators will set the conditions under which such crops can be grown so that the trait does not inadvertently spread to other plants. Regulators will also resolve in the approval process whether any portion of crops used for these purposes can also be sold for human food or animal feed. It will be important to the safety and public acceptance of these uses of biotechnology that means exist to ensure compliance with any such conditions or restrictions.

Even in this high-volume, highly efficient bulk commodity system, well-established analytical methods and other measures ensure that violative levels of conventional chemical pesticides rarely reach consumers. The StarLink case revealed that the government lacks access to some of the basic analytical tools required to provide similar assurance for biotech crops.



Biotechnology Pipeline

The issues involved in the postmarket oversight of biotech crops and foods would be simpler if the future commercialization of biotechnology were limited to the two traits (herbicide resistance and incorporation of the insecticidal Bt toxin) and the three staple crops (soybeans, corn, and cotton) that are in widespread use today. The research-and-development pipeline for biotechnology is full, however, of a great many applications that will pose postmarket challenges of the kind already outlined here as well as others unforeseen.¹⁸

More than three dozen additional food crops have been approved for field testing, including various grains, fruits, and vegetables.¹⁹ Many of these crops are being tested with the herbicide and insect-resistance traits already in widespread use or for other agronomic purposes, such as resistance to viruses, fungi, bacteria, insects and mites, or plant nematodes or for improved performance under conditions such as drought or high soil salinity. These applications have potentially high benefits but may also require new controls to minimize possible risks to the environment.²⁰

This broad range of GM food crops is also being developed and tested for traits that would directly benefit consumers. One company has genetically modified soybean and canola plants to be high in oleic acid, a desirable form of dietary fat,²¹ and another is investigating GM tomatoes with higher levels of the antioxidant lycopene.²² Researchers are developing varieties of rice with beta carotene to combat vitamin A deficiency and with iron to prevent anemia.²³ Another company is testing wheat that has been genetically modified to reduce a common wheat allergy, and several companies have developed applications of biotechnology that can control the ripening and potentially improve the flavor and shelf life of tomatoes.²⁴ As foods with specific beneficial attributes are offered to consumers, it may be necessary to have in place some combination of regulatory and marketplace controls to ensure that consumers get what they expect and pay for.²⁵

Finally, plants are being genetically modified to produce pharmaceuticals (so-called biopharming) or other industrial nonfood substances. In Canada, hirudin, an anticoagulant agent, is already being produced commercially in transgenic plants.²⁶ In the United States, several companies are conducting biopharming field trials, most often in corn.²⁷ The National Corn Growers Association sees “pharmaceutical farming” as an example of “high-value” agriculture that could involve tens

18 For an overview of agricultural biotechnology applications under development, see Pew Initiative 2001c.

19 The food crops for which field trials have been approved include alfalfa, apple, barley, beet, carrot, cassava, coffee, corn, cranberry, cucumber, eggplant, grape, grapefruit, lettuce, melon, oat, onion, papaya, pea, peanut, pear, pepper, peppermint, persimmon, pineapple, plum, potato, rapeseed, rice, soybean, squash, strawberry, sugar cane, sunflower, sweet potato, tomato, walnut, watermelon, and wheat (Information Systems for Biotechnology 2002c).

20 NRC 2002.

21 Pew Initiative 2001c, 34.

22 Pew Initiative 2001c, 32.

23 Pew Initiative 2001c, 33.

24 Pew Initiative 2001c, 38.

25 The controls might include identity standards, labeling of consumer-oriented product attributes, and criteria for identity preservation of the specially modified food. Such controls would need consideration not only for GM crops and foods but also for ones conventionally modified in a way that is material to the consumer’s purchase decision or health.

26 Giddings et al. 2000.

27 Information Systems for Biotechnology 2002b.

of thousands of acres of corn mass-producing pharmaceuticals and vaccines.²⁸ For this to happen, however, regulators will have to address the potential of the plants with pharmaceutical traits to outcross to food crops, presumably by using buffer zones and other measures to minimize the possibility of such gene flow. USDA has already imposed such standards on biopharming field trials. One of the issues we consider in this report is whether the regulatory system is prepared to ensure compliance with such standards.

Plants that are being genetically modified to produce a wide range of substances for industrial use (enzymes and other proteins, modified starches, oils, waxes, and plastics) will present the same issues.²⁹ Bacterial cellulase, an industrial enzyme that breaks down plant cell walls and is used in alcohol production, has been produced experimentally in a GM plant.³⁰ Two chemicals used in medical and biochemical diagnostic kits—avidin and beta-glucuronidase—have been produced commercially in GM corn. Other potential industrial applications of plant biotechnology include “natural” polymers that could be used to produce useful fibers resembling silk, elastin, collagen, and keratin and that could possibly replace the conventional plastics used in such everyday items as credit cards with a biodegradable polymer. Not all of these possibilities will prove commercially feasible, but none is likely to be realized in the absence of controls to ensure that plants genetically modified for nonfood purposes do not enter the food supply, whether through biological gene flow or inadvertent physical commingling with food crops.³¹

Objectives of Postmarket Oversight

Before we discuss the current postmarket oversight programs of USDA, EPA, and FDA and the issues confronting those programs, it is important to review the objectives of postmarket oversight programs. These objectives provide the framework for analyzing how the programs are working today and whether they are prepared for the future challenges of biotechnology.

Traditional Objectives

In the previous section, we touched on the traditional and widely accepted objectives of postmarket oversight in the health and environmental regulatory arena. In general, postmarket oversight complements premarket oversight by

- fostering compliance with conditions of use or other restrictions imposed on a product during the premarket review process;
- detecting noncompliance with regulatory requirements or health and environmental problems not foreseen during premarket review;

28 NCGA 2002, 9.

29 Pew Initiative 2001c, 53.

30 Pew Initiative 2001c, 53.

31 Pew Initiative 2001c, 54–55.

- taking enforcement action to correct and, when appropriate, penalize noncompliance; and
- managing follow-up investigations, market disruptions, and other consequences of regulatory noncompliance and the discovery of unforeseen problems.

These objectives are interrelated. Fostering compliance entails providing information and guidance on the regulatory requirements so that individuals and companies clearly understand their responsibility. It also depends on the existence of a credible regulatory compliance and enforcement program. Complying with regulatory requirements can be costly and inconvenient.

Although the majority of enterprises make substantial and good-faith efforts to comply, some do not. For all parties, a credible government compliance program fosters compliance by ensuring that the costs and inconvenience of regulation are imposed fairly on all participants in a particular market and that noncompliance bears its own costs. Effective inspection and monitoring programs for detecting noncompliance are well established as tools for fostering compliance, and they provide the capability to detect unforeseen problems.



A credible government compliance program fosters compliance by ensuring that the costs and inconvenience of regulation are imposed fairly on all participants in a particular market and that noncompliance bears its own costs.

Enforcement action to correct noncompliance with a safety standard or other regulatory requirement (a product recall or seizure, a legal injunction against future noncompliance, or a withdrawal of a product license or permit) most immediately protects the health or environmental interest for which the standard or requirement was imposed. The withdrawal of StarLink seed from the market and the recall of foods containing StarLink corn protected consumers against possible allergenicity of the Bt protein in StarLink (Cry9C protein). Strong enforcement action also has an important deterrent effect and thus fosters the compliance of others, especially when fines or other penalties are imposed for intentional or negligent wrongdoing.

The final traditional objective of postmarket oversight noted above—managing investigations, market disruptions, and other consequences of noncompliance and unforeseen problems—is important for several reasons. Investigations to determine the cause of a particular problem, such as the inquiry FDA and EPA made into how StarLink entered the human food supply, can inform strategies and specific interventions to prevent the problem from recurring. Major cases of noncompliance with regulatory requirements can cause expensive market disruptions by creating uncertainty among purchasers about the safety and legality of products and, in the event of large recalls, shortages of products in the marketplace. Regulatory agencies are called upon in these cases to generate and disseminate good information about the safety and legality of products in commerce, and to respond to often intense demand for decisions and actions to minimize or end the disruption. In the StarLink case, the agencies were under particularly strong pressure to assure foreign importers that the U.S. corn they were buying was safe and lawful.

In this report, we focus heavily on the preparedness of the current postmarket regulatory regimes at USDA, EPA, and FDA to achieve these traditional objectives of postmarket regulatory oversight with respect to GM crops and foods.

Maintaining Public Confidence

Beyond these traditional regulatory objectives of postmarket oversight is one that involves the more subjective goal of maintaining public confidence in a product, a technology, the safety of the food supply, or the government's regulatory program. This objective deserves attention because public confidence is an issue important to many discussions about the regulation of biotech crops and foods. We comment briefly on public confidence as an outcome of regulatory oversight, as an objective of the regulatory system, and as a guide to regulatory decisionmaking.

There is little question that one of the outcomes of regulatory oversight of products that can affect human health and the environment is some impact on public confidence in those products. When public confidence in a regulatory program is high, as with FDA's regulation of new drugs, public confidence in the products tends to be high. Likewise, when the public sees problems in the regulatory program, confidence in the products can be weak. The Alar "apple scare" of the late 1980s stemmed in part from a prominent television news program's description of extensive delays by EPA in resolving questions about the cancer-causing potential of Alar, a chemical widely used in apple production, coupled with intensive media scrutiny and advocacy campaigns that damaged public confidence in EPA and the safety of apples. Many parents temporarily stopped serving apples to their children.

More broadly, in the food arena, regulatory oversight can affect public confidence in the food supply as a whole, or some component of it.³² This effect is subjective and difficult to measure. As a general matter, however, Americans have a fairly high level of confidence in the safety of the food supply, which is sometimes expressed as, "they wouldn't let it be sold if it weren't safe."³³ This sentiment is mirrored as fairly high public confidence in FDA and USDA, the principal agencies responsible for regulating food safety. In 1993, however, when shortcomings in the U.S. meat inspection program were revealed in the wake of a serious outbreak of food-borne disease associated with the bacterium *Escherichia coli* (E. coli) O157:H7 in ground beef, public confidence in the meat supply dropped, and the meat industry sought system improvements to restore public confidence.³⁴ Indeed, most of the major changes in the U.S. food safety regulatory system over the past 100 years have come in response to highly publicized problems that shook public confidence in the safety of the food supply or some component of it.

Public confidence in the safety of the food supply is not only affected by the regulatory system; it also is a legitimate objective of the regulatory system.³⁵ Public confidence in the safety of food is a valuable public good. It enables consumers to select a diverse, healthy diet without undue concern about the safety of the choices they make. It contributes to an environment in which new food technologies can be accepted on the basis of what they do for consumers and the food system rather than concern about safety. Confidence in the safety of the food supply is also what people want: people want peace of mind about the food they eat and serve to their families.

32 U.S. FDA and USDA 2000.

33 FMI 2002, 41.

34 Sugarman 1994.

35 This statement reflects the opinion of the authors, which has been expressed elsewhere (Taylor 2002, 190).

For purposes of this report, we assume that public confidence in the safety of the food supply is an intended and desired outcome of the postmarket oversight of biotechnology. Public confidence stands on a different footing, however, from the traditional objectives outlined above. Public confidence in food safety is affected by not only the government but also—very importantly—the food industry, public interest advocacy groups, and the media. Moreover, the contribution of the regulatory agencies to public confidence is indirect. The government’s contribution to public confidence in food safety is primarily a consequence of how regulatory agencies perform their traditional pre- and postmarket functions and, for purposes of this report, how well they achieve the traditional objectives of postmarket oversight. We focus our analysis of postmarket oversight of biotechnology on those traditional objectives and treat the desired outcome of public confidence as only part of the context for the analysis.

We thus do not treat public confidence in the food supply as an objective that should directly guide regulatory decisionmaking. In the interviews we conducted in researching this report, there was broad agreement that the government’s regulatory programs should be guided by what is required to achieve health, environmental, and other regulatory purposes rather than what some might argue is required to achieve public confidence. We keep that perspective in mind as we describe and analyze the government’s postmarket oversight of biotechnology.

Responsibility for the nature of “the government’s” current postmarket oversight of biotechnology is shared by the U.S. Congress and the executive branch agencies, principally USDA, EPA, and FDA. Some of the issues and options we discuss are addressable only through congressional action, that is, through new substantive legislative or appropriation of additional resources. Others can be addressed by the agencies under current law through their own policymaking processes or by reallocating existing resources. We recognize that, even in the latter case, any significant change in approach probably would require at least congressional acquiescence. We intend for our analysis to inform participants in both of these branches of government and to support what should be a collaborative assessment of whether and to what extent change is needed in current postmarket oversight programs.

Current Postmarket Oversight Regimes

In this section, we provide an overview of the postmarket regulatory regimes in place for biotech crops and foods at USDA, EPA, and FDA. Because postmarket oversight in this area exists largely to complement premarket regulation, the premarket roles of the agencies are described somewhat to provide needed context; the premarket regulatory regimes have been discussed in detail by others. For example, the USDA and EPA systems for making decisions about the entry of biotech crops and food into the environment or market have been discussed in recent reports from the National Research Council³⁶; the FDA system is well described in two Federal Register notices³⁷; and an accessible overview of biotechnology regulation at all three agencies is posted on the website of the Pew Initiative on Food and Biotechnology.³⁸

³⁶ NRC 2000, 2002.

³⁷ U.S. FDA 1992, 2001.

³⁸ Pew Initiative 2001b.

BASIC MISSION AND AUTHORITY

USDA oversees the environmental release of certain categories of plants, including the field testing that normally precedes the commercialization of GM crops. Within USDA, the Animal and Plant Health Inspection Service (APHIS) has regulatory responsibility for GM crops. APHIS has the very broad mission of safeguarding the animal and plant resources of the United States from pests, noxious weeds, and disease, whether domestic or international in origin. With a budget in excess of \$1 billion and more than 8,600 employees, APHIS conducts agricultural quarantine inspections at the nation's borders, monitors animal health, carries out pest- and disease-eradication efforts, and enforces animal welfare laws.³⁹ In 1987, following the publication of the Coordinated Framework, APHIS was charged “to manage and oversee regulations to ensure the safe and rapid development of the products of biotechnology.”⁴⁰ In August 2002, the APHIS biotechnology responsibilities were consolidated in a new Biotechnology Regulatory Services unit which, when fully operational, will have a budget of about \$4 million and a staff of 25, “to focus on USDA’s key role in regulating and facilitating biotechnology.”⁴¹ From a budgetary perspective, biotechnology oversight is a small part of what APHIS does.

The authority of APHIS to regulate GM crops comes from the Plant Protection Act (PPA), enacted in 2000,⁴² which consolidated and enhanced the authority in two other laws that APHIS had been using to regulate in this area, namely, the Federal Plant Pest Act and the Plant Quarantine Act. The PPA gives APHIS broad authority to regulate plant pests and noxious weeds in order to protect agriculture, public health, and the environment. APHIS uses this authority to regulate the release of GM plants into the environment. The APHIS review of such releases is the sole vehicle through which the government regulates the environmental impacts of a GM crop, unless the crop has been modified to have a pesticidal property, in which case EPA conducts its own environmental review prior to authorizing commercialization of the crop.

APHIS carries out its responsibilities for GM crops in accordance with a regulation entitled “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” (referred to as the Part 340 regulation).⁴³ This regulation was adopted under the statutes that preceded the PPA and has not been updated to reflect the PPA’s expanded purpose and authority. For example, the statutes on which APHIS (and thus the APHIS regulation) relied previously tied the agency’s jurisdiction over GM crops to the potential for a crop to be a plant pest and did not rely on the Federal Noxious Weed Act. This distinction raises the question of whether APHIS has properly exercised its statutory authority when it has considered in its review of GM plants a plant’s potential for weediness and other potential environmental considerations that do not fall within

39 See the U.S. Department of Agriculture’s FY 2003 Budget Summary (USDA n.d.). Under the Homeland Security Act of 2002, the APHIS border inspection function will be transferred to the new Department of Homeland Security. This does not directly affect APHIS oversight of GM crop field trials, but the long-term impacts, if any, are uncertain.

40 USDA APHIS n.d., “Facts about APHIS.”

41 USDA APHIS 2002.

42 The PPA was enacted as part of the Agricultural Risk Protection Act (Public Law 106–224) and is codified at Title 7, Sections 7701–7772.

43 7 CFR Part 340.

the definition of a plant pest. Such considerations have been a standard feature of the APHIS review. The PPA's definition of "noxious weed" includes any plant that "can injure or cause damage to [not only plants but also] other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment." This authority appears broad enough to cover APHIS's actions under its current program. Uncertainty about the strict legal basis for APHIS to require action as a result of its broad environmental review of GM crops under the current regulation will remain, however, until the regulation is updated to reflect the new PPA authority. In the following sections, we describe the APHIS program in practice.

PREMARKET OVERSIGHT BY APHIS

As used here to describe the APHIS regulatory program, the term "premarket" refers to activities undertaken by APHIS prior to authorizing the release of a GM crop into the environment for a

field trial or another purpose. "Postmarket" refers to activities that occur after environmental release, including activities to ensure that the conditions imposed on the field trial or other release are observed.

The APHIS Part 340 regulation, mirroring the definitions in the Federal Plant Pest Act, defines "plant pest" broadly, including known plant pests as well as virtually any

organism from a listed genus known to contain a plant pest. APHIS has concluded that an organism from a genus known to contain a plant pest could "directly or indirectly" harm a plant.⁴⁴ Because most GM crops use a genus listed in Part 340 as a donor, recipient, or vector agent, most GM crops are considered to be "regulated articles" and their developers are thus required to meet the APHIS regulatory requirements before releasing the crop into the environment through a field trial or any other means of release.⁴⁵ Developers can gain authorization for field trials through a notification process or by obtaining approval for a field trial permit. After field trials and before commercialization, it is common practice for the developer of a GM crop to petition for and obtain a determination of "nonregulated status," after which the crop is typically referred to as "deregulated."⁴⁶

44 7 CFR 340.1, Definitions.

45 7 CFR 340.0, Restrictions on the introduction of regulated articles. Some GM crops may fall outside the broad definition of "plant pest" and thus may not, legally, be regulated articles. It is common practice, however, for developers of GM crops to bring their crops into the APHIS regulatory system without regard to this legal distinction.

46 Deregulation is not, however, required for the commercialization of a GM crop, and some crops (such as ones modified to produce a pharmaceutical protein) likely will be used commercially as regulated products under an APHIS permit.



Uncertainty about the strict legal basis for APHIS to require action as a result of its broad environmental review of GM crops under the current regulation will remain until the regulation is updated to reflect the new PPA authority.

Notification is a streamlined procedure for obtaining APHIS authorization for a field trial. It is available for GM plants that meet certain eligibility criteria designed to exclude plants that are likely to pose risks to other plants or the environment.⁴⁷ In addition, the field trial must be conducted under performance standards designed to ensure the proper containment of the GM plant so that neither it nor its offspring will spread or persist in the environment.⁴⁸ Within 30 days of receiving a notification certifying that these criteria and performance standards will be met, and after receiving input from the state department of agriculture where the trial will be conducted, APHIS either acknowledges that the trial “is appropriate” under the notification procedure or denies permission for the trial to proceed.⁴⁹ Notification has become the primary vehicle for authorizing field trials of GM crops; about 95–98% of field trials proceed under the streamlined procedure.⁵⁰

Permits are available for GM plants that do not qualify for the notification procedure or are denied field trial permission in response to a notification.⁵¹ The permit application requires the submission of much more detailed information on the GM crop and how it was transformed, the purpose and manner of conduct of the field trial, and the procedures that will ensure containment during and after the trial.⁵² Permits are subject to an extensive review by APHIS designed to

47 7 CFR 340.3, Notification for the introduction of certain regulated articles. The criteria are as follows: (1) the GM plant must be of a species that is not listed as a “noxious weed” or that otherwise has not been determined by APHIS to be a weed; (2) the introduced genetic material is “stably integrated” into the genome; (3) the function of the introduced genetic material is known, and its expression in the regulated article does not result in plant disease; (4) the introduced genetic material does not cause the production of an infectious entity, encode substances that are known or likely to be toxic to nontargeted organisms, or feed or live on the plant species or encode products intended for pharmaceutical use; (5) the introduced genetic sequences derived from plant viruses meet certain criteria to ensure that they do not pose a significant risk of the creation of any new plant virus; and (6) the plant has not been modified to contain certain specified genetic material from animal or human pathogens. See 7 CFR 340.3(b), Regulated articles eligible for introduction under the notification procedure.

48 7 CFR 340.3(c), Performance standards for introductions under the notification procedure. The performance standards address (1) shipping and maintenance at destination to ensure containment, (2) inadvertent mixing with materials that are not part of the environmental release, (3) maintaining identification of the plants during the trial and devitalization of the plants after the trial, (4) precluding viable vector agents with the regulated article, (5) avoiding persistence in the environment, and (6) eliminating volunteer offspring. The sponsor of the field trial must also provide APHIS access to locations and information that will facilitate its oversight of the trial.

49 7 CFR 340.3(e), Administrative action in response to notification.

50 A. Fouldian, quoted in Ervin et al. 2000.

51 7 CFR 340(e)(5).

52 7 CFR 340.4(a), Application for permit. The application requires information about the applicant and developer; the type of permit requested; all scientific, common, and trade names and all designations necessary to identify the donor organisms, recipient organisms, vectors or vector agents, and composition of each regulated article that is a product and regulated article; descriptions of means of movement, anticipated or actual expression of altered genetic material in the regulated article, and molecular biology of the system used to produce the article; country and locality where donor and recipient organisms, vectors and agents, and the regulated article were collected, developed, and produced; the purpose of the introduction of the regulated article, quantity to be introduced, and a proposed schedule; descriptions of safeguards and processes to prevent contamination, release, escape, and dissemination of the regulated article; descriptions of intended destination, uses, and distribution of the regulated article; a description of biological material accompanying the regulated article during movement; and a description of the proposed method of final disposition of the regulated article.

ensure that the plant, as grown during the trial, is not a plant pest. If the permit is granted, the applicant must take steps to ensure containment and to provide APHIS with access to locations and information that facilitate oversight of the trial.⁵³

In 2001, APHIS authorized through the notification and permit processes 1,111 field trials for biotechnology-derived crops that covered 57,000 acres. Since 1986, APHIS has authorized through these processes more than 8,200 field trials for biotech crops.⁵⁴

Based on field-trial data and other data generated during the course of product development, developers of GM crops who want to commercialize a crop free of the restrictions imposed under the Part 340 notification and permit processes commonly file a *petition for determination of non-regulated status*.⁵⁵ The petition must include data and information that will enable APHIS to determine whether the GM crop is a plant pest.⁵⁶ APHIS also requires information to evaluate the potential environmental impact of the crop under the National Environmental Policy Act,⁵⁷ but deregulation decisions are required by law to be made under the criteria applicable to plant pests under the Part 340 regulation. If APHIS determines that the GM crop is not a plant pest, then it grants the petition and accords the crop “deregulated” status, which means that the crop and its descendants are no longer subject to regulation by APHIS under Part 340 regulations. APHIS has deregulated more than 50 crops under this procedure.⁵⁸ If the petition for deregulation is denied, then APHIS retains oversight authority, and any release of the plant into the environment—commercial or otherwise—is regulated through the notification or permit process.⁵⁹

53 7 CFR 340.4(f), Permit conditions. The conditions are as follows. (1) The regulated article shall be maintained and disposed of (when necessary) in a manner so as to prevent the dissemination and establishment of plant pests. (2) All packing material, shipping containers, and any other material accompanying the regulated article shall be treated or disposed of in such a manner so as to prevent the dissemination and establishment of plant pests. (3) The regulated article shall be kept separate from other organisms, except as specifically allowed in the permit. (4) The regulated article shall be maintained only in areas and premises specified in the permit. (5) An inspector shall be allowed access, during regular business hours, to the place where the regulated article is located and to any records relating to the introduction of the regulated article. (6) The regulated article shall, when possible, be identified with a label showing its name and date of importation. (7) The regulated article shall be subject to the application of measures determined by the administrator to be necessary to prevent its accidental or unauthorized release. (8) The regulated article shall be subject to the application of remedial measures (including disposal) determined by the administrator to be necessary to prevent the spread of plant pests. (9) A person who been issued a permit shall submit to APHIS a field test report within 6 months after termination of the field test. (10) In the event of the following occurrences, APHIS shall be notified in the specified time period and manner: (i) in the case of any accidental or unauthorized release of the regulated article, orally notified immediately on discovery and notified in writing within 24 hours; (ii) if the regulated article or associated host organism is found to have characteristics substantially different from those listed in the application for a permit or suffers any unusual occurrence (e.g., excessive mortality or morbidity, or unanticipated effect on nontargeted organisms), in writing as soon as possible but not later than 5 working days. (11) A permittee, his or her agent, or any person who seeks to import a regulated article into the United States shall (i) import or offer the regulated article for entry only at a port of entry that is designated by an asterisk in 7 CFR 319.37-14(b); (ii) notify the Biotechnology, Biologics, and Environmental Protection Division of APHIS promptly on arrival of any regulated article at a port of entry, by such means as a manifest, customs entry document, commercial invoice, waybill, broker's document, or notice form provided for such purpose; and (iii) mark and identify the regulated article in accordance with 7 CFR 340.5.

54 Information Systems for Biotechnology 2002a.

55 7 CFR 340.6, Petition for determination of nonregulated status.

56 Required information in a petition for deregulation includes a description of the biology of the unmodified recipient plant and information to identify the recipient plant in the narrowest taxonomic grouping applicable; experimental data and publications; a description of the differences in genotype between the regulated article and the unmodified recipient; a description of the phenotype of the regulated article, including any adverse or environmental consequences of introduction, such as weediness, effects on nontargeted species, and plant pest risk characteristics; and field test reports from all trials conducted under permit or notification (USDA APHIS 1996; 7 CFR 340).

