AGRICULTURAL BIOTECHNOLOGY:

Critical Issues and Recommended Responses from the Land-Grant Universities

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A Report to the Experiment Station Committee On Organization and Policy (ESCOP) and the Extension Committee On Organization and Policy (ECOP)

January 21, 2000*

(*minor word changes 1/25/2000)

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SECTION I
Introduction

With the advent of genetic engineering (i.e., the inter-specific transfer of DNA using a gene vector) of microbes (ca. 1974), plants (ca. 1983), and finally animals (ca. 1985), it became apparent that agriculture had much to gain from the new biotechnologies. It was easy to see that the transfer of highly desirable genetic traits across species barriers could be used to solve some previously intractable problems. New forms of disease and pest resistance could be substituted for environmentally unfriendly pesticides. More nutritious foods could be engineered with the addition of genes coding for nutrients and vitamins. Plants and animals could be made to be more productive, grow faster, or produce less pollution.

Some of these "dream products" are now a commercial reality. Genetically engineered corn, soybean, and cotton cultivars now extend over nearly 50 percent of the production areas for these commodities in the United States. Other engineered agricultural commodities are in the R&D "pipeline" and soon will be available to American farmers and ranchers.

But all has not progressed as originally planned. American farmers are today faced with some tough decisions regarding the continued use of crop seeds that are genetically engineered. Consumer acceptance of some of the products of agricultural biotechnology has been poor, especially in European markets where organized resistance to the products of biotechnology is intense. American farmers and ranchers are finding that the loss of their traditional overseas markets is significant, and they expect that this will likely continue to be a contributing factor to the present difficulties many farmers are facing.

Farmers are now asking if they should continue to produce the products of biotechnology. If produced, will they be able to sell them? Some commodity associations are recommending that farmers not plant genetically engineered crops in 2000 despite their superior performance and potential for profitability. Their markets are seen as being at risk.

To address this situation, the Experiment Station Committee on Organization and Policy (ESCOP) and the Extension Committee on Organization and Policy (ECOP) of the National Association of State Universities and Land-Grant Colleges (NASULGC) recently formed an agricultural biotechnology task force (see Appendix 1 for the membership). The task force was to provide a factually based, independent analysis of the current controversy over the market acceptance of foods that have been genetically engineered, and make some recommendations for immediate actions that could be undertaken by the land-grant university (LGU) community. It is important to note that the enormity of the tasks to be done suggests that some activities might be well shared with others in some carefully formed strategic partnerships.

The LGU community is particularly well suited to address this topic through a number of activities. To organize its recommendations, the task force explored a set of nine related issues by teleconference. Small teams of task force members then drafted responses to those nine issues. The draft statements were then critiqued by all the task force members through e-mail exchanges and modified to represent a consensus view.

The LGU community could make overarching contributions for engagement on the issues relevant to consumer acceptance of the products of biotechnology through **education** (both formal and informal) and **research**. For both functions there are a set of **critical issues** and **possible responses** by the LGUs. It is from this perspective that the task force has prepared the following report for consideration by the ESCOP and ECOP communities.

This report is structured to allow the reader to quickly cover the **critical education and research issues** thought to be most relevant to the task force's charge. This is followed by a set of **recommended responses** for the LGU community. The final section gives more detailed treatment to **the defining topics** that seem to be driving the current agricultural biotechnology controversies.

SECTION II
CRITICAL ISSUES

Education

Education is vital to inform producers, consumers, and leaders about the full range of challenges and opportunities associated with modern agricultural biotechnology. It includes the need to explain the science behind biotechnology as well as the reasons it is being used. Such education is challenging because it now must be done in a climate of controversy and growing suspicion about the technology. The LGU system is in a unique and important position to serve as a third-party source of factual and credible information to help balance the discussions on agricultural biotechnology.

Surveys conducted over the past decade document the critical need for consumer education in modern agricultural biotechnology. Results have shown that awareness of agricultural biotechnology in the United States has generally remained low except during times of intense media coverage. Results also show that most consumers have relatively little understanding of, or interest in, the science behind biotechnology. They also tend to have little familiarity with the processes used in traditional agriculture (e.g., crop breeding). Most tend to take food access for granted, and they give little thought thought to how it is grown or produced until the media focuses on a particular issue. These educational needs present the LGU system with important educational challenges and opportunities.

