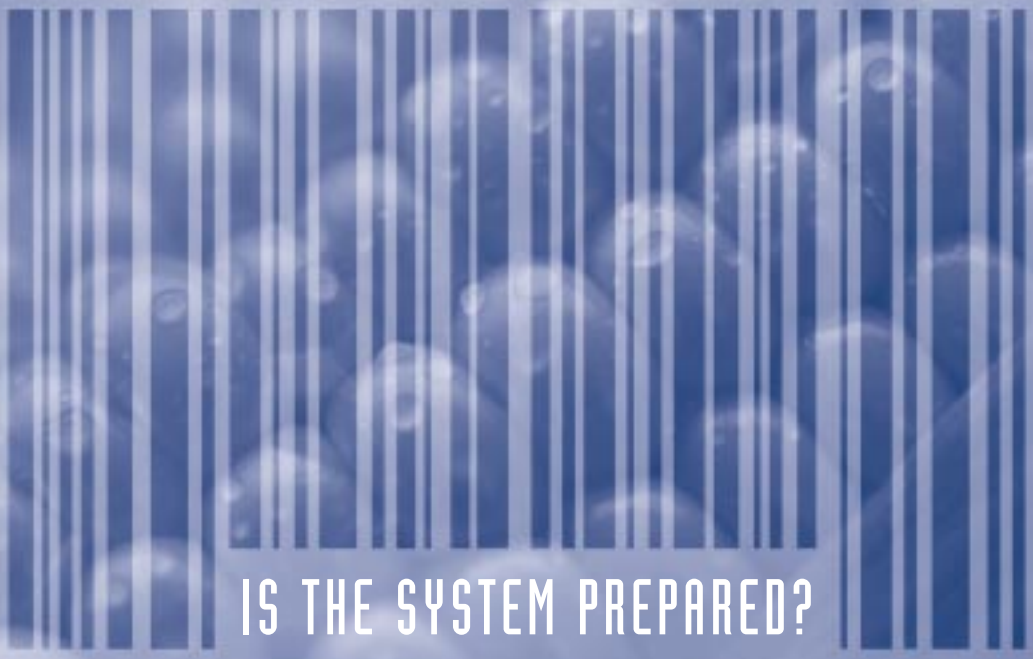
Post-Market Oversight of Biotech Foods



IS THE SYSTEM PREPARED?

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?

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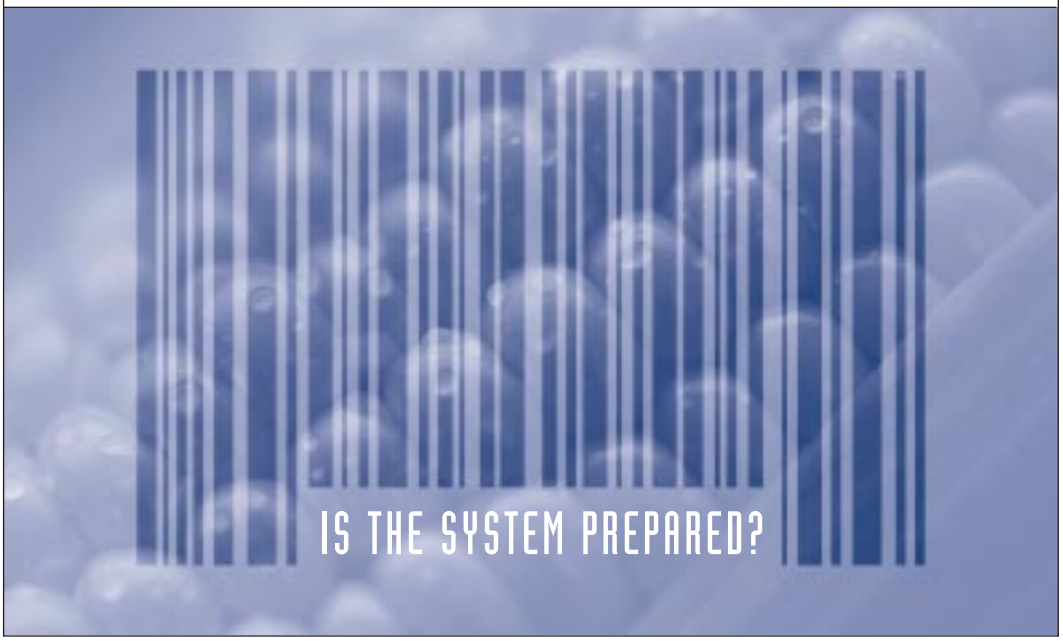