57 APHIS routinely issues a Finding of No Significant Impact (FONSI) which, under NEPA, means that a complete Environmental Impact Assessment (EIA) need not be conducted.

58 For a list of the deregulated crops, see Information Systems for Biotechnology 2002b.

59 White 2002.

POSTMARKET OVERSIGHT BY APHIS

LEGAL AUTHORITY.

In addition to the authority to establish the premarket environmental release procedures just outlined, APHIS has broad powers under the PPA to investigate and take action against plant pests or noxious weeds encountered in the field (referred to here as “postmarket oversight”). It has broad authority to compile information and to conduct any investigations it considers necessary to administer and enforce the PPA. APHIS has specific authority to conduct warrantless inspections of vehicles or persons in interstate commerce believed to be carrying a plant pest and can obtain search warrants to enter any premises for the purpose of enforcing the act.⁶⁰ It can subpoena people and records to obtain the information it needs to enforce the act. APHIS can seize and destroy articles believed to be plant pests or noxious weeds and can order owners of property to treat or destroy materials that pose risks to plants, public health, or the environment. It can administratively impose civil penalties up to \$50,000 for individuals (\$1,000 for first-time offenders) and \$250,000 for corporations and other legal entities, no more than \$500,000 for all violations adjudicated in a single proceeding. Criminal remedies are also available, with fines and incarceration for up to one year.

All of these powers and remedies apply to GM crops undergoing field trials under the Part 340 regulation. In regulations governing GM crops, APHIS uses its broad legal authority to impose specific requirements to ensure that it can monitor field trials being conducted under the notification and permit procedures. The notification regulations require the sponsor of the trial to notify APHIS of any “unusual occurrence” during the trial, provide field test reports after the trial is completed, and provide access to the trial site and records relating to the trial to evaluate compliance with the criteria and performance standards governing conduct of the trial.⁶¹ The permit regulations impose similar requirements for access to the location of the trial and associated records. They also provide more specific notification requirements in the event of an accidental or unauthorized release of the test crop and reiterate the authority of APHIS to take any necessary remedial actions during the trial, including disposal of the test article, to prevent the spread of a potential plant pest or regulated article. Most significantly, the permit regulations authorize APHIS to impose any “supplemental” conditions it considers necessary to prevent the “dissemination and establishment” of plant pests.⁶²

Crops that have deregulated status are not subject to these Part 340 regulations. Under the PPA, they can be brought back within the regulatory control of APHIS if the agency determines that the crop is a plant pest or noxious weed, presumably on the basis of new information brought to the agency’s attention by the developer, a petitioner, or new analysis. APHIS, however, has no systematic program in place for monitoring plants after they are deregulated.⁶³

60 APHIS enforcement authority is subject generally to the interstate (or international) commerce requirement except that, in certain emergency situations, it can address problems in intrastate commerce.

61 7 CFR 340.3.

62 7 CFR 340.4.

63 CEQ and OSTP 2001.

POSTMARKET OVERSIGHT PROGRAM.

The APHIS Biotechnology Regulatory Services (BRS) unit has primary responsibility for managing pre- and postmarket oversight of GM crops. It collaborates with the APHIS Investigative and Enforcement Services and state departments of agriculture.⁶⁴

The postmarket oversight program consists primarily of inspecting field-trial sites to verify compliance with conditions imposed under the notification and permit regulations. Inspections are managed through two APHIS regional field offices. Inspections of sites conducting trials under the notification procedure are conducted by field personnel, who have generalist training and experience related to the broad mission of APHIS but are not biotechnology specialists. Inspections of permit trial sites are conducted by biotechnology specialists from APHIS headquarters or a state department of agriculture. The collaboration with the states is informal, and its effectiveness depends to a large extent on the relationship between the state and APHIS, which varies from state to state.⁶⁵



Inspections of permit trial sites are conducted by biotechnology specialists from APHIS headquarters or a state department of agriculture. The collaboration with the states is informal, and its effectiveness depends to a large extent on the relationship between the state and APHIS, which varies from state to state.

APHIS says it inspects annually about 10% of the notification trial sites, which are chosen for inspection on the basis of past compliance records of the institution conducting the trial and how the crop, gene, or institution involved fits with BRS's overall inspection priorities.⁶⁶ The purpose of the field-trial inspection is to determine compliance with the performance standards governing the trial, and inspections are

conducted in accordance with the *Biotechnology Inspection Manual*.⁶⁷ Inspectors review the site-specific protocols developed by those conducting the trials (referred to as trial sponsors) to ensure that the protocol is adequate to meet the performance standards, and they verify that the protocol is being followed.⁶⁸ Failure to cooperate with the inspector, have an adequate protocol, or follow the protocol can trigger compliance action, ranging from a warning to termination of the trial and destruction of the plants as well as civil penalty and criminal remedies possible under the broad enforcement powers of the PPA.

Field trials conducted under permits are considered by APHIS to pose high potential risks. APHIS attempts to inspect permit trial sites at least annually. The inspectors, highly trained biotechnology specialists, verify compliance with the general conditions for permit trials in the regulations as well as any supplemental conditions imposed on the trial through the permit process. The inspections entail collecting and reviewing the records and data the cooperator is required to keep and submit to APHIS as well as inspecting the facility to verify the containment of GM organisms.⁶⁹

64 USDA APHIS 2001; White 2002.

65 White 2002.

66 White 2002.

67 USDA MRP APHIS PPQ 2002.

68 APHIS has provided guidance for developing field-trial protocols in a guide that reflects scientifically accepted practices for the crop but allows a degree of flexibility for cooperators to adapt the protocols to their needs (USDA APHIS n.d., "User's Guide for Introducing Genetically Engineered Plants through the Notification Process"). For example, registrants have the option to choose a containment method, which could be detasseling, physical isolation, or one of the other five most commonly used methods.

69 Information Systems for Biotechnology 2002a.

As in notification trials, failure to comply with permit conditions or to otherwise create a risk to plants, public health, or the environment during a permit trial can trigger the full spectrum of PPA remedies and penalties, including permit revocation; crop destruction; and recovery by APHIS of the costs of removal, disposal, or other actions needed to solve a plant pest problem. Civil penalties and criminal prosecution are also possible, depending on the severity of the violation. APHIS encourages voluntary compliance by pursuing lesser penalties in cases in which the responsible party voluntarily reports the violation rather than being caught through inspections.⁷⁰ Although APHIS enforcement authority over field trials is robust, we have not been able to obtain documentation of the extent to which they have been used in practice or assess the degree to which compliance with the regulatory conditions attached to trials has been achieved. The 2002 soybean scare involving the failure to contain a pharmaceutical plant in a permitted field trial is the most visible example to date of how APHIS can use its enforcement authority (see box, **The ProdiGene Incident**).

The personnel and financial resources available for these inspection and compliance activities are limited. According to the APHIS website, the BRS biotechnology program at agency headquarters consists of nine biotechnologists, a branch chief, one program assistant, five regulatory permit specialists, and a chief of Biotechnology Program Operations.⁷¹ The inspectors are drawn from the general pool of APHIS inspectors, not dedicated to the biotechnology program.

We could not determine what portion of the \$4 million BRS budget or APHIS resources is devoted to postmarket activities. It appears to be modest, however, compared with the number of field trials for which APHIS is responsible because a large portion of the \$4 million must cover the costs of managing the notification, permit, and petition processes.

For GM crops that have been deregulated through the petition process and have been commercialized, there is no systematic program of postmarket oversight. These crops are not subject to regulatory control under the PPA, unless and until APHIS finds them to be a plant pest or noxious weed on the basis of new data or analysis. This means that there is no ongoing monitoring by APHIS of the potential plant pest or noxious weed, or of the environmental impacts of commercialized GM crops. In contrast, EPA's oversight of GM crops modified to have a pesticidal property (such as the Bt crops) is ongoing. The lack of ongoing monitoring by APHIS was one of the issues of concern in a recent report on regulating the environmental effects of GM plants.⁷²

70 White 2002.

71 USDA APHIS n.d., "Biotechnology Staff."

72 NRC 2002.

EPA

BASIC MISSION AND AUTHORITY

EPA's responsibility for GM crops and plants stems from its regulatory jurisdiction over agricultural pesticides,⁷³ which is applied when a plant is genetically modified to contain a pesticidal trait. EPA calls such traits plant-incorporated protectants (PIPs)⁷⁴ and regulates them under the same statutes that apply to conventional chemical pesticides. EPA's mandate is to ensure that pesticides, including PIPs, are used in a manner that protects human health and the environment. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),⁷⁵ EPA decides whether and under what conditions a PIP may be used in the field. Under the Federal Food, Drug, and Cosmetic Act (FFDCA),⁷⁶ EPA decides whether and under what conditions the pesticidal substance may be present in food. EPA's pesticide regulatory program is administered by the Office of Pesticide Programs (OPP).

PREMARKET OVERSIGHT BY EPA

Under FIFRA, EPA must authorize field testing and the commercial use of pesticides. EPA authorizes field testing by issuing experimental use permits (EUPs) that allow the use of the pesticide in the field to gather the data necessary to support an application for commercial use.⁷⁷ For PIPs that involve GM crops, EPA shares jurisdiction over field trials with APHIS, which must also authorize the trial under the notification and permit processes discussed earlier.

A pesticide cannot be sold or used commercially unless it has been approved (or "registered") by EPA for that use in response to an application submitted by the pesticide's developer or sponsor (commonly called the "registrant"). Under FIFRA, registration of a pesticide requires a finding by EPA that the pesticide will not cause "unreasonable adverse effects on the environment,"⁷⁸ which include "any unreasonable risk to man or the environment" and any dietary risk that is not allowable under the FFDCA.⁷⁹ EPA makes this determination with respect to the specific uses and conditions of use proposed by the party seeking registration,⁸⁰ and EPA has broad authority to impose additional conditions and restrictions on use as needed to avoid unreasonable adverse effects.⁸¹ As a general rule, these conditions and restrictions are reflected in the registration document for the pesticide product and are legally enforceable. For example, for GM plants containing the Bt toxin trait, EPA approved the registrations on the condition that growers maintain

73 The term "pesticide" includes "any substance ... intended for preventing, destroying, repelling, or mitigating any pest" [7 USC 136(u)].

74 U.S. EPA 2001d.

75 7 USC 136 et seq.

76 21 USC 321 and 346, as amended by the Food Quality Protection Act, Public Law 104-170.

77 40 CFR Part 172, Experimental use permits. EPA issues experimental use permits (EUPs) on the basis of a showing by the field trial sponsor that limited planting of the crop will not lead to any unreasonable adverse effects. EPA can impose various controls under EUPs that include data requirements for a notification, such as the identity of the microorganism constituting the microbial pesticide and a description of the proposed testing program; requirement of any information regarding potential adverse effects; and enforcement powers to seek penalties for violations.

78 7 USC 136a(c)(5).

79 7 USC 136a(bb).

80 7 USC 136a(a).

81 7 USC 136a(d).

“refuges” (portions of the field where a non-Bt version of the crop is planted) to minimize the development of resistance to the toxin among insects; for StarLink corn, EPA restricted its use to animal feed. For conventional chemical pesticides, use restrictions are normally included on the product label, and the farmer or other applicator of the pesticide has a legal obligation, enforceable directly by EPA, to comply with the restrictions. As discussed in the next section, the enforcement of use restrictions is handled differently for GM crops containing a PIP.

To ensure the safety of food produced from a GM plant containing a PIP, EPA cannot register a PIP unless it has granted a tolerance or exempted the PIP from the tolerance requirement under FFDCA Section 408. A tolerance establishes a limit on the amount of a pesticide or PIP that can lawfully be present in food. Tolerances are set at levels that ensure that the residue is safe, defined as a “reasonable certainty that no harm will result from aggregated exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.”⁸² EPA cannot grant a tolerance unless a practical analytical method exists for detecting and measuring pesticide levels in the food commodity produced from the treated crop.⁸³

EPA’s postmarket oversight of PIPs extends only to the enforcement of FIFRA-related requirements. FDA is responsible for enforcing the FFDCA, including any pesticide tolerances issued by EPA.



As an alternative to a tolerance, EPA can exempt a pesticide from the tolerance requirement if the same safety standard is met.⁸⁴ EPA uses this authority when it does not consider a tolerance necessary to keep exposure to the pesticide within safe levels, and in that case, EPA has the discretion not to require that a practical analytical method be available. For all Bt crops, EPA has granted tolerance exemptions for the anticipated presence of the toxin in food or animal feed and has not required an analytical method.⁸⁵

POSTMARKET OVERSIGHT BY EPA

EPA’s postmarket oversight of PIPs extends only to the enforcement of FIFRA-related requirements. FDA is responsible for enforcing the FFDCA, including any pesticide tolerances issued by EPA. EPA enforces FIFRA primarily through state agencies under the Pesticide Cooperative Agreement Program. Under this program, EPA establishes inspection and enforcement priorities and makes grants to states to support their FIFRA-enforcement activities.

⁸² 21 USC 346a(b)(2).

⁸³ 21 USC 346a(b)(3).

⁸⁴ 21 USC 346a(c).

⁸⁵ In the StarLink case, EPA did not grant a tolerance or tolerance exemption for the presence of the Cry9C protein in human food because it had not approved StarLink corn for human use and thus did not anticipate the presence of the Cry9C protein in the human food supply.

LEGAL AUTHORITY.

Under FIFRA, EPA has extensive and complex legal authority to enforce the terms of a pesticide registration against the registrant and users of the pesticide.⁸⁶ EPA can cancel the registration and stop sale of a product if its registrant violates the terms and conditions of the registration. The use of a pesticide by any person in violation of the conditions and restrictions in the label is a violation of federal law. To investigate and correct violations of registration or label conditions, EPA can

- require that registrants and applicators of restricted (more risky) pesticides keep detailed records;
- inspect establishments where pesticides are made, stored, or sold and be given access to records kept there; and
- enter premises where restricted pesticides are used.

EPA can impose civil penalties up to \$5,500 per violation for registrants or commercial applicators and up to \$1,100 for private applicators (such as farmers) after a warning for a first offense. EPA also can seek criminal penalties for knowing violations, with fines and prison up to \$55,000 and one year for registrants and commercial applicators and \$1,100 and 30 days for private applicators.⁸⁷ Other postmarket legal authority available to EPA includes the authority to require adverse effect reporting by registrants and to require registrants to generate and submit data (“data call-in”) on newly identified safety or environmental issues in order to continue their registration.⁸⁸

Because FIFRA gives the states primary enforcement authority, they typically enact their own pesticide laws that are generally consistent with FIFRA. Because FIFRA does not authorize entry onto farms to monitor compliance with labeled use restrictions on pesticides, such access to monitor compliance with refuge requirements or an animal feed restriction (as in the case of StarLink) is a matter of state law.

POSTMARKET OVERSIGHT PROGRAM.

As noted earlier, EPA’s postmarket oversight program is managed through cooperative agreements with the states based on priorities established by EPA’s OPP and Office of Enforcement and Compliance Assurance. The priorities are established in a guidance document that sets goals for the compliance and enforcement programs and provides guidance on preferred approaches to enforcement and on activities that are eligible to receive funding under the cooperative agreements.⁸⁹ The current OPP guidance document focuses on four areas affecting health and environmental protection: worker safety, applicator certification, water quality protection, and

⁸⁶ 7 USC 136f, Books and records; 136g, Inspection of establishments; 136i–1, Pesticide recordkeeping; 136j, Unlawful acts; 136k, Stop sale, use, removal, and seizure; 136l, Penalties; 136q, Storage, disposal, transportation, and recall.

⁸⁷ McDonnell 2002.

⁸⁸ 7 USC 136a, Registration.

⁸⁹ U.S. EPA n.d.

endangered species protection; PIPs and FIFRA enforcement with respect to PIPs are not mentioned. These activities are thus not funded by EPA in its grants to the states, and the states conduct little, if any, compliance and enforcement activity with respect to PIPs.

EPA's compliance program for Bt crops is based on enforcement against the registrant of its obligations under the registration. As a condition of registration, registrants of Bt crops must enter into a contractual agreement with every farmer who buys Bt seed, according to which the farmer agrees to plant a refuge to minimize the development of Bt resistance in insects. EPA does not consider the bags of seed purchased by the farmer to be a pesticide. Thus, the bags of Bt seed do not bear a FIFRA label, and the farmer is under no legal obligation to EPA to comply with the planting restrictions.⁹⁰ In this approach, the farmer's legal obligation is to the seed company and the registrant under private contract law, through the so-called grower agreement. Under these agreements, farmers agree to "compliance assistance visits" and "compliance assessment visits" by the registrants, and a farmer can lose the right to purchase Bt seed in the future by not complying with the refuge requirement and other restrictions. This system includes independent compliance surveys to verify overall compliance with the refuge requirement, and in the absence of compliance rates EPA considers acceptable, EPA can cancel or decline to renew the registration. The effectiveness of this approach to enforcement is one of the issues we analyze in **Current Issues**.

Because EPA relies on the efforts of registrants to enforce PIP use restrictions and because the cooperative agreement program with the states does not address biotechnology, the agency essentially devotes zero compliance and enforcement resources to the postmarket oversight of PIPs. This approach reflects at least three considerations:

- EPA has determined that the four priority areas identified in OPP's guidance document are higher priority health and environmental concerns.
- The total funds available to fund the state programs is small, approximately \$20 million, and thus must be allocated carefully to have any real effect.
- EPA considers the grower agreement approach a viable alternative to any realistically achievable government compliance program.

In addition, the Bt crops are registered by EPA for limited periods of time and thus must be reregistered periodically. The registrants are required to collect and submit data on how the crops have been used and the impacts they may have had on such environmental concerns as the development of resistance to the pesticidal crops in targeted insect pests and the effects of the crops on nontargeted species. Reregistration gives EPA the opportunity to reevaluate whether products have been used as intended and whether they have adverse impacts, and to consider this information in deciding whether and under which circumstances the use of the products should be continued. This process serves as a surrogate for information that could theoretically be gathered through traditional compliance and monitoring.

90 U.S. EPA 2001d.

BASIC MISSION AND AUTHORITY

FDA has broad jurisdiction over the food safety aspects of GM foods other than the pesticidal traits that EPA regulates. FDA regulates GM foods under the food additive and general food safety provisions of the FFDCFA.⁹¹ Under these provisions, FDA can take action to remove any food from the market that contains an added substance that may be injurious to health, and the law requires premarket approval of most substances intentionally added to food, unless the substance is generally recognized as safe (GRAS).⁹² The FDA's regulation of biotech foods is managed by the agency's Center for Food Safety and Applied Nutrition (CFSAN), whose overall mission is to "protect consumers by ensuring that the nation's food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled."⁹³

PREMARKET OVERSIGHT BY FDA

FDA's approach to premarket oversight of biotech foods is described in a policy statement issued in 1992.⁹⁴ The policy describes the scientific evaluation that the agency expects developers of GM plants to conduct to determine whether their products are safe and whether any safety question might cause the GM food not to be GRAS and thus require premarket approval as a food additive. Under this policy, FDA presumes that a traditional whole food, such as a tomato, is GRAS and that a GM food remains GRAS if it is "substantially equivalent" to its conventional counterpart. A GM food is substantially equivalent to a conventional one if the genetic modification has not resulted in any compositional change in the plant that would raise a safety question, such as the addition of a novel protein or the elevation of the level of a potentially toxic substance significantly above naturally occurring levels.⁹⁵ If such a change has been made, then the added substance may be considered a food additive and require premarket review and approval through a statutory process that empowers FDA to impose any conditions of use it deems necessary to ensure the food's safety.⁹⁶ Food additive petitions are required by law to include a "practicable method" for determining the quantity of the additive in food.⁹⁷ If genetic modification does not produce a change in the food sufficient to make it a food additive, then there is no statutory or other legal requirement for premarket approval or any premarket involvement by FDA.

In light of the novelty of the scientific and regulatory issues posed by GM foods and the discretion accorded to developers of new foods to make their own initial safety determinations, FDA created in the 1992 policy statement a voluntary notification process through which FDA and

91 21 USC 321(s), 342, and 348.

92 21 CFR Parts 170 and 171.

93 U.S. FDA CFSAN 2001a.

94 U.S. FDA 1992.

95 Other circumstances under which FDA could require premarket review and approval of biotechnology-derived products include the following: (1) the gene transfer produces unexpected genetic effects; (2) nutrients in the bioengineered food differ from those in traditional varieties; (3) the sources of the newly introduced genetic material come from a food plant associated with allergies; (4) the food contains marker genes that theoretically may reduce the therapeutic effects of clinically useful antibiotics; (5) the plants are developed to make substances such as pharmaceuticals or polymers, and will also be used for food; or (6) the food to be used for animal feed has different nutrients or toxicants (Vogt and Parish 1999). Whether FDA will require premarket review and approval is determined on a case-by-case basis according to information submitted by the sponsor in its voluntary premarket notification.

96 21 USC 348(c)(1)(A).

97 21 USC 348(b)(2)(D).

developers of GM foods could consult and FDA could review the basis of the developers' determinations of substantial equivalence. All GM foods under FDA's jurisdiction have entered the market through this voluntary consultation process.⁹⁸ As of October 2002, FDA had completed 55 consultations.⁹⁹ Of these, 28 were for corn, canola, rice, soybean, sugar beet, and other crops genetically modified to be herbicide resistant. Sixteen covered the safety of the nonpesticidal component of crops modified to incorporate the Bt trait of resistance to insects. The remainder included modifications to slow the ripening of tomatoes, make squash and papaya resistant to viruses, improve the fatty acid profile of canola, and reduce phytate in animal feed.

At the successful conclusion of this process, FDA issues a letter stating that it has reviewed the developer's submission and has no questions. The agency does not make its own safety judgment, impose conditions on food use, or require any analytical method be provided by the sponsor. In response to public concern about the voluntary nature of the consultation process, in January 2001, FDA proposed to make the notification mandatory but left other features of the process unchanged.¹⁰⁰

POSTMARKET OVERSIGHT BY FDA

FDA's overall food regulatory program is responsible for the safety and labeling of the entire American food supply except meat and poultry. About 50,000 food manufacturing, processing, and storage establishments and a high volume of food imports are overseen by a field staff of about 1,700 people, including inspectors, laboratory technicians, and administrative personnel.¹⁰¹ FDA's legal authority for the postmarket oversight of biotech foods is the same as its authority for other foods under its jurisdiction. To date, FDA has not found it necessary to establish a separate postmarket oversight program for biotech foods.

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LEGAL AUTHORITY.

FDA's authority to conduct postmarket compliance monitoring and enforcement in the food safety area is grounded in the FFDCAs as enacted in 1938. It does not include some of the authority that APHIS and EPA have under PPA and FIFRA. For example, FDA does not have broad access to records, lacks subpoena authority for foods, and cannot stop sales or recall orders; however, it can request voluntary recalls to remove a food from the market. The agency also lacks the authority to impose civil penalties for violations of food safety requirements. FDA can, however, conduct warrantless inspections of places where food is being made, held, or sold

98 In one instance, a selectable marker gene used in the production of tomatoes and other crops was reviewed and approved by FDA as a food additive. 21 CFR 173.170.

99 U.S. FDA CFSAN 2002b.

100 U.S. FDA 2001.

101 U.S. GAO 2001a.

and can collect and analyze product samples.¹⁰² With proper evidence of a safety problem, it can go to court to seize unsafe products,¹⁰³ enjoin their further manufacture and distribution,¹⁰⁴ or seek criminal penalties.¹⁰⁵

POSTMARKET OVERSIGHT PROGRAM.

FDA has no planned postmarket oversight program for biotech foods. As observed in its response to the StarLink incident, FDA has substantial capabilities to react to postmarket problems and can divert laboratory, inspection, and compliance resources to address such problems as needed. The agency does not, however, conduct any product sampling or inspection related to biotech foods. This distinction reflects FDA's sense of the relative priority of biotech foods in relation to other foods from a public health and regulatory perspective.¹⁰⁶ The issues raised by the lack of an FDA postmarket oversight system are discussed as part of the next section, **Current Issues**.

Current Issues

In this section, we identify and analyze five issues that present potential problems in the current system of postmarket oversight for GM crops and foods. The issues cut across all three agencies and involve the basic structure of the current system as well as more specific policy and regulatory problems. While not exhaustive of the potential post-market oversight issues, the ones presented here cover the topics that, based on the authors' research and judgment, are most likely to be of continuing interest and concern to the agencies and their constituencies.

The purpose of this analysis is to inform policymakers and constituents about the issues, not to recommend or advocate specific policy or program change. As revealed in the preceding section, **Current Postmarket Oversight Regimes**, the agencies devote relatively little effort to the postmarket oversight of biotech foods. We explore the rationale for this approach and speculate on how it might hold up in the future as new applications of biotechnology emerge from the development pipeline. We also examine two current policy issues: management of the adventitious presence of GM traits, and the identity preservation or traceability of GM crops and foods. These issues are important in their own right today and promise to become increasingly important as the number and diversity of GM crops and foods increase. We believe that they also reflect broader issues that will in part determine society's response to biotechnology—particularly issues of control and choice—that are beyond the scope of this paper but that certainly will affect how the government ultimately handles the postmarket oversight of GM crops and foods. We reveal some of the complexities and competing considerations embedded in these issues.

¹⁰² 21 USC 374.

¹⁰³ 21 USC 334.

¹⁰⁴ 21 USC 332.

¹⁰⁵ 21 USC 333.

¹⁰⁶ U.S. FDA CFSAN 2002a

Lack of Systematic Oversight of “Deregulated” Crops by USDA

ISSUE

Once APHIS clears a GM crop for unrestricted release, movement, and import by granting it “deregulated” status, the agency lacks authority under current regulations to impose conditions on its use, including requirements that someone—the developer of the crop or other parties—monitor its environmental impact. Additionally, APHIS has no program of its own to monitor the environmental impact of deregulated GM crops. Should APHIS retain postmarket control over GM crops that are currently being granted deregulated status in order to require postmarket monitoring by the crop’s sponsors and users or to carry out its own monitoring program?