Points to Consider:

1. ***Whom should we educate?*** The range of target audiences for education is wide. In general, it will be most effective to reach the public by focusing on the key opinion leaders who shape the public's perception and understanding of issues. One key audience for an education program includes individuals and organizations involved at various points in the food production, processing, and distribution system. But the food production and distribution system is complex and involves groups with different perspectives on biotechnology and different information needs. Traditionally, the LGU system has worked with commodity associations and other farm groups to ensure that farmers receive practical information that will allow them to use the latest technology in agricultural production effectively and efficiently. Effort in this area will still be vital. At the end of the system, which is closest to consumers, are the food retail (grocery) and restaurant industries, which need information about biotechnology so they can make informed decisions and better respond to consumer questions. Education should also be targeted to food processors and manufacturers, particularly those that purchase agricultural commodities produced through biotechnology. Another important target audience includes members of the media and other communicators. A small segment of media representatives, such as science writers, may already have the scientific background to understand and cover biotechnology stories. However, most media representatives, including general assignment reporters, food writers, and editors, would benefit from better access to non-technical information and approachable experts. Science teachers, extension educators, and other educators would also be important audiences for an education program. In addition, elected and appointed public sector leaders need information about biotechnology to support decisions about research and public policy development. These leaders need practical information, insights into consumer attitudes, and a balanced overview of the major issues associated with food biotechnology. Various public interest organizations and other citizen groups also form an important target audience because they are interested in and outspoken about the use of biotechnology.

2. ***What do people want to know about biotechnology?*** Consumers are quite interested in learning about the benefits of biotechnology—why it is being used and what is in it for them as consumers and for society. Next, they want an assurance that the products have been shown to be safe for human consumption and the

environment. A response to this concern should include transparent information about any credible risks. It is also important to explain the current governmental oversight process and the types of tests that currently are performed on such products. The explanation should include the fact that the crops developed through modern biotechnology are more closely regulated and carefully tested than are those varieties developed through traditional breeding. Finally, people are genuinely curious about what modern biotechnology actually is. One effective way to explain this would be to draw comparisons between food biotechnology and the use of traditional breeding in agriculture as well as discuss how biotechnology is used to develop new medicines and to improve human health care. This would provide consumers with a realistic, historical context within which to understand modern agricultural biotechnology.

3. ***What are the most appropriate terms to use in describing biotechnology?*** A number of terms are often used interchangeably when describing the uses of modern biotechnology in agriculture and food production. Research has consistently shown that certain terms such as "genetic engineering" are perceived as much more negative than terms such as "agricultural biotechnology." In fact, the term "genetically modified organism" is the most negative term for consumers. The term "organism," which may imply a health concern related to viruses or bacteria, is also partly a misnomer because the food ingredients used are no longer organisms. Other terms with a very negative connotation include "transgenic" and "Bt-toxin." It will be important to use meaningful and neutral terms that clearly and truthfully indicate that modern biotechnology has been involved in food production and processing.

4. ***How can we educate about biotechnology?*** Most of the information people have gotten so far has been received passively through the mass media. There are clearly some significant limitations associated with using this form of mass communication for educational efforts. In fact, many consumers have become quite skeptical about the media's credibility on controversial issues. Research shows that there is a clear need for a more proactive and integrated educational campaign that builds awareness and generates interest in learning more. Such a campaign could best be accomplished through such mechanisms as toll-free numbers and Internet sites hosted by third parties, such as universities. It also would help to establish and maintain a clearinghouse of information that describes all the products that have been approved, including the foods in which such ingredients might be found. The Web address and phone numbers could be widely publicized through the media, point-of-purchase displays, and other means. Such approaches would make it easy for people who want information to get it and would also build consumer confidence that this is a transparent system with opportunities for informed and meaningful consumer choice.