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Preface

The September 2000 discovery of StarLink corn in taco shells caught the public and much of the American food system by surprise. StarLink was one of several varieties of corn that had been genetically modified to produce its own insecticide. The U.S. Environmental Protection Agency (EPA) had approved StarLink only for animal feed because tests had suggested that the specific insecticidal protein in the genetically modified corn might be a human allergen. StarLink was therefore not approved for use in human food.

The discovery of StarLink where it was not supposed to be caused a public uproar. The group that first reported it, Genetically Engineered Food Alert, used the finding to argue for stronger government regulation of biotech crops and foods. The food industry recalled foods containing StarLink from the market out of concern about the possible impact of StarLink on the safety and public acceptance of their products. Corn traders faced disruption of their export markets. And commentators suggested the U.S. regulatory system had failed by not preventing the problem from occurring in the first place. A chronology of the StarLink case is provided in Appendix A.

The government also acted, declaring StarLink's presence in human food unlawful, working with the food industry to accomplish the necessary recalls and attempting to calm grain markets and the concerns of foreign trading partners. In addition, EPA announced that it would no longer approve the registration of pesticidal traits in genetically modified plants if the plants were not also approved for human food use. This action would appear to preclude future StarLink-type episodes by ensuring that all pesticide-producing genetically-modified crops on the market would be approved as safe for humans to eat.

Such a perspective on the StarLink incident, however, would be far too simple. StarLink may prove to be a one-time experience—and it has not been linked conclusively to any adverse effects—but its importance extends well beyond the specific facts. StarLink put a public spotlight on the regulatory system for biotech food. It raised questions about how the system works today and whether it is prepared for the challenges it will face in the future. These challenges were underscored again recently with a "near miss": material from a variety of corn engineered to produce an animal vaccine, made by a company named ProdiGene, turned up in soybeans destined for the food supply. Fortunately, the corn was detected by government inspectors in time to keep it out of the food supply.

This report addresses a subset of the questions about biotechnology regulation. This report is one of several reports on aspects of the U.S. regulatory system for biotechnology prepared by the Pew Initiative on Food and Biotechnology. Much of the public debate about biotechnology prior to StarLink focused on whether, and under what circumstances, biotech products should enter the environment and marketplace: what standards, testing, and review procedures should be required *prior to* biotech crops being planted and biotech foods sold? This report addresses issues that arise *after* the products enter the environment or the marketplace—when the crop is in the field, commodities are in commerce, and foods are being prepared and marketed to consumers:

- Is the regulatory system prepared to ensure compliance with use restrictions or other conditions imposed by regulators to protect health or the environment?
- More broadly, what is the appropriate degree of control over biotech foods and crops after they enter the environment or the marketplace?
- What role can and should the government play in achieving this control?
- How do the postrelease and postmarket oversight issues posed by biotech crops and foods compare with those posed by conventionally produced ones?

This report is intended to inform the public, policymakers, and other interested parties in the biotechnology debate. The report identifies issues and provides factual background and analysis, rather than offering policy recommendations. There are no "right" answers or single solutions to the issues presented. The issues involve subjective values and a range of competing considerations and interests that should be sorted out in public processes.

The Pew Initiative on Food and Biotechnology commissioned Resources for the Future (RFF) to prepare this report. We would like to acknowledge authors Michael R. Taylor and Jody S. Tick, of RFF for their collaboration and thoughtful examination of these issues.

We hope that our analysis contributes to an informed debate and, in the end, to good public policy. This report, like all of our projects, is made possible through a grant from The Pew Charitable Trusts to the University of Richmond. The opinions expressed in this report are those of the authors and do not necessarily reflect the views of The Pew Charitable Trusts.