ANALYSIS

CONTRAST OF APHIS APPROACH WITH EPA.

The APHIS approach to clearing a GM crop for unrestricted release, which in most cases amounts to clearing the crop for commercialization, is not a typical regulatory approach. As a general rule, regulatory agencies making market-entry decisions do not declare the product “deregulated” but rather retain and commonly exercise authority to impose conditions on the use of the product and, in some cases, to require monitoring, reporting of potential adverse effects, or both. This is true of FDA’s regulation of food additives and drugs, as well as EPA’s approach to regulating PIPs and pesticides in general under FIFRA.

EPA retains jurisdiction over and routinely imposes conditions on the use of products registered under FIFRA, including requirements for the monitoring of environmental impacts and data collection to inform future regulatory decisionmaking about the product. For PIPs produced in Bt crops, EPA has approved registrations on the condition that each registrant collect and submit to EPA data on whether the PIPs harm nontargeted insect species and on how Bt affects resistance among targeted insect species. Moreover, Bt registrations are time limited and require renewal based on whether the data collected by the registrant continue to show that the products do not pose unreasonable risks to the environment.

EPA’s clear authority under FIFRA to impose such conditions is justified by the inherent nature of pesticides: by design, they are toxic to some form of life and thus require tight control to ensure that they do not pose unreasonable risks. The use of this authority over Bt crops is further justified by the novelty of some of the environmental issues the crops pose and the difficulty of resolving all such issues conclusively in premarket testing and risk assessment. Data generated from large-scale commercial use may be the only way to provide adequate, long-term assurance that the products are not posing unreasonable risk to human health or to the environment.¹⁰⁷

107 NRC 2002, chapter 6

GM crops that do not contain pesticides may not pose the same toxicity issues as PIPs and thus, depending on other features of the plant, may or may not warrant the same regulatory control as PIPs. The case for postmarket oversight to detect adverse environmental impacts, however, is based on the scientific difficulty of anticipating or ruling out all potential impacts at the time of first commercialization. Although the products APHIS has deregulated so far may be unlikely to cause future harm to plants, public health, or the environment, making this prediction with respect to the growing number and diversity of GM crops that will go through the APHIS process in coming years may be more difficult. Bt is the only EPA-regulated trait that is in widespread commercial use. Most of the products in the development pipeline do not have pesticidal properties. They thus will go through the APHIS Part 340 process and receive their only regulatory oversight for environmental impacts under a system that does not generally allow for monitoring and other postmarket oversight of commercial crops.¹⁰⁸

THE NATIONAL ACADEMY OF SCIENCES (NAS) REPORT.

The lack of systematic monitoring of GM crops is addressed in some detail in *Environmental Effects of Transgenic Plants*, a 2002 report by the National Research Council (NRC) and published by NAS.¹⁰⁹ The report addresses several issues surrounding the notification, permit, and deregulation processes, including the need for postcommercialization testing (to validate the precommercial risk assessment that led to the product's approval) and the monitoring of environmental effects (to verify that what was predicted occurs and to detect unforeseen effects). It presents a rationale for the postcommercial monitoring and validation testing of transgenic crops, grounded in principles of quality control and in the inherent scientific difficulty and uncertainty of predicting systemic ecological effects on the basis of field trials that are necessarily small relative to the commercial scale. It states, "APHIS's regulatory process has never led to the release of a transgenic plant that clearly caused environmental damage. However, without systematic monitoring, the lack of evidence of damage is not necessarily lack of damage."¹¹⁰

On this basis, the report recommends postcommercialization validation testing and environmental monitoring of GM crops.¹¹¹ It suggests specific approaches to such testing and monitoring and calls for the involvement of all public constituents and an independent body separate from APHIS in the development of monitoring programs. It notes some of the difficulties of conducting such monitoring, including the expense, the lack of baseline data, the general lack of an adequate environmental monitoring program for agricultural and natural ecosystems, and insufficient numbers of trained people to conduct environmental monitoring. It also stresses the need for a process that "allows clear regulatory responses to findings from environmental monitoring."¹¹² Retaining post-market regulatory control in this fashion would require a fundamental change in the APHIS approach to the regulation of GM crops and possibly legislative change.

¹⁰⁸ The exception would be a crop that is required to remain under permit because of some identified risk and that, economically, can be used for commercial purposes under the permit restrictions.

¹⁰⁹ NRC 2002.

¹¹⁰ NRC 2002, 168.

¹¹¹ NRC 2002, 192–218.

¹¹² NRC 2002, 218.

QUESTIONS FOR POLICYMAKERS AND CONSTITUENTS.

In considering a change to a system with stronger postmarket oversight (including postcommercialization testing and monitoring), APHIS, other policymakers, and constituents would have to address several questions, including the following:

- Do the potential environmental risks (and surrounding uncertainties) associated with nonpesticidal GM crops warrant postcommercialization validation testing and environmental monitoring?
- If such testing and monitoring are appropriate for GM crops, should they be required for all new plant varieties with similar new traits introduced by mutagenesis or other more conventional means?
- Is there a basis for across-the-board postcommercialization testing and monitoring of GM crops, or should they be done on a case-by-case basis, when specific potential risks justify it?
- What potential risks justify heightened postmarket oversight—risks associated with outcrossing through pollen drift? toxic or other effects on nonplant species?
- Under what circumstances is the potential outcrossing of transgenes an environmental concern that justifies monitoring? Should such monitoring address the simple presence of transgenes in nontargeted plants or some specific environmental consequence of outcrossing (such as the creation of herbicide-resistant weeds)?
- Who should conduct and pay for monitoring—the developer of the product? the user? APHIS? some other body?
- In considering possible postmarket controls, what consideration should be given to the benefits of the GM crop?
- Who should develop the baseline data that may be required to conduct meaningful monitoring of the environmental effects of GM crops? Is investment in developing such data a public-sector (government) function? a private-sector task? a shared responsibility?
- Do the analytical methods and other technical tools that would be required for effective monitoring exist?
- What, if any, new legislation would APHIS need to conduct or require postcommercialization testing and monitoring for crops that it is currently deregulating? Does APHIS have the legal option to keep crops under permit, following the completion of field trials, to impose such controls?

- Does APHIS have the financial and personnel resources required to carry out a postcommercialization testing and monitoring program?
- What regulatory options should be available to APHIS to act on the basis of postcommercialization testing and monitoring data? What standards should govern actions by APHIS to reduce plant and environmental risk based on postcommercialization data?

POSSIBLE PATHWAYS.

These risk assessment and risk management questions are difficult to answer. Determining the nature and degree of potential environmental risks and characterizing the attendant uncertainties is a risk assessment problem. Determining who should conduct monitoring and what should be done with the results (including what degree of risk might justify heightened postmarket oversight and regulatory action) is a risk management problem. In the NAS report, NAS strongly suggests that there are risks worth worrying about, especially with regard to future developments in agricultural biotechnology.

In light of these circumstances, policymakers could choose from among several paths, without necessarily being limited to one:

- Do nothing, presumably based on a judgment that the premarket oversight by APHIS is sufficient (or could be adequately improved) to minimize postmarket risks.
- Collect information on environmental impacts that is readily available from public sources and encourage developers and users of GM crops to submit monitoring and impact data voluntarily.
- Invest in the generation of data required to establish environmental baselines for assessing the impacts of GM crops.
- Invest in the research and generation of data required to better assess potential risks to the environment from specific GM crops.¹¹³
- Establish a program to require postcommercialization testing and monitoring of GM crops that under the current system would be deregulated, on a case-by-case basis, as APHIS determines is necessary.
- Establish an across-the-board postcommercialization testing and monitoring program for GM crops.

¹¹³ A current research program jointly administered by the USDA Cooperative State Research, Education, and Extension Service and the Agricultural Research Service is the Biotechnology Risk Assessment Research Grants Program (BRARGP). By funding university-based research projects, BRARGP assists federal regulatory agencies in making science-based decisions about the safety of introducing into the environment GM organisms, including plants, microorganisms, fungi, bacteria, viruses, arthropods, fish, birds, mammals, and other animals. The amount available for support of this program in FY 2002 (approximately \$1.5 million) is projected to double in FY 2003 (USDA CSREES and ARS n.d.).

CONSTITUENT PERSPECTIVES.

The choice of any one of these pathways has significant policy implications, resource implications, or both and thus likely will be made through a public process and with constituent input. Some analysts and constituents consider the current system to be working adequately and believe that the biosafety risk assessments conducted prior to field trials are thorough enough to ensure the safety of GM plants.¹¹⁴ In a statement made in response to the NAS report, however, the administrator of APHIS seemed to embrace the need for change, saying that many of the suggestions either were being put into place or were being considered, adding, “APHIS is currently assessing options for monitoring already commercialized transgenic plant products. The agency can already bring the organisms back under regulation if a plant pest risk is discovered. However, the agency is considering whether it may be appropriate in some instances for research agencies to gather additional environmental information through nonregulatory means.”¹¹⁵

One proponent of the nonregulatory approach says that it is in a company’s best interest to report any adverse environmental effects from its product after deregulation to ensure the integrity of the product as well as the viability of developing new biotech plants in the future.¹¹⁶ The Biotechnology Industry Organization (BIO) put the NAS report and the current system in a positive light, supporting the “overall tone and tenor of the NAS document” and saying that the report “confirms the effectiveness of a comprehensive regulatory system that has been in place for more than a decade, and which has reviewed and granted more than 30,000 field permits without a single incidence of injury to human health or the environment.”¹¹⁷

The environmental and consumer communities tend to share NAS’s concern about the lack of a systematic, mandatory approach to monitoring. Three representatives, in a letter to Secretary Veneman, stated, “The NAS report makes a strong case for post-commercialization field research to monitor ecological and environmental impacts, both over time and across landscapes. This sound and important recommendation is crucial and will require USDA to set aside adequate resources...”¹¹⁸

114 Persley et al. 1999.

115 USDA 2002a.

116 Porter 2002.

117 BIO 2002.

118 Mellon et al. 2002.

EPA's Approach to Enforcing Use Restrictions on PIPs

ISSUE

No direct regulatory accountability exists between the grower and EPA regarding compliance with PIP use restrictions, unlike for traditional pesticides. Instead, EPA has regulatory accountability only over the registrant; grower accountability is established contractually between the farmer and the registrant through “grower agreements.” Is this private contractual approach to enforcement adequate to ensure compliance with use restrictions that EPA has established to achieve important public purposes?

ANALYSIS

THE PRACTICAL ENFORCEMENT PROBLEM.

The PIP products on the market today all involve corn or cotton plants genetically modified to produce Bt toxin for purposes of insect control. The enforcement issue is important with respect to Bt because of the extensive adoption of Bt corn and Bt cotton by U.S. farmers and because the ability to impose use restrictions has been an important factor in EPA's decisions to allow the marketing of Bt crops. Limiting StarLink's approval to animal feed and industrial use was one

such restriction, and the failure of the regulatory and grain trading and processing system to keep StarLink corn out of the human food supply has made the enforcement of PIP use restrictions an important issue. The general consensus among the people we interviewed in government, industry, and the broader constituent community is that in the StarLink case, too little attention was paid to achieving compliance with the animal- or industrial-use restriction, and the system failed.

One likely reason for that failure is that, even though growers and the company selling StarLink agreed not to grow or sell the product for human use, the registrant's educational and outreach program for growers was not implemented thoroughly enough to ensure grower compliance.

Perhaps more important for the future, however, is the requirement that all Bt corn and Bt cotton crops be planted with non-Bt refuges as part of an insect resistance management (IRM) plan. In this case, affirmative compliance programs are in place, and no Bt crop is likely to be approved and marketed in the future without one.¹¹⁹ We thus focus our analysis on the enforcement of the Bt IRM use restriction. However, the same issues would arise with respect to any future PIP that has potential to produce adverse environmental impacts or poses a food safety concern and that



The general consensus among the people we interviewed in government, industry, and the broader constituent community is that in the StarLink case, too little attention was paid to achieving compliance with the animal- or industrial-use restriction, and the system failed.

¹¹⁹ The development of insect resistance is biologically unavoidable for any insecticide, whether a conventional chemical insecticide or one produced by a plant as a result of genetic modification. Insect resistance associated with Bt crops has been a particular concern to EPA because the conventionally derived Bt toxin is one of the few insecticides widely accepted and used in organic crop production. A significant increase in Bt resistance would reduce the utility of this insect-control agent for which the organic farming industry has few alternatives.

EPA decides should be managed through restrictions on use. If such restrictions are needed to ensure that the product satisfies the FIFRA standard of posing no unreasonable adverse effects on the environment or to protect food safety, compliance with the restrictions will be important to ensure public safety and public confidence in biotechnology.

As discussed earlier, the need to rely on private enforcement through grower agreements arises, as a legal matter, from EPA's categorization of the GM seed sold to farmers as a "treated article" rather than a pesticide product. Conventional pesticide products bear a pesticide label with which the grower is legally required to comply. PIPs do not bear such a label, so the grower has no direct legal or regulatory accountability to EPA for compliance. EPA has legal leverage over the registrants, stemming from EPA's authority under FIFRA not only to require that IRM programs be established in accordance with EPA's specifications but also to revoke or refuse to renew registrations if the programs do not meet EPA's specifications as designed and implemented.

In analyzing EPA's approach to enforcing PIP use restrictions, it is important to recognize the practical limitations on EPA's ability to directly enforce pesticide use restrictions, whether on PIPs or conventional pesticides, even if there were no legal constraint. For example, of more than 400,000 U.S. farms that grow corn for grain, some 18% planted Bt corn.¹²⁰ The limited resources available for FIFRA enforcement would make it impossible for EPA and its state enforcement partners to directly monitor these growers for compliance with Bt refuge requirements at a meaningful level, especially given the other high-priority FIFRA enforcement needs to which EPA currently allocates resources. This resource limitation is compounded by the historical resistance of growers to on-farm government enforcement of FIFRA, which creates a real political obstacle to strong government enforcement of PIP use restrictions. Thus EPA has good reason to consider private enforcement the only practical alternative.

IRM COMPLIANCE ASSURANCE PROGRAMS.

To address this practical compliance problem, EPA has required companies registering Bt products to establish IRM plans and compliance assurance programs (CAPs) as a condition of registration. EPA's requirements for IRM CAPs for Bt crops and the biotechnology industry's response to these requirements are still evolving.

In October 2001, EPA announced its decision to renew registrations for Bt corn and provided new guidance on the elements of an acceptable IRM plan and CAP for Bt corn.¹²¹ EPA established refuge requirements that it concluded would be adequate to minimize the development of insect resistance to Bt under various circumstances (a non-Bt refuge equal to at least 20% of the Bt corn plantings within a half-mile of the Bt plantings). Registrants were then required to adopt a program to ensure that the refuge requirements were met, consisting principally of grower education, grower agreements (under which the grower is bound contractually to comply with EPA's refuge requirements), and a CAP.

¹²⁰ USDA NASS 2001; USDA ERS 2002.

¹²¹ U.S. EPA 2001b.

The registrant's CAP must be designed to evaluate the extent to which growers comply with the refuge requirements and to take "such actions as are reasonably needed" to ensure that growers who do not comply "either do so in the future or lose their access to the Bt corn product."¹²² The CAPs should include guidance for such elements as

- training for the registrant's representatives who make on-farm visits to assess compliance with the refuge requirements,
- a system for the registrant to investigate tips and complaints about noncompliance,
- a "phased compliance approach" under which first-time violations trigger remedial measures by the registrant to gain compliance and failure to comply two years in a row results in the registrant denying the product to the grower the next year,
- an annual statistical survey conducted by an independent third party to measure the degree of compliance, and
- monitoring conducted by registrants to detect the emergence of insect resistance to Bt.¹²³

Registrants are required to coordinate their compliance programs because the failure of any one customer to comply could induce resistance despite others' compliance. EPA's October 2001 registration document described these elements in fairly general terms, expecting that the registrants would flesh out the details in their own CAPs.

In essence, this system makes the registrants the enforcers of regulatory requirements that EPA has established under FIFRA to minimize environmental impact. This approach has generated some controversy; EPA's Scientific Advisory Panel (SAP) has stated that reliance on industry to monitor and enforce compliance was "a major problem" but ultimately endorsed EPA's general approach.¹²⁴ In January 2002, a coalition of companies holding Bt corn registrations, collaborating through the Agricultural Biotechnology Stewardship Technical Committee (ABSTC), submitted to EPA *Bt Corn IRM Compliance Assurance Program for 2002*.¹²⁵ This detailed document describes how the companies would implement each of the elements prescribed by EPA. It includes, for example, criteria for deeming a tip or complaint of noncompliance "legitimate" and thus worthy of investigation; criteria for considering deviations significant and details on the remedial measures registrants would take to gain compliance depending on the significance of the deviation; and the circumstances under which a grower would be denied access to Bt corn.

In March 2002, the Center for Science in the Public Interest (CSPI) submitted to EPA detailed comments on the industry CAP.¹²⁶ CSPI announced that the CAP requirements in EPA's October 2002 reregistration document "showed promise as an effective means of assessing and responding to noncompliance" but characterized the "actual implementation" described in the industry's plan as "grossly inadequate." CSPI called for stronger approaches to detecting noncompliance, for example, through more effective use of field inspections and more liberal approaches to investigating tips and complaints. It also criticized the criteria for categorizing significant violations as being too narrow and recommended that the situations that result in denial of access to Bt corn be broadened.

122 U.S. EPA 2001b, V 12.

123 U.S. EPA 2001b, V 7–20.

124 U.S. EPA 2001b, IID 12.

125 ABSTC 2002a.

126 Jaffe 2002.

In June 2002, EPA provided the ABSTC comments on the industry CAP.¹²⁷ EPA called for strengthening the program in several ways to improve the likelihood that noncompliance would be detected, to broaden the criteria for deeming a violation significant, and to strengthen and bring more industry-wide consistency to the registrants' response to noncompliance. This latter improvement would include more intensive remedial measures and the possibility of denying growers access to Bt on a regional basis if noncompliance is abnormally high in any given area. In response, the ABSTC made some but not all of the adjustments in the CAP requested by EPA.¹²⁸ EPA found the revised CAP "acceptable" but noted that "improvements may be necessary in the future depending on how these programs actually function."¹²⁹

LEVEL OF COMPLIANCE ACHIEVED TO DATE.

One key measure of the success of the private contractual approach to ensuring grower compliance with PIP use restrictions is the level of compliance achieved. Bt crop registrants are required not only to implement a program for ensuring compliance but also to measure compliance through grower surveys. In January 2002, ABSTC submitted to EPA the results of its *Bt Corn Insect Resistance Management Grower Survey* for the 2001 growing season.¹³⁰ This statistically representative telephone survey reflected the responses of 552 corn growers, and results were stratified across four regions. Growers responded anonymously. Nationwide, 87% of growers reported planting the minimum required refuge size. Of this 87%, 92% reported planting the refuge within the required distance of the Bt planting, which means that 80% of corn growers nationwide reported full compliance with refuge requirements in the 2001 growing season. ABSTC reported a nationwide compliance rate of 71% for the 2000 growing season.¹³¹

80% of corn growers nationwide reported full compliance with refuge requirements in the 2001 growing season. ABSTC reported a nationwide compliance rate of 71% for the 2000 growing season.



The data reported by ABSTC do not permit the regional calculation of the percentage of farmers who complied with both the size and distance requirements. Rates of compliance with the refuge size requirement were reported regionally and ranged from a low of 77% in the South¹³² to a high of 90% in the Corn Belt.¹³³ The regional compliance rates for distance (from a low of 81% in the South to a high of 91% in the Corn Belt) were reported only as a percentage of all growers, rather than of growers known to have complied also with the size requirement. If one assumes that those national rates of compliance with the distance requirement approximate the regional rate of compliance by growers who also complied with the size requirement, then the regional rates of total compliance would range from about 62% in the South to about 82% in the Corn Belt.

127 Andersen 2002.
128 Abramson 2002.
129 Andersen 2002.
130 ABSTC 2002b.
131 ABSTC 2001.

132 Including Tennessee, North and South Carolina, and Mississippi.
133 Encompassing eastern Iowa and northern Illinois.

These data are informative, but they do not by themselves provide a sufficient basis for evaluating the adequacy of the current approach to ensuring compliance with PIP use restrictions. First, it is difficult to know how reliable the survey is as a measure of actual compliance. It relies on self-reporting by growers of their failure to comply with a contractual obligation, knowing that the failure to comply could cause them to lose access to a valued technology. Although the survey was conducted anonymously, it places complete reliance on the ability of farmers to accurately report activities that may have occurred months in the past and their willingness to report noncompliance. Some underreporting is possible.¹³⁴ Moreover, the compliance rates are not correlated with the corn acreage of each farmer, so it is impossible to assess compliance as a percentage of the total corn crop.

Second, neither EPA nor ABSTC has established a standard for what constitutes an adequate level of compliance. This may simply reflect scientific uncertainty about the relationship between rates of refuge compliance and development of insect resistance. EPA acknowledges that some noncompliance is inevitable and that some level of noncompliance can be tolerated without significantly increasing the risk of resistance.¹³⁵ It is not clear scientifically, however, what an acceptable level of noncompliance would be, and under FIFRA, a regulatory standard on this issue would require a complex balancing of costs and benefits that may not be feasible to undertake.

Third, the adequacy of the current approach should be assessed in part on the basis of what could be accomplished with other approaches. It is impossible to know, however, what level of compliance would be achieved by an approach that relied on government inspectors and direct enforcement against farmers or on some hybrid approach, such as one that combined some direct government enforcement with the private contractual approach. For practical reasons (resource and political constraints), it is difficult to imagine that a government-only approach to grower compliance would be more effective than the current one. The strength of the current approach is that it taps into the self-interest of the technology providers and the growers in maintaining the effectiveness of Bt for insect control. The other weakness of relying on government enforcement alone is that the imposition of penalties against farmers requires at least one warning and involves negligible fines.

QUESTIONS FOR POLICYMAKERS AND CONSTITUENTS.

The experience to date raises several questions for policymakers and constituents concerning the future enforcement of PIP use restrictions. Although our analysis focuses on IRM-related restrictions, several important questions relate to enforcement of any PIP use restriction that EPA may impose in the future, whether for environmental or food safety purposes. With respect to food safety, after the StarLink incident, EPA declared that it would no longer approve a PIP for animal use that was not also approved for human use, thus presumably avoiding the need to enforce a split use restriction. This stance has not been codified by EPA in any binding or formal way,

¹³⁴ EPA expressed a similar concern in October 2001 when it reregistered Bt corn: "Without confirmatory visits to individual farms (i.e., audits), it is impossible to verify the accuracy of grower responses" (U.S. EPA 2001b, IID 12).

¹³⁵ U.S. EPA 2001b, IID 11.

however, and it is unclear whether EPA will be able legally to maintain this policy if it encounters a PIP in a crop that is suitable and intended only for animal use and fully satisfies all FIFRA and FDCA requirements for that use.

In such a context, the practical ability of growers and others to comply with (and EPA to enforce) use restrictions will include:

- Is EPA's reliance on private contractual obligations to enforce PIP use restrictions fundamentally sound for the long term? Will compliance results be acceptable? Will they be publicly credible?
- Will this approach be as effective and credible when (in contrast to managing Bt resistance) the interest underlying the PIP use restriction is one that involves no direct economic benefit to the technology provider or grower, such as biodiversity protection, impact on nontargeted species, or food safety?
- Are there feasible ways to improve the effectiveness and credibility of the current approach at a reasonable cost, such as supplementing it with on-farm confirmatory audits or setting standards or targets for compliance that must be met on a regional as well as a national basis?
- Are there any feasible alternatives to the current approach, that is, ones that would not place primary reliance on private enforcement through grower agreements?
- Should the option of direct government enforcement be retained to back up the private enforcement approach? Is EPA's current position (not to subject the grower to legal accountability) one the agency could change, or would legislation be required?

POSSIBLE PATHWAYS.

It is unclear from our analysis what, if any, fundamental changes are required in EPA's approach to enforcing PIP use restrictions. Experience can and will bring improvements in the CAP specifics for IRM-related restrictions on Bt crops. Ultimately, the adequacy of the current approach probably will be judged on the basis of whether and how rapidly resistance to Bt develops. If resistance develops more rapidly than expected or to a greater extent in areas with relatively low compliance rates, then the current compliance approach likely will come under intense scrutiny and criticism; if the IRM program proves successful over time, then the current enforcement approach will likely gain credibility and support.

In response to the questions posed above, possible pathways include the following:

- Hold the current course; consider and make incremental improvements in the current program for the enforcement of IRM use restrictions, but otherwise retain the fundamental approach.
- Have registrants conduct on-farm compliance audits as part of an effort to determine the effectiveness of the current program.

- Increase private and public investment in IRM to increase the chance that potential problems are detected early.
- Add a public component to the current compliance program, presumably involving on-farm compliance inspections by states on EPA's behalf, with whatever increases in resources and legal authority would be required to do that in a meaningful way.

CONSTITUENT PERSPECTIVES.

The on-farm government enforcement of pesticide use restrictions has serious practical and political constraints, as reflected in the perspectives of constituents on the issue of how PIP use restrictions should be enforced. No major constituent we interviewed called for a fundamental shift from private to public enforcement of PIP use restrictions. One farmer representative affirmed that farmers would likely reject use of GM crops rather than accept on-farm government inspections but also acknowledged, in the context of StarLink, the importance of compliance with use restrictions and suggested a greater investment of government resources to ensure compliance.¹³⁶

The companies developing and marketing Bt crops affirm that “promoting compliance with IRM requirements is of overriding importance to both registrants and farmers alike.”¹³⁷ They support the current approach to compliance through grower agreements and private CAPs, citing the economic incentive growers and registrants have to minimize resistance and preserve the effectiveness of the Bt crops.