5. ***Who should provide people with information about biotechnology?*** An effective educational program will require an ongoing partnership among government, industry, universities, consumer groups, and others. In the United States, consumers have consistently reported the greatest trust in information from government agencies, university scientists, and third-party scientific organizations. The LGU system should play a major role in providing consumers and leaders with the latest information about all aspects of food biotechnology. Food manufacturers should be responsible for providing information about their own branded food products. Farmers would be important and credible sources for providing information about their own experiences and needs relative to biotechnology.

6. ***How should we maintain our credibility and neutrality?*** It is important to recognize that the disagreements over scientific facts, social values, and other types of issues are contributing to the conflicts over agricultural biotechnology. For example, scientific research is able to identify and evaluate the relative severity and incidence of potential food safety and environmental risks. This is an important and appropriate role for the LGU system. It will be important that the data be collected and interpreted in a systematic and unbiased manner to maintain trust in our system. However, many of the issues that are also of concern to the public will not be addressed through the use of biological or natural sciences -- they require more attention to social science. These include ethical and societal issues, as well as some of the key issues related to labeling and consumer choice. These values-based issues involving opposing views can be best addressed in a public policy education manner similar to how we have successfully addressed other environmental issues. Our approach should be to help the public evaluate both sides of the issue. However, it is important to realize that the agricultural community and the USDA look to the LGU system for support and assistance in helping to ensure that there are viable markets for the commodities that farmers choose to produce using seeds developed through modern

biotechnology. Whatever the pressures, the LGU system needs to maintain its objectivity and call only for a science-based approach to regulatory decision making, including product approval.

Research

The LGU system should give greater priority to research projects that fill gaps in the scientific understanding of the risks, benefits and costs associated with agricultural biotechnology. This science-based knowledge is essential for a more informed dialogue and effective policy and regulation of biotechnology.

For the products of biotechnology there is a small set of human health and environmental safety topics that have been widely identified as having the most pressing need for further research. These topics are:

Allergenicity: One of the most widely cited concerns about genetic engineering is that it will introduce into foods with no known allergy problems genes that trigger allergic reactions. The case of a test product using a gene derived from Brazil nuts-a food to which a significant number of people are known to be allergic-appears in virtually all discussions of agricultural biotechnology. Current tests for potential allergens are crude and insufficiently predictive. Research to improve allergenicity screening is sorely needed. Research needs include basic research examining the physiological mechanisms of food allergies as well as applied research such as developing better predictors of allergic effects.

Pleiotropic effects of gene insertions: A second area in need of research attention is the positional (pleiotropic) effects of gene insertions, especially when gene expression may not be predictable. Unanticipated genetic effects may occur from genetically engineered organisms, and these effects need to be better understood.

Secondary plant metabolites: A third widely cited concern about genetic engineering is that the introduction of novel genes will result in unanticipated and/or enhanced expression of secondary plant compounds with potential toxic activity. At present, the understanding of these effects is limited and further research would help improve regulatory scrutiny.

Gene flow: The most widely cited ecological concern about genetically engineered plants is that gene flow from crop plants to wild relatives could lead to substantial improvements in fitness, i.e., the emergence of "superweeds" or plants that negatively impact herbivore populations. There are also concerns about the movement of genetically engineered traits that are environmental hazards, or that are seen as potential human health risks. Little is currently known about the process of gene flow to wild relatives. In particular, gene flow from traditionally bred crop plants to relatives has not been adequately characterized, nor has the effect of novel genes on plantness fitness been well studied. Further research on these topics could lead to significant improvements in regulatory capabilities.

Environmental benefits: It is often argued that the use of crops genetically engineered to express pesticidal compounds can improve environmental quality by reducing reliance on chemical pesticides. Impact assessment research is needed to verify whether such claims are accurate and, if so, the extent and circumstances under which such reductions are achieved.

The LGU system is also uniquely positioned to provide substantive research on the socioeconomic and policy issues associated with biotechnology. The following topics have been identified as research priorities:

Benefits and costs from use of bioengineered crops: Net economic benefits have likely been generated by the market introduction of bioengineered crops. The magnitude of economic benefits and costs as well as their distribution among technology providers, farmers, merchants and consumers is not known. Research is needed to assess the economics and distributional impacts of agricultural biotechnologies.