Michael Rodemeyer

Executive Director

Pew Initiative on Food and Biotechnology

April 2003

Acknowledgements

In addition to conducting an extensive literature review, we interviewed more than 30 people from all segments of the food system—representatives of food companies, technology providers, agricultural producers, grain traders and processors, representatives of consumer and environmental groups, and government regulators and policy officials (names and affiliations are listed in Appendix B). The people we interviewed were generous with their time and expertise. The insights and the information they provided were essential to the development of this report, and we thank them.

We also thank the individuals to whom we circulated a draft of the report for review (names and affiliations are listed in Appendix C). We received from these reviewers many useful comments and corrections, which we have carefully considered and incorporated as fully as possible. We thank the Pew Initiative on Food and Biotechnology for support of our work in researching and writing this report. Finally, we extend a special thanks to Aracely Alicea, formerly a research assistant at Resources for the Future, for contributions to this report. However, the authors are solely responsible for any errors of omission, fact, or interpretation. The opinions expressed in this report are those of the authors and do not necessarily represent the views of the Pew Initiative, Resources for the Future, or any of the interviewees or reviewers who contributed to it.

Executive Summary with Key Findings and Questions to Consider

Preface

The broad regulatory question addressed in this report is whether current U.S. government policies and programs provide an adequate level of "postmarket" oversight of biotechnology-derived crops and foods to ensure their safety for health and the environment. This is oversight that occurs *after* the products enter the environment or the marketplace—when the crop is in the field, commodities are in commerce, and foods are being prepared and marketed to consumers. The broader social policy question is what degree of postmarket control society wants over biotech crops and foods to address concerns that go beyond the normal regulatory focus on safety. In this report, we address both questions with an eye to the future. Agricultural biotechnology is in its commercial infancy; only a few products are on the market today, but a rich pipeline of products is on the drawing board.

With respect to currently marketed products, the system of postmarket oversight has not resulted in any documented harms to human health or the environment. Recent experiences, however, with StarLink corn and ProdiGene's vaccine-producing plant demonstrate the importance of postmarket oversight, not only for achieving traditional food safety and environmental objectives but also for ensuring the orderly working of food and commodity markets and maintaining public confidence in the food supply. Looking ahead, we see potential vulnerabilities in the oversight system that stem primarily from a lack of priority and resources for postmarket oversight and from unresolved questions about the government's proper role in addressing issues that arise after products are in the marketplace.

We explore these vulnerabilities for the purpose of informing the public, policymakers, and constituents in the biotechnology debate. We identify issues and provide factual background and analysis, rather than offering policy recommendations. There are no "right" answers or single solutions to the issues we discuss. They involve subjective values and a range of competing considerations and interests that should be sorted out in public processes. This report is intended to contribute to an informed debate and, in the end, to good public policy.

Introduction

RATIONALE AND SCOPE OF THE REPORT

- We examine the programs of the three regulatory agencies responsible for agricultural biotechnology: the U.S. Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS), the U.S. Environmental Protection Agency (EPA), and the U.S. Food and Drug Administration (FDA).

- APHIS, EPA, and FDA have focused most of their regulatory attention and resources on deciding which biotech crops and foods can be safely released into the environment or allowed to be commercialized, and under what conditions and restrictions (we refer to this activity as "premarket" oversight).
- In September 2000, StarLink corn, approved only for use in animal feed, was detected in food intended for human consumption. This event shifted substantial government and public attention for the first time to the "postmarket" oversight of biotech crops and foods (i.e., regulatory activities designed to ensure that any conditions and restrictions on the use of products are observed and that problems are promptly detected and corrected).
- In November 2002, APHIS discovered that an experimental biotech corn, developed by ProdiGene and designed to produce a vaccine for pigs, had contaminated soybeans intended for use as human food.
- The StarLink and ProdiGene cases have challenged the adequacy of postmarket oversight as currently practiced by the three regulatory agencies and have put the issue of postmarket oversight on the agenda of food system constituents, including government; the biotechnology, agricultural, and food industries; and the consumer and environmental advocacy communities.

Biotechnology and Its Challenges

AGRICULTURAL BIOTECHNOLOGY

- We use the term "agricultural biotechnology" to refer to the use of recombinant DNA techniques and related tools of modern biotechnology to genetically modify crops used in the production of food, feed, and fiber. The resulting products are referred to interchangeably as "biotech" or "genetically modified" (GM) crops and foods.

