TENDING THE FIELDS:
STATE & FEDERAL ROLES IN THE OVERSIGHT OF GENETICALLY MODIFIED CROPS

MICHAEL R. TAYLOR
JODY S. TICK
DIANE M. SHERMAN

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

DECEMBER 2004

TABLE OF CONTENTS

III. Current State Oversight Activities and Stakeholder Perspectives: An Overview

IV. Vignettes on Major Issues

PREFACE

For the last several years, the Pew Initiative on Food and Biotechnology has published an annual round-up of state legislative activities dealing with genetically modified (GM) food and agricultural biotechnology. From those studies, it has become apparent that states are on the "front line" of agricultural biotechnology, where they serve as the initial responders to the promises and conflicts that can accompany the introduction of any novel technology into the marketplace.

In the present study, we asked Michael Taylor, Jody Tick, and Diane Sherman of Resources for the Future, who had previously studied post-market issues for us, to take a look at how state regulators were responding to agricultural biotechnology, and how the federal-state partnership to ensure food safety and protect the environment was faring.

As did PIFB's state legislative surveys, Taylor, Tick, and Sherman found a diverse range of state regulatory responses to agricultural biotechnology. Not surprisingly, most states with large agricultural sectors are intensely interested in the economic promise of agricultural biotechnology. Many are eager to capture the economic development and growth potential of a new technology that could provide added value to low-priced commodity crops. States recognize, however, that such economic benefits could be jeopardized if public anxiety or market access for conventional crops is threatened. As a result, states have an important stake in the regulation of agricultural biotechnology not only to protect health and safety, but also to advance and protect important economic interests. Although they tend to defer to the scientific and technical expertise at the federal regulatory agencies on safety issues, states generally want to be a full partner with federal regulators to ensure that state interests are adequately addressed.

States have long shared responsibility with the federal government for inspection and enforcement of laws regulating pesticides and plant pests - the laws under which genetically modified crops are typically regulated. In addition to participating in the review of permits for genetically modified crops, states have a particular interest in, and responsibility for, oversight of field trials to ensure that experimental GM crops do not accidentally commingle with crops headed for the food supply. This is especially true in the case of crops that have been modified to produce non-food substances, such as compounds used for industrial or pharmaceutical production. In

such cases, states are not only concerned about potential food safety or environmental issues, but also the economic damage that could result to existing agricultural production.

A key question is whether the states have adequate legal tools, technical expertise, and financial resources to play a complementary, collaborative role in the regulation of agricultural biotechnology. Based on the research conducted for this report, the answer varies from state to state, but there appears to be a fairly broad sentiment among those interviewed for this report that many states are not as well prepared as they might be, and that in particular the financial resources available for state level biotech oversight are inadequate.

The legal frameworks under which the states and federal agencies are working to regulate biotechnology also raise a number of issues that state and federal regulators are actively working to address. One issue, which has been the subject of litigation in Hawaii, deals with Confidential Business Information, or CBI. Applicants for permits to conduct field trials of GM crops are required to submit information to the federal agencies so that the agencies can assess risks; the companies usually claim that much of the information is CBI which, under federal law, may not be disclosed. That often prevents the federal agencies from sharing the information because some state "sunshine" laws would require states to disclose such information. Without the information, states may not have an adequate basis on which to make an independent determination about the safety of the field trials, and they thus rely on informal means to obtain information, such as the voluntary cooperation of the biotechnology companies.

A second issue arising from the legal framework concerns pesticidal substances that are produced within plants that have been genetically modified (so-called "plant-incorporated protectants," or PIPs). Field tests of traditional (or conventional) experimental pesticides are regulated both by EPA (under an Experimental Use Permit, or EUPs) and by the states. While EPA approves EUPs for field trials of PIPs, for a number of reasons, EPA does not consider either the seed or the GM plant to be "pesticides" under the law. As a result, states are unsure whether they have the same independent authority to oversee the field trials of PIPs as they do for traditional pesticides.

The report documents diverse and innovative state approaches to developing policies that take into account local interests and issues. The report contains a number of examples of state responses, including efforts by Colorado to develop a public participation process for the consideration of "pharmaceutical" crops, a North Carolina initiative to develop identity preservation criteria for both biotech and conventional tobacco crops, and the efforts in a number of states to develop their own regulatory approaches.

The report does not contain policy recommendations. Instead, the purpose of this report is simply to bring the wealth of work occurring at the state level to the attention of a broader audience and to assist states in learning from each other. A better understanding of the critical role that states play in the oversight of agricultural biotechnology also helps provide a clearer picture of the overall regulatory framework that applies to this technology.

The Initiative gratefully acknowledges the work of Michael R. Taylor, Jody S. Tick, and Diane M. Sherman of Resources for the Future, for their usual thoughtful work and careful research. We share their hope that this report will contribute to informed debate and sound public policy development.

The opinions expressed in this report are those of the authors and do not necessarily reflect the views of the Pew Charitable Trusts, which supports the Pew Initiative on Food and Biotechnology through a grant to the University of Richmond.

Michael Rodemeyer
Executive Director

PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY
December 2004

ACKNOWLEDGEMENTS

Throughout the research and writing of this report, we interviewed more than 35 people from the biotechnology stakeholder community. Their names and affiliations are listed in Appendix C. We thank all of them for their time and invaluable assistance. A special debt of gratitude is owed to several state officials who took the time to help educate us on the role of the state regulatory programs. These include Bill Dickerson, Tobi Jones, Jim Miller, Terry Mitchell, Robin Pruisner, Lyle Wong, and Mitchell Yergert.

We also thank the many individuals who reviewed and provided valuable comments on one or more sections of the report, including Stanley Abramson, Rebecca Bech, Terry Bourgoin, Thomas Bundy, John Caravetta, Bill Dickerson, Sancho Dickinson, Gary Dykstra, Lochiel Edwards, Bob Ehart, Doug Farquhar, Eric Flamm, Warren Goetsch, Mary Hanks, Karen Heisler, David Heron, Daniel Hilburn, Greg Jaffe, Peter Jenkins, Tim Johnson, Tobi Jones, Paul Liemandt, Kathleen McGrath, Jim Miller, Bob Mungari, John (Jack) Neylan, Bill Northey, David C. Nunenkamp, Adrian Polansky, Robin Pruisner, Cameron Smoak, Ralph Stoaks, Terry Mitchell, Jeffrey Weispfenning, Marian White, Lori Witham, Lyle Wong, and Mitchell Yergert.

Finally, we thank the Pew Initiative on Food and Biotechnology for its financial support of our work, valuable research suggestions, and careful review of the report.

Though we have benefited greatly from the effort and knowledge of others, we are solely responsible for the content of the report, including any errors or omissions of fact or interpretation. Unless otherwise noted, the opinions expressed in this report are those of the authors alone and do not necessarily represent the views of the Pew Initiative on Food and Biotechnology, Resources for the Future, or any of the interviewees or reviewers who contributed to the report's development.

Michael R. Taylor
Jody S. Tick
Diane M. Sherman

RESOURCES FOR THE FUTURE
December 2004

TENDING THE FIELDS:
State & Federal Roles in the Oversight of Genetically Modified Crops

Michael R. Taylor
Jody S. Tick
Diane M. Sherman

Resources for the Future

I. INTRODUCTION

Purpose of the Report

THIS REPORT EXAMINES THE ROLE of state governments in the regulatory oversight of crops and foods produced using the tools of modern biotechnology (hereafter referred to as "biotech crops and foods"). Though modern biotechnology encompasses many tools and techniques, this report focuses on the oversight of crops that have been genetically modified using recombinant DNA (rDNA) techniques, as well as the human foods and animal feeds derived from them.[1] Prompted by scientific and commercial progress in the application of rDNA techniques in a number of industrial, medical, and agricultural settings, the White House issued in 1986 a policy statement, the Coordinated Framework for Regulation of Biotechnology,[2] outlining how the federal government would regulate this new technology. The Coordinated Framework lodged primary responsibility for regulating the safety of agricultural biotechnology for health and the environment with three federal agencies: the Animal and Plant Health Inspection Service (APHIS) in the U.S. Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA) in the Department of Health and Human Services. In the years since 1986, regulatory oversight of biotech crops and foods in the United States has occurred predominately at the federal level through the programs of these agencies.

State governments, however, also have an interest in the regulatory oversight of biotech crops and foods, and, increasingly, there has been legislative and regulatory activity at the state level. State governments are interested in the same food safety and environmental issues that are the primary focus of the federal regulatory effort. But they also are frontline responders on issues and concerns raised within their borders about the effects that biotech crops and foods might have locally, especially on agricultural interests in the state. Thus, while this report focuses on regulatory programs that address such issues as whether and under what conditions biotech crops can be safely planted, it also examines how those programs are affected at the state level by both safety and economic concerns. At the federal level, several USDA agencies also deal with marketing and other economic issues associated with agricultural biotechnology, including the Grain Inspection Packers and Stockyards Administration (GIPSA), the Agricultural Marketing Service (AMS), and the Foreign Agricultural Service (FAS). The programs of these agencies do not directly impinge, however, on the state regulatory activities that are the focus of this report and thus are beyond its scope.

---

1 The predominant biotech food crops grown in the United States are corn and soybeans. Some of the production of these biotech crops is used to make human food ingredients, but most is used as animal feed. The use of the term "biotech crops and foods" in this report refers to both the human and animal food uses of biotech crops.

2 Office of Science and Technology Policy 1986.

State-level activity on biotech crops and foods appears likely to continue and perhaps intensify in the future. States come at biotechnology issues from diverse perspectives and have taken a range of approaches to dealing with them. This report was developed in the hope of providing policymakers and stakeholders at state and federal levels with a resource outlining similarities and differences in both the pressures felt and the approaches taken to date on biotechnology issues in different states. Despite the heterogeneity among state approaches to agricultural biotechnology, a number of common themes and challenges have arisen among the states. It is anticipated that, by compiling information on current state-level activities, highlighting the issues that many states have in common, and providing examples of how states are approaching key issues, this report might promote a learning process that will help inform and improve future policymaking about the role states might play in this dynamic area of public policy.

Resources for the Future ("RFF") prepared this report for The Pew Initiative on Food and Biotechnology ("the Pew Initiative"). It is one of a number of studies the Pew Initiative has sponsored or conducted to examine issues surrounding regulation of agricultural biotechnology.[3] This is the second report that the Pew Initiative has commissioned RFF to prepare. The first was the 2003 report titled, Post-Market Oversight of Biotech Foods: Is the System Prepared? (hereafter "Post-Market Report"),[4] which will be cited frequently here. That report examined the roles of the federal agencies in overseeing biotech crops after they have entered the environment, whether for field trials under containment conditions or for commercial production, or after they have been introduced to the food supply. This report follows up on the Post-Market Report by examining from the state perspective some of the same topics that were addressed from the federal perspective in the first report, such as field trial oversight. But this report explores more broadly the interests, roles, and activities of the states in the pre- and post-market regulation of biotech crops and foods.

Research Approach

As in the Post-Market Report, this paper provides information and analysis on a variety of issues, but it does not make recommendations as to what states should or should not do in overseeing biotech crops and foods. The intent is to provide a baseline of information on the subject as well as the perspectives of a range of policymakers, experts, and stakeholders on key issues concerning the role of the states.

---

3 The previous studies are posted on the Pew Initiative website, www.pewagbiotech.org

4 Taylor and Tick 2003.

The report provides a national overview of the federal-state relationship regarding the regulation of biotech crops and foods. For reasons of feasibility and focus, 17 states were selected for more targeted data collection: Arizona, California, Colorado, Hawaii, Illinois, Iowa, Kansas, Maine, Minnesota, Montana, New York, North Carolina, North Dakota, Oklahoma, Oregon, Texas, and Vermont. These are not the only states with interests or activities concerning biotech crops and foods. They were selected, however, based on such factors as the importance of agriculture in the state, the level of field trial and commercial activity involving biotech crops and foods, the extent of legislative and regulatory activity, and whether biotechnology is a visible or controversial issue in the state.

Information outlining the activities in these states was collected from three major sources. The first source consisted of publicly available materials, including various websites, government documents, published reports and analyses, and other materials describing the activities of the states in overseeing biotech crops and foods. While scholarly literature and other traditional sources of research and writing were also searched, very little previous work on this topic was uncovered.

The second source of information was the response received to a written survey of policymakers, experts, and stakeholders. This survey was sent to approximately 440 people across the country and resulted in 78 responses. The survey instrument and compilation of responses are in Appendix B. Though an effort was made to solicit responses from people with diverse interests and perspectives, we do not claim that the survey recipients are statistically representative of the universe of policymakers, experts, and stakeholders, and the respondents were a self-selected subset of the pool of survey recipients. Nevertheless, the survey respondents were geographically diverse and included federal and state government employees, agricultural producers, representatives of commodity and trade groups, biotechnology and food company representatives, and consumer and environmental advocates. Some interests were better represented than others. Agricultural producers and producer groups were best represented, comprising 25% of the responses, with state employees and people with academic or research interests in biotechnology close behind at 23% and 22%, respectively. Consumer and environmental group representatives contributed 12% of the responses, while commercial interests (biotechnology, seed, and food companies and commodity traders and groups) together contributed 10%. Despite the diverse perspectives of these various stakeholders, the responses to specific questions were consistent enough in some respects to provide useful insights. A number of the respondents also provided supplementary written comments, which were useful. Some of these comments have been quoted in the report with the generous permission of the respondents.

Finally, interviews were conducted in person and on the telephone with over 35 key individuals from diverse institutions and perspectives, including people in state and federal government, agricultural producers and food industry representatives, scientists, and consumer and environmental advocates. These interviewees, who are listed in Appendix C, were generous with their time and insights. They provided key information on current issues at the state level and made it possible for this report to delve below the surface of the official documents, published literature, and survey responses to develop a practical feel for the issues. These individuals are gratefully acknowledged for their time and help.

Overview of the Report

The report includes five sections. Section II, immediately following this Introduction, describes the interests that states have in biotech crops and foods and their regulation. These interests include health and the environment, economic development, preserving market access, and responding to the concerns of local citizens and stakeholders. While state governments and their constituencies certainly embrace the need to protect human health and the environment, most see this as primarily a federal government function. The interest and regulatory activity in state government is driven to a large extent by the marketing and other economic concerns of the state's agricultural producers.

Section III provides an overview of current regulatory programs at the state level and stakeholder perspectives on those programs. State regulatory programs generally parallel the federal programs for oversight of biotech crops and foods administered by APHIS, EPA, and FDA. Section III briefly describes these parallel programs, including the statutory authority, programs, and resources available at the state level for such activities as oversight of field trials involving biotech crops, enforcement of use restrictions on commercial crops, and oversight of plants genetically modified to produce substances that can be used for pharmaceutical or other nonfood purposes, in order to protect the food supply from inadvertent contamination. In addition to drawing upon government documents and websites for descriptions of state-level activity, this section uses survey and interview responses to report the perspectives of stakeholders on such questions as the importance and priority of oversight at the state level, the adequacy of state statutory authority and resources, and whether and how state programs might be improved.

The interest and regulatory activity in state government is driven to a large extent by the marketing and other economic concerns of the state's agricultural producers.

Section IV illustrates how particular states are handling some specific policy and process issues that are both important (and often controversial) in that state and of potential interest and importance in other states. These vignettes include:

- The process through which states participate when APHIS issues permits for field trials of plants genetically modified to produce pharmaceutical substances (hereafter "pharma crops"), drawing on the Colorado experience;
- The handling of confidential business information (CBI) as illustrated by pending litigation in Hawaii;
- The role state advisory bodies may play regarding decisions to allow commercial planting of biotech crops, drawing on the California Rice Commission experience with pharmaceutical-producing rice;
- A possible state role in containment and identity preservation of biotech crops and foods, focusing on tobacco in North Carolina;
- The experience with biotech-specific regulatory statutes in North Carolina, Minnesota, and Iowa;
- Efforts at the state level to legislate restrictions on biotech crops on economic and social grounds, illustrated by the experience in North Dakota and elsewhere with Roundup Ready wheat.

The purpose of these vignettes is to share experiences and ideas among state and federal policymakers and other stakeholders in the debate over regulation of biotech crops and foods. The diversity of concerns and activities seen around the country richly affirms the characterization of the states as the "laboratory of democracy." The hope is that, through shared experience, the states and the federal government can work toward solutions to issues posed by biotech crops and foods that, as much as possible in our diverse society, meet the needs of all.

Section V identifies questions that seem likely to be important in future discussions of the role of state governments in the oversight of biotech crops and foods.

The report also includes two noteworthy appendices. The first, Appendix A, is a state-by-state digest of information on each of the 17 states examined. It builds on the overview in Section III by providing details on why biotechnology is of interest in each state, some of the key issues that have arisen, and the statutes, agencies, and resources currently or potentially involved in oversight. The purpose of this appendix is to provide further factual texture concerning current activities at the state level and some basis for comparison of activities and issues from state to state. This appendix illustrates both the commonality and diversity of what is occurring across the country in state-level oversight of biotech crops and foods. Appendix B provides the questions from the survey conducted for this report and a digest of the responses.

II. THE STATES' INTERESTS IN OVERSIGHT OF BIOTECHNOLOGY

Contrasting the Federal and State Interests: An Overview

ON PAPER, THE STATE REGULATORY STRUCTURES and programs that are, or could potentially be, applied to biotech crops and foods parallel the federal programs administered by APHIS, EPA, and FDA. Like the federal programs, state programs typically involve the state departments of agriculture, environmental protection, and health, which administer plant health, pesticide, and food safety laws similar or related in their function to the federal laws. There are fundamental differences among states, however, in both the motivations for and objectives of state involvement in regulation of biotech crops and foods.

As discussed in the Post-Market Report, the declared purpose and primary focus of the federal regulatory program for biotech crops and foods is ensuring that statutory standards concerning food and feed safety, plant health, and environmental protection are met.[5] There is an ongoing debate about whether the federal program is fully equipped to deal with all the issues that might arise in this arena, especially with regard to crops and foods in the developmental pipeline.[6] However, most stakeholders want the federal regulatory agencies to have effective programs to address health and environmental issues and to stay focused on science-based implementation of those programs rather than on the social and economic issues surrounding biotechnology.[7]

These generalizations about what stakeholders seek at the federal level are not meant to imply that there is no disagreement about the role of federal agencies with respect to agricultural biotechnology. Some contend that the federal government is a promoter of agricultural biotechnology and that its regulatory program is less stringent than it should be in addressing health and environmental issues.[8] Some consumer groups have called for traceability and mandatory labeling to facilitate informed choice in the marketplace between biotech and nonbiotech foods.[9] Some elements of the

5 Taylor and Tick 2003; United States Regulatory Agencies Unified Biotechnology Website.

6 Pew Initiative on Food and Biotechnology 2004(b).

7 Taylor and Tick 2003.

8 For example, one survey respondent noted that the "USDA has a conflicted mission, both to promote GEOs (genetically engineered organisms) and to protect farmers from their adverse consequences."

9 Campaign to Label Genetically Engineered Foods 2004.

organic food industry, the environmental community, and other groups who see their economic and social interests being affected by biotechnology have argued for other regulatory policies at the federal and state level to protect those interests.[10]

At the state level, however, the declared government interests and the expectations of stakeholders are different and even more diverse than at the federal level. Most state government officials and many stakeholders say that the primary responsibility for human health and environmental protection should rest at the federal level and that the states should not try to duplicate the federal role in this regard.[11] Rather, as the remaining discussion in this section will indicate, the common sentiment among officials and stakeholders at the state level is that state regulation of biotechnology is necessary and important to address local concerns, most of which relate to the welfare of local agricultural producers and other economic interests of the state. Ensuring health and environmental protection is important to states, but the economic motivations for regulation and other forms of government activity, while different from state to state, are much closer to the surface at the state level than at the federal level.

The following discussion of specific state interests in biotechnology regulation—including health and environmental concerns, capturing the economic benefits of biotechnology, preserving market access, and responding to citizens and stakeholders—will demonstrate more clearly some of the diverse and conflicting points of view regarding the state roles in overseeing agricultural biotechnology.

Health and Environmental Concerns

Food safety and environmental protection are certainly as important to state officials (and their local constituencies) as they are to federal officials. However, based on interviews and responses to the survey, many feel that states lack the resources and specialized expertise to duplicate what APHIS, EPA, and FDA do in these traditional areas of regulation, and that it is best for states to rely on federal decisions. People working in state government

---

10 EPA's close scrutiny and regulation of *Bt* crops (crops altered to be insect resistant by virtue of producing a toxin produced naturally by the bacterium *Bacillus thuringiensis*) is arguably an example since its purpose is to minimize the development of insect resistance so that naturally occurring *Bt* can remain available to the organic produce industry; Taylor and Tick 2003, 17 and 70.

11 An illustrative perspective on this issue was provided by an academic observer in response to a survey question: "States shouldn't reinvent the wheel; federal agencies have sufficient expertise and authority to properly regulate these issues. State involvement in these regulatory issues will only increase regulatory burden, at taxpayers' expense, with no objective increase in safety or public confidence." Survey responses are on file with the authors.

expressed a particular desire to be able to rely on federal decisions about whether and under what conditions a biotech crop is safe for the environment and whether a biotech food is safe. Relying on federal oversight to address these areas was seen by many as an effective way of managing limited state resources.

Another advantage of federal oversight from the state perspective is consistency across the country. If left to individual states, a patchwork of differing state-level approaches to regulation might result, which could be inefficient and disruptive.[12] Bill Dickerson, Director of the Plant Industry Division of the North Carolina Department of Agriculture and Consumer Services and current President of the National Plant Board, stresses the need for strong federal laws to protect North Carolina's environmental and economic interests, noting that some states have been less active than others in overseeing biotechnology and yet are part of the same ecological system. He observes that, without strong federal regulation, insufficient regulatory oversight in one state could potentially affect other states and their agricultural industry.[13]

As discussed in greater detail in sections III and IV, however, a general willingness to defer to the federal agencies on the basic food and environmental safety decisions does not mean that the states see no role for themselves on health and environmental regulatory matters. The states generally seek a collaborative relationship with the federal agencies. They prefer a process that keeps them informed about new permits and approvals, as well as the basis for them. Also, to varying degrees, states seek a hands-on role in ensuring that conditions placed on products to ensure their safety are adequate to address local circumstances and are strictly observed. The states have a clear preference for an active role in both initial approval decisions and compliance oversight when decisions related to plant health have implications for local agricultural producers.

There are clear exceptions to these prevailing views about the state role regarding health and environmental issues, namely among people who have concerns about or oppose biotechnology or who doubt the adequacy of federal oversight. For example, in response to a survey question, a representative of a regional farmer's union said:

> If the federal regulatory process regulated for health and safety, the states may not need to send their own inspectors out, or create elabo-

12 Polansky 2004; Smoak 2004.

13 Dickerson 2004.

If left to individual states, a patchwork of differing state-level approaches to regulation might result, which could be inefficient and disruptive.[12]

> rate review processes. However, until the federal process is substantially reformed, conscientious state agencies may find that it is in the best interest of their citizens to repeat the regulatory and oversight process.[14]

In an interview, the leader of an advocacy group that is critical of federal government oversight expressed support for state-by-state regulation as a way to push the federal government toward stronger, more consistent regulation.[15]

In response to the survey, a New York-based leader in the organic farming community assigned "medium importance" to state regulatory oversight of biotech crops and foods, observing that there is a role for state agencies in tracking or researching state-level environmental impacts of biotech crops, but that:

> [New York] has had inadequate spending levels and has been reducing spending for much of its environmental regulatory work in the last decade. While there are many environmental issues where strong state activity and creativity have been helpful in moving the federal government and the country forward, the nature of genetic engineering of crops, how crops are grown, etc., makes it a very difficult issue to imagine a way where extra aggressive state regulatory action will be really helpful.[16]

There are also strong voices arguing from a different vantage point for a very limited state role in regulatory oversight of biotech crops and foods. For example, an academic with a research interest in biotechnology said in a survey response:

> This should not be a state effort at all. There is a fully adequate system for regulation of biotech crops. States' interests should be "at the table" and included in all federal discussion and approvals but they do not need a second tier system. Biotechnology is already over-regulated.[17]

While states do not appear to be developing duplicative scientific review capacities and regulatory processes to address the core food and environmental safety issues posed by biotech crops and foods, most want a seat at the table with their federal counterparts so they can be confident—and can assure their constituencies—that those issues have been addressed and do not impair other state interests in biotech crops and foods.

---

14 Survey responses are on file with the authors.

15 Kimbrell 2004.

16 Survey response of Sarah Johnston, Executive Director of the Northeast Organic Farming Association of New York.

17 Survey response of Bruce Chassy, University of Illinois, Urbana Campus.

Capturing the Economic Benefits of Biotechnology

In many states, the success of agriculture is important to the state's economy. Thus, promotion and protection of agricultural interests is a state government objective. Biotechnology is widely perceived in the agricultural community as an important tool farmers can use to increase their efficiency, productivity, and global competitiveness in basic commodities (corn, soybeans, and cotton), as well as being a possible source of new value-added products.[18] Under these circumstances, farmer access to and public acceptance of biotechnology become state economic interests.

In some states, biotechnology is regarded not only as another useful tool for farmers, but also as an engine for broader economic development. In Iowa, for example, the governor has made the development and application of agricultural biotechnology a central theme of his economic development strategy for the state.[19] Hawaii and Arizona, by virtue of their isolation from commodity food crop production, are seen by some in those states as having a comparative economic advantage in the conduct of field trials and other biotechnology research which should be exploited.[20] A number of states have established research centers and have provided loans, tax incentives, and other economic assistance to foster local development of biotechnology.[21]

By linking biotechnology and economic development, state policymakers necessarily take on an interest in regulatory oversight of the technology. This interest can run in two potentially conflicting directions. On the one hand, the greater the interest in biotechnology for economic development purposes, the greater the interest in ensuring that it receives the regulatory oversight required to gain market and consumer acceptance. Survey research conducted by the Pew Initiative and others links the prospects for biotechnology's economic success with the effectiveness and credibility of regulatory oversight. In a recent Pew survey, for example, respondents made clear that government approval of the safety of biotech food would increase the likelihood of consumer acceptance.[22]

---

18 Taylor and Tick 2003, 20–21.

19 Michael Blouin, director of the Iowa Department of Economic Development, told attendees at a biotech conference that "a fledgling biotech industry will be a cornerstone of Iowa's future economy" (notes on file with the authors).

20 See Hawaii Summary in Section IV. Sheldon Jones, formerly of the Arizona Department of Agriculture and now with the Arizona Agribusiness Council, believes Arizona should be aggressive in attracting to the state field trials involving biotech crops and should capitalize on the economic potential of agricultural biotechnology, especially as applied to development of crops producing pharmaceutical or industrial substances. S. Jones 2004.

21 The Pew Initiative on Food and Biotechnology reported a "large increase throughout the U.S. in the number of bills supporting biotechnology, particularly as a tool for economic development." Fifty pieces of state legislation were introduced in support of biotechnology in 2003, compared with eight in 2001–2002. Pew Initiative on Food and Biotechnology 2004(a). See also Battelle Technology Partnership Practice and SSTI 2004.

22 Pew Initiative on Food and Biotechnology 2003.

This perspective is corroborated in an indirect but interesting fashion by the survey conducted for this report. The majority of people who chose to respond to the survey apparently see the potential economic value of biotechnology, reporting by nearly 2-1 margins that they expect the future impact of biotech crops and foods will be positive for U.S. farmers, the food industry, and consumers. Interestingly, over half of the respondents who said they expected the future impact of biotech crops and foods to be positive also said that regulatory oversight should be more stringent than oversight of other techniques for producing improved seed varieties and food crops.[23] While this self-selected group of respondents may or may not be representative in their optimism about biotechnology, they apparently see the link between the success of biotechnology and regulatory oversight.

States that embrace biotechnology in an effort to promote economic development may favor strong regulatory oversight to promote consumer acceptance. However, linking biotechnology with a state's economic development plans creates a potential conflict—or at least the appearance of a conflict. Namely, some might believe that rigorous regulation could hinder states' efforts to encourage the development and adoption of biotechnology. The biotechnology industry, for example, typically advocates regulatory approaches that minimize the delays and costs associated with regulation, while achieving the desired level of health and environmental protection. In the case of agricultural biotechnology, however, there is considerable debate about what constitutes the "desired level" of protection and what degree of precaution should be observed in the face of the scientific uncertainty that is associated with the introduction of any new technology.

These debates place state governments in a difficult and potentially conflicted position, especially since state departments of agriculture frequently are in the position of being both a promoter and a regulator of biotechnology.[24] The state regulatory officials who responded to the survey, as well as those who were interviewed, appear to be earnestly engaged in conducting or attempting to craft regulatory oversight regimes that satisfy the needs of their states. Moreover, to the extent that health and environmental concerns are addressed at the federal level and states focus on issues that are primarily of importance to agriculture, the potential for genuine conflicts of interest at the state level is diminished.

It is not always possible, however, to draw a clear line between the interests of agriculture and the broader public. For example, as discussed in the next subsection, containing the flow of gene traits from biotech crops to conventional crops affects more than a farmer's interest in maintaining crop integ-

---

23 Specifically, 56% of the respondents who expect biotechnology to be positive for farmers think oversight should be more stringent; 51% of those who expect it to be positive for the food industry and 52% of respondents who expect it to be positive for consumers have the same view.

24 Ehart 2004.

rity and market access. It can also affect food marketers and consumers who want to ensure that organic crops satisfy regulatory standards and consumer expectations and that unwanted materials, such as materials from pharma or industrial crops, are kept out of the food supply. In light of the complex array of often competing interests that are affected by biotech crops and foods, the potential conflict between the economic development and regulatory roles of state governments generates criticism in some quarters.[25]

Preserving Market Access

States clearly have an interest in both ensuring public and environmental safety and fostering biotechnology-driven economic growth in general. However, in many states, attention to oversight of biotech crops and foods is mainly driven by a specific economic interest in protecting existing agricultural economies and preserving the marketing opportunities, both domestically and internationally, of local farmers. As previously discussed, there is some general relationship between the perceived adequacy of regulatory oversight and public acceptance of biotech crops and foods. But the interest addressed in this section concerns the other side of the coin: ensuring that commercial markets remain open for the *nonbiotech* crops and foods (both conventional and organic) that are produced by a state's farmers.

No issue involving biotech crops and foods has received more attention within state governments, the agricultural community, and from the media, than the technology's potential to hurt market access for conventional and organic crops. The three most prominent manifestations of the issue are the StarLink episode, in which biotech corn approved only for animals entered the human food supply;[26] the ProdiGene incident, in which trace amounts of a biotech corn crop modified to produce a pig vaccine was found in soybeans intended for human food use;[27] and the debate in the northern plains states over whether to ban the planting of biotech wheat in order to protect access to foreign markets in which biotech wheat is not approved and is likely to be rejected by consumers.[28]

25 A representative of an environmental group that is highly critical of biotechnology and its regulation at both the federal and state levels said in response to a survey question: "State attitudes and enforcement is [sic] currently driven entirely by commercial interests, without any concern for the environment or consumer interests. There must be oversight that is not driven by desire to please seed companies."

26 Taylor and Tick 2003, 90–105.

27 Taylor and Tick 2003, 88–89.

28 See Section IV, Legislating Restrictions on Biotech Crops on Economic and Social Grounds.

...in many states, the strongest motivator and shaper of the state interest in oversight of biotech crops and foods is their specific economic interest in protecting their current agricultural economies and preserving the marketing opportunities of their farmers, both domestically and internationally.

None of these cases involved any demonstrated human health risk or adverse environmental impact. Rather, the common concern in each case was the possibility that the access of corn, soybean, or wheat farmers to domestic or international markets might be cut off or impaired due to the potential unwanted presence of biotech varieties. Food processors would not purchase corn that might contain the unapproved StarLink gene. Consumers would rebel if they thought the soy ingredients in their food products were contaminated with a pharmaceutical substance. And Japanese and European markets might be closed to U.S. wheat growers if biotech varieties were introduced in the northern plains states.

The potential for cross-contamination or accidental loss of control of biotech crops or foods to negatively impact market access has generated a substantial policy debate at the national level. Some have expressed concern over whether federal regulatory standards and the associated enforcement are robust enough to prevent contamination incidents such as those involving StarLink and ProdiGene. Others question what the federal government's role should be in meeting the expectations and demands of foreign markets through such measures as labeling, process verification, identity preservation, and traceability.[29] In general, the federal regulatory agencies have focused on either ensuring that growing and handling practices for biotech crops are sufficient to prevent the unwanted presence of biotech-derived material in crops and foods, or establishing criteria for accepting certain levels of the so-called "adventitious presence" of such material.[30] But there have been concerns expressed in some quarters about whether agencies are sufficiently monitoring compliance.[31]

Given these past events and existing federal efforts to manage this issue, states find themselves on the frontline when it comes to ensuring market access for their farmers. If a particular set of farmers in a state feel that their markets are threatened by the planting of biotech crops in proximity to theirs, they come first to their state department of agriculture or their legislature with requests for assistance. Preserving market access for conventional and organic crops is thus one of the most significant drivers of state interest in regulating biotech crops and foods. It manifests itself in the desire expressed by many state regulators to develop a closer collaboration with APHIS in the permitting and inspection of field trials, as well as in the pressure within some states for legislatures and administrative agencies to intervene on essentially economic grounds in decisions about whether to allow commercialization of certain biotech crops, such as biotech wheat in North Dakota or rice in California.

---

29 Taylor and Tick 2003, 71–84.

30 Taylor and Tick 2003, 63 and 68–69.

31 Northey 2004.

The primacy of these economic concerns as a driver of state regulation of biotech crops and foods is reflected in the survey results as well. When asked to indicate the importance they attach to state regulatory oversight on particular topics, more respondents gave "high importance" to the topic of the unintended presence in food of pharmaceutical or industrial substances than to any other topic. When asked what importance they placed on particular regulatory activities, more respondents gave "high importance" to ensuring compliance with field trial conditions than to any other activity. We take these results to be reflective of the priority that stakeholders give to preventing the kind of unwanted presence of biotech materials that can disrupt market access.

Responding to Concerns of Local Citizens and Stakeholders

Preserving market access for a state's farmers is just one example of a local concern that can drive a state's interest in regulation of biotech crops and foods. There are others that go beyond the economic interests of farmers, such as the interest some consumers express in insulating organic crops and foods from the presence of biotech-derived components, or being able to choose between biotech and nonbiotech foods through labeling. In some states and communities, particularly those where environmental awareness and advocacy are strong, there may be local groups with special concerns about maintaining biodiversity, avoiding impacts on nontarget species, or other ecological issues.

Whatever the local concern, it is more likely to be brought forcefully to bear at the state government level than at the federal level, and it is the natural tendency of government at all levels in our democratic society to seek ways to respond. In the arena of biotech crops and foods, the response could take many forms, including efforts to influence federal decisions or carry out local enforcement of federal rules, set and enforce different standards than the federal standards, expand opportunities for public participation in state decisionmaking, or even consider crop- or technology-specific bans. We see examples of all of these across the United States and will describe some of them in detail in Section IV's policy vignettes.

There are two points to emphasize here. The first is to underscore the difference it makes for state governments that they are at the frontline of democratic governance and thus so much closer to the concerns of local citizens than the federal regulatory agencies. This is not a criticism of the federal agencies. It is a fact built into our federal system of government, in which both the state and national governments have sovereign duties and practical political accountability to their citizens that overlap but that also differ in important respects. One difference is that the federal regulatory agencies can much more readily resist pressures and demands from local groups than can state agencies. Given the responsive nature of state governments and the fact that their concerns reside mostly within their own borders, it is not surprising that local citizens and other stakeholders have a more pronounced impact on state policies than on federal agencies.

The second and related point is that, in the end, state governments are only responsible for what happens in their state. They do not have the same need federal agencies have to consider the national implications and precedential impacts of their actions for national regulatory policies and programs. Thus, while state agencies must operate within the bounds of applicable state laws, they have somewhat greater latitude in framing policy or adopting new legislation to consider and respond to local interests, whether it is the economic impact of a specific biotech crop on local farmers or a local environmental impact.

Conclusion

It is clearly in the best interests of both the federal agencies and the states to efficiently share resources and responsibilities with respect to the oversight of agricultural biotechnology. To a large extent, states have expressed a desire to have the FDA, EPA, and APHIS act as the primary, although not exclusive, managers regarding issues of food, feed, and environmental safety. There is no unanimity on this point, however, as there are those who suggest a need for a significantly more active state role, as well as those who suggest biotechnology is already over-regulated and that additional state efforts in this arena are inappropriate.

Capturing the economic benefits of biotechnology and ensuring that existing agricultural economies are not adversely impacted by it are the two state interests that appear to most greatly influence their current and desired involvement in regulatory oversight of biotechnology.

Capturing the economic benefits of biotechnology and ensuring that existing agricultural economies are not adversely impacted by it are the two state interests that appear to most greatly influence their current and desired involvement in regulatory oversight of biotechnology. Similarly, pressures from citizens and other local stakeholders are more acutely felt at the state level than may be true at the federal level. It is critical in the discussions that follow of state oversight of biotech crops and food to remember that state governments have their own constituencies and interests, and, while there are many shared values and interests between the federal and state governments, there are differences that matter, legitimately, for public policy.

III. CURRENT STATE OVERSIGHT ACTIVITIES AND STAKEHOLDER PERSPECTIVES: AN OVERVIEW

THE DIVERSITY OF STATE INTERESTS IN biotech crops and foods has spawned a diversity of state activity, including a rising level of legislative interest. According to the Pew Initiative's recent report on state legislative activity, 130 pieces of legislation related to agricultural biotechnology were introduced during 2003, of which 27 passed during that year.[32] The introduced legislation included measures to support the development of biotechnology by establishing research centers and providing economic incentives (38% of the total); establishing studies or task forces (19%); regulating biotech crops, animals, or foods in some manner (13%); addressing liability and agricultural contracting issues (15%); establishing moratoria (6%); or addressing labeling (7%). The majority (70%) of the bills and resolutions passed by state legislatures were measures to support biotechnology.[33]

While the level and diverse nature of the current state legislative activity provides context for this report, its major focus is on activities at the state level that relate specifically to regulatory oversight. Only one of the bills passed in 2003 involved regulation of agricultural biotechnology,[34] but, throughout the country, many states are involved today, in widely varying ways, in the regulatory oversight of biotech crops and foods. The purpose of this section of the report is to provide an overview of these activities and stakeholder perspectives on them. Just as the federal Coordinated Framework grounded federal regulation of biotechnology in existing law, current state regulatory activities involving biotech crops and foods are generally grounded in plant health, pesticide, and food safety regulatory programs that predated agricultural biotechnology. These programs typically parallel the federal programs addressing the same topics and operate to varying degrees in collaboration with the federal programs. To understand the regulatory issues and challenges that states are facing today, it is important to understand at least the key elements of the state programs, the federal-state interaction, and the perspectives on them among regulators and their stakeholders. This section addresses these topics, and shares observations drawn from the survey regarding the importance of state regulatory oversight. Section III also serves as background for both Section IV, which discusses some of the challenging issues that are likely to be important to the future of state oversight, and Appendix A, which contains a more detailed state-by-state analysis.

32 Pew Initiative on Food and Biotechnology 2003.

33 Pew Initiative on Food and Biotechnology 2003.

34 Pew Initiative on Food and Biotechnology 2003. Arkansas passed a law requiring that the Arkansas Department of Health establish and administer a biological agents registry, which appears likely to have little if any impact on agricultural biotechnology.

Importance of State Regulatory Oversight

As discussed in Section II, the interests that motivate state oversight of biotech crops tend to be local in nature and driven largely by agricultural interests. There is also a strong tendency at the state level toward a reliance on federal oversight to ensure that biotech crops and foods are safe for human health and the environment. When survey respondents were asked about the importance of federal and state oversight to address specific topics, a larger percentage consistently attached "high importance" to federal oversight than to state, as shown in Chart 1. Though we cannot claim the survey responses are statistically representative of the views of state biotech stakeholders generally, they are in line with what was said consistently by other sources about the importance of federal regulation to address core health and environmental issues.

When asked about the general importance of state oversight in light of the federal role, less than one-third said it was of "high importance," while 43% said it was of "medium," or "medium-high" importance, as shown in Chart 2.

CHART 1: RATIOS COMPARING RESPONDENTS WHO WEIGH FEDERAL AND STATE REGULATORY OVERSIGHT AS OF "HIGH IMPORTANCE" FOR VARIOUS TOPICS

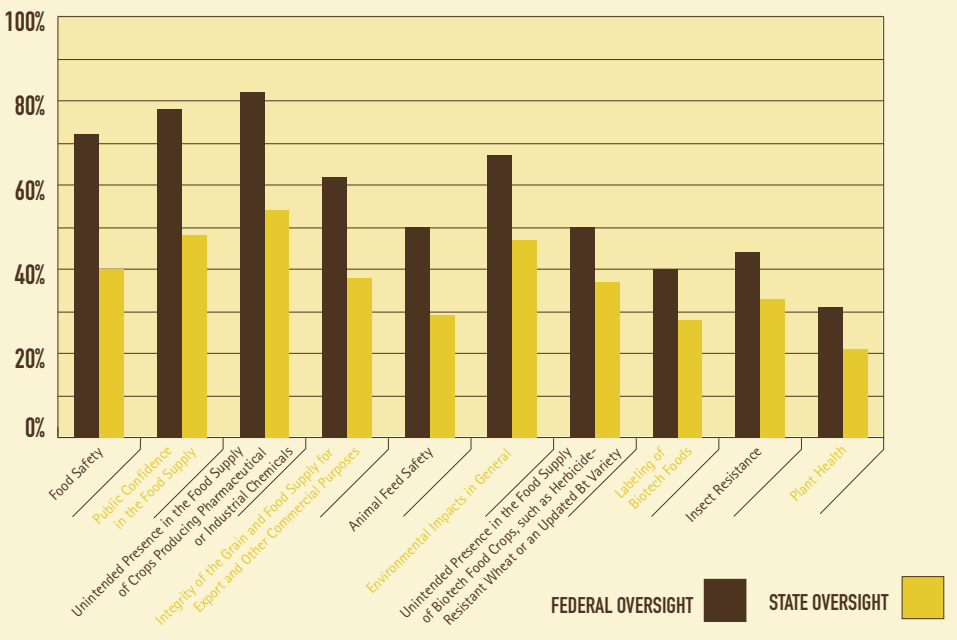
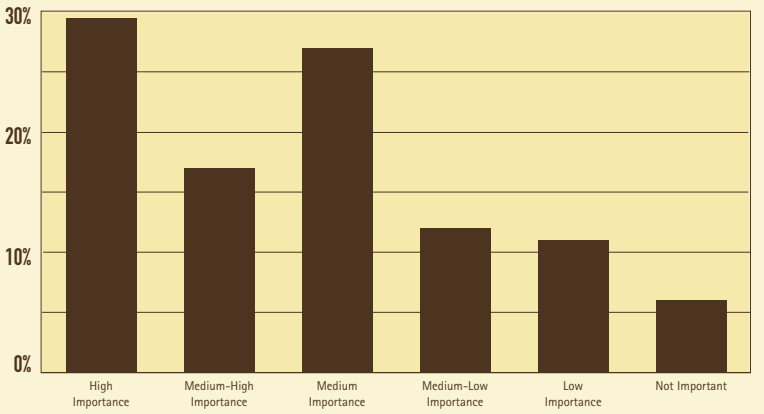
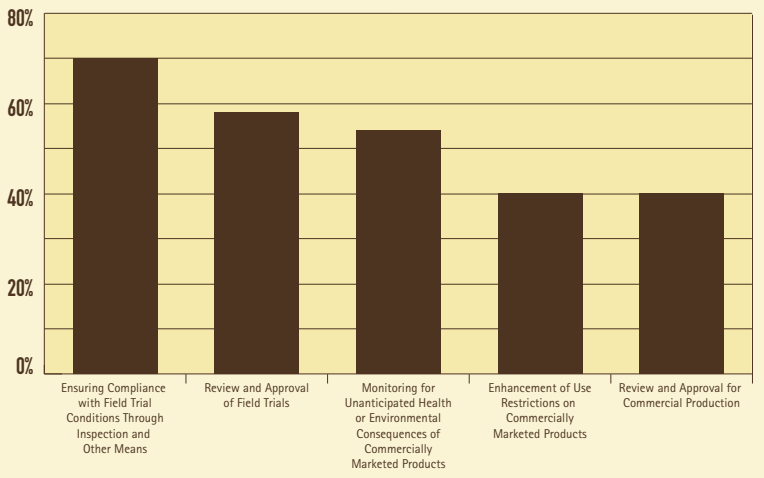


CHART 2: PERCENTAGE OF RESPONDENTS ATTACHING VARIOUS LEVELS OF IMPORTANCE TO STATE REGULATORY OVERSIGHT IN GENERAL



When asked about the importance of state governments being involved in specific types of regulatory activities concerning biotech crops and foods, a higher percentage (over two-thirds) of respondents placed "high" or "medium-high" importance on "ensuring compliance with field trial conditions through inspection and other means" than on any other activity. Next was "review and approval of field trials," with over half attaching "high" or "medium-high" importance to this activity. See Chart 3 below. This response is not surprising in light of the perceived link between field trials of controversial or novel applications of biotechnology (such as biotech wheat or those that produce pharmaceutical substances in plants) and possible adverse impacts on market access, a primary interest driving state oversight. It is thus also not surprising that oversight of field trials is by far the most active area in state regulation of biotech crops and foods.

CHART 3: PERCENTAGE OF RESPONDENTS ATTACHING HIGH OR MEDUIM-HIGH IMPORTANCE TO STATE REGULATORY OVERSIGHT FOR VARIOUS TOPICS



The Federal-State Relationship

The federal-state relationship concerning regulatory oversight of biotech crops and foods is grounded in the parallel federal and state programs that deal generally with plant protection, pesticides, and food safety. This reflects one of the key characteristics of biotechnology regulation in the United States, which is that it is based on statutes and regulatory programs that long predate biotechnology. The central policy judgment embedded in the federal government's 1986 Coordinated Framework for the Regulation of Biotechnology, which was intended to establish a "comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products," was that biotechnology would be regulated using current statutory authorities, rather than any new biotechnology-specific law.[35] Thus, federal regulation of agricultural biotechnology was folded into the plant protection program administered by APHIS in the U.S. Department of Agriculture (USDA), the pesticide program administered by EPA, and the food safety program administered by FDA. To the extent that states have been active in the regulation of biotech crops and foods, it has generally been pursued through the state programs that parallel these federal ones.[36] In fact, as outlined below, the legal scope and authority and programmatic activities of the state programs are strongly influenced, and in some instances legally controlled, by federal law and federal actions.

Despite the reliance within the Coordinated Framework on preexisting statutes and programs, the nature of the federal-state relationship and the roles of each player are different when comparing biotechnology and other plant protection and pesticide issues the federal and state programs typically address. For example, in the traditional plant pest arena, the federal government has relied heavily on state plant protection programs to detect and manage problems affecting agricultural producers because the problems are typically local in nature, with respect both to control measures and economic impact. Even large-scale problems such as the Medfly infestation of fruit trees in California and karnal bunt disease in wheat produced in a number of states in the southwest are typically detected locally and have adverse impacts on farmers in specific geographic locations. APHIS plays a critical role in managing the interstate and international aspects of these events, but nonetheless depends upon and tends to be deferential to the expertise and judgment of local officials who have primary responsibility for managing plant health in the affected states. This is due, in part, to the fact that understanding and managing such hazards relies on the use of diagnostic techniques and the visible detection of problems by field-based experts. Conversely, in the case of biotechnology oversight, the locus of

35 Office of Science and Technology Policy 1986.

36 See Taylor and Tick 2003, for additional information on both the pre- and postmarket federal regulatory programs for biotech crops and foods.

most relevant scientific expertise and techniques for understanding hazards is in the laboratory and not generally accessible at the field level. The locus of leadership and action is thus at the federal level, where, as discussed below, APHIS controls the central feature of biotech crop regulation, which is the authorization of field trials.

Biotechnology has spawned a similar shift in roles and responsibilities from the states to the federal government in the area of pesticides as managed by EPA. For conventional pesticides, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) gives states primary responsibility for enforcing use restrictions and other EPA regulatory controls that are reflected in the labeling of pesticide products. Pesticides that are produced and used in genetically-modified plants are subject to regulation under FIFRA. Because EPA regulates only the pesticidal substance itself (called a "plant-incorporated protectant," or PIP), and not the seed or plants producing the pesticide, the biotech seeds and plants distributed for use on farms do not bear an enforceable pesticide label. The states therefore do not have a FIFRA enforcement role with respect to commercialized PIPs. Instead, EPA regulates the use of PIPs in the field, including ensuring compliance with use restrictions imposed as a condition of registration, by requiring registrants to perform activities related to seed sales as a condition of being able to maintain their registrations. For example, companies registering *Bt* crops are required to establish contracts with growers under which growers agree to plant crops in accordance with the conditions of registration designed to minimize development of insect resistance. States have no role in monitoring compliance with these private contractual agreements.

These shifts in roles and responsibilities are illustrative of the federal and state governments' efforts to oversee biotech crops and foods in a way that meets both national and local needs. Dialogue is underway to refine and improve the way agencies at both levels work together. The remainder of this section provides an overview of the federal biotech regulatory programs as they exist today, the federal-state relationship for each program, and the roles states play.

Plant Protection Programs: APHIS and the States

APHIS Authority, Organization, and Resources

At the federal level, APHIS regulates biotech crops under the authority of the Plant Protection Act of 2000 (PPA).[37] The PPA consolidated and enhanced two laws that APHIS had used previously to regulate biotech crops, namely the Federal Plant Pest Act and the Plant Quarantine Act.[38]

---

37 Crops that are genetically modified to produce a pesticidal substance are also regulated by EPA under FIFRA, as discussed below.

38 Taylor and Tick 2003.

The PPA gives APHIS broad authority to regulate plant pests and noxious weeds in order to protect agriculture, public health, and the environment. The PPA also carried forward and enhanced the extensive enforcement powers to ensure that its requirements, including field trial conditions, are met.[39] APHIS uses its authority under the PPA to regulate most releases of biotech crops into the environment, whether for field testing, importation, or commercialization, and has issued regulations (codified in Part 340 of the APHIS regulations) that spell out how its statutory authority applies to biotech crops.[40]

The APHIS regulations establish the process by which the agency regulates introductions of biotech crops (and other "genetically engineered" organisms) that may pose a plant pest risk. The regulations refer to such crops and organisms as "regulated articles." The regulations define "introductions" to include importation, interstate movement, and release into the environment. APHIS regulates field trials involving these activities by one of two authorization mechanisms: issuance of a permit, or a notification procedure. The Part 340 regulations also provide a mechanism for APHIS to make a determination of nonregulated status, meaning essentially that the genetically engineered organism does not meet the definition of a regulated article, because it does not pose a plant pest risk. After a determination of nonregulated status with respect to a biotech crop, APHIS no longer has authority to regulate the crop under Part 340, which means there is no requirement for authorization from APHIS for future introductions of the crop. Parties seeking to commercially market a biotech crop typically seek a determination of nonregulated status prior to commercialization so that the crop can be freely planted without further APHIS oversight.

Importantly, the APHIS Part 340 regulations were issued under the plant pest and quarantine laws that predated the PPA and whose jurisdiction was limited to control of plant pests. Relying on the new authority under the PPA to address broader environmental issues, APHIS recently announced its intent to propose amendments in its regulations to enhance its oversight of possible environmental impacts of biotech crops beyond those involving plant pest concerns.[41]

In 2002, APHIS created a new unit, the Biotechnology Regulatory Service (BRS), "to focus on USDA's key role in regulating and facilitating biotechnology," saying it would improve how the agency carries out its regulatory responsibilities and put APHIS in a better position to address the issues brought up in the National Academy of Sciences report, Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation.[42] The

---

39 Taylor and Tick 2003, 28–31. Subtitle B of the Plant Protection Act, 7 USC 7731 et seq.

40 The APHIS plant protection regulations are codified at 7 CFR Part 340 (2002); USDA APHIS 2000.

41 USDA APHIS 2004.

42 USDA APHIS 2002.

main regulatory functions of BRS are to authorize field trials for biotech crops, enforce conditions placed on field trials, and make decisions about whether biotech crops can be granted nonregulated status and thus be planted without further regulation. These functions are performed by BRS' regulatory and policy coordination divisions.

BRS has a staff of about 35, including two Plant Pest and Quarantine Program (PPQ) regional biotechnologists stationed in the field in Colorado and North Carolina. The field staff of the APHIS PPQ, which administers the PPA for nonbiotech plants, is also available to conduct compliance inspections for BRS, but, for most of the PPQ field staff, biotechnology inspections comprise only one part of their job.[43] The FY 2004 budget for BRS is $5.4 million.[44]

State Authority, Agencies, and Resources

Legal Authority

Protection of plant health through the control of plant pests is a long-standing function of state government. It is a crucial economic issue and a necessity in agricultural states to protect food crops from harm; plant pest control is important also to protect ornamental plant producers. Virtually every state thus has some form of statutory authority to control plant pests and protect plant health through quarantines and other measures. For the 17 states examined for this report, these statutes are identified in the state-by-state information summaries in Appendix A.

As a matter of constitutional law, state regulation of biotech crops to protect plant health, human health, and general environmental safety falls within the traditional police powers of the state. However, such powers can be preempted (or overridden) by the federal government under the U.S. Constitution's Supremacy Clause, which empowers the federal government to determine when federal laws and regulatory programs displace state laws and regulations. The PPA contains a provision that expressly preempts state regulation "in interstate commerce" of any plant or other article (such as seeds) to protect against plant pests or noxious weeds if APHIS has acted to regulate the plant or other article, unless the state regulations are

43 USDA APHIS n.d.(a).

44 Garrison 2004.

As a matter of constitutional law, state regulation of biotech crops to protect plant health, human health, and general environmental safety falls within the traditional police powers of the state. However, such powers can be preempted (or overridden) by the federal government under the U.S. Constitution's Supremacy Clause, which empowers the federal government to determine when federal laws and regulatory programs displace state laws and regulations.

"consistent with and do not exceed" the APHIS requirements.[45] As written, the PPA preemption provision leaves legal room for the states to protect plant health on issues that are purely local in nature and not addressed by the federal government. But, once the federal government has acted to regulate a particular biotech crop (such as by issuing a permit), there is considerable legal uncertainty about a state's authority under plant health laws to impose its own regulatory restrictions on the crop if they are different from or in addition to federal requirements, even to address local plant health concerns. The uncertainty is due to the inherent complexity of the PPA's preemption provision and to the lack of any court cases interpreting where "interstate commerce," and thus federal preemption, ends under the PPA.

The uncertainty about state authority over biotech crops also arises from the fact that only a few states have adopted laws or regulations specifically governing biotech crops. See Table 1 on the following page. Admittedly, the federal PPA itself does not specifically mention biotech crops or other biotech plants. It was enacted in 2000, however, with biotechnology and associated regulatory issues being very much on the minds of its supporters and sponsors, and the PPA's language was written broadly enough to encompass biotech crops. Moreover, APHIS has issued detailed regulations spelling out how the federal law applies to biotech plants, leaving little doubt that APHIS is statutorily empowered at the federal level to regulate biotech crops.[46]

In Minnesota, the one state that has a comprehensive, biotech-specific crop regulatory law requiring state permits,[47] the authority to require and enforce permits is clear, except to the extent that a state action might be invalid under the PPA's preemption provision. Other states rely on prebiotech plant health laws, and there are different perspectives from state to state and uncertainty about what authority these laws give the states over such matters as the permitting of biotech field trials. One crucial issue is whether a state could legally prohibit the conduct of a field trial that APHIS had authorized or impose conditions that APHIS had chosen not to impose. This issue is discussed further in Section IV.

Despite these legal uncertainties regarding the scope of state authority to regulate biotech crops, which arise primarily from the preemption provision of the PPA, APHIS recognizes that the states have legitimate interests in biotech field trials and has thus established a collaborative relationship with the states in the oversight of biotech field trials.

---

45 Section 436 of the PPA, 7 USC 7756.

46 7 CFR 340.

47 Minnesota's statute requires developers to obtain state authorization through a notification or permit process (in addition to meeting federal requirements) prior to release of a biotech crop into the environment, such as in a field trial, and authorizes the commissioner of agriculture to accept, place conditions on acceptance, or deny authorization based on the potential for the crop to cause adverse environmental effects and/or human harm. Minnesota Statutes 2003a. Oklahoma has a biotech statute with similar provisions to the Minnesota law, but with one major difference: it exempts anyone who has "applied for regulatory approval(s) from the appropriate federal agency." Oklahoma Department of Agriculture n.d.

TABLE 1: BIOTECH-SPECIFIC REGULATORY STATUTES

STATE	BIOTECH STATUTE?	DESCRIPTION
Arizona	No	While AZ does not have a biotech statute, it does have a biotech regulation that reinforces APHIS regulations for notifications and permits. The regulation allows for additional information to be obtained by the department to ensure proper containment of the GMO. Genetically Engineered Organisms and Products (Ariz. Admin. Code Supp. § R3-4-901 (2004))
California	No	
Colorado	No	
Hawaii	Genetically Modified Organisms (19 Haw. Rev. Stat. § 321-11.6 et seq. (2003))	Requires applicants to submit a copy of federal notification or permit applications to the state.
Illinois	Release of Genetically Modified Organisms Act (430 III. Comp. Stat. § 95/0.01 et seq. (2004))	Requires applicants to submit a copy of federal notification or permit applications to the state and county official where release will occur, including a summary of CBI-redacted information. The state may seek public input or expertise in its review of a federal permit or notification.
Iowa	No	
Kansas	No	
Maine	Genetically Engineered Plants and Seeds (7 Me. Rev. Stat. Ann. § 1051 et seq. (2003)) and The Labeling Foods Free of Genetic Engineering (7 Me. Rev. Stat. Ann. 530-A et seq. (2003))	Requires biotech seed dealers or manufacturers to keep a list of growers who purchase GM seed. Foods containing 1% or less of GM materials can be labeled GM-free.
Minnesota	Genetically Engineered Organisms Minn. Stat. (§ 18F.01 et seq. (2003)) and Experimental Genetically Engineered Pesticide Product Registration (Minn. Stat. § 18B.285 (2003))	Provides comprehensive authority to the state to issue permits and notifications for field testing of GM plants and the release of experimental pesticide producing GM plants. Provides for inspections, penalties for violations, and process to commercialize GM crops.
Montana	No	
New York	No	
North Carolina	No; a biotech-specific statute passed in 1989 was allowed to "sunset" in 1995	
North Dakota	No	
Oklahoma	Oklahoma Agriculture Biotechnology Act (2 Okla. Stat. § 11-35 et seq. (2004))	Provides comprehensive authority to the state to regulate GM crops only if applicants are not regulated by a federal agency.
Oregon	No	
Texas	No	
Vermont	Pest Survey (6 Vt. Stat. Ann. § 1030 et seq. (2003)) and (6 V.S.A. § 611(c) et seq. (2004))	Requires applicants to obtain a state permit for sale, movement, or release of a GM plant determined to be a plant pest. Requires all seed to be labeled with GMO seed labeling specifying the traits of the seed and safe handling instructions.

Agencies

In most states, plant health regulatory responsibilities are carried out by the state's department of agriculture through such organizational subdivisions as Minnesota's Agricultural Resources Management and Development Division, Oklahoma's Plant Industry and Consumer Services Division, and Hawaii's Plant Quarantine Branch.[48] Biotech oversight is normally a function of these existing units rather than any special biotech unit, such as BRS at the federal level. The exceptions to this allocation of functions are North Carolina and Texas. North Carolina enacted a biotech-specific law in 1989 that expired in 1995 and was not replaced. It continues to have, however, a Biotechnology Services Program within its Plant Industry Division, which provides "a liaison relationship between the citizens of North Carolina and federal government agencies regulating different facets of the agricultural biotechnology industry."[49] Texas, through its Biotechnology Regulatory Program, promotes the development and adoption of biotech plants and "evaluates risks by reviewing applications and requiring adequate safeguards before allowing controlled experiments to be conducted within the state."[50]

Resources

At the state level, the resources available for regulatory oversight of biotech crops for plant health purposes are very limited. The organizational units responsible for plant health in general are typically very small, and many states rely on the part-time efforts of one or a few individuals within these units to carry out or coordinate the state's biotech oversight activities. For example, Mary Hanks, Sustainable Agriculture and Integrated Pest Management Supervisor at the Department of Agriculture in Minnesota, is one of two staff people working on oversight of biotech crops and foods in the state. Dr. Hanks allocates approximately 10% of her time to biotech oversight activities, which must cover all of the non-PIP notification and permit reviews (about 38 per year) as well as any inspections of field trials the state chooses to conduct.[51] At one time, a Minnesota Department of Agriculture staff member was funded to work full-time implementing Minnesota's biotech statute. After the implementing rules were released, however, it was concluded not enough biotech work existed to sustain a full-time person.

Robin Pruisner is the State Entomologist in Iowa's Department of Agriculture and Land Stewardship and, as such, she has lead responsibility for regulatory oversight of biotech crops and foods. While there have been between 80 and 130 notifications and permit field trials per year over the last three years submitted to her office, she spends only about 2% of her time on biotech crops and foods.[52]

---

48 See the state-by-state summaries in Appendix A for the names of the organizational units overseeing biotech crops and foods in the 17 states on which we focused.

49 North Carolina Department of Agriculture and Consumer Services 2003b.

50 Texas Department of Agriculture n.d.(a).

51 Hanks 2004.

52 Pruisner 2004 and Information Systems for Biotechnology 2004(a).

Dwight Harder, Assistant Director of the Arizona Department of Agriculture, commented that personnel turnover in his state's Plant Services Division, most likely due to low pay, has made it difficult to maintain a consistent system for reviewing APHIS field trial permit applications.[53] The relationship between resources and the availability of the personnel and expertise required to oversee biotech crops also was addressed in a survey response from a California state government employee. He said California's technical expertise is "fully adequate," but added the following caveat:

> The expertise resides in the University of California; however there is some expertise in government agencies. A few in government agencies have in-depth knowledge, however they are tasked with other responsibilities—their plates are full. Without the time and funding for networking and continuing education, the few who are knowledgeable will soon lose their expertise. The government needs to recognize the need for a biotechnology policy person in such departments as the Food and Agriculture, Pesticide Regulation and Health Services and fund such a position.

States currently receive no federal financial support for their plant protection programs and thus rely solely on their own resources for any biotech oversight. No state was found to have a specific budget line item for plant health-related biotechnology regulatory activities. As seen in California and many other states, regulators often stretch their resources and fill gaps in technical expertise by seeking expert advice through state universities or establishing volunteer advisory committees to provide guidance on biotech regulatory decisions. In addition, recognizing the scarcity of state-appropriated funds from tax revenues, some states are considering permit application fees as a possible source of funds to support the necessary review effort. According to Robin Pruisner, the state entomologist in Iowa:

> In all likelihood, no general fund monies from the state budget will be made available. Permit fees, to be paid by the company requesting the permit will be necessary—and most likely the only source of funding—unless the federal government wants to assist. However, federal monies are year to year, and it's difficult to build a solid program when funding is always in the balance.

Another state considering permit fees is Colorado, according to Jim Miller, Director of Policy and Communications in the Commissioner's Office of the Colorado Department of Agriculture. He noted that the benefits of this revenue source would have to be weighed against the chance it might threaten Colorado's ability to attract new business in the biotech field.[54]

53 Harder 2004.

54 Miller 2004.

States currently receive no federal financial support for their plant protection programs and thus rely solely on their own resources for any biotech oversight.

State Role in Authorizing Field Trials

Oversight of field trials is a central feature of the APHIS regulatory program for biotech crops. Field trials are conducted because they enable the developer of a biotech crop to evaluate the crop's performance, and thus its potential value for farmers, under actual growing conditions. They are often useful as well for regulatory purposes to generate information required to evaluate whether the crop poses a plant pest risk and to determine the conditions under which it can be safely grown.

For most biotech crops developed to date, the APHIS regulatory program has focused on authorizing and overseeing field trials and making decisions based on field trial data about whether a crop is safe for other plants and the environment and can be planted, for commercial purposes or otherwise, without further regulation.[55] Typically, when the field trial data indicate to APHIS that the crop does not threaten other plants, the agency grants the crop nonregulated status, which means it can be grown in the United States without further APHIS oversight. Thus, for most crops subject to regulation only by APHIS (pesticidal crops are also regulated by EPA); the field trial oversight process is the regulatory process. In contrast to EPA's approach to regulating biotech plants that produce pesticides, there is usually no post-commercialization oversight of the crop. An important exception to this approach applies to plants that are genetically modified to produce pharmaceutical substances. According to a statement posted on the agency's website, "APHIS envisions that plants which produce drugs and biologics will always be grown under APHIS permit and will be regulated concurrently by FDA and USDA." [56]

The current state involvement in authorization of field trials is almost entirely derivative of the APHIS program. Only three states (Minnesota, Oklahoma, and Vermont) were found to issue their own authorizations of field trials, and these do so based in whole or in part on the prior authorization of the trial by APHIS.[57] This state of play reflects many factors, including the legal uncertainties and resource constraints outlined above, as well as the preference of many at the state level not to duplicate scientific assessments of potential health and environmental impacts already made by APHIS. Consequently, rather than engage in a second, and possibly duplicative, process for approving field trials, the states can and often do seek to protect their interests with respect to local release of biotech crops through participation in the APHIS authorization process.

---

55 Taylor and Tick 2003, 29–31.

56 Specifically, the agency has stated on its website that "APHIS envisions that plants which produce drugs and biologics will always be grown under APHIS permit and will be regulated concurrently by FDA and USDA." USDA APHIS n.d.(d).

57 Oklahoma exempts the requirement for a state permit if the registrant has received a federal permit.

As noted earlier, APHIS can authorize biotech field trials by the issuance of a permit or through a streamlined notification process. The notification process is available for trials involving familiar crops and traits that are considered to be low-risk. To qualify for authorization through the notification process, a field trial must satisfy certain criteria established by APHIS and be carried out in accordance with certain performance standards that ensure adequate containment and other controls are observed.[58] Currently, up to 90% of biotech field trials, totaling to date about 8,952, have been authorized through the notification process.[59]

Permits are required for field trials on biotech crops that do not meet the notification criteria or are denied authorization by notification. Thus, products that pose potentially greater risks or otherwise require closer oversight, such as ones that produce pharmaceutical or industrial substances, require permits. Given their potential to pose larger risks or be controversial, crops requiring permits naturally tend to be of greater interest to the states, and the state interaction with the BRS permit process is one of the most substantial components of current state biotech regulatory activity.