Environmental and consumer groups such as CSPI have been critical of how the current program is being implemented but call for improvement in the system rather than a fundamental shift away from private enforcement. In a September 2001 comment to EPA on the overall IRM program, Environmental Defense said it was “to the agency’s credit” that it required IRM plans but criticized the size and location elements of the refuge requirements as inadequate to prevent the development of Bt resistance in insects.¹³⁸ The group also recommended strengthening the current requirements for resistance monitoring, compliance assurance, and remedial action, calling them “not up to the task.”

¹³⁶ Frederickson 2002.

¹³⁷ ABSTC 2002a, 1.

¹³⁸ Goldberg 2001.

Lack of an FDA Compliance Program for Biotech Foods

ISSUE

FDA is responsible for enforcing EPA's pesticide tolerances and tolerance exemptions as well as FDCA food safety provisions as they apply to and govern the market entry of nonpesticidal GM crops. FDA also has jurisdiction over the safety and labeling of all food products made from GM crops or ingredients other than meat, poultry, and processed egg products, which are regulated by USDA. FDA currently has no affirmative postmarket inspection or compliance program for GM crops or foods. Should FDA establish such a program?

ANALYSIS

This issue was raised by the StarLink incident, in which the unlawful presence of StarLink corn in human food was first detected by an advocacy group and would not have been detected by the regulatory system due to a lack of a regulatory monitoring system. FDA lacked an analytical method that would have enabled it to find StarLink corn, had it chosen to look. In considering whether FDA should establish a postmarket oversight program, it is important to examine the scope of FDA's jurisdiction, the agency's other priorities, the rationale for the current lack of oversight, and the issues that might justify oversight.

Practical scope of FDA's jurisdiction.

The biotech products and issues potentially subject to postmarket oversight by FDA fall into three categories:

- Bt crops and foods made from Bt crops, to ensure they are covered by an EPA tolerance or tolerance exemption (food products containing StarLink corn are in this category);
- nonpesticidal GM crops and food products produced from these crops, to verify whether they have passed through FDA's voluntary consultation process and whether any such crops or foods in the market pose a safety concern (this category includes crops genetically modified to be herbicide resistant and foods made from these crops); and
- any food product made from a pesticidal or nonpesticidal GM crop and non-GM foods labeled as "GM free," to enforce applicable labeling requirements.



FDA'S BUDGET CONSTRAINTS AND PRIORITY SETTING.

FDA's food regulatory jurisdiction is broad and challenging. It includes most of the food supply, some 50,000 domestic food processing and storage establishments, millions of import shipments annually, and many pressing food safety problems, including the persistent problem of food-borne disease associated with the microbiological contamination of food and the more recent threat of bioterrorism. Despite FDA's broad and difficult mission, the budget for its food regulatory program historically has been tight. The total budget in FY 2002 was \$405 million, nearly \$100 million of which came in a supplemental appropriation earmarked for addressing bioterrorism. In recent

years, with its available resources, FDA has achieved an average inspection frequency of about once every five years for domestic food establishments and only 1–2% of imports.

Due to budget constraints, FDA must constantly set priorities and adjust the use of its resources. FDA's food priorities for FY 2002

are heavily weighted toward activities that directly address significant food safety problems, such as food-borne disease and bioterrorism threats.¹³⁹ In the biotech area, FDA's priorities focus on premarket oversight, including ensuring that allergenicity issues are resolved scientifically before GM foods enter the market.



The bigger issue, however, is the lack of an ongoing, affirmative FDA compliance program to monitor the food supply for potential violations of safety or labeling requirements.

RATIONALE FOR THE LACK OF AN AFFIRMATIVE FDA COMPLIANCE PROGRAM.

In the StarLink case, FDA demonstrated its capacity to marshal resources and take compliance action in response to a specific problem involving GM foods. The bigger issue, however, is the lack of an ongoing, affirmative FDA compliance program to monitor the food supply for potential violations of safety or labeling requirements. FDA has such programs for the residues of conventional pesticides in foods as well as other categories of food and potential food regulatory compliance problems, such as seafood safety; the microbiological safety of juice, fresh produce, and other foods; compliance of infant formula with premarket review, good manufacturing practice and labeling requirements; and the labeling and safety of dietary supplements.¹⁴⁰ These compliance programs generally include work plans for inspections and other surveillance activities, criteria for bringing enforcement actions, and designated resources to carry out the programs.

Several factors help explain why FDA does not have such a program for biotech crops and foods:

- FDA relies on its premarket notification and consultation process to provide the agency with information on the GM crops and foods entering the market under its jurisdiction. Based on its review of that information, coupled with the absence of reports of adverse health effects

139 U.S. FDA CFSAN 2002a.

140 U.S. FDA 2002.

associated with these products after several years of marketing, FDA determines that they do not to pose any food safety concern and do not require postmarket oversight or a compliance program to protect public health.

- FDA's labeling policy for GM foods does not require routine labeling of the products as genetically modified. Thus, there is no FDA-required biotech labeling in the marketplace and consequently no need for a compliance program for such labeling.
- FDA does not have analytical methods that would enable the agency to conduct routine sampling and testing of GM foods, and its premarket oversight program does not require the technology provider to supply such methods.¹⁴¹ The development of such methods by FDA would require a considerable investment of resources, in part because, in many cases, the methods would have to be specific to the crop, the modification, and the kinds of processed food products to be monitored.
- Postmarket oversight of GM foods is a low priority for FDA because there has not been a clearly defined public health or consumer protection rationale for it, and the agency has chosen to address other higher-priority problems with its limited resources.

POSSIBLE ISSUES THAT MIGHT JUSTIFY POSTMARKET OVERSIGHT BY FDA.

In light of the StarLink incident and the nature of the biotech crops that are in the development pipeline, several issues might be candidates for postmarket oversight by FDA now or in the future. Some potentially relate to safety and some more to regulatory compliance and public confidence. They are offered to foster discussion.

Market entry of nonpesticidal crops.

FDA's current regulatory program for biotech foods is premised on essentially universal cooperation by the biotechnology industry with the voluntary notification system. Two possible functions of postmarket oversight by FDA would be to (1) identify any GM products in the market that have not gone through the voluntary notification and consultation process so that their safety could be evaluated and a determination made on whether the product triggers the approval process for food additives and (2) verify that products that have entered the market through the existing process conform to the descriptions and analyses provided to FDA regarding the details of the inserted gene construct, the composition of the resulting food, and any other safety-related attribute. Oversight activities might include inspection of seed companies and marketplace sampling of food products. FDA and the major biotechnology companies believe that all the GM

¹⁴¹ FDA could request the provision of an analytical method as part of its premarket notification process, but it has not done so, and FDA lacks the legal authority to require a method in the context of that voluntary process.

crops and foods that have entered the market under FDA's jurisdiction have done so through the notification process. The value of postmarket oversight would be to verify that the process is working as intended and claimed and to detect any cases of noncompliance.

This issue presents several practical problems for FDA oversight:

- FDA lacks analytical methods that would permit screening the food supply for each of the specific gene constructs that are known to have entered the market; however, no substantial technical barriers to developing such methods exist.
- If traits enter the market without FDA's knowledge, the technical obstacles to oversight are significant; no generic methods would permit FDA to distinguish generally between GM and non-GM crops and foods.
- When methods are available, the amount of sampling and testing required to detect relatively rare events would be large and expensive; this approach assumes that any such testing would focus on the raw agricultural commodities of potential concern, but the methodological and cost constraints would be even greater if FDA were to attempt to monitor processed foods with multiple ingredients.
- FDA lacks the authority to examine food industry records that might document whether GM ingredients are present in products.
- FDA's inspection force is already overextended and focused on more readily demonstrable safety concerns.

The presence of GM crops and products where they do not belong.

Under several situations, GM crops and foods that are lawful for sale in the United States and have met applicable safety standards for their intended use could enter the food supply under conditions that are unlawful or undesirable and disruptive. These situations, when unintended, are sometimes referred to as involving the "adventitious presence" of the GM crop or food, a subject that is discussed separately in **Adventitious Presence of Genetic Traits in Nontargeted Crops and Foods**. When such situations involve Bt or any future pesticidal trait subject to mandatory premarket review by EPA, the presence of the pesticidal compound in a food for which it is not approved (such as in the StarLink case) is unlawful. In other cases, the adventitious presence of a GM trait may be disruptive without being illegal (such as the presence of approved GM crops in export channels when not approved for sale in the receiving country).

Using traditional food crops to "grow" pharmaceuticals or chemicals for industrial use is a possible future issue of adventitious presence. Although GM crops used to produce such substances are expected to remain subject to APHIS permitting and oversight while in the ground, the presence in the food supply of the crops or the substances they produce would raise legal and regulatory issues for FDA and also could be quite disruptive of the food supply because of the likely consumer rejection of food potentially contaminated with such substances, regardless of the

degree of actual safety concern. The marketplace reaction to potentially contaminated soybeans in the case of ProdiGene Inc. illustrated this point. Postmarket oversight activities in such cases might include inspection of the grain trading and processing system (to ensure that the containment and segregation required for legal compliance are observed) and the sampling of food products in the marketplace. In situations involving legal and regulatory issues, the value of postmarket oversight would be to create incentives for compliance and to detect violations; in situations involving potential disruption, the value would be to have some basis for maintaining confidence in the system by commercial participants and consumers and for responding to problems when they arise.

This issue presents several practical problems for FDA oversight:

- FDA lacks the analytical methods and required resources and continues to have competing priorities, as outlined for the previous issue.
- The government is still developing a policy to address adventitious presence; the policy aspects of this issue are discussed separately in *Adventitious Presence of Genetic Traits in Nontargeted Crops and Foods*.

Imports of GM crops and foods.

As the commercial use of biotechnology expands internationally, the likelihood that GM crops and foods produced elsewhere will be offered for import into the United States will increase. If not approved in the United States (in cases where such approval is required) and if not adequately reviewed for safety in the exporting country, such crops and foods could pose legal and food safety concerns. GM crops and foods are not required to be labeled as such, and thus imported GM products will not be readily identifiable. Because of the sensitivity of the U.S. marketplace to biotechnology issues, major importers may take steps to ensure that they are aware of whether the product is from a GM source and that the product can be lawfully and safely used in the United States. FDA oversight likely would include the agency's use of its authority to detain and inspect imports and reject products that "appear" to be adulterated or misbranded. The value of oversight in this case is the same as in any situation: to provide incentives for compliance with food safety laws, and to detect and address possible violations.

This issue presents several practical problems for FDA oversight:

- FDA would face the same problems as for the previously mentioned possible issues of FDA postmarket oversight.
- The diversity of possible foreign sources of GM foods is great. No information base on GM traits and foods that might be offered for import, however, exists to serve as a starting point for targeting surveillance activities.¹⁴²

¹⁴² The Biosafety Protocol, an international agreement negotiated in 2000 under the United Nation's Convention on Biological Diversity, would establish an information clearinghouse within a framework that would ensure transparent and accountable oversight of the international movement of "living modified organisms" (including some GM crops and foods). The protocol has not been ratified, and the United States is neither a signatory to the protocol nor a member of the convention (United Nations 2000).

Enforcement of GM-related labeling rules.

Although there is no labeling requirement for GM crops and foods under U.S. law, FDA policy requires labeling if the product is materially different to consumers in terms of safety (for example, possible allergenicity), nutritional attributes, or some other manner. In addition, FDA has provided draft guidance on the conditions under which a product may be labeled “genetically modified” or “GM free.”¹⁴³ One newspaper sampled food products labeled as GM free and found some to contain GM ingredients, suggesting the need for oversight and possible enforcement.¹⁴⁴ Postmarket oversight in labeling typically involves the sampling of products and product labeling to evaluate compliance with labeling rules and investigation in response to complaints from consumers or competitors. As products that bear or should bear GM-related labeling enter the market, compliance oversight and enforcement of labeling rules would be valuable to foster compliance and ensure that consumers can rely on labels to make informed choices and protect their safety.

This issue presents the same practical problems for FDA oversight as for the other issues; of those issues, lack of analytical methods and lack of access to food industry records pose the most significant obstacles to enforcement.

QUESTIONS FOR POLICYMAKERS AND CONSTITUENTS.

The issue of whether FDA should develop a postmarket oversight program may be different today than it was 2 years ago and is likely to be different 2 years and 10 years from now as the range of GM products expands and public concerns evolve. The factors that will determine the need for such a program are likely to remain the same: public health priorities, resources, technical and practical feasibility, and the importance placed on public confidence and FDA’s role in maintaining it. Although many constituents argue that specific regulatory decisions should be based on science and public health, the goal of maintaining public confidence in the regulatory system and a technology frequently influences resource allocation and the establishment of new programs.

These factors suggest the questions policymakers and constituents may be asking now and in the future:

- Do food safety or other consumer protection interests warrant FDA’s investment of resources in postmarket oversight of GM foods and crops, taking into account other priorities?
- Does some other justification for FDA oversight, such as avoiding market disruptions, justify providing FDA additional resources earmarked for that purpose?
- Can the technical constraints on postmarket oversight (for example, the need for practicable analytical methods for the full range of commercial gene traits and the large number of samples required to monitor compliance in the conventional fashion) be overcome? at what cost? to be borne by whom?

¹⁴³ Though labeled “draft,” the guidance is the operative policy of the agency (U.S. FDA CFSAN 2001).

¹⁴⁴ Callahan 2001.

- Might technological advances or new compliance strategies (such as private third-party testing and certification) overcome or compensate for the current constraints on postmarket oversight by FDA?
- Does FDA have all the legal tools it needs to conduct effective postmarket oversight?
- Is maintaining public confidence in the food supply, in biotechnology, or in FDA a sufficient basis for FDA to establish a postmarket oversight program?

POSSIBLE PATHWAYS.

Whether to pursue the development of an FDA postmarket oversight program will depend on answers to the preceding questions as well as others. If such a program is worth pursuing, possible pathways include the following:

- Require technology providers to develop and make available to FDA practicable analytical methods that could be used to monitor the presence of GM traits in crops, food products, or both.
- Develop FDA’s laboratory capacity to analyze GM crops and foods so it is prepared to respond to problems like the StarLink incident, but defer investing in an active surveillance program until the need (in terms of food safety or consumer protection) is more clearly demonstrated.
- Develop focused FDA compliance programs to address defined issues, such as the possible unlawful presence of pesticidal traits in foods for which they are not approved, imports of GM foods that have not been reviewed by EPA or FDA, and the enforcement of restrictions on the presence in food of crops genetically modified to produce pharmaceuticals or industrial chemicals.
- Foster collaboration between FDA and the biotechnology and food industries on private third-party testing and certification programs to verify compliance with regulatory requirements.

CONSTITUENT PERSPECTIVES.

Very little constituent discussion has addressed the need for an affirmative FDA postmarket oversight program. Representatives of industry, consumers, and environmental groups widely agree that FDA and other government agencies should base their policies and resource allocations on achieving substantive objectives for food safety, consumer protection, and the environment—not “public confidence,” although the constituent and government response to the ProdiGene incident seemed to be motivated by concerns about public confidence in the system.

Constituents, including industry representatives, emphasize the importance of ensuring strict compliance with FDA regulatory requirements, but the general perspective is that this goal should be accomplished by means other than traditional postmarket compliance activity. For the StarLink and ProdiGene incidents and other instances of the unlawful or adventitious presence of GM traits in food products, constituents emphasize the importance of making decisions at or before market entry to make postmarket compliance more likely. For StarLink, this meant supporting EPA's policy not to grant split use approvals in the future. In response to the ProdiGene incident, many in the food industry and consumer community are urging that pharmaceutical plants not be grown in the same geographic regions where food crops are grown. For adventitious presence in general, this approach means deciding prior to market entry what levels of the inadvertent presence of a GM trait in various crops for which it is not approved (such as through outcrossing or unavoidable commingling) will be permissible.

Those involved in the grain trade—growers, traders, and processors—stress the need for industry to take responsibility and work together across the food chain in new, more collaborative ways to ensure that domestic and foreign regulatory requirements are met and that the integrity and credibility of grain markets are maintained. A market-based approach to identity preservation, discussed under **Identity Preservation and Traceability of Biotech Foods to Their Source**, is one possible vehicle for such collaboration. The general perspective among these groups is that the government can play at most a supportive role in efforts to protect the integrity and credibility of grain markets.

Adventitious Presence of Genetic Traits in Nontargeted Crops and Foods

ISSUE

The seed industry and grain trades have long recognized, as a result of biological gene flow and physical commingling, the adventitious presence of low levels of seed and grain varieties (and accompanying genetic traits) other than the ones intended to be present in their products. It has been accepted as unavoidable because of the biological nature of seed production and the high-volume U.S. grain-handling system. Although recognized as an issue within the trade, adventitious presence was not controversial publicly before the introduction of biotechnology. Public and trade sensitivities about biotechnology, differing regulatory situations among trading partners, and the possibility of safety concerns (as in the case of StarLink) have made the adventitious presence of GM traits controversial. How should the regulatory system address this phenomenon?

ANALYSIS

The adventitious presence of GM traits in conventional seeds, crops, and resulting food products is one of the most vexing issues facing the biotechnology industry and the regulatory agencies. The StarLink incident brought the issue to the public stage, but the possibility of the adventitious presence of GM traits now pervades the grain industry and, in turn, affects members of the food processing industry, some of whom seek to avoid the presence of GM ingredients in their products. The issue thus has practical importance as a commercial problem—as recently as December 2002, Japan rejected a shipment of U.S. corn that contained trace amounts of StarLink corn—as well as a regulatory one. It also has potentially far-reaching implications as a public issue because of the desire of some consumers to avoid GM foods for a host of personal reasons.

The U.S. regulatory agencies have been working with the White House Office of Science and Technology Policy (OSTP) to devise a policy for managing adventitious presence as it occurs in the context of biotechnology. On August 2, 2002, OSTP published a notice for public comment outlining proposed actions the regulatory agencies are considering to address the issue. The following analysis is intended to assist constituents in their consideration of proposed government policies and related issues.

DEFINITION AND EXAMPLES OF “ADVENTITIOUS PRESENCE.”

It is important to define “adventitious presence” as used in the analysis to follow. The term is itself somewhat controversial because, to some people, it appears to obscure the human role in a GM trait being where it should not be and to make light of what some would more bluntly call “contamination.”¹⁴⁵ According to the American Seed Trade Association (ASTA), “adventitious presence refers to the unintended or unintentional presence of another seed variety or genetic material, and/or trait(s) from another variety as a result of natural, mechanical or human means.”¹⁴⁶ Pioneer Hi-Bred International Inc. defines “adventitious presence” as the “unintended presence of genetic material or seed from another variety, crop, or weed in a seed *or grain shipment*”¹⁴⁷ (emphasis added).

These definitions convey the sense of the term as we use it in this report, with the following qualification of the term “unintended.” If a GM trait is present where it does not belong as a result of the negligent failure of a responsible party to observe a regulatory restriction or other recognized standard of care (such as a seed purity specification), then the presence of the trait may be unintended, but it would not be fairly described as “adventitious.” It would be better

¹⁴⁵ Merrigan 2002.

¹⁴⁶ ASTA n.d., “What Is Adventitious Presence in Seed?”

¹⁴⁷ Pioneer Hi-Bred International 2001.

described as unlawful or inappropriate contamination. As used in this report, “adventitious presence” refers to the situation in which the trait is present where it should not be despite the apparent compliance with applicable regulatory restrictions and other recognized standards of care by all parties. This understanding of the term is useful because it focuses attention on one of the central problems in addressing adventitious presence, which is determining the appropriate standard of care for avoiding the unintended contamination of food with GM traits.

Under the definitions offered by ASTA and Pioneer, as qualified in the previous paragraph, the source of an unintended seed variety or genetic trait could be a conventional variety or a variety improved through biotechnology. Historically, adventitious presence has been a common and accepted phenomenon in the conventional seed industry and levels of adventitious presence have not been a subject of government regulation, even though the unintended variety or genetic trait

in the seed is naturally incorporated in the crops and food products produced from the seed. The adventitious presence of non-GM seed has been recognized and managed through industry standards and practices. For example, industry standards allow “certified seed” for certain crops to be 99% pure and have tolerances for weeds, other varieties, and other crops altogether.¹⁴⁸ Most seed in the United States is not certified,

however, whereas it is in other countries. The United States historically has relied on truth-in-labeling on seed bags, as required by the Federal Seed Act,¹⁴⁹ to ensure that grower expectations for seed purity are met.¹⁵⁰ The public has had little awareness or concern about adventitious presence in this conventional seed context.

The issue of adventitious presence is strikingly different, however, in the context of biotechnology. In the StarLink case, which may have involved negligent contamination and adventitious presence, the presence of Bt in crops and foods for which it was not approved was a matter of prominent regulatory and public concern. More recently, The Wall Street Journal reported in April 2002 that one variety of commercially marketed glyphosate-resistant canola seed may contain a glyphosate-resistance gene trait, GT200, that was similar to but distinct from the marketed trait, although none had been detected in U.S. seeds.¹⁵¹ GT200 had not been through a U.S. government premarket review process. Because it does not produce a pesticide like StarLink corn, GT200 is under FDA’s jurisdiction, which means that it is subject to FDA’s voluntary consultation process rather than a mandatory premarket approval, and thus its presence in the U.S. food supply would likely not violate U.S. food law.¹⁵² Nevertheless, Monsanto Company, which had potential legal responsibility for GT200, brought the problem to the attention of USDA and FDA,



This understanding of the term is useful because it focuses attention on one of the central problems in addressing adventitious presence, which is determining the appropriate standard of care for avoiding the unintended contamination of food with GM traits.

148 Gustafson 2002, 7.

149 7 USC 1551–1611. The Federal Seed Act is administered by the USDA’s Agricultural Marketing Service, which has issued detailed regulations implementing the act (7 CFR Part 201).

150 Fernandez 2002.

151 Ananova 2002; Murphy 2002.

152 Murphy 2002, 29.

informing the agencies that GT200 “has the potential to be present in low, adventitious levels in commercial canola varieties.”¹⁵³ Monsanto also put the trait through the FDA consultation process, at FDA’s suggestion, and sought the agency’s concurrence that GT200 was as safe as conventional canola varieties and thus its presence not a cause for concern. Monsanto satisfactorily completed the FDA consultation process for GT200,¹⁵⁴ thus defusing the situation and avoiding the need for recalls by food companies that would not want even a trace amount of an “unapproved” GM trait in their products. The ASTA nevertheless observed that “GT200 points to the need for another policy change: allowable tolerances for trace amounts of biotechnology events found in crops and seeds.”¹⁵⁵

HOW ADVENTITIOUS PRESENCE OCCURS.

Unintended contamination resulting in the adventitious presence of GM material in crops and foods can occur at four levels of the commercial chain, at least: seed production, on-farm commercial grain production, grain handling and transport, and food manufacturing and processing.¹⁵⁶

No commercial seed variety is genetically pure.¹⁵⁷ Seed production is a biological process undertaken in open environments.¹⁵⁸ The natural process of pollen drift is a major contributor to adventitious presence and can occur even in enclosed nursery settings if adventitious pollen is present that could be introduced into the seed; adventitious presence also results from the human role in seed production, such as through “pollen mixing during seed production or through inadvertent mixing with other parent seed lines when seed companies plant, harvest, transport or condition their seed products.”¹⁵⁹ Organizations representing the world seed industry state that “a certain level of adventitious presence of ‘off-types’ is unavoidable with respect to the crop reproduction biology and the production processes.”¹⁶⁰ However, the risks of contamination through cross-pollination are not the same for every type of grain. Although corn readily cross-pollinates, soybeans do not and thus are not vulnerable to the adventitious presence of traits through this mechanism.

During grain production, adventitious presence can occur for many of the same reasons as in seed production, including cross-pollination, pollen mixing, or inadvertent mixing of seed or grain in planters or in other equipment.¹⁶¹ Regrowth from a previous crop, known as “volunteer” growth, can also result in pollen from the old grain seed mixing with the new crop, as occurred in the ProdiGene case.

Human actions at the farm production level and in the first steps of grain distribution are also factors in the occurrence and extent of adventitious presence. Factors include the size of the buffer zone between a conventional and a GM crop as well as commingling in storage bins, grain

153 Ananova 2002; Murphy 2002, 28.

154 Ditto 2002.

155 Murphy 2002, 29.

156 Murphy 2002, 29.

157 ASTA n.d., “Isn’t Each Commercial Seed Variety Genetically Pure?”

158 ASTA n.d., “Can’t Adventitious Biotech Presence Be Eliminated?”

159 Pioneer Hi-Bred International 2001.

160 FIS and ASSINSEL 2000.

161 FIS and ASSINSEL 2000.

elevators, or trucks that are not cleaned out completely. Grower practices, including failure to comply with grower agreements calling for buffer zones and segregation, may have contributed to the unintended presence of StarLink corn in the human food chain, although it has not been demonstrated conclusively.¹⁶²

At the level of grain handling and transport, adventitious presence results from the intrinsic nature of the high-volume bulk handling system for grains in the United States.¹⁶³ This system is enormously efficient and permits the movement in commerce of huge volumes of grain at low cost. The segregation of specific strains and varieties of single crops (such as corn) beyond broad grading categories was not one of the intended functions of the bulk commodity system as

designed. Grain from many sources is commonly commingled when it is shipped, stored, and processed. Segregating GM grain from conventional grain would require either parallel infrastructure and grain-handling systems, or expensive cleaning and monitoring of equipment and facilities to prevent commingling.

In food manufacturing and processing, adventitious presence may occur when an

adventitiously contaminated crop or ingredient is used to produce a food product or when GM and non-GM ingredients inadvertently commingle at the manufacturing plant due to lapses in ingredient control or incomplete cleaning of equipment or storage facilities.¹⁶⁴

UNAVOIDABLE NATURE OF ADVENTITIOUS PRESENCE.