PUBLIC PERSPECTIVE ON BIOTECH CROPS AND FOODS

- Biotech crops and foods are different from conventionally derived ones because biotechnology can cross species lines, for example, by transferring insect-resistance genes from bacteria to food crops.
- In a recent survey sponsored by the Pew Initiative on Food and Biotechnology, 65% of respondents questioned the safety of biotech foods, despite the assurances of scientists and government regulators that the food is safe.
- For many people, biotechnology raises social, economic, religious, and ethical issues that influence their perspective on how the technology should be regulated.

REGULATORY PERSPECTIVE ON BIOTECH CROPS AND FOODS

- Biotechnology poses challenges to postmarket oversight and control that differ from those of conventional agricultural and food technologies (e.g., chemical pesticides), because GM crops can potentially reproduce and cross with non-GM varieties.
- The ability of biotechnology to engineer pharmaceutical or industrial substances into crops calls for an unprecedented degree of regulatory control over crop production because of the widely shared view that such crops should not enter the human food supply.
- The isolation of biotech crops from others for marketing or regulatory purposes is difficult because of their biological nature and the limitations of existing bulk commodity handling systems.
- The lack of regulatory uniformity between the United States and major trading partners (i.e., biotech crops and foods approved in the United States commonly are not approved in the European Union or Japan) raises postmarket control issues for the trading system and questions about the U.S. government's role in ensuring that trade is not unduly disrupted.

BIOTECHNOLOGY PIPELINE

- Forthcoming biotech crops with agronomic traits beyond the insect- and herbicide-resistance traits in use today, such as resistance to drought and disease, may have competitive advantages and other features presenting environmental issues that could require a different approach to monitoring.
- As biotech food products enter the market with improved taste, nutrition, or other benefits for consumers, issues such as identity preservation and labeling will arise that may justify heightened postmarket oversight and control.

Objectives of Postmarket Oversight

- Traditional objectives of postmarket regulatory oversight that generally apply in the health and environmental arena also apply to biotech crops and foods.
- The core objectives are to ensure compliance with regulatory restrictions and conditions of use that are intended to protect health or the environment and to discover and solve safety and regulatory problems when they arise.
- A secondary but important objective is to maintain public confidence in the safety and integrity of the food supply by taking actions that are effective and publicly credible for this purpose.
- These objectives should guide analysis of whether the system of postmarket oversight is adequate in design and is performing effectively.

Current Postmarket Oversight Regimes

USDA, EPA, and FDA regulatory programs for biotech crops and foods are based on statutory and regulatory frameworks that were already in place in 1986, when the federal government first considered how biotechnology should be regulated. Although the statutes provide the agencies with important legal tools, the agencies' regulatory approaches vary considerably, reflecting the different types of products they oversee and the nature of the statutes and regulatory systems that were in place prior to the development of modern biotechnology.

USDA

- The role of USDA in the oversight of agricultural biotechnology is to regulate field trials of biotech crops, which it does through APHIS under the Plant Protection Act (PPA).
- Under the PPA, APHIS has broad legal authority to regulate field trials in order to protect agriculture, public health, and the environment. It authorizes more than 1,000 field trials each year and inspects field trials for compliance with containment and other restrictions it might impose.
- The APHIS budget for pre- and postmarket oversight of biotech field trials is about $4 million.
- Under the APHIS program, most crops are "deregulated" at the successful completion of field trials. As a result, most commercialized biotech crops are not subject to any systematic program of controls or postmarket oversight.

EPA

- The role of EPA in the oversight of agricultural biotechnology is to regulate the health and environmental safety of biotech crops that have been genetically modified to produce pesticides, which EPA also calls plant-incorporated protectants (PIPs). This role includes evaluating the safety of PIPs in food.
- EPA has extensive legal authority to require premarket testing of PIPs and crops containing them as a condition of approval and to impose restrictions on the use of PIPs to ensure food safety and prevent unreasonable adverse environmental effects. One example of such a restriction is planting restrictions on Bt crops to minimize the development of resistance to Bt in insects.
- EPA holds a PIP's sponsor accountable for ensuring that farmers comply with postmarket restrictions. In contrast to chemical pesticides, however, EPA has interpreted the law in a way that insulates farmers from direct legal accountability to EPA for compliance with PIP use restrictions.