Permit applications are submitted to BRS by the party legally responsible for satisfying the APHIS regulatory requirements for the biotech crop, which is typically, but not always, the company that developed the crop. As spelled out in the APHIS regulations, the application must contain detailed information on the basis of which APHIS can evaluate whether the crop poses a potential plant pest risk and whether the trial can be conducted under conditions that adequately guard against that risk.[60] This includes information on the biology of the plant that has been modified; the manner in which the plant has been genetically modified (including details on the transformation technique, the transferred gene construct, and its expression products); information relating to the potential plant pest properties of the biotech plant; the plans for the field trial, including location, size, and duration; and measures to contain the crop and dispose of it following the trial. The applicant is required to identify and provide justifications for information in the application that it considers a trade secret or confidential business information (CBI), categories of information that are exempt from public disclosure under the Freedom of Information Act (FOIA). Under its regulations, BRS has 120 days to review and act on the permit application.

During this review period, BRS seeks comment on the application from the state plant health officials in the state in which the proposed trial is to take place. The purpose of seeking state comment is to determine if the state concurs that the trial can be undertaken safely or if the state can identify issues or concerns that should preclude the trial from occurring or justify

58 Taylor and Tick 2003, 226–28; USDA APHIS n.d.(g).

59 Information Systems for Biotechnology 2004(d).

60 7 CFR 340.4(a).

additional limits or conditions. To obtain this comment, BRS sends the state agency a "CBI-deleted" copy of the application, a preliminary APHIS assessment of the application (including the reasons APHIS believes the trial can be conducted safely under the proposed permit conditions), and a form on which the state can indicate its concurrence or nonconcurrence and offer any comments or additional conditions on the permit the state would like APHIS to consider. Withholding CBI from the state is an important and sensitive feature of the permit review process because it can deny state regulators information that is relevant to a scientific review of the crop's plant pest potential. The information considered by applicants to be CBI often includes not only the details of the genetic transformation of the crop, but even the location of the field trial. BRS reviews the applicant's CBI claims and justifications, but generally concurs with them,[61] which means that the version of the permit application provided to the state frequently contains little information beyond that which identifies the company or applicant and the crop that has been modified. APHIS says, however, that it is usually able to provide state regulatory officials with "a description that summarizes the information relevant to safety concerns."[62]

State access to CBI raises difficult legal and practical issues for all parties. The companies that submit the permit applications have a range of business interests that motivate them to protect their CBI from public disclosure. APHIS is constrained legally from allowing public disclosure of trade secrets and CBI, and it encounters legal and practical difficulties in assessing whether the information labeled CBI by the company is in fact legally protected from disclosure and, given the disclosure laws in various states, whether the states would be able legally to protect the information under their own disclosure laws if it were in their custody. The states are generally respectful of CBI concerns, but, if they do not receive the complete package of information in the permit application, it is difficult for them to conduct their own substantive review and provide BRS with meaningful comments. State officials interviewed for this report explain that they are typically able to obtain the information they need directly from the applicant company under conditions that protect the CBI from public disclosure but permit the state to conduct a review and provide BRS with comments.[63] The CBI issue, including the APHIS policy and procedure, is discussed in further detail in the Section IV policy vignette on a pending Hawaii lawsuit challenging that state's withholding of CBI under state disclosure law.

61 Hoffmann 2004. The BRS reviews of CBI claims are not made public, and the rigor of the review is not known by the authors.

62 Bech, 2004.

63 Yergert 2004; Hanks 2004; Pruisner 2004.

Withholding CBI from the state is an important and sensitive feature of the permit review process because it can deny state regulators information that is relevant to a scientific review of the crop's plant pest potential.

Because the entire permit process for a field trial is to be completed in 120 days, the time for review by the state is limited normally to 30 days.[64] Ordinarily the review is conducted internally without a public comment process, though several states report that they consult with experts from local universities. As discussed in Section IV, however, Colorado is developing a public process as part of its review of permits for trials involving pharma crops.

Based on its review of the permit application, a state can concur with BRS in the granting of the permit, concur but propose additional conditions, or object to the permit. Notably, the state's response and comments to BRS are advisory; they are not legally binding on APHIS. However, according to Rebecca Bech, Associate Deputy Administrator of APHIS, BRS has never issued a field trial permit over the objections of a state or without accommodating additional conditions for the trial that may have been recommended by the state to minimize specific state concerns.[65] APHIS issued a total of 1,220 field trial permits during the period 1987–2004.[66]

State Role in Field Trial Inspections and Enforcement

Whether a field trial is authorized by permit or through the notification process, the party receiving the authorization from APHIS is legally required under the PPA to comply with all permit conditions and applicable performance standards throughout the trial. Inspections to ensure compliance are a key component of the APHIS program and appear to be an important potential avenue for collaboration between APHIS and the state plant health agencies.

As a general rule, APHIS/PPQ seeks to inspect a minimum of 10% of the notification trials and all permitted trials at least once, while it may inspect permitted pharmaceutical/industrial trials five or more times per year.[67] Most field trial inspections are initiated by BRS at headquarters, but they are expedited, coordinated, and tracked by the Regional Biotechnologist (RBT). The RBT requests a PPQ field work unit to conduct these inspections and encourages these federal inspectors to conduct additional notification inspections, beyond those initiated by BRS, when time is available.[68] The PPQ State Plant Health Director notifies the state department of agriculture prior to conducting an inspection so that a state inspector can accompany the APHIS inspector if the state so chooses. The extent to which states participate with APHIS in field trial inspections varies widely from state to state and depends on such factors as the state agriculture department's priorities and resources, its statutory mandate, and the number and type of field trials conducted in the state. Of the states featured in this study,

64 Turner 2003.

65 Bech 2004.

66 Information Systems for Biotechnology 2004(e). ISB's statistics are based on data provided to ISB by APHIS.

67 Stoaks 2004.

68 Stoaks 2004.

Hawaii has been the site of more field trials, including both permit and notification trials, than any other state and of the most field trials for crops producing pharmaceuticals.[69] The Hawaii Department of Agriculture routinely inspects field trials with APHIS and also conducts some inspections independent of APHIS.[70]

In interviews, several state regulators expressed interest in accompanying APHIS on more field trial inspections, citing their comparative advantage in terms of knowledge of local conditions and the need for the state to build public confidence by providing local citizens first-hand assurance that the trials are being conducted properly.[71] Some state officials have cited inspections as an area in which collaboration between APHIS and the states could be improved.[72] The states are admittedly constrained, however, by their very limited resources and, in some cases, lack of trained inspectors. According to Associate Deputy Administrator Bech, BRS is developing plans to establish a pilot project to train and certify state officials, which could allow them to conduct inspections of notification trial sites on behalf of APHIS without an APHIS inspector being present.[73] This presumably would advance the joint federal and state interest in conducting credible and more frequent inspections of field trial sites, though, beyond development and presentation of the training modules, APHIS appears at present not to have additional resources to support state-conducted inspections. However, APHIS is planning, in conjunction with the National Association of State Departments of Agriculture, an ongoing dialogue with the states to explore the possibility of expanding cooperation in a number of areas, including inspections.[74]

States are typically not involved in APHIS compliance actions that are taken based on inspections of field trials. Inspection reports are sent to BRS headquarters, and violations of field trial permit conditions or APHIS regulations are either handled by BRS, through corrective guidance to the sponsor of the trial or a written warning, or referred to the APHIS Investigative and Enforcement Services (IES) for possible legal action, depending on the severity of the infraction.[75] IES determines what enforcement action to take and what penalties to pursue. Civil penalties can be as high as $250,000 per violation or $500,000 per adjudication, or twice the gross gain realized or loss caused as a result of any violation.[76] An average of 2% of the field trials from 1990–2001 have resulted in APHIS finding some compliance infraction.[77]

---

69 Information Systems for Biotechnology 2004 (c).

70 Wong 2004.

71 Dickerson 2004.

72 Polansky 2004.

73 Bech 2004.

74 Bech 2004.

75 USDA APHIS n.d.(e).

76 7 USC 7734(b)(1)(A) and (B). USDA APHIS n.d.(i).

77 USDA APHIS n.d.(h).

While states have no real role in APHIS enforcement actions, Minnesota's biotech law gives that state's commissioner of agriculture the authority to take action under state law in the event of a field trial violation. This action can include various investigative efforts to having the crop destroyed.[78] No other state biotech-specific statute provides the same authority.

State Role Regarding the Deregulation of Biotech Crops

Prior to commercialization of a biotech crop, developers typically seek a determination from APHIS of nonregulated status for the plant line in question. Nonregulated status means that the plants will no longer be subject to the requirement for APHIS to authorize activities such as planting in the environment and interstate movement—activities that are all typical of agricultural production. In contrast to the role they play in the field trial permit process, the states are not part of the formal APHIS process that considers requests for nonregulated status.

When the developer of a biotech crop believes it has gathered sufficient data from field trials to demonstrate that the crop will not be a plant pest and can be released safely into the environment, it can petition BRS for nonregulated status.[79] APHIS reviews the petition for completeness and then publishes a notice in the Federal Register seeking public comment. States can and do submit comments to APHIS through this public comment process. If a petition for nonregulated status is granted, the crop is no longer regulated by APHIS and is, as a practical matter, beyond the regulatory reach of the state as well with respect to any plant pest concern. APHIS can bring a deregulated crop back under its regulatory jurisdiction if it can, based on new information, demonstrate that the plant is a plant pest. But APHIS does no monitoring of deregulated crops for this purpose.

Since 1987, 60 petitions for nonregulated status have been granted for crops with traits such as herbicide tolerance (27 petitions) and insect resistance (18), while 26 petitions have been withdrawn, 1 rejected as incomplete, and 1 voided. As of June 2004, 12 petitions for nonregulated status were pending at APHIS.[80]

---

78 Hanks 2004.

79 7 CFR 340.6.

80 Information Systems for Biotechnology 2004.(a).

Pesticidal Plants: EPA and the States

EPA Legal Authority, Organization, and Resources

For plants that have been genetically modified to produce a pesticidal substance,[81] the substance itself is regulated by EPA under the same laws EPA uses to regulate conventional agricultural pesticides, namely the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)[82] and the pesticide tolerance provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA).[83] FIFRA gives EPA broad authority to oversee pesticide field trials—by issuing experimental use permits (EUPs)—and to regulate the commercial manufacture, sale, and use of pesticides—by registering pesticide products for particular uses.

Like APHIS field trial permits, EUPs provide authorization for the conduct of field trials.[84] Under FIFRA, however, an EUP can be issued for a previously unregistered use of a pesticide only for the purpose of collecting the data needed to register the use. If the experimental pesticide contains a chemical or combination of chemicals that has not previously been used in a registered pesticide, EPA can require that the EUP applicant provide data demonstrating that the experimental use will not cause unreasonable adverse effects on the environment. Also, while APHIS regulates field trials regardless of acreage, FIFRA requires an EUP only when the cumulative acreage in the trial exceeds 10 acres.

Registration of a pesticide, which authorizes its commercial use in the environment, requires that the party seeking registration (the registrant) demonstrate that the proposed use will not cause "unreasonable adverse effects on the environment."[85] This includes "any unreasonable risk to man or the environment" and any dietary risk that is inconsistent with the standards under Section 408 of the FFDCA.[86] Under Section 408 of the FFDCA, EPA establishes tolerances (or legal limits) for pesticide residues that occur in food as the result of the authorized use of a pesticide product. The tolerances are based on a determination that there is a "reasonable certainty that no harm will result from aggregated human exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information."[87] Section 408 also authorizes EPA to grant exemptions from the requirement of a tolerance if it concludes that the safety standard can be met without a tolerance in place. Registration of a PIP

---

81 Under the statutory definition of "pesticide," pesticidal functions include "preventing, destroying, repelling, or mitigating any pest." 7 USC 136 (u). "Pest" includes "any insect, rodent, nematode, fungus, weed." 7 USC 136 (t).

82 7 USC 136 et seq.

83 7 USC 321 and 346, as amended by the Food Quality Protection Act, Public 104-170.

84 7 USC 136c (Experimental Use Permits).

85 7 USC 136a(c) (5).

86 7 USC 136a (bb).

87 21 USC 346a (b)(2).

or any food-use pesticide requires that either a tolerance or an exemption be in place. To date, all registered PIPs have been granted tolerance exemptions.

EPA calls the pesticide produced by a genetically modified plant a "plant-incorporated protectant" (PIP). To date, the only significant commercial application of biotechnology to produce a PIP is the genetic modification of corn and cotton to produce the *Bt* toxin, a protein that is toxic to some insects that are plant pests, but not to mammals. Several variants of the *Bt* toxin occur in nature as a product of the bacterium *Bacillus thuringiensis,* and have a long history of use in organic agriculture as a conventionally applied pesticide to control insects. Plants can be genetically modified to produce the *Bt* toxin by transferring the gene responsible for its production from the bacterium to plants. The environmental concern posed by *Bt* crops that has received the most EPA attention is that resistance to the toxin may develop among insects, which would result in a loss of effectiveness over time of both the modified plants and the traditional use of the bacterium in organic agriculture. To address this concern, EPA requires registrants to adopt an Insect Resistance Management (IRM) Plan, which includes contracts with growers whereby the latter agree to perform such activities as including non-*Bt* refuges in their fields and limiting the percentage of the farmer's acreage that can be planted in the *Bt* version of the crop.

As previously alluded to, EPA's policies and regulations governing oversight of PIPs under FIFRA and the FFDCA[88] apply to the transferred *Bt* gene and the pesticidal substance it expresses, which are regulated as pesticides under FIFRA and the FFDCA. But the commercially distributed seeds and plants are not regulated as pesticides. In contrast, seeds containing PIPs for use under experimental use permits (EUPs) and seed increase permits *are* sold and regulated as labeled pesticide products. This dual approach has important consequences for how PIP use restrictions can be enforced and for the overall role of the states in oversight of PIPs.[89]

In the case of conventional pesticides, use restrictions are set forth in the EPA-approved label that accompanies a pesticide product. It is a violation of federal law (and typically state law as well) to use the pesticide other than in accordance with the label. This establishes a direct line of legal accountability between the user of the pesticide, such as a farmer, and the government. Federal and state regulators can inspect the farmer's use of a pesticide and take enforcement action to stop and penalize violations. However, because commercially marketed PIPs do not bear a pesticide label, no FIFRA-enforceable requirements are placed on the farmer or other user to comply with any use restrictions imposed by EPA at the time of registration.

88 U.S. EPA 2001.

89 For background on this issue, see Taylor and Tick 2003 at 32–35 and 44–50.

However, because commercially marketed PIPs do not bear a pesticide label, no FIFRA-enforceable requirements are placed on the farmer or other user to comply with any use restrictions imposed by EPA at the time of registration.

As an alternative to enforcement of PIP planting restrictions through the label, EPA has placed conditions on product registrations that the registrant must satisfy in order to maintain and renew the registration. Registrants are accountable to EPA for their customers' compliance with any use restrictions that are part of these conditions. Registrants are required to enter into "grower agreements" that make farmers contractually obligated to the registrant to comply with the use restrictions, and the registrant must establish as part of its IRM Plan a Compliance Assurance Program (CAP), which includes periodic monitoring and surveys to verify farmer compliance with the use restrictions.

Enforcement of PIP planting restrictions thus comes not through any government compliance or enforcement activity at the point of use, but through private contractual remedies exercised by the registrant. These remedies may include, for example, refusal by the registrant to sell to the noncomplying farmer in future growing seasons. This approach to PIPs removes government inspectors and compliance officials, at both the federal and state level, from the role they normally play in enforcing pesticide use restrictions. From the perspective of the states, the approach clouds their authority and diminishes their willingness to play any role in regulatory oversight of PIPs, as discussed below.

EPA regulates PIPs through both headquarters and regional offices and through formal collaboration with the states. EPA considers and issues EUPs and registrations for PIPs through the Biopesticides and Pollution Prevention Division (BPPD) in the Office of Pesticide Programs (OPP). For pesticides in general, including PIPs, compliance policy and the management of EPA's role in enforcement cases are handled by the Office of Enforcement and Compliance Assurance (OECA). The Agriculture Division, Office of Compliance, manages compliance policy and targeting strategies. The Toxics and Pesticides Enforcement Division, Office of Regulatory Enforcement, is responsible where headquarters' involvement is needed in active enforcement cases. Inspections of places where pesticides are produced, sold, and used are largely conducted by state partner agencies, and sometimes by EPA regional offices.

The total budget for EPA's overall pesticide regulatory program is approximately $80 million.[90] Publicly available EPA budget documents do not disclose the amount devoted to regulation of PIPs. However, in light of EPA's broad responsibility and active programs for regulating conventional pesticides, the amount available to oversee PIPs is presumably a small fraction of the total budget.

---

90 U.S. EPA n.d.(c).

State Authority to Regulate Pesticides in General

In contrast to the PPA, which says through its preemption provision what states cannot do regarding plant health regulation, FIFRA affirmatively authorizes states to regulate pesticides.[91] Moreover, FIFRA authorizes EPA to enter into cooperative agreements with states and provide financial resources to support state pesticide programs.[92] It also provides that states "shall have primary enforcement authority for pesticide use violations," if certain conditions are met.[93] All but two states have primary use enforcement authority over both private applicators (such as farmers) and persons who apply pesticides commercially. The exceptions are Wyoming, which has no enforcement primacy, and Colorado, which has primary enforcement authority for use violations by commercial applicators but not private ones.[94]

One of the conditions for granting a state primary responsibility for the enforcement of pesticide use violations, and obtaining EPA funding for the state pesticide program, is that the state have "adequate pesticide use laws and regulations."[95] For this reason, and presumably for other local reasons as well, most states have pesticide laws that closely mirror FIFRA, including provisions for overseeing experimental use and registering pesticides.[96] States are free under FIFRA to regulate pesticides as long as their regulations are at least as stringent as EPA's (i.e., do not allow any sale or use of a pesticide that is prohibited by FIFRA) and do not conflict with federal labeling and packaging restrictions. This means states have authority to place additional restrictions on the use of a pesticide or register pesticides for additional uses to meet local needs within the state, provided the use has not been previously denied, disapproved or cancelled by EPA.[97] It also provides states with the flexibility to take an independent approach to experimental use regulation.

For example, EPA requires EUPs for field testing of pesticides on over 10 acres of land, whereas California requires a permit (or research authorization (RA) as it is called in California) for most field testing of new pesticides, without regard to acreage.[98] In Hawaii, no experimental permit is required for trials in a laboratory, greenhouse, or field trial of less than one-fourth of an acre, but the state can limit or reduce the requested acreage for an EUP permit if information provided by the registrant is deemed either insufficient to support the proposed acreage or the limitation is necessary

91 7 USC 136v.

92 7 USC 136u.

93 7 USC 136w-1. U.S. EPA n.d.(a).

94 Neylan 2004.

95 7 USC 136w-1 (a)(1).

96 See the state-by-state summaries for the general pesticide regulatory statutes in the 17 states on which this report focuses.

97 7 USC 136v (c).

98 U.S. EPA n.d.(b); California Code of Regulations n.d.(c).

to protect the public.[99] States have authority under FIFRA to monitor and inspect federal EUPs for compliance with the permit conditions. Pesticide laws in the 17 states featured in this report are cited in the state-by-state summaries in Appendix A.

While states have abundant authority to regulate pesticide use within their borders, including the authority to conduct their own risk assessments and impose additional limitations on the experimental or commercial use of a pesticide beyond those imposed by EPA under FIFRA, states generally base their EUP and registration decisions on the EPA's assessments and decisions. Many states do not issue their own experimental permits for trials covered by an EPA-issued EUP. In addition, state registrations are commonly accomplished essentially by filing the EPA registration with the state. Rather than duplicating the EPA assessments, the states generally focus their programs on enforcement of FIFRA use restrictions and on oversight of local concerns such as the compliance of commercial and certified pesticide applicators with regulatory requirements. The prominent exception is California, which has its own very active program for evaluating pesticide risks, issuing research authorizations (the California parallel to the federal EUP), and registering pesticides.[100]

In contrast to the APHIS-state relationship, in which states comment on the federal field trial authorization decisions, states do not review EPA's EUPs in advance or play any role in EPA registration decisions. EPA provides public notification through the Federal Register when an EUP is authorized. Companies receiving an EUP from EPA are required to notify the relevant state agency prior to commencing the field trial to provide information to the state on planting location and other details, which is essential if the state has not required its own EUP.

In sum, as this system of federal-state cooperation is designed legislatively and works in practice for conventional pesticides, states have primary enforcement responsibility under FIFRA, and they focus much of their effort on conducting inspections and other enforcement activities on farms and elsewhere to ensure that pesticides are being used in accordance with the EPA-approved label.

99 Hawaii Department of Agriculture n.d.

100 California Code of Regulations n.d.(c).

In contrast to the APHIS-state relationship, in which states comment on the federal field trial authorization decisions, states do not review EPA's EUPs in advance or play any role in EPA registration decisions.

State Authority and Role in the Regulation of PIPs

Despite the strength and relative clarity of state authority to regulate pesticides in general, and the active enforcement role most states play with respect to conventional chemical pesticides, there is uncertainty and some confusion concerning the authority of the states in regulating PIPs. While there are minor exceptions, the states currently are not involved in regulatory oversight of PIPs.

This situation stems from the EPA position that, while the PIP itself (the *Bt* toxin expressed in the plant) is a pesticide, and must be regulated as such, the seeds and plants that subsequently contain the PIP do not have to be regulated as pesticides.[101] As discussed above, this interpretation means that, at the point in the system where states normally play an active role—that is, in overseeing pesticide use "on the farm"—there is no FIFRA-regulated pesticide use—i.e., no FIFRA-labeled product use—to oversee. The lack of a direct enforcement role for the state under federal law with respect to PIP use restrictions largely eliminates the standard rationale for states issuing their own registrations for PIPs, and most do not. This appears to be the case for practical or priority reasons rather than legal reasons since, under the typical state pesticide law, states could register PIPs on the same basis as EPA does or simply by relying on the EPA registration.

The state of California, with its traditionally more active program for overseeing pesticide field trials and registering pesticides, initially regulated PIPs as it would any pesticide product. However, following EPA's policy statement and proposed rule in 1994 clarifying its position regarding the regulatory status of PIPs and the plants that contain them, California decided to stop regulating PIPs at both the experimental and commercial stages.[102] Minnesota is the one state with a biotech-specific statute that specifically provides for the issuance of both experimental use and commercial registrations for PIPs.[103] Under Minnesota law, the agriculture commissioner has the authority to accept, deny, or register PIPs with conditions. The conditions may include a limited registration period, restrictions on the amount or number of products to be used, monitoring and inspection activities and schedules, reporting requirements, and termination procedures.[104]

The status quo leaves unresolved the state role in inspecting EPA-issued EUPs for PIPs and EPA's expectations of states in this regard. Some government inspection of these sites is presumably desirable to verify compliance with containment procedures and other EUP restrictions. This is because the alternative—a registrant-driven system for ensuring compliance that EPA has established for commercial planting of PIPs—is not applicable.

---

101 Liemandt 2004 and T. Jones 2004.

102 T. Jones 2004.

103 Minnesota Statutes 2003(d).

104 Minnesota Statutes 2003(d).

Moreover, as PIPs are currently regulated by EPA, EUPs are at the stage where EPA considers the requirements for conducting experimental planting and production to be directly enforceable. The main issue is whether state or federal inspectors will conduct the inspections needed to enforce the requirements.

For conventional pesticides, inspection of EUP sites is well-recognized as within the scope of state programs. For PIPs, however, states question whether they have the legal authority to inspect PIP EUP sites when, as is the case under state pesticide laws, their authority to inspect and take enforcement action against EUP violations is tied to the article in use being a pesticide. According to state officials interviewed for this report, EPA has informally used the analogy of "treated article" to explain its position that, while the PIP itself would be regulated as a pesticide, the seeds and plants containing them would not.[105] According to this reasoning, the seeds and plants are articles that bear or contain a pesticide, but are not themselves pesticides. This analogy is confusing because EPA has not formally categorized PIP-producing seeds and plants as treated articles for regulatory purposes, and EPA takes the position that PIP seeds used under EUPs and for seed increase *are* regulated pesticide products.[106]

Based at least in part on uncertainty about their legal authority, most states are not conducting PIP EUP inspections. Texas has conducted a few such inspections simply because EUP inspection is an element of the state's cooperative agreement with EPA. Of the 33 EUPs issued for trials in Texas, seven were for *Bt* crops.[107] Texas is, on the other hand, one of the few states to formalize its position of not registering PIPs, citing its judgment based on experience with approved *Bt* crops that the risks are not significant enough to warrant any state regulation in addition to EPA's oversight.[108]

California may inspect conventional pesticide EUPs and RAs within its borders, but, as a matter of announced policy, does not recognize PIPs as pesticides. It thus does not inspect PIP EUPs at all and does not issue its own RAs for PIPs.[109] Hawaii is another state that has adopted a policy of not regulating PIPs or inspecting PIP EUPs based on uncertainty about its legal authority and absence of direction or guidance from EPA. The PIP EUP inspections that have been conducted in Hawaii were conducted by EPA Region IX inspectors rather than by state pesticide regulators. South Dakota and a few states in the Southeast have reportedly conducted EUP inspections, in the latter case in response to requests from EPA regional officials.[110]

The importance of the EUP inspection issue was highlighted recently by three enforcement cases that resulted from inspections of EUP sites in

---

105 T. Jones 2004; Liemandt 2004; Boesch 2004.

106 Howie 2004.

107 Mitchell 2004. The 33 EUPs in Texas were issued between April 2000 and May 2004.

108 Texas Department of Agriculture n.d.(b).

109 T. Jones 2004.

110 Heisler 2004.

Hawaii conducted by inspectors from EPA's Region IX office in San Francisco. EPA does not currently have in place a formal compliance program for PIP EUPs that addresses such matters as the roles of EPA and the states in inspections or the desired frequency of inspections (EPA's Office of Enforcement and Compliance Assurance is reportedly developing one.[111]) EPA conducted the Hawaii inspections because the EUPs in question were granted in the absence of a tolerance or tolerance exemption covering the possible presence in food of the particular form of the *Bt* protein produced by the experimental corn. In such cases, the EUP requires special care in containment of the crop to prevent outcrossing of the *Bt* gene or physical commingling of the experimental crop with crops intended for food use. The EPA inspectors found various violations of the EUP conditions, which led to EPA enforcement action.[112]

If there is to be a more systematic federal-state program for inspecting EUP sites, the authority and role of the states will need to be clarified. At an EUP workshop convened by EPA on February 10-11, 2004, an EPA speaker from OECA suggested that, from EPA's perspective, the states have adequate authority to inspect PIP EUP sites and can do so under their existing cooperative agreements.[113] As noted earlier, many states question their authority and see a need for further guidance from EPA before taking on inspection of PIP EUPs. The State FIFRA Issues Research and Evaluation Group (SFIREG), a body constituted by the Association of American Pesticide Control Officials (AAPCO) to represent state views to EPA, has expressed concern about this issue, stating in a recent letter that "there has not been a robust dialogue on PIPs oversight and there is confusion over the role and expectations of the SLAs [state lead agencies] in providing oversight on the regulation of PIPs."[114] With respect to the issue of state legal authority to oversee PIP EUPs, the president of AAPCO, Tobi Jones, and the chair of SFIREG, Paul Liemandt, state that:

> "With use [by EPA] of the analogy of 'treated articles' ... as a means of explanation of the regulatory approach, the possible role of SLAs may have been downplayed or ignored. SLAs have no direct oversight on treated articles themselves, and in some instances, may be subject to state laws, which prohibit such a regulatory role."[115]

They say further that "[t]he lack of clarity in SLA role (expected/intended) appears, in part, to be related to the different perspectives of OPP and OECA" with OPP focused on scientific issues related to potential risks and OECA focused on FIFRA enforcement, and that the "lack of direction" from the EPA regional offices "has created another level of confusion regarding the focus of the inspection strategy and intent."

---

111 Heisler 2004.

112 U.S. EPA 2003.

113 U.S. EPA 2004(b).

114 Jones and Liemandt 2004. See also State FIFRA Issues Research and Evaluation Group 2003.

115 Jones and Liemandt 2004.

State Pesticide Regulatory Organizations and Resources

In most states, the regulatory oversight of pesticides is managed through state departments of agriculture. **(See the state-by-state summaries in Appendix A.)** Exceptions to this general rule include California and New York, where the states' environmental protection agency oversees pesticide regulation.

The responsible state organization is deemed the state lead agency (SLA) for purposes of negotiating cooperative agreements with EPA's relevant regional office. Each cooperative agreement is negotiated between the state and EPA based upon a state's needs and interests and EPA's national priorities, which are developed by OPP and OECA with input from the 10 EPA regional offices.[116]

For states with EPA cooperative agreements, the overall state pesticide program is funded with a combination of federal and state funds. The total EPA contribution in FY 2003 was $25 million, which was distributed among the states with cooperative agreements. Funding allocations averaged $538,000 and range from $281,000 for Colorado to $1.3 million for California.[117] The allocations are based on a formula that accounts for state-specific factors, such as population and amount of land in agriculture, among others. EPA and the states negotiate priorities for use of the cooperative agreement funds. Currently, no cooperative agreement includes any aspect of PIP oversight as a priority, and no federal funds are provided for this purpose. States are not precluded, however, from using federal resources in ways other than for the designated priorities in the cooperative agreement, which could include inspection of PIP EUPs.[119]

For the reasons discussed earlier, primarily uncertainty about legal authority and EPA's expectations, the states have allocated little or none of their own state resources to PIP oversight, beyond the occasional inspections of PIP EUPs that a few states have conducted. As the chair of SFIREG has made clear, the policy issue of whether and on what legal basis states should inspect PIP EUPs is an important one for state pesticide regulators. Until it is resolved, there is unlikely to be any significant funding of PIP-related activities by state governments.

The states' relationship with EPA contrasts in interesting ways with their relationship with APHIS. APHIS does not fund state plant health programs and operates under a law that limits the regulatory authority of the states.

---

116 EPA's guidance document lists the priority areas of: worker safety, e-commerce, antimicrobial testing program, label enforceability, and unregistered sources/product integrity.

117 American Association of Pesticide Control Officials 2003.

118 U.S. EPA 2004(a).

119 Neylan 2004.

However, APHIS is actively collaborating with the states on the oversight of biotech field trials. EPA, on the other hand, funds state pesticide programs and operates under a law that expressly empowers states to regulate pesticides and enforce federal pesticide laws. Yet, on PIPs, EPA has made decisions that eliminate the state enforcement role for commercialized PIPs and, in the view of some state officials, EPA has not been very collaborative with the states on such matters as PIP EUP oversight.

Food Safety: FDA and the States

There is no regular state activity addressing the safety of biotech crops and foods. The current and potential state role has been limited to collaborating with the federal agencies in cases like StarLink and ProdiGene, in which state personnel and resources were called upon to assist in managing a food-related compliance problem.

FDA Authority, Organization, and Resources

FDA uses the general food safety and food additive authorities in the Federal Food, Drug, and Cosmetic Act of 1938 (FFDCA), as amended, to regulate the safety of biotech foods. Under these laws, FDA operates a voluntary premarket notification and consultation system that provides biotech companies an opportunity to demonstrate that foods produced from their biotech crop are as safe as their traditional counterparts.[120] If the biotech food contains a protein or other new substance that is not "generally recognized as safe (or GRAS)," the food must go through a formal FDA premarket approval process in which the sponsor must prove scientifically that the new substance in the food is safe.

FDA's oversight of biotech foods is managed through the Division of Biotechnology and GRAS Notice Review, Office of Food Additive Safety, in FDA's Center for Food Safety and Applied Nutrition, which coordinates reviews with FDA's Center for Veterinary Medicine. Oversight of biotechnology is only one facet of what this office does. Other duties include man-

120 See Taylor and Tick 2003, 36–37; Pew Initiative on Food and Biotechnology 2004(b).

The states' relationship with EPA contrasts in interesting ways with their relationship with APHIS. APHIS does not fund state plant health programs and operates under a law that limits the regulatory authority of the states, but APHIS is actively collaborating with the states on the oversight of biotech field trials. EPA, on the other hand, funds state pesticide programs and operates under a law that expressly empowers states to regulate pesticides and enforce federal pesticide laws.

aging FDA's oversight of chemical food additives. Publicly available FDA budget documents do not provide a breakdown of resources devoted to oversight of biotech foods. In the period 2000–2003, FDA completed nine premarket consultations with developers of biotech food products and has completed 57 such consultations in total.[121] To date, other than the Kanamycin resistance marker gene in the first biotech food to be commercialized, no biotech foods have gone through the formal premarket approval process, and FDA has not established any postmarket oversight or compliance program specifically for biotech foods. FDA does not consider the biotech foods on the market today to pose a food safety risk or any consumer protection concern different from any other foods on the market today that would justify such a program, especially when considered in the context of FDA's other food safety priorities.[122]

In addition to its premarket safety review functions, FDA, acting through its Office of Regulatory Affairs and a network of field offices, is responsible for enforcing EPA's pesticide tolerances, which it does for conventional pesticides through a carefully planned sampling and testing program covering both domestic and imported foods.[123] To date, however, EPA has not issued a tolerance for the commercialized *Bt* crops, relying instead on granting exemptions from the requirement of a tolerance. This means that there is no postmarket enforcement role for FDA with respect to the pesticidal components of the registered *Bt* crops, FDA would have an enforcement role if in the future EPA issues a tolerance rather than a tolerance exemption for the presence of a PIP in food.[124] FDA would also be responsible for taking enforcement action against the presence of an unregistered PIP in the food supply.

To date, FDA's primary role with respect to postmarket oversight of biotech foods has been to respond to incidents such as StarLink, which involved the presence in human food of a PIP registered only for animal feed use, and ProdiGene, which involved the unintended, adventitious, and unauthorized presence of biotech-derived pharmaceutical material in the food supply. FDA's role in such cases is to investigate the possibility of unlawful or potentially harmful contamination of the food supply and take appropriate enforcement action, often in conjunction with other federal and state agencies, which would include the seizure of the food containing the unauthorized material.[125] For reasons of technical feasibility and public health priority, however, FDA does not have a planned program of compliance-monitoring to detect such situations or, for example, to monitor imports to be sure any biotech food from abroad satisfies U.S. food safety requirements.[126]

---

121 U.S. FDA 2004.

122 For further discussion of these points, see Taylor and Tick 2003, 37–38 and 51–58.

123 U.S. FDA CFSAN 1993–2001.

124 See Taylor and Tick 2003, 51–58.

125 See Taylor and Tick 2003, 88–105.

126 See Taylor and Tick 2003, 51–58.

State Authority, Organization, and Resources

Most states have food and drug regulatory statutes that, at least in their general food safety provisions, are similar to the FFDCA. See the state-by-state summaries in Appendix A for citations to these laws in the 17 states examined in this report. These laws provide for the removal of any food or food product from the market if found to be misbranded or adulterated, but they do not generally authorize state-based, premarket safety review of new food products, ingredients, or technologies. Traditionally, the states have not gotten involved in such safety reviews, preferring to leave this to FDA. This preference holds for biotech foods. As discussed in Section II, the states and most of their stakeholders prefer to rely on effective regulation at the federal level to ensure the safety of biotech foods. Research conducted for this report did not uncover any state program that sought to engage in the premarket safety review of biotech foods.

At the postmarket stage, however, when a significant incidence of possible contamination of the food supply has occurred, FDA routinely coordinates its response with state governments, which are often able to contribute personnel and testing facilities in crisis management situations or to help manage major enforcement cases. There are, however, no state biotech-specific laws governing enforcement of pesticide tolerances for biotech crops or the general food safety aspects of biotech foods, and no evidence states are developing programs to regulate the food safety aspects of biotech crops and foods. The closest related activity found at the state level is Oregon's Export Service Center, which provides analysis of biotech products to certify that the products meet foreign market requirements, but for export products only.[127]

Stakeholder Perspectives on State Biotech Oversight Activities

The survey of stakeholders conducted for this report included questions about the overall preparedness of the states to oversee biotech crops and foods and the adequacy of particular state regulatory tools and mechanisms, including statutory authority, resources, technical expertise, institutional organization and coordination at the state level, and state-federal collaboration. The results of this nonscientific survey should be read with caution. As noted earlier, the respondents are self-selected from a pool of interested experts and stakeholders developed by the authors and are the ones who had enough interest in the subject and enough motivation to

127 Oregon Department of Agriculture n.d.

respond. They are not representative of society as a whole and are not necessarily representative of the universe of biotech experts and stakeholders. They are close to the subject, likely to be well-informed, and tend to have sharper views on the issues than the average observer. For these reasons, the survey results have been interesting and useful. It is important to note also that, despite the diversity of the respondents' institutional affiliations, the results show striking consistency in several respects. The added narrative comments provided by some of the respondents illustrate the wide range of perspectives these stakeholders have on state oversight of biotech crops and foods.

In general, a majority of respondents from both inside and outside state government question the adequacy of state preparedness and tools for overseeing biotech crops and foods. With respect to the overall preparedness of the states to provide needed oversight of biotech crops and foods, just over half of respondents (54%) said the states are "poorly prepared" and an additional 18% said they are "somewhat unprepared." Only one in 20 respondents said the states are "well prepared," while one in five said the states are "somewhat prepared" to provide needed oversight.

As discussed in Section II, the majority of respondents to the survey expect biotech crops and foods to be "very positive" or "somewhat positive" for farmers, the food industry, and consumers. It is interesting to note that, even among those who are most optimistic about the potential benefits of biotechnology, expecting its impact to be "very positive," most (56%) see the states as "somewhat unprepared" or "poorly prepared."

The sense in a number of the narrative comments was that the states are unprepared at least in part because they have yet to give the subject much attention or are uncertain about their regulatory role in relation to the federal government. According to one respondent: "States by and large have left the biotech regulatory area up to the feds mostly because they seem unsure of what they would actually be regulating." Others emphasized the lack of statutory authority to, among other things, access CBI, as well as the states' lack of expertise: "I think that across the board, very few state agencies have the personnel or expertise to really review these applications. Also, they are not given the information they need to even begin a proper review of this technology."

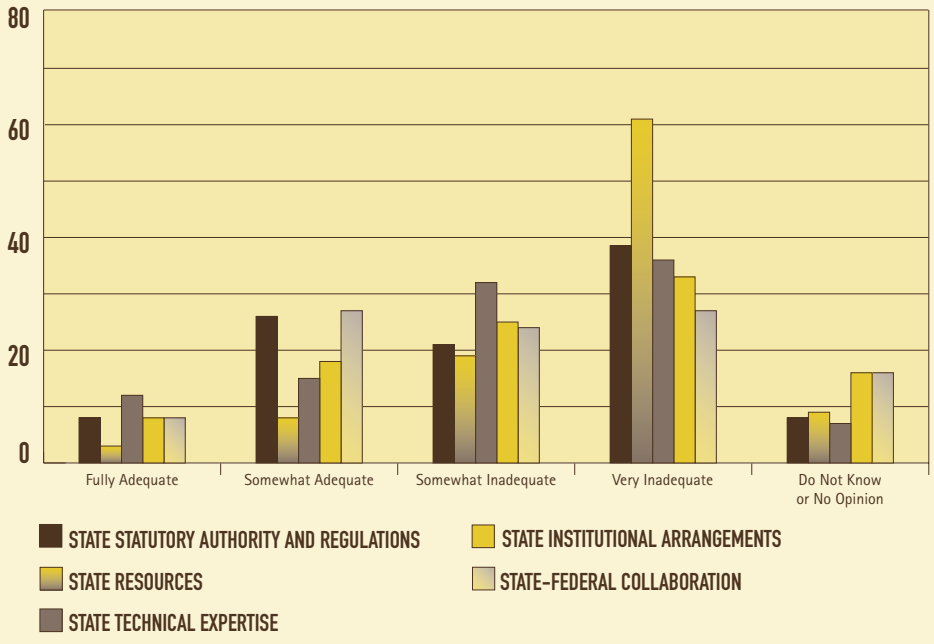
When asked on which topics the states seemed particularly well-prepared, respondents predictably emphasized enforcement of field trial restrictions based on the states' experience in that area and their local knowledge: "States have a much better ability than the feds to inspect because they have more relationships with the impacted community."

In general, a majority of respondents from both inside and outside state government question the adequacy of state preparedness and tools for overseeing biotech crops and foods.

Respondents were asked to comment on the adequacy of specific tools required for state oversight of biotech crops and foods, including statutory authority, resources, technical expertise, organization and coordination among state agencies, and state-federal collaboration. As reported in Chart 4, below, significant proportions of the respondents said the tools available to state governments in all these categories were "very inadequate" or "somewhat inadequate." The resources currently devoted to needed oversight were considered very or somewhat inadequate by more of the respondents (80%) than the other tools, with most of these saying resources are "very inadequate." This is not surprising in light of the extremely limited resources states are currently devoting to oversight of biotech crops and foods, as reported in the state-by-state summaries in Appendix A of this report.

In narrative comments, when asked how resources could be improved, some respondents cited the severe fiscal restraints state governments are facing across the country, and many suggested that state regulatory programs for biotech be funded by user fees charged to the regulated industry, including farmers and biotech companies, suggesting that this might be the only realistically available source of funding. Others suggested the possibility of federal funding to assist the states in overseeing biotechnology. There also

CHART 4: RESPONDENTS' PERSPECTIVES ON THE ADEQUACY OF STATE REGULATORY TOOLS AND MECHANISMS



were those who questioned the need for enhancing resources at the state level, including one who said, "I don't believe that precious state resources should be squandered on biotech regulation when there are real environmental and safety issues to contend with."

After resources, the technical expertise available to the states to provide needed oversight was considered inadequate by the largest proportion of respondents, with two-thirds considering the available expertise to be "very inadequate" or "somewhat inadequate." The lack of expertise within state agencies is tied to the lack of resources for hiring and training and the fact that biotech oversight responsibilities are commonly taken up as a side duty by state plant health and pesticide regulatory officials. The narrative comments note that significant expertise exists in many of the state universities and can be tapped by the states.

Over half of the survey respondents consider state statutory authority and regulations inadequate to some degree, with nearly two-fifths describing them as "very inadequate" and one-fifth considering them "somewhat inadequate." A quarter of the respondents consider state statutory authority and regulations "somewhat adequate," while only one in 12 find them "fully adequate." The narrative comments reveal that the perspectives underlying these figures are quite diverse. Some who consider the authority inadequate note the lack of biotech-specific regulatory statutes to address health and environmental issues, while others say the states should have authority to address the economic impact of biotech crops. Some felt that additional state authority is needed to fill gaps in federal oversight, while one said "I don't think that states should be involved in this area" and another said "it would be a huge mistake to have a patchwork of differing state laws and regulations, given the national nature of much of our food production."

Coordination at the state level and state-federal collaboration fared somewhat better in the eyes of the survey respondents than other regulatory tools and mechanisms, though half or more found the current situation somewhat inadequate or very inadequate on these points. In comments, some respondents spoke favorably of the current situation regarding state-federal collaboration, one saying that "collaboration with USDA BRS has been very good to date with one exception," which was access to CBI. One respondent said the state-federal relationship "is good and getting better," while another said "USDA and FDA work well with the state departments of agriculture; [but] the relationship with departments of health and environment is non-existent." Other respondents were more critical. One noted that state departments of agriculture, environment, and health "rarely work together," and another suggested that lack of interagency coordination was

The lack of expertise within state agencies is tied to the lack of resources for hiring and training and the fact that biotech oversight responsibilities are commonly taken up as a side duty by state plant health and pesticide regulatory officials.

a problem at both levels: "As with EPA-USDA, at the state level, there is minimal experience in joint oversight between state programs that implement APHIS and FIFRA programs. In some states, like California, these programs are in different state agencies altogether."

A number of respondents expressed criticism of the role of the federal government in relation to the states based on their belief that the federal agencies are too closely aligned with the interests of the biotech industry: "First, we must get the federal government to conduct adequate oversight. Then the federal government must tell the states the reality of the hazards of biotech crops and foods. Right now the federal government is promoting these products, not regulating them."

Biotech Interests and Activities in the 17 States

The overview of state biotech oversight activities provided so far in this section depicts both the commonality of issues arising across the country and the diversity of interests and perspectives among stakeholders at the state level. A collection of detailed information on biotech interests and activities in each of the 17 states is available in the form of state-by-state summaries in Appendix A.

Each summary provides a snapshot of agriculture in the state and information on the level of field trial and, where germane, commercial activity involving biotech crops. The summaries identify factors that may contribute to each state's interest in agricultural biotechnology and key issues that have arisen in the state, and they summarize each state's biotech-related regulatory and legislative activity. Finally, the summaries identify the state statutes and agencies that are currently, or could potentially, be applied to regulatory oversight of biotech crops and foods; and, when the information was available, they note the resources available for oversight of biotech crops and foods in the state. These summaries are recommended for readers with an interest in a particular state's biotech activity or who seek more details on how state-level activities compare across the country.

The summaries document how much the nature and level of biotech activity varies among the states, even among the 17 we selected based on indicia of relatively high interest in biotechnology. For example, based on a compilation of data current through May 4, 2004, three states lead the way in the number of field trials for which notifications or permits have been submitted to APHIS, but for quite distinct reasons. **(See Maps 6 & 7 of Appendix A)** The leader is Hawaii, with 1,606 notifications and 102 permits, which reflects Hawaii's advantages as a site for field trials due to its year-

round growing season and geographic isolation, rather than any significant level of commercial planting of biotech crops. Illinois and Iowa are second and third, with Illinois having 1,491 notifications and 148 permits and Iowa having 1,162 notifications and 46 permits. This reflects the fact that these states are centers for commercial planting of biotech corn and soybeans.

At the other end of the spectrum, Vermont, a state with significant public and legislative interest in biotechnology, much of it skeptical, has no field trial activity. No notifications for Vermont field trials have been submitted to APHIS; only one permit application was submitted, but no permit was issued. The next lowest number of notifications and permits is for Oklahoma, with 81 and nine, respectively. Ten of the 17 states (including Vermont and Oklahoma) have been proposed as sites in 300 or fewer field trial notifications and 67 or fewer permit applications.

Hawaii, Iowa, and California are cited in significantly more pharma crop permit applications (a total of 33) than any of the other states examined for this report, with 15, 9, and 9 pharma crop permit applications respectively. The remaining 14 states combined have been the proposed site for only 13 pharma crop trials. Hawaii, Iowa, and California appear to lead in this category for different reasons. Hawaii is a favored site for all field trials; Iowa wants its farmers to be able to commercialize pharma and industrial varieties; and California has a large and diverse agricultural economy and favorable growing conditions that are helpful to companies during crop development.

In addition to capturing quantitative information on each state's agricultural and biotech activities, the summaries in Appendix A help document one of the central observations of this report: the nature of any state's regulatory and legislative activity regarding biotech crops and foods reflects primarily the nature and interests of agriculture in the state. As indicated in Table 1 (Biotech-Specific Regulatory Statutes), only six of the 17 states have adopted biotech-specific regulatory statutes, while a large majority have adopted measures to foster development of biotechnology in the state, based on the technology's anticipated benefits to agriculture and the state economy as a whole.

Quite predictably, just as agricultural strengths and interests vary among the states, state responses to biotechnology vary. Iowa is one of the top five producers of corn and soybeans among the states, with 45% of its corn acres and 84% of its soybean acres planted with biotech varieties. Support for biotechnology is strong in Iowa; it is seen and actively supported by state leaders as a key to the future success of Iowa's agricultural economy. In Maine and Vermont, on the other hand, agriculture has little dependence on the major row crops that have been the focus of the current generation of

agricultural biotechnology applications. In those states, agriculture is characterized by smaller operations, including dairy and organic produce farmers, some of whom feel economically threatened by biotechnology, resulting in a more guarded public and legislative response. Vermont, for instance, has been a focal point of the debate over whether biotech foods should be labeled as such, presumably as a way to foster choice among consumers who might prefer to avoid biotech foods.

In states where biotechnology is seen as a beneficial tool for agricultural producers, concerns about market acceptance of the biotech crop or the impact of biotech varieties on the ability to export conventional varieties have driven the state's response. Such concerns have led North Dakota to consider a moratorium on planting of biotech wheat and California to reject the Rice Commission's recommendation for expedited approval for commercial planting of a pharma rice variety. Similarly, North Carolina has taken the lead in devising containment procedures for biotech tobacco plants that produce pharmaceutical substances. The state hopes this approach will both benefit North Carolina farmers who might seek to use such applications of biotechnology and protect growers of conventional tobacco, whose markets might be jeopardized if their crops were contaminated with a pharma variety.

For further information on biotech activities in particular states, see the summaries in Appendix A.

Conclusion

This section, coupled with the state-by-state summaries in Appendix A, provides a broad base of information on the frameworks that states employ, in conjunction with federal agencies, to oversee and regulate biotech crops and foods. It describes some of the challenges states have experienced in their effort to address the concerns of their constituents, be they related to food safety, environmental safety, or securing agricultural markets. A number of common issues have been identified by a diverse group of stakeholders, such as issues regarding state resources and statutory authority and how to both capture the economic benefits of biotechnology and protect the overall economic interests of a state's agricultural economy.

A number of states have taken or are considering taking steps to resolve some of the issues related to biotech oversight, in keeping with their local interests. It is possible that these efforts could help inform and be useful to other state governments, as well as interested stakeholders nationwide. The following section of the report presents six vignettes, or illustrative examples, of such efforts.

IV. VIGNETTES ON MAJOR ISSUES

THIS SECTION OF THE REPORT DRAWS ON experiences around the country to illustrate how states are addressing some of the major issues concerning state oversight of biotech crops and foods. A common theme among the six vignettes presented in this section is the effort of states, and biotech stakeholders at the state level, to act in furtherance or protection of particular state or local interests that they see being affected by biotech crops and foods.

Each vignette speaks to one or more of the issues that states and stakeholders have suggested are challenges to effective oversight of biotech crops and their adoption. For example, pharma crops have presented a number of challenges to state agricultural interests. These include both a lack of clear legal authority for states to regulate field trials and the lack of a formalized role for public input within the federal field trial permitting process (as illustrated by Colorado's attempt to instigate its own public process). In addition, it could be argued that state regulators and the public have insufficient access to CBI data in field trial permit applications (as exemplified by the Hawaiian vignette). There is also the issue of balancing efforts to facilitate the market opportunities associated with pharma and other new biotech crops, while preserving the identity of conventional crops (currently at issue in North Carolina). In addition, pharma crops illustrate the challenge of finding adequate expertise to help evaluate the potential risks and benefits of such technologies and the potential for conventional crops in a state to suffer decreased market access as a consequence of planting biotech crops (as addressed in the vignette on the role of the California Rice Commission). Similarly, the planting of any genetically modified crop—not just pharma crops—has the potential to affect negatively the market acceptance of other crops, conventional or organic, and some states have considered or taken steps to ensure their agricultural economies are not adversely impacted by the introduction of biotech crops. The vignette describing the reactions of North Dakota and other states to Roundup Ready wheat illustrates these challenges. A vignette on biotech-specific regulatory state statutes further illustrates the point made in Colorado's pharma crop story regarding the ambiguity of the legal authority of the states to regulate agricultural biotechnology.

The history and issues underlying each story are complex and lend themselves to detailed analyses that are beyond the scope of this report. The intent of the vignettes in this section is to capture enough background in each instance so that the potential implications of one state's experience for other states can be seen. The first vignette describes the evolving role of Colorado in the permitting of field trials involving pharma crops.

The State Role in Permitting of Pharmaceutical and Industrial Crops: Colorado's Development of a Public Process

The Issue in Brief

The genetic modification of crops to produce pharmaceutical substances ("pharma crops") and materials that have industrial uses ("industrial crops") presents both an opportunity and a challenge for state governments. These are potentially high-value applications of biotechnology that many believe can generate rich new opportunities for economic growth in regions currently dependent on the use of agricultural land to produce conventional crops and bulk commodities. On the other hand, while this application presents potential economic opportunity, the production of nonfood materials in crops also presents a different and more complicated and contentious set of issues from both a scientific and public perception perspective. These crops may be created to produce novel proteins or other substances that could pose a risk to human or animal health. There are concerns regarding their environmental safety as well. In addition, as the ProdiGene experience taught, even in the absence of any real safety concern, these crops can seriously compromise public perception and public acceptance—and prove disruptive to other agricultural interests—if they enter the food supply, whether through outcrossing or accidental commingling.[128]

This application of agricultural biotechnology is still in its infancy. To date, only 84 pharma and 17 industrial crop field trials have been authorized; no pharma crops and few industrial ones have been commercialized.[129] In 2002, 34 sites covering 130 acres of pharma crops were being field tested in the entire United States. In 2003, 16 sites were planted encompassing 75 acres,[130] although APHIS estimates the numbers will "increase significantly" over the next few years.[131] While pharma and industrial crops have yet to be significantly commercialized, states have already begun grappling with the unique challenges these crops pose as they strive to develop oversight approaches that will protect and advance the broad range of affected state interests.

Colorado, which has gained increasing attention from biotech companies as a promising site for pharma crop field tests, has been at the forefront of the issue. In response to public concerns about a particular proposed pharma field trial, the Colorado Department of Agriculture (CDA) has drafted procedures for the evaluation of all pharma and industrial crop field test permit applications involving Colorado, including, as main features, the creation of a technical advisory panel of third-party scientific experts and opportunities for public involvement in the process.[132] The Colorado experience with a proposed pharma field trial and the state's proposed procedures,

---

128 Petersen and Arntzen 2004.

129 Information Systems for Biotechnology 2004(f).

130 Clapp 2004.

131 USDA APHIS 2003(a).

132 Yergert 2004.

which are currently undergoing public comment and revision, illustrate what is at stake and one possible approach to striking a workable balance in state regulatory oversight of pharma and industrial crops.

Colorado and Other Stakeholder Interests

On May 27, 2003, Meristem Therapeutics, a French biotech company, submitted to APHIS the first application to field test a pharma crop in Colorado. The pharma crop in question was a corn variety that had been bioengineered to produce gastric lipase, [133] an enzyme used in the treatment of cystic fibrosis.[134] This signaled the beginning of what Mitchell Yergert, Plant and Insect Section Chief of CDA's Division of Plant Industry, which oversees the regulation of biotech crops in Colorado, anticipates could be significant interest on the part of both biotech companies and agricultural producers in field testing pharma and industrial crops in Colorado.[135] While Colorado views pharma crops as an opportunity to improve the state's competitive advantage and market share in the developing biotech sector,[136] there also are concerns about protecting the state's organic and conventional crops from contamination and maintaining a safe and marketable food supply.

Colorado's current governor, Bill Owens, has focused on raising the state's reputation in the biotechnology world. Colorado has worked to become a leader in technology generally as evidenced by the creation of the Governor's Office of Innovation and Technology in 1999 and of a cabinet-level technology position, something only one other state has done.[137] In 2001, along with the Governor's Commission on Science and Technology,[138] Governor Owens created the Colorado Technology Alliance (CTA).[139] The CTA, a nonprofit initiative funded by private industry donations, formed a Biotechnology Council consisting of government officials, university researchers, and biotech industry representatives[140] to further the governor's goal. The CTA commissioned the council to study how to develop an available workforce, create a supportive environment, and identify potential research topic areas that would help attract companies working on a range of biotech issues.[141] The resulting action agenda, published in April 2003, includes suggestions to explore opportunities to establish pharma crop production in Colorado and is supported by the Colorado Economic Development Commission, the Colorado Bioscience Association, and the Colorado Institute of Technology, among others.[142]

---

133 Information Systems for Biotechnology 2004(f).

134 Yergert 2004.

135 Yergert 2004.

136 Colorado Office of Innovation and Technology. n.d.

137 Colorado Office of Innovation and Technology 2003.

138 Colorado Office of Innovation and Technology 2003.

139 **Denver Business Journal* 2002.

140 Lofholm 2003.

141 *Denver Business Journal* 2002.

142 Colorado Office of Innovation and Technology 2003.

The Colorado Corn Growers Association, which expressed enthusiastic support for Meristem's efforts to bring biotech corn into the state, also hopes that Colorado can gain preeminence in the area of agricultural biotech.[143] In addition to the state's interest in promoting economic development, CDA's Jim Miller argues that, if Colorado does not accept and even embrace biotech crops, companies can easily take their products to nearby states, such as Nebraska, which could leave Colorado facing the same potential adverse consequences and regulatory issues (due, for example, to pollen drift from biotech corn), but without the economic return.[144]

Along with the potential for economic gain, however, is the potential for economic or social loss due to a loss of commodity markets overseas, a loss of organic certification for some producers, or a loss of confidence in the food supply that might result from cross-contamination between pharma and industrial crops and food crops. The Rocky Mountain Farmers Union and the Colorado Organic Growers have both voiced concerns about the potential contamination of organic and conventional crops.[145,146]

Some opponents of biotechnology and pharma crops are worried about genetic material contaminating soils, water, and microorganisms in fields as well as other crops, possibly presenting long-term risks.[147] Others point to potential risks to wildlife grazing on the biotech crop or from insects transferring pollen among plants.[148] The Western Colorado Congress, a grassroots alliance that works to "empower people to protect our communities and environment,"[149] has called for a moratorium on the planting of pharma crops until an open and public process can be followed to determine if each crop that might be field tested in Colorado is safe.[150] The organization points to the oft-cited 2004 National Research Council (NRC) report "Biological Containment of Genetically Engineered Organisms" to support their claims.[151] The NRC report advises that "[a]lternative nonfood host organisms should be sought for genes that code for transgenic products that need to be kept out of the food supply."[152] Additionally, 36 farmer and environmental groups sent a letter to Governor Owens asking for a moratorium on Meristem's application. They cited concerns about agricultural product integrity, food safety, and worker safety.[153] In response to the Meristem application, there have also been protests at the state capitol, op-ed pieces

143 Porter 2003.

144 Miller 2004.

145 Rocky Mountain Farmers Union 2003.

146 Porter 2003.

147 Porter 2003.

148 Brand 2004.

149 Western Colorado Congress n.d.

150 Auge 2003(b).

151 Patterson 2004(a).

152 National Research Council 2004, 6.

153 Martinez 2003.

in the newspapers, and letters to state officials by like-minded stakeholders, including not only environmental organizations, but also nutritionists, family farmers, and citizens.[154]

In addition to groups within Colorado, some international and national food corporations have voiced concerns about pharma crops and have opposed the use of food crops for pharmaceutical and industrial purposes due to food safety concerns. These corporations include Frito-Lay, Campbell Soup, and Kraft Foods,[155] as well as the umbrella trade groups, the Grocery Manufacturers of America (GMA) and the National Food Processors Association (NFPA).[156] GMA and NFPA are both urging that USDA implement stronger regulations and effective controls and procedures for pharma and industrial crops in order to prevent contamination of the food supply.[157,158] GMA points to the 2002 ProdiGene incident, in which soybeans meant for human consumption were contaminated with a biotech corn variety that had been modified to produce an experimental vaccine for pigs.[159] The industry has proposed that FDA undertake a food safety review of pharma and industrial crops prior to authorization of field trials to decide in advance what actions, if any, should be taken if the substances or compounds that the crops produce are found in the food supply. The Biotechnology Industry Organization (BIO) is reportedly considering supporting this recommendation as well.[160]

APHIS Tightens Standards

On March 6, 2003, APHIS announced new, more strict requirements—which took effect in the 2003 growing season—for field trials involving pharma and industrial crops.[161,162] These include more frequent APHIS inspections of field trial sites. APHIS now requires as many as five inspections per site at critical times during the growing season and another two for assessing volunteer plants in the following two years compared to the common practice for nonpharma biotech crops of a single inspection of one test site per permit.[163] APHIS also required contract growers and others involved with the development and production of pharma and industrial crops to have annual training on compliance with permit conditions. The agency required dedicated equipment for planting, harvesting, and storing pharma and industrial crops, and prescribed detailed confinement measures. It also

154 Byrne 2004(b).

155 Carman 2003.

156 Grocery Manufacturers of America 2002(a).

157 Grocery Manufacturers of America 2003.

158 National Food Processors Association 2003.

159 Grocery Manufacturers of America 2002(b). See also Cassidy and Powell 2002.

160 Clapp 2004.

161 USDA 2003.

162 Smith 2004

163 Stoaks 2004.

prohibited the growing of conventional corn within one mile of an open-pollinated pharma corn field test.[164] In addition to these new requirements for the 2003 season, APHIS issued an interim rule in August 2003, requiring that field trials for industrial crops be authorized only by permit rather than notification, [165] a procedure also followed for pharma crops.[166] In January 2004, APHIS published a notice of intent to prepare an environmental impact statement on revisions it is considering in its regulations, including possible new measures for pharma and industrial crops.[167]

Toward a New Public Process in Colorado

Colorado Encounters Meristem and the Pharma Phenomenon

Colorado has no statutorily-created permit or review process for biotech crops, including pharma and industrial crops, but has participated in the APHIS permit review process through the informal consultation process outlined in Section III. The consultation process between the states and APHIS does not authorize Colorado to block a pharma field trial, but the APHIS rules give the state 30 days to review the application,[168] and APHIS has assured Colorado that the federal agency would work with the state to resolve any concerns it may have.[169]

In response to increasing industry interest in Colorado as a site for field tests of pharma crops, CDA formed in early 2003 a three-person technical advisory panel of plant science and microbiology experts from Colorado State University and the University of Colorado at Boulder. On the first day the panel met in May 2003, the Meristem permit application, along with APHIS' preliminary assessment concurring with the issuance of the permit, was received by CDA.[170] Due to time limitations, and lacking an established process for the review of pharma field trial permit applications, CDA requested that the panel review the situation at that first meeting. To supplement its own assessment of the field trial application, the panel interviewed Meristem employees and the farmers who were to be contracted with Meristem to grow the corn.[171] Based on the panel's review and findings, CDA wrote a response to APHIS concurring with APHIS' proposed issuance of the permit provided APHIS included three additional conditions: (1) that APHIS inspect the site five times at specified stages during the year the corn is planted and twice during the following year at times when volunteer corn plants would be emerging, (2) that representatives from CDA accompany APHIS inspectors during each inspection, and (3) that CDA be

164 USDA APHIS 2003(a), 11338.

165 USDA APHIS 2003(b).

166 USDA APHIS n.d.(c).

167 USDA APHIS 2004.

168 7 CFR 340.4 (b).

169 Yergert 2003(a).

170 Auge 2003(a).

171 Byrne 2004(b).

allowed access to inspect the test plot whenever it deems necessary, provided it inform Meristem prior to the inspection.[172] APHIS agreed to these conditions and issued a one-year permit on June 5, 2003.[173] However, because this was after the optimal planting dates for corn, Meristem decided not to plant in 2003 and to consider spring 2004 as an option.[174]

The ad hoc review of the Meristem application generated public comments and debate about the procedures Colorado followed in that case and highlighted the potential need for a more well-defined process for CDA review of the field trial applications and APHIS assessments. One issue raised by some environmental organizations, including the Western Colorado Congress, concerned the composition of the expert panel. Some claimed that the members of the technical advisory panel may not have brought a balance of perspectives and may all have been pro-biotechnology.[175] Other issues highlighted by the Meristem experience included the quality and quantity of the data the state received, in light of the withholding by APHIS of CBI, including information on the acreage and specific location of the test site beyond county level, as well as the technology and gene construct used to produce the crop. Questions also arose over how the state or public could gain access to more information and whether the applicant had adequately described containment and other measures to address potential environmental impacts. Meristem cooperated with the state by providing additional information beyond what APHIS had provided, but some stakeholders expressed concern that all future permit applicants may not be as forthcoming.[176]

CDA Drafts New Pharma Crop Review Procedures

With these and other issues in mind, CDA drafted in the fall of 2003 its "Procedures for Evaluating Experimental Biotechnology Permits for Plant-Made Industrial and Pharmaceutical Products in Colorado" and asked for public comment.[177] In so doing, CDA stressed that it "does not have the resources, nor does it believe it to be necessary, to duplicate the review conducted by BRS," but that its role was to determine "whether there may be conditions unique to Colorado or the site that BRS did not take into

172 Yergert 2003(b).

173 Information Systems for Biotechnology 2004(f).

174 Byrne 2004(b).

175 Yergert 2004.

176 Yergert 2004.

177 Colorado Department of Agriculture 2003(a).

The ad hoc review of the Meristem application generated public comments and debate about the procedures Colorado followed in that case and highlighted the potential need for a more well-defined process for CDA review of the field trial applications and APHIS assessments.

account in their review."[178] Biotechnology Regulatory Services (BRS) is the agency within APHIS that reviews applications for pharma crop permits The CDA draft procedures consist of two parts. The first outlines the process CDA will go through when it receives a permit. The second describes the creation of a technical advisory panel of experts that will conduct a scientific review of the permit application, similar to the three-person panel that reviewed Meristem's application.

When it receives a permit application, CDA plans to post it on its website and send copies to the technical advisory panel. CDA will also notify the applicant that it has received the application and that CDA may seek the applicant's assistance in resolving any questions as well as ask the applicant to meet with CDA or the panel. The panel, which will be given copies of any public comments CDA receives about the permit, will issue its recommendations to the Colorado commissioner of agriculture. The commissioner, who has the final authority, will then determine CDA's response and notify USDA. This response will be posted promptly to the CDA website. However, since CDA expects that the panel will receive CBI during the review process, it anticipates that it will not be able to share all of the information gathered by the panel with the public. Finally, CDA says that, to monitor compliance, its staff will accompany APHIS on all inspections to any sites that have received an APHIS permit.[179]

As for the expert panel, CDA "recognizes it does not have the in-house expertise to conduct the scientific review necessary" and envisions the panel meeting that need. The panel will consist of experts in the fields of genetics, plant physiology, crop production, molecular biology, human health, and other similar sciences depending on the expertise needed to assess the nature of the specific crop addressed. The employment of panel members must be such that they will not benefit from receiving CBI. Service on the panel must be voluntary because Colorado has neither the resources nor the statutory backing to pay the experts. No federal funds have been allocated for the state oversight of biotech crops, and the state lacks funds of its own for that purpose.[180] Some have suggested that Colorado institute fees for permit review, although there is concern that this might deter biotech companies from coming to Colorado.[181]

Finally, the draft procedures include a list of questions to guide the panel's review, although the list is not exhaustive. These questions address the areas of gene expression, plot design, human health considerations, worker safety, wildlife and animal health considerations, among others.[182]

---

178 Colorado Department of Agriculture 2003(b).

179 Colorado Department of Agriculture 2003(b).

180 Yergert 2003(a).

181 Miller 2004.

182 Colorado Department of Agriculture 2003(b).

Issues Remain

As of August 2004, when this report went to press, CDA was reviewing over 30 comments it received on the draft procedures and was working on revising the procedures. Although most of the respondents focused on concerns they had with the draft, a few provided positive feedback, specifically in regard to CDA going on all inspections and its overall effort to create a defined process and seek public comment.