Benefits and costs of labeling: Labeling foods made with biotechnology products is often put forward as a simple matter of providing information that would allow consumers to make better choices. However, labeling is costly and little is known about the benefits or costs of labeling. More information is needed on the costs of segregating biotechnology crops throughout the marketing channel and the costs of monitoring compliance. Research on costs

and benefits for various labeling schemes as well as their distribution among various participants across the agricultural value chain and consumers can improve decision making in regulation and public policy relating to bioengineered products.

Structural impacts of biotechnology: Concerns over potential structural impacts of biotechnology in agriculture and the agrifood supply chain have been raised repeatedly. Improved understanding of the role of various corporate and public strategies in biotechnology on market structure and change is needed to facilitate policies that improve social welfare and minimize displacement.

Social values and institutional environments: A better understanding of the social values and institutional environments that spawn opposition to food biotechnology is needed for understanding public criticisms and concerns. It is also essential for accommodating the widest possible divergence of personal, social, and religious values and for arriving at socially optimal solutions.

SECTION III
RECOMMENDED RESPONSES

Inventory of Available Resources: A wide variety of informational materials is available in the public domain. These materials range from promotional pieces developed by the biotechnology industry to highly critical documents developed by the opponents of modern biotechnology. In the middle are a number of credible and meaningful statements by a variety of public and private sector organizations. Information is being disseminated through the mass media, the Internet, and a number of other channels. One of the challenges will be to find a clear and viable niche for LGU educational programs within this crowded information domain. This effort should include an inventory and evaluation of existing educational materials and programs to identify strengths and communication gaps.

Clearinghouse Function: Educational materials suitable for various audiences need to be prepared and updated as new information emerges. Materials such as *The Economics and Politics of Genetically Modified Organisms in Agriculture* (Bulletin 809, Office of Research, University of Illinois) and *Food Biotechnology in the United Sates: Science, Regulation, and Issues* (CRS, Library of Congress, Washington, DC) are highly instructive for an audience that already understands the fundamentals. A new set of materials better suited for a mass audience is essential. They should include audiovisual materials (such as videotapes) as well as publications. One government agency, such as the USDA's Economic Research Service or the National Agricultural Library, should serve as a clearinghouse for visuals and other educational materials. These could then be made available on-line and through other means.

The first steps might include

a) enhancing the National Agricultural Library's program on biotechnology to include relevant materials and to provide research support on values topics;
b) raising the profile and recognition of such research in the eyes of extension and experiment station staff;
c) developing materials that explain the relevance of these research areas to food biotechnology and that are appropriate to different audiences;
d) developing an extension program based on principles of risk communication; and
e) conducting research that will extend existing research and methods specifically to the case of food biotechnology.

Understanding Trade: The LGUs might develop materials explaining the organization of the world trading system, the rationale for science-based sanitary and phytosanitary standards, the benefits of expanded trade, and the limits on the use of trade to achieve domestic policy objectives.

Understanding Regulations: Federal regulation of biotechnology products is not well understood by the general public. Cooperative Extension might want to render a public service by developing materials to be used in campaigns designed to educate the public about how biotechnology products are regulated in the United States.

These materials should cover the following areas:

1. The statutory bases for biotechnology regulation under the Coordinated Framework.
2. Formal and informal reviews conducted by regulatory agencies prior to the testing and commercialization of biotechnology products.
3. The kinds of scientific information used to evaluate the risks of biotechnology products.
4. A history of biotechnology product reviews, approvals, and denials.

Broader education on the regulation of potential environmental and human health hazards would also be beneficial because misunderstandings on key issues seem to be widespread. Among the issues that should be addressed are

1. The importance of basing regulations on science for consistency and preventing the erection of trade barriers.
2. The necessity of accepting some risk and the impossibility of proving that something will never pose any risk.
3. Potential biases in current methods used to assess risk.
4. The enforceability of alternative regulatory measures, including labeling (i.e., the need for tests capable of distinguishing products produced by different methods).

Financing Research Priorities: ESCOP leaders should identify alternative sources of funding that may be used to support the listed research priorities at LGUs. Some CSREES national program leaders (NPL) are interested in applying for REE evaluation funds for projects on agricultural biotechnology acceptance issues. One or more LGUs could work in partnership with these NPLs to develop collaborative projects. One point of contact is John A. Michael, NPL in Social Science, ECS-CSREES, USDA (jmichael@reeusda.gov).