- EPA allocates no resources to traditional postmarket compliance activities for PIPs. Instead, it relies on annual reports by sponsors and the product "reregistration" process, which typically occurs about every five years, to evaluate whether a PIP has been used in accordance with regulatory restrictions and warrants reregistration.

FDA

- The role of FDA in the oversight of agricultural biotechnology is to regulate the safety of foods derived from biotech crops and to enforce EPA restrictions regarding the presence of PIPs in food. FDA's premarket oversight is based primarily on a voluntary consultation process through which FDA reviews the basis for a sponsor's safety assessment of new biotech foods, but the agency does not make its own safety determination.
- FDA's postmarket legal authority includes the right to collect product samples and to take court action to remove potentially unsafe or "adulterated" biotech foods from the market. FDA lacks authority, however, to examine producer or food industry records or to order recalls of unsafe products.
- In response to the StarLink and ProdiGene incidents, FDA demonstrated substantial capacity to respond to major regulatory problems, but the agency has no planned postmarket oversight program for biotech foods. This stance is based on FDA's judgement, as reflected in its announced priorities, that other food safety regulatory issues deserve higher priority from a public health perspective, as well as the practical difficulty of such oversight (because of a lack of analytical methods and other constraints).

Current Issues

LACK OF SYSTEMATIC OVERSIGHT OF "DEREGULATED" CROPS BY USDA

- Once APHIS grants "deregulated" status to a GM crop, that crop is cleared for unrestricted release, movement, and import. The agency lacks authority under current regulations to impose conditions on use of deregulated crops or to require that the developer of the crop or other parties monitor its environmental impact. Although APHIS can reassert regulatory control if it obtains evidence of problems, the agency has no program of its own to monitor the environmental impact of deregulated GM crops.
- A National Academy of Sciences committee has recommended that APHIS require postcommercialization validation testing and monitoring to ensure that GM crops perform as expected and do not cause unanticipated environmental problems.
- Questions for policymakers and constituents include the following:
    - Do the potential environmental risks (and surrounding uncertainties) associated with nonpesticidal GM crops warrant postcommercialization validation testing and environmental monitoring?

- Is there a basis for across-the-board postcommercialization testing and monitoring of GM crops, or should it be done on a case-by-case basis when specific potential risks justify it?
- Who should conduct and pay for monitoring—the developer of the product? the user? APHIS? some other body?
- 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 already exist?
- What, if any, new authority would APHIS need to conduct or require postcommercialization testing and monitoring for crops that it is currently deregulating?
- 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?

EPA'S APPROACH TO ENFORCING USE RESTRICTIONS ON PIPS

- No direct regulatory accountability exists between the grower and EPA regarding compliance with PIP use restrictions, unlike for traditional pesticides. Although product developers (called "registrants") are accountable to EPA, farmer accountability is established contractually between the farmer and the registrant through "grower agreements."
- EPA's PIP enforcement approach is based on EPA's legal interpretation that Bt seeds are "treated articles" rather than pesticides and on serious practical and political constraints that confront a government-only enforcement strategy.
- The major PIP use restriction in force today requires farmers to observe certain planting restrictions to minimize the development of resistance to Bt in insects. EPA enforces insect resistance management restrictions by requiring that registrants develop and successfully implement compliance assurance programs, under which registrants police and monitor farmer compliance with the restrictions.
- On the basis of self-reporting by farmers in anonymous surveys, the industry reported a nationwide compliance rate of 80%. Based on the survey results, we estimate that regional compliance rates ranged from about 62% to about 82% for the 2001 growing season. Noncompliance is potentially underreported, but whether it is and to what extent is unknown; EPA has not established any standards for what constitutes an adequate level of actual compliance.

- Questions for policymakers and constituents include the following:
  - 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 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 feasible alternatives to the current approach (i.e., ones that would not place primary reliance on private enforcement through grower agreements)?
  - Should the option of direct government enforcement at the farmer's level be retained to back up the private enforcement approach? Is EPA's current position (i.e., not to subject the grower to legal accountability) one the agency could change, or would legislation be required?