Critical responses included those from multiple respondents suggesting that CDA hire professional staff to review the permits rather than relying on volunteers or third-party contractors.[183] One argued that, although CDA may not have the in-house expertise to review pharma crop applications, employees in the Division of Wildlife and the Department of Public Health and the Environment have sufficient professional experience.[184] Various respondents stressed the need to ensure that the volunteer panel members are unbiased and will not benefit from the granting of permits, are experts in human and environmental health, and have an understanding of the various interests in Colorado, like organic farming. Two other concerns raised by a number of respondents were the lack of funds to carry out any regulations or enforcement[185] and the need for CDA to have access to adequate information for review of the permits.[186]

Some respondents were concerned about CDA's assertion that it would withhold from the public information gathered in its review that it considered confidential. These respondents urged CDA to set criteria for what it would withhold. Many respondents suggested CDA seek legislative authority to review and monitor pharma permits, with the aim of creating enforceable regulations and credibility in the eyes of companies.

Some, including Dr. Patrick Byrne, who had served on the panel that approved the Meristem permit, called for CDA to seek an extension from USDA, if needed, of the 30 days given to states to review a permit. A number also asked that the public notification of permit applications and decisions made by CDA include postings beyond the website and be more "active," such as through an e-mail list-serve in order to ensure the public is kept informed.[187] One respondent suggested that CDA provide notification through county newspapers of where field tests will occur, even if precise locations cannot be disclosed.[188]

Others stressed liability issues and concerns that the draft procedures would not be able to adequately address the potential negative impacts of pharma crops on organic and other agriculture in Colorado.[189] Still

183 Patterson 2004(b); Winter 2004; Johnnson 2004.

184 Patterson 2004(b); Wuerthele 2004.

185 Ott 2004.

186 Workman 2004.

187 Brower 2004; Byrne 2004(a).

188 Crowell 2004.

189 Drifmier 2004.

others urged CDA to deny all field test applications for pharma crops and to keep pharma crops out of Colorado. Some of these requests encompassed all biotech crops. Most of these comments, however, were conditional until companies could be held liable for unintended consequences or guarantee that there is zero risk of cross contamination. One of the respondents calling for zero tolerance, the Colorado Genetic Engineering Action Network, also stated that "it should be considered *likely* that more contamination will occur" in light of the ProdiGene episode and called for regulations to address any potential contamination, including minimum standards for preventing contamination and for the permit holder's liability should contamination occur.

Meristem, for its part, was in the process of deciding if and when to implement its approved field trial for pharma corn in Colorado. Company representatives have looked into and visited possible test sites at greenhouses near the town of Rifle in the northwest corner of the state and in a field near the town of Holyoke in Phillips County.[190] They had until June of 2004, when their initial permit expired, to decide, at which time they could submit an application for renewal of the permit. Meristem chose not to plant in Colorado in 2004,[191] but it reports that it is seeking an American site for its field trials because most of its potential business partners are in the United States; the scientific and political communities here are more supportive of the work than in France; FDA drug approval is the gold standard; and U.S. investors seem interested.[192] Overall, the company hopes that it will be able to complete clinical trials on its drug in time to apply for FDA approval in 2006.[193]

Other related activity in the state centers on the potential for legislation to give Colorado the explicit authority to implement regulations surrounding biotech crops, in order to ensure the protection of Colorado residents and their food source.[194] Currently, CDA claims that the Colorado General Assembly has not given it the "necessary statutory authority to promulgate rules and regulations" on pharma and industrial crops.[195] Representative Ray Rose, from Montrose, Colorado, has requested the drafting of such a bill,[196] which would also include fees the industry would pay for the state oversight, and is debating whether to introduce it this legislative session.[197]

190 Mason 2004.

191 Auge 2004.

192 Brand 2004.

193 Auge 2003(a).

194 Porter 2004(a).

195 Colorado Department of Agriculture 2003(b).

196 Mason 2004.

197 Porter 2004(a).

Other related activity in the state centers on the potential for legislation to give Colorado the explicit authority to implement regulations surrounding biotech crops, in order to ensure the protection of Colorado residents and their food source.

He has postponed introducing such a bill until APHIS completes the ongoing review of its regulations.[198] If legislation granting Colorado the power to regulate is passed, CDA has said it would like to have a clause protecting CBI from public disclosure. CDA believes the absence of such a clause could hinder its ability to receive information from companies that may be afraid that their confidential information could be released publicly, a fear partially grounded in Monsanto's declaration that Colorado has one of the most permissive open records laws of any state.[199] The Colorado Department of Public Health and the Environment has also told CDA that it would like a role in the regulation of pharma crops.[200]

Questions and Implications

One perspective on the future of pharma crops in Colorado is offered by an expert on the panel that approved the Meristem permit, Dr. Patrick Byrne, an Associate Professor in the Department of Soil and Crop Sciences at Colorado State University. He writes in an editorial for the BioScience News and Advocate that "[n]ow is not the time to forge ahead with PMP [plant manufactured pharmaceutical] trials" because "[t]here is too much public anxiety about producing pharmaceuticals in food crops, too many policy reviews underway, too many questions about gene containment." He calls for careful analysis of the costs and benefits in the name of providing long-term benefits for both medical patients and rural economies.[201] Growers in Holyoke, where the Meristem pharma corn may eventually be grown, have their own questions. They want to know where the test site would be and whether secrecy will cause problems in the small community of 2,800, how much Meristem will pay farmers, and if the community can live with the controversy and risk of vandalism to property.[202] The Rocky Mountain Farmers Union and some producers have begun looking into who will be liable in the event there is contamination. [203]

The experience in Colorado and the actions taken to date by CDA could inform the future regulation of pharma and industrial crops in other states, including how potential risks are dealt with and how public perception of the crops evolves. CDA's draft procedures provide an example to other states for addressing the mix of scientific issues and public sensitivities by integrating the use of voluntary outside scientific experts and opportunity for public comment.

The questions facing Colorado and other states as they pursue oversight of pharma and industrial crops include what legal authority they have to carry out oversight of these crops, what level of state oversight is sufficient or

198 Porter 2004(b).

199 Yergert 2004.

200 Yergert 2004.

201 Byrne 2004(b).

202 Brand 2004.

203 Carman 2003.

needed, how state oversight should be funded, and how the state can ensure it receives adequate information to assess individual permit applications. An additional question is what power the state has to influence the federal decision about the granting of a permit. The general view expressed among state officials is that state agencies, such as CDA, do not have the power to veto APHIS permit decisions.[204] So what would happen if CDA's technical advisory panel recommended such an action? The potential for conflict between state interests and the APHIS regulatory mission may force consideration of this issue as the potential of harnessing crops for the efficient production of pharmaceuticals and industrial products advances.

Confidential Business Information and State Oversight of Biotech Crops: Hawaii Litigation Airs the Debate

The Issue in Brief

Access to confidential business information (CBI) by state regulators is one of the most challenging issues in the relationship between APHIS and the state plant health regulators who oversee most biotech crop trials. When APHIS seeks state review and comment on a field trial permit application, it provides the state agencies the CBI-deleted version of the application out of concern that states will not be able, under their public records access laws, to keep the information confidential, as required by the federal Freedom of Information Act (FOIA).[205] Since the information considered CBI typically includes details about the biotech crop and field trial that are crucial to the state's review of the proposed permit, states often seek and obtain some or all of the information they need directly from the company seeking the permit, under conditions that preclude its public disclosure. While this may satisfy the state regulator's needs, information about the biotech crop, the design of the field trial, and the trial's location—details that interested stakeholders and members of the public might consider relevant to their understanding and evaluation of the trial and its potential impacts—is withheld from public disclosure.

In 2003, the Center for Food Safety (CFS), a public interest advocacy organization, requested from the state of Hawaii information in the state's files concerning field testing of pharma crops.[206] When the CFS request was partially denied by the Hawaii Department of Agriculture (HDOA),[207] CFS filed a lawsuit against HDOA under Hawaii's Uniform Information Practices

---

204 Yergert 2003(a). This view seems consistent with the language in the PPA's preemption provision, which we discuss further in the Vignette on Filling the State Legislative Gap.

205 Although federal regulations do not specify whether CBI can be redacted from notification applications, it is evident from records of APHIS-acknowledged notifications that some information has been redacted as CBI from notifications. See Information Systems for Biotechnology 2004(f). Also see Section III for more explanation of how states collaborate with APHIS on permits and notifications.

206 Moriwake. 2003.

207 Hawaii Department of Agriculture 2003(a).

Act (UIPA)[208] (hereafter the "CFS UIPA case"), claiming that its justifications for withholding the information were not supported by Hawaiian law and that the public needed to be kept informed about "these potentially harmful substances."[209] Though the lawsuit is technically addressing the meaning of Hawaii's public disclosure law, it is airing publicly the broader policy issues involved in how to balance the interest of companies in protecting their CBI, the need of state regulators for access to CBI, and the interest of the public in gaining access to information about biotech field trials. While these issues will not be resolved in any final way in this still-pending litigation, the arguments being made illustrate what is at stake and may help illuminate the pathway to future policymaking.

Hawaii's Interests

In Hawaii, interest in regulatory oversight of biotech crops is high, in part simply because the level of field trial activity is high. More field trial applications have been submitted for sites in Hawaii through the permit and notification procedures than in any other state, totaling 1,708 as of May 4, 2004; 157 of those field trials were active.[210] Fifteen of the issued permits are for pharma crops, which, again, is more than in any other state.[211] Most of the field trial activity involves corn and soybean crops, which are not important commercially in Hawaii, though a biotech version of one locally important crop (a papaya modified to resist ring spot virus) is being grown commercially. The popularity of Hawaii as a site for field trials is due to its year-round growing season, its geographic isolation from areas where corn and soybeans are being produced for food (which minimizes outcrossing risks), and what has been reported as less "political unrest" surrounding the issue of agricultural biotechnology compared to other areas.[212]

The sheer volume of biotech field trial activity and concerns about potential impacts on local agricultural and ecological interests have, however, begun to generate critical attention and efforts to challenge how the field trials and their oversight are being managed. The Hawaii Organic Farmers Association, a group of Kona coffee growers, and the Hawaiian Environmental Alliance (KAHEA) have expressed concern over the possibility of cross-contamination between biotech crops, especially those modified to produce either pharmaceutical proteins or industrial compounds, and nonbiotech crops and other organisms.[213,214] The Hawaii Island Genetic Engineering

208 UIPA, Haw. Rev. Stat. § 92F.

209 Moriwake 2003.

210 The possession by a company of an active notification or permit does not necessarily mean that the company is currently carrying out a field trial, but signifies that it is authorized to do so.

211 Information Systems for Biotechnology 2004(f).

212 Danninger 2002.

213 Earthjustice 2003(b).

214 Earthjustice 2004.

Action Network, CFS, and other national organizations that have targeted the high-profile state for political action complain that they are not able to obtain information about the location of biotech field trials in Hawaii[215] or the number of acres involved.[216] While APHIS and EPA rules establish buffer zones between biotech crops and other crops, Earthjustice, an environmental advocacy group, questions the effectiveness such of federal rules. It points to EPA's recent citations of two *Bt* corn producers for incomplete compliance with Experimental Use Permit (EUP) requirements[217] and to the incidents in Iowa and Nebraska concerning pharma corn produced by ProdiGene, a biotech company that also tests products in Hawaii, as proof that the existing system is insufficient.[218]

A common assertion among those challenging the current management of the field trial process in Hawaii is that Hawaii is a "sensitive ecosystem" and is home to more than a third of the endangered species in the United States, with more per square mile than anywhere else on earth.[219,220] Based on environmental concerns, CFS, KAHEA, Friends of the Earth, and the Pesticide Action Network of North America have sued USDA in U.S. District Court in Honolulu, claiming violations of the National Environmental Protection Act (NEPA) and Endangered Species Act (ESA) based on the nature of the APHIS process for approval of "open-air" field tests for pharma crops.[221] In addition to their NEPA and ESA claims, the plaintiffs argue that withholding CBI makes the APHIS permitting process less accessible to the public, results in potentially weaker safety protocols than necessary, and reduces the scientific quality in decisionmaking by precluding outside scientific comments on permit applications, including from other federal agencies, based on the information in the applications. They say the current approach to withholding CBI "prevents members of the public from assessing the impacts posed by [pharma crops] to their environment and local food supply and agricultural producers from analyzing their susceptibility to crop contamination" by pharma crops.[222] These CBI-related arguments are similar to the ones made by the plaintiff in the CFS FOIA case discussed below.

---

215 Earthjustice 2003(b).

216 TenBruggencate 2003.

217 These EPA enforcement cases involved trials conducted on behalf of Dow Agrosciences LLC and Pioneer High-Bred International on the islands of Molokai and Kauai.

218 Earthjustice 2003(b).

219 Pesticide Action Network 2003.

220 Earthjustice 2003(b).

221 The case, *Center for Food Safety, KAHEA, Friends of the Earth, Inc., and the Pesticide Action Network of North America v. Ann Veneman, Secretary, U.S. Department of Agriculture; William T. Hawks, Undersecretary of Agriculture for Marketing and Regulatory Programs; Bobby R. Acord, Deputy Administrator, U.S. Department of Agriculture, Animal and Plant Health Inspection Service; and Cindy Smith, Deputy Administrator, U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Biotechnology Regulatory Services Program,* Civil No. 03-00621, was brought by the Center for Food Safety (CFS), KAHEA, Friends of the Earth, Inc., and the Pesticide Action Network of North America. See Leone 2003.

222 Center for Food Safety 2003.

The HDOA, for its part, appears to be focused on meeting its responsibility to protect Hawaiian agriculture and maintaining public confidence in its ability to address Hawaii's specific conditions and concerns within the limits of the CBI rules and other rules governing its role. According to Lyle Wong of the Plant Industry Division of HDOA, Hawaii has been actively involved in communicating with APHIS and providing comments on permit applications, discussing proposed revisions to APHIS regulations, and participating in inspections after permits are issued.[223] HDOA wants to ensure that the APHIS-state collaborative process is as transparent as possible without compromising Hawaii's ability to obtain information and provide for the protection of its agriculture in whatever way is necessary. Although Mr. Wong feels confident that APHIS is not putting Hawaii at risk, he believes it has to find a way to manage the biotech field trial permitting process so that the public can be more involved, and can ultimately share his confidence in the system.[224]

The CBI Litigation and Debate

Basic CBI Disclosure Rules and Procedures Under Federal and State Laws

The CFS case against HDOA revolves around (1) the CBI exemption of the federal Freedom of Information Act, (2) the APHIS regulations governing review of field trial permits and notifications, (3) the meaning of Hawaii's public records statute (UIPA), and (4) how APHIS and the states collaborate in the permitting process.[225]

The federal FOIA specifically protects from public disclosure "trade secrets and confidential or financial information obtained from a person [that is] privileged or confidential."[226] In 1985, APHIS issued a "Policy Statement on the Protection of Privileged or Confidential Business Information," which offers further guidance on what qualifies for protection as CBI, namely information that is "(1) commercially valuable, (2) used in one's business, and (3) maintained in secrecy." The APHIS policy statement also gives examples of what can be considered trade secrets: "information relating to the production process" including "production data, formulas, and processes, and quality control tests and data, as well as research methodology and data generated in the development of the production process."[227] This APHIS policy statement provides guidance on the procedures that APHIS follows to protect trade secrets and CBI from public disclosure, in accordance with the federal FOIA. It has since been supplemented with guidance for permit applicants on providing APHIS written justification for their trade secret and CBI claims.[228]

223 Wong 2004.

224 Wong 2004.

225 Leone 2003.

226 5 USC 552(b)(4) (2003).

227 USDA APHIS 1985.

228 USDA APHIS 1985.

As part of its response in the CFS UIPA case, HDOA reaffirmed its adherence to the 1985 APHIS Policy Statement[229] as the basis for implementing UIPA with respect to CBI and provided justifications for classifying as CBI the following categories of information commonly included in field trial permit applications: (1) gene and gene product descriptions (gene construct information), (2) personal identifying information for company employees or cooperators, (3) crop location information, (4) proprietary know-how or methods, and (5) field trial characteristics (e.g., number of plants, acres, harvest volume, and field description).

Gene construct and crop location information, two of the categories that have received the most attention in the lawsuit and in Hawaii, are considered by HDOA to be CBI because the information would allow other companies to copy products in a lab or steal samples for lab analysis. HDOA classifies location information as CBI also because competitors could visit the plot to judge the size of the test, which might indicate where the crop is within the commercialization pipeline, and competitors or opponents of the technology could attempt to destroy the crops.[230] It appears from records of APHIS permits issued for trials in Hawaii that at times, although it is rare, identification of the type of crop itself, e.g., corn, is considered CBI by HDOA and thus withheld from public disclosure, as well as the phenotype, or the nature of the introduced trait.[231]

For each CBI claim in a field trial permit application, APHIS requires that the applicant submit a written justification, which APHIS reviews but does not publicly disclose, making it difficult to judge the rigor of the review.[232] The applicant must also supply two copies of the permit application—one with all CBI information included in the copy, which is labeled the "CBI Copy;" and the other with the CBI information deleted, which is labeled "CBI Deleted."[233] After APHIS receives these documents, its regulations provide that, upon certifying that the application is complete, APHIS "shall submit to the State department of agriculture of the State where the [field] release is planned, a copy of the initial review and a copy of the application marked, 'CBI Deleted', or 'No CBI' for State notification and review."[234]

According to Neil Hoffmann, Director of the Regulatory Division of BRS, no states are currently receiving company-submitted CBI information from APHIS in connection with the permit review process. This reflects, however, a change from past practices under which states could obtain CBI under some circumstances. For example, in 1989, APHIS sent a letter to HDOA detailing how it could request access to the CBI copies of biotech permit applications by providing evidence that the state needed the information, could protect it through state statute, promised to deny public records

229 USDA APHIS 1985.

230 Webber 2004.

231 Information Systems for Biotechnology 2004(f).

232 USDA APHIS n.d.(f).

233 7 CFR 340.4 (1997).

234 7 CFR 340.4(b) (1997).

requests for the information, and would advise the requester to seek the information from APHIS instead.[235] In response to a request in 1993 from the Hawaii Department of Health (HDH) seeking information about its ability to receive CBI documents, APHIS replied that, since Hawaii's procedures for protecting CBI "are equivalent to the Federal procedures," HDH was eligible to receive CBI, provided the company applying for the permit agreed.[236] Today, APHIS does not leave open this possibility of providing states with CBI in permit applications, reverting to the letter of its regulations on this point. APHIS has been unable, however, to document when this shift to a more strict nondisclosure policy occurred or the specific reasons for it. Dr. Hoffmann believes this policy will remain in place until there is some new, clear legal basis for protecting CBI from disclosure at the state level.[237]

As for statutory protections in Hawaii, the state's Uniform Information Practices Act (UIPA), specifies that the following records, among others, are not "required" to be disclosed: "government records that, by their nature, must be confidential in order for the government to avoid the frustration of a legitimate government function"[238] and "government records which, pursuant to state or federal law including an order of any state or federal court, are protected from disclosure."[239] Unlike under the federal FOIA, Hawaii's protections are discretionary, meaning that state agencies are not required to withhold covered information. Hawaii's Office of Information Practices (OIP) nevertheless uses FOIA, its legislative history, and federal case law for guidance to interpret the scope of UIPA's disclosure exemptions.[240]

The actual practice when HDOA receives a CBI-deleted field test permit application from APHIS has been that, if not enough information has been provided to complete a meaningful review, the agency will contact APHIS and/or the company with questions. Hawaii, like other states, reports that it typically is able to get the information it needs, including CBI, directly from the company on a voluntary basis, with assurances provided by the state that it will not disclose the CBI publicly. On this basis, HDOA is able to comment on the permit application, and the understanding at HDOA is that in every case APHIS has incorporated Hawaii's comments into the permit conditions.[241]

The CFS UIPA Lawsuit

When HDOA obtains additional information concerning a permit application, whether from APHIS or the company, private parties can request disclosure of that information under UIPA, as CFS did in the process leading up to its UIPA lawsuit. CFS made a broad request in May 2003 for records dealing with the field trial permitting process in Hawaii, asking specifically for the following: "All documents, records, and files in the possession of the

235 Foudin 1989.

236 Medley 1993.

237 Hoffman 2004.

238 Hawaii Revised Statutes 2003(b).

239 Hawaii Revised Statutes 2003(b).

240 Portney and Nuse 2001.

241 Wong 2004.

Department of Agriculture of the State of Hawaii relating to any and all ongoing field tests of genetically engineered pharmaceutical-producing plant varieties in the State of Hawaii, including but not limited to field tests conducted under United States Department of Agriculture (USDA) Permit No. 01-306-01R, issued to Hawaii Agricultural Research Center, and No. 01-257-01R, issued to Monsanto."[242] HDOA denied CFS access to all or portions of "[p]ermits and [i]nter-agency correspondence that are records of the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Biotechnology Regulatory Service"[243] and forwarded the request to the FOIA section of APHIS, as APHIS requests that states do.[244]

CFS chose not to pursue the UIPA request any further. Instead it filed a lawsuit in July 2003 through a judicial appeal process allowed by UIPA, seeking specifically to compel the state to provide access to details about pharma crop field trials, including what substances are being produced, how and where the substances are being released, and what the responsible authorities are doing to control them.[245,246]

HDOA Arguments Against Disclosure

In defense of its decision not to grant the CFS UIPA disclosure request, HDOA argued that disclosure of at least some of the requested information would result in the "frustration of a legitimate government function." That legitimate function, according to HDOA, is maximizing Hawaii's influence in the permitting and regulation of biotech crops in the state.[247] HDOA claims that the "[s]tate is the entity best positioned to advocate for both the health and safety and economic interests of its citizens and to engage in the delicate balancing that is required" and "[n]either corporations, individual citizens, special interest groups, nor even the federal government has the same level of interest and concern as does the State."[248] Hawaii argues gen-

242 Moriwake 2003.

243 Hawaii Department of Agriculture 2003(b).

244 Marquis 2003.

245 Complaint in *Center for Food Safety v. Department of Agriculture*, Hawaii, Civil No. 03-1-1509. July 23, 2003, 12. Available at Earthjustice 2003(a).

246 Earthjustice 2003(a).

247 Defendant Department of Agriculture, State of Hawaii's Memorandum in Opposition to Plaintiff's Motion for Summary Judgment in *Center for Food Safety v. Department of Agriculture*, Hawaii, Civil No. 03-1-1509-07 (RWP). September 19, 2003, 12.

248 Defendant Department of Agriculture, State of Hawaii's Memorandum in Opposition to Plaintiff's Motion for Summary Judgment in *Center for Food Safety v. Department of Agriculture*, Hawaii, Civil No. 03-1-1509-07 (RWP). September 19, 2003, 12. Ibid, at 6.

HDOA claims that the "[s]tate is the entity best positioned to advocate for both the health and safety and economic interests of its citizens and to engage in the delicate balancing that is required" and "[n]either corporations, individual citizens, special interest groups, nor even the federal government has the same level of interest and concern as does the State.

erally that, if it must disclose CBI, it will have great difficulty in the future obtaining the information it needs to play its vital biotech oversight role.[249]

HDOA argues in particular that it sometimes receives information on permit applications that appears to be CBI but has not been redacted, and that it often relies on other CBI information that it obtains directly from the companies that submitted the original permit application to APHIS. Hawaii argues that the chance such information might have to be released publicly by the state could compromise HDOA's ability to receive additional information from these sources in the future.[250] HDOA argues further that the federal FOIA CBI exception described above, which protects this type of information from disclosure on a federal level, protects the information at the state level as well.[251]

CFS Arguments Favoring Public Disclosure

CFS, speaking through Earthjustice, the public interest law firm representing CFS in the case, maintains that "HDOA does not have a leg to stand on in withholding from the public information that will undoubtedly reveal the state's negligence in failing to oversee these field trials."[252] CFS argues first and foremost that releasing the requested documents will not prevent the state from obtaining the information in the future and thus will not frustrate a legitimate government function because, under state law, the permit applicant is required to submit to the state a copy of the permit application it submits to APHIS. Hawaii's statutes require that: "Any applicant to any federal agency for any permit for or approval of ... field testing of genetically modified organisms ... shall submit one copy of that application to the [Hawaii Department of Health], at the same time that the application is submitted to the federal agency."[253] On this basis, the state is entitled to the information without relying on APHIS or the voluntary cooperation of the company, and thus disclosing the information under UIPA will not impair the state's ability to do its job. CFS argues further that the federal FOIA exemptions, including the CBI exemption, are not relevant in Hawaii because they apply only to federal agencies, not state entities.[254]

---

249 To further support its claim under this section of the UIPA, HDOA points to an opinion issued by the Office of Information Practices of the Hawaii Department of the Attorney General in December of 1992 that the "frustration exemption" section (Hawaii Revised Statutes (2003(b)) would exempt CBI on APHIS permit applications from being disclosed. See Loo 1992.

250 Defendant Department of Agriculture, State of Hawaii's Memorandum in Opposition to Plaintiffs Motion for Summary Judgment in *Center for Food Safety v. Department of Agriculture,* Hawaii, Civil No. 03-1-1509-07 (RWP). September 19, 2003, 7.

251 Hawaii Department of Agriculture 2003(b).

252 Earthjustice 2003(a).

253 Hawaii Revised Statutes 2003(a).

254 Complaint in *Center for Food Safety v. Department of Agriculture,* Hawaii, Civil No.03-1-1509. July 23, 2003. Available at Earthjustice 2003(a).

In December 2003, while the litigation was underway, HDOA completed its review of the information requested by CFS and supplied the requested documents with the CBI redacted. HDOA claimed that the portions of the records withheld contain information that: "(1) is confidential business information of permit applicants; (2) if disclosed would frustrate a legitimate government function because it would compromise security or would impair government access to information needed to protect public interests; (3) is protected from disclosure by state or federal law; or (4) is personal information," citing the same UIPA disclosure exceptions it had cited in the initial response to the CFS information request.[255] Earthjustice issued a press release stating its disappointment with the "blank documents" and its concern that the lack of information in the CBI-deleted permit applications the state receives from APHIS regarding the gene construct and location of the field trials hinders HDOA's ability to 'assess the tests' risks to public health and the environment."[256]

As this report went to press, the most recent activity in the CFS UIPA case was a court-imposed negotiation between the parties to review and possibly obtain agreement on the justifications for withholding from disclosure each item of redacted information. Earthjustice and CFS were in the process of reviewing and responding to the justifications provided by HDOA. The Biotechnology Industry Organization (BIO), which represents over 1,100 companies involved in the development of biotechnology and was granted permission by the court to intervene in the case, supplied its own list of justifications for considering various types of information to be CBI, focusing on the threat of vandalism to test plots.[257]

Related Activity

Other activities have occurred in Hawaii regarding CBI and the permitting of biotech crops that help frame and expand the debate about how CBI is managed by federal and state agencies.

Perhaps most significantly, in the federal lawsuit brought by environmental groups claiming that the APHIS permitting process for pharma crops violates NEPA and the ESA, a federal magistrate issued a ruling on June 29, 2004 denying a protective order in the pretrial discovery process for information on the location of field trials, concluding that such information was neither confidential business information nor a trade secret and thus could not be protected from public disclosure.[258] If this ruling stands up on appeal, it could affect the Hawaii UIPA case, as well as future handling by APHIS of field trial location information.

---

255 Hawaii Department of Agriculture 2003(c).

256 Earthjustice 2004.

257 Motion of the Biotechnology Industry Organization to Intervene, *Center for Food Safety v. Department of Agriculture, State of Hawaii,* Civil Action No. 03-1-1509-07 (D. Hawaii, November 3, 2003), Moriwake 2004.

258 Order Denying Defendants' Consolidated Motions for a Protective Order, *Center for Food Safety et al. v. Veneman et al.,* Civil Action No. 03-00621 DAE-BMK (D. Hawaii, June 29, 2004). This ruling was subsequently affirmed by the federal judge presiding in the case, but at the time this report went to press, the court had not ordered public release of the information on location of field trials.

In an indirectly related activity, the Parks and Agriculture Committee of the County Council of Maui in Hawaii drafted a resolution in 2004 that urges the Hawaii government to set up county advisory boards to offer input into Hawaii's decisions and regulations governing biotech crops in the state. The resolution urges "each advisory board to consider whether the county's residents have the right to know the location and nature" of biotech crops grown in their county, facts often redacted as CBI, as well as to review the risks and benefits involved with biotech crops and offer policy initiatives to the state.[259] HDOA testified before the Maui County Council to express its disapproval of the proposal due to HDOA's inability to provide CBI to the county and the lack of authority of the proposed boards to influence the permitting decisions of the federal government.[260] BIO also issued a statement against the resolution, emphasizing its desire for coordinated and consistent federal regulations.[261]

Challenges and Implications

The three significant challenges presented by the CBI issue are: (1) providing states ready access to the information they need to review field trial permit applications; (2) providing interested stakeholders and the general public with a sufficiently transparent permit process and enough information to instill confidence that the process adequately protects their interests; and (3) maintaining the confidentiality of CBI in a way that protects legitimate business interests and does not deter companies from continuing to conduct trials in a state.

As noted at the outset, the pending litigation in Hawaii will likely not resolve these broad challenges. It may well result in a ruling about the extent to which Hawaii, under its particular state law, is free to withhold information that APHIS considers confidential under federal FOIA principles. This could be significant beyond Hawaii since many states have public disclosure laws similar to Hawaii's.

When the litigation is complete, however, the basic problem of ready state access to CBI in APHIS' hands will likely remain. Much of the information contained in field trials on such matters as the details of the gene construct, the design of the field trial, and data on environmental safety generated in previous trials, if not previously disclosed, will continue to be considered CBI by APHIS and will not be disclosed to the states. If that is so, resolution of the first challenge—providing states ready access to the information they need to review field trials meaningfully—would appear to require either creative policy development at the federal level or legislation at the state level,

259 Resolution Urging the State to Establish Advisory Boards Regarding Genetically Modified Organisms. http://www.co.maui.hi.us/files/PA/Item/03reso-gmo3_ytwwasnld.pdf#xml=http://www.co.maui.hi.us/bin/texis/webinator/newsearch/xml.txt?query=genetically+modified&tdb=db&tid=dbb2385085401e4 (accessed May 27, 2004).

260 Kunimoto 2004.

261 Biotechnology Industry Organization 2004.

or perhaps some combination of the two. At the federal level, APHIS could reverse what appears to be its current presumption that states are unable or unwilling to protect CBI. The Hawaii case demonstrates Hawaii's willingness to do so in accordance with federal FOIA principles. If Hawaii's position is upheld by the court, this could provide the impetus and legal basis for a policy shift by APHIS back toward sharing with states the CBI copy of permit applications, subject to criteria concerning state laws and procedures for reviewing requests for public disclosure of government records.

At the state level, legislatures could ensure that state regulators obtain the necessary information by adopting statutes to require sponsors of field trials to submit to the state a complete copy of the permit application and all supporting data submitted to APHIS, as well as any other information that state regulators decide they need to evaluate the impact of proposed trials on the state's agricultural or other local interests. Only Minnesota has such a law today. As discussed in Section III, the preemption provisions of the PPA and FIFRA place some limitations on the regulatory actions states can take if they differ from federal actions, but they do not appear to preclude a state from requiring complete data submissions directly from the companies as a condition of being registered for planting in that state. Short of this step, state legislatures might have a role to play in adjusting their public disclosure laws to foster data sharing by APHIS, such as by clarifying the authority and obligation of the state to protect CBI under defined circumstances.

The second challenge—providing the public with a transparent permit process and adequate information about field trials—seems more difficult than the first, because it involves a much wider array of competing interests and values and there is a lack of consensus about how much transparency and information is enough. There is a balance to be struck that protects the company interest in guarding valuable trade secrets and CBI, whose disclosure would clearly cause the company significant economic harm, and the stakeholder and public interest in knowing enough about field trials to be able to comment and simply be aware of activity that could affect their interests. Typically, this balance is struck legislatively. At the federal level, Congress has struck the balance in quite different ways across the spectrum of product and technology categories that require some form of premarket data submission and review. Quite different policies have been adopted for public disclosure of data and public participation in premarket review processes for food additives, pesticides, human and animal drugs, and medical devices. While there is certainly some room within current law to improve the transparency of the review process for biotech crops and foods, fundamental change in the system would likely require legislation.

There is a balance to be struck that protects the company interest in guarding valuable trade secrets and CBI, whose disclosure would clearly cause the company significant economic harm, and the stakeholder and public interest in knowing enough about field trials to be able to comment and simply be aware of activity that could affect their interests.

Although the CBI issue can be viewed primarily as a legal and technical matter, significant values are at stake on both sides of the debate. As in many spheres of activity, knowledge is power for both public and private participants in the management and oversight of biotech crops and foods. It can also be the basis for public confidence and acceptance of biotech, or the lack thereof. How information about specific applications of biotechnology is shared is, therefore, one of the most crucial and difficult issues facing those responsible for public policy in this arena.

Role of State Advisory Bodies in Decisions to Commercialize Biotech Crops: California's Pharma Rice Experience

The Issue in Brief

Much of the concern about biotech crops at the state level involves issues related to containment of biotech crops and preservation of market access for the state's agricultural producers. These concerns are heightened when the time comes to consider moving from field trials to commercialization of a biotech crop. In the case of pharma rice, California has followed a procedure that gives a state-chartered, industry-based advisory body, the California Rice Commission (CRC), a role in the decisionmaking process. Under a statutorily-prescribed procedure applicable to all rice varieties, the commission evaluated whether the commercial planting of pharma rice in California would have an adverse impact on the marketability of conventional rice by virtue of possibly outcrossing or physically contaminating conventional rice, and it made recommendations concerning containment procedures that would be sufficient to prevent such adverse impact. The California experience provides an example and may offer lessons for how states might approach decisions on minimizing any possible negative impacts certain biotech crops may have on state agricultural interests.

California's Interests

California ranks second in the United States behind Arkansas in rice production, accounting for 20% of the U.S. total production of 43 million hundred weight (cwt).[262] The value of California's rice industry is $500 million, with $214 million of this attributed to growers and the balance to milling and subsequent stages of rice production. While U.S. rice production accounts for less than 2% of global production and its total value is small relative to the much larger international markets for corn, soybeans, and

262 USDA ERS 2001; California Agricultural Statistics Service n.d.. 1cwt=100 pounds.

wheat,[263] the U.S. and California rice industries rely heavily on access to foreign markets. Of the rice produced in the United States, 40% is exported, accounting for almost 12% of the global rice trade.[264] Of the different grain types traded internationally—short, medium, and long—California is the largest U.S. producer of medium-grain rice, with major export markets in Japan, Turkey, and Jordan. The United States supplies almost half of Japan's rice imports, making Japan the largest U.S. rice export market.[265]

The international rice market is described as "thin, volatile and risky," compared with other commodity markets.[266] Only 6% of total annual world production of rice is traded internationally, compared with 18% and 25%, respectively, of wheat and soybeans.[267] In addition, the current market outlook for U.S. rice exports is not positive. The U.S. share of the world rice trade has declined since the mid-1970s, from 28% in 1975 to 12% currently, and further declines are projected for 2004.[268]

These facts increase the sensitivity of U.S. rice producers to anything that could further jeopardize their markets, and the commercialization of pharma rice has emerged as a potential threat to the export market. Ventria Bioscience, a California-based biotech company, has developed a variety of rice genetically modified to produce two pharmaceutical proteins, lactoferrin and lysozyme, which are natural antibiotics used to treat both humans and animals. Concerns have been raised by members of the rice industry and others about the possibility that even small amounts of the pharma rice could find its way accidentally into nonpharma conventional rice, making it unacceptable for food use. Japan, which is California's largest export market (importing 40% of California's production), has been forthright in expressing concern about biotech products in general and the commercialization of pharma rice specifically.[269] In a letter to the CRC, the Japanese Rice Retailers Association stated that,

> [I]t is certain that the commercialization of [biotech] rice in the U.S. will evoke a distrust of U.S. rice as a whole among Japanese consumers, since we think it is practically impossible to guarantee no [biotech] rice contamination in non-[biotech] U.S. rice. As you know, most Japanese consumers react quite negatively to [biotech] crops. If the [pharma] crop is actually commercialized in the U.S., we shall strongly request the Japanese government to take necessary measures not to import any California rice to Japan.[270]

This marketplace resistance presents a dilemma to those California rice growers who see the potential benefits of biotech rice. According to the

263 USDA ERS 2001.

264 USDA ERS 2001.

265 Evans 2003.

266 USDA ERS 2001.

267 USDA ERS 2001.

268 Evans 2003.

269 Garofoli 2004.

270 Japanese Rice Retailers Association letter, quoted in Massa 2004(a).

Rice Producers of California, a group representing rice growers on public issues, "Biotechnology is seen as perhaps the most important new resource for achieving varietal improvement."[271] According to one rice grower, however, the California rice industry is justifiably concerned that pharma rice "would have serious consequences on our ability to sell California rice."[272]

Beyond the interest of the California rice industry in its export markets, others have expressed views on pharma rice and other pharma crops that are relevant to the public discussion in California. State and national consumer and environmental groups, such as Sierra Club California, Environment California, Consumers Union, and the Center for Food Safety, contend that, beyond the economic issues, there are many environmental and public health concerns raised by pharma rice.[273] The Biotechnology Industry Organization (BIO) argues, on the other hand, that the health benefits of pharma crops outweigh the risks and that the risks are adequately regulated by the federal government.[274] The industry also points out that the tremendous knowledge that exists about the genome of major food crops make them good platforms for pharma crop development and production. However, a recent report by the National Research Council on the biological containment of genetically modified organisms concluded that crops used to produce common food products would be a "poor choice" for use to produce pharma and industrial crops unless they can be grown under "stringent conditions of confinement."[275]

The California Rice Commission and the Ventria Request to Commercialize Pharma Rice

The California Rice Commission was created by the government of California to serve the interests of the California rice industry by expanding and maintaining the industry's markets.[276] It is composed of equal numbers of rice producers and rice handlers, with the option of including one "public member."[277] The commission is funded by an assessment placed equally on producers and handlers based on the volume of their production.[278] In 2000, the California legislature, in response to a proposal advanced by the CRC, enacted the Rice Certification Act of 2000[279] with the broad intent of

271 Rice Producers of California n.d.

272 Massa 2004(a).

273 Hansen et al. 2004.

274 Kelly 2004.

275 National Research Council 2004.

276 California Food and Agricultural Code, section 71000 et seq.

277 California Food and Agricultural Code, section 71050 (a).

278 California Food and Agricultural Code, section 71120 (a).

279 California Food and Agricultural Code, California Rice Certification Act of 2000, section 55000 et seq.

> [E]nsuring the consistently high quality of the rice produced, milled, distributed, or otherwise handled in the state by informing consumers, maintaining consumer confidence, and enhancing and protecting the reputation of California's rice industry throughout the nation and around the world.[280]

In furtherance of this intent, the Rice Certification Act focused on rice having "characteristics of commercial impact," which it defined as "characteristics that may adversely affect the marketability of rice in the event of commingling with other rice," including characteristics that require specialized equipment to identify, create a significant economic impact in their removal from commingled rice, or whose removal is infeasible.[281] The central thrust of the statutory scheme is to "maintain the integrity and prevent contamination of rice which has not been identified as having characteristics of commercial impact" by requiring that commercial impact rice comply with an identity preservation program and appropriate containment measures.[282]

The role of the CRC under the Rice Certification Act is to evaluate rice varieties, through its advisory board; identify ones having characteristics of commercial impact; identify and recommend appropriate identity preservation and containment measures; and recommend to the Department of Agriculture the regulations required to achieve the purposes of the act. The advisory board consists of 20 members appointed by the California Department of Agriculture and includes farmers, handlers, University of California specialists, and representatives from California Crop Improvement and the seed industry. The commission's advisory board recommends to the secretary of agriculture the conditions and systems for production and containment that it considers necessary to provide the needed protection.[283] Based on these recommendations, the secretary decides whether to initiate the recommended rulemaking, declines to do so, or asks for more information.[284] It is unlawful under the Rice Certification Act to produce or handle commercial impact rice varieties in a manner that does not comply with these regulations.[285]

In the fall of 2002, Ventria began formal discussions with the CRC on its intent to commercially plant its pharma rice during the 2004 planting season, and, in December 2003, Ventria submitted an application to APHIS to renew its California field trial permits.[286] In order for Ventria's pharma rice

---

280 California Food and Agricultural Code, California Rice Certification Act of 2000, section 55001.

281 California Food and Agricultural Code, section 55009.

282 California Food and Agricultural Code, sections 55040–55052.

283 California Code of Regulations n.d.(b). Specifically, the committee is mandated to "identify rice varieties that have characteristics of commercial impact and to propose appropriate regulations establishing terms and conditions for planting, production, harvesting, transporting, drying, storing, handling rice, seed application, field buffer zone, handling requirements, and identity preservation requirements."

284 California Food and Agricultural Code, section 55022.

285 California Food and Agricultural Code, section 55050.

286 Deeter 2004.

product to be commercialized in California, APHIS would have to authorize the necessary planting through the issuance of an appropriate permit.[287] Regulating pharma crops under permits—rather than granting them nonregulated status as the basis for commercial-scale planting—enables APHIS to continue to impose and enforce containment and other measures intended to avoid adverse impacts, such as contamination of the food supply.

Of the 84 permits for the field testing of pharma crops that APHIS has issued nationwide,[288] nine have been issued for trials in California, including for pharma rice, but APHIS has not to date authorized commercial production for any pharma crop. It is important to remember that an APHIS permit is only one regulatory hurdle developers of pharma crops must clear. The pharmaceutical substances the plants produce are subject to strict FDA premarket approval requirements.[289]

The commission referred Ventria's proposal for commercial planting to its advisory board. In its discussions with the commission, Ventria stipulated that its pharma rice had characteristics of commercial impact.[290] The focus of the commission's and advisory board's work was thus to determine conditions for planting and handling that would ensure adequate identity preservation and containment of the pharma rice consistent with the objectives of the Rice Certification Act.[291] In the course of its deliberations, the advisory board worked with Ventria to develop proposed conditions for the production and handling of the company's pharma rice. These included growing the pharma rice in Southern California, which is outside the state's rice belt; not seeding the rice from the air (a typical production method); ensuring a buffer zone of 100 feet between biotech rice and other crops; ensuring seed containers are sealed and numbered and silos are labeled and locked in order to keep pharma rice separate from other rice; and testing for the presence of the biotech pharma trait.[292]

The advisory board was reported to be "deeply divided" on the Ventria application,[293] with rice farmers on and off the board voicing objections to allowing commercial planting of the pharma rice because of concerns about negative market impacts like those detailed in the letter from Japanese rice retailers.[294] On March 29, 2004, by a vote of six to five, the advisory board recommended to the secretary of agriculture conditions and protocols under which Ventria's pharma rice could be planted commercially with adequate identity preservation and containment.[295]

---

287 Specifically, the agency has stated that "APHIS envisions that plants which produce drugs and biologics will always be grown under APHIS permit and will be regulated concurrently by FDA and USDA." USDA APHIS n.d.(d).

288 Information Systems for Biotechnology 2004(c).

289 U.S. FDA 2002.

290 Nunenkamp 2004.

291 California Rice Commission 2004(a).

292 *Sacramento Bee* 2004; California Rice Commission 2004(b).

293 Jacobs and Krieger 2004.

294 Japanese Rice Retailers Association letter, quoted in Massa 2004(a).

295 Silber 2004; California Rice Commission 2004(a).

There is no unanimity of opinion among rice growers or other groups in California on biotechnology in general or on pharma rice in particular.[296] The board vote elicited a sharp response, however, from stakeholders who are generally opposed to biotechnology or who have particular concerns about its application to pharma rice. Californians for GE-Free Agriculture disagreed with the board's vote and acceptance of the rice protocols, stating that "contamination is inevitable under this protocol and the CRC did not act in the best interests of California rice farmers or consumers."[297] Organic rice producer Bryce Lundberg concurred, reiterating concerns about the contamination of organic rice with pharma rice.[298] One rice farmer called the decision "bad news for farmers and California's rice industry."[299]

Given the timing of the commission's recommendation, Ventria needed a quick decision from the Department of Agriculture in order to have any chance of planting its pharma rice crop during the spring 2004 planting season. To expedite the process, the commission recommended that Ventria be granted an emergency exemption by the California Department of Food and Agriculture (CDFA), which would mean placing the regulations recommended by the commission in effect pending the normal public hearing and rulemaking process.

In a letter to Secretary of Agriculture A.G. Kawamura, dated April 1, 2004, consumer and environmental groups asked the secretary to deny Ventria's request for an emergency exemption, claiming that public input was not only essential in the decision to commercialize the first pharmaceutical crop, but that the health and environmental impacts of the pharma rice had not been sufficiently assessed by the company or a federal agency.[300] Tim Johnson, president of the CRC, said in a press report that many varieties of rice are currently kept separate and the rules put together for the biotech rice should suffice.[301]

CDFA Secretary Kawamura denied the recommendation of the commission's advisory board for an emergency exemption, finding that, while he "was prepared to go forward with a modified package on a non-emergency basis," he would not act on an emergency basis because it was unclear if the company had obtained federal approval and "it is very clear that many wish to comment prior to any planting made possible in any way by implementation of this regulation."[302] He returned the matter to the commission with instructions for further review. Ventria Chief Executive Officer Scott Deeter called this a minor setback and said the company has plans to reapply in California next year and is also considering other options, such as planting in Hawaii and states in the South.[303] Ventria and the biotech industry still asserted

296 Johnson 2004.

297 Renata Brillinger, quoted in Silber 2004.

298 Lundberg 2004.

299 Massa 2004(b).

300 Consumers Union 2004.

301 Silber 2004.

302 Nunenkamp 2004, quoting Secretary Kawamura, April 9, 2004. See *San Luis Obispo Tribune* 2004.

303 Elias 2004.

that the health benefits of the technology outweigh the risks, claiming that producing these proteins through crops is the most cost-effective and efficient means of reaching the most people. Planting 65 acres of pharma rice, they say, could generate 1,400 pounds of lactoferrin, which would be enough to treat 650,000 children with dehydration, a condition that kills 3 million infants each year worldwide, mostly in developing countries.[304]

Some California rice producers saw the decision as providing an opportunity to look to the future. The president of the Rice Producers of California has expressed a desire to educate farmers about the issue through town meetings, as the Ventria decision is certainly not expected to be the end of pharma rice or other pharma crops in the state.[305]

Following the California decision, the press reported that the U.S. Department of Agriculture's Biotechnology Regulatory Services subsequently denied a renewal of Ventria's field test permit because the rice was being grown too close to other crops destined for the food supply.[306] Scott Deeter, Ventria's CEO, said "the company would address the USDA's concern with its permit renewal application and still expected to receive approval to continue growing the genetically engineered rice on its current plot."[307] Ventria has since received APHIS approval to continue field testing its biotech rice in California.[308]

In anticipation of more companies applying for permits to field test pharma crops, the USDA recently published a notice in the *Federal Register* detailing its plans to enhance APHIS regulation of field tests involving food plants and crops that have been engineered to produce pharmaceutical and industrial compounds. The regulations APHIS is considering would include more stringent permit conditions, such as containment measures, an increase in compliance inspections, and increased communication between the agency and the public.[309]

Implications and Questions

The CRC provides an example of how state-chartered advisory bodies could participate in state decisionmaking about biotech crops and foods. The commission was chartered, of course, to address the potential impact on

304 Lee and Lau 2004.

305 Garofoli 2004.

306 *San Luis Obispo Tribune* 2004.

307 *San Luis Obispo Tribune* 2004.

308 Information Systems for Biotechnology 2004(b).

309 USDA APHIS 2003(a).

The commission was chartered, of course, to address the potential impact on marketability of rice varieties produced by any means, not just biotechnology, and its statutory charge, once characteristics having commercial impact have been found, is the relatively technical one of determining conditions for identity preservation and containment.

marketability of rice varieties produced by any means, not just biotechnology, and its statutory charge, once characteristics having commercial impact have been found, is the relatively technical one of determining conditions for identity preservation and containment. Varieties produced by conventional techniques but having characteristics of commercial impact—while important to trade and consumer interests regarding product quality and integrity—are likely to be less controversial than biotech varieties in general and pharma crops in particular.

In the pharma rice case, the commission found itself at the center of a contentious public debate about whether pharma rice should be commercialized in California. This occurred despite the fact that the Rice Certification Act empowered the commission only to help determine the conditions of planting that would ensure adequate identity preservation and containment, not to provide a forum for deciding whether to allow planting of commercial impact rice varieties. The Department of Food and Agriculture considers the decision on whether to allow planting of pharma rice to be reserved to the federal agencies.[310]

One lesson from the CRC experience with pharma rice concerns the difficulty of drawing a bright line between the technical issues of identity preservation and containment and the broader economic and market integrity concerns that have made the pharma rice case controversial. Potential impact on the "marketability" of rice is what makes a rice variety, such as pharma rice, subject to the identity preservation requirement of the Rice Certification Act. However, there is a subjective component to the concept of "marketability," which means that the technical criteria for accomplishing identity preservation might satisfy one party but be unacceptable to another. If the Japanese Rice Retailers Association is correct, any planting of biotech rice in California will affect the marketability of all California rice in Japan. It is not surprising that the commission process was seen by some as a forum for debating whether pharma rice should be planted in California.

Advisory bodies, such as the CRC, can play a very useful role in bringing relevant expertise and perspectives to bear on government decisions. One of the questions posed by the Ventria pharma rice case is whether, in the sensitive public context of agricultural biotechnology, the advisory body role can be successfully performed by an industry-based organization that represents some "but not all" commercial interests and is not charged with considering broader public and consumer interests. In the California case, comments made by farmers, the food industry, and consumer and environmental groups following the advisory board's recommendation suggest some stakeholders felt their concerns had not been adequately considered. The experience has raised several questions. Should the CRC's process be changed to deal with the unusually sensitive issues posed by biotech crops,

310 Nunenkamp 2004.

and especially pharma crops? Should representation on the advisory board be broadened? Should the statutory charge of the commission be broadened to take into account more subjective factors, such as consumer perception and foreign customer preferences, which influence whether a crop will have an adverse impact on the industry but that are not addressable through identity preservation and containment plans?

Alternatively, should an advisory process be developed to deal specifically with biotechnology-related issues, to consider issues and interests beyond those of the affected commodity sector, such as matters relevant to other commodity producers and handlers and consumers? This could be in addition to or as a substitute for a commodity-specific, industry-based advisory body. Clearly, the CDFA anticipated more public involvement in the ultimate decision about whether and under what conditions to approve pharma rice, but through what process? The advantage of a formal advisory body over isolated stakeholder comments is that it provides a vehicle for a group representing a range of interests and perspectives to become well-versed on the issues and deliberate in a way that can generate new ideas and solutions. The limitation is that it is rarely possible to comprise a body that truly represents all interests in a way that all interests find adequate, especially when recommendations or decisions run counter to a particular group's strongly held view.

Another approach to gaining input is to convene purely scientific advisory bodies. Many states currently solicit expertise from scientists in land grant universities or other institutions to aid regulatory officials in the oversight of biotechnology. Most, if not all, of these bodies or advisory committees are not paid, are convened on an ad hoc basis, and have no clearly defined mandate. Should more states formalize these entities to ensure adequate technical expertise is brought to bear on biotech issues? How distinct are the scientific and technical issues from the business concerns, market acceptance issues, and consumer confidence issues that are so prevalent at the state level? Is it possible and better to keep scientific advisory efforts separate, or to foster dialogue among experts and stakeholders who approach the issues from different knowledge bases and value perspectives?

In the end, on controversial issues, there is no substitute for transparent processes in which the responsible decisionmaking authority provides all interested parties with opportunities to present relevant information and offer their views and then renders its decision with a clear and well-documented explanation. There are many ways to structure such a process and gain the needed input. The California pharma rice experience illustrates one approach, and its possible pitfalls.

In the end, on controversial issues, there is no substitute for transparent processes in which the responsible decisionmaking authority provides all interested parties with opportunities to offer their views and provide relevant information and ultimately renders its decision with a clear and well-documented explanation of the basis for it.

Biotech Tobacco in North Carolina: A State-Driven Initiative to Ensure Identity Preservation of Commercialized Biotech Crops and their Conventional Counterparts

The Issue in Brief

Researchers and growers alike consider tobacco an excellent candidate crop for producing pharmaceuticals and other nonfood substances. The genetic composition of tobacco is well-understood,[311] it contains genes to produce about 4,000 chemicals, and it grows quickly.[312] In light of the pressure on tobacco farmers arising from the anti-smoking movement, new uses for the crop are in demand. Additionally, for pharma and industrial applications, tobacco has a significant advantage over many other crops because it is a nonfood crop. In a 2004 report, the National Academy of Sciences pointed out that nonfood biotech crops are less likely to inadvertently enter the food supply than food crops that have been genetically modified.[313] As a major tobacco-growing state, North Carolina has a strong interest in tobacco's potential as a biotech crop, but it is also imperative for North Carolina to preserve the genetic identity and purity of its profitable conventional strains of tobacco.

The recent NAS report concluded that, even with strict confinement procedures, the achievement of absolute isolation of biotech crops from nonbiotech crops is virtually impossible, in nature or after harvest.[314] The issues that arise from this conclusion for North Carolina and other tobacco-producing states include (1) how the identity of both biotech and nonbiotech tobacco crops can be maintained in a commercial setting, and (2) the respective roles of state governments and private actors in achieving this goal.

Working through the National Association of State Departments of Agriculture (NASDA), North Carolina is a key player in an effort to draft voluntary containment protocols for growing commercialized biotech tobacco. The protocols, which states could endorse, would provide the basis for a private certification process through which tobacco purchasers could be assured that recognized procedures had been followed to reduce the risk of cross-contamination of both conventional and biotech tobaccos, and thus preserve their identities. The certification process could be used as a marketing tool[315] and is a potential model for harnessing market forces to supplement government regulatory controls.

---

311 Dickerson 2004.

312 Associated Press 1994.

313 National Research Council 2004.

314 National Research Council 2004.

315 Dickerson 2004.

North Carolina's Biotech Interests and Activities

Tobacco has been the number one cash crop of North Carolina for years, and agriculture is North Carolina's number one industry, accounting for 22% of the state's income.[316] However, state tobacco farmers are anxious about declining demand for tobacco and steep reductions in federal market quotas, which jeopardize their livelihoods.[317] The development of alternative ways to make a profit from a crop that is both well-understood and at the core of North Carolina's heritage thus holds much promise for tobacco growers and the state's economy. Genetically modifying tobacco to efficiently produce pharmaceutical substances could also change the public perception of the crop from one thought of as a source of health risks to one celebrated as a source of health benefits, a change that would be welcomed in North Carolina.[318]

As biotech companies in the South Atlantic region of the United States increase their investments in pharma tobacco technology, there have been ongoing efforts in North Carolina to increase the state's market share of the biotechnology industry. Currently, the total biotechnology industry, including biomedical applications, in North Carolina ranks among the country's top five,[319] and in 2002 the North Carolina commissioner of agriculture stated that "biotechnology promises to have unlimited possibilities as scientists continue to push this area of science in new directions every day."[320]

Biomedical research, economic programs, and training in biotechnology have been supported since 2002 by the Golden LEAF Foundation, a nonprofit organization that receives one-half of its funds from North Carolina's tobacco settlement with cigarette manufacturers and provides grants for economic development activities.[321] Two other groups that provide support for biotech research, development, and commercialization efforts are the North Carolina Biotechnology Center, a nonprofit created in 1981 by North Carolina's General Assembly,[322] and an industry trade group, the North Carolina Biosciences Organization. Biotechnology research is conducted in many of North Carolina's public universities[323]—including North Carolina State University, where research is being conducted on pharma tobacco[324]—as well as through private ventures.

The efforts to develop biotech tobacco have drawn critical scrutiny, however, from some in North Carolina. Much opposition has come from tobacco growers themselves, who are worried about the potential for loss of genetic purity and market integrity should pharma tobacco contaminate

316 North Carolina Department of Agriculture and Consumer Services 2003(a).

317 Derksen 2004.

318 Associated Press 1994.

319 North Carolina Biotechnology Center 2004.

320 Phipps 2002.

321 Golden LEAF 2004.

322 North Carolina Biotechnology Center n.d.

323 Biotechnology Industry Organization 2001.

324 North Carolina Biotechnology Center. 2003.

conventional strains. Some concerned producers and other stakeholders drafted a bill that would have placed a moratorium on growing biotech tobacco in the state for any other purpose than a field trial, but the bill failed.[325] In 2001, a bill was introduced, but did not pass, with the stated purpose "to regulate the production, processing, and movement of experimental [meaning biotech] tobacco to ensure that experimental tobacco is not commingled with other tobacco." The legislation would have required anyone who intended to grow, process, store, sell, transport, or otherwise posses biotech tobacco to apply and pay for a license from the North Carolina commissioner of agriculture, as well as be subject to inspections by the commissioner.[326] The industry trade group, Biotechnology Industry Organization, argued against this legislative attempt, claiming it would "stigmatize North Carolina's promising agricultural research industry" and would serve to "stunt research and ultimately hurt farmers."[327]

It is possible that these regulatory efforts and negative sentiment toward genetically modified tobacco within the state may have deterred biotech companies from producing pharma crops in North Carolina. Today, permits are approved for the field testing of pharma tobacco varieties in the neighboring states of Virginia and South Carolina, and permit applications have recently been submitted for pharma tobacco trials in Montana and Kentucky. No permits for pharma field trials have been issued or even applied for in North Carolina, though permits have been granted for the field testing of other varieties of biotech tobacco, most of which are modified for insect control or herbicide resistance.[328]

Bill Dickerson heads the Plant Industry Division (PID) of the North Carolina Department of Agriculture and Consumer Services, which has regulatory responsibility for biotech crops in North Carolina. He is also president of the National Plant Board, which is a vehicle for collaboration among state plant health regulatory officials and for interaction with APHIS on plant health issues. He considers it PID's role to do whatever is necessary to protect conventional agriculture, while also positioning the state so that its farmers will be able to take advantage of biotechnology, including, if they choose, pharma tobacco technology.[329]

In its regulatory role, PID has been actively involved with the APHIS permitting process for biotech crops, at one time having a state law called the Genetically Engineered Organisms Act that gave a Genetically Engineered Review Board the authority to review and make decisions on biotech field trial permit applications independently of APHIS.[330] Although the statute has now expired, Mr. Dickerson says that PID continues to work closely with APHIS, takes the ability to comment on biotech field

---

325 Dickerson 2004.

326 North Carolina General Assembly 2001–2002.

327 Biotechnology Industry Organization 2001.

328 Information Systems for Biotechnology 2004(f).

329 Dickerson 2004.

330 106 N.C. Gen. Stat. § 765 et seq. (2003). For more on this law, see Vignette on Filling the State Legislative Gap.

trial applications seriously, has knowledgeable staff members, and maintains a close working relationship with academics and corporate individuals, who supply PID with valuable information needed to review their permit applications.[331] PID has a Biotechnology Services Program in place specifically to address biotechnology issues, a level of investment in biotechnology not many states have made.[332]

The North Carolina Farm Bureau has expressed views similar to PID's concerning biotechnology generally and biotech tobacco specifically, including its hope that biotechnology will benefit North Carolina producers. The Bureau supports developing clear guidelines for the handling of biotech tobacco in order to protect the value of conventional strains being grown in the state.[333]

Developing Identity Preservation and Containment Certification Guidelines

In response to the pressures and opportunities in North Carolina and recognizing the importance of the issue elsewhere, Bill Dickerson has worked with other state officials, as well as industry and biotech experts,[334] on a Tobacco Task Force Committee. The committee was commissioned by NASDA to develop voluntary protocols for preventing contamination across biotech and nonbiotech strains of tobacco. The protocols' full title further explains its structure and function: "Protocols to Prevent the Cross-Contamination of Genetically Engineered and Conventional Tobaccos during (1) Seed Identification and Handling, (2) Transplant Production, (3) Crop Production, (4) Crop Harvesting and Curing, (5) Crop Termination, and (6) Post Farm Marketing and Handling of Tobacco in the United States."[335]

The draft protocols include measures to preserve identity and prevent cross-contamination that address how the tobacco is cultivated, stored, and sold, as well as requiring recordkeeping for all stages of tobacco production from seed to market. The protocols provide that representative samples of harvested tobacco leaf be collected by USDA's Agricultural Marketing Service (AMS) and tested to confirm "the product's integrity" before shipment to the ultimate processor. Following harvest of a biotech tobacco crop, the field would be monitored for volunteer plants, which would be destroyed to ensure that the biotech crop does not contaminate subsequent tobacco or food crops.[336]

331 Dickerson 2004.

332 North Carolina Department of Agriculture and Consumer Services. 2003(b).

333 North Carolina Farm Bureau 2001.

334 Dickerson 2004.

335 NASDA 2003.

336 NASDA 2003.

The draft protocols include measures to preserve identity and prevent cross-contamination that address how the tobacco is cultivated, stored, and sold, as well as requiring recordkeeping for all stages of tobacco production from seed to market.

The protocols call for independent third parties to conduct necessary monitoring and verification that the prescribed procedures are followed, and they incorporate, by reference, process standards established by the International Standards Organization (ISO) as well as the "Identity Preserved Standards" established by the Association of Official Seed Certifying Agencies (AOSCA) or other "industry-recognized approved standards" for certifying seeds. The referenced AOSCA standards include crop-specific requirements for verifying that specific tolerance levels for genetic material resulting from biotechnology are met.[337,338] The overall procedures, process records, and test results used and generated throughout the assessment are to be made available for review by a designated third party that can certify that all objectives of the program have been met and the procedures and standards have been satisfied. This third party could be one of the field testing and lab certification agencies in AOSCA, the State Crop Improvement Association, AMS, or other approved inspection services.[339]

The idea is that the certification would foster confidence among both the public and commercial tobacco purchasers that cross-contamination between biotech and conventional tobacco had been prevented and that the identity and integrity of biotech and nonbiotech tobacco varieties had been preserved. The certification would supplement APHIS oversight by harnessing market incentives to achieve containment and identity preservation goals. APHIS has indicated that pharma crops will always be grown under permit (as well as being regulated concurrently by FDA), in contrast to the standard practice of deregulation under the PPA as the prelude to commercialization of biotech crops.[340] It is unclear, however, what containment or IP standards APHIS can impose under such a permit. Permit conditions under the Plant Protection Act must be justified as necessary to prevent risks posed by plant pests or noxious weeds. Although APHIS has established what it considers very effective containment protocols for pharma and industrial crops,[341] it may not be possible for APHIS to impose conditions that are based solely on economic or market-driven desires to preserve the identity and integrity of commercial crops. The certification system proposed by the Tobacco Task Force Committee would fill this void with respect to containment standards. It would also provide a means to ensure through third-party oversight and certification that the standards are met. APHIS and its state regulatory partners are unlikely ever to have the resources needed to provide the degree of compliance assurance potentially achievable through a market-driven certification program. These protocols, if adopted widely, would also have the advantage of providing consistent containment

337 Association of Official Seed Certifying Agencies 2003.

338 Association of Official Seed Certifying Agencies n.d.

339 NASDA 2003.

340 "APHIS envisions that plants which produce drugs and biologics will always be grown under APHIS permit and will be regulated concurrently by FDA and USDA." USDA APHIS n.d.(b).

341 USDA APHIS 2003(a); Bech 2004.

standards across all tobacco strains and growing regions. In contrast, under the current APHIS permit system, specific containment measures for biotech tobacco can vary from permit to permit, depending on what is needed to meet APHIS standards for containment and the safe planting of the crop.

Implications and Questions

The key difference between the proposed public-private certification system and the current APHIS regulatory approach is that the certification system is market-driven. The containment protocols would have the imprimatur of state government, but the criteria would be implemented by growers, who have an economic stake in the market integrity of their crops, and by tobacco buyers, who would likely want to include the protocols in their contracts with growers.[342] Bill Dickerson believes that certification will add value to certified tobacco crops by allowing them to bring higher market prices than uncertified crops. The eventual success or failure of the protocols, even if states choose to endorse them, thus hinges not on government action but on marketplace acceptance.[343] Reliance on the market may be the only realistic alternative in a world of limited government budgets, uncertain statutory authority to address purely economic concerns, and high public sensitivity about biotechnology, especially its use to produce pharma and industrial plants.

The proposed certification system has the potential not only to preserve the identity and integrity of tobacco products, but also to provide added assurance that pharma and other biotech tobacco crops would not inadvertently contaminate food crops. Some may question reliance on market mechanisms to help meet such public needs, and, presumably, if there were a risk of such contamination, APHIS or FDA should impose standards to prevent it. Even so, the problem remains of how to achieve adequate compliance and enforcement when government resources for inspection and other oversight are so limited.

If the public-private approach to certification of biotech tobacco proves successful, similar systems could be crafted for other biotech pharma and industrial crops or other biotech crops when added assurance of containment and identity preservation is desired.[344]

342 NASDA 2003.

343 Dickerson 2004.

344 Dickerson 2004.

The key difference between the proposed public-private certification system and the current APHIS regulatory approach is that the certification system is market-driven.

Filling the State Legislative Gap: Biotech-Specific Regulatory Statutes in North Carolina, Minnesota, and Iowa

The Issue in Brief

As discussed in Section III, most states do not have biotech-specific regulatory statutes, and there is a general preference among state regulators and stakeholders to rely on federal regulatory agencies to ensure the safety of biotech crops and foods for humans, plants, and the environment. Nevertheless, there is interest in some states in having at least an opportunity to consider these issues at the state level and having the legal tools to provide oversight that, in the judgment of local authorities, is needed to address local health and environmental concerns. In fact, 59% of respondents to the survey conducted for this report said that statutes and regulations at the state level are "very" or "somewhat" inadequate to provide needed oversight of biotech crops and foods.

To date, the efforts to fill this perceived gap in state regulatory authority are exemplified by experiences in three states—North Carolina, Minnesota, and Iowa—each of which has either enacted or considered enactment of laws establishing biotech-specific state regulatory programs to address health and environmental issues. A brief recap of the reasons states have had for these initiatives and their experiences with them is provided below, with brief commentary on the possible limitations on state authority to regulate separately in this area in light of existing federal laws and the constitutional principle of preemption. Efforts by states to legislate restrictions on biotech crops on economic grounds will be discussed in the vignette on biotech wheat that follows this one.