Risk Assessment Research: ESCOP leaders should visit with the CSREES administrator to review the portfolio of the Biotechnology Risk Assessment Research Program authorized in the 1990 Farm Bill. They should look at the pattern of past research awards as measured against the understood needs for biotechnology product acceptance, assess the elements of the annual request for proposals, and evaluate the adequacy of funding for the magnitude of the current situation. Alternative sources for biotechnology research grant funding might also be explored.

Assessment of Public Research: Research is needed to identify crops, varieties, and traits for which the public sector is most likely to make unique contributions. Research is also needed on the most effective methods for technology transfer, including considerations such as patenting new crop varieties, and licensing policies.

The LGUs would benefit from some self-evaluation as well. Criticisms that land-grant research is oriented toward products that can be commercialized by large agribusinesses or agrichemical interests recur repeatedly. Research should be undertaken to examine the extent to which land-grant research exhibits such an orientation.

Support for Public Dialogue: In public discussions about agricultural biotechnology, references are often made to a number of issues relating to consumer demand for new products, both domestically and abroad; to U.S. competitiveness in world markets; to international trade policies; and to the management of farm businesses. The LGU system could improve the quality of these public discussions by providing information on these issues through research and educational support. Some proactive dialogue initiatives could include the following:

1. Hold a forum with embassy science attachés in Washington, DC to discuss international perspectives on intellectual property rights and labeling issues vis-à-vis agricultural biotechnology.

2. Host a meeting with corporate leaders to discuss ways of easing restrictions on the use of protected intellectual property, especially as it relates to public sector research and development.
3. Ask the NASULGC Board on Agriculture to sponsor a systemwide audit of intellectual property materials now being used by land-grant universities without license to assess the degree of the problem and define the need for relief.
4. As a corollary, conduct a study on the distortions caused by public institutions seeking royalties versus providing public goods.
5. Offer to provide scholarly support for Congressional hearings on
    - the impact of two decades of issuing utility patents for living organisms on public sector research activities.
    - the benefits of international regulatory harmonization for agricultural biotechnology.
    - alternative approaches to product labeling, including the perspectives of agricultural producers and consumers.

Scientific Dialogue: The LGUs might also facilitate dialogue within the scientific community on controversial topics as they relate to agricultural biotechnology. These might include discussions on the issues related to product labeling requirements; the appropriate application of predictive environmental impact models in regulatory decision making; and the adequacy of refuge area strategies for selectively stabilizing pest populations.

SECTION IV
THE DEFINING TOPICS

Environment

Public discussions have raised a number of concerns about potential environmental effects of the use of crops derived from agricultural biotechnology. Among the most prominent are concerns

- that the flow of genetic material from genetically engineered crops to weed species will improve weed fitness;
- about the validity of industry claims that genetically engineered varieties can help improve environmental quality by reducing the use of chemical pesticides;
- that the development of resistance to introduced genetic material will undermine the efficacy of widely used pest control products; and
- that the use of marker genes will accelerate the spread of antibiotic resistance.

The LGU system can help inform discussions of these issues through research and education. In particular, research is sorely needed on all these topics because the current information base is inadequate.

The most widely cited ecological concern about genetically engineered plants is that gene flow from crop plants to wild or native plants could lead to substantial improvements in their fitness, i.e., the emergence of “superweeds.” Such gene flow could also negatively impact herbivores or plant symbionts of these plants, particularly if the herbivore is an endangered species. Little is currently known about this process. In particular, gene flow from traditionally bred crop plants to relatives has not been adequately studied, nor has the effect of novel genes on plant fitness. Concerns cited at present are fueled largely by speculation because little hard evidence exists about the likelihood or extent of gene flow. Further research on these topics could lead to significant improvements in regulatory capabilities by providing objective, factual information on the extent to which these adverse effects arise and the conditions under which they are likely to be significant.

Proponents of genetic engineering claim that the use of crops such as those genetically engineered to express pesticidal compounds can improve environmental quality by reducing reliance on chemical pesticides. Land-grant researchers can help verify whether this claim is accurate and, if so, the extent and circumstances under which such reductions are achieved.