LACK OF AN FDA COMPLIANCE PROGRAM FOR BIOTECH FOODS

- Although FDA is responsible for enforcing food safety requirements with respect to biotech foods, the agency currently has no affirmative postmarket inspection or compliance program for this purpose.
- The current situation rationally reflects FDA's budget constraints and priority setting, in light of the agency's judgment that currently marketed biotech foods are safe.
- As the number and diversity of biotech crops and foods increase, several issues may justify an affirmative compliance program: enforcing market-entry requirements, policing the inadvertent presence of GM traits and products in the food supply, monitoring possible imports of GM crops and foods to ensure safety and regulatory compliance, and enforcing labeling rules.
- If FDA decides that future circumstances warrant an affirmative compliance program for biotech foods, the agency's ability to mount such a program will be constrained by several practical issues: lack of appropriate, practical analytical methods; the large volume and expense of sampling and testing required to detect what would likely be relatively rare events; absence of an information base on the potentially great diversity of possible foreign sources of biotech foods; and lack of authority to examine food industry records that might document whether GM ingredients are present in products.

- Questions for policymakers and constituents include the following:
  - Do food safety or other consumer protection interests warrant FDA's investment of resources in the postmarket oversight of GM foods and crops, given 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 (e.g., 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?
  - Might technological advances or new compliance strategies (e.g., private, third-party testing and certification) overcome or compensate for the current constraints on postmarket oversight by FDA?
  - Is maintaining public confidence in the food supply, in biotechnology, or in FDA a sufficient basis for FDA to establish a postmarket oversight program?

ADVENTITIOUS PRESENCE OF GENETIC TRAITS IN NONTARGETED CROPS AND FOODS

- The low-level, unintended presence of seed varieties other than the ones intended has long been accepted by the grain trade and food industry as unavoidable because of the biological nature of seed production and the high-volume U.S. grain handling system. With the advent of biotechnology, this phenomenon (sometimes called "adventitious presence") has become a matter of public controversy and a vexing concern for the food system because of public sensitivities about biotechnology, differing regulatory situations among trading partners, and possible safety concerns.
- The adventitious presence of biotech substances is an important problem for several reasons:
  - Safety, to the extent the substance is an allergen or poses another risk;
  - Regulatory compliance, to the extent a genetic trait or product renders the food legally "adulterated," as in the StarLink case;
  - Domestic and international trade disruption, to the extent commercial customers reject commodities or foods with even trace amounts of biotech material; and
  - Public values and perceptions, to the extent individual consumers seek to avoid biotech foods for any social, economic, political, or ethical reason.
- Possible approaches to addressing the problem of adventitious presence include the following:
  - Ban all adventitious presence. Absolute avoidance of adventitious presence may be a physical and economic impossibility, which would make an absolute ban unenforceable.

- Respond on a case-by-case basis. This approach is what happened in response to StarLink and is the status quo; most observers consider this approach unacceptable.
- Set an across-the-board threshold or tolerance based on technological feasibility. This approach, currently being pursued by the European Union, would address regulatory and trade concerns.
- 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, proposed by the U.S government in August 2002, would address domestic safety and trade concerns but would not address the concerns of those who want to avoid any amount of biotech material or the concerns of trading partners whose policies differ (e.g., the European Union).

- Questions for policymakers and constituents include the following:
  - How should the regulatory system address the phenomenon of adventitious presence?
  - Under what circumstances and to what extent is the adventitious presence of a biotech substance a safety issue? Is it possible scientifically to address potential food safety concerns at the time of field trials or market entry?
  - Which regulatory concerns need to be resolved by an adventitious presence policy? Must every biotech substance in food have affirmative legal recognition through the regulatory process?
  - What policy is needed to minimize the trade impacts of adventitious presence? If U.S. policy were not harmonized with the policies of its trading partners, what would be the effect on trade?
  - Can any policy on adventitious presence address the concerns of consumers who prefer to avoid GM foods?