North Carolina

North Carolina was a pioneer in biotech regulation, being the first state in the nation to develop and enact a biotech-specific regulatory statute. The Genetically Engineered Organisms Act was signed into law in 1989, accompanied by the legislature's findings that:

> [B]iotechnology has enormous potential to benefit many fields of human endeavor ... the citizens of North Carolina may have concerns about the potential effects of planned introductions of new genetically engineered organisms on agriculture, public health and the natural environment ... certain introductions might pose unknown risks, and as such, require appropriate oversight. The General Assembly therefore determines that it

> is incumbent upon the State, working in concert with the federal regulatory authorities, to take responsible, timely and minimally burdensome measures to ensure that the public and the environment are protected ... while simultaneously allowing biotechnological research and product development to advance.[345]

The intent of the North Carolina law was to address public concerns about biotechnology through appropriate regulatory oversight so that the economic and other benefits of biotechnology could be enjoyed. It also reflected the desire of the state to cooperate with and, to the extent possible, rely upon federal regulatory assessments of biotech products. The core regulatory tool in the law was its prohibition of any environmental release of a genetically engineered organism (such as a field trial or commercial planting of a biotech crop) unless first authorized by a state-issued permit, or exempted from the requirement of a permit.[346] The law authorized the state to require that permit applications contain whatever information was needed to determine the potential adverse effects of the biotech crop or other product and, also, to impose such restrictions on the release as needed "to protect agriculture, public health or the environment." It also directed, however, that the permit applications follow the corresponding federal format "[t]o the extent feasible."

The law provided specifically that the state permit could be "based on the federal review and approval of the proposed release" if the state determines that the federal regulation of the release sufficiently protects agriculture, public health, and the environment in North Carolina."[347] In the spirit of minimizing the impact of the state regulatory process on the pace at which biotech products could be cleared for release, the regulations implementing the law provided that the state review process should occur during the same time-frame required for a federal permit and that public hearings would be commissioned only when the state "determines that significant public interest and justification exist."[348]

The adoption of the law was supported by a diverse set of stakeholders, and it was developed through a participatory process under the auspices of the North Carolina Advisory Committee on Biotechnology in Agriculture.[349] This committee, which included environmental organizations, the biotech industry, regulatory officials, and academics, was also instrumental in developing regulations to implement the law.

The law gave primary regulatory authority and policymaking responsibility to the Genetic Engineering Review Board (GERB), a ten-member body representing key state agencies, universities (including schools of agriculture and public health), farm organizations, the biotechnology industry, and the public interest community. [350] The GERB was authorized to delegate

345 North Carolina General Assembly 1989–1990.

346 North Carolina General Assembly 1989–1990, sections 106–772.

347 North Carolina General Assembly 1989–1990.

348 North Carolina Administrative Code n.d.

349 Information Systems for Biotechnology 1992.

350 North Carolina General Assembly 1989–1990.

functions other than rulemaking, but including the permitting process, to the North Carolina Department of Agriculture (NCDA), which was also given responsibility under the law for enforcement. For those found in violation of any aspect of the law, a penalty of up to $10,000 can be assessed, depending upon the severity of the infraction.[351]

The law directly addressed the CBI issue, specifically authorizing the state to call for the submission of CBI if needed to conduct a permit review.[352] The law set up an appeals process for applicants that objected to the submission of CBI, but, unless the state decides that the CBI is not necessary for the review, the applicant must either submit the information or withdraw the application.

A key feature of the North Carolina law was its sunset provision, under which the law would expire five years after enactment unless reauthorized by the General Assembly. By the end of 1995, the law lacked enough organized support for reauthorization and was allowed to expire. One factor may have been that the law was enacted well before field trials involving biotech crops took off in number, and, when the law expired, the first significant commercialization of biotech crops and foods was still a year away. Though stakeholder interest in biotechnology remained high, the law may simply have been ahead of its time in terms of sustained public and political interest in oversight of agricultural biotechnology at the state level. In addition, according to Bill Dickerson, the senior plant health regulator in North Carolina, the federal regulatory oversight system had come on line by the time the state law was due to expire, and there was confidence in North Carolina government circles that the federal process would adequately address the core safety and environmental issues.[353]

Minnesota

Minnesota's experience with biotech-specific regulatory legislation is quite different from North Carolina's. The law was enacted amid controversy and conflict, but remains on the books and in operation today.

Minnesota first enacted a biotech-specific regulatory statute in 1991 to address release of genetically engineered organisms for any purpose, including but not limited to agriculture. Originally, the state's Environmental Quality Board (EQB) administered the law, but, in 1994, the law was amended to give the commissioner of agriculture authority over agricultural applications of biotechnology,[354] which account for most of the biotech releases in the state. In contrast to the cooperative spirit surrounding enactment of North Carolina's biotech statute, the debate in Minnesota was heated. The biotechnology industry was not supportive of the legislation,

351 North Carolina General Assembly 1989–1990.

352 North Carolina General Assembly 1989–1990, sections 106–774.

353 Dickerson 2004.

354 Minnesota Statutes 2003(a).

feeling that the "rules are unduly alarmist, are redundant compared to existing federal regulations, and may cause some of the state's biotech firms to flee."[355] Those supporting the law said it was not meant to duplicate efforts of the federal government, but rather "to shore up gaps in the way the federal government regulates the planned release of GEOs (genetically engineered organisms) into the environment for commercial use."[356]

Compared to the North Carolina statute, the Minnesota law places less emphasis on regulation as a means to foster the advance of biotechnology and focuses more narrowly on health and environmental objectives. The stated purpose of the law is to "establish permits for the release of certain genetically engineered agriculturally related organisms to protect humans and the environment from the potential for significant adverse effects of those releases."[357] It achieves this purpose through a permitting process that is described in detailed regulations.[358]

The Minnesota regulations provide that federal documents, analyses, and regulatory actions can be considered in determining whether to grant a permit, but the Minnesota law and regulations also empower the commissioner of agriculture to require whatever data and impose whatever conditions are necessary to ensure that the proposed release "does not have the potential for unreasonable adverse effects on the environment."[359] Each permit review must be accompanied by the preparation of an Environmental Assessment Worksheet (EAW) prepared in accordance with the procedures and requirements of the EQB. [360] The EAW is a preliminary analysis conducted by the Department of Agriculture on the basis of which the department determines whether a full environmental impact statement is needed. The Minnesota biotech law encompasses all biotech crops, including ones that have pesticidal properties.[361] And, paralleling the APHIS oversight system under the federal Plant Protection Act, Minnesota has established a notification procedure, as an alternative to the permit process, for biotech plants that meet criteria suggesting lesser risk of adverse impact and that will be released under "performance standards" that ensure adequate containment.[362]

355 Zielinksi 1992.

356 Zielinksi 1992.

357 Minnesota Statutes 2003(a), § 18F.01.

358 Minnesota Rules n.d.(b).

359 Minnesota Statutes 2003(a), § 18F.07.

360 Minnesota Statutes 2003(b); Minnesota Rules n.d.(a).

361 Minnesota Rules n.d.(b), section 1558.0020, Subpart 13.

362 Minnesota Rules n.d.(b), section 1558.0060.

Compared to the North Carolina statute, the Minnesota law places less emphasis on regulation as a means to foster the advance of biotechnology and focuses more narrowly on health and environmental objectives.

After a permit application is accepted by the commissioner as complete and the EAW is available, the application and EAW are reviewed by an interdisciplinary group of experts selected by the commissioner and other state agencies, as appropriate. The state agency reviewers and agencies receive all data and information in the application, including CBI, which Minnesota calls "not public data" and protects from public disclosure under the Minnesota Government Data Practices Act.[363] The interdisciplinary reviewers, typically based in universities, receive a CBI-deleted copy of the EAW. They may seek and receive permission from the Department of Agriculture to review the EAW with CBI included if they sign a nondisclosure agreement and do not represent any business interest in competition with the applicant. The application is also distributed to the Legislative Reference Library and local governments and is made available to anyone who requests it, but with the "not public data" removed. To date, only one company has chosen to forgo a biotech field trial in the state because it would have to include CBI in its permit application.[364]

Persons holding permits or whose field trials or other releases have been authorized through the notification process are required to give regulators access to the release site for inspection to ensure compliance with the permit or notification conditions. Records on field releases must be retained for three years. The penalty for failing to comply with the permit or notification restrictions is revocation or suspension of the permit or notification, rather than any monetary penalties.

Finally, the Minnesota law and regulations provide for exemptions from the permit requirement for biotech crops when substantial evidence, including previous releases, demonstrate that the crop "can be released under alternative oversight without adverse effects to humans or the environment."[365]

Since 1995, the Minnesota Department of Agriculture has granted 66 permits for biotech field trials, authorized 524 biotech trials through the notification process, and granted 31 exemptions.[366] Two staff members in the Department of Agriculture manage the regulatory oversight of biotech crops; one has responsibility for pesticide-producing plants, while the other oversees all other biotech plants. As in other states, these regulators have other responsibilities as well, and the biotech component comprises a small percentage of their jobs. With the available resources, the state attempts to inspect a subset of the field trials conducted in Minnesota, including at least one site from each applicant company and each crop and type of genetic modification authorized for field trial. This resulted in inspections in connection with about 50% of the applications in 2003, though not every approved location under those applications.[367]

---

363 Minnesota Statutes 2003(c).

364 Hanks 2004.

365 Minnesota Statutes 2003(a), §18F.13.

366 Minnesota Department of Agriculture n.d.

367 Minnesota Department of Agriculture n.d.

The Minnesota law has remained controversial in some quarters. During legislative session 2003–2004, Senator Larry Pogemiller introduced a bill that would repeal the authority of the state Department of Agriculture to require permits for biotech crops. This bill passed the Senate, but died in the House.[368]

Iowa

As a Corn Belt state, Iowa has a long history in the development, field testing, and commercial production of biotech crops and a political climate that is generally very supportive of biotech crops and foods. The StarLink and ProdiGene incidents and the potential implications of future products coming down the biotech pipeline have prompted regulatory officials in the Iowa Department of Agriculture and Land Stewardship (IDALS) to consider whether the state's regulatory structure is prepared to protect Iowa's environment, citizens, and agriculture industry. In response to the survey conducted for this report, Robin Pruisner, the State Entomologist, said that, while Iowa is well-prepared to ensure compliance with field trial conditions, it is poorly prepared in other areas, such as review and approval of field trials, review and approval of products for commercial production, and monitoring for unanticipated health or environmental consequences of commercially marketed products. Iowa currently has no biotech-specific regulatory statute.

IDALS brought stakeholders together in 2003 to discuss the adequacy of the state's regulations for biotech crops with a view toward collaboratively developing and introducing legislation that would provide the state with explicit regulatory authority. Commodity groups and the biotech industry generally opposed additional state regulation of biotech crops on the ground that federal oversight is sufficient and that the burden of registration fees and state permit requirements would be an impediment to doing business in Iowa.[369]

Unable to put together a collaborative stakeholder process, IDALS drafted and submitted its own bill during the 2004 legislative session to address specifically pharma and industrial crops.[370] Modeled on the Minnesota law, the bill would establish a permit requirement for these crops, thus giving Iowa independent legal authority to regulate pharma and industrial crops. The bill calls on IDALS to establish rules for the permit system that are compatible with APHIS and FDA requirements. It would have given IDALS wide leeway to craft rules "to protect agricultural production in this state" and to impose conditions on the conduct of pharma and industrial crop field trials. The bill also would provide IDALS strong authority to conduct investigations and enforce the bill's permit and other requirements,

368 Minnesota Senate 2003–2004.

369 Pruisner 2004.

370 Pruisner 2004.

including authority to impose monetary penalties for violations. Finally, it would establish, as a financing mechanism for the new regulatory program, a permit application fee of up to $5,000, which would be deposited into the Pharmaceutical and Industrial Bioengineered Plant Compliance Fund for use in administering the program.

While it reflected IDALS' view of the statutory authority needed to oversee pharma and industrial crops in Iowa, the bill was never assigned to a committee and thus died in the 2004 legislative session.

Common Themes and Possible Limits on State Biotech Legislation

Adoption by a state legislature of any biotechnology-related legislation inevitably reflects diverse local concerns and politics and the serendipity of leadership by individuals or groups to conceive and push for enactment of a law. Meaningful generalizations about why states might adopt legislation are thus difficult to come by. Perhaps the central common theme in the three cases outlined above, however, is that states adopting legislation are of two minds. First, they seek authority independent of the federal government to make decisions about the development and application of biotechnology within their borders. Second, they still look to, and want to collaborate with, the federal government in assuring the safety of biotech crops and foods for health and the environment. States want a role, but they don't want to go it alone.

The most concrete practical consequence of state regulatory statutes may be their impact on state access to CBI. Without their own laws for overseeing and permitting biotech crops, states are dependent on APHIS for information concerning activity within the state, and, under the federal FOIA, as implemented by the APHIS CBI policy, APHIS shares relatively little information. The adoption of a state law and permit requirement cuts through the CBI issue. Rather than relying on APHIS or on the voluntary cooperation of companies to obtain detailed information, states with their own permitting law get the information on their own terms directly from the company seeking to conduct a trial in the state. Whether or not the state permit process results in any restrictions or other conditions on the trial that would not have been imposed by APHIS, the availability of the data to the states and its empowerment to act if necessary may serve an important purpose in terms of the state government's credibility and public confidence in its oversight of biotech crops.

The most concrete practical consequence of state regulatory statutes may be their impact on state access to CBI.

What if a state does choose to impose restrictions on a biotech field trial beyond those imposed by APHIS, or even to prohibit a trial authorized by APHIS? What are the limits on the state's authority? Unfortunately, the answer is not clear. The analysis required to address the question is grounded in the Plant Protection Act and its preemption provision.[371]

The PPA authorizes APHIS to regulate the "movement" of plants and other articles "in interstate commerce" and to regulate imports for purposes of controlling plant pests and noxious weeds or otherwise achieving the purposes of the PPA. The PPA's preemption provision prohibits states from regulating plants and other articles "in interstate commerce" *if* APHIS "has issued a regulation or order to prevent the dissemination of the ... plant pest, or noxious weed within the United States," except that a state may so regulate if its "prohibitions or restrictions ... are consistent with and do not exceed the regulations or orders issued by [APHIS]." It also prohibits states absolutely and without exception from regulating "in foreign commerce" to achieve the plant pest and noxious weed control purposes of the PPA.

Under this provision, states are clearly free to act to address local plant pest concerns if no interstate or foreign commerce is involved, and they can regulate movements "in interstate commerce" if APHIS has not acted. Even if APHIS *has* acted, such as by issuing a permit defining the conditions under which a biotech crop can be planted so as not to pose a plant pest risk, a state could presumably still have its own statutory permit requirement and issue its own permit establishing conditions that "are consistent with and do not exceed" the APHIS conditions.

But, suppose APHIS has granted a permit imposing certain restrictions to address a plant pest concern and the state, under its permit statute, wants to address the plant pest concern by imposing conditions on growing practices within its borders that exceed the APHIS conditions. Here, the answer is unclear, in part because the language of the PPA's preemption provision is unclear, and its meaning has yet to be interpreted by a court. The lack of any judicial interpretation reflects the absence to date of real conflict between APHIS and the states on the extent and boundaries of their respective legal authorities. The actual practice between APHIS and the states has been one of cooperation and accommodation. In the future, however, conflict could arise, such as if a state sought to prohibit as a plant pest a pharma crop for which APHIS had granted a permit.

371 7 USC 7756.

In that case, the state could argue that it is not preempted because it is not regulating the movement of anything in interstate commerce, only the growing of a crop solely within its borders. It could also argue that APHIS has not "issued a regulation or order to prevent the dissemination of the ... plant pest," but rather has, through the permit, authorized its dissemination. APHIS, on the other hand, could argue that its permit regulates both the movement of seed across state lines and the planting and growing of the crop, all of which is one continuous course of conduct that is "in interstate commerce." APHIS could also argue that the permit, with its conditions, exists for the very purpose of allowing the movement of the seed and the growing of the crop while *preventing* dissemination of a plant pest: the permit conditions keep the pharma plant from posing a plant health risk.

It is difficult to predict which side would win this argument. The state action would be subject to challenge in any event, of course, and would be most vulnerable to successful legal challenge if the planted seed had moved in interstate commerce.

Suppose, however, that the state sought to regulate a permitted pharma crop to address an environmental rather than plant pest concern. In this case, because current APHIS permitting regulations have been adopted only under the preexisting plant pest provisions of the PPA, the state would be on stronger footing in arguing that APHIS had not acted by "regulation or order" to address the environmental concern and thus that the PPA would not preempt the state action. As noted, the PPA preemption provision has not been tested in the courts. Any preemption challenge would be resolved based on both new legal interpretations and the particular facts of the case with respect, for example, to the purpose or purposes for which the state was regulating. This makes the outcome unpredictable.

It is also unpredictable when or whether the argument will take place in a meaningful setting. State and federal regulators have a strong interest in coexistence and collaboration, and thus it is reasonable to expect the pattern of accommodation on regulatory oversight of biotech crops will continue. States remain free as both a legal and practical matter to adopt their own permitting statutes and processes. Only if there is direct conflict between state and federal regulatory actions does an issue arise. In such an instance, both sides would have good arguments, and the outcome would remain uncertain until the courts step in to define the limits of state authority.

Legislating Restrictions on Biotech Crops on Economic and Social Grounds: Roundup Ready Wheat

The Issue in Brief

On May 10, 2004, Monsanto Company announced the suspension of its plans to commercialize Roundup Ready (RR) wheat.[372] This decision did not come in response to any health or environmental regulatory concern. Regulatory review was underway at APHIS and FDA, with most observers not expecting either agency to object to the product.[373] Monsanto's decision was driven, rather, by a declining wheat market and the apparent unreadiness of the market to accept the product. U.S. wheat producers had voiced concerns that their customers—foreign and domestic—might not accept RR wheat and that key export markets, such as Japan and Europe, might be closed to all U.S. wheat exports due to concerns within those markets that it would not be possible for the marketplace to adequately segregate biotech and nonbiotech wheat. Prior to Monsanto's decision, a number of U.S. wheat producers and other food system stakeholders had mounted a campaign in opposition to the commercialization of RR wheat, at least until the market acceptance issues had been resolved—a campaign that included efforts to persuade state legislators to take action against the commercialization of Roundup Ready wheat.

This experience illustrates acutely how economic concerns can drive activity at the state level and poses the question of what role state legislatures and governments should play in accepting or rejecting biotech crops and foods on economic or other social grounds, rather than for health or environmental reasons. It also raises the question of the authority of state governments to prohibit the planting of a biotech crop for economic reasons.

The Economic Interests of States

Wheat is an important agricultural commodity in the United States, ranking third, behind corn and soybeans, in planted acreage and gross farm receipts.[374] In 2002, total U.S. wheat production was over 1.6 billion bushels, valued at almost six billion dollars.[375] Almost half of the wheat produced in the United States is exported, accounting for approximately 7.5% of all U.S. agricultural exports by value.[376] The top wheat-producing states—Kansas, North Dakota, Washington, Montana, and Oklahoma—accounted for over half of the U.S. wheat production in 2002.[377]

372 Monsanto Company 2004. RR wheat is a genetically modified variety designed to be resistant to the herbicide Roundup®, a Monsanto Company product commonly used for weed control.

373 FDA has since completed its premarket consultation with Monsanto, which means the agency would not object to the marketing of foods produced from Roundup Ready wheat. Fabi 2004.

374 USDA ERS 2000.

375 USDA NASS 2003(a).

376 Western Organization of Resource Councils 2002.

377 Western Organization of Resource Councils 2002.

Compared with recent developments in the corn and soybean markets, however, the market for wheat has been in decline. Loss of global export market share, low real prices, and a drop in wheat harvested area from its peak in 1981—all have contributed to the decline of the U.S. wheat market.[378] This weak outlook has contributed to the contentious environment surrounding the commercialization of RR wheat. Monsanto had planned to introduce a spring wheat variety grown primarily in the Northern Plains states of North Dakota, Montana, South Dakota, and Minnesota.[379]

While some stakeholders raised agronomic, environmental, and food safety issues concerning the commercialization of RR wheat, the predominant concern voiced in the debate at the state level pertained to its potential economic impact, based on doubts about consumer acceptance and continued U.S. access to wheat export markets. For wheat growers, any threat to export markets is a grave concern. A customer survey conducted by a U.S. wheat trade group had shown strong resistance to RR wheat in key export markets, such as those in Asia.[380] Only a small percentage of respondents in Taiwan (18%) and South Asia (22%) said they would accept RR wheat.[381] The reaction in Japan, the largest export market for U.S. spring wheat,[382] is illustrative of the resistance to biotech wheat and the resulting economic problem. The Japanese Food Agency stated that "the import of [biotech] wheat would be almost impossible without consumers' acceptance and flour millers' demand, even after Japan provided the regulatory safety approval."[383] The Japan Flour Millers Association, whose members command over 90% of the total wheat market in Japan, has expressed concern about RR wheat based on anticipated consumer reaction.[384]

In light of these marketplace realities, a university researcher analyzed the short-term economic impact on U.S. wheat export markets of introducing RR spring wheat and concluded that "up to 30–50% of the foreign market for hard spring wheat and durum wheat exports could be lost."[385]

Arguably, one way to minimize the economic impact of RR wheat would be to establish a segregation system that would preserve the identity of the biotech and nonbiotech varieties and channel the RR wheat to markets where it would be accepted. This approach has been used to help ensure that U.S.-produced biotech corn that is not approved in Europe is channeled elsewhere. The practical limits of any segregation and identity preservation (IP)

---

378 USDA ERS 2000.

379 Wilson et al. 2003.

380 U.S. Wheat Associates 2002(b).

381 U.S. Wheat Associates 2002(b).

382 Japan imports 47 million bushels of U.S. spring wheat, followed by the Philippines (31.3 million), Taiwan (21.4 million), Italy (15.7 million) and Korea (13.3 million). North Dakota Wheat Commission 2002–2003.

383 North Dakota Wheat Commission 2002–2003.

384 U.S. Wheat Associates 2001.

385 Wisner 2003.

system are well recognized. As one respondent to a survey of grain elevator operators in North Dakota said, "it's impossible to have a segregation system with zero tolerances."[386] Some foreign markets have already indicated that, even with a well-functioning IP system, they will be forced to import wheat from other countries if RR wheat is commercialized in the U.S.[387]

Stakeholder Perspectives

Concerns about the commercialization of RR wheat have come from across the spectrum of stakeholders. Unlikely allies, such as wheat farmers, producer associations, the food industry, organic growers, consumer groups, environmental organizations, and states, have joined in opposition, with organic farmers being among the most vocal opponents. Even groups that have historically been supportive of biotechnology, such as trade associations, are raising concerns about the economic implications of RR wheat. For example, the U.S. wheat industry's position on biotechnology acknowledges that while "biotechnology research holds great promise for the future, ... our customers' needs and preferences are the most important consideration ... we strongly urge technology providers to obtain international regulatory approval and to ensure customer acceptance prior to commercialization."[388] Wheat growers who opposed commercialization of RR wheat were also wary of the possibility that the United States might approve the product without a parallel approval in Canada, thus risking loss of export markets to Canadian competitors.

The Farm Bureau's statement on agricultural biotechnology also emphasizes that access to international markets "is crucial for future trade of U.S. farm and ranch products."[389] To help ensure continued market access, the Farm Bureau has suggested that the White House designate a lead person to coordinate the administration's biotechnology policy and the efforts of the three main agencies that regulate biotechnology.[390]

The food industry, while confident of the safety of biotech crops and foods, is concerned about consumer perception and market acceptance of biotech wheat. Ron Triani of Kraft Foods noted that Kraft is unsure as to whether or not it will use biotech wheat in its products because of consumer concerns and emphasized that "we need to maintain consumer confidence in our products and we need to protect the equity of our brands."[391]

Monsanto has worked with the wheat industry and other stakeholders to address these concerns. In January 2002, Monsanto issued its RR wheat pledge, committing the company to not commercially releasing RR wheat until the following criteria had been met: (1) regulatory approval in the United States,

386 Institute for Agriculture and Trade Policy 2003.

387 U.S. Wheat Associates 2002a, 2002b.

388 U.S. Wheat Associates et al. 2004.

389 American Farm Bureau Federation 2004.

390 American Farm Bureau Federation 2004.

391 Triani 2003.

Canada, and Japan has been obtained; (2) appropriate regulatory controls are in place to ensure access to export markets; (3) appropriate grain handling protocols and analytical methods are developed and implemented; (4) grower stewardship programs and best management practices are in place; (5) varieties are of industry standards for end-use quality; and (6) export markets are secured.[392] The press reported in March of 2004, however, that Monsanto informed the wheat industry it was reconsidering its commitment to obtain regulatory approval from Canada prior to commercialization because the regulatory environment in Canada was proving difficult to navigate.[393]

Regulatory approval in Canada has proven difficult for Monsanto due to consumer and producer resistance. The Canadian stakeholder community has worked diligently to slow the commercialization of RR wheat. In a letter to Canadian Agriculture Minister Lyle Vanclief, wheat producer associations, marketing boards, and soil conservation associations argued that the government should include in its regulatory approval process a cost-benefit analysis of the market impacts of commercializing RR wheat.[394] In a news release, the Canadian Wheat Board (CWB), a producer-controlled grain marketing organization, asked Monsanto to "put the interests of their customers, western Canadian farmers, ahead of their own commercial interests and put the brakes on [RR wheat]."[395]

State Actions

With livelihoods on the line, Monsanto's RR wheat pledge apparently left many in the Northern Plains wheat-producing states unsatisfied. Some stakeholders in these states pursued individual actions to protect their economic interests, while others worked with regional and national advocacy organizations to put forth citizens' petitions, ballot measures, and state legislative proposals.

In March 2003, individual wheat farmers, state senators, and farmer organizations in the Northern Plains petitioned USDA to deny Monsanto's request for authorization to commercialize until the government fully assessed the environmental and economic ramifications of biotech wheat, including the feasibility of segregating it from nonbiotech wheat.[396] Almost a year later, additional groups, such as the Organic Trade Association, the Minnesota Farmers Union, and the National Catholic Rural Life Conference, joined in

392 Monsanto Company 2003.

393 Gillam 2004(b).

394 Hildebrand et al. 2003.

395 Canadian Wheat Board 2003.

396 Dakota Resource Council et al. n.d.

Some stakeholders in these states pursued individual actions to protect their economic interests, while others worked with regional and national advocacy organizations to put forth citizens' petitions, ballot measures, and state legislative proposals.

support of the original petition. This petition was considered significant because it "raised issues like loss of export markets and the danger of super weeds, that, frankly, the USDA has never looked at seriously before in other crops," according to the Institute for Agriculture and Trade Policy, an organization critical of agricultural biotechnology.[397]

The petition to USDA followed state legislative initiatives that had attempted to protect state economic interests.[398] North Dakota has been one of the most active and outspoken states on the commercialization of RR wheat. The state first considered legislation on the subject in 2001, based on the expectation that Monsanto would commercially introduce RR wheat between 2003 and 2005. This legislation would have provided the state's Seed Department with the authority to create a seed and crops verification program for producers who wanted to cultivate nonbiotech varieties for markets that would not accept biotech crops and foods.[399]

In 2003, a bill was introduced in the North Dakota legislature with the support of Commissioner of Agriculture Roger Johnson to mitigate the effects of biotech wheat on the state by creating a Transgenic Wheat Board. The bill would have charged the board with monitoring biotech wheat research and export market acceptance of biotech wheat, but it never made it out of committee. Other bills introduced in North Dakota addressed liability for contamination of nonbiotech crops with the biotech varieties and proposed requirements for seed retailers or distributors to obtain certificates of approval for biotech wheat seed prior to sale in the state.[400] Similarly, a ballot measure was proposed that would give the North Dakota agriculture commissioner power over whether or not genetically modified wheat seeds could be planted in the state, based on public hearings and consultation with a panel of experts.[401] Following Monsanto's decision not to pursue commercialization of RR wheat, the push to get this measure on the ballot was suspended.

Other states also introduced legislation to deal with the RR wheat issue. Montana legislators, for example, introduced nine bills on RR wheat from 2001 to 2003.[402] These included bills establishing a moratorium on biotech wheat, creating a Wheat Bond Board, establishing a committee to analyze market impacts of biotech wheat, and requiring the state department of agriculture to implement a certification process for the introduction of biotech wheat. From the perspective of the Montana Grain Growers Association (MGGA), the bills to regulate or restrict RR wheat were motivated by organic producers, groups concerned about the presence of large corporations in Montana agriculture, and others who feared loss of market share for Montana wheat due to consumer fear of biotechnology. The MGGA, on the other hand, was generally comfortable with the principles Monsanto had

397 Institute for Agriculture and Trade Policy 2004.

398 Dakota Resource Counsel 2003.

399 Cropchoice 2001.

400 North Dakota Legislative Assembly n.d.(a), n.d.(b), n.d.(c).

401 Associated Press 2004; Limvere et al. 2004.

402 Montana State Legislature 2001(a,b), 2003(a,b,d–h).

agreed to as the basis for deciding whether to market RR wheat.[403] Although the legislative efforts failed, the Montana legislature did pass a joint resolution in April of 2003 stating that "... genetically engineered wheat or barley should be grown in Montana only when there is acceptance of these genetically engineered crops by a majority of Montana's foreign markets."[404]

Current Status

In announcing that it was dropping plans to commercialize RR wheat, Monsanto said it was "realigning research and development investments to accelerate the development of new and improved traits in corn, cotton and oilseeds," and that it plans to discontinue field-level research on the biotech wheat. [405] The press reported that the company had indicated it would not necessarily withdraw its petition at APHIS for nonregulated status,[406] but as of June 17, Monsanto had retracted its RR wheat submissions from all the federal regulatory agencies except FDA.[407]

The wheat industry commended Monsanto's decision, commenting that, "This isn't the end of biotech in wheat ... this is just a decision by Monsanto that the market's not ready yet."[408] Though Monsanto said its decision was not based on public pressure—it cited declining market and planting acreage for spring wheat—consumer groups viewed the decision as a victory, asserting that issues of "[c]onsumer acceptance and the readiness of the commercial markets are as important as food and environmental safety for biotech crops these days."[409] Many Northern Plains wheat farmers were relieved by the decision. A representative of the North Dakota Farmers Union indicated that the group is not opposed to the technology. Rather, it is concerned about the potential loss of export markets that may occur if biotech wheat is commercialized at this time.[410]

Despite Monsanto's decision, the issues surrounding acceptance of GM wheat are not over. Syngenta AG, a Switzerland-based company, recently announced plans to release a fusarium-resistant biotech wheat variety as early as 2007.[411]

Implications and a Question About State Authority

In the end, Monsanto's decision not to proceed with RR wheat was driven by the marketplace. Many stakeholders in the debate had looked, however, to state governments to protect their economic and other social interests.

---

403 Stoner and Edwards 2004.

404 Montana Legislature 2003(g).

405 Monsanto Company 2004.

406 Pollack 2004.

407 Rampton 2004.

408 Coppock 2004.

409 Pollack 2004.

410 Pollack 2004.

411 Gillam 2004(a).

The willingness of political leaders to consider interventions was an important part of the backdrop for Monsanto's decision. It seems well-established at the federal level that government regulatory decisions related to biotech crops and foods should be made on the basis of traditional health and environmental concerns. At the state level, however, the potential economic impact of particular biotech crops on agricultural producers is felt more acutely, and their interests are more readily brought to bear through the political process. It seems likely that agricultural and other interest groups will continue to bring their concerns about biotechnology—pro and con—to state government.

This political dynamic raises important public policy questions about what if any role government should play in making choices concerning agricultural and food technologies that are based on economic and social issues, and about the impact of state-level decisions on the national market and regulatory system. Some would argue that the states should leave these decisions to the marketplace and that state-by-state action would be economically disruptive and in conflict with the national and international reality of our food and agricultural system. Others would contend that the states have a legitimate role to play in protecting local economic interests and that the economic and social consequences of some technology decisions are important enough to warrant government intervention.

An underlying issue in this policy debate concerns the legal power of states to restrict or prohibit particular applications of agricultural biotechnology on economic or social grounds. This is a complicated question of constitutional law for which there is no definitive answer, and a full analysis of the issue is beyond the scope of this report. The express preemption provision in the PPA and FIFRA's provisions concerning the authority of the states do not apply, because they address the power of states to regulate for plant health and environmental purposes that are the concern of those federal laws.

The issue must be considered in light of broader principles arising under the Supremacy Clause and the Commerce Clause of the U.S. Constitution. Under our federal system, states have broad power to act to protect the welfare of their citizens, and, under the Tenth Amendment to the Constitution, powers not delegated to the federal government—such as the power to regulate purely local matters—are specifically reserved to the states. On the other hand, the Commerce Clause gives the federal government broad powers to regulate matters in or affecting interstate and foreign commerce and the Supremacy Clause makes laws properly enacted by Congress the supreme law of the land. Moreover, the federal jurisdiction to regulate foreign commerce is exclusive: states are precluded from any role in regulating foreign commerce.

Under the Supremacy Clause, the federal government would likely have the power to prohibit states from blocking the planting of biotech crops and foods on economic or social grounds if it chose to exercise that power—that is, if Congress passed a law finding that decisions about planting biotech crops and foods, even within a state's own borders, have an important impact on interstate commerce and establishing as the policy of the federal government that any consideration of economic or social issues must occur at the federal level.

Congress has, of course, not passed such a law, and thus the question is whether, in the absence of a binding federal policy on consideration of economic and social issues, the states are free to act. This question would turn on application of the Supremacy and Commerce clauses. Under the Supremacy Clause, preemption of state law can be express (as when Congress declares its specific intent to displace state law) or implied (as when a state law conflicts with or interferes with achieving the objectives of federal law, or operates in an area that Congress intended to control exclusively).

Express preemption under the Supremacy Clause does not operate here because the PPA's preemption provision only preempts state regulation for plant pest and noxious weed control purposes; it does not address the preemption status of state actions to address broader environmental, economic, or social concerns. Thus, the first question in this Supremacy Clause implied preemption analysis would be whether a state restriction on a particular application of agricultural biotechnology, based on economic or social grounds, directly conflicts with some federal law concerning interstate commerce or interferes with achieving the objectives of the federal law. The second question is whether the federal government has fully occupied the field of decisionmaking about the planting of biotech crops and foods. In considering the first question, it is important to note that it is not enough for the executive branch of the federal government to have a policy on the question at hand; for implied preemption of a state law to occur, there must be a federal law with which the state law conflicts or whose objectives it frustrates.

Thus, under the doctrine of implied preemption, the practical questions appear to be: Is there a statutory policy at the federal level that precludes consideration of economic and social concerns at the state level or that would be frustrated by state action taken on that basis? Do the federal regulations administered by APHIS, EPA, and FDA fully occupy the field of decisionmaking about the planting of biotech crops and foods?

The Commerce Clause, which places the power to regulate interstate commerce in federal hands, raises similar questions. States are clearly prohibited from acting in ways that discriminate against interstate commerce. However, if the effects on intrastate and interstate commerce are even-handed, states are not precluded by the Commerce Clause from taking local actions that have incidental effects on interstate commerce, provided the burdens on interstate commerce are not clearly excessive in relation to the

local benefits of the action. On the other hand, if a state action is found to undermine the purposes of the Commerce Clause—in terms of having a well-functioning national economy—courts may preclude such action.

Finally, suppose a state sought to prohibit the growing of a particular biotech crop, such as RR wheat, specifically for the purpose of preserving access to foreign markets for its growers of conventional wheat. The express preemption provision of the PPA would not apply, and it is not clear on what basis such state action could be deemed preempted by implication under the Supremacy Clause. There is no clearly conflicting federal policy on the subject. In addition, the federal government arguably has not totally occupied the field of decisionmaking because its market entry standards for biotech crops and foods address only health and environmental concerns, not access to foreign markets or other economic and social concerns. Under the Commerce Clause, a balancing test applies to a state law regulating or affecting interstate, but nonforeign, commerce: the question under this test is whether the effects on interstate commerce are incidental and are outweighed by the local benefits. If so, the state action can stand.

But, what about the total exclusion of states from regulating foreign commerce? Does a state ban or restriction on the planting of a biotech crop for purposes of protecting the access of a state's farmers to foreign markets constitute regulation of foreign commerce? A state taking such action might argue that it is merely regulating local behavior for the benefit of its own citizens and that foreign commerce per se and parties outside the state are not affected. A party opposing such action might argue that access to foreign markets by U.S. producers is a national concern and that any state action that attempts to influence such access directly affects foreign commerce and conflicts with the exclusive federal jurisdiction to regulate foreign commerce. Clearly, if a court found that it was the intent or effect of a state action to regulate foreign commerce, such action would be constitutionally barred.

The purpose of reciting these principles and arguments is not to answer the question about whether a state could prohibit the introduction of a biotech crop or food for economic or other social purposes. The factual and legal issues that would be involved in the event a state took such action could vary widely and are likely to be complex. The result of a legal challenge would, in the end, turn on the circumstances of the particular case and thus is unpredictable. These principles suggest, however, that the questions that would be debated in a legal setting are not very different from the ones that should be considered from a policy perspective. They have to do with how, in our national economy and federal system of government, we reconcile local interests with the interests of our broader society. Fortunately, these issues are more often than not worked out through the political and policy process, or, as in the case of RR wheat, in the marketplace, rather than in the courts.

Under the Commerce Clause, a balancing test applies to a state law regulating or affecting interstate, but nonforeign, commerce: the question under this test is whether the effects on interstate commerce are incidental and are outweighed by the local benefits.

V. CONCLUSION AND QUESTIONS FOR THE FUTURE

The goal of this report is to compile and present information on state oversight of biotech crops and foods in a way that informs policymakers and stakeholders. The report does not draw conclusions about current state activities or make recommendations for change. Through the research conducted for this report, however, questions that seem to underlie much of the discussion and debate concerning the state role were identified. These are questions that seem likely to recur around the country and remain important to the debate for the foreseeable future. They are outlined here to help focus and stimulate future discussions.

Priority of Biotechnology for State Government

For any particular state, how important is biotechnology and the regulatory oversight of biotech crops and foods in relation to all the other topics that compete for the attention of agriculture, environmental, and health departments, and of the state government at large?

Scope of the Issues Appropriate for State Oversight

Should the state government limit its oversight role to traditional regulatory concerns involving food safety, plant health, and the environment? Should the state also tackle economic and social concerns associated with biotech crops and foods?

The State Role on Health and Environmental Issues

If state attention is focused on the traditional safety concerns of regulatory programs, what is the optimal role for the state in relation to and in collaboration with the federal government? Does the state need the autonomy that comes with having its own program and authority, or should it rely on collaboration with federal agencies under federal law? What steps are appropriate to achieve clarity and consistency in the overall national regulatory system?

The State Role on Economic and Social Issues

If the state chooses to address economic and social issues, what are the appropriate and constitutionally permissible state roles? What is an appropriate process for addressing these issues, taking into account the likely need for transparency and public participation in the process and credibility and acceptance of the outcomes?

The State Need for New Legal Tools

Given various possible roles a state could play, what, if any, new legal tools does the state need in terms of statutes and regulations? Is there a role for a model state law to promote uniformity in state laws and regulations?

Obtaining Appropriate Expertise

What expertise and other human resources does the state need to make sound decisions on agricultural biotechnology, and where can they be obtained? Should states build in-house expertise, or continue to rely heavily on outside expertise, such as university-based scientists? How should potential conflicts of interest be managed to preserve the objectivity and credibility of the decision process?

Paying for State Oversight

How can and should states pay for whatever oversight role they choose? Can it be funded with tax revenues? Is federal funding a viable option? Or is a fee-based system that relies on revenue from the farm and industrial sectors the preferred approach?

If the state chooses to address economic and social issues, what are the appropriate and constitutionally permissible state roles?

Improving APHIS-State Collaboration

How can the APHIS-state relationship and collaboration be improved to take advantage of state expertise in inspection and enforcement, improve data sharing and transparency, and foster closer interaction on policy and rulemaking? What is the solution to the CBI issue?

Resolving the State Role on PIPs

What role should the states play in overseeing PIP EUPs and enforcing use restrictions on commercialized PIPs? What priority does PIP oversight and enforcement have and deserve at the federal and state levels? How can collaboration between EPA and the states be enhanced?

Preparedness for Future Incidents

Overall, are the state and federal agencies well-prepared to respond to future incidents, along the lines of StarLink and ProdiGene, involving the presence of unwanted and illegal biotech materials in the food supply? What are the respective leadership, coordination, and support roles of FDA, other federal agencies, and the states?

This set of questions is by no means exhaustive, but it captures much of what state and federal regulators and agricultural officials are grappling with in their discussions about state oversight of biotech crops and foods. It is important to note that most of these questions are not unique to agricultural biotechnology. They are the kind that have arisen over many years in the food safety, plant health, and environmental arenas as federal and state governments have worked out their roles and relationships in our federal system. The biotech regulatory scene seems today to be more dynamic and challenging than most, however, due to the nature and power of the technology itself, the intensity and diversity of stakeholder interest, and the complexity of the government structures and programs in place to address them. It will require sustained effort and collaboration at all levels to find workable answers for today's hard questions.

REFERENCES

Adams, Jamie Clover. 2002. Comments from Kansas Secretary of Agriculture, "Proposed Federal Actions to Update Field Test Requirements for Biotechnology Derived Plants and to Establish Early Food Safety Assessments for New Proteins Produced by Such Plants." September 27. http://www.accesskansas.org/kda/News/news2002.htm (accessed May 18, 2004).

Agri-Business Council of Arizona. n.d. About ABC. http://www.agribusinessarizona.org/index.htm (accessed June 1, 2004).

American Association of Pesticide Control Officials. 2003. AAPCO Funding Needs Survey. http://aapco.ceris.purdue.edu/doc/surveys/FundSurvey0803.pdf (accessed June 4, 2004).

American Farm Bureau Federation. 2004. Agricultural Biotechnology—International Markets. www.fb.org/issues/backgrd/biotech-inter.04.pdf (accessed May 12, 2004).

Arizona State Legislature. 2004. Forty-sixth Legislature, Second Regular Session. SB1081 Status. http://www.azleg.state.az.us (accessed May 17, 2004).

Associated Press. 1994. Study Finds Good Side of Tobacco Leaf. *Chicago Tribune*. August 15, N6.

———. 2004. Ag Commissioner Could Veto Biotech Wheat. February 7.

Association of Official Seed Certifying Agencies. n.d. Programs & Systems: Identity Preserved. http://www.aosca.org/aoscaflash.html (accessed June 7, 2004).

———. 2003. "Yellow Books": Operational Procedures, Crop Standards and Service Programs Publication. ftp://www.aosca.org/opandcs.pdf (accessed June 7, 2004).

Auge, Karen. 2003(a). Colorado to Field "Biopharmed" Corn: State OKs Acres for Disputed Corn. *Denver Post,* June 16, A-01.

———. 2003(b). Biotech Corn Gets State's Approval. French Company Plans Crop in Phillips County. *Denver Post,* June 5, B-01.

———. 2004. State's First Bio-crop on Way; The Agriculture Department Sanctions Plans for Experimental Corn in Logan County. *Denver Post,* June 3.

Battelle Technology Partnership Practice and SSTI. 2004. Laboratories of Innovation: State Bioscience Initiatives 2004. Report prepared for the Biotechnology Industry Organization. Battelle Memorial Institute, June.

Bech, Rebecca. 2004. Personal communication with Rebecca Bech, Associate Deputy Administrator, Biotechnology Regulatory Services. May 12 and August 1.

Bernton, Hal. 2000. Hostile Market Spells Blight for Biotech Potatoes. *Seattle Times,* April 30, A1.

Bessette, Russell W., Keith Servis, and Jeffrey Saelens. 2001. New York: The Biotechnology State, a New Renaissance. *European Biopharmaceutical Review,* Autumn. http://www.nystar.state.ny.us/pa/papers01.htm (accessed June 4, 2004).

Biotechnology Industry Organization. 2001. Testimony of the Biotechnology Industry Organization (BIO) Regarding House Bill 1426: Regulating Production of Experimental Tobacco Plants. May. http://www.bio.org/foodag/state/nchb1426.asp (accessed June 28, 2004).

———. 2003(a). Government: A Survey of State Initiatives www.bio.org/govt/survey.html (accessed June 12).

———. 2003(b). Testimony in Opposition L.D. 1219, An Act to Establish a Moratorium on Genetically Engineered Plants. April 7. http://www.bio.org/foodag/state/mehb893.asp (accessed March 8, 2004).

———. 2004. Statement of the Biotechnology Regulatory Organization on HCR 270/HR180, Urging the State to Establish Advisory Boards Regarding Genetically Modified Organisms. Submitted to the Hawaii House Committees on Environment and Agriculture. April 7. http://www.bio.org/local/foodag/MauiResolution_HCR270_HR180.pdf (accessed May 26, 2004).

Boesch, Bob. 2004. Personal communication with Bob Boesch, Pesticides Program, Hawaii Department of Agriculture. August 18.

Brand, Rachel. 2004. Feed Corn, Meet "Pharma" Corn. *Rocky Mountain News,* March 13, 1C.

Brower, Diane. 2004. Letter from Diane Brower to the Colorado Department of Agriculture on Draft Procedures for Evaluating Biotechnology Permits for Plant Made Industrial and Pharmaceutical Products in Colorado. January 8.

Byrne, Patrick. 2004(a). Letter from Patrick Byrne, Associate Professor, Department of Soil Sciences, Colorado State University to the Colorado Department of Agriculture on Draft Procedures for Evaluating Biotechnology Permits for Plant Made Industrial and Pharmaceutical Products in Colorado. January 2.

———. 2004(b). Bio-pharm Crops: Proceed with Caution. Guest editorial. *BioScience News and Advocate,* February 17. http://www.bioscinews.com/files/news-detail.asp?NewsID=6269 (accessed May 20, 2004).

California Agricultural Statistics Service. n.d. California Agricultural Statistics Crop Years 1993–2002. *Agriculture Statistics Review.* ftp://www.nass.usda/gov/pub/nass/ca/AgStats/2002-ovw.pdf (accessed May 19, 2004).

California Code of Regulations. n.d.(a). Food and Agriculture, California Rice Certification Act of 2000, Section 55000. http://ccr.oal.ca.gov/ (accessed June 28, 2004).

———. n.d.(b). Food and Agriculture, Title 3, Section 2850 et seq.

———. n.d.(c). Article 13 Research Authorizations, Section 6260 et seq. http://ccr.oal.ca.gov/ (accessed June 2, 2004).

California Legislative Information. n.d. Bill Information. http://www.leginfo.ca.gov/bilinfo.html (accessed June 5, 2004).

California Rice Commission. 2004(a). California Rice Certification Act, Tackles Specialty Rice, Disease and GMO. Newsletter, March/April, Vol. 6, Number 3, http://www.calrice/org/industry/roster_comm.html (accessed May 25, 2004).

———. 2004(b). How Do We Keep Our Rice Varieties Separate? The California Rice Industry First in the World to Implement a Protocol.

Campaign to Label Genetically Engineered Foods. 2004. About Us. http://www.thecampaign.org/ (accessed June 6, 2004).

Canadian Wheat Board. 2003. CWB Asks Monsanto to Put the Brakes on Roundup Ready® Wheat, May 27. http://www.cwb.ca/en/news/releases/2003/052703.jsp?pm=1 (accessed April 21, 2004).

Carman, Diane. 2003. Biopharming Reaps Fear of Contamination. *Denver Post*. September 28, B-01.

Cassidy, Brenda, and Douglas Powell. 2002. Pharmaceuticals from Plants: The ProdiGene Affair. December 3. http://www.foodsafetynetwork.ca/gmo/prodigene.htm (accessed April 27, 2004).

Center for Food Safety. 2003. Re: Sixty Day Notice of Intent to Sue for Violations of the National Environmental Policy Act and the Endangered Species Act. March 5. http://www.kahea.org/gmo (accessed March 15, 2004).

Center for Rural Studies. 2002. Vermonters Report Overwhelming Support for Labeling of GMO Food Products. Vermonter Poll Press Release. March 6. http://crs.uvm.edu/vtrpoll/2002/releasegmo.htm (accessed June 29, 2004).

Chemical Market Reporter. 2002. BIO Revises Position on Pharma Crops Safety. December 9. http://www.findarticles.com/cf_dls/m0FVP/21_262/956276666/print.jhtml (accessed March 12, 2004).

Clapp, Stephen. 2004. Industry Seeks Food Safety Assessment of Biopharm Crops. *Food Chemical News*. March 1, 6.

Colorado Department of Agriculture. 2003(a). Colorado Department of Agriculture Seeking Input from the Public. November 24. http://www.ag.state.co.us/biotech.html (accessed December 11, 2003).

———. 2003(b). Draft: Evaluating Experimental Biotechnology Permits for Plant Made Industrial and Pharmaceutical Products in Colorado. http://www.ag.state.co.us/biotech.pdf (accessed May 20, 2004).

Colorado Office of Innovation and Technology. n.d. Office of Life Sciences and Biotechnology. http://www.oit.state.co.us/initiatives/biotech_home.asp (accessed May 24, 2004).

———. 2003. Colorado's Place in the Sun: A Bioscience Future, An Action Plan to Grow Colorado's Bioscience Cluster. Battelle Memorial Institute. April. http://www.oit.state.co.us/initiatives/techSector.asp (accessed May 24, 2004).

Consumers Union. 2004. Consumer & Environmental Groups Urge California Officials to Deny Firm's Request to Grow Pharmaceutical Rice. Press Release. April, 1. http://www.consumersunion.org/pub/core_product_safety/000957 (accessed May 18, 2004).

Coppock, Daren. 2004. Monsanto Co. Ends Plans for Biotech Wheat. *Associated Press,* May 11. http://www.nytimes.com/aponline/business/AP-Biotech-Wheat.html?pagewanted=print&position (accessed May 11, 2004).

Cropchoice. 2001. An Option for Growers of Non-Transgenic Crops? February 12. http://www.biotech-info.net/grower_options.html (accessed November 19, 2003).

Crowell, Peter. 2004. Letter from Peter Crowell to the Colorado Department of Agriculture on Draft Procedures for Evaluating Biotechnology Permits for Plant Made Industrial and Pharmaceutical Products in Colorado. January 9.

Dakota Resource Council. 2003. GM Defense. Dakota Counsel Newsletter Vol. 26, No. 3, April. http://www.drcinfo.com/newsletter/April2003.pdf (accessed June 10, 2004).

Dakota Resource Council, State Senator April Fairfield, National Family Farm Coalition, Northern Plains Resource Council, Northern Plains Sustainable Agriculture Society, State Senator John Tester, and Western Organization of Resource Councils. n.d. Citizens Petition Before the United States Department of Agriculture Animal and Plant Health Inspection Service. http://www.agobservatory.org/library/up/radedfiles/Citizen_Petition_before_the_United_States_Depa.pdf (accessed April 20, 2004).

Danninger, Lyn. 2002. EPA After Isle Biotech Firms: The Agency Says 2 Companies That Cultivate Genetically Altered Corn Have Violated Permits. *Honolulu Star-Bulletin,* August 14. http://starbulletin.com/2002/08/14/business/sotry1.html (accessed April 13, 2004).

Deeter, Scott. 2004. Personal communication with Scott Deeter, President and Chief Executive Officer, Ventria Biosciences. June 11.

Denver Business Journal. 2002. Institute Will Produce "Plan" for Colorado's Biotech Industry. December 6. http://denver.bizjournals.com/denver/stories/2002/12/02/daily55.html (accessed October 27, 2003).

Derksen, Ken. 2004. The Future of Farming. March 5. http://rdu.news14.com/content/nc_decides_2004/your_job_your_future/?SecID=363&ArID=46822 (accessed March 6, 2004).

Dickerson, Bill. 2004. Personal communication with Bill Dickerson, Director, Plant Industry Division, North Carolina Department of Agriculture and Consumer Services. February 18 and July 12.

Drifmier, Clark. 2004. Letter from Clark Drifmier, Senior Vice President, Aurora Organic Dairy, to the Colorado Department of Agriculture on Draft Procedures for Evaluating Biotechnology Permits for Plant Made Industrial and Pharmaceutical Products in Colorado. January 16.

Earthjustice. 2003(a). Genetically Engineered 'Biopharm' Crops in Hawaii: State Sued for Refusing to Disclose Information on Field Tests of Genetically Engineered Crops in Hawaii. Press Release. July 23. http://www.earthjustice.org (accessed February 23, 2004)

———. 2003(b). Lawsuit Challenges Open-Air Testing of Genetically Engineered 'Biopharm Crops.' Press Release. November 12. http://www.earthjustice.org/news/press.html (accessed March 15, 2004).

———. 2004. State of Hawaii Approves Field Tests of Genetically Engineered Crops Without Any Information: Documents Produced Reveal no Oversight by State Department of Agriculture. Press Release. February 17. http://www.earthjustice.org/news/press.html (accessed April 26, 2004).

Ehart, Bob. 2004. Interview with Bob Ehart, Animal and Plant Health Safeguarding Coordinator, National Association of State Departments of Agriculture. February 10.

Elias, Paul. 2004. California Regulators Derail Biotech Company's Rice Plans. *Associated Press*. April 9.

Eller, Donnelle. 2004. Biotech Brightens Future for Iowa. *Des Moines Register*. March 15. http://desmoinesregister.com/business/stories/c4780940/23801901.html (accessed March 16, 2004).

Evans, Martha, ed. 2003. *Rice Situation and Outlook Yearbook*. Market and Trade Economics Division, Economic Research Service. November. http://www.ers.usda/gov/publications/so/view.asp?f=field/res-bb/ (accessed May 19, 2004).

Fabi, Randy. 2004. FDA Approves Monsanto Biotech Wheat for Humans. *Reuters*. July 23.

Fitzgerald, Anne. 2004. Blouin Touts Biotech's Potential "Payoff." *Des Moines Register,* March 9. http://desmoinsregister.com/business/stories/c2122222/23746637.html (accessed March 16, 2004).

Food Biotechnology Task Force. 2003. A Food Foresight Analysis of Agricultural Biotechnology: A Report to the Legislature. January 1. http://www.cdfa.ca.gov/exec/pdfs/ag_biotech_report_03.pdf (accessed June 5, 2004).

Foudin, Arnold. 1989. Written communication from Arnold Foudin, Deputy Director of Biotechnology Permit Unit, Biotechnology, Biologics, and Environmental Protection, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, to Hawaii Department of Agriculture. July 26.

Garofoli, Joe. 2004. State's Rice Farmers Fear Biotech Incursion; Proposal for Genetically Engineered Crop Could Threaten Lucrative Foreign Markets. *San Francisco Chronicle*. April 8, A1.

Garrison, Judy. 2004. Personal communication with Judy Garrison, Administrative Officer, Biotechnology Regulatory Services. June 7.

Gillam, Carey. 2004a. Biotech Foods Keep Coming Despite Monsanto Setback. *Reuters,* May.

———. 2004b. Monsanto Raises Idea of U.S.-Only GMO Wheat Release. *Reuters,* March 16.

GMO Free Mendocino County. n.d. County Ordinance Prohibiting Growing of Genetically Modified Organisms. http://www.gmofreemendo.com/moreh.html (accessed January 27, 2004).

Golden Leaf (Long-Germ Economic Advancement Foundation). 2004. http://www.goldenleaf.org (accessed May 29, 2004).

Grand Junction Daily Sentinel. 2004. Legislator Delays Bill to Regulate Biocrops. February 12.

Grocery Manufacturers of America. 2002(a). GMA Urges Leadership to Implement Stronger Biopharmaceutical Regulations. News Release. November 21. http://www.gmabrands.com/news/ (accessed April 27, 2004).

———. 2002(b). GMA Urges the Use of Non-food Crops for Biotech Drugs. News Release. November 14. http://www.gmabrands.com/news (accessed April 27, 2004).

———. 2003. GMA comments to USDA on Docket No. 03-031-1: Field Testing of Plants Engineered to Produce Pharmaceutical and Industrial Compounds. http://gmabrands.com/publicpolicy/docs/comment_p.cfm?DocID=1135 (accessed April 27, 2004).

Hanks, Mary. 2004. Personal communication with Mary Hanks, Supervisor, Sustainable and Integrated Pest Management, Agricultural Resources Management and Development Division, Minnesota Department of Agriculture. April 5.

Hansen, Michael, Elisa Odabashian, Dan Jacobson, Bill Allayaud, Ronnie Cummins, and Lisa Archer. 2004. Letter from Michael Hansen, Senior Research Associate, and Elisa Odabashian, Consumers Union of United States; Dan Jacobson, Legislative Director, Environment California; Bill Allayaud, State Director, Sierra Club California; Ronnie Cummins, National Director, Organic Consumers Association, and Lisa Archer, Safer Food, Safer Farms Grassroots Coordinator, Friends of the Earth, to A.G. Kawamura, Secretary of the California Department of Food and Agriculture. April 1.

Harder, Dwight. 2004. Personal communication with Dwight Harden, Assistant Director, Arizona Department of Agriculture. February 6.

Hawaii Department of Agriculture. n.d. Administrative Rules: Department of Agriculture Title 4, Division of Plant Industry Subtitle 6. http://www.hawaiiag.org/hdoa/adminrules.htm (accessed October 15, 2003).

———. 2003(a). Defendant Department of Agriculture, State of Hawaii's Memorandum in Opposition to Plaintiffs Motion for Summary Judgment in Center for Food Safety v. Department of Agriculture, Hawaii, Civil No. 03-1-1509-07 (RWP). September 19.

———. 2003(b). Plant Quarantine Branch. Notice to Requester. To Isaac Moriwake, Earthjustice, o.b.o. the Center for Food Safety. June 6.

———. 2003(c). Plant Quarantine Branch. Supplemental Notice to Requester. To Isaac Moriwake, Earthjustice, o.b.o. the Center for Food Safety. December 17.

Hawaii Revised Statutes. 2003(a). Health Title 19, Genetically Modified Organisms, § 321-11.6 http://www.capitol.hawaii.gov (accessed July 14, 2004).

———. 2003(b). Uniform Information Practices Act, Title 8 § 92F-13(3) http://www.capitol.hawaii.gov (accessed July 14, 2004).

Hegeman, Roxana. 2003. USDA Scrambling to Catch Up with New Technology. *Associated Press State and Local Wire*. BC Cycle, October 22.

Heisler, Karen. 2004. Personal communication with Karen Heisler, Environmental Protection Agency, Region 9. May 25.

Hilburn, Dan. 2004. Personal communication with Dan Hilburn, Administrator, Plant Division, Oregon Department of Agriculture. June 29 2004.

Hildebrand, Terry, Lynn Jacobson, Ken Ritter, Weldon Newton, Trevor Cowieson, Bruce Webster, Neal Hardy, John Clair, Neil Wagstaff, and Paul Thoroughgood. 2003. Letter from Terry Hildebrand, President, Agricultural Producers Association of Saskatchewan; Lynn Jacobson, President, Alberta Soft Wheat Producers Commission; Ken Ritter, Chair, Canadian Wheat Board; Weldon Newton, President, Keystone Agricultural Producers; Trevor Cowieson, Past President, Manitoba-North Dakota Zero Tiller Farmers Association; Bruce Webster, Chair, Ontario Wheat Producers' Marketing Board; Neal Hardy, President, Saskatchewan Association of Rural Municipalities; John Clair, President, Saskatchewan Soil Conservation Association; Neil Wagstaff, President, Wild Rose Agricultural Producers; and Paul Thoroughgood, President, Winter Cereals Canada, Inc. to the Honourable Lyle Vanclief, P.C., M.P., Minister of Agriculture and Agri-Food Canada. March 31. http://www.cwb.ca/en/topics/biotechnology/closing_gap.jsp (accessed April 21, 2004).

Hoffman, Neil. 2004. Personal communication with Neil Hoffmann, Director of Regulatory Division, Biotechnology Regulatory Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture. March 12.

Howie, Steve. 2004. Personal communication with Steve Howie, Environmental Scientist, Agriculture Branch, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency. June 7.

Illinois Farm Bureau. n.d. IFB Position Statement – Biotechnology. http://www.ilfb.org (accessed February 20, 2004).

Illinois Department of Agriculture. 2001. Illinois Biotech Helping Feed the World. Press Release. June 25. http://www.agr.state.il.us/newsrels/r0628014.html (accessed February 23, 2004).

Information Systems for Biotechnology. n.d. A National Resource in Agbiotech Information, Regulatory Information. USDA Field Tests of GM Crops. Agricultural Experiment Station at Virginia Tech. http://www.isb.vt.edu (accessed March 2, 2004).

———. 1992. The ISB News Report, November. http://www.nbiap.vt.edu/news/1992/news92.nov (accessed April 26, 2004).

———. 2004(a). Field Test Information: Petitions and Phenotypes for Deregulation Status. www.isb.vt.edu (accessed June 1, 2004).

———. 2004(b). Field Test Release Permits Database for the U.S. http://isb.vt.edu (accessed June 7, 2004).

———. 2004(c). Regulatory Information: Field Test Information: Status of Field Test Permits by State. http://www.isb.vt.edu/cfdocs/isBtables2.cfm?tvar=7 (accessed June 1, 2004).

———. 2004(d). Field Test Information: Status of All Field Test Permits 1987–Present, June 3. http://www.isb.vt.edu/cfdocs/isBtables2.cfm?tvar=9 (accessed June 4, 2004).

———. 2004(e). Field Test Information August 10. www.isb.vt.edu (accessed August 20, 2004).

———. 2004(f). Field Test Releases in the U.S. http://www.isb.vt.edu/cfdocs/fieldtests1.cfm (accessed May 12, 2004).

Institute for Agriculture and Trade Policy. 2003. Elevator Survey on Deregulation of Genetically Engineered Wheat. March 19. http://www.iatp.org (accessed June 10, 2004).

———. 2004. Pressure Builds against Genetically Engineered Wheat: Farm, Religious and Consumer Groups Join Call for More Public Review of Monsanto's Pending Application. Press Release. February 18.

Iowa Department of Agriculture and Land Stewardship. 2004. Departmental Draft: The Iowa Pharmaceutical and Industrial Crops Act.

Iowa Environmental Council. 2000. The Iowa Environmental Council's position on Genetically Modified Organisms (GMOs) and the Environment. http:www.earthshare.org/n/pp_GMO.pdf (accessed February 19, 2004).

Iowa Legislature General Assembly. n.d. Track Legislation—Legislative Database Information. http://www.legis.state.ia.us/Legislation.html (accessed June 7, 2004).

Jacobs, Paul. 2004. Genetically modified rice crop blocked. *San Jose Mercury News*. April 10.

Jacobs, Paul, and Lisa M. Krieger. 2004. "Pharm Crop" Debates Take Root in California; Biotech Firm Wants to Test Rice That Produces Human Proteins. *San Jose Mercury News*. March 30.

Johnson, Melissa. 2004. Letter from Melissa Johnson to the Colorado Department of Agriculture 2004. Comments on Draft Procedures for Evaluating Biotechnology Permits for Plant Made Industrial and Pharmaceutical Products in Colorado. January 11.

Johnson, Roger. 2003. Testimony of Roger Johnson, Agricultural Commissioner, before the House Agriculture Committee. http://www.agdepartment.com/testimony/2003%20leg%20test/hb%201026-transgenic%20wheat%20bd.htm (accessed June 4, 2004).

Johnson, Tim. 2004. Letter from Tim Johnson, President and CEO, California Rice Commission to Mike Taylor. July 16.

Jones, Sheldon. 2004. Personal communication with Sheldon Jones, Executive Director, Agri-Business Council of Arizona. January 29.

Jones, Tobi. 2004. Personal communication with Tobi Jones, Assistant Director, Division of Registration and Health Evaluation, Department of Pesticide Regulation, California Environmental Protection Agency, and President, Association of American Pesticide Control Officials. April 14-15.

Jones, Tobi, and Liemandt, Paul. 2004. Letter from Tobi Jones, President of the Association of American Pest Control Officials, and Paul Liemandt, Chair, State FIFRA Issues Research and Evaluation Group, to Jody Tick. June 18 (on file with the authors).

Kansas Department of Agriculture. 2004. Kansas Ag Secretary Comments on Biotechnology Regulation. Press Release. March 31. http://www.accesskansas.org/kda/News/news.htm (accessed May 18, 2004).

Kansas Legislature. 2003–2004. S.B. 236: An Act Concerning Agricultural Production; Relating to Genetically Modified Organism Crops. http://www.kslegislature.org/cgi-bin/bills/index.cgi (accessed May 18, 2004).

———. 2003-2004. H.B. 2647. http://www.kslegislature.org/cgi-bin/bills/index.cgi (accessed May 18, 2004).

Kawamura, A.G. 2004. State Derails Plans for Genetically Modified Rice; SLO County Was Possible Site Proposed for Crop. In *San Jose Mercury News* and *San Luis Obispo Tribune*. April 10.

Kelly, Patrick M. 2004. Letter from Patrick M. Kelly, Vice President, Biotechnology Industry Organization; Matt Gardner, President, BayBIO; and Joseph Panetta, President, BIOCOM, to A.G. Kawamura, Secretary of Agriculture, California Department of Food and Agriculture, April 5. http://www.bio.org/local/foodag/20040405carice.pdf (accessed June 7, 2004).

Kimbrell, Andrew. 2004. Personal communication with Andrew Kimbrell, Executive Director, Center for Food Safety. January 26.

Kunimoto, Sandra Lee. 2004. Testimony of Sandra Lee Kunimoto, Chairperson, Board of Agriculture, State of Hawaii, before the Maui County Council. April 2.

Lau, Edie. 2004. Mendocino's Measure H Backers Overcome a Huge Fund-Raising Disadvantage. *Sacramento Bee*. http://www.sacbee.com/content/politics/ca/election/v-print/story/8396081p-9325630c.html (accessed March 3, 2004).

Lee, Mike, and Edie Lau. 2004. Biotech Company Cultivates New Field. *Sacramento Bee*. January 25. http://www.sacbee.com/content/business/agriculture/v-print/story/8160152p-9091767c.html (accessed February 11, 2004).

Leone, Diana. 2003. Suit Targets Genetically Altered Crops in Isles: U.S. Department of Agriculture fails to Properly Regulate Them, Several Groups Claim. *Honolulu Star-Bulletin,* November 13. http://starbulletin.com/2003/11/13/news/story12.hmtl (accessed January 21, 2004).