Members of the seed, grain, and food industries consider some degree of adventitious presence of GM traits to be unavoidable for the biological reasons already noted and because of the nature of the bulk commodity system.¹⁶⁵ For practical purposes, this claim is true. It is no doubt possible to reduce the frequency or level of inadvertent contamination, but only at an economic cost that would increase and likely become prohibitive as the acceptable frequency and level of adventitious presence approached zero.

Another factor limiting the ability to guarantee zero adventitious presence of GM traits in non-GM seeds, crops, and foods is the nature and cost of testing. The tests are destructive, and as one industry observer points out, ensuring zero adventitious presence in grain would require assaying all the seed in a bag or grain in a shipment, thus leaving no seed or grain for sale.¹⁶⁶ Even statistically valid sampling, sufficient to provide a reasonable assurance that a large volume of grain meets a zero tolerance, would be extremely expensive. According to ASTA, “despite the U.S. seed



Members of the seed, grain, and food industries consider some degree of adventitious presence of GM traits to be unavoidable for the biological reasons already noted and because of the nature of the bulk commodity system. For practical purposes, this claim is true.

¹⁶² Goldman 2002.

¹⁶³ Pioneer Hi-Bred International 2001. “As with any agricultural commodity, the global market for grains and oil seeds is based on the effectiveness of handling of high quantities of mainly homogeneous products. In the US, the strength of the grain marketing and processing system—efficiency—is counterbalanced by its inability to guarantee 100% varietal purity. This is due to the inevitable commingling that occurs during farming and other commodity operations, such as from equipment and on-farm storage; transportation systems involving trucks, rail cars, and barges; and elevator storage, including local, river, terminal, and plant elevators” (Porter 2001, 33).

¹⁶⁴ Pioneer Hi-Bred International 2001; Porter 2001, 33.

¹⁶⁵ Geisert 2002.

¹⁶⁶ Porter 2001, 35.

industry implementing enhanced quality assurance measures and adhering to high varietal purity standards, it is impossible to guarantee that seed moving in international commerce today will not contain small percentages of other varieties, or trace material from other varieties, including those improved through biotechnology.”¹⁶⁷

WHY ADVENTITIOUS PRESENCE IS A PROBLEM.

Adventitious presence was a common and uncontroversial phenomenon before the arrival of biotechnology, and according to ASTA, seed quality (“or its fitness for use”) is not affected by the adventitious presence of GM traits. Why, then, is it a problem now? The possible reasons fall into four categories: safety, regulatory consequences, trade impacts, and public values and perceptions.

From a scientific perspective, safety is not likely to be a significant issue if the GM trait involved has been evaluated and approved as safe for consumption in one category of foods (as is the case for most forms of Bt) and is present inadvertently at low levels in another category. Safety is more likely to be a scientific concern if the substance has not been approved for human consumption but is inadvertently present in human food, as with the form of Bt in StarLink corn. StarLink was a particularly difficult case because the data on human safety had been evaluated and found lacking with respect to a particular hazard (allergenicity).¹⁶⁸ The worst-case scenario from a safety perspective would be the adventitious presence of potentially harmful levels of a trait for producing a pharmaceutical or industrial chemical known to be allergenic or to have toxic properties in a food crop.

Even in the absence of a safety concern, the regulatory consequences of adventitious presence can be significant, especially for pesticidal traits whose presence in a crop or food is illegal per se in the absence of an EPA tolerance or tolerance exemption.¹⁶⁹ The absence of a tolerance or exemption makes it unlawful for the commodity or any food produced from the commodity to move in commerce and be sold to consumers, and it places great pressure on FDA and EPA to take regulatory action to correct the problem by requesting voluntary recalls or taking legal enforcement action. Large-scale recalls were the response to the StarLink case.

FDA and EPA also may be requested to cure the regulatory problem posed by adventitious presence by issuing a tolerance or other expression of acceptance to regulate unapproved material found in products already present or potentially present in the marketplace. FDA did this with Monsanto’s GT200 by running it through the consultation process. In an analogous situation involving the airborne drift of conventional chemical pesticides from one field and crop where they are legal to another where they are not, FDA has issued informal “action levels” indicating the level of inadvertent residue accepted as unavoidable and not worthy of regulatory action. Aventis CropScience, the manufacturer of StarLink corn, sought but was denied after-the-fact regulatory acceptance in the form of a temporary tolerance for StarLink corn in human food.¹⁷⁰ One of the objectives of the White House–led policy process is to address prospectively the regulatory problem posed by the adventitious presence of GM traits in crops and food products.

167 ASTA n.d., “Can’t Adventitious Biotech Presence Be Eliminated?”

168 Additional but still inconclusive analyses suggest there may be less reason for concern about StarLink’s allergenicity than originally thought (CDC 2001).

169 Under FDA’s jurisdiction, the same considerations would apply to a GM trait that qualifies as a food additive but has not been approved at all or for use in the food in which it is found. Nonpesticidal traits that are also not food additives, such as the common glyphosate–resistance trait, do not pose the same regulatory concern because their adventitious presence in a nontargeted crop or food is not unlawful per se.

170 Wichtrich 2001, 19.

The adventitious presence of a GM trait can also have substantial, adverse impacts on domestic and international trade, as evidenced by StarLink. Domestically, the discovery of StarLink corn in human food resulted in widespread recalls of corn and corn products. In addition, the organic industry has expressed concern that the adventitious presence of GM traits in organic crops, which can occur through cross-pollination, could jeopardize the integrity and public acceptance of organic foods.¹⁷¹ USDA's standards for organic foods preclude the use of GM crops and allow for unavoidable contamination with excluded substances but do not define "unavoidable."¹⁷² Internationally, U.S. corn exports to Japan and South Korea were seriously disrupted based on concern about the presence of even small amounts of the StarLink form of Bt, which was not approved in either country. Adventitious presence is also a limiting factor in U.S. grain exports to Europe, where traits approved in the United States generally have not been approved for sale. Europe is considering its own policy to address the adventitious presence of GM traits in crops and foods sold there, as discussed further below in this section. Absent a workable policy, the adventitious presence in conventional commodities of GM traits not approved in Europe, even at low levels, could preclude export of those commodities from the United States to Europe. The export of U.S. corn to Europe has been disrupted recently largely for this reason.¹⁷³

Finally, public values and perceptions may be affected by the adventitious presence of GM traits in unintended and undesired places. This impact is the most difficult to define and perhaps the most difficult to address. Many people say they prefer to avoid GM foods, for diverse reasons.¹⁷⁴ Some believe that safety concerns are unresolved. Others have personal, ethical, or religious objections to the genetic modification of plants through the techniques of modern biotechnology and to the consumption of GM foods. Some have broader social concerns about biotechnology, such as its possible impact on the economic and social structure of agriculture and its potential environmental impacts.

Regardless of a person's reason for preferring to avoid GM foods, adventitious presence is an obstacle to their doing so. To the extent that adventitious presence is unavoidable, it provides a basis for this group opposing the marketing of GM seeds in the first place. To the extent that adventitious presence is avoidable or can be minimized, this group has a basis to demand strict tolerances or labeling to assist them in avoiding GM foods. From this perspective, adventitious presence symbolizes the real or threatened loss of control over what one eats. In the large-scale, globalized food systems of industrialized countries, such control was lost to a substantial degree long before the advent of biotechnology. Nevertheless, the values and perceptions of people who have reservations about or oppose the use of biotechnology in the food supply are affected by the phenomenon of adventitious presence, and their values and perceptions will no doubt be present in the debate about how the government should address the problem.

171 Organic Trade Association 2000.

172 7 CFR Part 205; USDA AMS 2000.

173 ACGA 2002.

174 Pew Initiative 2001e.

QUESTIONS FOR POLICYMAKERS AND CONSTITUENTS.

There is wide agreement among food system constituents on the need for a policy to address the problems posed by the adventitious presence of GM traits. Some of the questions relevant to the formulation of such a policy follow:

- Under what circumstances and to what extent is the adventitious presence of a GM trait a safety issue? Is it possible scientifically to address any safety concern associated with the potential adventitious presence of a GM trait prospectively, at the time of field trials or market entry?
- Which regulatory concerns need to be resolved by an adventitious presence policy? Must every GM trait in food have affirmative legal recognition through the regulatory process? Is it necessary only for pesticidal traits, which are illegal per se unless approved by EPA? What policy is appropriate for products regulated by FDA, which are not generally illegal per se without approval? What role should APHIS play (adventitious presence could result from field trials before a product has been submitted to EPA or FDA)?
- What policy is needed to minimize the trade impacts of adventitious presence? Is harmonization with Europe and other major trading partners necessary? Is it possible?
- If U.S. policy is not harmonized with the policies of its trading partners, what will be the effect on trade?
- Can any policy on adventitious presence address the concerns of consumers who prefer to avoid GM foods?

POSSIBLE PATHWAYS.

The design and analysis of policies on adventitious presence should take into account as much as possible all of the potential impacts of the problem, including safety, regulatory, trade, and public impacts. It may be impossible, however, to devise a policy that fully addresses all of these issues in a way that satisfies the concerns of all constituents. Among the possible policy approaches are the following:

- Ban all adventitious presence. This policy approach is not feasible if a ban is to be seriously enforced. Adventitious presence can be minimized, at a cost, but it cannot realistically be subject to an enforceable ban. Enforcement of an across-the-board zero tolerance for adventitious presence would require, in at least some cases, penalizing individuals for events beyond their physical control, removing from commerce large quantities of food in the absence of a safety concern, or both. These consequences are likely to be unacceptable in the long run within the U.S. legal and political systems. One argument for this approach is that it is the only way to address the concerns of people who want to strictly avoid the consumption of foods containing or derived from GM traits. The arguments against it are that strictly avoiding all GM food is an objective that even a ban on adventitious presence would not achieve (because of the impossibility of complete compliance) and that the costs to society of attempting to achieve the objective, in terms of direct economic loss and market disruption, would substantially exceed the benefits to society.

- Respond to issues as they arise. This approach is the status quo. It assumes that some degree of adventitious presence is unavoidable and occurring today. Rather than address the issue with a generic policy, the regulatory system would respond to specific safety, regulatory, and trade problems as they arise, as the agencies did in response to StarLink. Under this approach, the government could take whatever action is appropriate—including setting retroactive tolerances or other regulatory thresholds or requesting recalls of affected commodities and foods—to resolve the problem. One argument for this approach is that adventitious presence is an unavoidable part of seed production and generally of little safety concern, and thus there is no justification or need for a blanket policy restricting it. One argument against this approach is that it fails to address the concern about the illegal presence of pesticidal traits in nontargeted crops and the concerns of trading partners and thus risks additional market disruptions.
- Set an across-the-board threshold or tolerance based on technological feasibility. This approach assumes that some degree of adventitious presence of GM traits is unavoidable and occurring today. It would involve setting a threshold or tolerance, applicable across the board to trace levels of any trait in any commodity, based on a generic judgment about the technological feasibility of avoiding adventitious presence at low levels. The goal would be to legalize and express regulatory acceptance of such trace levels in order to avoid market and trade disruptions. The assumption is that low levels of GM traits pose no significant safety concern, but the threshold would be set without regard to commodity- or trait-specific risk assessments.

One argument in favor of this policy approach is that it provides clear prospective guidance and a standard that those involved in producing food commodities and products can rely on as the basis for ensuring that their products will be lawful and acceptable in the marketplace. By selecting a single threshold based on a generic judgment about unavoidability, this approach respects the practical reality of adventitious presence, which is the reason for a policy in the first place, and avoids potentially time-consuming case-by-case assessments and the accompanying data-generation and decisionmaking costs for government and industry. One argument against this approach is that unavoidability varies, as do the costs of minimizing adventitious presence, and thus a single threshold level may not be appropriate in all cases. Moreover, a threshold set on this basis, without taking into account a risk assessment, may be more stringent than necessary to protect consumer safety and not defensible scientifically, or not stringent enough for safety purposes and thus not defensible on public health grounds.

The European Commission is pursuing an approach to the adventitious presence issue that involves the adoption of an across-the-board threshold, but only for GM traits that have been reviewed and found safe by an E.U. scientific committee but not yet approved for marketing. The commission has recommended a threshold of 1% for such GM crops and

plants,¹⁷⁵ and the European Parliament recently adopted a legislative resolution on adventitious presence with a 0.5% threshold.¹⁷⁶ In either case, the responsible party must be able to demonstrate that it took appropriate steps to avoid the GM material. The proposals also contemplate that, as advances in science and technology allow, lower thresholds will be adopted to reflect the improved ability to avoid the adventitious presence of GM traits. The ultimate outcome of the E.U. policymaking process remains to be seen; unresolved issues include whether the threshold or tolerance should be available only for GM traits approved by the European Union, for ones reviewed by its scientific committee but not yet approved (as has been proposed and adopted in the parliament resolution), or also for ones approved in another country but not in the European Union.

- Address the safety and regulatory status of the possible adventitious presence of GM traits on a case-by-case basis early in the field-testing stage, or otherwise prior to market entry, on the basis of a risk assessment. This approach is generally proposed by the United States. The document OSTP published in August 2002 did not use the term “adventitious presence” but rather defined the problem as “intermittent, low levels of biotechnology-derived genes and gene products occurring in commerce that have not gone through all applicable regulatory reviews.”¹⁷⁷ OSTP outlined three proposals for addressing this problem: (1) FDA would encourage developers of biotech food crops that contain a new protein to submit information about the protein’s potential toxicity and allergenicity at the field-trial stage, then review the information and respond in the same manner provided for in its current consultation process; (2) EPA would encourage developers of biotech food crops involving PIPs to seek approval for residues of PIPs “very early in the research and development process,” then evaluate and approve the levels using its authority for setting pesticide tolerance; (3) APHIS would strengthen field-testing controls on biotech crops not intended to be used for food or feed (such as those used to produce pharmaceuticals and industrial chemicals) to help prevent the outcrossing or commingling that could result in “intermittent, low levels” of such nonfood traits in food commodities. These measures are aimed at keeping low levels of biotechnology-derived genes and gene products out of commerce “until appropriate safety standards can be met.” If the policies are implemented by the agencies and taken advantage of by developers of new crops, then the practical consequence would be that the safety of the low-level presence of new biotech-derived proteins in food and feed would have been subject to the applicable regulatory review well in advance of commercialization. The OSTP notice does not address any of the trade or international harmonization issues associated with adventitious presence.

In general, the arguments in favor of the proposed U.S. approach are that it provides a risk assessment of the adventitious presence of the GM trait and, if there is no significant safety concern, provides the flexibility to allow the trait to be present at a level that protects consumer safety while minimizing the burden and costs of controlling the unavoidable presence of the GM trait. The argument against this approach is that risk-based thresholds set prior to

175 Byrne 2002.

176 European Parliament 2002. The European Council of Ministers has its own tolerance proposals: 0.4 for food and 0.5 for feed. Van der haegen 2003.

177 OSTP 2002.

full regulatory approval of a GM crop or food are not sufficiently strict to control and minimize the presence of unintended and unapproved GM traits, regardless of safety risk. It thus is not responsive to the concerns of those who prefer to avoid GM material to the maximum extent possible for reasons other than food safety.

FURTHER ANALYSIS AND QUESTIONS CONCERNING THE U.S. PROPOSALS.

The U.S. proposals are grounded firmly in the current practices of the three agencies. Those of FDA and EPA essentially involve encouraging the developers of GM crops to enter the regulatory review process for food safety earlier than they might otherwise and clarifying that the agencies will evaluate the safety of low levels of the new trait at that early stage. This approach breaks no new legal ground and involves familiar scientific issues. However, several points and questions deserve consideration in analyzing the proposals and their potential impact:

- The OSTP document refers to “intermittent, low levels” rather than “adventitious presence.” Does the policy apply only to the unintended presence of GM traits or also to intermittent, low levels that result from intentional commingling?
- The policy addresses the low-level presence of GM traits and assumes that the data and scope of scientific review will be commensurate with the likelihood of human exposure to the trait in food, yet the policy does not define “low” and does not specify how the agencies will ensure that the amount of the GM trait in food does not exceed this “low” level. Will the agencies set tolerances or other regulatory thresholds in some cases? EPA’s authority to do this is clear; FDA’s authority is not.
- If the agencies set tolerances or use some other tool to define what constitutes “low” as a general matter or in a particular case, how will the agencies enforce this level? Will they have the necessary analytical methods? What resources would be required to provide credible assurance that the actual presence of the GM trait is covered by the safety assessment and within the scope of the regulatory authorization?
- FDA’s early review of nonpesticidal GM traits would focus on any proteins that had not previously been evaluated by FDA and are new to the crop into which it is engineered. If a protein is new to this extent, would it be “substantially equivalent” under FDA’s 1992 policy and thus eligible to enter the market through the consultation process? When is a new protein not presumptively GRAS and thus considered a “food additive” that must go through an approval process before it can lawfully be present in food?
- How will EPA and FDA resolve scientifically whether a new protein is a potential allergen? Is this a different question requiring different data when the protein is assumed to be present at intermittent, low levels? Are the allergenicity and toxicity of the new protein the only safety concerns at this stage? Or should other possible impacts of the genetic modification on the composition and safety aspects of the plant also be considered?

- The U.S. proposals are fundamentally different in concept from the European proposals on adventitious presence. The U.S. approach recognizes that low levels of unapproved GM traits may enter the food supply as early as the field-trial stage and seeks to address the problem prospectively by gathering data and making a case-by-case, risk-based judgment on an acceptable level of exposure in food. The European Union also recognizes the unavoidability of low levels of GM traits in food, but its approach applies only to GM traits that have completed the full evaluation for health and environmental safety; it addresses the problem with these traits by setting an across-the-board threshold based on a generic judgment about the technological feasibility of avoiding such traits rather than case-by-case risk assessment. A lack of harmonization would mean that traits not yet evaluated or approved for commercialization in the United States but accepted in the United States as a result of going through the processes prescribed in the proposed policy would not be accepted in Europe unless the trait had completed the full E.U. safety evaluation and the actual level of the trait was below whatever tolerance Europe finally adopts. This lack of harmonization on adventitious presence reflects the larger gap between U.S. and European approaches to allowing field trials and the commercialization of GM crops and foods.

Nevertheless, what are the consequences of the United States adopting a policy on adventitious presence that is not consistent with the policies of Europe and other trading partners? If the levels allowed under the U.S. policy are higher than those of importing countries, the trade and public acceptance concerns that have made adventitious presence a contentious issue with trading partners will not be resolved.

CONSTITUENT PERSPECTIVES.

As noted earlier, constituents across the spectrum—technology developers, seed companies, growers, grain traders and exporters, food companies, and consumer groups—agree on the need for a policy to address adventitious presence. According to Pioneer Hi-Bred International, “managing the presence of small—but unintended and unavoidable—material is not just a seed issue. It spans the whole food industry.”¹⁷⁸

The common theme across the food system is that the StarLink experience was an important call to action on the issue. It demonstrated the need to be more rigorous in keeping unapproved GM traits out of the human food supply and the need for a policy that addresses, and gives regulatory sanction where appropriate, to unavoidable contamination. Constituents tend to agree that the problem of adventitious presence must be addressed prospectively, before market entry, rather than on a retrospective or ad hoc basis. This approach is based on the recognition that adventitious presence, when detected unexpectedly or with uncertainty about its safety or legality, has great potential to disrupt markets and undermine public confidence in the food system. Management of adventitious presence after the fact is thus widely regarded as an unacceptable approach.

178 Pioneer Hi-Bred International 2001.

Behind this consensus about the importance of the problem and the need to act exists some tension about where the responsibility lies. In reference to StarLink, a representative of the American Corn Growers Association (ACGA) expressed concern that “federal agencies responsible for guaranteeing the security of the U.S. food supply are not taking their role seriously enough when it comes to preventing the release of genetically modified (GMO) commodity varieties that are not approved for human consumption into the marketing system,” and “there is no excuse for allowing unapproved GMO varieties on the market and the biotech companies responsible for such contamination of the food supply should be held liable.”¹⁷⁹ The biotech companies, in turn, rely on grower agreements to minimize the adventitious presence that occurs through cross-pollination and purposeful commingling, whereas the growers stress unavoidability.¹⁸⁰ For food companies, who are in the position of receiving what the market can provide, adventitious presence is a sensitive customer and public relations issue; despite the impossibility of foods consistently

achieving zero tolerance, some customers seek non-GM products, and food companies frequently attempt to offer them.¹⁸¹

Adventitious presence is a particular concern for the organic industry. Many organic producers see the problem as one imposed on them by an approach to agriculture that conflicts with the approach to which they

and their customers strongly adhere. They resent the imposition of the cost and inconvenience associated with trying to prevent or minimize GM contamination of their crops (such as increased planting buffer zones), and they are concerned about the overall threat to the “brand” credibility of organic crops if they are eventually contaminated on a widespread basis with GM traits, even if unavoidably and at low levels.¹⁸²

Dealing with adventitious presence prospectively means deciding in advance the extent to which the presence of the GM trait in nontargeted crops and foods will be tolerated, presumably by establishing a tolerance or some other definition of what level is acceptable. While agreeing that acceptable levels should be determined, most commercial participants in the food system have not taken public positions on how they should be determined. One representative of the trade association representing technology providers has expressed a preference for an approach that uses risk assessment to make trait-by-trait determinations of safe levels for adventitious presence and sets acceptable levels at least partly on that basis, an approach that appears to be embodied to some extent in the notice published by OSTP in August 2002.¹⁸³ In light of the StarLink incident, one representative of an environmental organization questions whether it will be possible to establish that any exposure through adventitious presence will be safe for novel proteins intro-



While agreeing that acceptable levels should be determined, most commercial participants in the food system have not taken public positions on how they should be determined.

179 Dan McGuire, program director, Farmer Choice–Customer First, American Corn Growers Association, quoted in WorldFoodNet 2002.

180 “Segregation methods, including IP systems, cannot be used to achieve a zero tolerance, separating grains or seeds produced without or with the use of modern biotechnology. Simply put, a zero level of unauthorized ‘GM seed’ and derived product is unobtainable in practice. No segregation system can assure the complete absence of adventitious presence, particularly from either an analytical or a handling practices standpoint. Indeed, current IP systems, as well as grading and other quality standards, recognize this reality by allowing certain de minimis levels of various types of materials” (Porter 2001, 34).

181 Geisert 2002.

182 Merrigan 2002.

183 Phillips 2002.

duced through genetic modification.¹⁸⁴ This constituent and representatives of the organic industry have expressed concern about how any permissible threshold for unintended GM traits would affect the organic industry, which generally prefers to avoid GM traits altogether.¹⁸⁵

Many groups emphasize the importance of harmonizing U.S. policy on adventitious presence with the policies of trading partners. This approach would include harmonizing any specific tolerances, thresholds, or acceptable levels that governments might establish with respect to the adventitious presence of gene traits or their expression products. Grain exporter representatives stress the need for agreement with the European Union and Japan on an appropriate approach that deals effectively with trade and domestic issues, suggesting that this agreement could become the basis for forging a global consensus. They also note the need for capacity building among exporters to ensure compliance with any new standards.¹⁸⁶ The ASTA vice president for international marketing cited international harmonization as the “main problem,” citing two main obstacles to harmonization: the lack of a U.S. policy on adventitious presence and the lack of a clear mandate to FDA and EPA to harmonize their standards with those of trading partners.¹⁸⁷

Identity Preservation and Traceability of Biotech Foods to Their Source

ISSUE

Corn, soybeans, and other crops are generally traded as fungible commodities. Producers, processors, and marketers of crops and foods make no provision for preserving or distinguishing the identity of a lot, or foods produced from it, with respect to whether it contains GM traits. Nor do they make provisions for tracing a crop or food back to its point of origin. Europe is in the process of mandating the traceability and labeling of GM crops and foods, which in effect requires identity preservation (IP). The IP of GM and non-GM foods is being discussed widely in the United States to serve various purposes. What, if any, role should the U.S. government play in fostering the IP and traceability of GM crops and foods?

ANALYSIS

OVERVIEW.

The issues of IP and traceability are not unique to biotech crops and foods. “Identity preservation” relates to the ability of the producers, processors, and marketers of crops and foods to distinguish one lot from another on the basis of any desired attribute(s); “traceability” refers to their ability to identify the lot’s origin. In the case of biotech crops and foods, the IP issue has arisen in response to the need to assure some customers, including domestic food processors and retailers as well as

184 Goldberg 2002.

185 International Federation of Organic Agriculture Movements 2002; Siegel 2002. The organic standards promulgated by USDA’s National Organic Program accept the unavoidable presence of GM traits in organic crops, but USDA has not set any threshold or tolerance defining the upper limit on the level of contamination that is acceptable.

186 Martin and Miller 2001.

187 Condon 2002.

European importers, that crops and foods have been produced without the use of genetic modification. The issue of traceability has arisen, primarily in Europe, in the context of a broader societal interest in knowing the origin of food for food quality and safety reasons. In Europe, the issues are also linked to interest in requiring the labeling of biotech foods, because implementation of a biotech labeling requirement inherently requires some form of IP, traceability, or both.

Although IP has long been practiced in the U.S. food system for some product attributes unrelated to biotechnology, both IP and traceability require a level of control and documentation of how and where foods are produced that extends well beyond what is currently required in the bulk commodity handling system. In the context of biotech crops and foods, implementing IP and traceability would pose substantial challenges to and create substantial costs for U.S. food producers and processors.

There is little likelihood the U.S. government will require the IP of GM crops and foods, and in international settings such as the Codex Alimentarius Commission (or simply Codex),¹⁸⁸ the U.S. government has strongly opposed across-the-board traceability requirements like those being pursued in Europe. Market forces nevertheless are beginning to require U.S. producers and processors to address IP and traceability. The need for U.S. exporters to meet the requirements of Europe and other importing countries is one such force. Another is the emerging use of biotechnology to produce products with positive attributes for consumers or as a vehicle for manufacturing pharmaceuticals and industrial chemicals, which will make IP a practical necessity to ensure that consumers get what they are paying for and that the nonfood GM products are properly controlled.¹⁸⁹ The IP and traceability issues are also being pushed by individuals who believe that GM crops and foods require a greater degree of postmarket control than conventional ones for food safety, consumer choice, or other reasons. The central issue is whether the government has a role to play in ensuring IP for these purposes or whether the task should be left entirely to market forces and the private sector.