Another widely cited ecological concern is that the incorporation of pesticidal substances into crops will accelerate the spread of resistance to those substances, rendering them ineffective. Special concern has been raised about crops expressing toxins derived from *Bacillus thuringensis* (Bt). Bt is used in microbial form by organic growers who have few other acceptable compounds to use. It also has been used in situations in which human exposure is substantial and the available alternatives pose greater human health risks (e.g., gypsy moth control). Research is needed to improve understanding of how resistance develops and on effective strategies for avoiding or mitigating the emergence of pesticide resistance, such as the high dose/refuge approach currently advocated. Similar forms of research are needed for antibiotic resistance management.

These issues are not well understood by the general public. Extension could play an important role by providing current scientific information about them. A Web site containing explanations of these phenomena and links to the scientific literature on them would be especially useful.

Food Safety

Food safety is an issue for our domestic consumers, our international trading partners (including many members of the European Union and Japan), and consumer advocate organizations. In response to growing EU consumer concerns, the EU has said it will require labeling for any food containing more than 1 percent of genetically engineered ingredients. Due to perceived health risks including increased toxicity, increased allergenicity, and antibiotic resistance, 20 U.S. lawmakers will introduce legislation in 2000 that would require mandatory labeling for foods containing genetically engineered ingredients. Thus, food safety is inextricably linked to the concerns of agricultural biotechnology.

Under current U.S. policy, genetically engineered products that will be used as food are assessed for the following risks prior to marketing:

- unexpected genetic effects produced by the transfer of genetic material;
- toxin levels higher than those for other edible non-engineered varieties;
- nutrients differing from those in traditional varieties;
- introduced genes from sources associated with human allergies (i.e., milk, eggs, wheat, fish, shellfish, tree nuts, and soybeans);
- a new composition that differs substantially from comparable varieties;
- marker genes that potentially could transfer antibiotic resistance to clinically significant organisms;
- plants originally developed as a therapeutic or industrial product, not as a food product; or,
- nutrients or toxins making it unacceptable for animal feed.

As is typical in other industry food safety issues, risk assessment evidence for genetically engineered products is generated and compiled by the manufacturers according to FDA guidelines. Data are then submitted to the FDA for evaluation. Foods not excluded by the above conditions are recognized as equivalent to, and thereby as safe as, foods produced by more traditional technologies. Foods containing possible allergens, deviating substantially from comparable varieties, or posing other safety issues must be labeled.

This science-based system retains considerable support in the United States, where the media has presented the issues in a balanced fashion. However, in response to domestic concerns elicited by international commentary, the FDA conducted three public meetings in November and December 1999 on its policy for assuring the safety of bioengineered foods. Many other countries treat the process as unique and evaluate the safety of genetically modified foods similarly to the way they evaluate drug safety. Part of the disagreement appears to lie in the belief

that there is a lack of evidence that genetic engineering negatively affects food safety. The focus seems to be on "what if" rather than on "what is."

Trade, Business, and Economics

One concern raised repeatedly about agricultural biotechnology is that the introduction of crops modified for specific quality attributes will lead to an increase in vertical coordination (e.g., contract agriculture) due to buyers' need for quality assurance. These traits range from the relatively mundane, like higher oil content, to the more exotic, like pharmaceutical content. Contract agriculture is already widespread in some livestock sectors (poultry), in crops grown for processing, and in some crops grown for the fresh market. Many fear that farmers operating under contracts lose their independence and become mere low-level employees of giant agribusinesses. In principle, contract agriculture can have benefits for farmers, e.g., lower income variability, fewer credit constraints, and easier access to new technologies.

Some have argued that GATT, NAFTA, and similar international trade agreements undermine the ability of the United States to protect environmental quality and safeguard its food supply. The public at large has a limited understanding of how these trade agreements function, particularly with respect to sanitary and phytosanitary standards (SPS). There are significant divisions over the "non-scientific" use of sanitary and phytosanitary standards to inform or otherwise protect consumers about products. For example, consumers reluctant to buy products made with non-traditional food sources (i.e., dogs, cats) may be assured of the food's safety, but may still prefer to not purchase them. In this case, labeling or market exclusion may be justified. Spurious SPS have been used as barriers to trade. Limiting the ability of nations to engage in such practices requires mutual accountability to science-based standards. Similar considerations apply to the use of trade restrictions to achieve environmental protection goals abroad.