Liemandt, Paul. 2004. Personal communication with Paul Liemandt, Chair, State FIFRA Issues and Research Evaluation Group and Section Manager, Environmental Response, Minnesota Department of Agriculture March 17.

Limvere, Karl et al. 2004. Initiative Petition to the Secretary of State, State of North Dakota. http://www.state.nd.us/sec/forms/pdf/wheatmeasure.pdf (accessed August 12, 2004).

Lofholm, Nancy. 2003. State Hatches Biotech Plan: Colorado Deemed Ripe for More Research Firms, "Farmaceutical" Crops. *Denver Post*. January 6, B-01.

Loo, Lorna J. 1992. Written communication from Lorna J. Loo, Staff Attorney, Office of Information Practices, Hawaii Department of the Attorney General, to the Honorable John C. Lewin, Director, Hawaii Department of Health. December 20.

Lundberg, Bryce. 2004. The Campaign to Label Genetically Engineered Foods. In *The Campaign Reporter*. March. http://www.thecampaign.org/reporter0304.php (accessed June 8, 2004).

Mace, David. 2003a. Vermont Biotech Legislation Follows National Trends. *Barre Montpelier Times Argus*. June 11. http://timesargus.com/Archive/Articles/Article/66935 (accessed October 22, 2003).

———. 2003b. GMOs Remain Divisive Issue. *Barre Montpelier Times Argus*. October 23. http://timesargus.com/Story/73584.html (accessed May 18).

Mack, Sharon Kiley. 2003. Organic Farmers Back Moratorium; Genetically Engineered Plants Targeted. *Bangor Daily News*. April 3, B5.

Maine Organic Farmers and Gardeners Association. 2004. Support Maine's GMO Moratorium Bill. http://www.mofga.org/news20030317.html (accessed May 18, 2004).

Marquis, Michael S. 2003. E-mail communication from Michael S. Marquis, Assistant Director for Freedom of Information, Legislative and Public Affairs, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, to Carol Okada, Plant Specialist, Plant Quarantine Branch, Hawaii Department of Agriculture. March 15.

Martinez, Julia C. 2003. Protesters Urge Owens to Block "Biopharms." *Denver Post.* May 13, B-04.

Mason, K.C. 2004. Second Colo. Site Viewed for French Firm's "Biopharm." *Fort Morgan Times,* January 20. http://www.fortmorgantimes.com/Stories/0,1413,164%7E8305%7E1903768,00.html (accessed February 17, 2004).

Massa, Greg. 2004(a). Pharmaceutical Rice Is a No-Grow. *Sacramento Bee,* Editorials, B7, May 14.

———. 2004(b). California Rice Commission Approves Genetically Engineered Rice. Center for Food Safety. Press Release. March 29. http://64.78.7.168/page246.cfm (accessed May 18, 2004).

Medley, Terry. 1993. Written communication from Terry Medley, Director, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, to Robert Grossmann, Special Assistant to the Director, Hawaii Department of Health. January 22.

Miller, Jim. 2004. Personal communication with Jim Miller, Director of Policy and Communications, Commissioner's Office, Colorado Department of Agriculture, and authors. February 17.

Minnesota Biosciences Council. 2003. Letter from Minnesota Biosciences Council to Governor Tim Pawlenty. December 22. http://www.mnbio.org/governor/BioCouncilrecs1203.pdf (accessed June 6, 2004).

Minnesota Department of Agriculture. n.d. Regulation of Genetic Engineering in Minnesota. http://www.mda.state.mn.us/biotech/default.htm (accessed May 4, 2004).

Minnesota Department of Employment and Economic Development. 2003. Governor Appoints Minnesota Biosciences Council. News Release. August 5. http://www.deed.state.mn.us/news/release/2003/business05Aug03b.htm (accessed October 22, 2004).

Minnesota Rules. n.d.(a). Environmental Quality Board. Genetically Engineered Organisms, Chapter 4420. http://www.revisor.leg.state.mn.us/arule/4420/ (accessed May 3, 2004).

———. n.d.(b). Environmental Quality Board. Genetically Engineered Organisms, Chapter 1558 http://www.revisor.leg.state.mn.us/arule/1558/ (accessed June 21, 2004).

Minnesota Senate. 2003–2004. SF 246: State Environmental and Natural Resources Functions and Services Reorganization. http://www.leg.state.mn.us/leg/legis.asp (accessed June 21, 2004).

Minnesota State Legislature. n.d. Legislation and Bill Status. http://www.leg.state.mn.us/leg/legis.asp (accessed June 6, 2004).

Minnesota Statutes. 2003(a). Genetically Engineered Organisms, Chapter 18F. http://www.revisor.leg.state.mn.us/stats/18F (accessed March 17, 2004).

———. 2003(b). Environmental Quality Board. Genetically Engineered Organisms, Chapter 116C http://www.revisor.leg.state.mn.us/stats/116C/ (accessed May 3, 2004).

———. 2003(c). Section 13.01 (Government Data Practices Act). http://www.revisor.leg.state.mn.us (accessed July 14, 2004).

———. 2003(d). Experimental Use Pesticide Product Registration 18B.28 and Experimental Genetically Engineered Pesticide Product Registration 18B.285. http://www.revisor.leg.state.mn.us/stats/18B (accessed March 15, 2004).

Mitchell, Terry. 2004. Personal communication with Terry Mitchell, Director, Pesticides Registration, Texas Department of Agriculture and Consumer Services. March 10.

Monsanto Company. 2003. Field Research Demonstrates Value of Roundup Ready® Wheat, Technical Bulletin.

———. 2004. Monsanto to Realign Research Portfolio, Development of Roundup Ready® Wheat Deferred. Press Release. May 10. http://www.monsanto.com (accessed May 11, 2004).

Montana Department of Commerce. Research and Commercialization. http://www.commerce.state.mt.us/BRD/BRD_RCT.html (accessed November 17, 2003).

Montana State Legislature. 2001(a). HB 211: Moratorium on Genetically Modified Wheat. http://laws.leg.state.mt.us (accessed June 11, 2004).

———. 2001(b). HJR 6: Study Impacts of Genetically Modified Wheat. http://laws.leg.state.mt.us (accessed June 11, 2004).

———. 2003(a). HB 409: Montana Wheat Protection and Promotion Act. http://laws.leg.state.mt.us (accessed June 11, 2004).

———. 2003(b). HB 522: Revise Liability for Genetically Engineered Wheat. http://laws.leg.state.mt.us (accessed June 11, 2004).

———. 2003(c). Look Up Bill Information. http://laws.leg.state.mt.us/pls/laws03/law0203w$.startup (accessed May 19, 2004).

———. 2003(d). SB 266: Bond to Introduce Genetically Modified Wheat. http://laws.leg.state.mt.us (accessed June 11, 2004).

———. 2003(e). SB 440: Require Genetically Engineered Wheat Seed to be Sold with Instructions. http://laws.leg.state.mt.us (accessed June 11, 2004).

———. 2003(f). SJ 8: Resolution to Address Marketing of Genetically Engineered Grains. http://laws.leg.state.mt.us (accessed June 11, 2004).

———. 2003(g). Senate Joint Resolution 8: Introduced by Tester. April 8. http://data.opi.state.mt.us/bills/2003/billhtml/SJ0008.htm (accessed October 22, 2003).

———. 2003(h). SJ 30: Study Issues Related to Genetically Engineered Wheat. http://laws.leg.state.mt.us (accessed June 11, 2004).

Montana Wheat and Barley Committee. n.d. http://wbc.agr.state.mt.us (accessed March 26, 2004).

Moriwake, Isaac. 2003. Request by Isaac Moriwake, Earthjustice, o.b.o. the Center for Food Safety, to access a government record to Carol Okada, Plant Quarantine Branch, Department of Agriculture. May 23.

———. 2004. Personal communication with Isaac Moriwake, Attorney, Earthjustice. May 5.

NASDA (National Association of State Departments of Agriculture), Tobacco Task Force Committee. 2003. DRAFT: Protocols to Prevent the Cross-Contamination of Genetically Engineered and Conventional Tobaccos. June 3.

NFPA (National Food Processors Association). 2003. NAFTA comments to USDA on Docket No. 03-031-1: Field Testing of Plants Engineered to Produce Pharmaceutical and Industrial Compounds. http://www.nfpa-food.org/Comments/NFPACommentsPMP.htm (accessed April 27, 2004).

National Research Council. 2004. *Biological Confinement of Genetically Engineered Organisms*. Washington, DC: National Academies Press.

Neylan, John. 2004. Personal communication with John (Jack) Neylan, Agriculture Branch Chief, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency. March 24, June 7.

Nicholson, Blake. 2002. Farm Scene: North Dakota Farm Bureau Changes Policy on Biotech Wheat. *Associated Press*. November 26.

North Carolina Administrative Code. n.d. Chapter 48, Plant Industry Rules Section .0303(d) (repealed effective December 1995).

North Carolina Biotechnology Center. n.d. About Us: From the Mind to the Marketplace. http://www.ncbiotech.org/aboutus/aboutus.cfm (accessed October 23, 2003).

———. 2003. NCSU to Map Tobacco. *BT Catalyst*. January. http://www.ncbiotech.org/ncindustry/news/btcat/2003/January03/jan03-3.cfm (accessed April 15, 2003).

———. 2004. North Carolina Commits $64.5 Million to Train Biomanufacturing Workforce. News Release. August 18. http://www.ncbiotech.org/ncindustry/news/pr.cfm (accessed May 19, 2004).

North Carolina Department of Agriculture and Consumer Services. 2003(a). North Carolina Agricultural Overview. September 10. http://www.ncagr.com/stats/general/general1.htm (accessed March 6, 2004).

———. 2003(b). Plant Industry Division—Plant Protection Section: Biotechnology Services. http://www.ncagr.com/plantind/plant/biotech/biotec.htm (accessed June 7, 2004).

North Carolina Farm Bureau. 2001. Farm Bureau Fights to Support Biotechnology as Reliable Tool. News Release. May 18. http://www.ncfb.com/daily2001/News%20Releases/may_18_2001_news_release.htm (accessed May 31, 2004).

North Carolina General Assembly. 1989–1990. Genetically Engineered Organisms Act, http://www.ncleg.net/htm/1989/bills/current/version/ratified/senate/sbil004.full.htm (accessed April 26, 2004).

———. 2001–2002. HB 1426: Regulate Experimental Tobacco. May 7. http://www.ncga.state.nc.us/html2001/bills/AllVersions/House/H1426v1.html (accessed May 29, 2004).

North Dakota Department of Agriculture. n.d. A Message from Our Ag Commissioner. http://www.agdepartment.com/Roger.html (accessed June 4, 2004).

———. 2004. North Dakotans Hear Japanese Concerns on GMO Wheat. Press Release. March 26. http://www.agdepartment.com/2004press/other040326.htm (accessed June 4, 2004).

North Dakota Legislative Assembly. n.d.(a). 58th Session. HB 1026, A Bill for an Act to Create a Transgenic Wheat Board; and to Provide an Expiration Date. http://www.state.nd.us.lr/assembly (accessed June 11, 2004).

———. n.d.(b) 58th Session. SB 2304, A Bill for an Act to Create and Enact a New Chapter to Title 4 of the North Dakota Century Code, Relating to Damages for Cross-pollination with Transgenic Wheat; and to Provide for a Legislative Council Study. http://www.state.nd.us.lr/assembly (accessed June 11, 2004).

———. n.d.(c). 58th Session. SB 2408, A Bill for an Act to Create and Enact Eleven New Sections to Chapter 4-24 of the North Dakota Century Code, relating to a certificate of approval for the sale of transgenic wheat seed; and to provide a penalty. http://www.state.nd.us.lr/assembly (accessed June 11, 2004).

———. n.d.(d). 58th Session. Bills, Resolutions, and Journals. http://www.state.nd.us/lr/assembly/58-2003/leginfo/bills-res-jour/ (accessed June 4, 2004).

North Dakota Wheat Commission. Fiscal Year 2002–2003. Measures of Our Success: Annual Report to Producers. http://www.ndwheat.com/wc/programs/finalwheatprint.pdf (accessed March 19, 2004).

Nunenkamp, David. 2004. Personal communication with David Nunenkamp, Deputy Secretary, California Department of Food and Agriculture. July 19.

Office of Science and Technology Policy. 1986. Coordinated Framework for Regulation of Biotechnology: Announcement of Policy; Notice for Public Comment. *Federal Register* 51: 23302. June 26.

Oklahoma Department of Agriculture. n.d. Plant Industry and Consumer Services Division, Oklahoma Agriculture Biotechnology Act. http://www.oda.state.ok.us/forms/law/biotech.htm (accessed February 19, 2004).

Oklahoma Department of Commerce. 2001. The Future of Biotechnology in Oklahoma. *Commerce folio,* Vol. 10, No. 1. http://domino1.odoc.state.ok.us/homepage/folioarc.nsf/1059ead2ac9ec46d862565680053fdfa/99fa17a226a12ed686256a990074e8bc/$FILE/July2001Folio.pdf (accessed June 4, 2004).

Oklahoma EPSCoR: Biotechnology Network. n.d. http://epscorbiotech.okstate.edu/homepage.html (accessed June 4, 2004).

Oregon Department of Agriculture. n.d.(a). Export Service Center. http://oda.state.or.us/lab/esc.html (accessed November 21, 2003).

———. n.d.(b). http://oda/state.or.us/lab.index.html (accessed November 21, 2003).

———. n.d.(c). http://oda.state.or.us/information/tour/index.html

Organic Consumers Association. 2003. Boards of Supes Does Its Job: GMO-Free Mendocino Initiative to be Voted March, 2, 2004. Press Release. December 3. http://www.organiconsumers.org/ge/california_initiative.cfm (accessed December 17, 2003).

Ott, Julie. 2004. Letter from Julie Ott to the Colorado Department of Agriculture on Draft Procedures for Evaluating Biotechnology Permits for Plant Made Industrial and Pharmaceutical Products in Colorado. January 16.

Patterson, Bill. 2004(a). Biopharming Out in the Open: Experimental Crops Grown in the Open Air Should be Open to Public Scrutiny. *WCC Clarion,* 24(1). http://www.wcccongress.org/clarion.cfm (accessed February 27, 2004).

———. 2004(b). Letter from Bill Patterson to the Colorado Department of Agriculture on Draft Procedures for Evaluating Biotechnology Permits for Plant Made Industrial and Pharmaceutical Products in Colorado. January 8.

Perkins, Jerry, and Anne Fitzgerald. 2002. Biotech Takes Another Hit: Contamination Fears Could Hurt Changes for Economic Gain. *Des Moines Register,* November 24, 1M.

Pesticide Action Network. 2003. Update Services: USDA Sued for Overlooking Risks to Biopharm. November 20. http://www.panna.org/resources/panups/panup_20031120.dv.html (accessed May 24, 2004).

Petersen, Robert K.D., and Charles J. Arntzen. 2004. On Risk and Plant-Based Biopharmaceuticals. *TRENDS in Biotechnology* 22(2): 64-66.

Pew Initiative on Food and Biotechnology. 2003. Public Sentiment About Genetically Modified Food. September Update. http://pewagbiotech.org/research/2003update/ (accessed June 3, 2004).

———. 2004(a). Agricultural Biotechnology Remains Active Topic in State Legislatures in 2003. May. http://pewagbiotech.org/resources/factsheets/legislation/factsheet.php (accessed June 1, 2004).

———. 2004(b). Issues in the Regulation of Genetically Engineered Plants and Animals, April. http://pewagbiotech.org/research/regulation/Regulation.pdf (accessed June 2, 2004).

———. 2004(c). Legislation Tracker. http://pewagbiotech.org/resources/factsheets/legislation/ (accessed May 17, 2004).

Phipps, Meg Scott. 2002. Commissioner's Corner. September 2. http://www.ncagr.com/paffairs/articles/2002/9-02corner.htm (accessed March 6, 2004).

Polansky, Adrian. 2003. Comments from Adrian J. Polansky, Kansas Secretary of Agriculture, on *Federal Register* Notice Docket No. 03-031-1. May 9. http://www.accesskansas.org/kda/News/news.htm (accessed May 18, 2004).

———. 2004. Personal communication with Adrian Polansky, Kansas Secretary of Agriculture. March 16.

Pollack, Andrew. 2004. Monsanto Shelves Plan for Modified Wheat. *New York Times,* Business Day, Section C, May 11.

Porter, Aaron. 2003. Montrose Lawmaker to Back Pharmaceutical Crops in State. *Daily Sentinel.* September 28. http://www.gjsentinel.com/ (accessed February 17, 2004).

———. 2004(a). Bio-engineered Crops Could Face New Rules. *Daily Sentinel.* January 27. http://www.gjsentinel.com/ (accessed January 27, 2004).

———. 2004(b). Legislator Delays Bill to Regulate bio-crops. *Daily Sentinel.* February 12. http://www.gjsentinel.com/ (accessed February 12, 2004).

Portney, Jeffrey S., and Taya R. Nuse. 2001. The Door to Open Government in Hawaii. Tapping Official's Secrets. The Reporters Committee for Freedom of the Press. http://www.rcfp.org/tapping/index.cgi?key=HI#OUT4 (accessed April 1, 2004).

Pruisner, Robin. 2004. Personal communication with Robin Pruisner, State Entomologist, Entomology and Plant Science Bureau, Iowa Department of Agriculture and Land Stewardship. January 29.

Rampton, Roberta. 2004. Monsanto Withdraws GMO Wheat from All but U.S. FDA. *Reuters.* June 18 in Agnet.

Rathke, Lisa 2003. Genetic Engineering Critics Call for State Ban. *Associated Press State and Local Wire.* March 13, BC Cycle.

Rice Producers of California. n.d. Biotechnology. http://www.riceproducers.com/research_biotech.html (accessed August 20, 2004).

Rocky Mountain Farmers Union. 2003. Governor's Office Fails to Respond to Biopharm Moratorium Request. News Release. May 12. http://www.rmfu.org/News/Releases/releases.cfm (accessed October 17, 2003).

Ryan, George H. n.d. Illinois VentureTECH: A Status Report on Strategic Technology Investment Initiatives. http://www.illinois.gov/ITO/vtech.cfm (accessed May 18, 2004).

Sacramento Bee. 2004. Rules for Rice. http://www.sacbee.com/static/live/news/images/2004125biotech01.jpg (accessed February 11, 2004).

San Luis Obispo Tribune. 2004. State Derails Plans for Genetically Modified Rice; SLO County Was Possible Site Proposed for Crop. April 10.

Silber, Judy. 2004. Panel Sets Conditions for Sale of GMO Rice. *Contra Costa Times*. March 30.

Smith, Cindy. 2004. Letter from Cindy Smith, Deputy Administrator, Biotechnology Regulatory Services, U.S. Department of Agriculture to permit applicants. January 14. http://www.aphis.usda.gov/brs/letters/011404%20.pdf (accessed June 8, 2004).

Smoak, Cameron. 2004. Interview with Cameron Smoak, Assistant Commissioner, Consumer Protection Field Forces, Georgia Department of Agriculture, February 5 (notes on file with the authors).

State FIFRA Issues Research and Evaluation Group. 2003. Issues Status Report, June 2003. http://aapco.ceris.purdue.edu/ (accessed June 2, 2004).

Stoaks, Ralph. 2004. Personal communication with Ralph Stoaks, Plant Protection and Quarantine Western Regional Biotechnologist, Biotechnology Regulator Services, Animal and Plant Health Inspection Service. February 2.

Stoner, Jon, and Lochiel Edwards. 2004. Personal communication with Jon Stoner, Research Chair, and Lochiel Edwards, President, Montana Grain Growers Association. July 18.

Strickland, Roger. 2004. E-mail communication from Roger Strickland to Diane M. Sherman. June 2.

Taylor, Michael R., and Jody S. Tick. 2003. *Post-Market Oversight of Biotech Crops and Foods: Is the System Prepared?* A report commissioned by the Pew Initiative on Food and Biotechnology and prepared by Resources for the Future. April.

TenBruggencate, Jan. 2003. State Tops in Biotech Tests but Questions Remain on Risks. *Honolulu Adviser*. February 18, 1B.

Texas Department of Agriculture. n.d.(a). Regulatory Programs. Biotechnology. http://www.agr.state.tx.us/license/regulatory/index.html (accessed June 1, 2004).

———. n.d.(b). GMO Pesticide Registration Policy. No Date.

———. n.d.(c). Why Agriculture Is Important in Texas. http://www.agr.state.tx.us/about/intern/adm_ag_info.htm (accessed June 5, 2004).

Texas Medical Association. 2002. Health & Science: Report of TMA Task Force on Genetically Modified Foods. April. http://www.texmed.org/has/hpy/gmo_report.asp (accessed June 5, 2004).

Triani, Ron. 2003. Senior Director, Science and Regulatory Affairs, Kraft Foods. Center for Science in the Public Interest's Second Annual Science Policy Forum on Emerging Technologies: Genetically Engineered (GE) Wheat. National Press Club, Washington, DC. December 16. http://cspinet.org/new/pdf/wheat.trans/pdf (accessed April 21, 2004).

Turner, John T. 2003. Letter from John T. Turner, Biotechnologist, Permits and Risk Assessments, Plant Health Programs, Plant Protection and Quarantine, Animal and Plant Health Inspection Service, to Mitch Yergert, Colorado Department of Agriculture, Re: APHIS review of Meristem Therapeutics application to conduct a field test with corn genetically engineered to produce a pharmaceutical compound. May 8.

USDA (U.S. Department of Agriculture). 2003. USDA Strengthens 2003 Permit Conditions for Field Testing Genetically Engineered Plants. News Release. March 6. http://www.usda.gov/news/releases/2003/03/aphis030603.htm (accessed April 28, 2004).

USDA APHIS (Animal and Plant Health Inspection Service). n.d.(a). Additional Information and Contacts. http://www.aphis.usda.gov/brs (accessed April 7, 2004).

———. n.d.(b). Biotechnology Regulatory Services: Permitting, Notification, and Deregulation. http://www.aphis.usda.gov/brs/ (accessed June 8, 2004).

———. n.d.(c). Biotechnology Regulatory Services. Permitting Process http://www.aphis.usda/gov/brs/permitting_process.html (accessed August 18, 2004).

———. n.d.(d). Biotechnology Regulatory Services Website. Permits for Pharmaceuticals and Industrials. http://www.aphis.usda/gov/brs/ (accessed June 8, 2004).

———. n.d.(e). How Does BRS Resolve Compliance Infractions? http://www.aphis.usda.gov/brs/compliance7.html (accessed April 6, 2004).

———. n.d.(f). Instructions for Submitting Confidential Business Information (CBI) and CBI-Deleted Information. http://www.aphis.usda.gov/brs/pdf/instruction.pdf (accessed May 24, 2004).

———n.d.(g). APHIS/BRS, Notice to User, http://www.aphis.usda/gov/brs/noteuser.html (accessed March 31, 2004).

———. n.d.(h). What Is the Compliance History with APHIS' Biotechnology Regulations? http://www.aphis.usda/gov/brs/compliance9.html (accessed March 31, 2004).

———. n.d.(i). What Other Units Does BRS Work With in Investigating and Enforcing Its Regulations? http://www.aphis.usda.gov/brs/compliance8.html (accessed April 6, 2004).

———. 1985. Policy Statement on the Protection of Privileged or Confidential Business Information. *Federal Register* 50: 38561. September 23.

———. 2000. Plant Protection Act; Delegation of Authority Citations. *Federal Register* 65: 49471. August 14.

———. 2002. USDA Creates New Biotechnology Unit. Press Release. August 2. (http://www.aphis.usda.gov/lpa.new/2002/08/bioreorg.html) (accessed March 30, 2004).

———. 2003(a). Field Testing of Plants Engineered to Produce Pharmaceutical and Industrial Compounds. March 10. *Federal Register* 68: 11337 http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2003_register&docid=fr10mr03-7 (accessed March 16, 2004).

———. 2003(b). Introductions of Plants Genetically Engineered to Produce Industrial Compounds. *Federal Register* 68: 46434. August 6. http://www.aphis.usda.gov/brs/fedregister/BRS_20030806a.pdf (accessed June 28, 2004).

———. 2004. Environmental Impact Statement; Introduction of Genetically Engineered Organisms. *Federal Register* 69: 3271–3272. January 23. http://www.aphis.usda.gov/brs/fedregister/BRS_20040123a.pdf (accessed June 28, 2004).

USDA ERS (Economic Research Service). 2000. Briefing Room: Wheat, Background http://www.ers.usda.gov/Briefing/Wheat/background.htm (accessed May 11, 2004).

———. 2001. Briefing Room: Rice, Background. June 28. http://www.ers.usda.gov/Briefing/Rice/background.htm (accessed May 19, 2004).

———. 2002(a). Data: Farm Income. http://www.ers.usda.gov/farmincome/finfdmu.htm (accessed June 2, 2004).

———. 2002(b). Data: State Fact Sheets, Top 5 Agricultural Commodities. http://www.ers.usda.gov/StateFacts/ (accessed June 2, 2004).

———. 2003. Data: State Export Data. September. http://www.ers.usda.gov/data/stateexports (accessed May 18, 2004).

USDA NASS (National Agricultural Statistics Service). 2003(a). Agricultural Statistics. Chapter I Statistics of Grain and Feed. http://www.usda.gov/nass/pubs/agr-03/03_ch1.pdf (accessed May 11, 2004).

———. 2003(b). Agricultural Statistics. Crop Ranking: Major Field Crops, Rank by Production, Major States, 2002. http://www.usda.gov/nass/pubs/agr03/acro03.htm (accessed June 4, 2004).

U.S. Census Bureau. 2003. Statistical Abstract of the United States: 2003. No. 832. Percent of Corn, Soybean, and Cotton Acreage Planted with Genetically Modified Seed: 2000 and 2003. http://www.census.gov/prod/www/statistical-abstract-03.html (accessed June 4, 2004).

U.S. EPA (Environmental Protection Agency). n.d.(a). Pesticides: Regions, States, & Tribes, http://www.epa.gov/pesticides/local/summary.htm (accessed April 7, 2004).

———. n.d.(b). Pesticides: Registering Pesticides. http://www.epa.gov/pesticides/regulating/registering/ (accessed April 13, 2004).

———. n.d.(c). FY 2004 Annual Performance Plan and Congressional Justification. http://www.epa.gov/ocfo/budget/2004/2004cj.htm (accessed June 8, 2004).

———. 2001. 40 CFR Parts 152 and 174: Plant-Incorporated Protectants, Final Rules and Proposed Rule, *Federal Register* 66: 51340. July 19. http://www.epa.gov/pesticides/biopesticides/pips/pip_rule.pdf (accessed June 1, 2004).

——— 2003. Notice of Pesticide Use/Misuse Inspection Report for Pioneer Hi Bred International field trial site, January 1; Notice of Pesticide Use/Misuse Inspection Report for Mycogen Seeds field trial site, January 24; Notice of Pesticide Use/Misuse Inspection Report for Monsanto Company field trial site, January 23.

———. 2004(a). FY 2004 Update for the Core Program Guidance: Federal Insecticide, Fungicide, and Rodenticide Act Program. www.epa.gov/compliance/resources/policies/planning/2004MOA.pdf (accessed June 2, 2004).

———. 2004(b). Office of Pesticide Programs (OPP). Public Workshop: Plant-Incorporated Protectant (PIP) Experimental Use Permits (EUPs): Process and Compliance. Arlington, Virginia. February 10–11.

U.S. FDA (Food and Drug Administration). 2002. Guidance for Industry – Drugs, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals. September 6. http://www.fda.gov/cber/gdlns/bioplant.pdf (accessed August 28, 2004).

———. 2004. List of Completed Consultations on Bioengineered Foods. April. (http://www.cfsan.fda.gov/~lrd/biocon.html) (accessed June 8, 2004).

U.S. FDA CFSAN (Center for Food Safety and Applied Nutrition). 1993–2001. FDA Pesticide Residue Monitoring Program. http://www.cfsan.fda.gov/~dms/pesrpts.html (accessed June 14, 2004).

U.S. Wheat Associates. 2001. Biotechnology: USW Foreign Office Reports. April. http://www.uswheat.org/_85256A (accessed May 12, 2004).

———. 2002(a). Biotechnology: USW Foreign Office Reports. January. http://www.uswheat.org/__85256A31005736D3.nsf/0/5880C8B599EC737C85256D180068C67C?Open (accessed May 12, 2004).

———. 2002(b). GM Wheat: Customer Acceptability Survey, Results from Asia, September 30. www.uswheat.org/Biotech.nsf/0/ed867efc0f29c75285256d1/$FILE/SURVEY%20results%20-%20Asia.pdf (accessed May 12, 2004).

U.S. Wheat Associates, National Association of Wheat Growers, and the Wheat Export Trade Education Committee. 2004. Joint Biotechnology Position Statement. http://www.wheatworld.org/pdf/2004%20NAWG%20Resolutions.pdf (accessed May 12, 2004).

United States Regulatory Agencies Unified Biotechnology Website. n.d. Roles of the Agencies. http://usbiotechreg.nbii.gov/ (accessed June 3, 2004).

University of Illinois at Urbana-Champaign. Biotechnology Center. n.d. http://www.biotech.uiuc.edu/ (accessed February 23, 2004).

Vermont Legislature. 2003–2004. Bill Tracking System. H.0777: Genetically Engineered Seed. http://www.leg.state.vt.us/database/status/status.cfm (accessed May 18, 2004).

Webber, David A. 2004. Written communication from David A. Webber, Deputy Attorney General, Commerce and Economic Development Division, Hawaii Department of the Attorney General, to Isaac H. Moriwake, Attorney, Earthjustice. April 13.

Western Colorado Congress. n.d. WCC Mission. http://www.wccongress.org/staff.cfm (accessed March 5, 2004).

Western Organization of Resource Councils. 2002. Fact Sheet: United States Wheat Production, October. http://www.worc.org/pdfs/WORCproductionfactsheet.pdf (accessed May 10, 2004).

Wetzel, Dale. 2004. Proposal Would Give Ag Commissioner Veto Power Over Biotech Wheat Plantings. *Associated Press*. February 6.

Williams, Eesha. 2003. Lawmakers Consider Controls on GMOs. *Brattleboro Reformer*. March 11. http://www.reformer.com (accessed June 18).

Wilson, William W., Edward L. Janzen, and Bruce L. Dahl. 2003. Issues in the Development and Adoption of Genetically Modified (GM) Wheats. *AgBioForum* 6(3): 101-112. http://www.agbioforum.org/v6n3/v6n3a03-wilsom.pdf (accessed May 12, 2004).

Winter, Sarah. 2004. Letter from Sarah Winter to the Colorado Department of Agriculture on Draft Procedures for Evaluating Biotechnology Permits for Plant Made Industrial and Pharmaceutical Products in Colorado. January 12.

Wisner, Robert. 2003. Market Risks of Genetically Modified Wheat: The Potential Short-Term Impacts of GMO Spring Wheat Introduction on U.S. Wheat Export Markets and Prices. Iowa State University. October 30. http://www.agobservatory.org/library.cfm?filename=Market_Risks_of_Genetically_Modified_Wheat.pdf (accessed May 24, 2004).

Wong, Lyle. 2004. Personal communication with Lyle Wong, Administrator, Plant Industry Division, Hawaii Department of Agriculture. March 26, July 29.

Workman, Catherine. 2004. Letter from Catherine Workman to the Colorado Department of Agriculture on Draft Procedures for Evaluating Biotechnology Permits for Plant Made Industrial and Pharmaceutical Products in Colorado. January 15.

Wuerthele, Suzanne. 2004. Letter from Suzanne Wuerthele, Sierra Club Rocky Mountain Chapter, to the Colorado Department of Agriculture on Draft Procedures for Evaluating Biotechnology Permits for Plant Made Industrial and Pharmaceutical Products in Colorado. January 15.

Yergert, Mitchell. 2003(a). E-mail communication from Mitchell Yergert, Plant and Insect Section Chief, Division of Plant Industry, Colorado Department of Agriculture, to Wendy Fink, Program Associate for Science, The Pew Initiative on Food and Biotechnology. September 3.

———. 2003(b). Communication from Mitchell Yergert, Plant and Insect Section Chief, Division of Plant Industry, Colorado Department of Agriculture, to John Turner, Biotechnologist, Biotechnology Regulatory Services, Animal and Plant Health Inspection Service, Re: APHIS' Application: 03-086-01R, State Response to APHIS' Supplemental Conditions of an Application for the Movement of a Regulated Article Under 7 CFR 340. June 4.

———. 2004. Personal communication with Mitchell Yergert, Plant and Insect Section Chief, Division of Plant Industry, Colorado Department of Agriculture. January 23.

Zellar, Ron. 2004. E-mail communication from Ron Zellar, Information Specialist and Projects Coordinator, Montana Department of Agriculture, to Jody Tick. February 5.

Zielinksi, Dave. 1992. Genetic Engineering Rules Cause Heated Debate. *CityBusiness/Twin Cities,* Inc. Vol. 9, No. 45, Sec. 1, p. 11. April 20.

APPENDIX A: STATE-BY-STATE SUMMARIES

Introduction

This section presents information on biotech-related activity and regulatory oversight of biotech crops and foods in the 17 states that are the focus of this report. It is intended to provide a snapshot of what is happening in each state in a way that is of value both for understanding the status of biotech oversight in the individual states and as a basis for comparisons among the states. The information is provided in a standard format, which includes an overview of agriculture and biotech activity in each state; a table that presents the statutes, agencies, and resources applicable to each state's oversight of biotech crops and foods; and comments from the survey and interviews. Following the state-by-state summaries, several maps have been added which synthesize the data presented on each state as well as comparisons. They help clarify the agricultural contributions of each state, and illuminate the number of APHIS notifications and permit applications submitted. An explanation of the data and its sources is provided below.

Explanatory Notes

Overview

The Overview segment of each summary provides a snapshot of agricultural statistics to illustrate the nature and economic importance of the agricultural industry in the state. The data come from a variety of sources, mostly collected by USDA's Economic Research Service. The reported "value" of agriculture is the "net value added" from the agricultural industry in each state to the economy in that state, which ERS defines as the "total value of the farm sector's production of goods and services, less payments of other (nonfarm) sectors of the economy." This value is the same value added to the U.S. economy as well. ERS believes that net value added is the most accurate statistical representation of how much a state's agricultural industry adds to the economy and the gross state product,[412] and it provides a consistent basis for comparison, though many state departments of agriculture report larger numbers. We also present the "share of total U.S. agricultural production" for each state, which derives from dividing each state's net value added by the total U.S. net value added.[413]

---

412 Strickland 2004.

413 USDA ERS 2002(a).

The share of total U.S. agricultural exports that each state provides is derived by dividing the value of each state's share of total U.S. agricultural exports by the value of U.S. agricultural exports, both provided by ERS.[414] The top five commodities in each state, in order of cash receipts, are taken directly from ERS tables, and are listed in order of cash receipts.[415] Most summaries list the major field crops of which the state is among the top five producers nationally. The major field crops included in this assessment are corn (grain), soybeans, all wheat varieties, sorghum (grain), barley, oats, cotton (all), peanuts, rice, hay (all), alfalfa hay, tobacco (all), dry edible beans, and potatoes.[416] Some of the summaries also report the acres of cotton, corn, and/or soybeans in a state that are planted with biotech seed, a statistic taken from the Statistical Abstract of the United States.[417]

Each summary reports the status of biotech field trial activity in the state, as reflected in the number of APHIS notifications and permit applications that have been submitted, acknowledged, or deemed denied/withdrawn/void, as well as the number that were in effect as of May 4, 2004. Since each notification and permit is valid for a specified range of dates, not all notifications and permits that have been acknowledged or issued are in effect today. The summaries also break out the number of permits or notifications that have been submitted, acknowledged, or issued for pharma and industrial crops.[418]

Finally, the crops for which field trials have been authorized are identified. These and other data on the status of biotech field trial activity were collected from an on-line database—Information Systems of Biotechnology (ISB)—created and maintained by Professor Doug King at the Virginia Polytechnic Institute and State University through a grant funded by USDA's Cooperative State Research, Education, and Extension Service. The data for this database are provided by APHIS to ISB at regular intervals. Daily database updates of authorizations under consideration and granted by APHIS are available at the APHIS BRS website.

The numbers in the summaries are from data last updated on May 4, 2004.[419] It is important to note that the number of permits or notifications may be slightly underreported, and some crops may be missing from the list of crops. This is because, as is evident from records in ISB, the type of crop or the phenotype (the nature of the introduced trait) is at times redacted from publicly available information as confidential business information (CBI). However, these cases appear to be rare.

---

414 USDA ERS 2003.

415 USDA ERS 2003(b).

416 USDA NASS 2003(b).

417 U.S. Census Bureau 2003.

418 Currently, all pharma and industrial crop trials are authorized by permit, but prior to August 2003, APHIS authorized some industrial crop trials by notification. USDA APHIS 2003(b).

419 Information Systems for Biotechnology 2004(f).

Each summary provides a brief narrative overview of biotech activity and the status of biotech-related legislation in the state. These are by no means complete descriptions of activity in each state, but rather an attempt to capture the flavor of each state's interest and activity related to agricultural biotechnology. The examples of past and pending legislative activity are drawn mainly from the Pew Initiative on Food and Biotechnology's Legislation Tracker, [420] which provides a more complete compilation for interested readers. The summaries include both regulatory legislation—safety and trade/market regulations—and examples of measures aimed at promoting agricultural biotechnology and biotech-driven economic growth. A more complete digest of initiatives in the latter category is provided in a recent report prepared by the Battelle Memorial Institute for the Biotechnology Industry Organization (BIO).[421]

Regulatory Authority, Agencies, and Resources

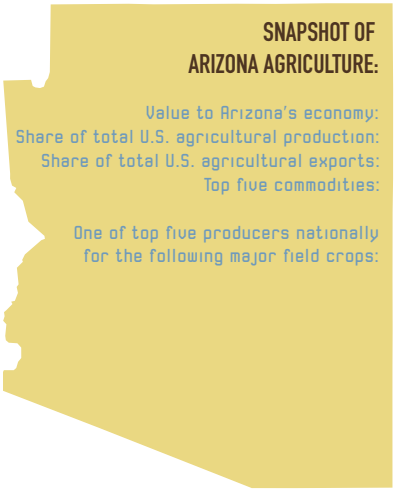
The second segment of each state summary is a table titled Regulatory Authority, Agencies, and Resources. This table focuses on regulatory oversight of biotech crops and foods and identifies the applicable or potentially applicable statutes and agencies. As the tables indicate, most states have not enacted biotech-specific regulatory statutes nor established specific biotech oversight units; to the extent they are active in regulatory oversight, most states rely on general plant health, pesticide, and food safety laws and existing organizations. The resource section places the generally very limited resources most states devote to oversight of biotech crops in the context of the overall budgets for the state department of agriculture and plant health protection programs. Because the states typically do not have separate budget line items for biotech regulatory oversight, the summaries generally provide informal estimates by knowledgeable state officials.

420 Pew Initiative on Food and Biotechnology 2004(c).

421 Battelle Technology Partnership Practice and SSTI 2004.

ARIZONA

OVERVIEW



SNAPSHOT OF ARIZONA AGRICULTURE:

Value to Arizona's economy:	$1,853,104,000
Share of total U.S. agricultural production:	2.41%
Share of total U.S. agricultural exports:	1.26%
Top five commodities:	Lettuce, cattle and calves, dairy products, cotton, and hay
One of top five producers nationally for the following major field crops:	None

Status of Biotech Field Trial Activity

238 distinct APHIS notifications submitted (230 acknowledged; 6 denied/withdrawn/void; 38 currently in effect)

---

46 distinct APHIS permit applications submitted (41 issued; 5 denied/withdrawn/void; 3 currently in effect)

---

1 APHIS permit issued for a variety of corn engineered to produce compounds used in pharmaceutical production

---

No APHIS notifications or permit applications submitted for crops engineered to produce compounds used in industrial applications

---

Other crops for which APHIS notifications and/or permit applications were submitted include: corn, cotton, alfalfa, beets, creeping bentgrass, lettuce, melons, rapeseed, rice, safflower, squash, tobacco, tomatoes, and wheat

Biotech Activity and Legislative Status

Biotech Activity and Interest

Biotech crops and foods, and the research industry associated with them, are of particular interest to some in Arizona because specific attributes of the state's environment may provide natural protection against the potential risk of cross-contamination between biotech and nonbiotech crops or other organisms. Sheldon Jones, who was previously with the Arizona Department of Agriculture and now works with the Agri-Business Council of Arizona, a nonprofit trade association,[422] emphasizes the ability of producers in Arizona to geographically isolate and control the growth of crops due to their need to irrigate select areas to create cropland in an otherwise dry region. Mr. Jones hopes Arizona will secure a reputation as an ideal place for the field testing of biotech crops.[423]

Although the Arizona Department of Agriculture does not currently have significant funding for the regulation of biotech crops and foods, it wants to be knowledgeable about the new technological developments in the field and prepared to oversee biotech crops that come to their state. They currently participate in the APHIS permitting process as much as they are able and have sought outside help from academics in some cases.[424]

Regulatory Legislation

While there is no biotech-specific regulatory statute in Arizona, there is a regulation that has existed within the Arizona Administrative Code since 1994 on Genetically Engineered Organisms and Products (Ariz. Admin. Code Supp. § R3-4-901 (2004)). The rule reinforces APHIS' regulations by explaining how Arizona will interact with the APHIS oversight process and by prohibiting field trials or commercialization of biotech crops in Arizona unless APHIS has authorized it through the permit or notification process or has granted the crop nonregulated status. It further requires that permit applicants demonstrate to the state that the biotech organism will be "handled in such a manner so that no genetically engineered organism or product accidentally escapes into Arizona's environment" and that the applicant will comply with Arizona quarantine rules that regulate plant, pests, and organisms that will be introduced into Arizona's environment (Ariz. Admin. Code Supp. § R3-4-901(B)(2)(a) (2004)). The rule also authorizes the Arizona Department of Agriculture to place additional restrictions, measures, and monitoring requirements on the permittee's actions, as well as the ability to request that APHIS deny, suspend, modify, or revoke a permit, if these actions are necessary to protect Arizona's agriculture, public health, or environment.

---

422 Agri-Business Council of Arizona n.d.

423 S. Jones 2004.

424 Harder 2004.

Nonregulatory Legislation

Although no legislation has been introduced in Arizona since 2001 that addresses the regulation of biotech crops and foods, two bills were introduced that address nonregulatory issues. An anti-crop-destruction bill (HB2481) was passed in Arizona during the 2001 legislative session,[425] and a bill that would have made ecological and animal terrorism a criminal offense was passed by the legislature in 2004 but vetoed by the governor (SB1081).[426]

REGULATORY AUTHORITY, AGENCIES, AND RESOURCES

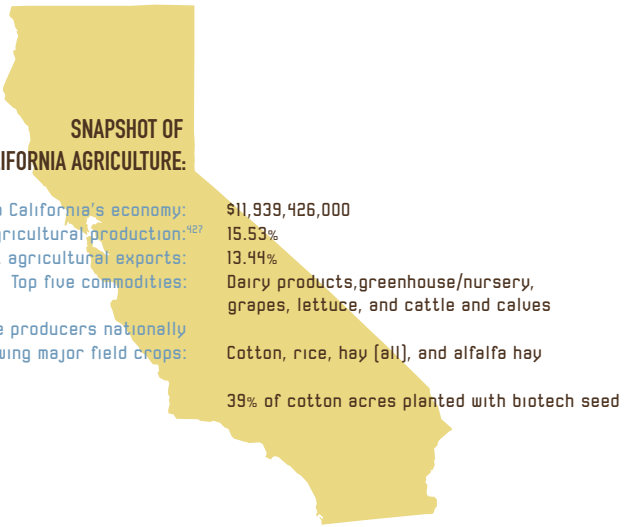
RELEVANT STATUTORY AUTHORITY			
Biotech-Specific Regulatory Statutes	Other Potential Statutory Authority Over Biotech Field Trials	Other Potential Statutory Authority Over PIPs	Other Potential Statutory Authority Over Biotech Food Safety
None; but regulations establish a process for overseeing biotech crops	General plant pest law: 3 Ariz. Rev. Stat. § 201 et seq. (2004) (Dangerous Plant Pests and Diseases)	General pesticide control laws: 3 Ariz. Rev. Stat. § 341 et seq. (2004) (Pesticides) 3 Ariz. Rev. Stat § 361 et seq. (2004) (Pesticide Control)	General food safety law: 36 Ariz. Rev. Stat. § 901 et seq. (2004) (Pure Food Control)
AGENCIES WITH CURRENT OR POTENTIAL BIOTECH ROLES			
Biotech-Specific	Plant Health	Pesticides	Food Safety
None	Arizona Department of Agriculture – Plant Services Division	Arizona Department of Agriculture – Environmental Services Division	Arizona Department of Agriculture – Environmental Services Division Arizona Department of Health Services
RESOURCES			
Arizona Department of Agriculture budget: $9,800,000 Budget for plant health protection: $3,300,000 Narrative description of budget for biotech crops and foods component: 20% of one FTE			

425 Pew Initiative on Food and Biotechnology 2004(c).

426 Arizona State Legislature 2004.

CALIFORNIA

OVERVIEW



SNAPSHOT OF CALIFORNIA AGRICULTURE:

Value to California's economy:	$11,939,426,000
Share of total U.S. agricultural production:[427]	15.53%
Share of total U.S. agricultural exports:	13.44%
Top five commodities:	Dairy products, greenhouse/nursery, grapes, lettuce, and cattle and calves
One of top five producers nationally for the following major field crops:	Cotton, rice, hay (all), and alfalfa hay
	39% of cotton acres planted with biotech seed

Status of Biotech Field Trial Activity

968 distinct APHIS notifications submitted (884 acknowledged; 76 denied/withdrawn/void; 102 currently in effect)

230 distinct APHIS permit applications submitted (210 issued; 19 denied/withdrawn/void; 8 currently in effect)

9 APHIS permits issued for varieties of corn, rapeseed, and rice engineered to produce compounds used in pharmaceutical production

2 APHIS permits issued for varieties of corn and an unidentified crop engineered to produce compounds used in industrial applications

Other crops for which APHIS notifications and/or permit applications were submitted include: alfalfa, apples, barley, beets, Brassica, carrots, corn, creeping bentgrass, cotton, grapes, Kentucky bluegrass, lettuce, melons, onions, peas, pelargonium, peppers, persimmons, petunias, potatoes, rapeseed, rice, soybeans, squash, strawberries, sunflowers, tobacco, tomatoes, walnuts, watermelons, and wheat

427 Using state's net value added and U.S. total net value added. Data source: USDA ERS 2002(a).

Biotech Activity and Legislative Status

Biotech Activity and Interest

The high level and diversity of biotech activity within California has caught the attention of many regulators, industry groups, and consumers in the state.

In the mid-1980s, the California legislature and the governor's office recognized the importance of the state's fledgling biotechnology industry, and a state task force was formed to address the state's preparedness for biotechnology developments. The task force prepared a 1986 document entitled, *California's Biotechnology Permits and Regulations – A Description,* which outlined existing state and federal authority and articulated the state's policy of deferring to the federal government whenever possible. It provided guidance to industry and interested parties on regulatory oversight under existing authority. Subsequent administrations and legislatures paid less attention to oversight issues until food safety became an issue in 2000, following the StarLink episode, and FDA sought public input on its oversight strategy.

The most prominent issues in the state currently include the controversy surrounding an application to commercialize pharma rice and a ban on biotech organisms in Mendocino County. Early in 2004, Ventria Bioscience sought approval for commercial planting of pharma rice in California. This generated substantial controversy among rice producers, the food industry and other stakeholders based on concern about possible cross-contamination of other rice and food crops. Although the California Rice Commission approved the proposal, recommending segregation, identity preservation protocols, and expedited approval, the California Secretary of Agriculture, A.G. Kawamura, returned the matter to the Rice Commission with instructions for further review.[428] This episode is discussed in more detail in Section IV's vignette, "Role of State Advisory Bodies in Decisions to Commercialize Biotech Crops: California's Pharma Rice Experience."

On March 2, 2004, the citizens of Mendocino County, California passed Measure H, which bans production of biotech animals, plant organisms, and transgenic bacteria and viruses in the county, creating the first such ban in the United States. The ban is not directed against the sale or use of genetically modified organisms, but does make it unlawful for any person, firm, or corporation to propagate, cultivate, raise or grow these organisms in Mendocino County. Measure H was initiated by a strong grassroots effort of the Mendocino Organic Network, a group of organic farmers, environmentalists, and consumer activists, and led by Els Cooperrider, an organic business owner.[429] Measure H gained national press interest and attention from the biotech industry, which vigorously opposed it.[430] The Mendocino Organic Network proposed the ballot measure to "protect the county's agriculture, environment, economy and private property from genetic pollution

428 Silber 2004; Jacobs 2004.

429 Organic Consumers Association 2003.

430 Lau 2004.

by genetically modified organisms."[431] The measure not only bans biotech production in the county, but establishes penalties for violations, and requires the county agricultural commissioner to enforce its provisions.[432] Similar measures were scheduled to will be on the November 2004 ballot in four other California counties.

Regulatory Legislation

California has banned production of biotech fish in the waters of the Pacific Ocean under state jurisdiction, [433] but it has no biotech-specific regulatory statute for plants. It has, however, mandated by law a study related to regulatory oversight of biotech crops and foods. After affirming the role of FDA, EPA, and USDA in regulating agricultural biotechnology, the statute created a Food Biotechnology Task Force in 2001 with the charge to identify and analyze issues to determine what California's role in overseeing this technology might be. The statute directs the task force and an advisory committee formed by the task force to look at national and international marketing issues, as well as address the potential benefits and impacts to health, the state's economy, and the environment from biotech crops and foods (Cal. [Agric.] Code § 491 et seq. (2003)). Findings, which were reported to the legislature and published in *A Food Foresight Analysis of Agricultural Biotechnology*, focused on the uncertainty of how agricultural biotechnology will be accepted into the international food system and raised concerns about the need to inform consumers, perform environmental and health analysis, and reassess federal and state oversight procedures.[434]

Nonregulatory Legislation

There are multiple places in California's statutes addressing nonregulatory aspects of agricultural biotechnology. The development and use of biotechnology for pest management is explicitly encouraged by one statute that creates a Pest Management Research Committee to award grants to public and private pest management research projects (Cal. [Agric.] Code § 12798 (2003)). Another statute describes the California State University Program for Education and Research in Biotechnology and indicates it is the "intent of the Legislature" to provide additional state funding to the University for this program (Cal. [Educ.] Code § 12798 (2003)). Numerous other sections encourage academic and economic growth in the biotechnology sector, among other technology or high-growth sectors.

A number of nonregulatory bills supporting biotechnology research in California have been introduced recently. Many have failed that would have extended the duration of or increased the amount of tax credits for companies and producers involved with biotechnology research, development, and manufacturing. One currently pending bill would grant counties the ability to exempt companies, including biotech companies, from paying property tax on newly constructed qualified manufacturing facilities during a startup

431 GMO Free Mendocino County n.d.

432 GMO Free Mendocino County n.d.

433 Pew Initiative on Food and Biotechnology 2004(c).

434 Food Biotechnology Task Force 2003.

period (AB1789). Two bills that created centers to address the workforce needs of the biotech industry were passed in recent years, one in 2001 that created the Pasadena Bioscience Center (SB327) and another in 2003 that created the San Diego Multiuse Biotechnology Training Center (AB1551). Additionally, a pending bill would acknowledge the creation of an East Bay Biotechnology Center on the campus of the California State University at Hayward (AB1885).[435]

REGULATORY AUTHORITY, AGENCIES, AND RESOURCES

RELEVANT STATUTORY AUTHORITY			
Biotech-Specific Regulatory Statute	Other Potential Statutory Authority Over Biotech Field Trials	Other Potential Statutory Authority Over PIPs	Other Potential Statutory Authority Over Biotech Food Safety
None	General plant pest law: Cal. [Agric.] Code § 5001 et seq. (2003) (Plant Quarantine and Pest Control)	General pesticide control law: Cal. [Agric.] Code § 12751 et seq. (2003) (Pesticides)	General food safety law: Cal. [Agric.] Code § (2003)
AGENCIES WITH CURRENT OR POTENTIAL BIOTECH ROLES			
Biotech-Specific	Plant Health	Pesticides	Food Safety
None	California Department of Food & Agriculture – Division of Plant Health & Pest Prevention Services, Permits & Regulations Program	California Environmental Protection Agency – Department of Pesticide Regulation	California Department of Food & Agriculture – Agricultural Commodities & Regulatory Services and Animal Health & Safety Services California Department of Health Services – Food & Drug Branch
RESOURCES			
California Department of Food and Agriculture budget: $209,388,250 Budget for plant health protection: $70,200,000 Narrative description of budget for biotech crops and foods component: CDFA does not identify biotechnology in its budget process, and no estimate of resources devoted to biotechnology was available.			

435 California Legislative Information n.d.

COLORADO

OVERVIEW

SNAPSHOT OF COLORADO AGRICULTURE:

Value to Colorado's economy:	$1,412,852,000
Share of total U.S. agricultural production:	1.84%
Share of total U.S. agricultural exports:	1.7%
Top five commodities:	Cattle and calves, corn, dairy products, greenhouse/nursery, and hay
One of top five producers nationally for the following major field crops:	Barley and potatoes

Status of Biotech Field Trial Activity

148 distinct APHIS notifications submitted (142 acknowledged; 4 denied/withdrawn/void; 13 currently in effect)

---

31 distinct APHIS permit applications submitted (22 issued; 9 denied/withdrawn/void; 3 currently in effect)

---

1 APHIS permit issued for a variety of corn engineered to produce a compound for pharmaceutical production

---

1 APHIS permit issued for a variety of rapeseed engineered to produce a compound for industrial applications

---

Other crops for which APHIS notifications and/or permit applications were submitted include: alfalfa, beets, corn, creeping bentgrass, potatoes, rapeseed, sunflowers, and wheat

Biotech Activity and Legislative Status

Biotech Activity and Interest

The major public debate in Colorado regarding biotech crops has centered on the permitting of pharma and industrial crops. The issue gained attention when Meristem Therapeutics was granted the first-ever approval to field test a variety of corn engineered to produce a compound for pharmaceutical production within the state in 2003 (see Section IV. for the vignette titled, "Permitting of Pharma Crops: The Experience in Colorado," for more details).[436] A range of stakeholders, including producers, producer groups, commodity groups, environmental groups, academics, and legislators, weighed in with opinions on the Meristem permit application as well as on the Colorado Department of Agriculture's subsequent public efforts to create a codified process for the state review of APHIS pharma and industrial biotech permit applications. The Colorado Department of Agriculture does not want to replicate APHIS' work, but rather believes it can contribute valuable information to the permit application review process, specifically regarding regional or local conditions.[437] However, it is unlikely that Colorado will seek statutory authority to regulate biotech crops and foods outside of this process because there are not enough resources currently to do so.[438] As for Bt crops, Colorado does not currently participate in their review or inspection, but rather defers to EPA's authority.[439]

Another area of interest for Colorado is the potential to attract new biotech ventures in order to fuel economic development. In 2001, Governor Bill Owens and the Governor's Commission on Science and Technology created the Colorado Technology Alliance (CTA), a nonprofit initiative funded by private industry donations.[440] CTA, in turn, formed a Biotechnology Council comprised of government, university, and industry representatives[441] who were commissioned to study how Colorado could develop a workforce, a supportive environment, and potential research areas to attract companies working on a range of biotechnology issues, such as agriculture, national security threats, and medical improvements.[442] With the assistance of the Battelle Memorial Institute, the council in April 2003 published an action agenda to help Colorado become a biotech hub.[443]

---

436 Yergert 2004.

437 Miller 2004.

438 Miller 2004.

439 Yergert 2004.

440 Denver Business Journal 2002.

441 Lofholm 2003.

442 Denver Business Journal 2002.

443 Colorado Office of Innovation and Technology 2003.

Regulatory Legislation

There is currently no state statute or regulation addressing the regulation of biotech crops and foods in Colorado, but there has been political activity in the area since 2001. A recent bill that died in the legislature would have required the labeling of biotech food, and an initiative in Denver to place a moratorium on serving biotech food in schools failed to get the requisite number of signatures to go on the ballot.[444] Most recently, Representative Ray Rose has been speaking about introducing a bill that would specifically provide CDA with the authority to regulate biotech crops and foods, although he has yet to do so (see Section IV. for the vignette titled, "The State Role in Permitting of Pharmaceutical and Industrial Crops: Colorado's Development of a Public Process"for more details,).[445]

Nonregulatory Legislation

Colorado has two statutes that address research in the area of biotechnology. One provides for a refund of the sales and use tax on materials used in Colorado for agricultural and nonagricultural biotechnology research and development (39 Colo. Rev. Stat. § 26-401 et seq. (2004)). The other creates an "advanced technology fund," whose monies are distributed by the Colorado Commission on Higher Education to individuals or public or private organizations engaged in advanced technology research programs or related technology transfer (23 Colo. Rev. Stat. § 1-106.5 (2004)). The explicit inclusion of biotechnology in this statute was introduced through legislation that passed during the 2003 legislative session (SB03-308). Another piece of legislation addressing nonregulatory issues in biotechnology that passed in 2002 in Colorado was an anti-crop-destruction bill (SB02-69).

444 Pew Initiative on Food and Biotechnology 2004(c).

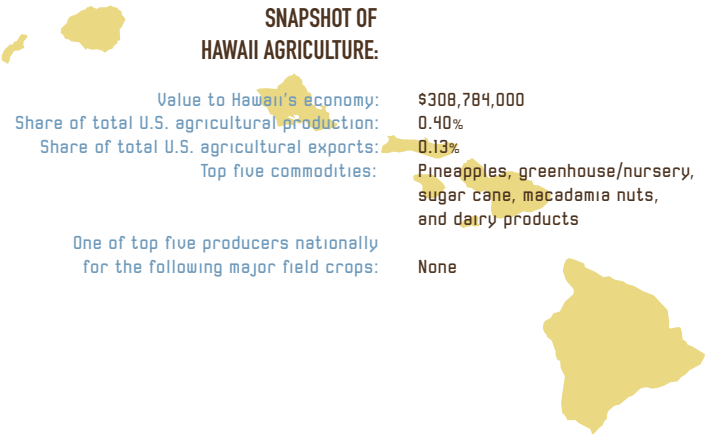
445 Grand Junction Daily Sentinel 2004.

REGULATORY AUTHORITY, AGENCIES, AND RESOURCES

RELEVANT STATUTORY AUTHORITY			
Biotech-Specific Regulatory Statutes	Other Potential Statutory Authority Over Biotech Field Trials	Other Potential Statutory Authority Over PIPs	Other Potential Statutory Authority Over Biotech Food Safety
None	General plant pest law: 35 Colo. Rev. Stat. § 4.0-101 et seq. (2003) (Colorado Plant Pest Act)	General pesticide control law: 35 Colo. Rev. Stat. § 9-101 et seq. (2003) (Pesticide Act)	General food safety law: 25 Colo. Rev. Stat. § 5-401 et seq. (2003) (Pure Food and Drug Law)
AGENCIES WITH CURRENT OR POTENTIAL BIOTECH ROLES			
Biotech-Specific	Plant Health	Pesticides	Food Safety
None	Colorado Department of Agriculture – Division of Plant Industry, Director	Colorado Department of Agriculture – Division of Plant Industry, Pesticide Registration Program	Colorado Department of Public Health & Environment
RESOURCES			
Colorado Department of Agriculture budget: FY 05 $29,755,680 Budget for plant health protection: FY 05 $1,990,655 Narrative description of budget for biotech crops and foods component: Biotech activities are supported by six staff members at the department; that support is equivalent to 0.5 of one FTE and $38,000.			

HAWAII

OVERVIEW



SNAPSHOT OF HAWAII AGRICULTURE:

Value to Hawaii's economy:	$308,784,000
Share of total U.S. agricultural production:	0.40%
Share of total U.S. agricultural exports:	0.13%
Top five commodities:	Pineapples, greenhouse/nursery, sugar cane, macadamia nuts, and dairy products
One of top five producers nationally for the following major field crops:	None

Status of Biotech Field Trial Activity

1,606 distinct APHIS notifications submitted (1,513 acknowledged; 84 denied/withdrawn/void; 150 currently in effect)

---

102 distinct APHIS permit applications submitted (88 issued; 13 denied/withdrawn/void; 7 currently in effect)

---

15 APHIS permits issued for varieties of corn, rice, and sugarcane engineered to produce compounds for pharmaceutical production

---

No APHIS notifications or permit applications submitted for crops engineered to produce compounds for industrial applications

---

18 crops total for which APHIS notifications and/or permit applications were submitted

---

Most APHIS notification and permit applications submitted for biotech varieties of corn

---

Other crops include: barley, coffee, cotton, lettuce, papaya, peanuts, pineapples, potatoes, rice, soybeans, sugarcane, sunflowers, tobacco, tomatoes, and wheat

Biotech Activity and Legislative Status

Biotech Activity and Interest

Biotechnology research is a major component of Hawaii's agricultural economy. Hawaii leads the country in the number of APHIS-authorized field trials, including the largest number of permits issued for pharma crops.[446] This reflects Hawaii's reputation as having conditions conducive for the testing and growing of biotech crops, including a year-round growing season.[447]

At the same time, an organic producer group representative commented in response to the survey that "Hawaii has a very fragile ecosystem" and "biotech companies are ... planting biopharmaceuticals possibly too close to seed corn grown for the entire U.S." One focus of attention in Hawaii today is a lawsuit brought by Earthjustice on behalf of the Center for Food Safety against the Hawaii Department of Agriculture to compel the department under Hawaii's open records law to release information about pharma crop field trials in the state.[448] A second lawsuit is being pursued in Honolulu against the USDA by Earthjustice, on behalf of the Center for Food Safety, KAHEA – the Hawaiian Environmental Alliance, Friends of the Earth, and the Pesticide Action Network of North America, seeking a halt to all "open-air" field testing of pharma crops until USDA performs assessments of the environmental and public health risks.[449] Since a large number of those field trails take place in Hawaii, the conclusions of the case are important to the state (see Section IV. for the vignette titled, "Confidential Business Information and State Oversight of Biotech Crops: Hawaii Litigation Airs the Debate," for more details).

Regulatory Legislation

Although Hawaii does not have a comprehensive statute addressing the regulation of biotech crops and foods, state law requires that anyone who submits an application to a federal agency "for any permit for or approval of any bioproduct, field testing of genetically modified organisms, or environmental impact assessment of genetically modified organisms," simultaneously submit a copy of the application to the Hawaii Department of Health (19 Haw. Rev. Stat. § 321-11.6 et seq. (2003)).

Legislative activity addressing regulatory aspects of agricultural biotechnology issues in Hawaii is high. Many bills that would appropriate funds to assess the long-term effects of growing biotech crops in Hawaii have been introduced over the last three years. In 2001 and 2002, a number of bills calling for the labeling of genetically modified foods, or the labeling of nongenetically modified foods, died in the legislature. However, the labeling of both foods and seeds is addressed by a set of bills introduced in 2003

---

446 Information Systems for Biotechnology 2004(f).

447 TenBruggencate 2003.

448 Center for Food Safety v. Department of Agriculture, Hawaii, Civil No. 03-1-1509-07, 2003.

449 Leone 2003.

and carried over into 2004, the second year of this legislative session, that require conventional farmers to be notified of nearby biotech crops and that discuss liability issues concerning cross-pollination between biotech crops and nonbiotech crops (HB1281, HB1033, SB601).[450] Bills requiring the reporting to Hawaii's legislature of research dealing with genetic modification and establishing permits for the release of specific genetically modified organisms have also been introduced.

Two bills that were introduced in 2003 and carried over to the 2004 legislative session would require companies to disclose the location of biotech field trials as well as contract with organizations to conduct safety evaluations (SB1640 and SB1436). Additional legislation that was introduced in 2003 included a set of three resolutions mandating the study of biotechnology in the context of sharing genetic resources and preserving biological diversity, and a similar bill that was carried over into the 2004 session (SB643). One other bill would impose a moratorium on planting biotech kona coffee while the consequences of introducing this coffee into Hawaii are evaluated and a permitting process is set up (HB99). Two pieces of legislation that did not get past the 2003 session would have requested a task force to recommend statutory and regulatory frameworks for GM organisms in Hawaii, while another would have established a working group to assess the ethical, health, ecological, and agricultural consequences of GM organisms in Hawaii.[451]

Nonregulatory Legislation

The Hawaii legislature has created a Hawaii technology investment program that allows individual investors to contribute to a venture capital fund whose monies are invested in technologies, including biotechnology (13 Haw. Rev. Stat. § 221F-51 et seq. (2003)). The state also exempts from excise taxes the proceeds from any research, development, sale, or production of agricultural biotechnology and other biotechnology products (13 Haw. Rev. Stat. § 209EF-11 (2003)).

In Hawaii's General Assembly, a few nonregulatory bills addressing biotechnology that failed in recent years include two bills to address the liability of manufacturers of genetically modified organisms and a bill to include transgenic produce in the definition of "fresh fruits, fresh vegetables, and coffee."[452] As in many other states, however, an anti-crop-destruction bill did pass in the 2001 legislative session holding vandals liable for double the damage they cause (SB640).

A significant volume of legislation related to agricultural biotechnology research and education, as well as economic growth and development, has been introduced in Hawaii since 2003. An array of bills were introduced

450 Pew Initiative on Food and Biotechnology 2004(c).

451 Pew Initiative on Food and Biotechnology 2004(c).

452 Pew Initiative on Food and Biotechnology 2004(c).

to appropriate funds or set up working groups surrounding this topic, although only two of these pieces were passed or adopted in 2003. One set up a group to develop a strategic plan for workforce development for industries, including the biotechnology industry (SB837), and the other, a legislative resolution, urged the promotion of careers in areas of economic development, including biotechnology (HCR185).[453] Most of the 25 bills introduced in 2003 were carried over to 2004.