BACKGROUND ON IP AND TRACEABILITY.

Identity preservation goes beyond the crop segregation that is already practiced within the bulk commodity system, such as the separation of white corn from other types of corn. In one sense, IP is tied to traceability:

Though segregation implies that specific crops and products are kept apart, segregation systems do not typically entail a high level of precision and do not necessarily require traceability...An identity preservation (IP) system identifies the source and/or nature of the crop or batch of food ingredients. IP systems are stricter than segregation systems and tend to require documentation, that is, traceability, to guarantee that certain traits or qualities are maintained throughout the food supply chain.¹⁹⁰

188 Codex is a joint program of the Food and Agriculture Organization of the United Nations and the World Health Organization. The concept of traceability, as well as guidelines for undertaking it, is being discussed in several Codex committees, namely, the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology, the Codex Committee on Food Labeling, the Codex Committee on General Principles, and the Codex Committee on Food Import and Export Inspection and Certification Systems (Codex Alimentarius Commission n.d.).

189 The widely recognized need to control crops used to produce pharmaceuticals and industrial chemicals is illustrated by the ProdiGene incident of November 2002.

190 Golan, Krissoff, and Kuchler 2002.

Long before biotechnology, IP was used by grain producers and processors for commercial purposes, such as to provide a cereal maker with oats of a certain quality or a baker with specialty wheat varieties. It now is being used to meet the needs of food processors that have decided not to include GM ingredients in their products:

IP systems are seen as an effective tool for segregating GM from non-GM crops. Farmers use IP systems to grow specific crops, aiming to preserve their identity and prevent mixing with other crops through all stages of production, from ‘seed to shelf.’ This is accomplished through strict growing and handling procedures, including crop segregation, field inspections, equipment cleaning and, in the case of GM crops, sampling and GMO testing. Each stage is documented to ensure that a crop can be traced back to a farmer’s field. In contrast to mass-produced commodities such as corn and soybeans that are sold on the open market, IP products are grown and processed according to a buyer’s specifications.¹⁹¹

In response to the StarLink incident¹⁹² and broader marketplace demands, IP systems have been developed by major U.S. companies including ConAgra (“ConAgra chose IP Track to automate its identity preserved grain marketing program”¹⁹³), General Mills (“using IP to ramp up its ability to develop grain varieties for specific products”¹⁹⁴), Cargill (“Cargill’s InnovaSure program, an IP system for corn dry milling at Illinois Cereal Mills, was able to provide StarLink-free corn products to customers like Kellogg’s, General Mills and Frito-Lay”¹⁹⁵), and Dupont (“the company is moving toward segregation and identity preservation for complex reasons. ‘It is not simply driven by GM/non-GM, but is part of an ongoing drive for efficiency, testing and brand protection’”¹⁹⁶).

Farmers are responding to the same market forces, including competition in international markets from growers in such countries as Brazil and China.¹⁹⁷ AgraMarke Inc., a 500-member cooperative based in northeast Kansas, has established an IP system:

Currently, most of AgraMarke’s customers want corn that has not been genetically modified...AgraMarke members must agree to strict planting, harvesting and storage guidelines to guarantee that their crops meet customer specifications and are neither tainted by pollen drifting from other fields nor mixed with unapproved varieties. Some members only grow identity-preserved varieties to streamline the process and protect against problems.¹⁹⁸

191 Roseboro 2001.

192 “The co-mingling of StarLink corn in the U.S. grain supplies in 2000 triggered industry-wide efforts to improve outlets for identity-preserved grains and to enhance the technologies that automate identity preservation” (NCGA 2002, 10).

193 Clapp 2001a.

194 Clapp 2001b.

195 Pew Initiative 2001d.

196 Pew Initiative 2001d, 19.

197 PR Newswire 2001.

198 Palmer 2001a.

Estimates of the portion of grain commodities that are identity preserved vary widely. According to the National Corn Growers Association, “approximately 10% of the U.S. corn crop now qualifies as identity preserved.”¹⁹⁹

The ability to know the identity and characteristics (including the origin) of a particular lot is the outcome of an IP system. Traceability is a system of records and documentation that contributes to achieving this outcome. A traceability system establishes the chain of custody of a lot and how it has been handled and links the lot to its origin.²⁰⁰

It is important to distinguish between “traceability” and “traceback.” These terms have been at the heart of a debate between the United States and Europe over whether Codex should establish an international standard for the traceability of GM crops and food products. A Codex discussion paper on traceability, prepared by the French government, gives four reasons for establishing a

traceability standard for GM products: to support product withdrawals if a health risk is established, to facilitate the identification and monitoring of unintended and long-term health effects, to assist “the control of labeling,” and to facilitate IP.²⁰¹ The



According to the National Corn Growers Association, approximately 10% of the U.S. corn crop now qualifies as identity preserved.

European Union supports such a standard, asserting that traceability is needed to meet multiple objectives, including food safety, product quality, and consumer information. The E.U. position on traceability for GM crops and foods is grounded in the “general principle” that traceability should be required for all foods and that GM foods should be labeled as such to provide “freedom of choice for consumers.”²⁰²

The United States opposes mandating traceability for GM products, taking the position that such a mandate is not justified on any of the grounds cited in the Codex discussion paper.²⁰³ The U.S. comment on the Codex discussion paper cites the International Organization for Standardization (ISO) definition of “traceability” and its linkage of the term to IP for product quality; it claims that traceability is not designed to ensure food safety and is not a prerequisite for it. For the purposes of food safety, the United States “prefers the use of the term traceback rather than trace-

199 NCGA 2002, 10. The U.S. Grains Council provides a similar estimate of 10.5% (including segregated non-GMO corn and low-temperature-dried corn) of the amount of the U.S. corn crop designated as IP or value-enhanced corn for 2000, which dropped to 6.9% in 2001 (U.S. Grains Council 2001, 2002). Representatives of the Economic Research Service confirm the decline in IP corn from 250,000 acres in 2000 to 100,000 acres in 2001 and estimate that the total share of IP corn (including all corn types that go through some form of segregation except blue, white, and organic) was 5.4% in 2001 (Smith and Elbehri 2002). Note: These figures include corn for all uses not just human consumption.

200 The International Organization for Standardization defines traceability in Standard 8402 as “the ability for the retrieval of the history and use or location of an article or an activity through a registered identification.” It includes “a system of record keeping and documentation by operators that enables a retroactive tracking of the movement of a product or ingredient through the chain” (Codex 2001).

201 Codex 2001.

202 European Commission 2001.

203 U.S. Codex Delegation 2001, 1.

ability because of the term's historical usage and the public health understanding and meaning that is associated with the term." The purpose of traceback, according to the same document, "is to locate and, as necessary, remove a food or food ingredient from the marketplace when a specific public health problem has been identified." The U.S. food safety agencies routinely conduct traceback investigations on specific products and lots, using available records and information, in response to food-borne illness outbreaks or in connection with product recalls.²⁰⁴ Traceability essentially involves putting in place in advance, for all products and lots, the system of records that makes traceback immediate and automatic. The U.S. position is that, given the potentially significant costs of traceability systems, it "does not support traceability programs that have no basis in food safety or public health protection;" GM foods "are not inherently unsafe," are subject to "a complete and appropriate safety assessment" prior to marketing, and thus do not warrant the establishment of traceability systems. It also "strongly opposes" traceability for the purpose of labeling GM foods and dismisses IP as the basis for mandating traceability on the grounds that IP systems "relate entirely to private buyer-seller relationships;" in other words, IP should be left to the marketplace.²⁰⁵

CONSTRAINTS AND INCENTIVES.

Several important constraints and incentives should be considered in determining what role the U.S. government might play in assuring IP and traceability for GM products and whether these issues should be left entirely to market forces and the private sector. The constraints include adventitious presence and the need for standards, potential economic costs, and uncertain legal authority. The incentives that could affect public or private decisionmaking include marketplace pressures to establish IP and traceability as well as the nature of the products in the biotechnology pipeline.

Adventitious presence and the need for standards.

IP implies maintaining, to some defined degree, the purity of a particular lot. The possibility of the adventitious presence of GM traits is an obvious constraint on IP because it is virtually impossible to absolutely ensure that the identity of a particular lot of a grain commodity or food product has been completely preserved, for example, as "free" of GM traits or of ingredients derived from a GM crop. This constraint has to be taken into account in any IP system, whether established by government or by private parties. It requires considering the establishment of tolerances or standards, possibly including process-based standards, that define the degree of purity that will be deemed acceptable for any given trait, crop, or food. Such tolerances or standards would presumably reflect technical feasibility as well as the availability of analytical methods

204 According to the CFSAN website, "traceback" is "a term used in epidemiology to describe the process by which the origin or source of a cluster of contaminated food is identified." The primary objective of a traceback is to support food safety investigations: "Tracebacks may stop the additional sale and distribution of contaminated food, thus preventing further exposure or spread of the infection. For example, if an outbreak is determined to be caused by a suspected food, investigators conducting the traceback analysis would determine where the restaurant or grocery store purchased the food, who supplied the wholesaler, and finally, on which farm it was grown. Since wholesalers and retailers often buy food from multiple vendors, the traceback to the farm step requires extensive detective work. The various stages that the food traveled would be examined to deduce where the pathogen was transferred to the product" (U.S. FDA CFSAN n.d.). However, traceback investigations are often frustrated by the middlemen, because distributors, wholesalers, truckers, and retailers do not keep detailed records of the kind required to support a traceback investigation because they do not need them (Clapp 2001c).

205 U.S. Codex Delegation 2001, 178.

and testing protocols or other means of verifying that the defined degree of purity had been achieved. The possible roles of government include establishing the tolerances or standards, validating analytical methods, certifying testing laboratories, conducting its own testing, or some combination of these roles.

Economic costs of IP.

The IP of GM or non-GM crops and the traceability that normally accompanies it come at a price because they require extra effort on the farm and throughout the grain-handling and food-processing system. The costs flow primarily from the need for segregation and record keeping.²⁰⁶ For example, farmers producing non-GM corn or soybeans first have to obtain seed of appropriate purity and then keep the non-GM crop physically separate from GM crops in the field and in harvesting and storage, which involves equipment cleaning and possibly a separate storage facility.²⁰⁷ Grain elevators and subsequent handlers and processors of the non-GM grain must undertake similar efforts to maintain physical separation and prevent the possibility of inadvertent contamination. At each step, records must be kept, and testing may be required to meet a purchaser's requirements for verification that non-GM identity has been preserved. An important variable in determining the magnitude of the costs is the degree of purity required in a non-GM commodity. The greater the purity required, the greater the likely costs associated with maintaining segregation and preventing adventitious contamination.²⁰⁸

The simplest indicator of the economic cost of IP is the premium paid in the marketplace for non-GM grain. According to a study reported in 2000, exporters in 1999 were receiving a premium of \$0.22 per bushel for non-GM soybeans²⁰⁹ at a time when the price per bushel was approximately \$4.00–5.00.²¹⁰ The study also reported that farmers at a central Illinois grain elevator were receiving a \$0.10 premium, presumably to cover the farmers' costs of IP, suggesting that the costs of IP incurred by those handling the grain between the farmer and the point of export were no greater than \$0.12 per bushel.

A Canadian study reported that the costs of IP systems were 15–20% higher than those of conventional products.²¹¹ This study and others suggest that current estimates may not reflect the costs of significantly expanded use of IP because of the loss of flexibility and the greater opportunity costs that could be incurred as larger portions of the grain-handling infrastructure are committed to identity-preserved, non-GM commodities; another potential opportunity cost might result from “the need to meet specific delivery dates set by IP contracts, which would mean relinquishing the option to hold grain until it can sell at a better price.”²¹²

206 Binkley 2002.

207 Gustafson 2002, 8.

208 Kalaitzandonakes 2001, 10.

209 Bullock, Desquilbet, and Nitsi 2000.

210 Good 2002.

211 Smyth and Phillips 2001, 34.

212 Maltzbarger and Kalaitzandonakes 2000.

Currently, IP practices and costs are being determined in the marketplace on the basis of requirements demanded by domestic and foreign customers. Little research has been reported on the costs that might be incurred as a result of government-imposed IP requirements, but some commentators suggest the cost would be even higher,²¹³ presumably because the regulatory imposition of IP would restrict the flexibility of the grain-handling system to meet the IP needs of customers in the most efficient manner possible.

As a practical matter, costs will be a constraint on the government's inclination to mandate IP or traceability.

Legal authority.

Another constraint on government action is the scope of its legal authority. FDCA gives no explicit authority to EPA or FDA to mandate the adoption of IP or traceability systems. The use limitations that the agencies can place on GM products under the provisions for pesticide tolerance and food additive approval may imply the need for segregation and containment (as in the case of StarLink), but the agencies have generally relied on the sponsors and users to devise specific systems for complying with use restrictions. This authority has not been used to mandate IP and traceability systems of the kind we discuss in this section. If the agencies attempted to mandate such systems as part of the approval process, they would have to demonstrate that the systems are needed and would be effective for that purpose.

Under the general provisions of the FDCA related to food adulteration, FDA might have the authority to issue regulations requiring IP or traceability if it could demonstrate that such regulations were necessary to prevent a food safety problem. Based on FDA's position concerning the safety of currently marketed GM foods, FDA probably could not meet this requirement with respect to GM foods in general. In the event that a particular GM trait or food posed a safety concern that FDA believed could be addressed through an IP or traceability system, FDA would bear the burden of demonstrating the adequacy of the proposed system to protect consumers and why, under such a system, the product would comply with the FDCA's food safety provisions despite the safety concern.

Similarly, under the FDCA's labeling authority, FDA could attempt to mandate IP or traceability to prevent a product from being misbranded. FDA currently takes the position, however, that the FDCA does not require that GM and non-GM foods be distinguished or labeled as such in the absence of some compositional or functional difference in the food that would be material to consumers.²¹⁴ There thus would not appear to be any basis under FDA's misbranding authority to mandate across-the-board IP for GM foods. In draft guidance on the labeling of foods as "GM free" or having been "produced without using biotechnology," FDA cited the need for companies making such claims to be able to substantiate them.²¹⁵ Because (according to the FDA guidance)

²¹³ Maltzbarger and Kalaitzandonakes 2000.

²¹⁴ U.S. FDA CFSAN 2001b.

²¹⁵ U.S. FDA CFSAN 2001b, 6.

the analytical methods that would be required to fully verify such claims are generally not available, a manufacturer making them may have to adopt “special handling” practices, such as segregation, backed up by “certifications or affidavits from farmers, processors, and others in the food production and distribution chain... to document that foods are obtained from the use of traditional methods.”²¹⁶ Although FDA does not purport to establish legal requirements with its guidance document, its reasoning implies that IP and traceability could be mandated by FDA to the extent FDA considers them necessary to avoid misbranding products bearing non-GM claims or claims that a product has been improved through genetic modification.

Marketplace pressures to establish IP and traceability.

The most compelling incentives to establish IP and traceability systems are coming from the marketplace, rather than from the need to satisfy any U.S. regulatory or legal requirements. The incentives

flow currently from customer-driven demand for non-GM products. Customers include domestic food processors who are responding to consumer concerns and foreign purchasers who may seek non-GM products for regulatory and consumer reasons. What the marketplace demand for non-GM products will be in the future is difficult to predict with any certainty. Because current incentives for IP and traceability

come from the marketplace, however, today’s government must determine what, if anything, it should do to support market-driven IP and traceability systems.

Biotechnology pipeline.

In the future, incentives for IP and traceability will change as products are produced that provide direct consumer benefits, such as improved taste, nutrition, or safety and as GM crops are used to “grow” pharmaceuticals or industrial chemicals that should stay out of the food supply. The marketplace incentives will remain high because the value of products with consumer benefits cannot be realized unless their identity can be preserved, and food processors and consumers will have a heightened interest in assurances that the crops or foods they buy does not contain material from plants used to produce nonfood chemicals, unless the plant has been approved as safe for human consumption.



In the future, incentives for IP and traceability will change as products are produced that provide direct consumer benefits, such as improved taste, nutrition, or safety and as GM crops are used to “grow” pharmaceuticals or industrial chemicals that should stay out of the food supply.

216 U.S. FDA CFSAN 2001b, 7.

The need to consider the regulatory imposition of IP and traceability requirements may also be heightened by products in the biotechnology pipeline. The consumer products presumably will be marketed on the basis of claims concerning the added nutritional or other value introduced through biotechnology. IP of some kind will be required to ensure those claims are truthful. For plants used to produce nonfood chemicals, regulators will likely impose strict requirements to ensure that the edible portion of such plants is kept separate from the food supply or channeled to a human or animal use that is safe. Clearly, effective IP or traceability of some kind would be necessary to ensure compliance with such requirements. In these cases, government will have to consider how far its role should extend in setting performance standards or criteria for IP and traceability systems and in mandating specific procedures.

ROLE OF THE USDA GRAIN INSPECTION, PACKERS, AND STOCKYARDS ADMINISTRATION.

The USDA Grain Inspection, Packers, and Stockyards Administration (GIPSA) is the federal agency whose mission relates most directly to the IP and traceability of GM and non-GM crops. Its overall mission is to facilitate the marketing of agricultural products, including cereals and oilseeds, and to “promote fair and competitive trading practices for the overall benefit of consumers and American agriculture.”²¹⁷ With respect to grain, it performs this mission generally by setting identity and quality standards and carrying out testing programs under the U.S. Grain Standards Act.²¹⁸ After the discovery of StarLink corn in the human food supply, GIPSA played a central role in setting up testing protocols to assure Japan and other major importers of U.S. corn that the product they were receiving was free of StarLink (see *StarLink Corn: A Chronology* in Appendix A).

Since the StarLink incident, GIPSA has stepped up its biotechnology program, the purpose of which is to “lend order to the development of voluntary IP and product segregation procedures to the extent they emerge from the private sector.”²¹⁹ GIPSA sees its role as supporting the development of market-driven IP systems by ensuring the availability of reliable tests to analyze crops for GM traits, providing testing services through its laboratories, evaluating and certifying the proficiency of private labs, and possibly providing a voluntary program to verify the effectiveness of IP processes and other “new marketing mechanisms.” GIPSA stresses that its function is to add value to the marketing system “by augmenting, not supplanting, existing marketing mechanisms.”²²⁰ GIPSA has established a Biotechnology Reference Laboratory to serve as a center for developing and evaluating test methods for GM crops, as well as a Rapid Test Performance Evaluation Program to validate the effectiveness of the fast and economical analytical methods that will be required to implement IP programs.

217 USDA GIPSA n.d., “GIPSA Backgrounder.”

218 7 USC 71 et seq.

219 USDA GIPSA and AMS 2000.

220 USDA GIPSA n.d., “GIPSA’s Biotechnology Program.”

In August 2002, in recognition of the continuing shift “from a supply-driven to a consumer-driven market” for food commodities, including the “emergence of... a niche market for non-biotechnology-derived products,” GIPSA and the Agricultural Marketing Service (AMS) jointly announced plans to establish voluntary systems to verify that market-based IP systems are working as intended.²²¹ GIPSA has limited itself to date to this technical support role, working in response to marketplace IP initiatives, rather than attempting to move the market in the direction of IP. GIPSA has not addressed the issue of purity standards for IP programs, leaving that to the marketplace or the regulatory standards of importing countries. GIPSA lacks the mandate and probably the legal authority to require or set binding standards for IP programs.

QUESTIONS FOR POLICYMAKERS AND CONSTITUENTS.

The key questions concern how government and the private sector should interact to meet emerging marketplace demands for IP and traceability, and may include the following:

- With respect to the current generation of biotech crops and foods, under what circumstances, if any, should government mandate the adoption of IP, traceability systems, or both?
- Should the government set purity, verification, or other standards that must be followed by private parties that voluntarily choose to market their products as identity preserved?
- Should the government provide nonbinding guidance to assist private parties in developing consistent and credible IP and traceability systems?
- Is the technical support role currently being played by GIPSA sufficient? Should it be continued? expanded? changed?
- How can the expertise in private companies be accessed and made widely available to the government and others to foster effective IP and traceability systems?
- Regarding crops in the biotechnology pipeline, such as crops modified for improved nutrition or to produce pharmaceutical proteins, under what circumstances, if any, should government mandate the adoption of IP systems, traceability systems, or both? Should such systems be required only for safety reasons? to ensure the integrity of claims for value-added GM crops and foods? in neither case? for other reasons?
- Does FDA have adequate legal authority to mandate IP, traceability, or both for food safety and labeling reasons?
- What roles should be played by GIPSA and other agencies in considering government-mandated IP and traceability systems?
- What role should the government play in supporting the development of nonmandatory IP for future biotech products?

²²¹ USDA GIPSA and AMS 2002.

POSSIBLE PATHWAYS.

For the current generation of biotech products, constituents have little interest in considering the mandatory IP of GM or non-GM crops because they recognize that the need for IP is driven primarily by the market. The one instance in which effective, government-mandated IP might have addressed a legitimate regulatory need was to manage the split approval of StarLink, but in the aftermath of that difficult experience, a broad swath of constituents agreed that the best solution was to avoid split approvals rather than to attempt to manage them through IP. Thus, the pathways outlined here focus on possible roles for government in supporting voluntary IP for current products and preparing to deal with the IP challenges that may be posed by products in the biotechnology pipeline, such as foods with special nutritional attributes or crops used to produce pharmaceutical or industrial materials.

Pathways for consideration include:

- Increase government investment in the development of practical analytical methods. FDA and GIPSA acknowledge that the lack of an adequate inventory of practical analytical methods for detecting GM traits in crops, food ingredients, and finished food products is a limiting factor in the development of efficient, effective IP and traceability systems. GIPSA is making a modest investment in developing new methods (\$2 million was requested for this purpose in FY 2001)²²² but only to address the detection of GM traits in grain commodities under GIPSA's jurisdiction. FDA is investing little or no resources in the development of biotech-detection methods for GM crops or processed ingredients and foods derived from them, presumably because of the lack of priority or defined regulatory need for such methods.
- Require that the developers of GM crops and foods provide to the government and make publicly available a practical analytical method for each GM trait. As discussed earlier, analytical methods have not been required as a condition of market entry for any of the current biotech products, whether they entered the market under EPA or FDA jurisdiction. Clearly, such a requirement would facilitate IP and traceability throughout the food chain, but there are several issues to consider. One is legal authority, which is probably clear at EPA but uncertain for FDA unless the product is a food additive. Another is how sensitive the methods must be, which would require consideration of how pure an identity-preserved crop or food must be. A third issue is how broadly applicable the methods should be, given that many GM traits will be present not only in the raw grain commodity in which it is inserted but also in a diverse array of processed ingredients and foods (such as breakfast cereals, corn-based snack foods, or any of the many soy-containing processed foods), each of which could pose different analytical challenges and thus variations in the detection methods that would be useful at a practical level.
- Increase government laboratory capacity and make it available to private parties for managing IP and traceability systems. Such a service presumably should be provided on a fee-for-service

222 USDA GIPSA n.d., "FY 2001 Budget Summary."

basis, especially because it would help private parties meet market-driven needs for IP and traceability, at least in the near term. The potential advantages of a government-run testing program are to capitalize on the expertise and testing capabilities already developed by the government at public expense, to achieve economies of scale, and to enjoy the credibility that results from having the verification testing for an IP system conducted by an objective public laboratory.

- Certify private laboratories to support IP and traceability systems. Government certification of labs has worked in other contexts as a means to ensure that testing is conducted in accordance with recognized procedures and to provide a basis for confidence in the test results. Private testing could be more efficient over the long term than a government-run testing program.
- Develop guidelines for IP and traceability systems. Although there is little likelihood the government will consider mandating IP and traceability systems, it could potentially improve the consistency, effectiveness, and credibility of the systems that private parties are developing voluntarily by establishing guidelines or criteria for effective systems. The issues that might be addressed in such guidance include acceptable thresholds for adventitious presence (i.e., the degree of purity expected in an IP commodity or food), the nature of sampling and testing required to verify IP, and the nature of records required to document IP and traceability.
- Begin policy development on IP and traceability for products in the pipeline. In the foreseeable future, the regulatory agencies will be asked to clear for market entry GM products that most constituents will agree need a greater degree of postmarket control than current products, whether to be sure that consumer value is being delivered as promised or to control whether and under what circumstances nonfood GM plants should enter the food supply. It remains to be seen whether the government will consider it appropriate to require some form of IP or traceability and under what circumstances. Given the history of government's role in this area, legal uncertainties, and the inevitable controversy surrounding the subject, the government could begin now to examine its options and develop criteria to guide its decisions.

CONSTITUENT PERSPECTIVES.