IDENTITY PRESERVATION AND TRACEABILITY OF BIOTECH FOODS TO THEIR SOURCE

- Grain commodities are generally traded with no provision for preserving the identity of a lot, or foods produced from it, with respect to whether they are genetically modified, or 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.
- The U.S. government and most U.S. constituents consider the IP of GM and non-GM foods to be a commercial issue that should be determined on the basis of what sellers need to do to satisfy their customers.

- The U.S. government opposes the European approach to traceability (i.e., a government mandate that food producers keep records required to conduct immediate tracebacks of foods to their origin) on the grounds that it has no public health justification, would be unduly costly, and would disrupt trade.
- Although government-mandated IP and traceability are not likely to be implemented in the United States, marketplace demands of customers are pressuring commodity producers and traders to develop IP and traceability systems. As much as 10% of the U.S. corn crop is currently processed under IP systems, and marketplace pressures for IP are expected to grow as the biotechnology pipeline produces crops and foods that directly benefit consumers.
- USDA's Grain Inspection, Packers, and Stockyards Administration (GIPSA) and Agricultural Marketing Service (AMS) have announced plans to support market-driven IP systems by providing analytical methodologies, testing services, and possibly certification programs to help ensure that private IP systems deliver what they promise.
- Other possible approaches to IP and traceability include the following:
  - 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. The more extensive availability of methods would support public and private IP and traceability efforts.
  - Certify private laboratories to support IP and traceability systems. Private testing could be more efficient over the long run than a government-run testing program.
  - Develop guidelines for privately managed IP and traceability systems. Government guidelines could potentially improve the consistency, effectiveness, and credibility of private IP and traceability systems.
- Questions for policymakers and constituents include the following:
  - What, if any, role should the U.S. government play in fostering the IP and traceability of GM crops and foods?
  - With respect to the current generation of biotech crops and foods, under what circumstances, if any, should government mandate the adoption of IP systems, traceability systems, or both?
  - Regarding crops in the biotechnology pipeline (e.g., crops modified for improved nutrition or to produce pharmaceutical proteins), 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? for other reasons?
  - Does FDA have adequate legal authority to mandate IP, traceability, or both for food safety and labeling reasons?

- 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?

Conclusion

In this report, we address two broad questions: is the system prepared? and prepared to do what? Our analysis casts doubt on the preparedness of the current postmarket oversight program to achieve its traditional objectives, including the enforcement of regulatory restrictions and the detection and correction of unanticipated health or environmental problems. For products it has deregulated, APHIS lacks a regulatory handle to require systematic data collection by sponsors to detect unforeseen plant pest 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. FDA has no affirmative compliance and enforcement program for biotech crops and foods and, as evidenced by the StarLink experience, lacks some of the basic tools to determine whether the biotech products already on the market comply 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 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.

The real challenge for the postmarket oversight system lies ahead. Future applications of biotechnology to produce an increasing number and diversity of GM crops and foods—products that may contain novel proteins or promise increased consumer benefits—and to "grow" pharmaceuticals and industrial chemicals in plants, will call, in many cases, for tighter regulatory control to protect human health and the environment. They also will call into serious question whether the overall structure and approach to postmarket oversight in place today is adequate to ensure compliance and 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 to considering whether the system is prepared for the future: what degree of postmarket control does society want over GM crops and foods? With respect to conventional agricultural and food technologies (e.g., pesticides, animal drugs, and food additives), the degree of control desired and what postmarket oversight should do in achieving it are fairly well established. Postmarket oversight programs for these technologies 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 desired degree of postmarket control. This lack of consensus reflects some scientific uncertainties about the safety and environmental impacts of biotechnology that will gradually diminish as the science develops and becomes more certain. The lack of consensus also reflects, however, conflicting or uncertain social values. 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 so far 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 questions for which there are no scientific answers, but such value-laden issues are the norm in public policy.

Scientific uncertainty and differences over values are deeply embedded in the issues of adventitious presence and identity preservation, and they fuel most of the current controversies surrounding biotechnology. To answer our two broad questions—is the system prepared? and prepared to do what?—the scientific uncertainties need to be acknowledged and their implications defined; the value issues need to be put on the table and debated. Then, in light of the defined and probably still-conflicting values, the desired degree of postmarket control for biotech crops and foods must be determined. The details of public policy will flow from there.