REGULATORY AUTHORITY, AGENCIES, AND RESOURCES

RELEVANT STATUTORY AUTHORITY			
Biotech-Specific Regulatory Statutes	Other Potential Statutory Authority Over Biotech Field Trials	Other Potential Statutory Authority Over PIPs	Other Potential Statutory Authority Over Biotech Food Safety
19 Haw. Rev. Stat. § 321-11.6 (2003) (Genetically modified organisms)	General plant pest law: 11 Haw. Rev. Stat. § 152-1 et seq. (2003) (Noxious Weed Control)	None	General food safety law: 19 Haw. Rev. Stat. § 328-1 et seq. (2004) (Hawaii Food, Drug, and Cosmetic Act)
AGENCIES WITH CURRENT OR POTENTIAL BIOTECH ROLES			
Biotech-Specific	Plant Health	Pesticides	Food Safety
None	Hawaii Department of Agriculture – Plant Industry Division, Plant Quarantine Branch	Hawaii Department of Agriculture – Plant Industry Division, Pesticides Branch	Hawaii Department of Health – Food & Drug Branch and Sanitation Branch
RESOURCES			
Hawaii Department of Agriculture budget: FY 04 $12,500,000 Budget for plant health protection: FY 04 $4,360,000 Narrative description of budget for biotech crops and foods component: The Hawaii Department of Agriculture, at this point in time, does not have a position dedicated solely to biotechnology issues. For resources allocated to biotechnology activities, the breakdown is: Plant Special, one individual, approximately 40% of time for permit reviews, field inspections and related activities; two Plant Quarantine inspectors, Maui and Kauai, approximately 10% of time to assist USDA, APHIS in field inspections; Plant Quarantine Program Manager, approximately 20% of time; Plant Industry Administrator, approximately 10% of time; and other program staff in Plant Industry participate in biotechnology issues to some extent, but the activities overall are not a significant part of the FTE.			

453 Pew Initiative on Food and Biotechnology 2004(c).

ILLINOIS

OVERVIEW

SNAPSHOT OF ILLINOIS AGRICULTURE:

Value to Illinois' economy:	$2,609,556,000
Share of total U.S. agricultural production:	3.39%
Share of total U.S. agricultural exports:	6.21%
Top five commodities:	Corn, soybeans, hogs, cattle and calves, and greenhouse/nursery
One of top five producers nationally for the following major field crops:	Corn and soybeans
	28% of corn acres planted with biotech seed
	77% of soybean acres planted with biotech seed

Status of Biotech Field Trial Activity

1,491 distinct APHIS notifications submitted (1,410 acknowledged; 64 denied/withdrawn/void; 175 currently in effect)

---

148 distinct APHIS permit applications submitted (124 issued; 24 denied/withdrawn/void; 8 currently in effect)

---

2 APHIS permits issued for varieties of corn engineered to produce compounds for pharmaceutical production

---

2 notifications APHIS acknowledged for industrial-producing varieties of corn and soybeans; 2 APHIS permits issued for varieties of corn and rapeseed engineered to produce compounds for industrial applications

---

30 crops total for which APHIS notifications and/or permit applications were submitted

---

Most APHIS notification and permit applications submitted for biotech varieties of corn and soybeans

---

Other crops include: alfalfa, barley, beets, carrots, corn, cotton, creeping bentgrass, Kentucky bluegrass, melons, petunias, potatoes, rapeseed, rice, soybeans, sunflowers, squash, tobacco, tomatoes, and wheat

Biotech Activity and Legislative Status

Biotech Activity and Interest

In 1987, Illinois became the first state in which a biotech crop was planted, marking the beginning of what the Illinois Department of Agriculture touts as its "leadership in agricultural biotechnology."[454] In 1997, the Illinois Department of Agriculture funded an initiative called the "Strategic Plan for the Biotechnology Industry" with a group of more than 100 industry, academic, and government leaders, which was supported by Governor George Ryan.[455] In 2000, Governor Ryan supported the creation of a strategy for investing state resources in education, research, and development in advanced technology, including biotechnology, called Illinois VentureTECH, which was organized through the Illinois Technology Office.[456]

The Illinois Farm Bureau similarly supports agricultural biotechnology. In a position statement, it lists the following tenets: "We support an increase in research funding on the use and development of biotechnology. We encourage development of standardized thresholds, regulations, testing methodologies for biotechnology enhanced products at the state, national and international levels. We support efforts seeking to maintain domestic and international markets for crops produced using biotechnology."[457] A high level of research is performed at the state universities, including the University of Illinois at Urbana-Champaign, which has a Biotechnology Center where microbial, plant, insect, and animal genomics are studied.[458]

Regulatory Legislation

Illinois is also one of the few states with a law on the books regarding the regulation of biotech crops and foods. Illinois' Release of Genetically Modified Organisms Act makes the Illinois Department of Agriculture the reviewer for field trials and PIPs. The field trial applicant must submit its permit application or notification, with CBI redacted, to the department within seven days of having submitted the information to the federal government. The applicant must also submit a summary of the CBI to the

454 Illinois Department of Agriculture 2001.

455 Biotechnology Industry Organization 2003(a).

456 Ryan n.d.

457 Illinois Farm Bureau n.d.

458 University of Illinois at Urbana-Champaign n.d.

state Department of Agriculture. Ten or more days before a field trial, the applicant must submit a notice to the county chief executive officer, and the mayor or president of municipalities in the county, where the release will occur. The statute stipulates that the department may hold a meeting, take public comments, conduct a technical review, or seek the expertise of academics or the Illinois Department of Public Health when reviewing the applicant's information to determine what comments to send to the federal regulatory agency. The statute further provides for the confidential treatment of information submitted in regards to this Act, and it provides the department discretion to waive all or part of the law's requirements for specific biotech products if it determines that regulation of the field trial is not "necessary to protect the public health or the environment" (430 Ill. Comp. Stat. § 95/0.01 et seq. (2004)).

Nonregulatory Legislation

At least two measures have been enacted to advance the development of agricultural biotechnology in Illinois. The Biotechnology Sector Development Act authorizes the Illinois Department of Agriculture to assess the state of and promote economic development and research in the area of biotechnology (20 Ill. Comp. Stat. § 230/1 et seq. (2004)). Another law passed during the 2003 legislative session established a Private Equity Task Force to investigate Illinois' state resources and programs aimed at developing agricultural biotechnology, among other industries, and to investigate the amount of technology transfer in these industries (SR89).[459] An anti-crop-destruction bill was introduced in 2001, but it failed to pass.

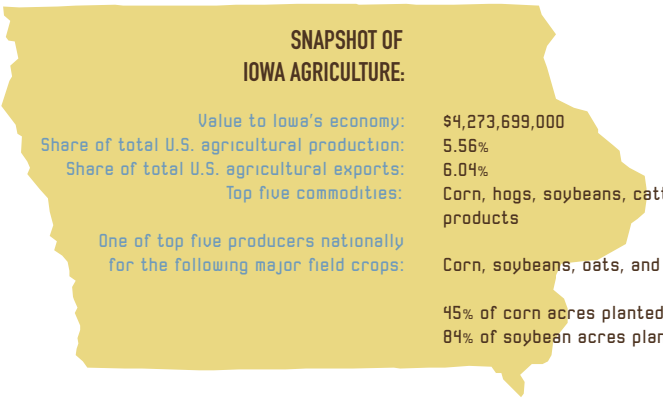
459 Pew Initiative on Food and Biotechnology 2004(c).

REGULATORY AUTHORITY, AGENCIES, AND RESOURCES

RELEVANT STATUTORY AUTHORITY			
Biotech-Specific Regulatory Statutes	Other Potential Statutory Authority Over Biotech Field Trials	Other Potential Statutory Authority Over PIPs	Other Potential Statutory Authority Over Biotech Food Safety
430 Ill. Comp. Stat. § 95/0.01 et seq. (2004) Release of Genetically Engineered Organisms	General plant pest law: 505 Ill. Comp. Stat. 90/1 et seq. (2004) (Insect Plant and Pest Disease Act)	General pesticide control law: 415 Ill. Comp. Stat. 60/1 et seq. (2004) (Illinois Pesticide Act)	General food safety law: 410 Ill. Comp. Stat. § 620/1 et seq. (2004) (Illinois Food, Drug and Cosmetic Act)
AGENCIES WITH CURRENT OR POTENTIAL BIOTECH ROLES			
Biotech-Specific	Plant Health	Pesticides	Food Safety
Illinois Department of Agriculture	Illinois Department of Agriculture – Bureau of Environmental Programs and Bureau of Agricultural Product Inspection	Illinois Department of Agriculture – Bureau of Environmental Programs Illinois Environmental Protection Agency	Illinois Department of Agriculture
RESOURCES			
Illinois Department of Agriculture budget: $108,600,000 Budget for plant health protection: $1,054,000 Narrative description of budget for biotech crops and foods component: Specific budget amounts dedicated to biotech crops and foods component are unknown as this area is spread across multiple bureaus within the state Department of Agriculture as well as other state agencies.			

IOWA

OVERVIEW



SNAPSHOT OF IOWA AGRICULTURE:

Value to Iowa's economy:	$4,273,699,000
Share of total U.S. agricultural production:	5.56%
Share of total U.S. agricultural exports:	6.04%
Top five commodities:	Corn, hogs, soybeans, cattle and calves, and dairy products
One of top five producers nationally for the following major field crops:	Corn, soybeans, oats, and alfalfa hay
	45% of corn acres planted with biotech seed
	84% of soybean acres planted with biotech seed

Status of Biotech Field Trial Activity

1,162 distinct APHIS notifications submitted (1,094 acknowledged; 51 denied/withdrawn/void; 129 currently in effect)

---

46 distinct APHIS permit applications submitted (41 issued; 5 denied/withdrawn/void; 3 currently in effect)

---

8 APHIS permits issued and 1 pending for varieties of corn engineered to produce compounds for pharmaceutical production

---

No APHIS notifications or permit applications submitted for crops engineered to produce compounds for industrial applications

---

15 crops total for which APHIS notifications and/or permit applications were submitted

---

Most APHIS notifications and permit applications submitted for biotech varieties of corn and soybeans

---

Other crops include: alfalfa, barley, beets, creeping bentgrass, Kentucky bluegrass, oats, poplar, rapeseed, sunflowers, and tobacco

Biotech Activity and Legislative Status

Biotech Activity and Interest

A state with a majority of its land area devoted to agriculture, Iowa is a major producer of commodity crops and leads the nation in total value of biotech crops. It is also a popular state for field testing biotech crops.

Support for biotechnology in Iowa is strong. Michael Blouin, Director of the Iowa Department of Economic Development, told attendees at a biotech conference in 2004 that a growing biotech industry will be a cornerstone of Iowa's future economy and commented that the life sciences will "become the manufacturing base of the 21st century" for the state.[460] The Department of Economic Development is working to develop a state strategic plan for pursuing biotech economic opportunities.[461] Many of Iowa's commodity organizations, producers, and legislators strongly support the development of pharma crops in Iowa and as a potential means of rural revitalization.[462] Thus, when BIO initially took the position following the 2002 ProdiGene incident[463] that research field trials for pharma corn plants should be located outside of the Midwest farm belt, the Iowa groups objected. In light of USDA decisions on oversight of pharma crops, BIO clarified its position in a letter to the Iowa senator who had urged BIO to reconsider.[464]

Some Iowa advocacy organizations are concerned, however, about the environmental risks of biotechnology. The Iowa Environmental Council says in its position paper on biotechnology that, while the technology has potential to help humanity, very little research and analysis has been undertaken on the environmental risks of the technology.[465]

Regulatory Legislation

Iowa currently has no biotech-specific regulatory statute. In 2003, the Iowa Department of Agriculture and Land Stewardship (DALS) developed a bill that would have given the department its own regulatory authority over pharmaceutical and industrial crops so that it would not be dependent on APHIS or the voluntary cooperation of the companies to obtain information on and provide oversight of biotech crops. The bill would have required a state permit for field trials of such crops and authorized inspection and compliance audits of field trial sites to ensure permit conditions are being met.[466] The bill was not supported by the agricultural sector or biotechnology industry and was not actively considered by the legislature.[467] For further details on this bill, see "Filling the State Legislative

460 Fitzgerald 2004.

461 Eller 2004.

462 Perkins and Fitzgerald 2002.

463 Cassidy and Powell 2002.

464 Chemical Market Reporter 2002.

465 Iowa Environmental Council 2000.

466 Iowa Department of Agriculture and Land Stewardship 2004.

467 Pruisner 2004.

Gap: Biotech-Specific Regulatory Statutes in North Carolina, Minnesota, and Iowa" in Section IV.

A number of other bills dealing with regulatory, labeling, containment, and liability issues have been introduced since 2001, but none has passed. One would have placed a moratorium on the sale of seeds that had been genetically modified to be sterile. Others would have required the labeling of biotech seeds, including one that required inclusion in the labeling of seeds of environmental risk information, management practices to reduce the risk of cross-contamination to nonbiotech crops, and financial risks associated with marketing the crop. The bill would have also placed liability for damages to nonbiotech crops on the seed manufacturer if the management practices are followed, a provision included in many of the liability bills introduced in Iowa. Two of the labeling and liability bills also included requirements for the Iowa Crop Improvement Association to study biotech seed issues, including containment and marketing concerns. Other bills would have required a containment plan to be approved by the Iowa DALS; regulated the possession, sale, and transport of biotech seed for nonfood crops; specifically addressed contamination of corn and soy crops by establishing a grain integrity indemnity fund, and prohibited the malicious destruction of biotech crops.[468,469]

Another set of bills would have protected the farmer's right to save biotech seeds and prohibited the unfair pricing of biotech seeds by requiring technology charges to be uniformly applied in national and international markets. Another bill would have precluded farmers who save biotech seeds from seeking compensation for contamination or other damage by the biotech crop.[470]

Nonregulatory Legislation

A number of measures have been adopted in Iowa to provide economic incentives and supports for the development of agricultural biotechnology. The Iowa Agriculture Industry Finance Act includes biotech business ventures among those that may be supported through financing by an Iowa agricultural industry finance corporation (1 Iowa Code § 15E.201 et seq. (2003)). A bill passed in 2003 added agricultural biotechnology companies to the list of potential recipients of financial assistance through the Iowa Values Fund (HF692). Another bill that passed in 2003 created a New Capital Investment Program, which makes companies involved with value-added agricultural products or biotechnology eligible for a variety of financial incentives, including tax refunds and credits for research and other expenses (HF677).[471,472]

---

468 Iowa Legislature General Assembly n.d..

469 Pew Initiative on Food and Biotechnology 2004(c).

470 Pew Initiative on Food and Biotechnology 2004(c).

471 Iowa Legislature General Assembly n.d.

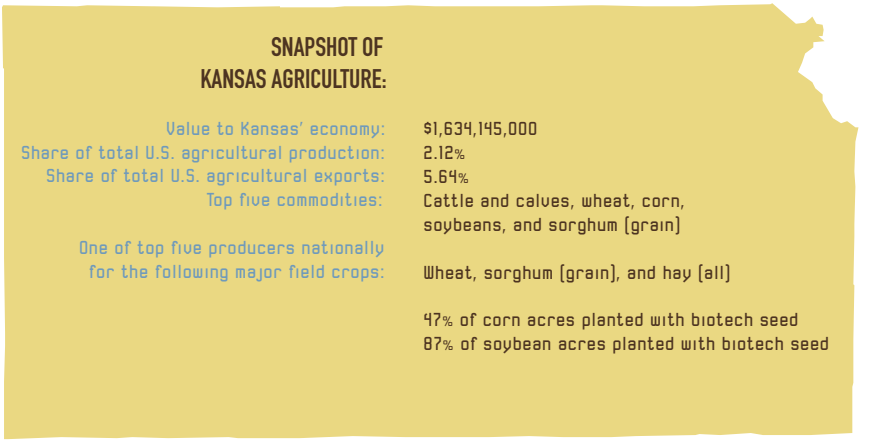
472 Pew Initiative on Food and Biotechnology 2004(c).

REGULATORY AUTHORITY, AGENCIES, AND RESOURCES

RELEVANT STATUTORY AUTHORITY			
Biotech-Specific Regulatory Statutes	Other Potential Statutory Authority Over Biotech Field Trials	Other Potential Statutory Authority Over PIPs	Other Potential Statutory Authority Over Biotech Food Safety
None	General plant pest law: 5 Iowa Code § 177A.1 et seq. (2003) (The Iowa Crop Pest Act)	General pesticide control law: 5 Iowa Code § 206.1 et seq. (2003) (Pesticide Act of Iowa)	General food safety law: 5 Iowa Code § 189.1 et seq. (2003) (General Provisions)
AGENCIES WITH CURRENT OR POTENTIAL BIOTECH ROLES			
Biotech-Specific	Plant Health	Pesticides	Food Safety
None	Iowa Department of Agriculture & Land Stewardship – Plant Management & Technology Division, Entomology & Plant Science Bureau	Iowa Department of Agriculture & Land Stewardship – Pesticide Bureau	Food & Consumer Safety Bureau – Inspections & Appeals
RESOURCES			
Iowa Department of Agriculture and Land Stewardship budget: FY 04 $16,989,251 Budget for plant health protection: FY 04 $578,000 Narrative description of budget for biotech crops and foods component: Iowa has two entomologists that spend a percentage of their time, amounting to $10,000 a year, on biotech activities.			

KANSAS

OVERVIEW



SNAPSHOT OF KANSAS AGRICULTURE:

Value to Kansas' economy:	$1,634,145,000
Share of total U.S. agricultural production:	2.12%
Share of total U.S. agricultural exports:	5.64%
Top five commodities:	Cattle and calves, wheat, corn, soybeans, and sorghum (grain)
One of top five producers nationally for the following major field crops:	Wheat, sorghum (grain), and hay (all)
	47% of corn acres planted with biotech seed
	87% of soybean acres planted with biotech seed

Status of Biotech Field Trial Activity

273 distinct APHIS notifications submitted (260 acknowledged; 8 denied/withdrawn/void; 61 currently in effect)

25 distinct APHIS permit applications submitted (22 issued; 3 denied/withdrawn/void; 7 currently in effect)

1 APHIS permit issued for a variety of corn engineered to produce compounds for pharmaceutical production

1 APHIS permit issued for a variety of corn engineered to produce compounds for industrial applications

7 crops total for which APHIS notifications and/or permit applications were submitted

Most APHIS notifications and permit applications submitted for biotech varieties of corn and soybeans

Other crops include: alfalfa, creeping bentgrass, sorghum, tobacco, and wheat

Biotech Activity and Legislative Status

Biotech Activity and Interest

The Kansas Department of Agriculture has been active in expressing its ideas and concerns regarding the oversight of biotech crops and foods. Kansas Secretary of Agriculture Adrian Polansky has stated that he believes biotechnology "holds some real potential benefits for Kansas farmers and the health of Kansans and world consumers," but that it must be "carefully monitored."[473] Secretary Polansky wants the federal government, rather than states, to be in charge of determining if a biotech crop or food is safe for human health and the environment.[474] However, both Secretary Polansky and his predecessor have expressed concern that federal regulations on biotech crops and foods are not stringent enough and do not allow for enough state input.

Kansas has been active in commenting on federal regulatory policies, generally arguing for more rigorous oversight. In 2002, when the federal Office of Science and Technology Policy sought public comment on proposed actions to update the federal field test requirements for biotech crops, then Kansas Secretary of Agriculture Jamie Adams, with input from agricultural associations in the state, submitted a list of recommendations. These included making all federal oversight procedures mandatory and inspecting all field trial sites and greenhouse facilities.[475] In March 2003, when APHIS asked for comments on ways to improve its regulation of biotech crops that produce pharmaceuticals and industrial compounds, Secretary Polansky, again with input from producer, agribusiness, sustainable agriculture, and industry groups, submitted comments reiterating his recommendations from the 2002 comments and that Kansas considered appropriate oversight "most important to this technology, to agriculture and to the public's confidence in U.S. food production." He further stated that Kansas had "hoped to see more of those recommendations incorporated into APHIS' proposed rules."

In its submission to APHIS, Kansas called for APHIS to, among other things, provide more information to states on the permits themselves so the states might be better able to analyze the permits, and to consider contracting with the state regulatory agencies to perform inspections, possibly implementing an application fee.[476] Most recently, the Kansas Department of Agriculture responded to APHIS' request for comments on its proposed environmental impact statement for biotech organisms.[477] Secretary Polansky, again after seeking input about concerns within Kansas, praised APHIS' actions as "an important step by USDA to update its regulations to keep pace with technology" and provided a list of questions and concerns the environmental impact statement needs to address.[478]

---

473 Hegeman 2003.

474 Polansky 2004.

475 Adams 2002.

476 Polansky 2003.

477 USDA APHIS 2004.

478 Kansas Department of Agriculture 2004.

Because Kansas is the nation's top wheat producer, with approximately one-third of Kansas farmers being wheat growers, the state has a particular interest in the possible commercialization of biotech wheat, which Monsanto recently halted for the time being. See "Legislating Restrictions on Biotech Crops on Economic and Social Grounds: Roundup Ready® Wheat" in Section IV.

Regulatory Legislation

Kansas has not adopted a biotech-specific regulatory statute, but a bill to adopt one was introduced during the 2003 session of the Kansas legislature. The bill, SB236, died in committee, but it had distinctive features that are worth noting. The bill would have established a state "certification" requirement for the commercialization of biotech crops and a public process for considering the granting of certification. Under the bill, the certification review by the department would have included not only an environmental review, but also a marketability impact review, which is not currently addressed directly by any federal or state current oversight program. The bill provided that the department must determine that issuing a certificate would "result in important economic development" and that "the benefits of issuing the certificate [would] exceed any costs to agriculture and the Kansas economy," taking into account such factors as:

- the marketability of the specific biotech crop in foreign and domestic markets;
- whether the biotech crop can be effectively segregated from conventional and organic varieties;
- whether there is a value from the biotech crop to producers, consumers, and the Kansas economy;
- whether growth of the biotech crop may threaten public health and safety or lead to noxious weeds;
- whether ecological contamination from the biotech trait can be prevented; and
- whether the export market will be reduced or eliminated for Kansas producers by commercialization of the biotech crop in Kansas.

After the department review is completed, two public hearings would be held to discuss the review, after which the department would make a final decision to grant or deny the certificate authorizing commercial planting of the specific biotech crop. The bill would also have made seed manufacturers liable for contamination of conventional crops unless the grower failed to follow the use directions, and it would have prohibited the biotech companies from charging farmers technology fees if their conventional crops are contaminated with a biotech variety. The legislation would also have required that the department be notified of plans for field trials of biotech crops. Farmers growing crops within one mile of the test plot would also have to be notified.[479]

479 Kansas Legislature 2003–2004.

Nonregulatory Legislation

On the nonregulatory side, Kansas recently signed into law legislation creating a Kansas bioscience authority to promote research, development, education, and economic growth in the area of the biosciences, which is defined in the bill as including agricultural biotechnology (HB2647).[480] An anti-crop-destruction bill was passed in Kansas in 2001 (SB36).[481]

REGULATORY AUTHORITY, AGENCIES, AND RESOURCES

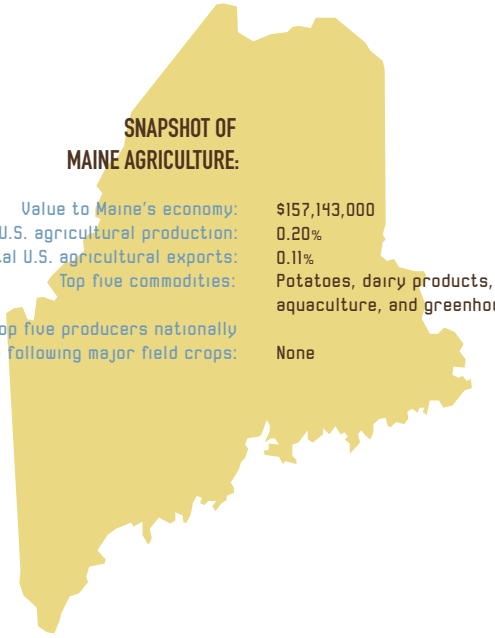
RELEVANT STATUTORY AUTHORITY			
Biotech-Specific Regulatory Statutes	Other Potential Statutory Authority Over Field Trials	Other Potential Statutory Authority Over PIPs	Other Potential Statutory Authority Over Biotech Food Safety
None	General plant pest law: 2 Kan. Stat. Ann. § 2112 et seq. (2003) (Plant Pest and Agriculture Commodity Certification Act)	General pesticide control law: 2 Kan. Stat. Ann. § 2201 et seq. (2003) (Agricultural Chemical Act of 1947)	General food safety law: 65 Kan. Stat. Ann. § 601 et seq. (2003) (Food, Drugs and Cosmetics)
AGENCIES WITH CURRENT OR POTENTIAL BIOTECH ROLES			
Biotech-Specific	Plant Health	Pesticides	Food Safety
None	Kansas Department of Agriculture – Plant Protection & Weed Control Program	Kansas Department of Agriculture – Pesticide & Fertilizer Program	Kansas Department of Agriculture – Dairy Program Kansas Department of Health & Environment – Bureau of Consumer Health
RESOURCES			
Kansas Department of Agriculture budget: FY 03 $20,147,328 Budget for plant health protection: FY 03 $961,156 Narrative description of budget for biotech crops and foods component: No resources are budgeted for biotech activities.			

480 Kansas Legislature 2003-2004.

481 Pew Initiative on Food and Biotechnology 2004(c).

MAINE

OVERVIEW



SNAPSHOT OF MAINE AGRICULTURE:

Value to Maine's economy:	$157,143,000
Share of total U.S. agricultural production:	0.20%
Share of total U.S. agricultural exports:	0.11%
Top five commodities:	Potatoes, dairy products, chicken eggs, aquaculture, and greenhouse/nursery
One of top five producers nationally for the following major field crops:	None

Status of Biotech Field Trial Activity

136 distinct APHIS notifications submitted (122 acknowledged; 14 denied/withdrawn/void; none currently in effect)

23 distinct APHIS permit applications submitted (21 issued; 2 denied/withdrawn/void; none currently in effect)

No APHIS permit applications submitted for crops engineered to produce compounds for pharmaceutical production

No APHIS notifications or permit applications submitted for crops engineered to produce compounds for industrial applications

3 crops total for which APHIS notifications and/or permit applications were submitted

Most APHIS notifications and permit applications submitted for biotech varieties of potatoes

Other crops include: corn and cotton

Biotech Activity and Legislative Status

Biotech Activity and Interest

Biotech varieties of potatoes account for all but two notifications and permits in Maine. However, none of these are currently in effect, which means there should be no field trial activity in the state. Efforts to commercialize biotech potatoes have been stymied by concerns of key export markets and french-fry producers.[482] Despite relatively little planting of biotech crops in Maine, public interest in the subject has been high.

Maine was previously home to a Commission on Biotechnology and Genetic Engineering, which in 1996 recommended mandatory federal labeling of biotech foods,[483] but the statute establishing the Commission, enacted in 1987, was repealed in 1999 (7 ME. Rev. Stat. Ann. § 231 et seq (2003)). Today, organic and sustainable agriculture groups are active within the state on the topic of biotech crops and foods, and in 2003 the Maine Department of Agriculture, Food and Rural Resources held a forum on biotechnology to discuss the technology as well as its risks and potential gains.

Regulatory Legislation

Maine does not have its own permitting program for biotech crops, but relies upon the APHIS process to add supplemental conditions on the movement or release of regulated articles. It does, however, have two quasi-regulatory laws. One requires a biotech seed manufacturer or dealer to maintain a nonpublic list of growers who purchase biotech seed and their location and to provide the grower instructions on how to use the biotech product to best prevent cross-contamination of nonbiotech seeds or crops. The law gives the Maine Commissioner of Agriculture authority to inspect the list of growers if he or she receives a claim of cross-contamination (7 ME. Rev. Stat. Ann. § 1051 et seq. (2003)). Maine's other regulatory statute, the Labeling Foods Free of Genetic Engineering Act, provides that foods with 1% or less genetically modified material can be labeled as free of genetically modified ingredients and gives the Department of Agriculture authority to investigate a business operation that makes a claim of selling nonbiotech products. After June 30, 2004, misbranding a product under this law is a civil violation and violators can be fined (7 ME. Rev. Stat. Ann. 530-A et seq. (2003)).

---

482 Bernton 2000.

483 Maine Organic Farmers and Gardeners Association 2004.

A bill that would have placed a three-year moratorium on planting genetically modified plants in Maine died recently in the legislature.[484] The Joint Standing Committee on Agriculture, Conservation and Forestry held a hearing on the bill, and many individuals and groups testified in support or opposition,[485] including BIO.[486]

Nonregulatory Legislation

Maine has also adopted measures to support development of biotechnology.[487] One establishes a Center for Innovation in Biotechnology to promote development in the sector (5 ME. Rev. Stat. Ann. § 13141 (2003)), and another includes biotechnology among the technologies to be addressed at the Maine Technology Institute, whose purpose is to "encourage, promote, stimulate and support research and development activity leading to the commercialization of new products and services" (5 ME. Rev. Stat. Ann. § 15302(2) (2003)) as part of a state economic development strategy (5 ME. Rev. Stat. Ann. § 15301 et seq. (2003)). A similarly aimed program, the Applied Technology Development Center System, also contributes support to biotechnology research (ME. Rev. Stat. Ann. § 15321 (2003)). Biotechnology is listed among the areas of work in which small businesses are eligible to receive funds through the Small Enterprise Growth Fund (5 ME. Rev. Stat. Ann. § 381 et seq.).

---

484 Pew Initiative on Food and Biotechnology 2004(c).

485 Mack 2003.

486 Biotechnology Industry Organization 2003(b).

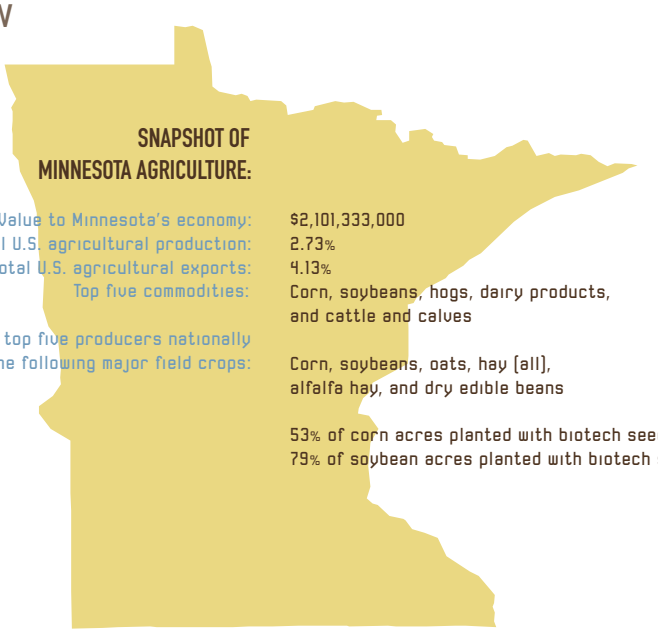
487 Biotechnology Industry Organization 2003(a).

REGULATORY AUTHORITY, AGENCIES, AND RESOURCES

RELEVANT STATUTORY AUTHORITY			
Biotech-Specific Regulatory Statutes	Other Statutory Authority Over Biotech Field Trials	Other Potential Statutory Authority Over PIPs	Other Potential Statutory Authority Over Biotech Food Safety
7 ME. Rev. Stat. Ann. § 1051 et seq. (2003) (Genetically Engineered Plants and Seeds) and 7 Me. Rev. Stat. Ann. 530-A et seq. (2003) (Labeling Foods Free of Genetic Engineering)	General plant pest law: 7 ME. Rev. Stat. Ann. § 2101 et seq. (2003) (Plant Industry)	General pesticide control law: 7 ME. Rev. Stat. Ann. § 601 et seq. (2003) (Maine Pesticide Control Act of 1975)	General food safety law: 22 ME. Rev. Stat. Ann. § 2151 et seq. (2003) (Maine Food Law)
AGENCIES WITH CURRENT OR POTENTIAL BIOTECH ROLES			
Biotech-Specific	Plant Health	Pesticides	Food Safety
Maine Department of Agriculture, Food & Rural Resources	Maine Department of Agriculture, Food & Rural Resources –Division of Plant Industry	Maine Department of Agriculture, Food & Rural Resources –Office of Agriculture, Natural & Rural Resources, Pesticide Control Programs and Board of Pesticides Control	Maine Department of Agriculture, Food & Rural Resources Maine Department of Human Services – Bureau of Health, Division of Health Engineering, Earth & Lodging Program
RESOURCES			
Maine Department of Agriculture, Food and Rural Resources budget: $24,185,745 Budget for plant health protection: $2,419,320 Narrative description of budget for biotech crops and foods component: Approximately 10% of the time of the director of the Division of Plant Industry is spent working on issues and programs relating to biotech crops.			

MINNESOTA

OVERVIEW



SNAPSHOT OF MINNESOTA AGRICULTURE:

Value to Minnesota's economy:	$2,101,333,000
Share of total U.S. agricultural production:	2.73%
Share of total U.S. agricultural exports:	4.13%
Top five commodities:	Corn, soybeans, hogs, dairy products, and cattle and calves
One of top five producers nationally for the following major field crops:	Corn, soybeans, oats, hay (all), alfalfa hay, and dry edible beans
	53% of corn acres planted with biotech seed
	79% of soybean acres planted with biotech seed

Status of Biotech Field Trial Activity

553 distinct APHIS notifications submitted (524 acknowledged; 25 denied/withdrawn/void; 60 currently in effect)

---

74 distinct APHIS permit applications submitted (66 issued; 8 denied/withdrawn/void; 5 currently in effect)

No APHIS permit applications submitted for crops engineered to produce compounds for pharmaceutical production

---

1 APHIS permit issued for a variety of corn engineered to produce compounds for industrial applications

---

Crops for which APHIS notifications and/or permit applications were submitted include alfalfa, barley, beets, corn, creeping bentgrass, peas, petunias, poplar, potatoes, rapeseed, soybeans, sunflowers, and wheat

Biotech Activity and Legislative Status

Biotech Activity and Interest

The governor of Minnesota, Tim Pawlenty, has encouraged growth of the biotechnology industry. Governor Pawlenty hosted the Governor's Biosciences Summit and recently created the Minnesota Biosciences Council. The council has the dual charge of providing advice to the governor and legislature on biosciences policy development and providing strategies that will support the growth of the industry.[488] The council, chaired by the commissioner of the Minnesota Department of Employment and Economic Development, is a governor-appointed, volunteer panel of members that include representatives from academia, government, the legal field, and industry.

In December 2003, the council provided recommendations to Governor Pawlenty on how to establish Minnesota as a national and international leader in the biosciences. Key recommendations included allocating financial resources to assist in the development and stimulation of the biotech industry; establishing an interdepartmental working group to coordinate the Minnesota Department of Employment and Economic Development along with the Minnesota Department of Agriculture with the University of Minnesota and Minnesota State Colleges and Universities to work on developing Minnesota's agricultural bioscience sector, among others; developing a public awareness campaign by the Minnesota Department of Agriculture on the advantages of bio-based materials to promote value-added agricultural products; and requiring state regulatory agencies to conduct a review of existing rules affecting the bioscience industry and propose new rules to accommodate the industry's growth.[489]

Regulatory Legislation

Minnesota is the only state with a comprehensive regulatory statute that creates a separate state permitting system for biotech crops. Minnesota regulates the release—i.e., the "placement or use of a genetically engineered organism outside a contained laboratory, greenhouse, building, structure, or other similar facility or under other conditions not specifically determined by the commissioner to be adequately contained" (Minn. Stat. § 18F.02(8) (2003))—of all biotech organisms in the state through a statute that was established in 1991 "to protect humans and the environment from the potential for significant adverse effects of those releases" (Minn. Stat. § 18.01 (2003)). The statute requires an individual who wants to release a biotech organism in Minnesota to submit an application and pay a fee to the Minnesota commissioner of agriculture. The commissioner has the authority to issue permits with or without conditions, as well as to revoke a permit or approval of commercial use and/or sale terms if conditions on the

488 Minnesota Department of Employment and Economic Development 2003.

489 Minnesota Biosciences Council 2003.

permit are violated or the terms or conditions are found to be inadequate to protect the environment (Minn. Stat. § 18F.01 et seq. (2003)). The state Environmental Quality Board (EQB) also has statutory authority specific to biotechnology (Minn. Stat. §116C.91-97 and §116D). The EQB authority extends to those genetically engineered organisms that are not agriculturally related. The law's opponents consider it redundant to federal regulations, while its supporters emphasize its focus on environmental impacts and indicate it will "shore up gaps in the way the federal government regulates the planned release of GEOs (genetically engineered organisms) into the environment for commercial use."[490] For more details on the Minnesota law, see "Filling the State Legislative Gap: Biotech-Specific Regulatory Statutes in North Carolina, Minnesota, and Iowa" in Section IV.

Minnesota's pesticide control law also has a provision requiring registration with the Minnesota commissioner of agriculture of organisms, including plants, that have been genetically modified to achieve a pesticidal purpose (Minn. Stat. § 18B.01(10b) (2003)). This law establishes regulatory oversight for PIPs similar to that provided other plants in the Genetically Engineered Organisms statute (Minn. Stat. § 18B.285 (2003)).

Legislation was introduced recently that would end Minnesota's authority to issue its own permits for biotech crops (SF246). An omnibus budget bill addressing the environment, natural resources, agricultural, and rural development contained this same provision at one time, but the language was removed as the House and Senate debated different versions of the bill.[491] Other bills related to regulation of biotech crops that have been introduced but not passed since 2001 include bills that would have eliminated exemptions for certain biotech crops from having to undergo environmental assessments prior to receiving a release permit; funded a task force to develop protocols for labeling products as free of biotech ingredients; and required biotech seed manufacturers to provide instructions on how to use their seed to prevent cross-contamination of nonbiotech crops and to notify producers near areas to be planted with biotech seed. The latter bill also would have made manufacturers liable for damage from cross-contamination and would have provided for foods to be labeled as free of biotech ingredients.[492] Another pending bill would set up a program whereby producers could register with the state to save seeds harvested from biotech crops for subsequent plantings (SF1356).

Nonregulatory Legislation

Minnesota has adopted measures to support the development of biotechnology in the state, including a program passed in 2003 to create biotechnology and health industry property zones in which businesses can receive incentives, including multiple types of tax credits, for job creation and

490 Zielinksi 1992.

491 Minnesota State Legislature n.d.

492 Pew Initiative on Food and Biotechnology 2004(c).

facility expansion (HF7). One of the motivations for the legislation was to encourage biotechnology and health science companies to locate near Minnesota's academic and research institutions in order to spark research and development in these sectors and aid in the commercialization of discoveries. A bill that would have appropriated funds for soybean biotechnology research recently failed.[493]

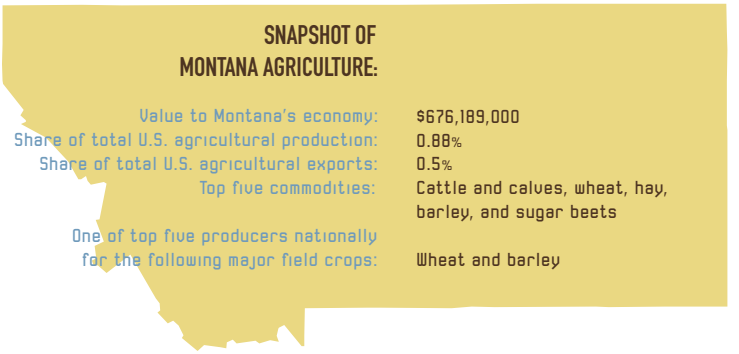
REGULATORY AUTHORITY, AGENCIES, AND RESOURCES

RELEVANT STATUTORY AUTHORITY			
Biotech-Specific Regulatory Statutes	Other Potential Statutory Authority Over Biotech Field Trials	Other Potential Statutory Authority Over PIPs	Other Potential Statutory Authority Over Biotech Food Safety
Minn. Stat. § 18F.01 et seq. (2003) (Genetically Engineered Organisms) and Minn. Stat. § 18B.285 (2003) (Experimental genetically engineered pesticide product registration)	General plant pest law: Minn. Stat. § 18.011 et seq. (2003) (Pest Control)	General pesticide control law: Minn. Stat. § 18B.01 et seq. (2003) (Pesticide Control)	General food safety law: Minn. Stat. § 31.01 et seq. (2003) (Food)
AGENCIES WITH CURRENT OR POTENTIAL BIOTECH ROLES			
Biotech-Specific	Plant Health	Pesticides	Food Safety
Minnesota Department of Agriculture – Agricultural Resources Management & Development Division	Minnesota Department of Agriculture – Agronomy & Plant Protection Division, Plant Pest Survey Program	Minnesota Department of Agriculture – Agronomy & Plant Protection Division	Minnesota Department of Agriculture
RESOURCES			
Minnesota Department of Agriculture budget: $81,035,043 Budget for plant health protection: $2,262,000 Narrative description of budget for biotech crops and foods component: Two people within the Minnesota Department of Agriculture spend a portion of their time on the oversight of biotech crops and foods. One of these is Mary Hanks, Sustainable Agriculture and Integrated Pest Management Supervisor, who allocates approximately 10% of her time to biotech oversight activities, which cover all of the non-PIP notification and permit reviews and any field inspections.			

493 Minnesota State Legislature n.d.

MONTANA

OVERVIEW



SNAPSHOT OF MONTANA AGRICULTURE:

Value to Montana's economy:	$676,189,000
Share of total U.S. agricultural production:	0.88%
Share of total U.S. agricultural exports:	0.5%
Top five commodities:	Cattle and calves, wheat, hay, barley, and sugar beets
One of top five producers nationally for the following major field crops:	Wheat and barley

Status of Biotech Field Trial Activity

122 distinct APHIS notifications submitted (115 acknowledged; 7 denied/withdrawn/void; 16 currently in effect)

---

18 distinct APHIS permit applications submitted (14 issued; 4 denied/withdrawn/void; none currently in effect)

No APHIS permit applications submitted for crops engineered to produce compounds for pharmaceutical production

---

No APHIS notifications or permit applications submitted for crops engineered to produce compounds for industrial applications

---

Most APHIS notifications and permit applications submitted for biotech varieties of wheat

---

Other crops include: alfalfa, barley, beets, corn, creeping bentgrass, potatoes, and rapeseed

Biotech Activity and Legislative Status

Biotech Activity and Interest

Because wheat is such an important crop in Montana's agricultural economy, the primary focus of biotechnology discussions within Montana has been on market acceptance of biotech wheat and the impact of possible commercialization of biotech wheat on markets for conventional wheat varieties in light of the possibility of cross-contamination. This issue is discussed more fully in Section IV ("Legislating Restrictions on Biotech Crops on Economic and Social Grounds: Roundup Ready® Wheat").

In response to Monsanto's proposed commercialization of its herbicide-resistant (Roundup Ready) biotech wheat, the Montana legislature considered numerous bills on the subject, including bills to place a moratorium on the planting of biotech wheat; create task forces to study the potential market effects in Montana of growing biotech wheat or other crops; study liability concerns, methods of segregating biotech wheat during production and harvesting, and development of various wheat traits beneficial to consumers or producers; require biotech seed manufacturers to provide instructions for the safe use of their products and to assume liability for their products; require companies that want to plant commercial biotech wheat to pay a $10 million bond to a new Wheat Bond Board; and require the Montana Department of Agriculture to create a certification and monitoring program for biotech wheat that involves public notification and a registry.

Ultimately, a joint resolution addressing biotech wheat and barley passed during the 2003 legislative session. The resolution emphasizes the importance to Montana of access to international wheat markets and recommends that biotech wheat and barley not be introduced for commercial production until the market for such products is ensured. The resolution calls for continued research in crop characteristics that would appeal to the needs of consumers as well as be economically beneficial for producers. The resolution also recommends researching methods for reducing cross-contamination during growth as well as through the mixing of harvested grains (SJ8).[494]

494 Montana State Legislature 2003(c).

Regulatory Legislation

Notwithstanding these acute economic concerns about the impact of biotech wheat, Montana has not adopted its own regulatory statute or permitting program for biotech crops. The director of the Montana Department of Agriculture, Ralph Peck, testified in 2003 before the Montana legislature that the nation needs one legal framework for biotech crops and foods in order for Montana to be able to compete in national and world markets, and that the federal government is in the best position to analyze, approve, and regulate biotech crops.[495]

Nonregulatory Legislation

The Montana Department of Agriculture works to support its wheat and barley growers through the Wheat and Barley Committee, a producer-funded and directed checkoff organization whose mission is "to protect and foster the health, prosperity, and general welfare of this industry by encouraging and promoting intensive, scientific, and practical research into all phases of the wheat and barley culture and production, marketing, and end-use and, further, to aid in the development of markets for wheat and barley grown in Montana." The committee funds projects at Montana State University, including projects investigating agricultural biotechnology.[496] Montana also funds research and commercialization of biotech crops through a board housed within the Montana Department of Commerce, which the legislature created in 1999.[497] Montana passed an anti-crop-destruction law in 2001, which holds individuals who damage crop research facilities liable for direct or consequential damages as well as court costs (HB387).[498]

495 Zellar 2004.

496 Montana Wheat and Barley Committee n.d.

497 Montana Department of Commerce n.d.

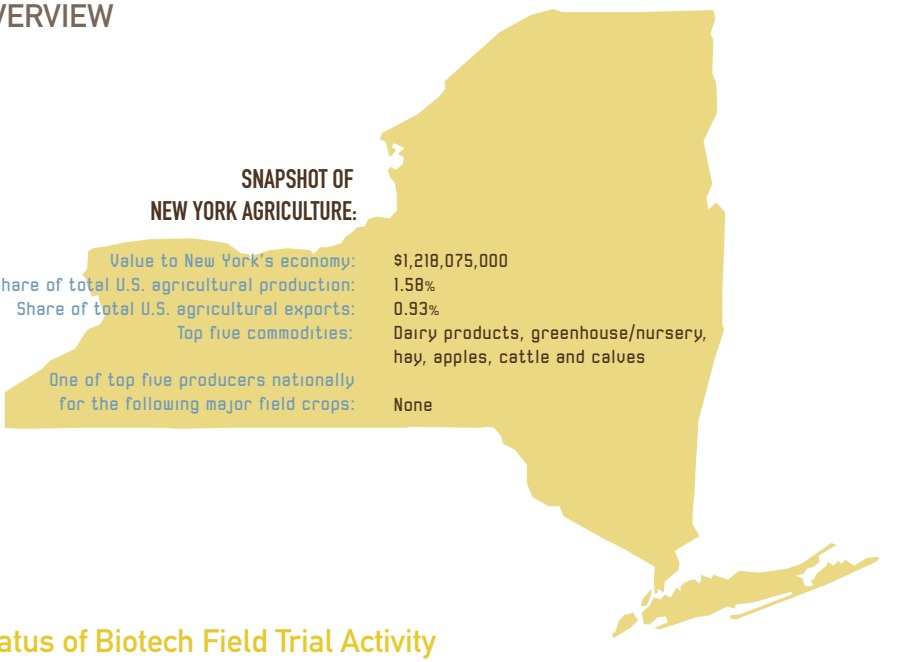
498 Pew Initiative on Food and Biotechnology 2004(c).

REGULATORY AUTHORITY, AGENCIES, AND RESOURCES

RELEVANT STATUTORY AUTHORITY			
Biotech-Specific Regulatory Statutes	Other Potential Statutory Authority Over Biotech Field Trials	Other Potential Statutory Authority Over PIPs	Other Potential Statutory Authority Over Biotech Food Safety
None	General plant pest law: 80 Mont. Code Ann. § 7-105 et seq. (2003) (Disease, Pest, and Weed Control)	General pesticide control law: 80 Mont. Code Ann. § 8-101 et seq. (2003) (Pesticides)	General food safety law: 50 Mont. Code Ann. § 31-101 et seq. (2003) (Montana Food, Drug, and Cosmetic Act)
AGENCIES WITH CURRENT OR POTENTIAL BIOTECH ROLES			
Biotech-Specific	Plant Health	Pesticides	Food Safety
None	Montana Department of Agriculture – Agricultural Sciences Division, Field Service Bureau	Montana Department of Agriculture –Agricultural Sciences Division, Technical Service Bureau, Licensing, Registrations and Auditing	Montana Department of Agriculture Montana Department of Livestock
RESOURCES			
Montana Department of Agriculture budget: FY 04 $14,411,968 Budget for plant health protection: FY 04 $633,168 Narrative description of budget for biotech crops and foods component: Time spent reviewing APHIS permits and conducting inspections equates to less than 5% of one FTE.			

NEW YORK

OVERVIEW



SNAPSHOT OF NEW YORK AGRICULTURE:

Value to New York's economy:	$1,218,075,000
Share of total U.S. agricultural production:	1.58%
Share of total U.S. agricultural exports:	0.93%
Top five commodities:	Dairy products, greenhouse/nursery, hay, apples, cattle and calves
One of top five producers nationally for the following major field crops:	None

Status of Biotech Field Trial Activity

196 distinct APHIS notifications submitted (171 acknowledged; 22 denied/withdrawn/void; 27 currently in effect)

47 distinct APHIS permit applications submitted (40 issued; 5 denied/withdrawn/void; 2 currently in effect)

No APHIS permit applications submitted for crops engineered to produce compounds for pharmaceutical production

1 APHIS permit issued for a variety of corn engineered to produce compounds for industrial applications

19 crops total for which APHIS notifications and/or permit applications were submitted, which include alfalfa, apples, American chestnut, barley, corn, cucumber, Cucurbita texana squash, grapes, melons, potatoes, squash, tomatoes, and wheat

Biotech Activity and Legislative Status

Biotech Activity and Interest

Biotech activity is relatively low in New York, but is seen by the state government as part of a high-tech economic growth strategy. The New York State Emerging Industry Jobs Act, a tax cut package aimed at fueling economic growth in high-tech industries, including biotechnology, was passed in the late 1990s. In 2000, Governor George E. Pataki established the New York State Office of Science, Technology, and Academic Research (NYSTAR) to develop and promote the high-technology industry, including the biotechnology sector, primarily through the provision of grants and other support for university-industry collaborative research. In 2001, New York created eight Strategically Targeted Academic Research (STAR) Centers and five Advanced Research Centers (ARC) to be organized through NYSTAR, which was the largest one-time investment in high-technology or biotechnology in the state's history.[499]

Regulatory Legislation

New York currently has no biotech-specific regulatory statute. Bills addressing various regulatory issues have, however, been introduced in the legislature. For example, a recently introduced bill (A10094) would require the registration of biotech seeds and living organisms, as well as the public disclosure of all of the effects of the seed or organism on health, agriculture, and the environment. A number of bills have been introduced that would impose a moratorium on planting biotech crops. One such bill would impose a blanket five-year moratorium (A02826), while another would block only seeds modified to be sterile through so-called "terminator" technology (A00998). Another pending bill would direct the New York State departments of Health and Environmental Conservation to study the effects of biotech organisms on agriculture, health, and the environment and, along with the New York State Department of Agriculture and Markets, develop regulatory standards for the use of biotech organisms (A01809).

---

499 Bessette et al. 2001.

Bills have been introduced but not passed on biotech-related labeling; some would have required the labeling of food products with biotech ingredients (such as A04206), while others would have authorized the labeling of products as free of genetically modified organisms (such as A04458). One bill would have required the commissioner of agriculture and markets to create a registry of biotech-free producers.

Other bills have addressed the potential problem of cross-contamination of nonbiotech crops or other plants. One pending bill would require anyone who sells or distributes biotech seeds to provide instructions for their use to avoid cross-contamination. This bill also would direct the commissioners of agriculture and markets, and environmental conservation, to develop regulations to facilitate surveillance for unintended cross-fertilization (A02761). Other bills would give producers the right to sue biotech crop or animal manufacturers if their products are contaminated by genetically modified material and protect producers from lawsuits by such manufacturers for illegally using their technology if the producer could prove the introduction was unintentional (A01911).[500]

Nonregulatory Legislation

Though included in overall high-tech initiatives, agricultural biotechnology has not been singled out in New York for investment incentives or other economic development assistance. An anti-crop-destruction bill was introduced but did not pass.[501]

500 Pew Initiative on Food and Biotechnology 2004(c).

501 Pew Initiative on Food and Biotechnology 2004(c).

REGULATORY AUTHORITY, AGENCIES, AND RESOURCES

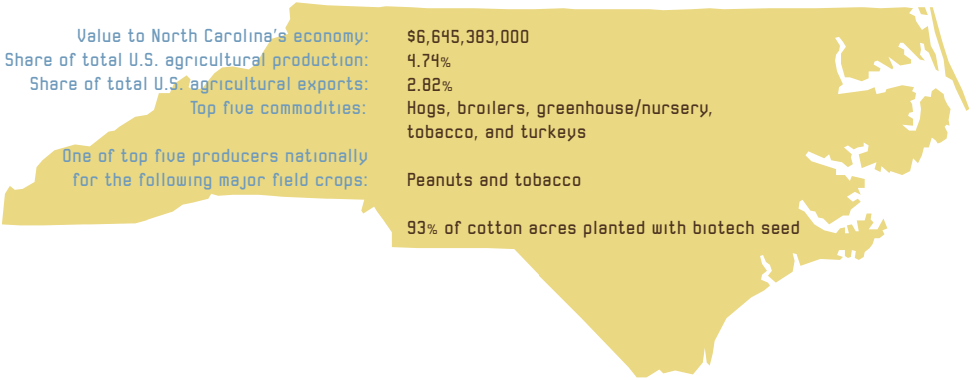
RELEVANT STATUTORY AUTHORITY			
Biotech-Specific Regulatory Statutes	Other Potential Statutory Authority Over Biotech Field Trials	Other Potential Statutory Authority Over PIPs	Other Potential Statutory Authority Over Biotech Food Safety
None	General plant pest law: N.Y. [Agric. & Mkts.] Law § 161 et seq. (2004) (Prevention of Disease in Trees and Plants; Insect Pests; Sale of Fruit-Bearing Trees)	General pesticide control law: N.Y. [Envtl. Conserv.] Law § 33-0101 et seq. (2004) (Pesticides)	General food safety law: N.Y. [Agric. & Mkts.] Law § 198 et seq. (2004) (Adulteration, Packing, and Branding of Food and Food Products)
AGENCIES WITH CURRENT OR POTENTIAL BIOTECH ROLES			
Biotech-Specific	Plant Health	Pesticides	Food Safety
None	New York State Department of Agriculture & Markets – Division of Plant Industry	New York State Department of Environmental Conservation – Pesticide Product Registration Program, Enforcement & Compliance Assurance Bureau	New York State Department of Agriculture & Markets New York State Department of Health – Bureau of Community Sanitation & Food Protection
RESOURCES			
New York Department of Agriculture and Markets budget: $80,800,000 Budget for plant health protection: $3,300,000			

NORTH CAROLINA

OVERVIEW

SNAPSHOT OF NORTH CAROLINA AGRICULTURE:

Value to North Carolina's economy:	$6,645,383,000
Share of total U.S. agricultural production:	4.74%
Share of total U.S. agricultural exports:	2.82%
Top five commodities:	Hogs, broilers, greenhouse/nursery, tobacco, and turkeys
One of top five producers nationally for the following major field crops:	Peanuts and tobacco
	93% of cotton acres planted with biotech seed



Status of Biotech Field Trial Activity

312 distinct APHIS notifications submitted (292 acknowledged; 18 denied/withdrawn/void; 24 currently in effect)

54 distinct APHIS permit applications submitted (48 issued; 6 denied/withdrawn/void; 2 currently in effect)

2 APHIS permits issued for varieties of tobacco mosaic virus (TMV) engineered to produce compounds for pharmaceutical production

1 APHIS permit issued for a variety of corn engineered to produce compounds for industrial applications

19 crops total for which APHIS notifications and/or permit applications were submitted

Most APHIS notifications and permit applications submitted for biotech varieties of corn, cotton, and tobacco

Other crops include: potatoes, rapeseed, soybeans, squash, tomatoes, and wheat

Biotech Activity and Legislative Status

Biotech Activity and Interest

North Carolina has long been active in attempting to attract more biotechnology firms and spark economic development based on agricultural biotechnology, with a major focus on biotech tobacco. One of the major debates in North Carolina has been about the use of biotech tobacco to produce pharmaceutical substances. Some are concerned that the pharma tobacco could contaminate conventional tobacco through out-crossing or accidental commingling. The North Carolina Farm Bureau has spoken out, both about the potential benefits of biotechnology, including offering alternative uses for tobacco, and the need for guidelines for the handling of biotech tobacco.[502] No permit applications have been submitted to APHIS to field test pharma tobacco in North Carolina, but such permits have been issued in other states, and permits for other types of biotech tobacco, such as insect- or herbicide-resistant varieties, have been granted for North Carolina.[503]

The North Carolina Department of Agriculture and Consumer Services is interested in helping North Carolina reap the economic benefits of biotech tobacco, while not jeopardizing the market for conventional tobacco strains. To that end, the department is playing a key role in the development of protocols for the identity preservation and containment of commercialized biotech and nonbiotech tobacco, which producers could voluntarily adopt. The protocols are being developed under the auspices of the National Association of State Departments of Agriculture and would involve a certification procedure that could verify genetic purity and product integrity.[504] For more details, see "Biotech Tobacco in North Carolina: A State-Driven Initiative to Ensure Identity Preservation of Commercialized Biotech Crops and their Conventional Counterparts" in Section IV.

Regulatory Legislation

Although North Carolina does not currently have specific statutory authority to regulate biotech crops and foods, the now-defunct Genetically Engineered Organisms Act provided North Carolina with a parallel process for issuing field test permits separate from APHIS permits from 1989 until 1995 (106 N.C. Gen. Stat. § 765 et seq. (2003)). The act created a ten-member Genetic Engineering Review Board, which had authority to review applications for the field testing of biotech crops in North Carolina and establish advisory committees to help with the review. The act gave the board power to add additional restrictions and measures to permits as well as deny,

---

502 North Carolina Farm Bureau 2001.

503 From information gathered on May 12, 2004, from Information Systems for Biotechnology 2004(f).

504 Dickerson 2004.

suspend, modify, or revoke the permits. The act also established penalties for violating any part of the law or any rule of the Board. Although providing for a separate state permitting process, the act did include the caveat that North Carolina was not seeking to duplicate federal regulations, specifying that the board had the option of issuing a permit "based on the federal review and approval of the proposed release if the board determines that federal regulation of the release sufficiently protects agriculture, public health, and the environment in North Carolina."[505] For more details, see "Filling the State Legislative Gap: Biotech-Specific Regulatory Statutes in North Carolina, Minnesota, and Iowa."

Only one piece of legislation addressing the regulation of agricultural biotechnology has been introduced since 2001. The bill, which failed, would have required individuals taking part in business dealings involving biotech tobacco to obtain a license from the North Carolina commissioner of agriculture.[506] Some stakeholder groups tried, but failed, to pass legislation that would have prevented the commercial planting of biotech tobacco in the state.[507]

Nonregulatory Legislation

As far back as 1982, North Carolina's General Assembly established the nonprofit North Carolina Biotechnology Center to support biotechnology research, development, and commercialization.[508] The state offers investment tax credits for individuals investing in the biotechnology industry (105 N.C. Gen. Stat. § 419 et seq. (2003)). The Golden LEAF Foundation, a nonprofit group that receives one-half of its funds from North Carolina's tobacco settlement with cigarette manufacturers, provides grants for economic development activities, including those involving biotechnology.[509] A pending bill would give the University of North Carolina funds to establish a biomanufacturing training center and emphasizes the need for more growth in industries such as those developing pharma crops (SB943).[510]

An anti-crop-destruction bill passed in North Carolina in 2001 that holds individuals liable for double the amount of damages they cause (HB218).[511]

---

505 North Carolina General Assembly 1989–1990.

506 Pew Initiative on Food and Biotechnology 2004(c).

507 Dickerson 2004.

508 North Carolina Biotechnology Center n.d.

509 Golden LEAF 2004.

510 Pew Initiative on Food and Biotechnology 2004(c).

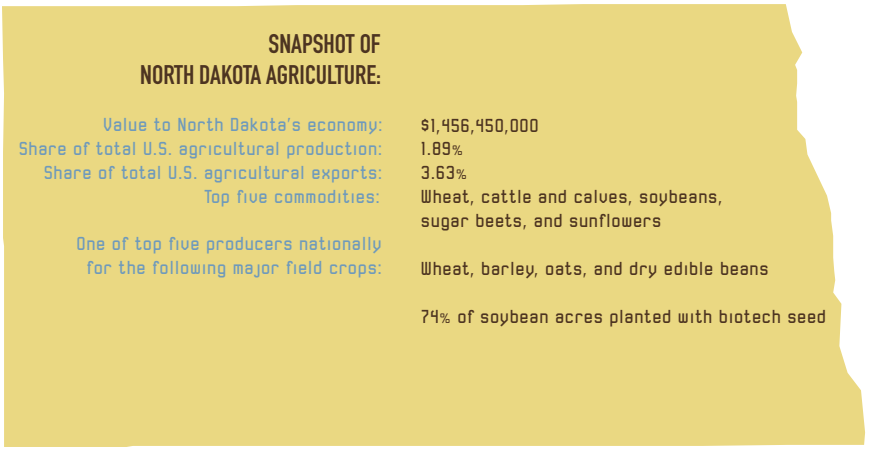
511 North Carolina General Assembly 2001–2002.

REGULATORY AUTHORITY, AGENCIES, AND RESOURCES

RELEVANT STATUTORY AUTHORITY			
Biotech-Specific Regulatory Statutes	Other Potential Statutory Authority Over Biotech Field Trials	Other Potential Statutory Authority Over PIPs	Other Potential Statutory Authority Over Biotech Food Safety
None	General plant pest laws: 106 N.C. Gen. Stat. § 419 et seq. (2003) (Plant Pests) 106 N.C. Gen. Stat. § 65.42 et seq. (2003) (North Carolina Biological Organism Act)	General pesticide control law: 106 N.C. Gen. Stat. § 65.22 et seq. (2003) (Structural Pest Control Act of North Carolina of 1955)	General food safety law: 106 N.C. Gen. Stat.§ 120 et seq. (2003) (Food, Drug and Cosmetic Act)
AGENCIES AND PROGRAMS			
Biotech-Specific	Plant Health	Pesticides	Food Safety
None	North Carolina Department of Agriculture & Consumer Services – Plant Industry Division, Plant Protection Section, Biotechnology Services	North Carolina Department of Agriculture & Consumer Services – Food and Drug Protection Division, Pesticide Section	North Carolina Department of Agriculture & Consumer Services – Food and Drug Protection Division and Meat & Poultry Inspection Service North Carolina Department of Environmental and Natural Resources – Division of Environmental Health
RESOURCES			
North Carolina Department of Agriculture and Consumer Services budget: $50,000,000 Budget for plant health protection: $3,600.000 (state-appropriated only) Narrative description of budget for biotech crops and foods component: Approximately $25,000-$30,000			

NORTH DAKOTA

OVERVIEW



SNAPSHOT OF NORTH DAKOTA AGRICULTURE:

Value to North Dakota's economy:	$1,456,450,000
Share of total U.S. agricultural production:	1.89%
Share of total U.S. agricultural exports:	3.63%
Top five commodities:	Wheat, cattle and calves, soybeans, sugar beets, and sunflowers
One of top five producers nationally for the following major field crops:	Wheat, barley, oats, and dry edible beans
	74% of soybean acres planted with biotech seed

Status of Biotech Field Trial Activity

219 distinct APHIS notifications submitted (207 acknowledged; 9 denied/withdrawn/void; 20 currently in effect)

---

67 distinct APHIS permit applications submitted (59 issued; 8 denied/withdrawn/void; 3 currently in effect)

---

1 APHIS permit issued for a variety of safflower engineered to produce compounds for pharmaceutical production

---

2 APHIS permits issued for varieties of corn and safflower engineered to produce compounds for industrial applications

---

11 crops total for which APHIS notifications and/or permit applications were submitted, including alfalfa, barley, beets, corn, cotton, potatoes, rapeseed, safflower, soybeans, sunflowers, and wheat

Biotech Activity and Legislative Status

Biotech Activity and Interest

Agriculture is North Dakota's largest industry, comprising 37% of the state's economy when ag-related business is included.[512] North Dakota also has the second largest acreage of organic cropland, behind California.[513] Because wheat production makes up a large portion of agricultural production in North Dakota, the biotech debate in the state has focused primarily on biotech wheat.

In 2003, the North Dakota commissioner of agriculture, Roger Johnson, met with anti-biotech delegates from Japan, the leading export market for North Dakota wheat. The delegates provided Commissioner Johnson with a petition signed by 414 Japanese organizations and companies asking the state to reject commercialization of biotech wheat and indicating they would stop buying North Dakota wheat if biotech wheat is commercialized in the state. Commissioner Johnson urged the delegation to begin considering the national and international policies that would be needed to guide the introduction of biotech wheat into the world marketplace. He also indicated that consumer demands, as well as sound science, have to be taken into consideration when North Dakota makes its decisions about how to proceed on the issue of biotech wheat.[514]

In testimony provided earlier in 2003 by Jeff Olson, program manager at the North Dakota Department of Agriculture on behalf of Commissioner Johnson, the importance of ensuring regulatory and market acceptance of biotech wheat before allowing commercialization was also stressed. Mr. Olson further indicated that "it is the wheat industry whose interests should dominate with respect to commercialization of new transgenic wheat events" and the industry should be given the authority to determine if and when commercialization occurs.[515] The North Dakota Farm Bureau, for its part, changed its stance on the commercialization of biotech wheat in 2002, adopting a cautious approach rather than pushing for a moratorium.[516] For more on the debate about biotech wheat in North Dakota and other Northern Plains states, see "Legislating Restrictions on Biotech Crops on Economic and Social Grounds: Roundup Ready® Wheat" in Section IV.

Regulatory Legislation

North Dakota has no specific statutory authority to regulate biotech crops and foods. A ballot measure to provide such authority specifically with respect to wheat is being developed, however, with the active involvement of a former secretary of state and state senator in North Dakota, Jim Kusler.

---

512 North Dakota Department of Agriculture n.d.

513 Wetzel 2004.

514 North Dakota Department of Agriculture 2004.

515 Johnson 2003.

516 Nicholson 2002.

This initiative would require public hearings, consultations with experts, and the North Dakota commissioner of agriculture's approval before biotech wheat could be planted in the state. The measure would give the commissioner the power to veto plantings and is focused on the issue of market acceptance. Although it is uncertain what the outcome of the measure will be, Commissioner Johnson has stated that the measure "certainly is one of the different alternatives that the public ought to be considering."