For some constituents, IP is the wave of the future for biotechnology. A representative of the Missouri Corn Growers Association said, "if any good comes from the StarLink episode, it will be from emphasizing the need to move farmers and millers toward an identity-preserved system."²²³ In a news story citing the recognition by food companies that nutrient-enriched or other value-

223 Palmer 2001a, B5.

enhanced GM products will need to be identified as “genetically engineered” because they will be marketed as premium products, a public interest advocate observed that “biotechnology itself, if it’s successful, will be a big driver toward identity-preserved production. Otherwise, it won’t recoup its costs.”²²⁴

Constituents generally recognize that market forces drive IP; they also agree that government imposition of IP requirements through regulation should be avoided. A leading consumer advocate stressed that IP is currently a commercial response to market demand and that even the support services, such as testing and certification of IP programs, should be managed as much as possible through private organizations, rather than government, to avoid the diversion of public resources.²²⁵ Another public interest representative said the government’s roles on IP should include setting tolerances to define the acceptable level of purity and “encouraging” the development of IP systems.²²⁶ A representative of a leading technology provider suggested that government should consider setting tolerances as part of the effort to encourage establishment of workable IP systems.²²⁷

Industry trade associations strongly oppose mandating IP and traceability, stressing potential costs and the efficiencies of the bulk handling system. A representative of CropLife America wrote the following:

Some have suggested that the answer to consumer demands for grains and other products not developed through the use of modern biotechnology is to utilize costly forms of segregation, including identity preservation (IP) and channeling systems. These systems, which will allow varying degrees of separation depending upon the purity allowed, are all characterized by segregation of products with distinguishable characteristics from all other similar products. However, these approaches are smaller scale, higher cost systems that occur outside of the existing bulk commodities system. These higher priced, niche market approaches simply cannot be economically applied to the bulk commodity system, which operates by economies of scale.²²⁸

The food processing industries are concerned about the European proposal to mandate traceability as a means of implementing labeling for biotech foods. The Grocery Manufacturers of America (GMA) opposes the European Commission’s proposals for the tracing and labeling of biotech foods, arguing that requiring companies to trace and label all product ingredients, including highly refined oils and starches that do not contain any detectable transgenic DNA or protein from biotech commodities, would create significant technical barriers to trade for U.S. food and beverage companies.²²⁹

224 Manning 2000.

225 Foreman 2002.

226 Caplan 2002b.

227 Gadsby 2001.

228 Porter 2001, 34.

229 Kochenderfer 2001, 22.

Grain traders and exporters tend to link the IP issue with the problem of adventitious presence and focus on the need for international harmonization of biotech approval systems and adventitious presence policies so that there will be less need for IP. Representatives of the North American Export Grain Association emphasized the inevitability of adventitious presence and the practical limitations on control of commodity purity in calling for international harmonization of regulatory systems and approvals.²³⁰ From their perspective, GM crops should not be approved in the United States until they are approved by key trading partners, suggesting that grain traders should not be put in the position of handling international trade commodities that have not gained regulatory and consumer acceptance in the countries to which they could be shipped, advertently or inadvertently. Similarly, an ASTA representative stressed international harmonization at the approval stage as the key to solving the problem of adventitious presence and lack of foreign regulatory approvals that are an important part of the current motivation for establishing IP systems.²³¹

The skepticism within the export community regarding IP as a solution to the export problems facing GM crops and foods was captured in a recent report by the General Accounting Office (GAO):

According to industry representatives, the competitive advantage of the U.S. grain handling system results from the commingling of bulk commodity crops, including conventional and biotech varieties. Any regulatory measure that would ultimately lead to segregation or traceability would raise handling costs and potentially undermine the efficiency and competitiveness of this system, they maintain. While growers generally support biotechnology, some actors in the agricultural sector, notably exporters, have been critical of biotech companies for marketing varieties in the United States that have not yet been approved in major market countries.²³²

USDA officials involved in the market acceptance and trade of biotechnology also stress the difficulty of imposing IP on “what has always been a homogeneous product,” claiming it could “create havoc.”²³³ They emphasize the need for “a synchronous approval process internationally.”

230 Martin and Miller 2001.

231 Condon 2002.

232 U.S. GAO 2001b.

233 Schechtman and Hegwood 2002; Shipman and Pitchford 2002; Slutsky 2002.

Conclusion

The title of this report poses what seems to be a simple question about the U.S. government's postmarket oversight of biotech crops and foods: is the system prepared? This question cannot be answered, however, without first answering another question: prepared to do what? We give at least a partial answer to the second question in **Objectives of Postmarket Oversight**. We want the system of postmarket regulatory oversight to foster compliance with conditions of use or other restrictions imposed during the premarket review process; detect noncompliance and unforeseen health and environmental problems; take appropriate enforcement action to correct and penalize noncompliance; and manage follow-up investigations, market disruptions, and other consequences of noncompliance and unforeseen problems.

Our research casts doubt on the preparedness of the current postmarket oversight program to achieve these traditional objectives. For the products it has deregulated, APHIS lacks a regulatory handle to require systematic data collection by sponsors to detect unforeseen plant pests or environmental problems. EPA and its regulatory partners in the states have no program to provide direct oversight and enforcement of environmentally important PIP use restrictions, and EPA is still working out with the biotech industry how to ensure the effectiveness of the compliance programs that PIP registrants are required to establish through their private contractual relationships with growers. FDA has no affirmative compliance and enforcement program for biotech crops or foods and lacks some of the basic analytical tools to test whether the biotech products already on the market are in compliance with applicable regulatory requirements.

We do not conclude that these gaps in postmarket oversight have resulted in widespread noncompliance with regulatory requirements or any specific food safety or environmental problems. The general experiences of StarLink and ProdiGene reveal some potential vulnerabilities in this regard but also show that the agencies have substantial resilience and capability to react to significant compliance problems when they do arise.

With respect to the traditional objectives of postmarket oversight, the real challenge for the system lies ahead. The biotechnology pipeline is likely to produce an increasing number and diversity of GM crops and foods, including ones that involve novel proteins, claims of consumer benefits, and nontraditional uses of plants, such as the manufacture of pharmaceuticals and industrial chemicals. Many of these future applications of biotechnology will require tighter regulatory control to protect human health and the environment, and they will call into serious question whether the current overall structure and approach to postmarket oversight is adequate to ensure compliance and to maintain public confidence in the regulatory system. There almost certainly will be a need to enhance the resources devoted to postmarket oversight and to consider strategies that effectively harness public and private resources to ensure that consistent and credible compliance with regulatory requirements is achieved.

Beyond this need to achieve the traditional objectives of postmarket oversight, biotechnology raises a more fundamental issue that is centrally important in considering whether the system is prepared for the future: what degree of postmarket control does society want over GM crops and foods? The degree of control desired and what postmarket oversight should do in achieving it is fairly well established for conventional agricultural and food technologies such as pesticides, animal drugs, and food additives. Health and environmental standards are widely recognized, pre-market approval systems are broadly accepted, and public expectations can be met by ensuring that products pass scientific muster at market entry and are used in accordance with the conditions established by the regulatory agencies. A general, if perhaps unspoken, consensus exists about the degree of control society wants over these conventional technologies, and postmarket oversight programs can be evaluated from the perspective of whether that degree of control is being provided.

Biotechnology is different, because societal consensus is still lacking about the degree of post-market control desired. This lack of consensus is based in part on some scientific and technical uncertainties, including:

- Is it possible to predict the future environmental effects of a GM plant that has been deregulated by APHIS on the basis of field trials?
 - How great should concern be about compliance with buffers and refuges in light of the potential effects of Bt crops and other PIPs on insect resistance, nontargeted species, and biodiversity in general?
 - Is it technologically feasible to measure the broad ecological effects of GM crops or to enforce strict standards for adventitious presence or identity preservation?
- Do biotech foods pose unpredictable risks of allergenicity that warrant greater postmarket oversight than other foods?

Questions like these can most likely be answered as science and technology improve and develop more certainty. The lack of consensus about the appropriate degree of postmarket control over biotech crops and foods also reflects, however, conflicting or uncertain social values, such as:

- What level of precaution is appropriate when faced with the potential risks of biotech crops and foods?
- How should the regulatory system address the fact that most of the benefits of the current technologies are enjoyed by one subset of society—the technology providers and farmers—whereas the potential risks are experienced by society at large?

- How hard should the system work to satisfy the preferences of those who would rather avoid GM foods altogether?
- Who should bear the inconvenience and economic costs of whatever degree of protection and control is deemed appropriate?

These are value-laden questions for which there are no scientific answers. It is the combination of scientific and technical uncertainty and differences over values that fuels most of the current controversies surrounding biotechnology.

To answer our two broad questions—*is the system prepared?* and *prepared to do what?*—the scientific and technical uncertainties must be acknowledged and their implications understood; the value issues need to be put on the table and debated. Then, in light of the defined and probably still-conflicting values, society must determine the degree of postmarket control it desires for biotech crops and foods. The details of public policy will flow from there.



The ProdiGene Incident

On November 13, 2002, the U.S. Department of Agriculture (USDA) announced it was investigating the possible contamination of soybeans by corn plants that had been genetically modified by ProdiGene Inc. (College Station, TX) to produce an experimental vaccine for use against a viral disease in pigs (Fabi 2002a). Inspectors from the USDA, Animal and Plant Health Inspection Service (APHIS), detected the contamination during an inspection of a Nebraska soybean field where the pharmaceutical corn had been field-tested in 2001. In apparent violation of APHIS containment requirements mandated in an APHIS field trial permit, the farmer had not fully removed the corn plants from the field, and a few stalks had grown as “volunteers” during the 2002 growing season. Because the soybeans harvested from the contaminated field had been commingled with other soybeans, APHIS ultimately quarantined 500,000 bushels of potentially contaminated soybeans to prevent any trace of pharmaceutical protein from entering the food supply. U.S. Food and Drug Administration officials said that the small amount of unapproved corn material found in the soybeans posed minimal, if any, risk to consumers (Cassidy and Powell 2002).

Despite the lack of a real safety concern, reaction to the event was swift, intense, and broad. The Biotechnology Industry Organization (BIO), representing technology providers, claimed the discovery proved that the regulatory system works, because the alleged permit violation was discovered by APHIS inspectors. The president of the National Food Processors Association, however, said the incident “very nearly placed the integrity of the food supply in jeopardy,” and another food industry spokesman called ProdiGene’s lack of compliance an “unacceptable risk to the U.S. food supply” (Fabi 2002; GMA 2002). Food industry officials questioned the sufficiency of current containment procedures and, in a meeting with Secretary of Agriculture Ann Veneman, urged strengthening the regulations for pharmaceutical plants. The Center for Science in the Public Interest (CSPI), a prominent consumer advocacy group, said the alleged permit violations by ProdiGene demonstrated that the biotechnology

industry “cannot be trusted to meet its obligations of safeguarding the food supply and environment” (CSPI 2002a). Declaring that it was unknown whether similar violations had gone undetected, CSPI called for “a robust inspection and enforcement program” (CSPI 2002b).

On December 6, USDA announced that ProdiGene, without admitting or denying any violations of the Plant Protection Act, had agreed to pay a fine of \$250,000, reimburse USDA the approximately \$3,000,000 required to destroy the 500,000 bushels of soybeans, and post a \$1,000,000 bond (USDA 2002b). To guard against future incidents and allay the concerns of the food industry, BIO has urged its members not to plant pharmaceutical plants in major food crop production areas, a policy that has caused an uproar among farmer groups in the Corn Belt who want the option to plant high-value genetically modified crops.



The StarLink Incident: A Challenge to the System

StarLink, the trade name of several genetically modified corn hybrids produced by Aventis CropScience (Research Triangle Park, NC), was genetically modified to contain a common soil bacterium, *Bacillus thuringiensis* (Bt), to produce its own insecticidal protein or pesticide (Cry9C protein) for protection against the European corn borer. Because of inconclusive tests on the potential of the Cry9C protein to cause allergic reactions in humans, the U.S. Environmental Protection Agency (EPA) granted StarLink a so-called split registration, designating StarLink for animal feed and industrial use only.

In September 2000, StarLink corn was detected in the human food supply. Genetically Engineered Food Alert (GEFA), a coalition of consumer and environmental organizations, discovered it in taco shells sold in grocery stores and alerted the media and the government (Kaufman 2000a). StarLink was soon identified in products from corn chips to corn dogs. Kraft Foods, the largest food corporation in the United States, promptly recalled 2.5 million boxes of Taco Bell-brand taco shells and discontinued production of the shells until it could ensure that the stock meal did not contain StarLink corn. Other large U.S. food and animal feed processors, including Kellogg, ConAgra, and Archer Daniels Midland, temporarily closed their grain mills.

Aventis collaborated with the government to contain StarLink corn and voluntarily withdrew its registration to provide additional assurance that StarLink would not be sold or grown in the future. To prevent further mixing of StarLink corn into the human food supply, Aventis agreed with USDA to launch a \$20-million buyback program, offering producers a premium of \$0.25/bushel above the market price (Segarra and Rawson 2001).

Even with these containment efforts, StarLink corn was found throughout the food system. Aventis reported that, although StarLink constituted a very small percentage of total U.S. corn production (0.4–0.5%), it could take four years to remove StarLink from food channels (Reuters 2000). In response to the StarLink experience, EPA said it would no longer grant “split” approvals for genetically modified crops.

The StarLink incident raised a host of issues related to health, international trade, consumer confidence, and regulatory oversight. The human health concern stemmed from tests that revealed that the Cry9C protein is heat resistant and does not break down easily in the human digestive system and thus might be a potential allergen. After reviewing 34 reports of allergic reactions to StarLink corn, the EPA Scientific Advisory Panel found a “medium likelihood” that Cry9C is a potential allergen but that, given the low levels of StarLink corn in the U.S. diet, there is a “low probability” of allergenicity in the exposed population (SAP 2000). A June 2001 study by the Centers for Disease Control did not find evidence that StarLink corn had produced allergic reactions in humans (CDC 2001).

The international trade impacts of StarLink corn were substantial. Japan and South Korea, two of the largest importers of U.S. corn, implemented a zero tolerance for StarLink corn and turned to China, Brazil, Argentina, and South Africa to meet more of their corn demand (Cropchoice 2001). This shift cost U.S. farmers tens of millions of dollars. To reestablish trade with Japan and South Korea, the United States implemented confidence-building measures such as extensive testing protocols for corn exports to ensure the absence of StarLink in corn intended for human use.

In the United States, the StarLink incident raised the visibility of agricultural biotechnology and undermined public confidence in the food system. More than 1,600 private citizens and groups filed comments on StarLink corn with EPA (U.S. EPA 2000a). In a November 2000 Reuters poll, 54.4% of the adults surveyed said that the StarLink recall concerned them “because it raises questions about our food supply,” whereas 24.9% said it did not concern them (Cropchoice 2000).

Of greatest relevance to this report, the StarLink incident shined the public spotlight on the regulatory system for biotech foods and crops. In particular, it raised questions about the preparedness of the system to oversee biotech products after they have entered the market. Those questions are the subject of this report.

Appendix A

StarLink Corn: A Chronology

- March 14, 1997:** The U.S. Environmental Protection Agency (EPA) issues an experimental use permit (EUP) to Plant Genetic Systems (PGS), a predecessor of Aventis CropScience, to test corn seeds containing the Cry9C protein on 3,305 acres in 28 states (Segarra and Rawson 2001).
- April 4, 1997:** PGS submits an application to EPA to register Cry9C protein and the genetic material inserted in corn to produce it (cry9C DNA) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The application requested that Cry9C protein and cry9C DNA be registered for use in corn, without limitation on the corn's use in human food or animal feed. PGS simultaneously petitioned EPA for exemption from the requirement for a tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA) for Cry9C protein and the cry9C gene (Plant Genetic Systems 1997).
- August 8, 1997:** EPA announces in the Federal Register the PGS application to register the Cry9C pesticide under FIFRA (U.S. EPA 1997c).
- September 19, 1997:** EPA announces in the *Federal Register* the PGS petition for a full exemption from the requirement of a tolerance for Cry9C residues in or on all the raw agricultural commodities under FFDCA (U.S. EPA 1997a).
- November 26, 1997:** EPA announces in the *Federal Register* the PGS request for a temporary “split” exemption from the requirement of a tolerance that would allow the Cry9C protein to be present only in animal feed, based on unresolved questions about the human allergenicity of the protein (U.S. EPA 1997b).
- April 10, 1998:** EPA issues a final rule establishing the temporary split tolerance exemption for Cry9C (U.S. EPA 1998a).
- May 12, 1998:** EPA issues a registration to Aventis CropScience for StarLink corn that limits its use to animal feed and nonfood industrial applications. This split registration was granted while more data were to be gathered to assess the potential allergenicity of the Cry9C protein. One condition of the registration was that PGS would obtain signed agreements with growers that they would comply with the animal feed use restriction (U.S. EPA 2001a).
- May 22, 1998:** EPA publishes in the *Federal Register* a final rule granting a permanent split tolerance exemption for the Cry9C protein and cry9C DNA residues, allowing their use “only in corn used for feed; as well as in meat, poultry, milk, or eggs resulting from animals fed such feed” (U.S. EPA 1998b).

October 1998: The registration of Cry9C protein and its associated DNA is transferred from PGS to AgrEvo USA Co., which had bought the StarLink business from PGS (Hoechst 1997).

November 1998: AgrEvo submits a new petition seeking to extend the tolerance exemption to all raw agricultural commodities.

April 7, 1999: EPA publishes in the *Federal Register* a notice announcing the filing of the AgrEvo tolerance exemption petition and seeking comment on the potential allergenicity of the Cry9C protein. This issue was raised because the Cry9C protein had been found in in vitro studies to have some of the characteristics of an allergen, including being heat resistant and potentially slow to digest, characteristics not possessed by other marketed Cry proteins (U.S. EPA 1999a).

December 21, 1999: EPA publishes a notice in the *Federal Register* asking for scientific input and public comments on how to assess the potential allergenicity of Cry9C in establishing that the “reasonable certainty of no harm” safety standard for pesticide residues has been met. EPA wants this input before considering AgrEvo’s request for a full exemption under FFDCA (U.S. EPA 1999b).

February 29, 2000: A subpanel of the EPA Scientific Advisory Panel (SAP) is convened to define the issues and methods involved in assessing the allergenicity of Cry9C and to consider whether the Cry9C protein and other proteins having similar characteristics might be human allergens. (By this time, Aventis had been formed by the merger of AgrEvo and Rhône-Poulenc Ag Company, and Aventis CropScience had assumed the FIFRA registration for StarLink corn [Segarra and Rawson 2001].)

April 5, 2000: The National Academy of Sciences (NAS) publishes a report initiated by the National Research Council addressing the health, environmental, and regulatory issues posed by genetically modified (GM) “pest-protected” plants, such as those modified to contain Cry9C and other *Bacillus thuringiensis* (Bt) toxins. The report states that Cry9C raises concerns of allergenicity due to the protein’s relative stability in a simulated gastric environment. The NAS report advises EPA to improve testing for the human and environmental impacts of Bt crops and make the results of these tests, rather than just the agency’s evaluation, more available to the public (NRC 2000).

July 19, 2000: Genetically Engineered Food Alert (GEFA), a coalition of food safety and environmental organizations, announces a campaign “to take genetically engineered ingredients off American grocery shelves until they are fully tested and labeled” and calls specifically on the Campbell Soup Company to remove such ingredients from its products (GEFA 2000b).

August 9, 2000: EPA announces new review processes for plant pesticide registrations, including Cry9C, in view of the NAS recommendations (Segarra and Rawson 2001).

September 18, 2000: *The Washington Post* reports that in tests conducted for GEFA, an independent laboratory (Genetic ID) had found traces of genetic material from StarLink in Kraft's Taco Bell Home Originals taco shells in grocery stores in Washington, DC. The taco shells had been manufactured in Mexico. Some government officials expressed skepticism about the testing process, and Rep. Dennis J. Kucinich (D-Ohio) said, "Discovery of the unapproved corn shows that genetically engineered ingredients are not well regulated" (Kaufman 2000c).

September 22, 2000: Kraft Foods recalls all taco shells sold nationwide in supermarkets under the Taco Bell brand after tests confirm they were made with StarLink corn that was not approved for human consumption; shells sold through Taco Bell restaurants, which use a different supplier, are not affected (Brasher 2000).

- Kraft's Taco Bell brand taco shells had been made by chipmaker Sabritas (unit of PepsiCo Inc.) at a plant in Mexicali, Mexico, with corn from the Dallas-based Azteca Milling plant in Plainview, Texas (Fulmer 2000b; Brasher 2000).
- Azteca Milling claims to have bought corn from farmers under contract, who grow only varieties on a list issued by the company; no GM corn was on the list (Pollack 2000).
- Garst Seed Company had distributed StarLink seed (Pollack 2000).

September 26, 2000: Aventis CropScience announces that it has told seed distributors to stop selling StarLink corn hybrids for the 2001 crop, as a way to minimize the chance that unapproved corn will enter the food supply (Hesman 2000).

- Sano Shimoda, president of BioScience Securities Inc., a brokerage, investment banking, and corporate advisory firm for industry sectors that are being affected by agricultural biotechnology, says, "The taco shell incident illustrates the difficulty of keeping commodity grains separated for proper uses.... Obviously the real world of agriculture created the problem" and "right now it's almost impossible to track commodity grain through the entire processing chain" (Hesman 2000).
- Azteca Mill stops making and selling yellow flour, which accounted for 15–20% of its output (Pollack 2000)
- Azteca Mill says it will begin testing corn for presence of StarLink using a new test by Strategic Diagnostics (Pollack 2000).

September 27, 2000: In a letter to President Bill Clinton, GEFA criticizes the U.S. Food and Drug Administration's (FDA's) oversight of biotech foods, including its lack of a method for detecting Cry9C in food, and calling for strengthening of premarket testing and postmarket oversight (GEFA 2000a). Environmentalists, food manufacturers, and biotech proponents call for ban on genetically altered crops that have not been cleared for use in food (Fulmer 2000a).

- EPA officials say they are considering ending the practice of granting partial crop approvals as part of a review of its policies for dealing with engineered crops.

- EPA determines that licenses expiring the following year for eight genetically altered corn varieties will not be extended until EPA decides how to deal with relatively new types of crops, according to Stephen Johnson, Deputy Assistant Administrator, Office of Pesticides and Toxic Substances.

September 29, 2000: The U.S. Department of Agriculture (USDA) and Aventis begin taking aggressive steps to locate and direct all StarLink and buffer corn to approved uses. Aventis informs growers of USDA's Corn Containment Program under which the Commodity Credit Corporation will purchase StarLink corn (including StarLink itself plus corn planted as a buffer around StarLink fields for resistance management purposes) at a price equal to the October 2, 2000, county price plus a premium of \$0.25/bushel. Aventis will reimburse USDA for the full purchase price of the corn plus activities associated with storage, inspection, transportation, and auditing (USDA and EPA 2000; Segarra and Rawson 2001).

October 1, 2000: The federal government's StarLink purchase program is estimated by industry experts to involve 45 million bushels of corn and cost approximately \$68 million. Securities analysts are confident that Taco Bell's core customers are unconcerned by StarLink and do not expect the incident to have a measurable effect on Taco Bell's sales (Tribune News Services 2000b).

October 6, 2000: USDA releases an alert reminding the grain trade that StarLink corn may not be lawfully sold for use in human food or for export.

October 12, 2000: The Safeway supermarket chain recalls its store-brand taco shells after a GEFA coalition finds StarLink corn in them. The shells are produced by Mission Foods Corp. of Irving, TX, a subsidiary of Mexico's Gruma Corp. The recall extends into Canada (Kaufman 2000f).

October 12, 2000: Aventis announces the voluntary cancellation of its registration of StarLink in response to urging from EPA (Johnson 2000).

Mid-October 2000: EPA requests FDA's assistance in evaluating reports from consumers alleging adverse effects associated with foods thought to contain Cry9C protein. FDA subsequently enlists the collaboration of the Centers for Disease Control and Prevention (CDC) on the evaluation.

October 18, 2000: StarLink again is found in taco shells made for Safeway supermarkets by Mission Foods of Irving, TX. The company recalls all foods made with yellow corn and begins to use white corn in all of its products (Severson 2000).

October 19, 2000: Aventis claims that corn from the 2000 crop apparently was sold by farmers to dozens, and perhaps hundreds, of grain elevators across the country, which unknowingly distributed it to millers and processors for use in human food (Kaufman 2000a).

- John Wichtrich, vice president and general manager of Aventis CropSciences, estimates that 88% of StarLink corn was either being stored on farms or used for feed, but an additional 9 million bushels had already left farms. Of that corn, Aventis is trying to track it down and buy it back.
- Aventis estimates that its costs associated with buying back StarLink corn will be \$100 million; Aventis is paying to test commingled corn in many grain elevators.
- Wichtrich says growers have indicated that some did not know the StarLink corn was only approved for animal or industrial use, or they forgot restrictions. “A lot of this corn was grown on a small section of larger farms, and sometimes farmers just harvested it all together.”

October 22, 2000: Mission Foods pulls all of its corn-based products from stores other than Safeway, including Kroger, Albertson’s, and H-E-B (Ivanovich 2000).

October 22, 2000: Kellogg Co. shuts down a Michigan plant because it cannot guarantee corn used in production would be free of a GM grain approved only for animal consumption. Big grain suppliers are unable to certify that their corn is not mixed with genetically altered corn. StarLink was mixed with regular corn in several sites around the country. Nine million bushels of StarLink are reportedly still unaccounted for by Aventis (Tribune News Services 2000a).

October 24, 2000: Four grain industry organizations (American Farm Bureau Federation, National Corn Growers Association, North American Export Grain Association, and the National Grain and Feed Association) write to Agriculture Secretary Dan Glickman, calling for urgent government action to define the terms under which StarLink corn may be exported in order to protect U.S. export markets (Grain industry 2000a).

October 24, 2000: Aventis asks EPA to convert its pending tolerance petition into a petition for a time-limited tolerance that would apply to (and legalize) only the unapproved human uses of the StarLink corn already in the food supply. Aventis also submits new evidence to support its case that the grain is safe, including new information about the speed at which the Cry9C protein breaks down in the human stomach. Aventis says, “New tests and risk assessments concluded that consumer exposure to foods containing the corn is, even under worst-case scenarios, many thousands of times smaller than that required to sensitize individuals and lead to a later allergic reaction” (Van Wert 2000; Aventis CropScience 2000a).

October 25, 2000: U.S. government lifts export restrictions on StarLink so exporters can ship corn with “trace amounts” for use as animal feed only to countries where it is approved for that use (USDA, FDA, and U.S. EPA 2000).