There has been considerable concern that biotechnology has led to an increase in market concentration in the seed industry, allowing giant agricultural /chemical firms to extract dollars from farmers via high seed prices and possibly stifling future innovation as firms attempt to exploit their existing patents to the fullest. Theoretical research to date indicates that new crop varieties may enhance competition in some cases, as Round-Up Ready soybeans appear to have done in the soybean herbicide market.

There is considerable economic literature on R&D generally and on the adoption of new crop varieties, especially in developing countries, but very little has been written on the economics of crop and livestock breeding and on the appropriate roles of the public and private sectors. Economic theory suggests that the public sector should focus on crops, varieties, or specific traits that the private sector is unlikely to find profitable but are nevertheless socially beneficial. Examples include those for which patents cannot be enforced, those with potential markets too small to justify private investment, or those that have non-marketable attributes, such as enhanced environmental quality.

Intellectual property rights (IPRs) are temporary monopoly rights granted to man-made inventions and discoveries. Implicit to such awards is the recognition that imitation is far cheaper than original invention and in the absence of legal protection innovators cannot capture economic value from their discoveries. Imitators can appropriate it all. Accordingly, IPRs intend to provide economic incentive for investment in creative activities. (For a history of IPRs see Appendix 2.).

IPRs are said to have a significant influence on the structure of commercial agriculture for a variety of reasons. Some of these structural changes may alter the face of American agriculture as we have known it.

On the surface, granting of IPRs for plants and animals has had the intended effect. Private investment has increased drastically both in research and germplasm development. In the United States, private R&D investment has increased steadily since 1970 and has surpassed public investment in recent years. Several significant issues have emerged from this shift, however.

In the current agricultural knowledge system, the private and public sectors both collaborate and compete. A portion of private investment in biological and biotechnology research has been regularly outsourced to universities and

other public institutes and laboratories through research contracts, collaborative research and development agreements, material exchanges, intellectual property licenses, and use of university researchers on scientific boards and in think tanks.

Private financing of public sector agricultural research has caused significant concerns, however. It has been argued that the private sector is unduly influencing the public research agenda, directing it toward socially suboptimal targets. Moreover, critics say it is doing so by paying only at the margin after the public has paid for the significant infrastructure of the LGU system and other public research organizations.

There are arguments for enhanced private-public sector interactions as well. Such arguments point to synergies between private and public research, which increase the efficiency of agricultural knowledge generation and transfer. Other arguments focus on the need for public research to stay connected with cutting-edge research in the private sector.

Alternative roles and interactions of the private and public sectors lead to different efficiency and equity outcomes. Efficiency improves when more innovation results from a given set of scarce resources and when better solutions emerge to satisfy food and fiber needs while sustaining existing resources for future generations. The issue of equity, on the other hand, deals explicitly with how the resulting benefits and costs are distributed among different social groups and among current and future generations. Efficiency and equity are inextricably connected and, in most cases, move in opposite directions. Hence, highly efficient outcomes may not be equitable. It is desirable that the public and private sectors define their roles in ways that efficiency and equity considerations are balanced.

There are instances where restricted access to biotechnologies and germplasm transfer due to IPRs has caused significant inefficiencies. Material transfer agreements (MTAs) are now common place for managing material exchanges. However, MTAs involve high transaction costs (e.g., record keeping, negotiation), placing a heavy toll on researchers' time and often blocking the commercialization of important technologies because they impede the ability of parties to reach agreeable terms with one or more claimants. As a result, many contemporary MTAs are overly restrictive and impede research and development, especially for institutions that lack legal support.

Access to technology is most problematic in the case of less developed countries (LDCs), which stand to benefit the most from biotechnology in addressing their pressing need for food and fiber. However, lack of IPRs protection has slowed technology transfer to LDCs. The weakening financial situation of the CGIAR system has further worsened this balance. It is imperative that processes be devised that facilitate quick transfer of biotechnology to LDCs while safeguarding the rights of the technology providers,. More generally, the effectiveness of the existing IPRs framework for transferring agricultural biotechnology knowledge must be examined and improved upon when possible.