The legislature has passed bills that encourage the legislative council to study and report back to the legislature on risks to health, the environment, and the food supply posed by biotech crops (HB1338), and that, in anticipation of the possible commercialization of biotech wheat, direct the North Dakota commissioner of agriculture to provide for inspecting, analyzing, and verifying the genetic identity of seeds and crops. The latter law also directs the commissioner to devise identifying labels for seeds and crops (SB2235). The goal of the legislation is to provide a certifying service for nonbiotech seed that could be used as a marketing tool. According to the state seed commissioner, Ken Bertsch, establishing "this program will give [North Dakota] enough time to be out ahead of any kind of genetically modified wheat," and the state has achieved its goal if the program "produces additional profit for farmers."[517]

Other legislative attempts aimed specifically at regulation of biotech wheat were defeated. One would have required a certificate to sell biotech wheat seed in North Dakota. Another would have created a Transgenic Wheat Board to monitor scientific, legislative, and regulatory efforts toward biotech wheat at state, federal, and international levels; gauge market acceptance for biotech wheat in national and international markets; evaluate whether any new state or federal legislation would be needed for the production of any commercialized biotech wheat in North Dakota; and recommend any of the needed legislation or state regulations.[518]

Nonregulatory Legislation

In contrast to a number of other states, North Dakota has not established economic incentives and other programs to promote biotech development, though it passed a resolution in 2001 urging North Dakota State University to host a center for biotech research (HCR3031). It also passed an anti-crop-destruction bill in 2001, making individuals who damage or destroy crops or livestock liable for double the cost of damage incurred (SB2280).

---

517 Cropchoice 2001.

518 North Dakota Legislative Assembly n.d.(d).

REGULATORY AUTHORITY, AGENCIES, AND RESOURCES

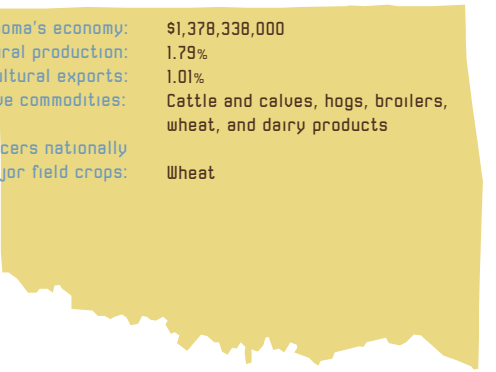
RELEVANT STATUTORY AUTHORITY			
Biotech-Specific Regulatory Statutes	Other Potential Statutory Authority Over Biotech Field Trials	Other Potential Statutory Authority Over PIPs	Other Potential Statutory Authority Over Biotech Food Safety
None	General plant pest law: 4 N.D. Cent. Code § 33-01 et seq. (2003) (Plant Pests)	General pesticide control law: 4 N.D. Cent. Code § 35-01 et seq. (2003) (North Dakota Pesticide Act of 1975) and 4 N.D. Cent. Code § 18-01 (Pesticide Registration)	General food safety law: 19 N.D. Cent. Code § 02.1-01 et seq. (2003) (North Dakota Food, Drug and Cosmetic Act)
AGENCIES WITH CURRENT AND POTENTIAL BIOTECH ROLES			
Biotech-Specific	Plant Health	Pesticides	Food Safety
None	North Dakota Department of Agriculture – Plant Industries Program Area	North Dakota Department of Agriculture – Plant Industries Program Area, Pesticide Registration Program, and Pesticide Enforcement & Compliance Assistance Program	North Dakota Department of Agriculture North Dakota Department of Health – Food & Lodging Division
RESOURCES			
North Dakota Department of Agriculture budget: $6,800,000 Budget for plant health protection: $159,000 Narrative description of budget for biotech crops and foods component: About 15% of one FTE is devoted to biotech activities, which translates into about $11,000 annually in salary and operating expenditures.			

OKLAHOMA

OVERVIEW

SNAPSHOT OF OKLAHOMA AGRICULTURE:

Value to Oklahoma's economy:	$1,378,338,000
Share of total U.S. agricultural production:	1.79%
Share of total U.S. agricultural exports:	1.01%
Top five commodities:	Cattle and calves, hogs, broilers, wheat, and dairy products
One of top five producers nationally for the following major field crops:	Wheat



Status of Biotech Field Trial Activity

81 distinct APHIS notifications submitted (74 acknowledged; 5 denied/withdrawn/void; 21 currently in effect)

---

9 distinct APHIS permit applications submitted (8 issued; 1 denied/withdrawn/void; none currently in effect)

---

1 APHIS permit issued for a variety of alfalfa engineered to produce compounds for pharmaceutical production

---

No APHIS notifications or permit applications submitted for crops engineered to produce compounds for industrial applications

---

12 crops total for which APHIS notifications and/or permit applications were submitted, including alfalfa, corn, Italian ryegrass, peanuts, perennial ryegrass, potatoes, soybeans, squash, tobacco, and wheat

Biotech Activity and Legislative Status

Biotech Activity and Interest

Oklahoma has had relatively little biotech activity in terms of field trial notifications and permits. Nevertheless, the state government sees agricultural biotechnology as a contributor to economic development. The Oklahoma Department of Commerce has specifically touted the efforts of one venture capital operation, Emergent Technologies, Oklahoma, LP, to build up the biotechnology industry in Oklahoma through its funding and other support activities;[519] and Oklahoma State University maintains a Biotechnology Network, which offers technical facilities at a fee to any public or private scientist in Oklahoma working on biotech issues.[520]

Regulatory Legislation

In 1990, the Oklahoma legislature adopted a biotech regulatory statute, called the Agriculture Biotechnology Act, to "protect agriculture and public health from intentional or unintentional release of genetically engineered biological articles into the environment" through a permit system. It was intended, at a stage well before commercialization of biotech crops and foods, to fill any possible gaps in federal oversight. Thus, only products not regulated by a federal agency would have to apply for a state permit to develop, maintain, manipulate, and/or release a biotech organism. The act also provides the Oklahoma Department of Agriculture, Food, and Forestry authority to deny, suspend, and revoke any permit and to inspect any premises where it believes activities governed by the act may be taking place. The act protects CBI, using the same language APHIS uses in its 1985 "Policy Statement on the Protection of Privileged or Confidential Business Information."[521]

Nonregulatory Legislation

Oklahoma has also adopted statutes addressing economic development and research opportunities in biotechnology. The Oklahoma Science and Technology Research and Development Act was intended to help the state establish itself as a "premier information technology and biotechnology center." It established a board to provide leadership to the Oklahoma Center for the Advancement of Science and Technology and the Oklahoma Institute of Technology and to facilitate public-private collaboration through these institutions (74 Okla. Stat. § 5060.1 et seq. (2004)). Oklahoma law also directs the Oklahoma State Regents for Higher Education to encourage educational efforts in the realm of biotechnology and other technology fields (70 Okla. Stat. § 3206.3 (2004)).

Only a few pieces of legislation addressing biotechnology have been introduced in Oklahoma since 2001, all nonregulatory in nature. One, an anti-crop-destruction bill, failed to pass.[522]

---

519 Oklahoma Department of Commerce 2001.

520 Oklahoma EPSCoR: Biotechnology Network. n.d.

521 2 Okla. Stat. § 11-35 et seq. 2004; USDA APHIS 1985.

522 Pew Initiative on Food and Biotechnology 2004(c).

REGULATORY AUTHORITY, AGENCIES, AND RESOURCES

RELEVANT STATUTORY AUTHORITY			
Biotech-Specific Regulatory Statutes	Other Potential Statutory Authority Over Biotech Field Trials	Other Potential Statutory Authority Over PIPs	Other Potential Statutory Authority Over Biotech Food Safety
2 Okla. Stat. § 11-35 et seq. (2004) (Oklahoma Agriculture Biotechnology Act)	General plant pest law: 2 Okla. Stat. § 3-32.1 et seq. (2004)	General pesticide control law: 2 Okla. Stat. § 3-81 et seq. (2004)	General food safety law: None
AGENCIES WITH CURRENT OR POTENTIAL BIOTECH ROLES			
Biotech-Specific	Plant Health	Pesticides	Food Safety
Oklahoma Department of Agriculture, Food & Forestry – State Board of Agriculture	Oklahoma Department of Agriculture, Food & Forestry – Plant Industry & Consumer Services Division	Oklahoma Department of Agriculture, Food & Forestry – Plant Industry & Consumer Services Division, Pesticides	Oklahoma Department of Agriculture – Meat, Dairy & Egg Inspection Division
RESOURCES			
Oklahoma Department of Agriculture, Food, and Forestry budget: $38,000,000 Budget for plant health protection: $604,000 Narrative description of budget for biotech crops and foods component: Biotech oversight inspection and permit concurrence is usually assigned to the pesticide registration program administrator, who typically concurs with the USDA decision since the department does not have anyone on staff with any expertise in biotechnology, and makes biotech facility inspections in conjunction with the USDA State Plant Health Director about once every two years. The estimated cost of all the time involved with biotech oversight in the Oklahoma Department of Agriculture would average less than $1,000/year.			

OREGON

OVERVIEW

SNAPSHOT OF OREGON AGRICULTURE:

Value to Oregon's economy:	$1,467,241,000
Share of total U.S. agricultural production:	1.91%
Share of total U.S. agricultural exports:	1.22%
Top five commodities:	Greenhouse/nursery, cattle and calves, dairy products, hay, and potatoes
One of top five producers nationally for the following major field crops:	Potatoes

Status of Biotech Field Trial Activity

299 distinct APHIS notifications submitted (266 acknowledged; 30 denied/withdrawn/void; 29 currently in effect)

---

39 distinct APHIS permit applications submitted (33 issued; 5 denied/withdrawn/void; none currently in effect)

No APHIS permit applications submitted for crops engineered to produce compounds for pharmaceutical production

---

1 APHIS permit issued for a variety of alfalfa engineered to produce compounds for industrial applications

---

19 crops total for which APHIS notifications and/or permit applications were submitted, including alfalfa, apples, corn, melons, pears, petunias, poplar, potatoes, rapeseed, squash, strawberries, tomatoes, and wheat

Biotech Activity and Legislative Status

Biotech Activity and Interest

Agriculture still plays a major role in Oregon's economy, with 80% of its agricultural products shipped out of the state and half of those exported to other countries.[523] Agricultural biotechnology has been a hot topic in Oregon, although acreage of biotech crops in the state is relatively small compared to Midwestern states. Since a good portion of Oregon's agriculture is exported, and the state is in a strategic location as an import/export point for the nation's agricultural commodities, the Oregon Department of Agriculture has set up a program with Oregon State University to provide pre-export analysis and certification of raw and finished food products. Food products are tested for pesticide residue, food chemistry, and microbiology, as well as biotech content. The Export Service Center offers this service to provide assurance that exported food products comply with labeling laws in other countries.[524]

One controversial biotech issue has been the field testing of Roundup Ready bentgrass.[525] Bentgrass, commonly used as turf for golf courses and athletic fields in northern climates, is a perennial crop with wild relatives, which has raised questions concerning the potential for contamination of non-GM bentgrass and other crops. To mitigate contamination concerns, the field test was comprised of 400 acres located in a control area in Jefferson County of 11,000 acres outside the western portion of the state where bentgrass is grown.[526] To date, issues related to the containment of GM bentgrass have kept the crop from being granted nonregulated status by APHIS.

Regulatory Legislation

Oregon currently has no biotech-specific regulatory statute. Perhaps the most contentious and highly publicized biotech issue in Oregon was the 2002 Ballot Measure 27, which would have put into place the first law in the United States requiring the labeling of all foods with biotech ingredients sold or distributed in or from a state. Although the measure got the requisite number of signatures to be added to Oregon's ballot, it failed to pass.[527] In 2003, a bill that would have prohibited any future attempts by the state or local governments to impose their own biotech food labeling laws, unless the requirements were endorsed by FDA, was introduced in the legislature, but failed to pass. Another unsuccessful piece of legislation would have prohibited the release of biotech plants in unconfined areas and required biotech research performed at state institutions to be registered.[528]

523 Oregon Department of Agriculture n.d.(c).

524 Oregon Department of Agriculture n.d.(a).

525 Hilburn 2004.

526 Hilburn 2004.

527 Pew Initiative on Food and Biotechnology 2004(c).

528 Pew Initiative on Food and Biotechnology 2004(c).

Nonregulatory Legislation

Oregon has adopted a measure that makes it illegal to interfere with agricultural research, imposing liability for the cost of any damage done and the cost of repeating any experiment that failed as a result of damage (HB2385).

REGULATORY AUTHORITY, AGENCIES, AND RESOURCES

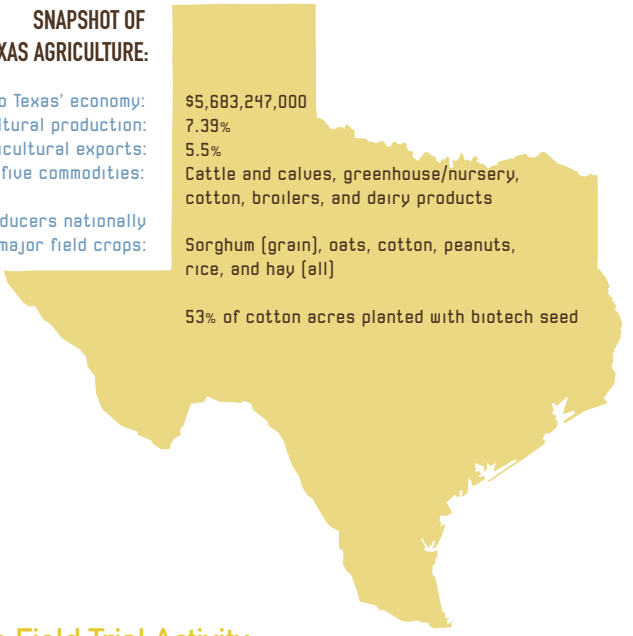
RELEVANT STATUTORY AUTHORITY			
Biotech-Specific Regulatory Statutes	Other Potential Statutory Authority Over Biotech Field Trials	Other Potential Statutory Authority Over PIPs	Other Potential Statutory Authority Over Biotech Food Safety
None	General plant pest law: Or. Rev. Stat. § 570.005 et seq. (2003) (Plants; Inspection, Quarantine, Pest and Weed Control)	General pesticide control law: Or. Rev. Stat. § 634.005 et seq. (2003) (State Pesticide Control Act)	General food safety law: Or. Rev. Stat. § 616.010 et seq. (2003) (Food and Other Commodities)
AGENCIES WITH CURRENT OR POTENTIAL BIOTECH ROLES			
Biotech-Specific	Plant Health	Pesticides	Food Safety
Oregon Department of Agriculture –Laboratory Services, Export Service Center	Oregon Department of Agriculture – Plant Division, Natural Resources Program Area	Oregon Department of Agriculture – Pesticides Division, Food Safety & Consumer Protection Area	Oregon Department of Agriculture – Animal Health Division and Food Safety Division Oregon Department of Human Services – Office of Public Health Systems, Environmental Services & Consultation
RESOURCES			
Oregon Department of Agriculture budget: $84,000,000 Budget for plant health protection: $8,000,000 Narrative description of budget for biotech crops and foods component: 10% of one FTE, which includes a small percentage of time for two or so state regulators.			

TEXAS

OVERVIEW

SNAPSHOT OF TEXAS AGRICULTURE:

Value to Texas' economy:	$5,683,247,000
Share of total U.S. agricultural production:	7.39%
Share of total U.S. agricultural exports:	5.5%
Top five commodities:	Cattle and calves, greenhouse/nursery, cotton, broilers, and dairy products
One of top five producers nationally for the following major field crops:	Sorghum (grain), oats, cotton, peanuts, rice, and hay (all)
	53% of cotton acres planted with biotech seed



Status of Biotech Field Trial Activity

404 distinct APHIS notifications submitted (385 acknowledged; 18 denied/withdrawn/void; 52 currently in effect)

58 distinct APHIS permit applications submitted (51 issued; 4 denied/withdrawn/void; 4 currently in effect)

3 APHIS permits issued and 1 pending for varieties of corn and tomatoes engineered to produce compounds for pharmaceutical production

1 APHIS permit issued for a variety of corn engineered to produce compounds for industrial applications

20 crops total for which APHIS notifications and/or permit applications were submitted

Most APHIS notifications and permit applications have been submitted for biotech varieties of cotton

Other crops include: alfalfa, beets, carrots, corn, grapefruit, melons, melon squash, onions, potatoes, rapeseed, rice, soybeans, squash, sugarcane, and tobacco

Biotech Activity and Legislative Status

Biotech Activity and Interest

Texas ranks second in the nation in agricultural production,[529] and there has been substantial field trial activity in the state. Agricultural biotechnology has not been a major topic of controversy in the state,[530] but there has been interest in the technology from the scientific, consumer protection, and economic development perspectives, and Texas is one of a few states with a separate program to review APHIS field trial permits.

In 2002, the Texas Medical Association created a Task Force on Genetically Modified Foods to study food safety and other issues connected with agricultural biotechnology that physicians should understand. Its conclusions and recommendations included the following:

> No scientific evidence has been published that shows genetically modified foods released to market are unsafe to eat. Genetically modified foods should continue to be studied and monitored for safety. Consumers need to have access to credible and scientifically reliable information on genetically modified foods. Currently, institutional and commercial practices and agreements may impede sharing of research results, which slows scientific progress. More effort needs to be made on sharing genetic research data. Innovative partnerships between public and private entities should be created to encourage the ethical sharing of scientific research findings. Rigorous, effective and comprehensive governmental oversight is essential to the development of genetically modified products to ensure the highest level of public health safety. The risks of any genetically modified food—including the long-term effects of changing plant, bacterial, viral, and fungal flora—must be weighed against the benefits that any new food has to offer. For consumers to have confidence in genetically modified foods, they must see that the benefits outweigh the risks; such education must be made available in a non-biased, scientific way.[531]

Regulatory Legislation

Texas does not have a biotech-specific regulatory statute, but it has established within its Department of Agriculture a separate biotechnology regulatory unit, operating under its general plant pest and pesticide laws, to address agricultural biotechnology and review APHIS permit applications.[532] Texas has adopted a specific policy that it will not require state registration of PIPs because they do not appear to pose risks that would justify state

529 Texas Department of Agriculture n.d.(c).

530 Mitchell 2004.

531 Texas Medical Association 2002.

532 Texas Department of Agriculture n.d.(a).

regulation on top of EPA's regulatory oversight.[533] Texas is, however, one of the few states that participate in the inspection of PIP field trial tests that are being conducted under EPA experimental use permits (EUPs). The Texas cooperative agreement with EPA requires a certain number of EUP inspections per year. Only a handful (fewer than 10) EUPs are typically issued annually in Texas, of which about half may be for PIPs.[534]

Only one bill related to the regulation of biotechnology has been introduced in the state legislature since 2001. This bill would have placed a moratorium on genetically engineering crops or livestock usually used as food products or animal feed to produce pharmaceutical substances or industrial compounds. It died in committee in 2003.[535]

Nonregulatory Legislation

Texas has enacted several biotech-related laws addressing research and economic development, all prior to 2001.[536] The Education Code establishes an Institute of Biosciences and Technology at Texas A&M University to conduct biotech research "at the interface between agriculture, veterinary science, and human medicine" (3Tex. [Educ.] Code Ann. § 86.62 (1) (2003)). Another section of the code establishes an advanced technology program to provide funds to public and private institutions of higher education to conduct applied research in areas including biotechnology and agriculture (3 Tex. [Educ.] Code Ann. § 143.001 et seq. (2003)). Economic development from biotechnology is encouraged through the creation of a Southeast Texas Biotechnology Park to support growth and development of biotech enterprises and commercialization of biotech research (4 Tex. [Gov't] Code Ann. § 488.001 et seq. (2003)), through the use of the Texas Economic Tourism and Development Office to "coordinate state efforts to attract, develop, or retain technology industries" in the biotech sector, among others (4 Tex. [Gov't] Code Ann. § 481.0296 (2003)), and through the provision of funds from the Texas Economic Development Bank for efforts in the biotech sector, among others (4 Tex. [Gov't] Code Ann. § 489.213 (2003)).

---

533 Texas Department of Agriculture n.d.(b).

534 Mitchell 2004.

535 Pew Initiative on Food and Biotechnology 2004(c).

536 Pew Initiative on Food and Biotechnology 2004(c).

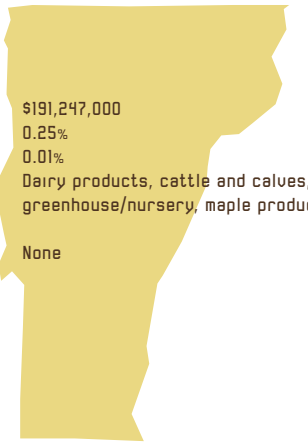
REGULATORY AUTHORITY, AGENCIES, AND RESOURCES

RELEVANT STATUTORY AUTHORITY			
Biotech-Specific Regulatory Statutes	Other Potential Statutory Authority Over Biotech Field Trials	Other Potential Statutory Authority Over PIPs	Other Potential Statutory Authority Over Biotech Food Safety
None	General plant pest law: 5 Tex. [Agric.] Code Ann. § 17.001 et seq. (2003) (General Control)	General pesticide control law: 5 Tex. [Agric.] Code Ann. § 76.001 et seq. (2003) (Pesticide and Herbicide Regulation)	General food safety law: 6 Tex. [Health & Safety] Code Ann. § 431.001 et seq. (2003) (Texas Food, Drug, and Cosmetic Act)
AGENCIES WITH CURRENT OR POTENTIAL BIOTECH ROLES			
Biotech-Specific	Plant Health	Pesticides	Food Safety
Texas Department of Agriculture – Regulatory Programs, Biotechnology	Texas Department of Agriculture – Regulatory Programs, Quarantine	Texas Department of Agriculture – Pesticide Registration Program, and Compliance & Program Development	Texas Department of Health
RESOURCES			
Texas Department of Agriculture budget: FY 04 $61,330,483 Budget for plant health protection: FY 04 $2,362,111 Narrative description of budget for biotech crops and foods component: TDA Plant Quality and Pest Management Programs receive, acknowledge, and file PIP permits using about 1% of its resources for this purpose.			

VERMONT

OVERVIEW

SNAPSHOT OF VERMONT AGRICULTURE:



Value to Vermont's economy:	$191,247,000
Share of total U.S. agricultural production:	0.25%
Share of total U.S. agricultural exports:	0.01%
Top five commodities:	Dairy products, cattle and calves, greenhouse/nursery, maple products, and hay
One of top five producers nationally for the following major field crops:	None

Status of Biotech Field Trial Activity

No APHIS notifications submitted

---

1 distinct APHIS permit submitted (none issued; 1 denied/withdrawn/void; none currently in effect)

No APHIS permit applications submitted for crops engineered to produce compounds for pharmaceutical production

---

No APHIS notifications or permit applications submitted for crops engineered to produce compounds for industrial applications

Biotech Activity and Legislative Status

Biotech Activity and Interest

Although no biotech field trials have been authorized in Vermont, there is a high level of legislative activity and consumer activism in the state concerning agricultural biotechnology. Vermont is home to politically active organic farming communities and has few growers of the major commodity crops that are most likely to be genetically modified.[537] Vermont's agricultural secretary, Stephen Kerr, is working to foster a political and regulatory climate that would support the coexistence of organic and biotech crops in the state and has been developing rules that would protect organic crops from contamination with biotech material. Secretary Kerr believes that Vermont will not have the power to regulate biotech crops unless they can show a hazard to human health or the environment. He also believes that suing the federal government or having producers sue other producers or biotech companies will not be productive for either the parties to the litigation or Vermont's economy.[538] Many groups are protesting these efforts and advocate Vermont being a biotech-free state. One indication of consumer attitudes in Vermont toward biotech food comes from a poll conducted in 2002 by the Center for Rural Studies, a nonprofit research organization based at the University of Vermont. This poll found that 96% of registered voters in Vermont want biotech foods labeled as such.[539]

Regulatory Legislation

The one biotech-related regulatory law in Vermont requires the labeling of genetically engineered seeds as such, the provision of instructions for their safe use, and annual reporting on their sale by the manufacturer to the secretary of agriculture (SB777).[540] There is no biotech-specific state law governing biotech field trials or commercialization of biotech crops and foods.

Reflecting the public's attitudes, however, numerous biotech regulatory bills have been introduced in the Vermont legislature.[541] At the end of 2002 and beginning of 2003, 70 towns, representing a little less than one-third of the population in the state, passed nonbinding resolutions about biotech issues at the town hall level.[542] Most involved the labeling of biotech foods or the placing of a moratorium on growing biotech crops and were viewed as input to the Vermont Legislature. These concerns were later captured in a set of bills introduced in both the Vermont Senate and House during the 2003–2004 legislative session addressing the labeling of biotech foods (SB163 and HB351), the placing of a moratorium on the growing of biotech crops (SB162 and HB353), and the establishment of a registration process for the sale or distribution of biotech seeds or crops (SB165 and HB352).

---

537 Mace 2003(a).

538 Mace 2003(b).

539 Center for Rural Studies 2002.

540 Vermont Legislature 2003–2004.

541 Biotechnology Industry Organization 2003(a); Pew Initiative on Food and Biotechnology 2004(c).

542 Rathke 2003.

One of these bills, which passed the Senate in 2004 and is currently in the House, would hold biotech companies liable for damages resulting from a failure to provide information or misrepresenting information on biotech crops. The bill would also create an advisory committee on genetic engineering to study the effects of and potential regulation of agricultural biotechnology in Vermont (SB164).[543]

REGULATORY AUTHORITY, AGENCIES, AND RESOURCES

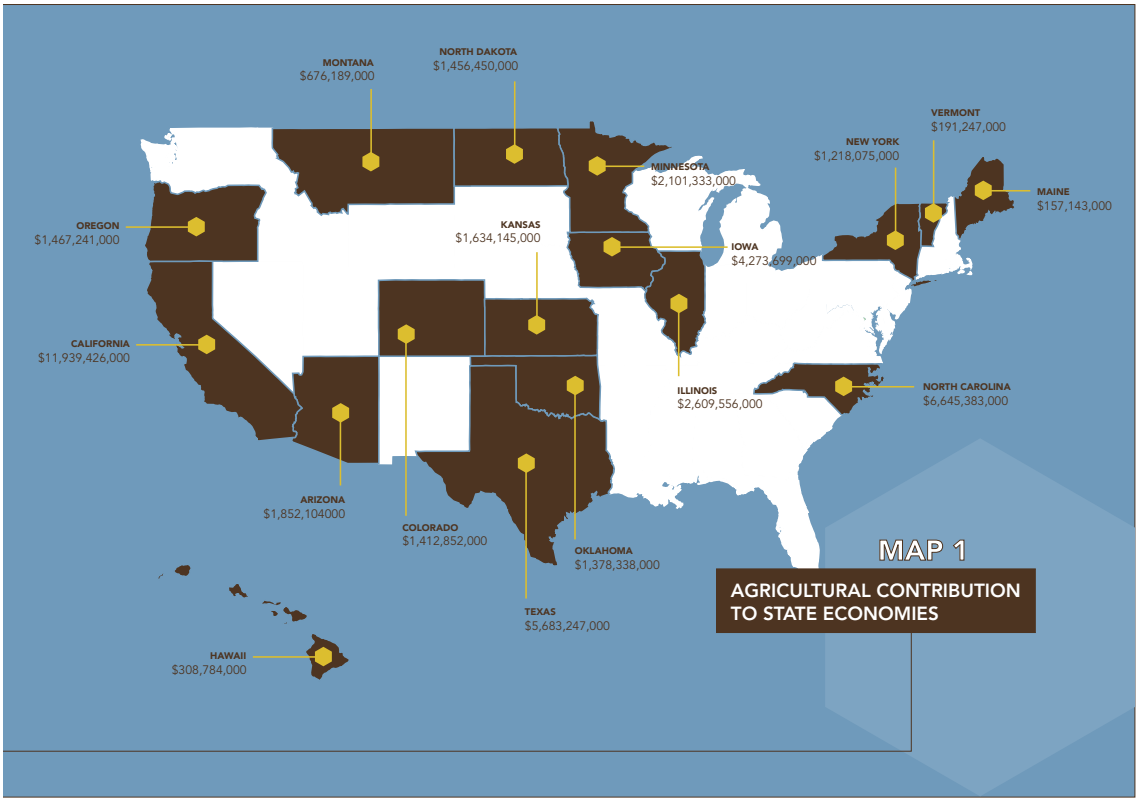
RELEVANT STATUTORY AUTHORITY			
Biotech-Specific Regulatory Statutes	Other Potential Statutory Authority Over Field Trials	Other Potential Statutory Authority Over PIPs	Statutory Authority Over Biotech Food Safety
6 Vt. Stat. Ann. §611 et seq.	Generic plant pest law: 6 Vt. Stat. Ann. § 1030 et seq. (2003) (Pest Survey)	Generic pesticide control law: 6 Vt. Stat. Ann. § 1101 et seq. (2003) (Control of Pesticides)	Generic food safety law: 18 Vt. Stat. Ann. § 4023 et seq. (2003) (Pure Food and Drugs)
AGENCIES WITH CURRENT OR POTENTIAL BIOTECH ROLES			
Biotech-Specific	Plant Health	Pesticides	Food Safety
Vermont Agency of Agriculture, Food & Markets	Vermont Agency of Agriculture, Food & Markets – Plant Industry & Laboratories Division	Vermont Agency of Agriculture, Food & Markets – Plant Industry & Laboratories Division and Vermont Pesticide Advisory Council	Vermont Agency of Agriculture, Food & Markets – Animal Health Section and Food Safety & Consumer Assurance Vermont Department of Health – Food & Lodging Program
RESOURCES			
Vermont Agency of Agriculture, Food & Markets budget: Not available Budget for plant health protection: $250,000 (approximately) Narrative description of budget for biotech crops and foods component: 1% of an FTE in Plant Industries spends time on the state biotech activities related to seed reporting and labeling.			

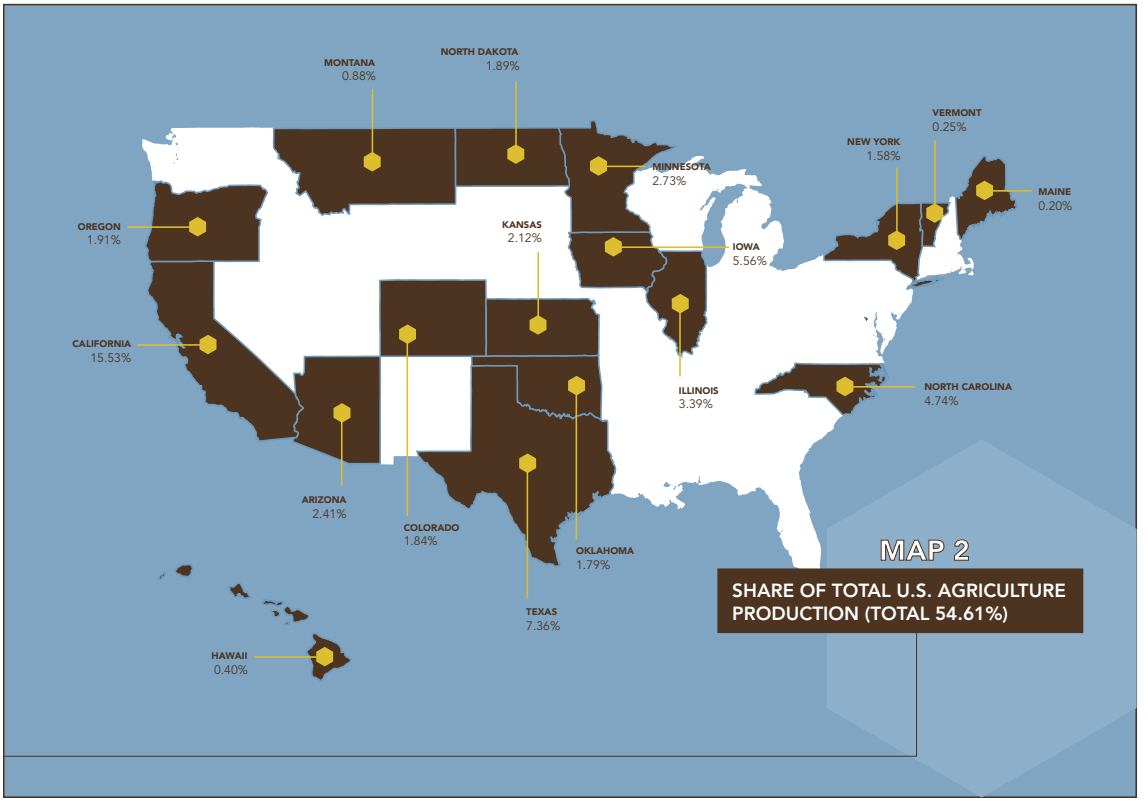
543 Williams 2003; Pew Initiative on Food and Biotechnology 2004(c).

APPENDIX A (CONTINUED)

MAPS

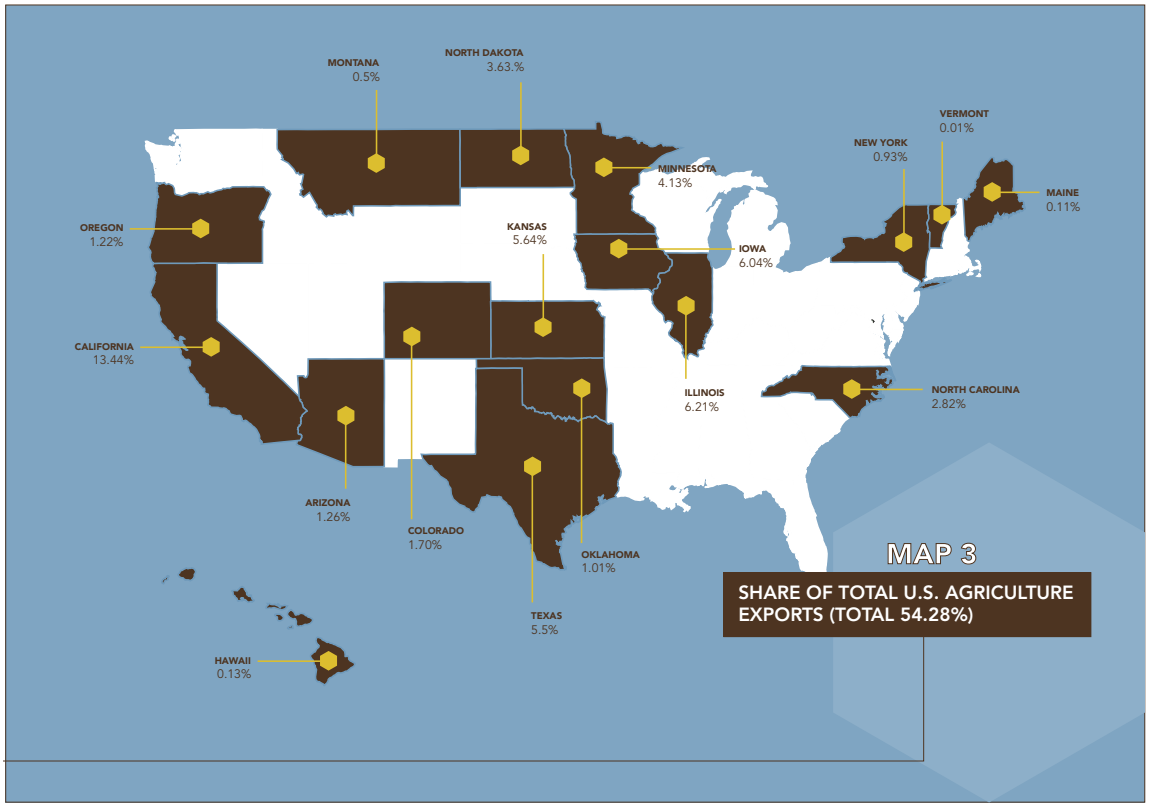
The following maps synthesize the information presented in each of the preceeding state summaries. They are intended to facilitate state-to-state comparisons with respect to agricultural contributions as well as APHIS notifications and permit applications.





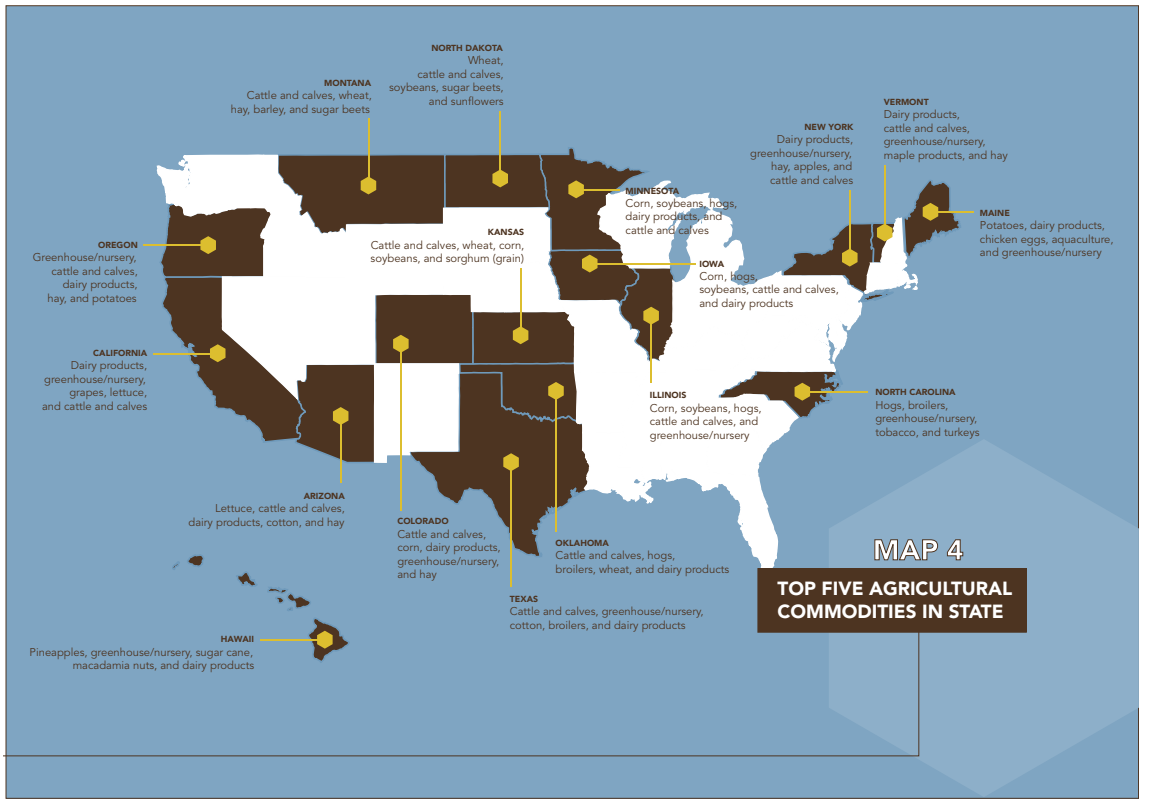
MAP 2

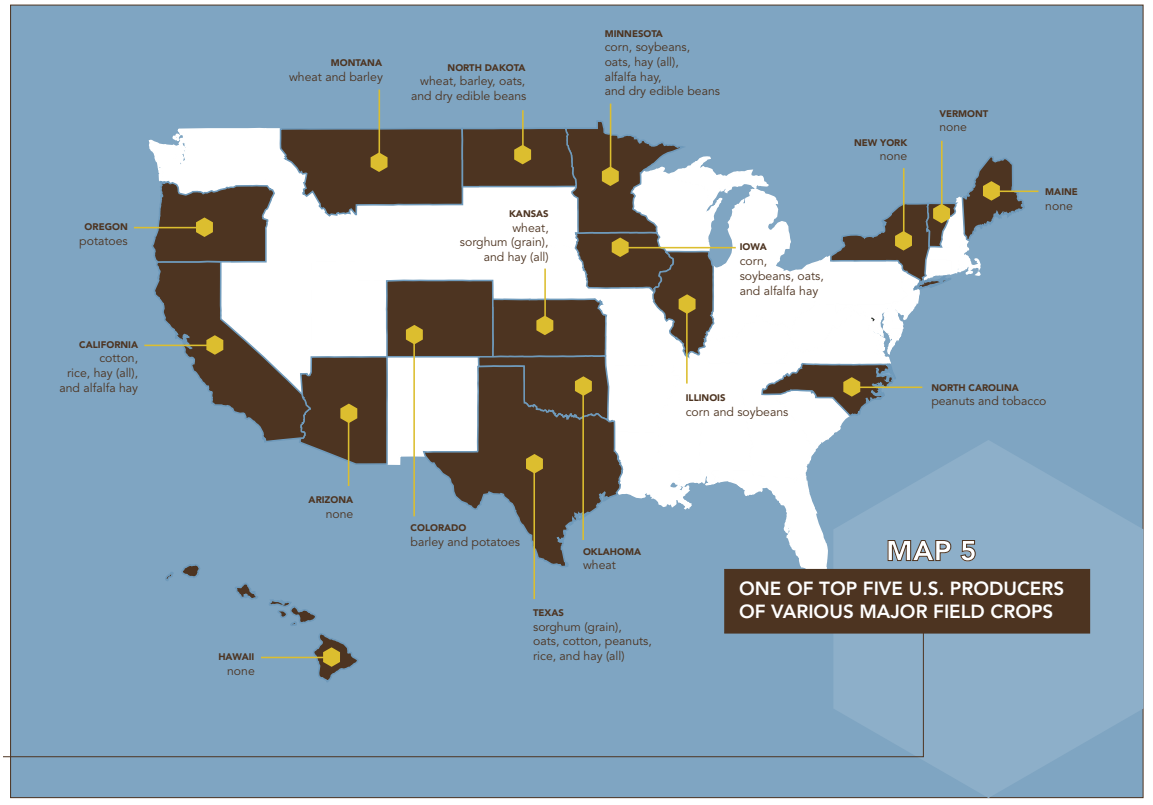
SHARE OF TOTAL U.S. AGRICULTURE PRODUCTION (TOTAL 54.61%)

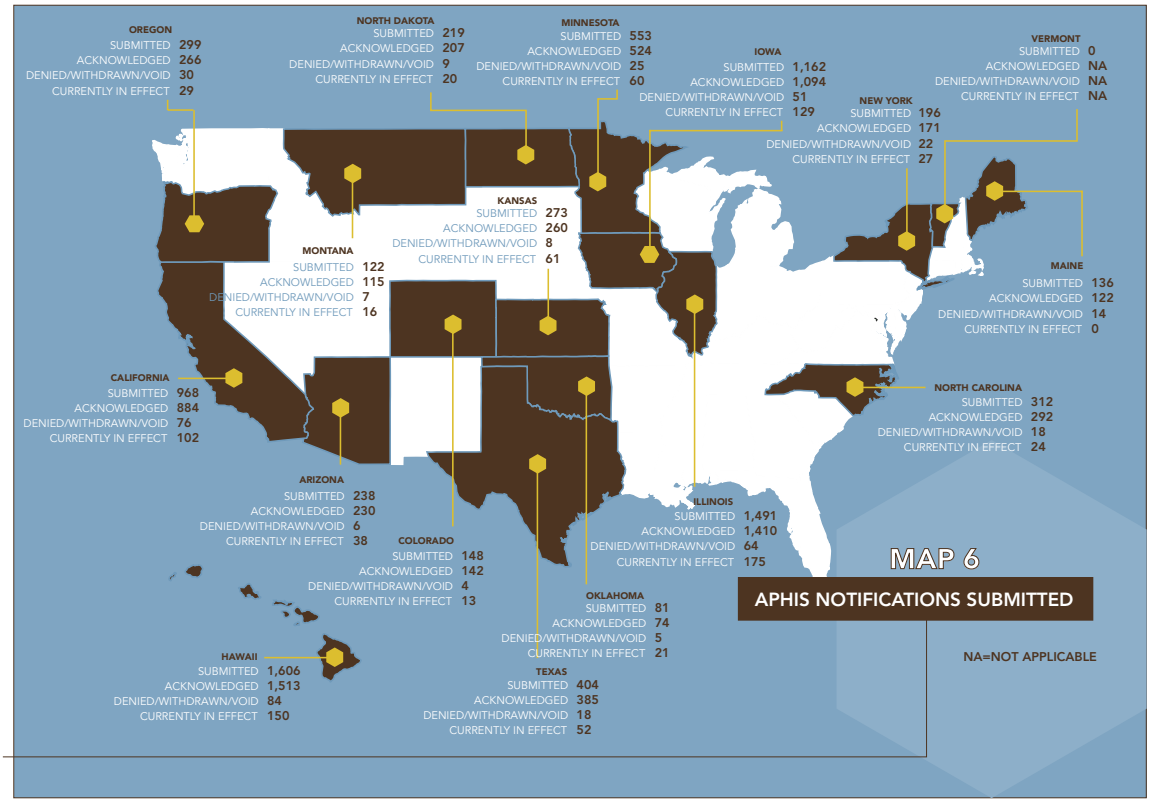


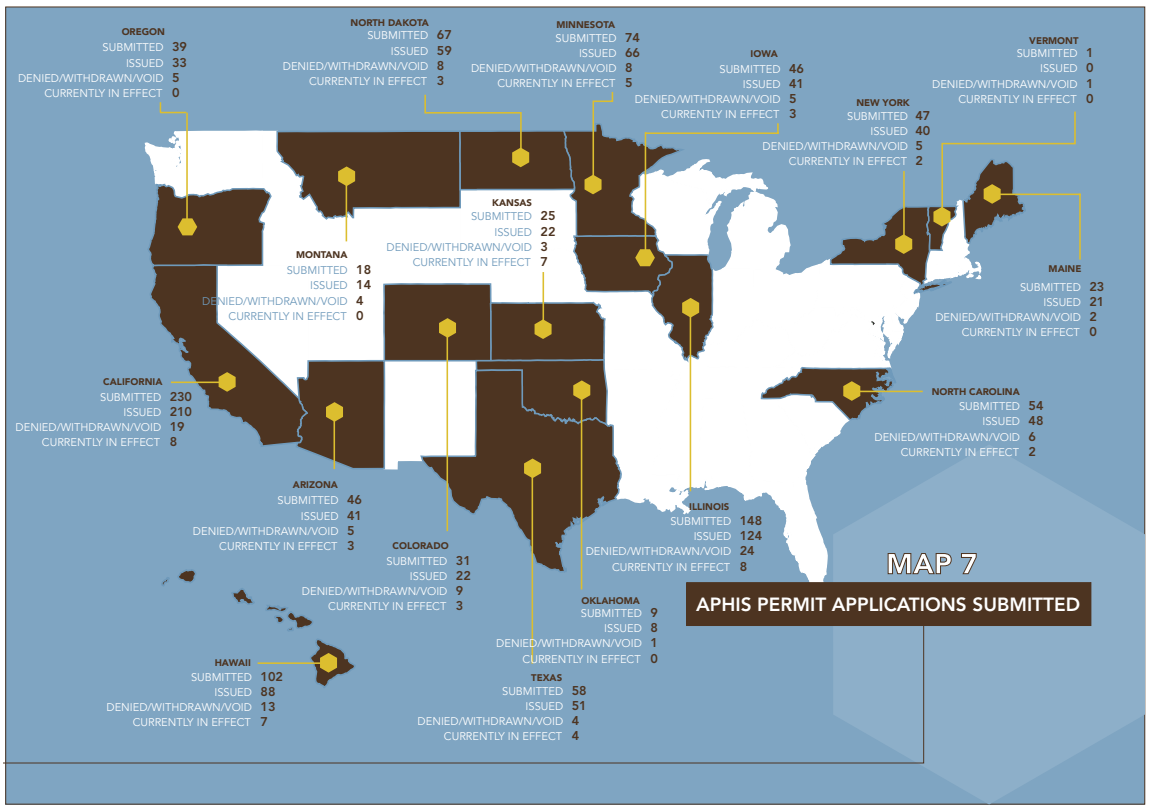
MAP 3

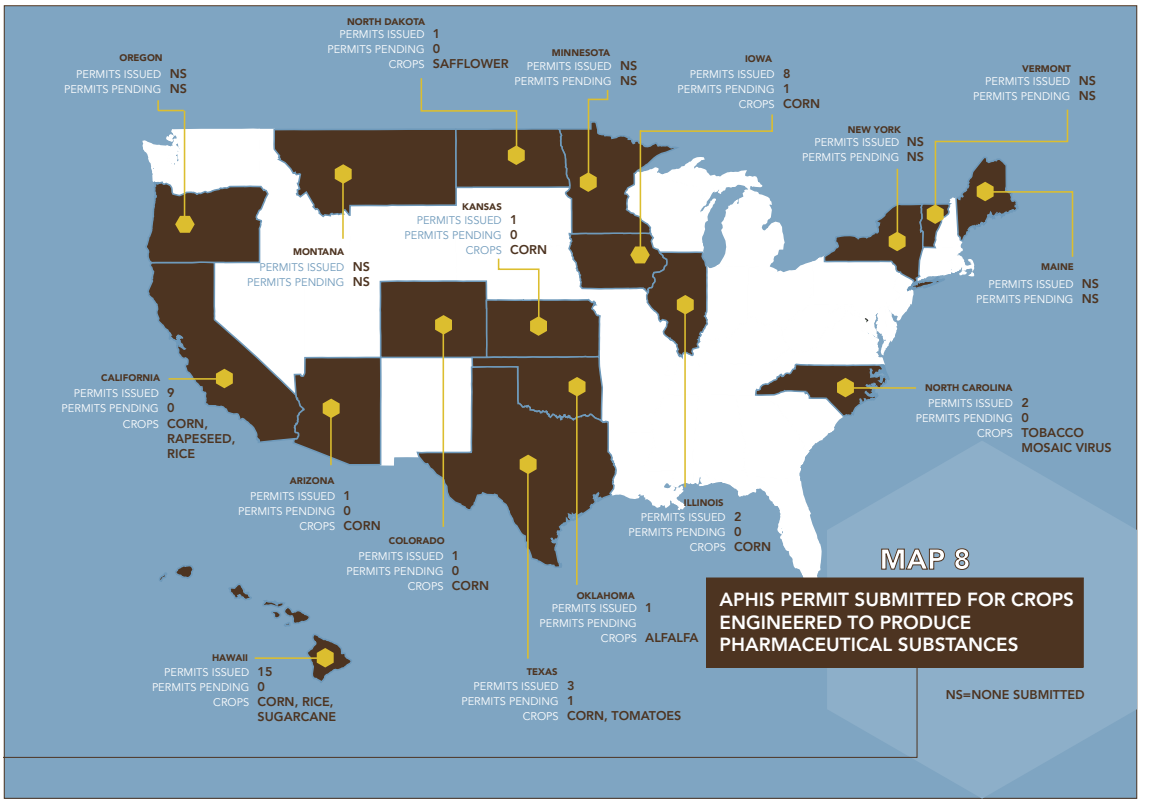
SHARE OF TOTAL U.S. AGRICULTURE EXPORTS (TOTAL 54.28%)

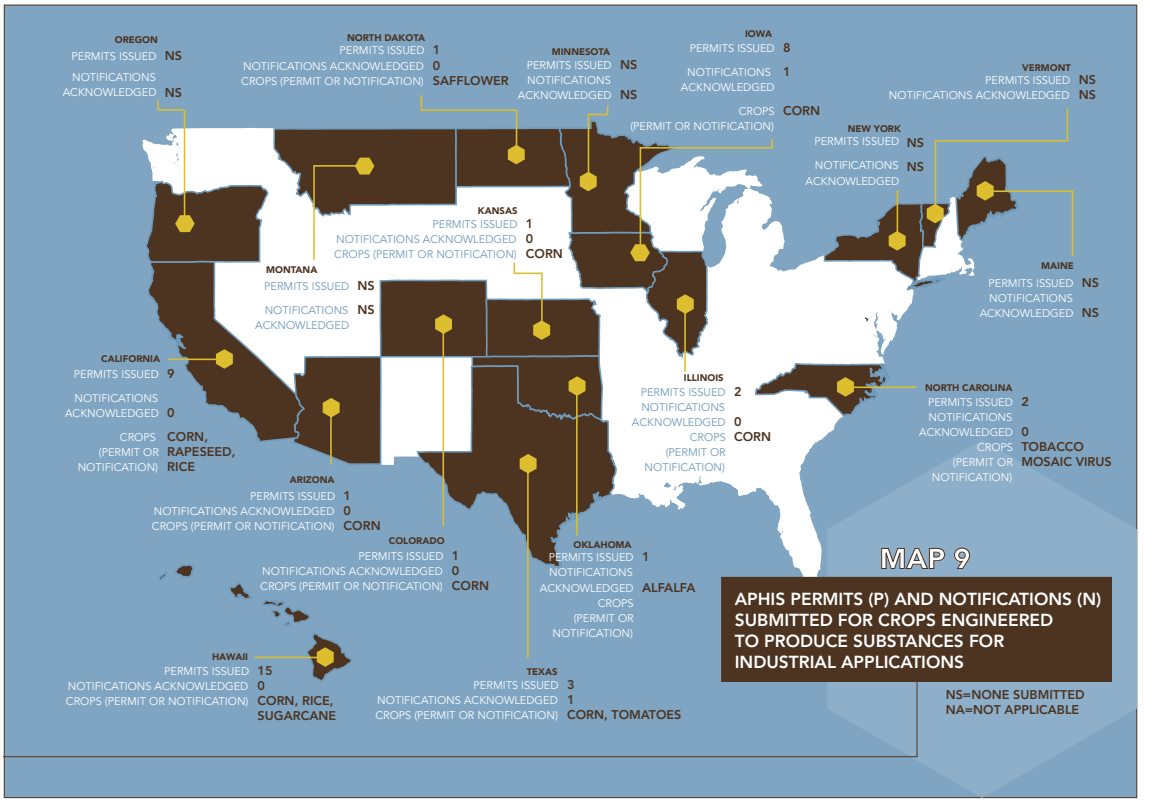

NORTH DAKOTA
Wheat, cattle and calves, soybeans, sugar beets, and sunflowers
MONTANA
Cattle and calves, wheat, hay, barley, and sugar beets
VERMONT
Dairy products, cattle and calves, greenhouse/nursery, maple products, and hay
NEW YORK
Dairy products, greenhouse/nursery, hay, apples, and cattle and calves
MINNESOTA
Corn, soybeans, hogs, dairy products, and cattle and calves
MAINE
Potatoes, dairy products, chicken eggs, aquaculture, and greenhouse/nursery
OREGON
Greenhouse/nursery, cattle and calves, dairy products, hay, and potatoes
KANSAS
Cattle and calves, wheat, corn, soybeans, and sorghum (grain)
IOWA
Corn, hogs, soybeans, cattle and calves, and dairy products
CALIFORNIA
Dairy products, greenhouse/nursery, grapes, lettuce, and cattle and calves
ILLINOIS
Corn, soybeans, hogs, cattle and calves, and greenhouse/nursery
NORTH CAROLINA
Hogs, broilers, greenhouse/nursery, tobacco, and turkeys
ARIZONA
Lettuce, cattle and calves, dairy products, cotton, and hay
COLORADO
Cattle and calves, corn, dairy products, greenhouse/nursery, and hay
OKLAHOMA
Cattle and calves, hogs, broilers, wheat, and dairy products
TEXAS
Cattle and calves, greenhouse/nursery, cotton, broilers, and dairy products
HAWAII
Pineapples, greenhouse/nursery, sugar cane, macadamia nuts, and dairy products
MAP 4
TOP FIVE AGRICULTURAL COMMODITIES IN STATE


MINNESOTA
corn, soybeans, oats, hay (all), alfalfa hay, and dry edible beans
MONTANA
wheat and barley
NORTH DAKOTA
wheat, barley, oats, and dry edible beans
VERMONT
none
NEW YORK
none
MAINE
none
OREGON
potatoes
KANSAS
wheat, sorghum (grain), and hay (all)
IOWA
corn, soybeans, oats, and alfalfa hay
CALIFORNIA
cotton, rice, hay (all), and alfalfa hay
ILLINOIS
corn and soybeans
NORTH CAROLINA
peanuts and tobacco
ARIZONA
none
COLORADO
barley and potatoes
OKLAHOMA
wheat
TEXAS
sorghum (grain), oats, cotton, peanuts, rice, and hay (all)
HAWAII
none
MAP 5
ONE OF TOP FIVE U.S. PRODUCERS OF VARIOUS MAJOR FIELD CROPS


OREGON
SUBMITTED 299
ACKNOWLEDGED 266
DENIED/WITHDRAWN/VOID 30
CURRENTLY IN EFFECT 29
NORTH DAKOTA
SUBMITTED 219
ACKNOWLEDGED 207
DENIED/WITHDRAWN/VOID 9
CURRENTLY IN EFFECT 20
MINNESOTA
SUBMITTED 553
ACKNOWLEDGED 524
DENIED/WITHDRAWN/VOID 25
CURRENTLY IN EFFECT 60
IOWA
SUBMITTED 1,162
ACKNOWLEDGED 1,094
DENIED/WITHDRAWN/VOID 51
CURRENTLY IN EFFECT 129
VERMONT
SUBMITTED 0
ACKNOWLEDGED NA
DENIED/WITHDRAWN/VOID NA
CURRENTLY IN EFFECT NA
NEW YORK
SUBMITTED 196
ACKNOWLEDGED 171
DENIED/WITHDRAWN/VOID 22
CURRENTLY IN EFFECT 27
KANSAS
SUBMITTED 273
ACKNOWLEDGED 260
DENIED/WITHDRAWN/VOID 8
CURRENTLY IN EFFECT 61
MONTANA
SUBMITTED 122
ACKNOWLEDGED 115
DENIED/WITHDRAWN/VOID 7
CURRENTLY IN EFFECT 16
MAINE
SUBMITTED 136
ACKNOWLEDGED 122
DENIED/WITHDRAWN/VOID 14
CURRENTLY IN EFFECT 0
CALIFORNIA
SUBMITTED 968
ACKNOWLEDGED 884
DENIED/WITHDRAWN/VOID 76
CURRENTLY IN EFFECT 102
NORTH CAROLINA
SUBMITTED 312
ACKNOWLEDGED 292
DENIED/WITHDRAWN/VOID 18
CURRENTLY IN EFFECT 24
ARIZONA
SUBMITTED 238
ACKNOWLEDGED 230
DENIED/WITHDRAWN/VOID 6
CURRENTLY IN EFFECT 38
ILLINOIS
SUBMITTED 1,491
ACKNOWLEDGED 1,410
DENIED/WITHDRAWN/VOID 64
CURRENTLY IN EFFECT 175
COLORADO
SUBMITTED 148
ACKNOWLEDGED 142
DENIED/WITHDRAWN/VOID 4
CURRENTLY IN EFFECT 13
OKLAHOMA
SUBMITTED 81
ACKNOWLEDGED 74
DENIED/WITHDRAWN/VOID 5
CURRENTLY IN EFFECT 21
HAWAII
SUBMITTED 1,606
ACKNOWLEDGED 1,513
DENIED/WITHDRAWN/VOID 84
CURRENTLY IN EFFECT 150
TEXAS
SUBMITTED 404
ACKNOWLEDGED 385
DENIED/WITHDRAWN/VOID 18
CURRENTLY IN EFFECT 52
MAP 6
APHIS NOTIFICATIONS SUBMITTED
NA=NOT APPLICABLE


OREGON
SUBMITTED 39
ISSUED 33
DENIED/WITHDRAWN/VOID 5
CURRENTLY IN EFFECT 0
NORTH DAKOTA
SUBMITTED 67
ISSUED 59
DENIED/WITHDRAWN/VOID 8
CURRENTLY IN EFFECT 3
MINNESOTA
SUBMITTED 74
ISSUED 66
DENIED/WITHDRAWN/VOID 8
CURRENTLY IN EFFECT 5
IOWA
SUBMITTED 46
ISSUED 41
DENIED/WITHDRAWN/VOID 5
CURRENTLY IN EFFECT 3
VERMONT
SUBMITTED 1
ISSUED 0
DENIED/WITHDRAWN/VOID 1
CURRENTLY IN EFFECT 0
NEW YORK
SUBMITTED 47
ISSUED 40
DENIED/WITHDRAWN/VOID 5
CURRENTLY IN EFFECT 2
KANSAS
SUBMITTED 25
ISSUED 22
DENIED/WITHDRAWN/VOID 3
CURRENTLY IN EFFECT 7
MONTANA
SUBMITTED 18
ISSUED 14
DENIED/WITHDRAWN/VOID 4
CURRENTLY IN EFFECT 0
MAINE
SUBMITTED 23
ISSUED 21
DENIED/WITHDRAWN/VOID 2
CURRENTLY IN EFFECT 0
CALIFORNIA
SUBMITTED 230
ISSUED 210
DENIED/WITHDRAWN/VOID 19
CURRENTLY IN EFFECT 8
NORTH CAROLINA
SUBMITTED 54
ISSUED 48
DENIED/WITHDRAWN/VOID 6
CURRENTLY IN EFFECT 2
ARIZONA
SUBMITTED 46
ISSUED 41
DENIED/WITHDRAWN/VOID 5
CURRENTLY IN EFFECT 3
ILLINOIS
SUBMITTED 148
ISSUED 124
DENIED/WITHDRAWN/VOID 24
CURRENTLY IN EFFECT 8
COLORADO
SUBMITTED 31
ISSUED 22
DENIED/WITHDRAWN/VOID 9
CURRENTLY IN EFFECT 3
OKLAHOMA
SUBMITTED 9
ISSUED 8
DENIED/WITHDRAWN/VOID 1
CURRENTLY IN EFFECT 0
HAWAII
SUBMITTED 102
ISSUED 88
DENIED/WITHDRAWN/VOID 13
CURRENTLY IN EFFECT 7
TEXAS
SUBMITTED 58
ISSUED 51
DENIED/WITHDRAWN/VOID 4
CURRENTLY IN EFFECT 4
MAP 7
APHIS PERMIT APPLICATIONS SUBMITTED


OREGON
PERMITS ISSUED NS
PERMITS PENDING NS
NORTH DAKOTA
PERMITS ISSUED 1
PERMITS PENDING 0
CROPS SAFFLOWER
MINNESOTA
PERMITS ISSUED NS
PERMITS PENDING NS
IOWA
PERMITS ISSUED 8
PERMITS PENDING 1
CROPS CORN
VERMONT
PERMITS ISSUED NS
PERMITS PENDING NS
NEW YORK
PERMITS ISSUED NS
PERMITS PENDING NS
KANSAS
PERMITS ISSUED 1
PERMITS PENDING 0
CROPS CORN
MONTANA
PERMITS ISSUED NS
PERMITS PENDING NS
MAINE
PERMITS ISSUED NS
PERMITS PENDING NS
CALIFORNIA
PERMITS ISSUED 9
PERMITS PENDING 0
CROPS CORN, RAPESEED, RICE
NORTH CAROLINA
PERMITS ISSUED 2
PERMITS PENDING 0
CROPS TOBACCO MOSAIC VIRUS
ARIZONA
PERMITS ISSUED 1
PERMITS PENDING 0
CROPS CORN
ILLINOIS
PERMITS ISSUED 2
PERMITS PENDING 0
CROPS CORN
COLORADO
PERMITS ISSUED 1
PERMITS PENDING 0
CROPS CORN
OKLAHOMA
PERMITS ISSUED 1
PERMITS PENDING
CROPS ALFALFA
HAWAII
PERMITS ISSUED 15
PERMITS PENDING 0
CROPS CORN, RICE, SUGARCANE
TEXAS
PERMITS ISSUED 3
PERMITS PENDING 1
CROPS CORN, TOMATOES
MAP 8
APHIS PERMIT SUBMITTED FOR CROPS ENGINEERED TO PRODUCE PHARMACEUTICAL SUBSTANCES
NS=NONE SUBMITTED


OREGON
PERMITS ISSUED NS
NOTIFICATIONS ACKNOWLEDGED NS
NORTH DAKOTA
PERMITS ISSUED 1
NOTIFICATIONS ACKNOWLEDGED 0
CROPS (PERMIT OR NOTIFICATION) SAFFLOWER
MINNESOTA
PERMITS ISSUED NS
NOTIFICATIONS ACKNOWLEDGED NS
IOWA
PERMITS ISSUED 8
NOTIFICATIONS ACKNOWLEDGED 1
CROPS (PERMIT OR NOTIFICATION) CORN
VERMONT
PERMITS ISSUED NS
NOTIFICATIONS ACKNOWLEDGED NS
NEW YORK
PERMITS ISSUED NS
NOTIFICATIONS ACKNOWLEDGED NS
KANSAS
PERMITS ISSUED 1
NOTIFICATIONS ACKNOWLEDGED 0
CROPS (PERMIT OR NOTIFICATION) CORN
MONTANA
PERMITS ISSUED NS
NOTIFICATIONS ACKNOWLEDGED NS
MAINE
PERMITS ISSUED NS
NOTIFICATIONS ACKNOWLEDGED NS
CALIFORNIA
PERMITS ISSUED 9
NOTIFICATIONS ACKNOWLEDGED 0
CROPS (PERMIT OR NOTIFICATION) CORN, RAPESEED, RICE
NORTH CAROLINA
PERMITS ISSUED 2
NOTIFICATIONS ACKNOWLEDGED 0
CROPS (PERMIT OR NOTIFICATION) TOBACCO MOSAIC VIRUS
ARIZONA
PERMITS ISSUED 1
NOTIFICATIONS ACKNOWLEDGED 0
CROPS (PERMIT OR NOTIFICATION) CORN
ILLINOIS
PERMITS ISSUED 2
NOTIFICATIONS ACKNOWLEDGED 0
CROPS (PERMIT OR NOTIFICATION) CORN
COLORADO
PERMITS ISSUED 1
NOTIFICATIONS ACKNOWLEDGED 0
CROPS (PERMIT OR NOTIFICATION) CORN
OKLAHOMA
PERMITS ISSUED 1
NOTIFICATIONS ACKNOWLEDGED
CROPS (PERMIT OR NOTIFICATION) ALFALFA
HAWAII
PERMITS ISSUED 15
NOTIFICATIONS ACKNOWLEDGED 0
CROPS (PERMIT OR NOTIFICATION) CORN, RICE, SUGARCANE
TEXAS
PERMITS ISSUED 3
NOTIFICATIONS ACKNOWLEDGED 1
CROPS (PERMIT OR NOTIFICATION) CORN, TOMATOES
MAP 9
APHIS PERMITS (P) AND NOTIFICATIONS (N) SUBMITTED FOR CROPS ENGINEERED TO PRODUCE SUBSTANCES FOR INDUSTRIAL APPLICATIONS
NS=NONE SUBMITTED
NA=NOT APPLICABLE

APPENDIX B

STATE BIOTECHNOLOGY OVERSIGHT SURVEY QUESTIONNAIRE

Oversight of Biotech Crops and Foods: The Role of the States

Purpose and General Instructions

This survey is part of a research project on the role of state governments in regulatory oversight of biotech crops and foods being conducted by researchers at Resources for the Future (RFF). The goal of the project is to inform future policymaking in this area by providing policymakers and stakeholders with background information and analysis on the current and potential future oversight roles of the states. RFF is pursuing this project under a contract with the Pew Initiative on Food and Biotechnology. The principal investigator is RFF Senior Fellow Mike Taylor.