- October 26, 2000:** Japanese Consumers' Union has detected StarLink corn in snack foods and animal feed—the first indication that StarLink has spread overseas. StarLink is not approved for any use in Japan (Kaufman 2000d; Strom 2000).
- October 26, 2000:** The business section of the *Toronto Star* reports that StarLink is spilling over into Canada but no one is telling consumers (Laidlaw 2000). Canadian Food Inspection Agency officials claim that StarLink has not crossed the border (*The Gazette* 2000).
- October 26, 2000:** FDA issues instructions to its field offices to collect samples of selected processed foods made from yellow corn and analyze them for the presence of Cry9C DNA for the purpose of removing products containing Cry9C from interstate commerce. The assignment is accorded a “top” priority with sampling and analysis to be completed by December 15, 2000 (U.S. FDA 2000).
- October 27, 2000:** Government officials report having tracked down all but 1.5% of the StarLink crop, leaving 1.2 million bushels of the 80-million bushel crop unaccounted for, down from 4.5 million bushels that could not be traced earlier in the week. EPA also announces that it is unlikely the agency will grant any more split registrations (Zitner 2000).
- October 31, 2000:** EPA announces Aventis' submission of additional data on the potential allergenicity of Cry9C and outlines the process EPA will follow to review the data and reach a conclusion. EPA makes the information available to the public with a 30-day comment period (Segarra and Rawson 2001).
- November 2, 2000:** The same grain industry associations that wrote to Agriculture Secretary Dan Glickman on October 24 write again, calling for strong government intervention to enforce Aventis' financial obligations to the grain trade, prevent further commingling of StarLink with other corn, and provide “assurances to consumers in the U.S. and globally that the U.S. supply of corn and corn products is safe and reliable” (Grain industry 2000b).
- November 2, 2000:** USDA finalizes a test and documentation protocol to assure the government of Japan that corn imported from the United States does not contain detectable amounts of StarLink corn.
- November 3, 2000:** Japan accepts the USDA StarLink testing plans. The same day, Wilson Foods, a Utah company, becomes the third U.S. processor to recall corn products found to contain StarLink corn. It recalls corn products sold in grocery stores in Utah, Idaho, and Montana.

- November 9, 2000:** After an internal review, the Aventis CropScience Board of Management issues a status report on the effort to contain StarLink and its financial impact on the company. Aventis claims that it voluntarily withdrew its StarLink registration after discussion with EPA because it wanted to ensure that “in the future no new StarLink corn will be grown for any use in the U.S. or for export until a new registration for both food and feed use has been obtained” (Aventis CropScience 2000a).
- November 13, 2000:** EPA issues a preliminary evaluation of Aventis’ submission on the allergenicity of Cry9C, concluding that the potential dietary exposure to the Cry9C protein is quite low but that existing evidence is insufficient to determine whether the Cry9C protein is a human allergen (U.S. EPA 2000b; *The Washington Post* 2000).
- November 13, 2000:** GEFA representatives write to EPA Administrator Carol Browner to express concern that the process for reviewing the latest Aventis submission on allergenicity does not provide the public sufficient access to data or adequate time to comment meaningfully on the evidence. They ask EPA to take additional steps to ensure “transparency and public involvement” in the process (Dunkel and Mendelson 2000).
- November 14, 2000:** South Korea recalls 32,000 pounds of tortillas based on the presence of StarLink corn; USDA officials claim the corn may have been exported to Korea through a third party (*The Washington Post* 2000).
- November 14, 2000:** Sixteen state attorneys general call on Aventis to do more to reduce economic loss to farmers, including implementing an expedited claims process, increasing transportation and storage capabilities, making staff available to answer questions, providing more testing resources, and taking further steps to accept responsibility for financial losses (Attorneys general 2000; Kaufman 2000e).
- November 15, 2000:** Aventis announces plans to divest Aventis CropScience as part of a plan to focus the company on its pharmaceutical business (Aventis 2000).
- November 17, 2000:** U.S. corn sales are reported to have declined due in part to StarLink concerns in South Korea and Japan (Bloomberg News 2000).
- November 20, 2000:** USDA issues final Protocol for Food Corn Exported to Japan (USDA GIPSA 2000).
- November 21, 2000:** Garst Seed Company announces that “limited quantities” of a single, non-StarLink corn hybrid produced by Garst in 1998 appears to contain “a small percentage” of the Cry9C protein. Garst asks Aventis CropScience to include this corn within its StarLink containment program (Aventis CropScience 2000b; Garst Seed Company 2000).

November 22, 2000: Aventis reportedly faces “enormous” legal liabilities because of the StarLink recalls (Kaufman 2000b).

November 28, 2000: EPA’s Scientific Advisory Panel (SAP) meets to consider the evidence on Cry9C allergenicity, including summaries of the FDA–CDC joint investigation of reported adverse events to date.

December 1, 2000: The SAP concludes that there is a “medium” likelihood that Cry9C is a potential allergen but that the levels of Cry9C that possibly exist in the human food supply present a “low” likelihood of eliciting an allergic reaction in exposed individuals. Children may be more sensitive than adults. The panel emphasizes that further study of those persons reporting an allergic reaction would be valuable and recommends other actions already begun by EPA, including containment efforts, evaluation of new data on the effects of processing on Cry9C residues, and review of new and existing analytical methods for measuring amounts of StarLink corn in processed food (SAP 2000).

December 10, 2000: The press reports that growers who were involved in the StarLink incident will choose to plant conventional corn, based on a concern that the StarLink controversy will affect consumer confidence and the farmers’ credibility; companies such as Frito-Lay and Gerber refuse to use GM organisms (GMOs) in their products (Stroud 2000).

December 18, 2000: The U.S. Embassy in Tokyo issues a Statement of Intent with Respect to the Export of U.S. Corn. This statement reaffirms U.S. commitment to the November 2, 2000, testing and documentation protocol to ensure that no StarLink corn will be exported from the United States to Japan.

January 23, 2001: Aventis agrees to contracts with 17 states, including Nebraska and Iowa, to reimburse farmers and grain elevators for costs related to detecting, sorting, shipping, and marketing StarLink corn. Farmers and grain elevators that have incurred costs as a result of the StarLink incident can apply for reimbursement until February 15, 2001. The executive director of the Nebraska Corn Board says the StarLink incident has affected farmers’ ability to export U.S. corn as much as any past occurrence (Hord 2001).

February 15, 2001: Taco Bell’s sales have been hurt by consumer concern about the taco shell recall and that its parent company, Tricon Global Restaurants Inc., has set up a \$15 million loan pool to help franchises; earlier reports had indicated that Taco Bell’s sales would not be hurt by the StarLink recall (Bloomberg News 2001a).

February 19, 2001: A commentator contends in *Fortune* magazine that the StarLink incident “has revealed the shortcomings of federal oversight and has pointed up the inability of the grain-handling industry to segregate subtly different products” (O’Reilly 2001).

February 21, 2001: Japan and the United States agree to strengthen measures already in place to ensure that no StarLink corn is exported to Japan. The agreement between Japan's Ministry of Health, Labor, and Welfare and USDA is intended to tighten a screening system approved in November 2000, according to a statement from the U.S. Embassy in Tokyo (AP 2001b).

March 7, 2001: USDA announces plans to purchase corn seed containing the Cry9C protein from several small seed companies to ensure that it is not used in the spring planting; the cost will be \$15 million to \$20 million (USDA 2001).

March 7, 2001: EPA announces that in the future, it will not grant split registrations of biotech products. EPA also releases a draft report on the effects of processing on Cry9C, indicating that wet milling virtually eliminates the protein, whereas dry milling does not.

March 8, 2001: New lab tests commissioned by Greenpeace find that Morningstar Farms Veggie Burgers and Meat-Free Corn Dogs contain GM soy and StarLink corn (Fulmer 2001).

March 9, 2001: The USDA cuts its projection for U.S. corn exports for the fourth time in the past four months, forecasting 2 billion bushels, down from 2.05 billion bushels the previous month. Private analysts say the estimates may be reduced by another 50 million bushels in the coming months. Prior to the first StarLink detection, projected corn exports were 2.175 billion bushels (Sachdev 2001).

March 31, 2001: American farmers reportedly are expected to plant more genetically engineered soybeans and cotton this year than ever before, despite the uncertainty surrounding the issue and the difficulty of segregating genetically engineered crops (Simon 2001).

April 24, 2001: StarLink is reported to have been found in additional products, such as corn bread, polenta, and hush puppies. Aventis officials say the levels detected are very low. FDA is testing the blood of about 20 people who believe they may have suffered allergic reactions (Kaufman 2001).

April 30, 2001: USDA reports that Illinois farmers plan to plant 59% of their soybean acres with GM crops; however, farmers plan to cut back slightly on biotech corn. The biotech beans require farmers to make fewer trips through the fields when fuel prices are high (AP 2001a).

May 4, 2001: Missouri Attorney General Jay Nixon is reportedly suing the maker of StarLink corn. Nixon says the company marketed the corn to Missouri farmers but did not tell them about the restrictions and failed to label the seed properly. The suit seeks to have Aventis pay Missouri farmers, grain elevators, and others for their losses and to fine the company up to \$1,000 for each violation (Hesman 2001).

June 9, 2001: Tricon agrees to pay Taco Bell franchises \$60 million for sales lost after the recall of Taco Bell taco shells that contained StarLink corn. Taco Bell franchises maintain that sales were hurt by the recall, even though the taco shells were supplied only to supermarkets (Bloomberg News 2001b).

June 12, 2001: FDA reports to EPA on the results of its joint study with CDC on the reported adverse events allegedly associated with Cry9C. FDA and CDC did not find any evidence that hypersensitivity to the Cry9C protein was responsible for the self-reported allergic responses that people experienced in fall 2000. Blood samples had been taken from 17 people, which some said was too limited a number to resolve the allergenicity issue (Reuters/AP 2001).

June 14, 2001: Grain importers in Japan and Korea, the two top U.S. corn buyers, say results of the CDC study will not affect their decision against importing StarLink corn because it is not approved for human consumption in the United States. South Korea's Korea Corn Processing Industry Association has asked foreign suppliers since late last week to replace U.S. corn with South American corn (Hur 2001).

June 21, 2001: Some farmers are reported to be establishing systems to produce "identity preserved" crops and cattle–farm products whose chain of custody can be documented from beginning to end—so they can satisfy market demand and potentially get a premium price for identity-preserved products such as GMO-free crops. A spokesman for the Missouri Corn Growers Association said, "If any good comes from the StarLink episode, it will be from emphasizing the need to move farmers and millers toward an identity-preserved system" (Palmer 2001b)

July 4, 2001: StarLink is found in a white corn product for the first time. The FDA discovered genetic material from StarLink corn in Kash n' Karry White Corn Tortilla Chips. In response to the 2000 recall of Taco Bell products, many manufacturers had switched from yellow to white corn (*The Washington Post*/Reuters 2001).

- Food Lion and Kash n' Karry grocery chains pull their store-brand white corn tortilla chips in response to FDC concerns about StarLink GM corn detected in the chips (AP 2001c).
- Both chains are owned by Delhaize Group, which alerts its food chains in Belgium, Greece, and the Czech Republic.

July 6, 2001: Frito-Lay Inc. says it is confident that its white corn products do not contain traces of StarLink yellow corn. A spokeswoman says the corn is tested before it leaves the farms and is strip-tested before it comes into the processing plants; this practice was initiated following the fall 2000 recall of Taco Bell products (Reuters 2001).

- July 11, 2001:** U.S. government tests are cited as finding that 10 of the 11 samples collected from consumers who complained of allergic reactions to StarLink corn did not contain the GM corn. Wise Foods Inc. says no StarLink genetically altered corn was detected in tests of its white corn tortilla chips; however, extra tests on all white corn shipments are being performed as an additional precaution (*The New York Times/Reuters* 2001).
- July 17, 2001:** At the SAP meeting on Cry9C allergenicity, Aventis urges EPA to set a standard of 20 parts per billion of Cry9C protein in human food and to remove from sale any foods with more than that amount. Aventis also maintains that corn inevitably will find its way into the human food supply but that processing the corn would remove 82–99% of the protein (Agence France Presse English 2001).
- July 18, 2001:** Keith Finger, a Florida optometrist, tells SAP scientists that he’s allergic to StarLink grain despite a negative government blood test. Some scientists on EPA’s SAP had questioned the effectiveness of the test and why the government had not sought out more potential victims by contacting doctors around the country; federal officials had claimed they lacked the money for wider-ranging tests (AP/Reuters 2001).
- July 18–19, 2001:** The SAP subpanel that was convened to evaluate the new information on allergenicity submitted by Aventis, EPA, CDC, FDA, and USDA reports to EPA that the studies did not provide enough data to formulate an opinion on a safe tolerance level for Cry9C protein in food (*The Wall Street Journal* 2001).
- July 24, 2001:** Seventeen states announce that they have entered into a second agreement with Aventis to compensate farmers whose corn was tainted by the company’s gene-altered StarLink corn, and two food companies from South Korea announce plans to buy 52,500 tons of corn for human food use, but not from the United States because of concerns about StarLink (Arasu 2001).
- July 25, 2001:** The SAP issues its report to EPA based on its July 17–18 meeting, reaffirming findings from previous scientific assessments that there is a “medium” likelihood that Cry9C protein is a potential allergen. The SAP agrees that information is inadequate to establish a reasonable scientific certainty that exposure would not be harmful to public health (SAP 2001).
- July 27, 2001:** Based on the SAP conclusion, EPA announces that “establishing a tolerance (legal residue limit) for StarLink in human food products is not currently supported” (Deegan 2001).
- September 4, 2001:** According to a government document, the U.S. government and Aventis had at least some indication that StarLink might have entered the human food supply more than six months before GEFA discovered it in taco shells. A survey commissioned by Aventis CropScience and conducted in December 1999 reported that 2 of 230 farmers growing StarLink had sold the corn for food use or export; another 12.6% said they did not know what happened to the corn after they sold it (Pollack 2001).

October 5, 2001: The U.S. grain industry is still on the lookout for StarLink corn, one year after the unapproved variety entered the food chain and disrupted exports. Even though StarLink was not planted in the United States this year, major grain processors are checking for it in corn from this year's harvest. One Iowa grain dealer said, "We're looking forward to the new crop coming out of the field, but we're still going to have to deal with StarLink for the next couple years." Agronomists maintain that it was next to impossible to predict how much StarLink could have remained in corn stocks, but the percentage of this year's \$9.24 billion U.S. corn harvest testing positive will surely be lower than last year (Stebbins 2001).

October 9, 2001: The USDA's Grain Inspection, Packers, and Stockyards Administration (GIPSA) validates a new dipstick-format test to detect StarLink GM corn. Neogen's Agri-Screen for Cry9C Strip Test requires only water and 10 minutes or less to detect as little as 1 kernel of StarLink among 800 corn kernels (Neogen 2001).

October 17, 2001: After a nearly two-year-long review process, EPA determines that Bt corn does not pose unreasonable risks to human health or to the environment and extends the Bt corn registration for an additional seven years. In doing this, EPA increases environmental and compliance monitoring requirements. The companies holding registrations will be required to implement insect resistance-management plans, educate growers on best practices to mitigate insect resistance, and require all growers to sign contractual agreements before planting (U.S. EPA 2001c).

November 15, 2001: Trader Joe's agrees to ban GM ingredients from its thousands of private-label products. Activist group Greenpeace had been pressuring Trader Joe's to drop GMOs for about a year, holding demonstrations outside stores. Trader Joe's claims it had been considering dropping GMOs for some time, especially after the September 2000 StarLink corn incident (*Los Angeles Times* 2001)

December 27, 2001: The USDA's Grain Inspection, Packers, and Stockyards Administration (GIPSA) validates a new test to detect Cry9C in StarLink corn. Strategic Diagnostics Inc. (a provider of biotechnology-based diagnostic tests for a broad range of agricultural, industrial, and water-treatment applications) developed and commercialized a new test to detect the insect-resistant trait in corn that generally provides results in five minutes, is simple to use, and does not require refrigeration (AgWeb 2001).

January 9, 2002: The results of a Reuters survey of more than 300 growers, conducted at the American Farm Bureau Federation's annual meeting, indicate that American farmers will shrug off European and Asian concerns about GM food and boost U.S. biotech corn plantings by more than 13% this year. The biggest expected increase is in biotech corn plantings (13.8–19.3%, depending on the variety). This increase appears to be due mostly to the end of the year-long controversy over StarLink GM corn, which contaminated some 430 million bushels of the U.S. corn supply. Bob Stallman, president of the Farm Bureau, said, "We've learned a lot from StarLink, and producers have learned to ask a lot more questions. There's a greater degree of comfort with biotech products and the marketing of them" (Doering 2002).

January 15, 2002: Traders say that the Japanese appetite for U.S. corn for food consumption will likely return to normal in mid-2002, because this year's U.S. crop apparently is untainted by the banned StarLink biotech corn. However, some skeptical Japanese food importers are still concerned about U.S. corn shipments since traces of StarLink GM corn were found in domestic food and animal feed made from imported U.S. corn in October 2000 (Hur 2002).

February 21, 2002: The National Research Council releases *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation* (NRC 2002), which provides recommendations to USDA for improving its regulation of transgenic plants and for monitoring environmental effects (Kearney and Durham 2002).

March 7, 2002: A U.S. federal judge says he will approve a \$9 million settlement of a class-action lawsuit against several major food companies that sold products containing GM corn: Kraft Foods Inc., Kellogg Co., Azteca Foods Inc., and Mission Foods Corp. Under the settlement, \$6 million in coupons will be placed on foods—from taco shells to corn dogs—made by these companies. Any money not redeemed through the coupons will go to a yet-to-be-determined nonprofit or charitable group that protects consumer interests. An additional \$3 million will be used to administer the program and pay lawyers' fees. The lawsuit also includes Aventis CropScience USA Holding Inc., which developed and marketed the corn, and Garst Seed Co., which sold seed contaminated with StarLink corn (Carroll 2002).

April 3, 2002: The U.S. agricultural attaché in Japan says that although few corn shipments from the United States to Japan show traces of the StarLink gene, the Japanese health minister intends to continue testing for StarLink. The attaché predicts that if the U.S. industry continues segregation efforts and the level of StarLink detection in the U.S. corn crop remains at zero, then the U.S. corn import share in 2002 will rebound (Johnston 2002).

April 15, 2002: The press reports that GT200, a material developed by Monsanto in the 1990s to resist Roundup herbicide but never approved, was detected last year in Canadian seed and it could be present in supplies sold in the United States, potentially for the past three years. Monsanto has requested exemption from the U.S. government, and the contamination in Canada has forced Monsanto to recall hundreds of tons of treated canola seed because Japan—a primary destination for Canadian canola exports—hasn't approved GT200. Monsanto officials say they're not sure how the material got into the seed in the first place (Bernard 2002).

May 1, 2002: U.S. corn is shedding the stigma of StarLink, the unapproved transgenic variety that slipped into the food chain in late 2000, but grain companies are not letting their guard down just yet against the rogue crop (Arasu 2002).

August 2, 2002: The Office of Science and Technology Policy releases proposed new policies for plants derived from biotechnology. The policies are intended to mitigate the “likelihood of the occurrence of intermittent, low levels of biotechnology-derived genes and gene products from crops under development for food or feed use until all appropriate safety standards have been met” (OSTP 2002).

August 2, 2002: USDA creates a new unit within the Animal and Plant Health Inspection Service to specifically focus on issues of agribiotechnology. The Biotechnology Regulatory Service will be the main program for regulation, risk assessment and permitting of biotechnology (USDA APHIS 2002).

December 27, 2002: Japan finds traces of StarLink corn in a shipment from the U.S. bound for Tokyo’s food supply (Fabi 2002b).

Appendix B

Interviewees

Stanley Abramson and Rachel Lattimore, attorneys-at-law, Arent Fox Kintner Plotkin & Kahn, PLLC

James Aidala, senior vice president, Jellinek, Schwartz and Connolly (formerly associate assistant administrator, U.S. Environmental Protection Agency)

Richard Caplan, environmental advocate, U.S. Public Interest Research Group

Mark Condon, vice president, International Marketing, American Seed Trade Association

Michael Fernandez, director of science, Pew Initiative on Food and Biotechnology (formerly associate administrator, Agricultural Marketing Service, U.S. Department of Agriculture)

Carol Tucker Foreman, director, Food Policy Institute, Consumer Federation of America

David Fredrickson, president, and **Kristi Schlosser**, government relations representative, National Farmers Union

Clifford Gabriel, deputy to the associate director, Office of Science and Technology Policy, Executive Office of the President

Margaret Gadsby, director, Public and Government Affairs, Communications, and Stewardship, Aventis CropScience

Sarah Geisert, manager, International Regulatory and Food Safety, General Mills

Rebecca Goldberg, senior scientist, Environmental Defense

Lynn R. Goldman, professor, Environmental Health Sciences, Bloomberg School of Public Health, Johns Hopkins University (formerly assistant administrator, Office of Prevention, Pesticides, and Toxic Substances, U.S. Environmental Protection Agency)

David Hegwood, special counsel, Office of the Secretary, U.S. Department of Agriculture

William Jordan, deputy director, Antimicrobials Division, Office of Pesticide Programs, U.S. Environmental Protection Agency

Robert Lake, director, and **Anne Depman**, policy analyst, Office of Regulations and Policy, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration

Sue MacIntosh, product safety manager, and **Barbara Henry**, expert toxicologist, Aventis CropScience

Gary Martin, president and CEO, and **Kirk Miller**, director, International Programs and Regulatory Affairs, North American Export Grain Association Inc.

Richard Merrill, professor, School of Law, University of Virginia

John Neylan, chief, Agriculture Branch, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency

Michael Phillips, executive director, Food and Agriculture Section, Biotechnology Industry Organization

Leah Porter, executive director, and **Isi Siddiqui**, senior director, Biotechnology and Trade, CropLife America.

Michael Schechtman, biotechnology coordinator, Office of the Secretary, U.S. Department of Agriculture

David Shipman, acting administrator, and **John Pitchford**, director, Office of International Affairs, Grain Inspection, Packyards, and Stockyards Administration, U.S. Department of Agriculture

Bernice Slutsky, senior policy advisor, Foreign Agricultural Service, U.S. Department of Agriculture

James White, branch chief, Biotechnology Regulatory Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture

Appendix C

Reviewers

Stanley Abramson, attorney-at-law, Arent Fox Kintner Plotkin & Kahn, PLLC

Thomas Bundy, deputy assistant general counsel (retired), Regulatory Division, General Counsel, U.S. Department of Agriculture

Michael Fernandez, director of science, Pew Initiative on Food and Biotechnology (formerly associate administrator, Agricultural Marketing Service, U.S. Department of Agriculture)

Eric Flamm, senior advisor, Office of the Commissioner, Office of Policy, Planning, and Legislation, U.S. Food and Drug Administration

Cliff Gabriel, deputy to the associate director, Office of Science and Technology Policy, Executive Office of the President

Margaret Gadsby, director, Public and Government Affairs, Communications, and Stewardship, Aventis CropScience

David Heron, biotechnologist, Animal and Plant Health Inspection Service, U.S. Department of Agriculture

Greg Jaffe, director, Biotechnology Project, Center for Science in the Public Interest

William Jordan, deputy director, Antimicrobials Division, Office of Pesticide Programs, U.S. Environmental Protection Agency

Kathleen Merrigan, director, Agriculture, Food, and Environment Program, and Assistant Professor, Gerald J. and Dorothy R. Friedman School of Nutrition Science and Policy, Tufts University (formerly administrator, Agricultural Marketing Service, U.S. Department of Agriculture)

Richard Merrill, professor, University of Virginia School of Law

John Neylan, chief, Agriculture Branch, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency

John Pierce, director, Strategic Planning and Resources, Crop Genetics Research and Development Group, DuPont

Mimi Sen, advisor, Agricultural and Environmental Science, California Department of Food and Agriculture

David Shipman, acting administrator, Grain Inspection, Packyards, and Stockyards Administration, U.S. Department of Agriculture

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About the Authors

Michael R. Taylor

Mike Taylor is a senior fellow at Resources for the Future (RFF; a nonprofit research organization that has been conducting independent research on natural resource and environmental issues for nearly 50 years), where he is director of the Risk, Resource, and Environmental Management Division. His personal research addresses policy and institutional issues that affect food security in developing countries and food safety as a global concern.

Taylor has served in government, practiced law in Washington, and worked in private industry. He was administrator of the U.S. Department of Agriculture's Food Safety and Inspection Service from 1994 to 1996, deputy commissioner for policy at the U.S. Food and Drug Administration (FDA) from 1991 to 1994, and an FDA staff lawyer and executive assistant to the FDA commissioner from 1976 to 1981. He practiced food and drug law and was a partner in the law firm of King & Spalding for 10 years, then served for 16 months as vice president for public policy at Monsanto Company before joining RFF in June 2000.

Taylor is co-chair of the National Academy of Sciences (NAS) Committee on the Use of Third Party Toxicity Research with Human Participants and a member of the NAS Committee on the Implications of Dioxin in the Food Supply. He also served on the NAS Committee on Defining Science-Based Concerns Associated with Products of Animal Biotechnology, which recently published a report entitled *Animal Biotechnology: Science-Based Concerns* (National Academies Press, 2002).

Taylor is an adjunct professor of law at Georgetown University Law Center and a member of the board of trustees of Resolve Inc., a nonprofit organization involved in mediation and dispute resolution on environmental and public health issues for government agencies and private entities nationwide. He earned a law degree from the University of Virginia and a B.A. in political science from Davidson College.

Jody S. Tick

Jody Tick is a research associate at RFF, where she works with the Global Food System Program. Her research focuses on regulatory issues of the U.S. food safety system and international food security concerns related to how developed-country policies affect the capacity of developing countries to create successful food systems. She received an M.S. from the Agriculture, Food, and Environment Program at Tufts University and a B.A. in environmental studies from Boston University.