The purpose of this survey is to collect a broad cross section of expert and stakeholder perspectives on the state oversight of biotech crops and foods. The information obtained through the survey will inform RFF's description and analysis of issues and will be included in RFF's report, along with a list of the survey respondents. Survey responses will be reported in aggregate form, and no response will be attributed to any individual without that individual's express approval. Question 2 of the survey will ask you about the level at which you wish to share your responses.

When you have completed this survey, please mail it to: Jody Tick, Resources for the Future, 1616 P Street, NW, Washington, DC 20036. You may also contact Jody at tick@rff.org or 202-328-5152 if you have any questions about this survey.

We ask that you please complete and return this survey no later than January 23, 2004.

Respondent Profile

1. In order to accurately track responses, we ask that you identify yourself through your e-mail address. This information will NOT be used to quote your responses unless you expressly approve doing so in Question 2.

E-mail address: _____

2. Please indicate the level at which you would like us to share your responses by indicating which of the following statements you agree with.

___ "You have my permission to quote my responses and attribute them to me."
___ "You have my permission to quote my responses without attributing them to me by name."
___ "You do not have my permission to quote my responses; instead you may use them only as part of the overall results and data analysis."

3. Please indicate the state or states whose biotechnology regulatory activities are familiar to you.

   All states – national (check): ___
   OR
   Individual states (list): _____

4. Please check the one or more categories below that best describe your professional interest or involvement with biotech crops and foods and their regulation.

___ Academic or research interest in biotechnology
___ Agricultural producer or producer group representative
___ Biotechnology company employee or representative of biotech industry
___ Commodity trader or commodity group representative
___ Consumer group employee
___ Environmental group employee
___ Federal government employee with responsibilities related to regulatory oversight of biotech crops and/or foods
___ Federal government employee without responsibilities related to regulatory oversight of biotech crops and/or foods
___ Federal legislative staff
___ Federal legislator
___ Food company employee or food industry representative
___ Journalist
___ Seed company employee or seed industry representative
___ State government employee with responsibilities related to regulatory oversight of biotech crops and/or foods
___ State government employee without responsibilities related to regulatory oversight of biotech crops and/or foods
___ State legislative staff
___ State legislator
___ Other, please specify: _____

Perspectives on Biotechnology

5. Impact on Farmers

What is your personal expectation concerning the overall future impact of biotech crops and foods on the interests of farmers in the United States?

___ Very positive
___ Somewhat positive
___ Somewhat negative
___ Very negative
___ Do not know or no opinion

6. Impact on the Food Industry

What is your personal expectation concerning the overall future impact of biotech crops and foods on the interests of the food industry in the United States?

___ Very positive
___ Somewhat positive
___ Somewhat negative
___ Very negative
___ Do not know or no opinion

7. Impact on Consumers

What is your personal expectation concerning the overall future impact of biotech crops and foods on the interests of consumers in the United States?

___ Very positive
___ Somewhat positive
___ Somewhat negative
___ Very negative
___ Do not know or no opinion

8. Safety

What is your personal assessment of the safety of biotech crops and foods for human health and the environment?

___ Completely safe
___ Mostly safe
___ Somewhat safe
___ Somewhat unsafe
___ Mostly unsafe
___ Completely unsafe
___ Safety is too variable to generalize
___ Do not know or no opinion

Perspectives on Regulatory Oversight

9. NEED FOR OVERSIGHT

Compared to other techniques for producing improved seed varieties and food crops, does agricultural biotechnology warrant more or less stringent regulatory oversight to protect health, the environment, and the overall interests of the food system?

___ Much more stringent
___ Somewhat more stringent
___ Same stringency
___ Somewhat less stringent
___ Much less stringent
___ No oversight required
___ Do not know or no opinion

10. IMPORTANCE OF POTENTIAL TOPICS FOR OVERSIGHT IN GENERAL

For each of the following topics related to biotech crops and foods, please indicate the importance you attach to regulatory oversight, whether by the federal or state governments.

	High importance	Medium-High importance	Medium importance	Medium-Low importance	Low importance	Not important
Environmental impacts in general						
Insect resistance						
Plant health						
Food safety						
Animal feed safety						
Unintended presence in the food supply of crops producing pharmaceuticals or industrial chemicals						
Unintended presence in the food supply of biotech food crops, such as herbicide-resistant wheat or an updated Bt variety						
Public confidence in the food supply						
Integrity of the grain and food supply for export and other commercial purposes						
Labeling of biotech foods						
Other, please specify:						
Other, please specify:						
Other, please specify:						

11. Importance of Potential Topics for Federal Oversight

For each of the following topics related to biotech crops and foods, please indicate the importance you attach to regulatory oversight specifically by the federal government.

	High importance	Medium-High importance	Medium importance	Medium-Low importance	Low importance	Not important
Environmental impacts in general						
Insect resistance						
Plant health						
Food safety						
Animal feed safety						
Unintended presence in the food supply of crops producing pharmaceuticals or industrial chemicals						
Unintended presence in the food supply of biotech food crops, such as herbicide-resistant wheat or an updated Bt variety						
Public confidence in the food supply						
Integrity of the grain and food supply for export and other commercial purposes						
Labeling of biotech foods						
Other, please specify:						
Other, please specify:						
Other, please specify:						

12. Importance of State Oversight in General

In light of the federal role in regulatory oversight of biotech crops and foods, what importance do you attach to state oversight in general?

___ High importance
___ Medium-High importance
___ Medium importance
___ Medium-Low importance
___ Low importance
___ Not important

13. IMPORTANCE OF POTENTIAL TOPICS FOR STATE OVERSIGHT

For each of the following topics related to biotech crops and foods, please indicate the importance you attach to regulatory oversight specifically by state governments, either in lieu of or to complement federal regulation.

	High importance	Medium-High importance	Medium importance	Medium-Low importance	Low importance	Not important
Environmental impacts in general						
Insect resistance						
Plant health						
Food safety						
Animal feed safety						
Unintended presence in the food supply of crops producing pharmaceuticals or industrial chemicals						
Unintended presence in the food supply of biotech food crops, such as herbicide-resistant wheat or an updated Bt variety						
Public confidence in the food supply						
Integrity of the grain and food supply for export and other commercial purposes						
Labeling of biotech foods						
Other, please specify:						
Other, please specify:						
Other, please specify:						

14. IMPORTANCE OF STATE INVOLVEMENT IN VARIOUS TYPES OF STATE REGULATORY ACTIVITIES

Please indicate the importance you attach to state governments being involved in the following types of possible regulatory activities concerning biotech crops and foods.

	High importance	Medium-High importance	Medium importance	Medium-Low importance	Low importance	Not important
Review and approval of field trials						
Ensuring compliance with field trial conditions through inspection and other means						
Review and approval for commercial production						
Enforcement of use restrictions on commercially marketed products						
Monitoring for unanticipated health or environmental consequences of commercially marketed products						
Other, please specify:						
Other, please specify:						
Other, please specify:						

15. Overall Preparedness of State Governments

How would you describe the overall preparedness of the states with which you are familiar to provide needed oversight of biotech crops and foods?

___ Well prepared
___ Somewhat prepared
___ Somewhat unprepared
___ Poorly prepared
___ Do not know or no opinion

If there are topics on which you consider these states to be particularly well prepared, please specify: _____
_____
_____

If there are topics on which you consider these states to be particularly poorly prepared, please specify: _____
_____
_____
_____

16. Adequacy of State Statutory Authority and Regulations

How would you describe the adequacy of current statutory authority and regulations in the states with which you are familiar to provide needed oversight of biotech crops and foods?

___ Fully adequate
___ Somewhat adequate
___ Somewhat inadequate
___ Very inadequate
___ Do not know or no opinion

Do you have specific ideas for improving these states' statutes or regulations? If so, please specify: _____
_____
_____
_____

17. Adequacy of State Resources

How would you describe the adequacy of the financial resources devoted to needed oversight of biotech crops and foods by the states with which you are familiar?

___ Fully adequate
___ Somewhat adequate
___ Somewhat inadequate
___ Very inadequate
___ Do not know or no opinion

Do you have specific ideas for increasing, decreasing, or reallocating these states' resources? If so, please specify: _____
_____
_____
_____

18. Adequacy of State Technical Expertise

How would you describe the adequacy of the technical expertise available in the states with which you are familiar to provide needed oversight of biotech crops and foods?

___ Fully adequate
___ Somewhat adequate
___ Somewhat inadequate
___ Very inadequate
___ Do not know or no opinion

Do you have specific ideas for improving the technical expertise in these states? If so, please specify: _____
_____
_____
_____

19. Adequacy of State Institutional Arrangements

How would you describe the adequacy of the way in which the relevant institutions (e.g., agriculture, environmental, and health departments) in the states with which you are familiar are organized and coordinate their efforts to provide needed oversight of biotech crops and foods?

___ Fully adequate
___ Somewhat adequate
___ Somewhat inadequate
___ Very inadequate
___ Do not know or no opinion

Do you have specific ideas for improving these states' institutional arrangements? If so, please specify:_____
_____
_____
_____
_____

20. Adequacy of State-Federal Collaboration

How would you describe the adequacy of the collaboration between the states with which you are familiar and the federal government in providing needed oversight of biotech crops and foods?

___ Fully adequate
___ Somewhat adequate
___ Somewhat inadequate
___ Very inadequate
___ Do not know or no opinion

Do you have specific ideas for improving state-federal collaboration? If so, please specify: _____
_____
_____
_____

21. Prioritizing Improvements in State Oversight

Please identify and rank in order of importance the areas in which you believe state oversight of biotech crops and foods should be improved. Place a 1 next to the most important topic for regulation, and number the others from there. Omit from your ranking areas that you marked above, in Questions 16-20, as fully adequate.

___ Statutory authority and regulations
___ Budgets
___ Technical expertise
___ Institutional arrangements
___ State-federal collaboration
___ Other, please specify: _____
___ Other, please specify: _____
___ Other, please specify: _____

22. Prioritizing Biotech Regulatory Oversight in Relation to Other State Activities

Compared to other activities for which state agriculture, environmental, and health departments are responsible, what priority would you assign regulatory oversight of biotech crops and foods?

___ High (among the top third in priority)
___ Medium (among middle third in priority)
___ Low (among bottom third in priority)
___ None (no state effort should be devoted to oversight of biotech crops and foods)

If you would you like to comment further on this question, please do so here:

_____
_____
_____
_____

23. If you would like to provide any further information or comments on state oversight of biotech crops and foods, please do so here:

_____
_____
_____
_____

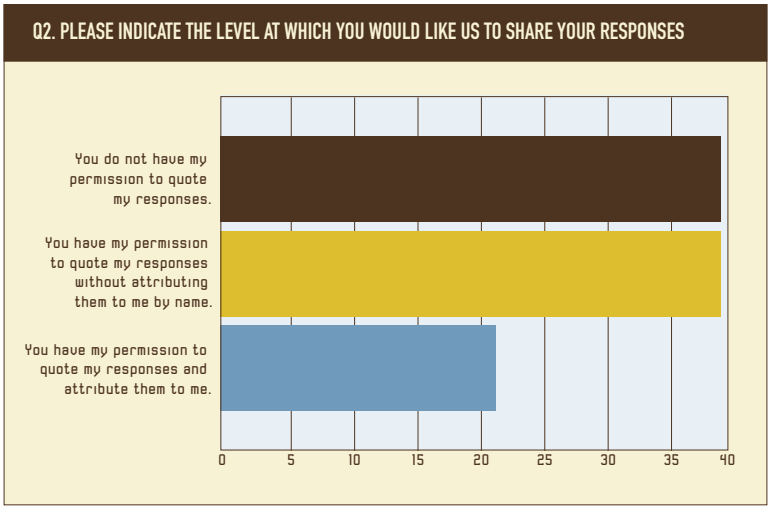
24. If you would like us to provide you with a copy of our report when it becomes available, please supply your name and contact information.

_____
_____
_____
_____

APPENDIX B (CONTINUED)

STATE BIOTECHNOLOGY OVERSIGHT SURVEY RESULTS AND ANALYSIS

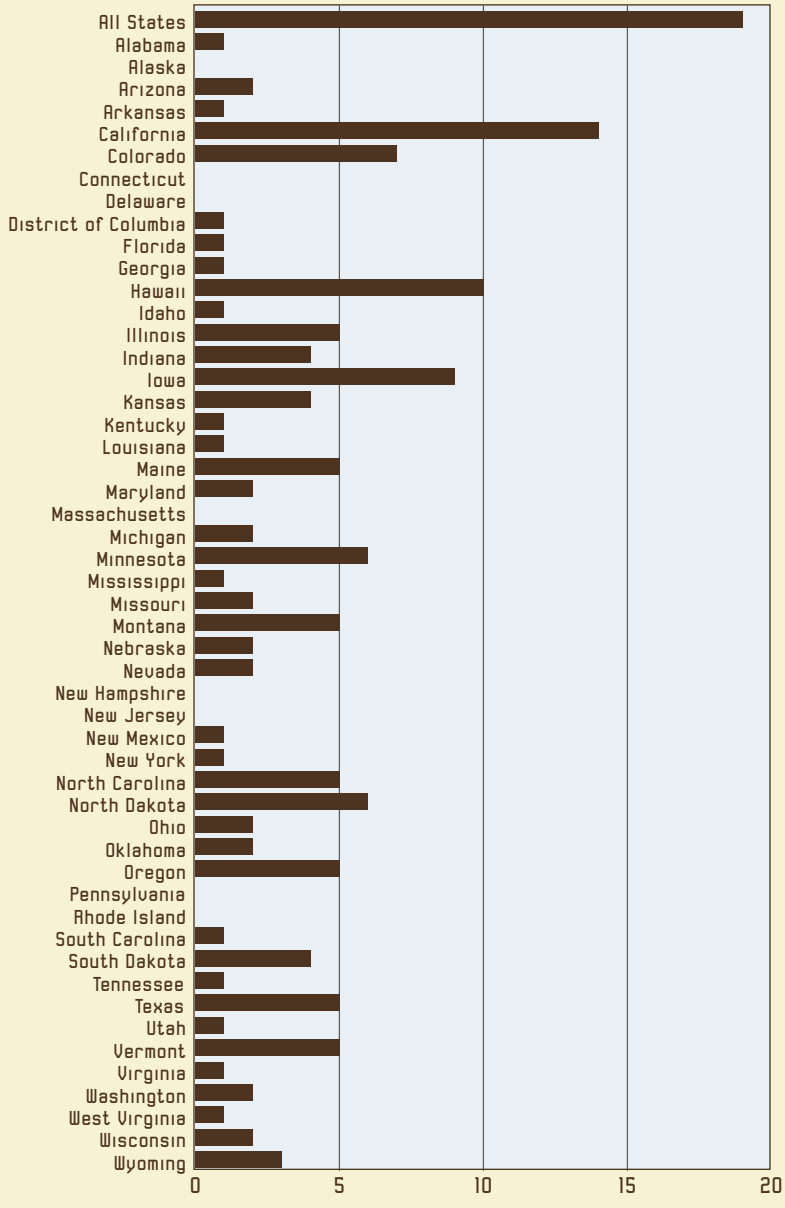
- Analyzing 78 responses.



Q.2 Please indicate the level at which you would like us to share your responses by indicating which of the following statements you agree with.

CHOICE	COUNT	PERCENTAGE ANSWERED
You have my permission to quote my responses and attribute them to me.	16	21.1%
You have my permission to quote my responses without attributing them to me by name.	30	39.5%
You do not have my permission to quote my responses; instead, you may use them only as part of the overall results and data analysis.	30	39.5%

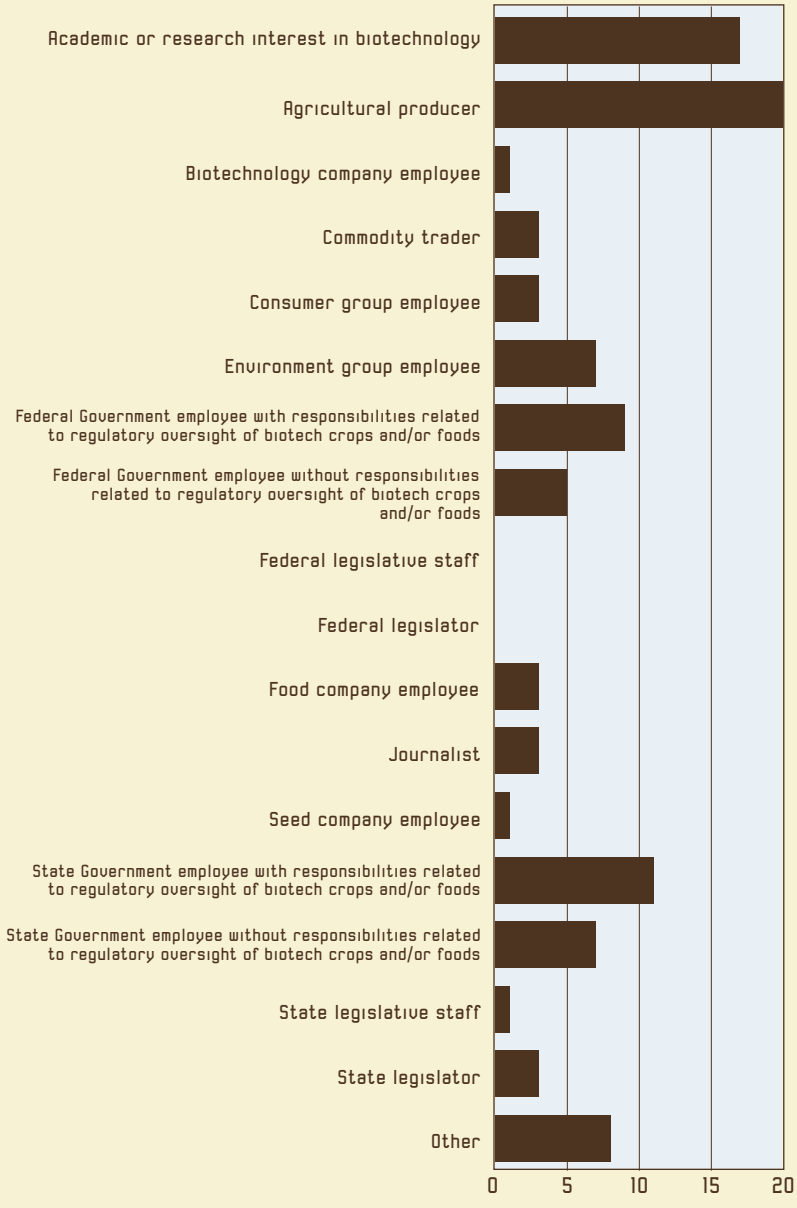
Q3. PLEASE INDICATE THE STATE OR STATES WHOSE BIOTECHNOLOGY REGULATORY ACTIVITIES ARE FAMILIAR TO YOU.



Q.3 Please indicate the state or states whose biotechnology regulatory activities are familiar to you.

CHOICE	COUNT	PERCENT OF SAMPLE
All states - national	19	24.4%
Alabama	1	1.3%
Alaska	0	0.0%
Arizona	2	2.6%
Arkansas	1	1.3%
California	14	17.9%
Colorado	7	9.0%
Connecticut	0	0.0%
Delaware	0	0.0%
District of Columbia	1	1.3%
Florida	1	1.3%
Georgia	1	1.3%
Hawaii	10	12.8%
Idaho	1	1.3%
Illinois	5	6.4%
Indiana	4	5.1%
Iowa	9	11.5%
Kansas	4	5.1%
Kentucky	1	1.3%
Louisiana	1	1.3%
Maine	5	6.4%
Maryland	2	2.6%
Massachusetts	0	0.0%
Michigan	2	2.6%
Minnesota	6	7.7%
Mississippi	1	1.3%
Missouri	2	2.6%
Montana	5	6.4%
Nebraska	2	2.6%
Nevada	2	2.6%
New Hampshire	0	0.0%
New Jersey	0	0.0%
New Mexico	1	1.3%
New York	1	1.3%
North Carolina	5	6.4%
North Dakota	6	7.7%
Ohio	2	2.6%
Oklahoma	2	2.6%
Oregon	5	6.4%
Pennsylvania	0	0.0%
Rhode Island	0	0.0%
South Carolina	1	1.3%
South Dakota	4	5.1%
Tennessee	1	1.3%
Texas	5	6.4%
Utah	1	1.3%
Vermont	5	6.4%
Virginia	1	1.3%
Washington	2	2.6%
West Virginia	1	1.3%
Wisconsin	2	2.6%
Wyoming	3	3.8%

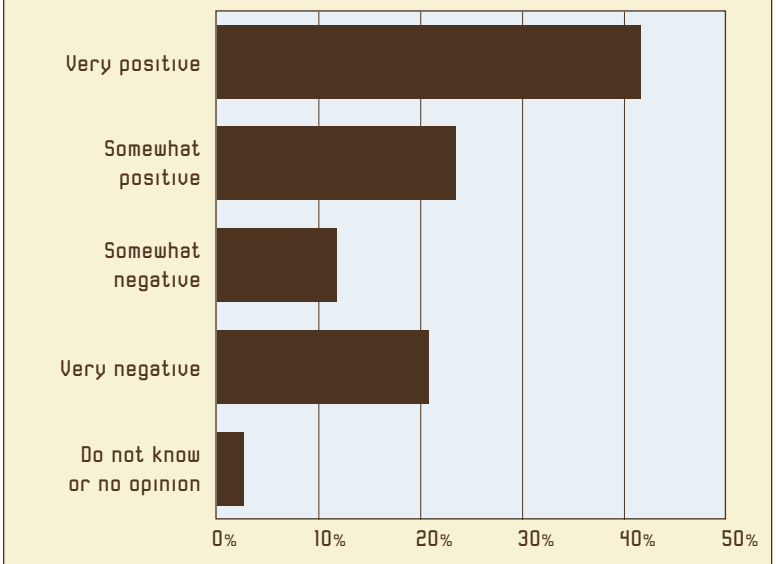
Q4. PLEASE CHECK THE ONE OR MORE CATEGORIES THAT BEST DESCRIBE YOUR PROFESSIONAL INTEREST WITH BIOTECH CROPS, FOODS, AND REGULATIONS



Q.4 Please check the one or more categories below that best describe your professional interest or involvement with biotech crops and foods and their regulation.

CHOICE	COUNT	PERCENT OF SAMPLE
Academic or research interest in biotechnology	17	21.8%
Agricultural producer or producer group representative	20	25.6%
Biotechnology company employee or representative of biotech industry	1	1.3%
Commodity trader or commodity group representative	3	3.8%
Consumer group employee	3	3.8%
Environmental group employee	7	9.0%
Federal government employee with responsibilities related to regulatory oversight of biotech crops and/or foods	9	11.5%
Federal government employee without responsibilities related to regulatory oversight of biotech crops and/or foods	5	6.4%
Federal legislative staff	0	0.0%
Federal legislator	0	0.0%
Food company employee or food industry representative	3	3.8%
Journalist	3	3.8%
Seed company employee or seed industry representative	1	1.3%
State government employee with responsibilities related to regulatory oversight of biotech crops and/or foods	11	14.1%
State government employee without responsibilities related to regulatory oversight of biotech crops and/or foods	7	9.0%
State legislative staff	1	1.3%
State legislator	3	3.8%
Other, please specify:	8	10.3%

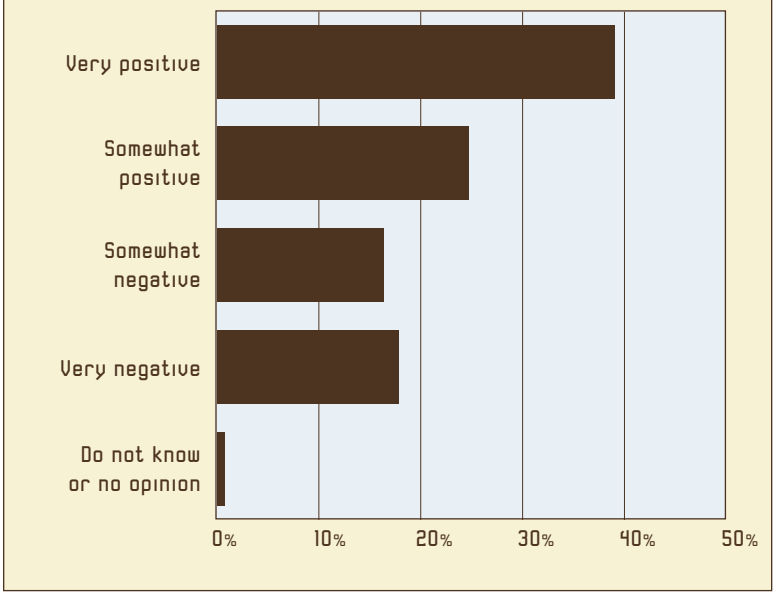
Q5. IMPACT ON FARMERS



Q.5 Impact on Farmers: What is your personal expectation concerning the overall future impact of biotech crops and foods on the interests of farmers in the United States?

CHOICE	COUNT	PERCENTAGE ANSWERED
Very positive	32	41.6%
Somewhat positive	18	23.4%
Somewhat negative	9	11.7%
Very negative	16	20.8%
Do not know or no opinion	2	2.6%

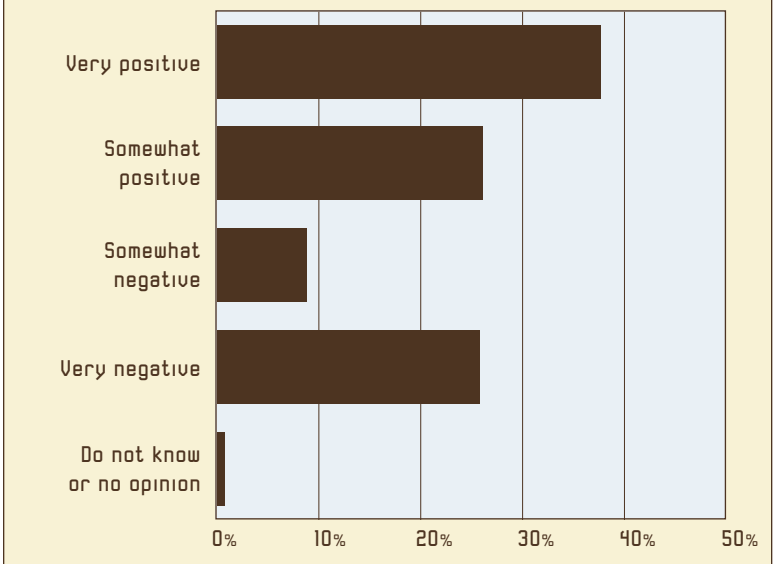
Q6. IMPACT ON THE FOOD INDUSTRY



Q.6 Impact on the Food Industry: What is your personal expectation concerning the overall future impact of biotech crops and foods on the interests of the food industry in the United States?

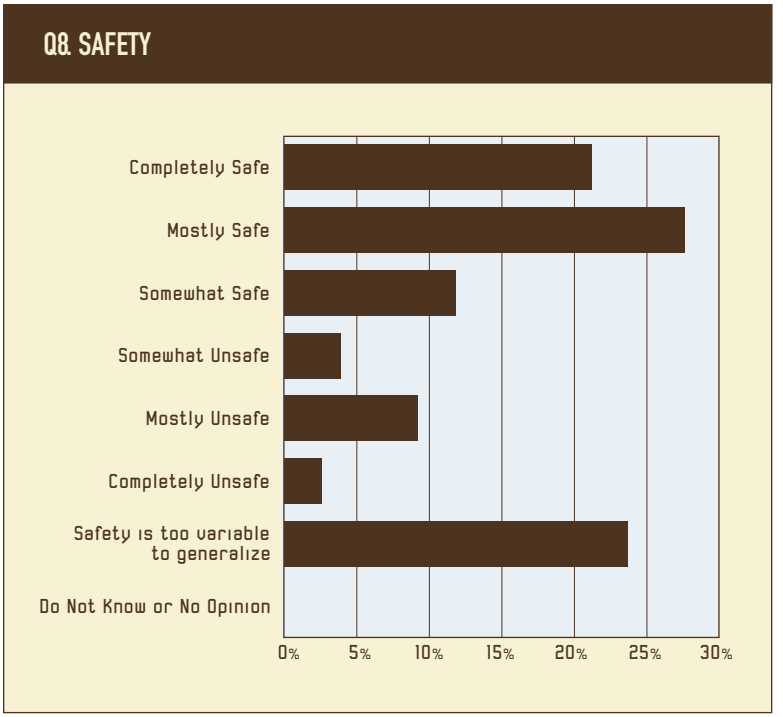
CHOICE	COUNT	PERCENTAGE ANSWERED
Very positive	30	39.0%
Somewhat positive	19	24.7%
Somewhat negative	13	16.9%
Very negative	14	18.2%
Do not know or no opinion	1	1.3%

Q7. IMPACT ON CONSUMERS



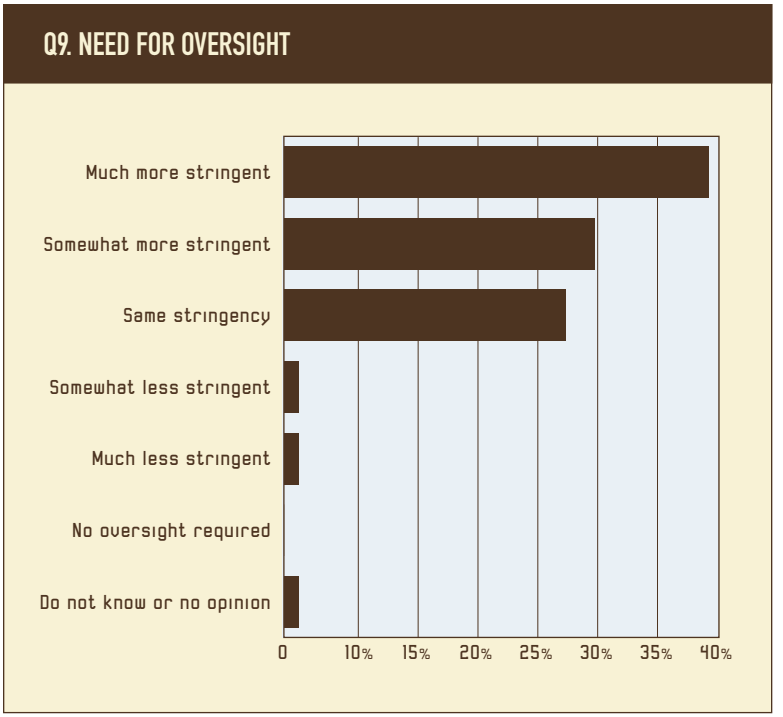
Q.7 Impact on Consumers: What is your personal expectation concerning the overall future impact of biotech crops and foods on the interests of consumers in the United States?

CHOICE	COUNT	PERCENTAGE ANSWERED
Very positive	29	37.7%
Somewhat positive	20	26.0%
Somewhat negative	7	9.1%
Very negative	20	26.0%
Do not know or no opinion	1	1.3%



Q.8 Safety: What is your personal assessment of the safety of biotech crops and foods for human health and the environment?

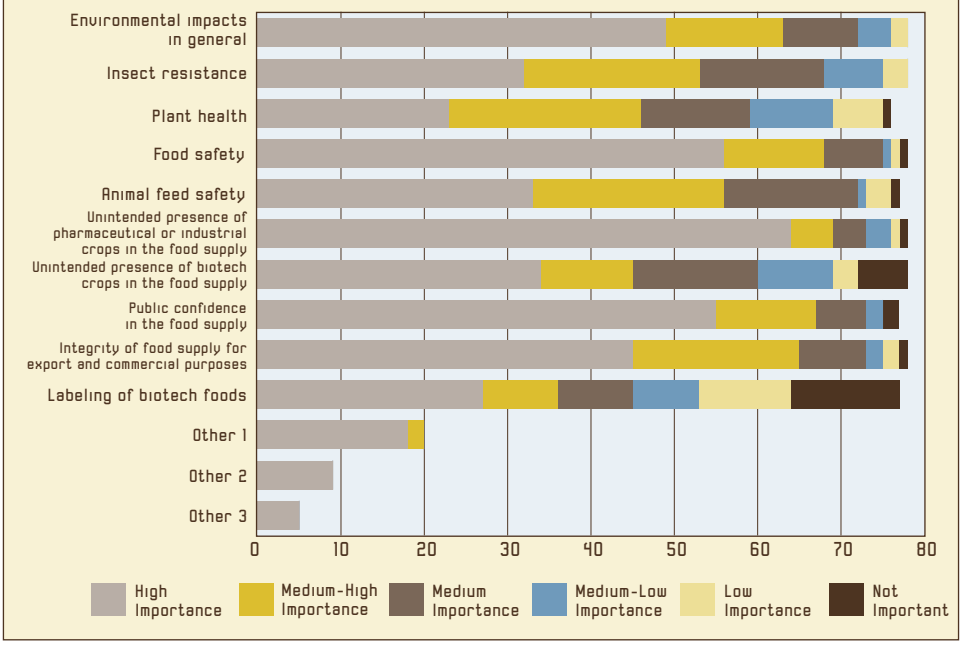
CHOICE	COUNT	PERCENTAGE ANSWERED
Completely safe	16	21.1%
Mostly safe	21	27.6%
Somewhat safe	9	11.8%
Somewhat unsafe	3	3.9%
Mostly unsafe	7	9.2%
Completely unsafe	2	2.6%
Safety is too variable to generalize	18	23.7%
Do not know or no opinion	0	0.0%



Q.9 Need for Oversight: Compared to other techniques for producing improved seed varieties and food crops, does agricultural biotechnology warrant more or less stringent regulatory oversight to protect health, the environment, and the overall interests of the food system?

CHOICE	COUNT	PERCENTAGE ANSWERED
Much more stringent	30	39.0%
Somewhat more stringent	23	29.9%
Same stringency	21	27.3%
Somewhat less stringent	1	1.3%
Much less stringent	1	1.3%
No oversight required	0	0.0%
Do not know or no opinion	1	1.3%

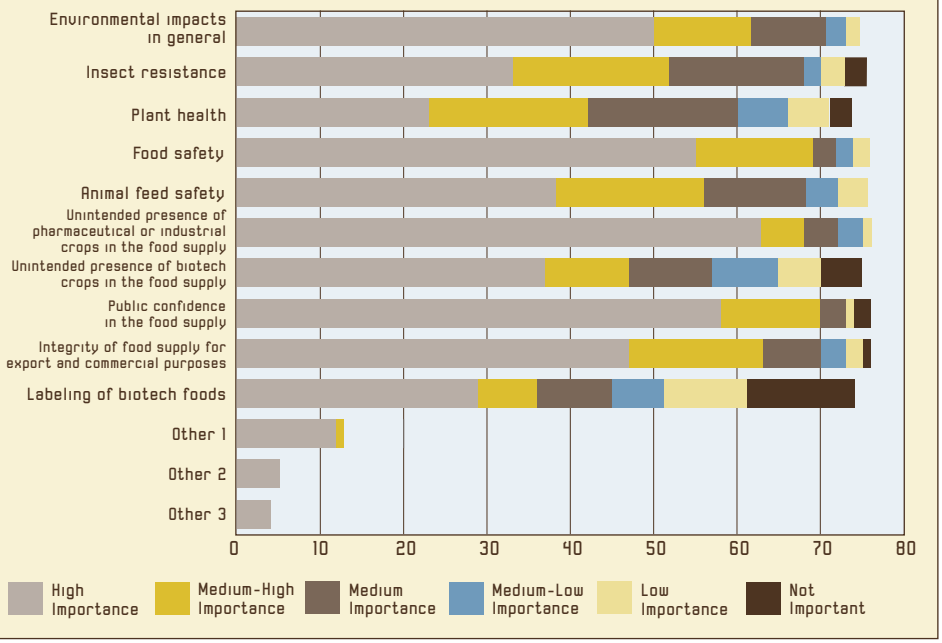
Q10. IMPORTANCE OF POTENTIAL TOPICS FOR OVERSIGHT IN GENERAL



Q.10 Importance of Potential Topics for Oversight in General: For each of the following topics related to biotech crops and foods, please indicate the importance you attach to regulatory oversight, whether by the federal or state governments.

Topic	High importance	Medium-High importance	Medium importance	Medium-Low importance	Low importance	Not important
Environmental impacts in general	49	14	9	4	2	0
Insect resistance	32	21	15	7	3	0
Plant health	23	23	13	10	6	1
Food safety	56	12	7	1	1	1
Animal feed safety	33	23	16	1	3	1
Unintended presence in the food supply of crops producing pharmaceutical or industrial chemicals	64	5	4	3	1	1
Unintended presence in the food supply of biotech food crops, such as herbicide-resistant wheat or an updated Bt variety	34	11	15	9	3	6
Public confidence in the food supply	55	12	6	2	0	2
Integrity of the grain and food supply for export and other commercial purposes	45	20	8	2	2	1
Labeling of biotech foods	27	9	9	8	11	13
Other 1	18	2	0	0	0	0
Other 2	9	0	0	0	0	0
Other 3	5	0	0	0	0	0

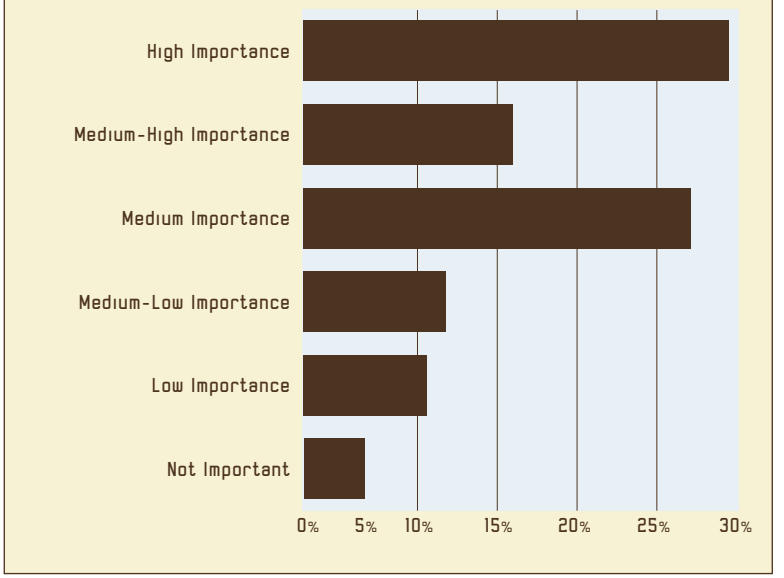
Q11. IMPORTANCE OF POTENTIAL TOPICS FOR FEDERAL OVERSIGHT



Q.11 Importance of Potential Topics for Federal Oversight: For each of the following topics related to biotech crops and foods, please indicate the importance you attach to regulatory oversight specifically by the federal government.

Topic	High importance	Medium-High importance	Medium importance	Medium-Low importance	Low importance	Not important
Environmental impacts in general	50	12	9	3	2	0
Insect resistance	33	19	16	2	3	3
Plant health	23	19	18	6	5	3
Food safety	55	14	3	2	2	0
Animal feed safety	38	18	12	4	4	0
Unintended presence in the food supply of crops producing pharmaceutical or industrial chemicals	63	5	4	3	1	0
Unintended presence in the food supply of biotech food crops, such as herbicide-resistant wheat or an updated Bt variety	37	10	10	8	5	5
Public confidence in the food supply	58	12	3	0	1	2
Integrity of the grain and food supply for export and other commercial purposes	47	16	7	3	2	1
Labeling of biotech foods	29	7	8	6	10	13
Other 1	12	1	0	0	0	0
Other 2	5	0	0	0	0	0
Other 3	4	0	0	0	0	0

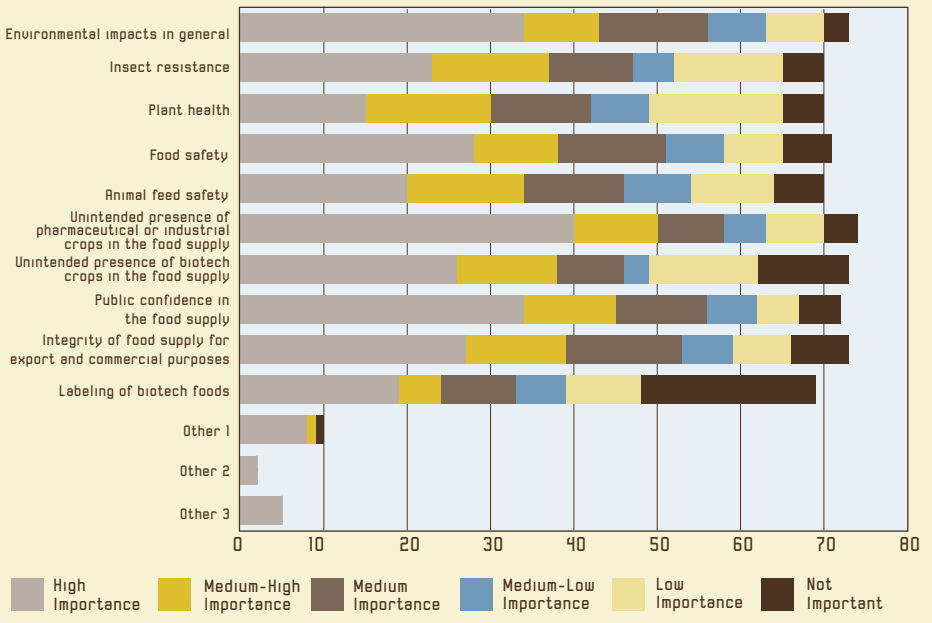
Q12. IMPORTANCE OF STATE OVERSIGHT IN GENERAL



Q.12 Importance of State Oversight in General: In light of the federal role in regulatory oversight of biotech crops and foods, what importance do you attach to state oversight in general?

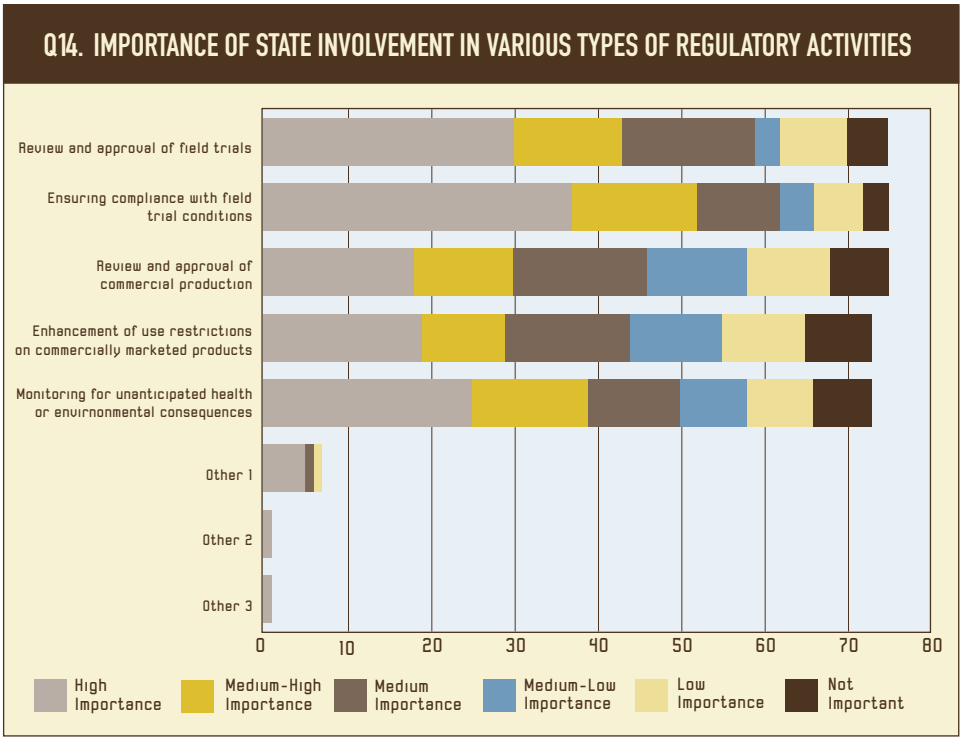
CHOICE	COUNT	PERCENTAGE ANSWERED
High importance	22	29.3%
Medium-High importance	12	16.0%
Medium importance	20	26.7%
Medium-Low importance	9	12.0%
Low importance	8	10.7%
Not important	4	5.3%

Q13. IMPORTANCE OF POTENTIAL TOPICS FOR STATE OVERSIGHT



Q.13 Importance of Potential Topics for State Oversight: For each of the following topics related to biotech crops and foods, please indicate the importance you attach to regulatory oversight specifically by state governments, either in lieu of or to complement federal regulation.

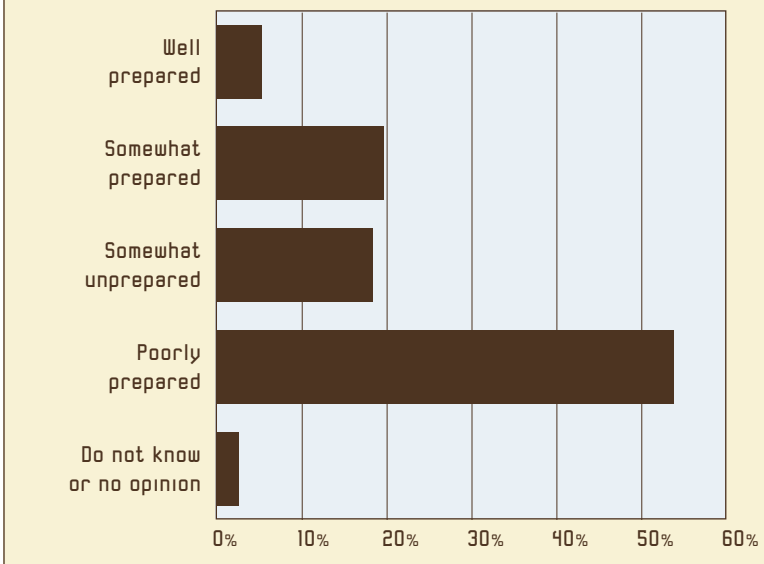
Topic	High importance	Medium-High importance	Medium importance	Medium-Low importance	Low importance	Not important
Environmental impacts in general	34	9	13	7	7	3
Insect resistance	23	14	10	5	13	5
Plant health	15	15	12	7	16	5
Food safety	28	10	13	7	7	6
Animal feed safety	20	14	12	8	10	6
Unintended presence in the food supply of crops producing pharmaceutical or industrial chemicals	40	10	8	5	7	4
Unintended presence in the food supply of biotech food crops, such as herbicide-resistant wheat or an updated Bt variety	26	12	8	3	13	11
Public confidence in the food supply	34	11	11	6	5	5
Integrity of the grain and food supply for export and other commercial purposes	27	12	14	6	7	7
Labeling of biotech foods	19	5	9	6	9	21
Other 1	8	1	0	0	0	1
Other 2	4	0	0	0	0	0
Other 3	2	0	0	0	0	0



Q.14 Importance of State Involvement in Various Types of Regulatory Activities: Please indicate the importance you attach to state governments being involved in the following types of possible regulatory activities concerning biotech crops and foods.

Topic	High importance	Medium-High importance	Medium importance	Medium-Low importance	Low importance	Not important
Review and approval of field trials	30	13	16	3	8	5
Ensuring compliance with field trial conditions through inspection and other means	37	15	10	4	6	3
Review and approval for commercial production	18	12	16	12	10	7
Enhancement of use restrictions on commercially marketed products	19	10	15	11	10	8
Monitoring for unanticipated health or environmental consequences of commercially marketed products	25	14	11	8	8	7
Other 1 (specify below)	5	0	1	0	1	0
Other 2 (specify below)	1	0	0	0	0	0
Other 3 (specify below)	1	0	0	0	0	0

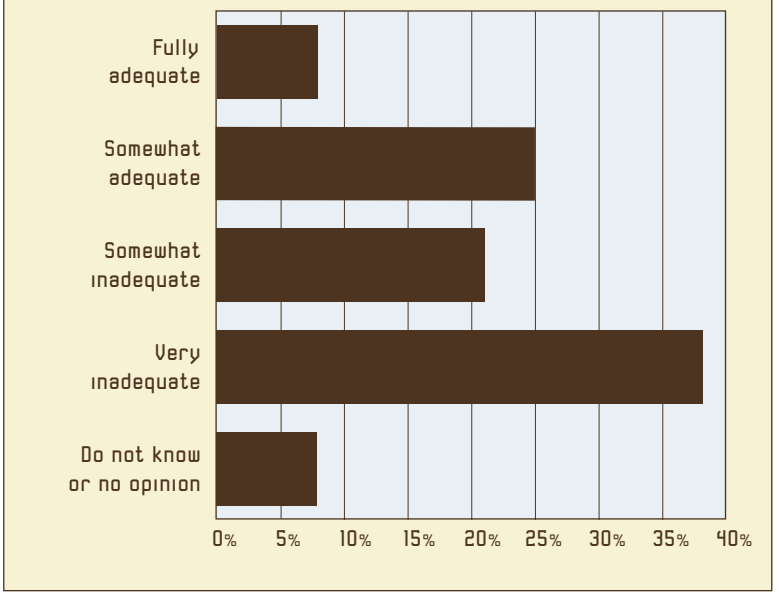
Q15. OVERALL PREPAREDNESS OF STATE GOVERNMENTS



Q.15 Overall Preparedness of State Governments: How would you describe the overall preparedness of the states with which you are familiar to provide needed oversight of biotech crops and foods?

CHOICE	COUNT	PERCENTAGE ANSWERED
Well prepared	4	5.3%
Somewhat prepared	15	19.7%
Somewhat unprepared	14	18.4%
Poorly prepared	41	53.9%
Do not know or no opinion	2	2.6%

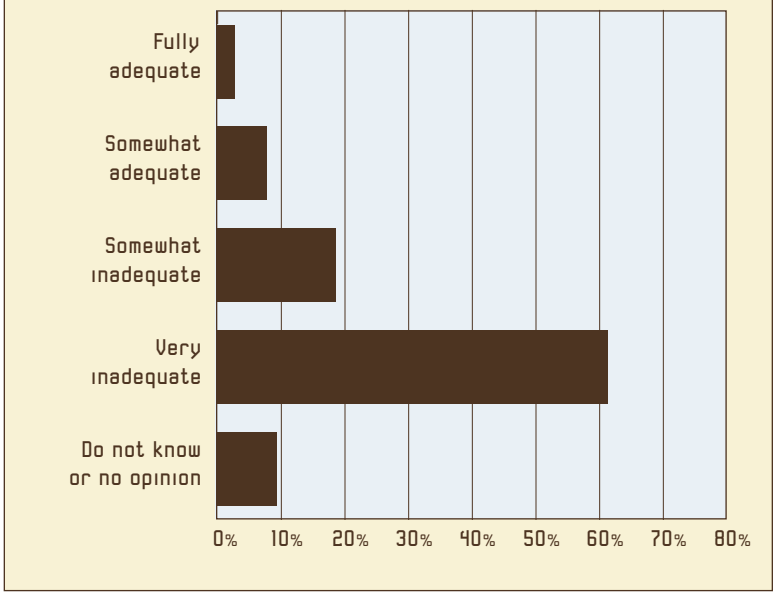
Q16. ADEQUACY OF STATE STATUTORY AUTHORITY AND REGULATIONS



Q.16 Adequacy of State Statutory Authority and Regulations: How would you describe the adequacy of current statutory authority and regulations in the states with which you are familiar to provide needed oversight of biotech crops and foods?

CHOICE	COUNT	PERCENTAGE ANSWERED
Fully adequate	6	7.9%
Somewhat adequate	19	25.0%
Somewhat inadequate	16	21.1%
Very inadequate	29	38.2%
Do not know or no opinion	6	7.9%

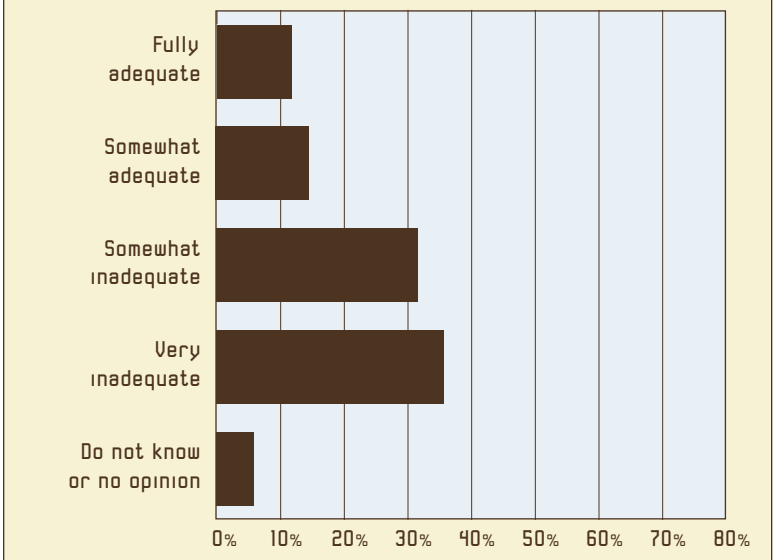
Q17. ADEQUACY OF STATE RESOURCES



Q.17 Adequacy of State Resources: How would you describe the adequacy of the financial resources devoted to needed oversight of biotech crops and foods by the states with which you are familiar?

CHOICE	COUNT	PERCENTAGE ANSWERED
Fully adequate	2	2.7%
Somewhat adequate	6	8.0%
Somewhat inadequate	14	18.7%
Very inadequate	46	61.3%
Do not know or no opinion	7	9.3%

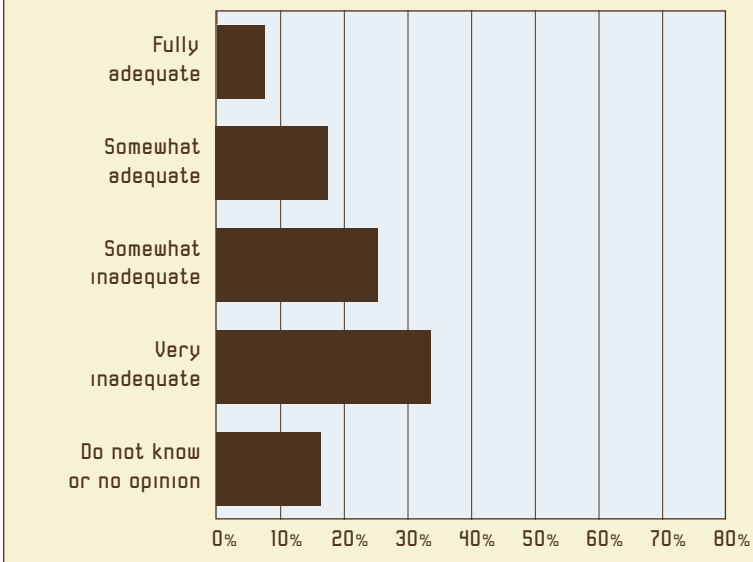
Q18. ADEQUACY OF STATE TECHNICAL EXPERTISE



Q.18 Adequacy of State Technical Expertise: How would you describe the adequacy of the technical expertise available in the states with which you are familiar to provide needed oversight of biotech crops and foods?

CHOICE	COUNT	PERCENTAGE ANSWERED
Fully adequate	9	11.8%
Somewhat adequate	11	14.5%
Somewhat inadequate	24	31.6%
Very inadequate	27	35.5%
Do not know or no opinion	5	6.6%

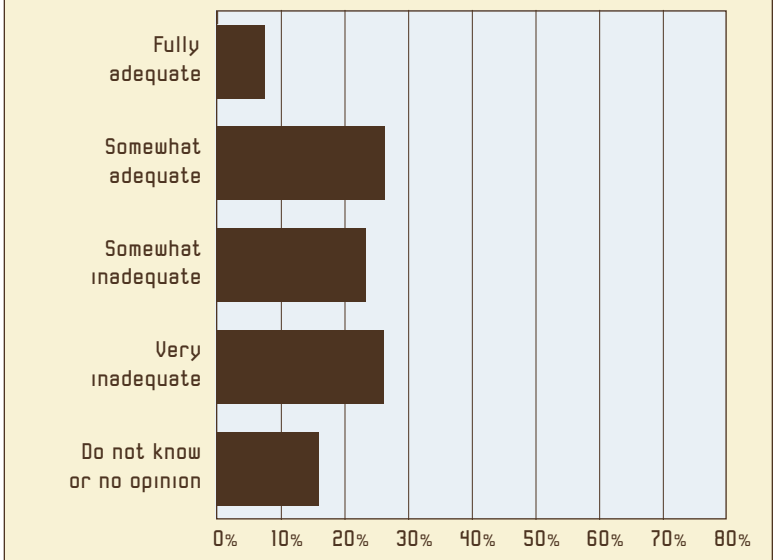
Q19. ADEQUACY OF STATE INSTITUTIONAL ARRANGEMENTS



Q.19 Adequacy of State Institutional Arrangements: How would you describe the adequacy of the way in which the relevant institutions (e.g., agriculture, environmental, and health departments) in the states with which you are familiar are organized and coordinate their efforts to provide needed oversight of biotech crops and foods?

CHOICE	COUNT	PERCENTAGE ANSWERED
Fully adequate	6	7.9%
Somewhat adequate	14	18.4%
Somewhat inadequate	19	25.0%
Very inadequate	25	32.9%
Do not know or no opinion	12	15.8%

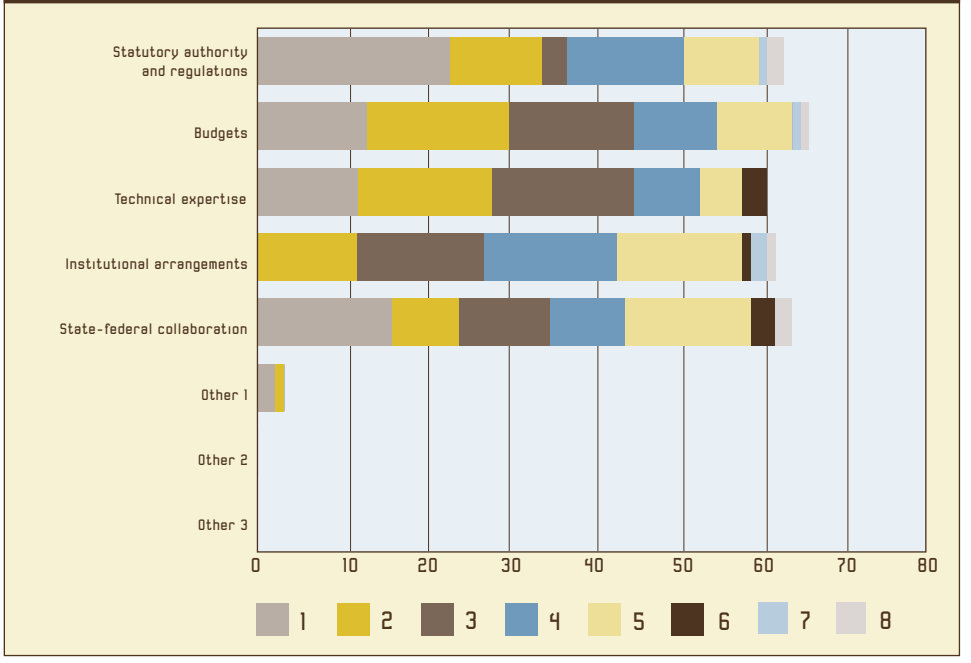
Q20. ADEQUACY OF STATE-FEDERAL COLLABORATION



Q.20 Adequacy of State-Federal Collaboration: How would you describe the adequacy of the collaboration between the states with which you are familiar and the federal government in providing needed oversight of biotech crops and foods?

CHOICE	COUNT	PERCENTAGE ANSWERED
Fully adequate	6	7.9%
Somewhat adequate	20	26.3%
Somewhat inadequate	18	23.7%
Very inadequate	20	26.3%
Do not know or no opinion	12	15.8%

Q21. PRIORITIZING IMPROVEMENTS IN STATE OVERSIGHT



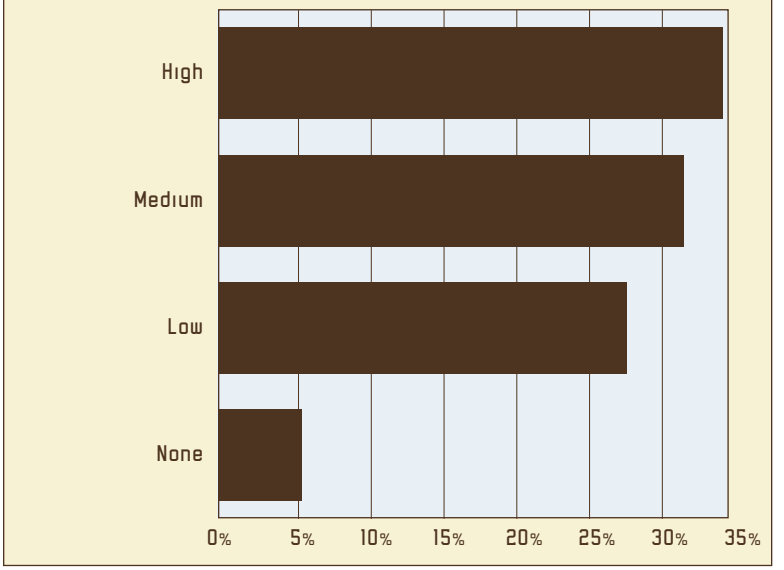
Q.21 Prioritizing Improvements in State Oversight: Please identify and rank in order of importance the areas in which you believe state oversight of biotech crops and foods should be improved. Place a 1 next to the most important topic for regulation, and number the others from there. Omit from your ranking areas that you marked above, in Questions 16-20, as fully adequate.

TOPIC	1*	2	3	4	5	6	7	8**
Statutory authority and regulations	23	11	3	14	9	0	1	2
Budgets	13	17	15	10	9	0	1	1
Technical expertise	11	17	17	8	5	3	0	0
Institutional arrangements	0	11	16	16	15	1	2	1
State-federal collaboration	16	8	11	9	15	3	0	2
Other 1 (specify below)	2	1	0	0	0	0	0	0
Other 2 (specify below)	0	0	0	0	0	0	0	0
Other 3 (specify below)	0	0	0	0	0	0	0	0

*most important

**least important

Q22. PRIORITIZING BIOTECH REGULATORY OVERSIGHT IN RELATION TO OTHER STATE ACTIVITIES



Q.22 Prioritizing Biotech Regulatory Oversight in Relation to Other State Activities: Compared to other activities for which state agriculture, environmental, and health departments are responsible, what priority would you assign regulatory oversight of biotech crops and foods?

CHOICE	COUNT	PERCENTAGE ANSWERED
High (among the top third in priority)	26	34.7%
Medium (among the middle third in priority)	24	32.0%
Low (among the bottom third in priority)	21	28.0%
None (no state effort should be devoted to oversight of biotech crops and foods)	4	5.3%

APPENDIX C

List of Interviewees

1. Rebecca Bech, Associate Deputy Administrator, Biotechnology Regulatory Services, Animal and Plant Health Inspection Service
2. Gary Beil, President and Chief Executive Officer, Minnesota Crop Improvement Association
3. Daren Coppock, Chief Executive Officer, National Association of Wheat Growers
4. Bill Dickerson, President, National Plant Board, and Director, Plant Industry Division, North Carolina Department of Agriculture and Consumer Services
5. Bob Ehart, Animal and Plant Health Safeguarding Coordinator, National Association of State Departments of Agriculture
6. Doug Farquhar, Program Director, Agriculture and Rural Development Standing Committee, National Conference of State Legislatures
7. Judy Garrison, Administrative Officer, Office of the Deputy Administrator, Biotechnology Regulatory Services, Animal and Plant Health Inspection Service
8. Mary Hanks, Supervisor, Sustainable Agriculture and Integrated Pest Management, Agricultural Resources Management and Development Division, Minnesota Department of Agriculture
9. Dwight Harder, Assistant Director, Arizona Department of Agriculture
10. Karen Heisler, Agriculture Initiative, Region 9, U.S. Environmental Protection Agency
11. Neil Hoffman, Director, Regulatory Division, Biotechnology Regulatory Services, Animal and Plant Health Inspection Service

12. Stephen Howie, Environmental Scientist, Agriculture Branch, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency

13. Dan Jacobson, Legislative Director, Environment California

14. Gregory Jaffe, Director, Biotechnology Project, Center for Science in the Public Interest

15. Sheldon Jones, Executive Director, Agri-business Council of Arizona

16. Tobi Jones, President, Association of American Pesticide Control Officials, and Assistant Director, Division of Registration and Health Evaluation, Department of Pesticide Regulation, California Environmental Protection Agency

17. Patrick Kelly, Vice President, State Government Relations, Biotechnology Industry Organization

18. Andrew Kimbrell, Executive Director, The Center for Food Safety

19. Karil L. Kochenderfer, Biotechnology Coordinator, Federal Legislative Issues, Grocery Manufacturers of America

20. Paul Liemandt, Chair, State FIFRA Issues and Research Evaluation Group and Section Manager, Environmental Response, Minnesota Department of Agriculture

21. Kathleen McGrath, Director, State Government Relations, Biotechnology Industry Organization

22. Jim Miller, Director of Policy and Communications, Office of the Commissioner, Colorado Department of Agriculture

23. Terry Mitchell, Director, Pesticide Registration, Texas Department of Agriculture

24. Jennifer Yezak Molen, Animal and Plant Safeguarding Coordinator, National Association of State Departments of Agriculture

25. Isaac Moriwake, Attorney, Earthjustice

26. Jack Neylan, Agriculture Branch Chief, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency

27. Adrian Polansky, Secretary of Agriculture, Kansas Department of Agriculture

28. Robin Pruisner, Chief, Entomology and Seed Bureau, Plant Management and Technology Division, Iowa Department of Agriculture and Land Stewardship

29. Ann Schmidt, Manager, Communications, California Rice Commission

30. Cameron Smoak, Assistant Commissioner, Consumer Protection Field Forces, Georgia Department of Agriculture

31. Cindy Smith, Deputy Administrator, Biotechnology Regulatory Services, Animal and Plant Health Inspection Service

32. Ralph Stoaks, Western Biotechnologist, Plant Protection and Quarantine, Animal and Plant Health Inspection Service

33. David Swack, Director, Administration and Resources Management Support Staff, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency

34. Gerret Van Duyn, Manager of Environmental and Biotechnology Policy, National Cotton Council of America

35. Lyle Wong, Administrator, Plant Industry Division, Hawaii Department of Agriculture

36. Mitch Yergert, Plant and Insect Section Chief, Division of Plant Industry, Colorado Department of Agriculture