Industry Structure and Consolidation

A barrage of mergers and acquisitions (M&As) in the seed and biotechnology industries executed by few large biotechnology and agrochemical companies at sensational prices has attracted much attention over the last few years. These M&As coincided with the commercial introduction of first-generation agricultural biotechnology products, which were adopted at unprecedented rates. For some, the lofty acquisition prices and high adoption rates raised expectations about the prospect value of agricultural biotechnology. For others, they raised significant concerns about increasing market concentration and power. Interestingly, issues of value and structure are flip sides of the same coin. New value possibilities resulting from innovation tend to set in motion entrepreneurial efforts, which typically result in structural change.

Alternative explanations have been proposed about the underlying motives of the recent rush to M&As in the biotechnology and seed industries. These include:

- The ability of biotechnology firms to profit from their innovation depended on the strength of intellectual property coverage and the ease of imitation. Most crop biotechnologies that reached the market over the last few years demonstrated significant degree of imitation and involved overlapping patents that were

heavily contested in courts. Under these circumstances, high-quality proprietary germplasm, a key complementary asset for commercialization, proved to be a stronger asset than biotechnology know-how and IPRs. Under such conditions, vertical integration into the seed business and ownership of germplasm became a primary strategy of agricultural biotechnology firms.

- Because of the complementarity of biotechnology and germplasm, increased coordination of such assets was necessary for commercialization. There were significant impediments, however, to structuring effective contracts that would distribute profits among biotechnology and seed companies. Because of the significant time lags involved in genetically engineering and developing commercial amounts of germplasm with desirable traits, contracts that coordinated biotechnology and seed assets were structured years before reaching market. Accurate valuation of the individual contribution of the interdependent technology and germplasm to the final technological advance (e.g., higher yields) was difficult to assess. Such jointedness led to indeterminate schemes for profit sharing and incomplete contracts. Incomplete contracts predictably led to costly re-negotiations and friction. Accordingly, biotechnology firms resorted to vertical ownership so that such costs were minimized.

- The recent engagement of agricultural biotechnology companies in genomic research elevated R&D budgets to levels that could be justified only by significantly expanded sales. Given the current size of the global input markets, presence in markets and increased market shares were pursued.

Others have argued that M&As in the agricultural biotechnology and seed industries represent efforts for corporate control and dominance of the agrifood industry. Irrespective of one's perspective on the underlying motives, some key issues remain.

Market Access and Competition: Through M&As, the biotechnology and seed industries have consolidated around a small number of diversified multinational firms with significant capabilities in discovery, product development, and distribution. Strong concerns exist about market access and market foreclosure. Key questions remain. Is there enough competition in the biotechnology industry to ensure that innovation will not be impeded in the long run? Is the seed market competitive, or will farmers continue to be squeezed between higher seed prices and lower commodity prices? These and other related issues remain largely unanswered.

Impacts on Structure of Production Agriculture: Initial evidence suggests that first-generation agricultural biotechnology (e.g., insect resistance, herbicide resistance) is scale neutral and does not encourage consolidation in farming. However, there is sufficient evidence that second-generation biotechnologies, which involve introduction of crops with enhanced qualities, will encourage vertical coordination throughout the agricultural supply chain and production contracts in agriculture. On the one hand, there are concerns about the control implications of such contracts on farming. On the other, there are arguments suggesting that such contracts and production systems can lead to increased value and reduced risk for farmers. Further research is needed to determine the positive and negative effects of such production systems. These issues must be addressed within the broader context of a sustainable agriculture and must explicitly consider effects on ownership, control, and social capital.

Potential for Continuing Industry Consolidation: In anticipation of the commercial introduction of second-generation biotechnologies, various forms of vertical coordination have already emerged in the market. They vary from long-term contractual agreements to joint ventures and vertical ownerships. What will then be the structural impact of second-generation biotechnologies when they become commercial?

One key lesson from the recent past is that the relative strength and uniqueness of biotechnology IPRs and relevant distribution assets will have much to do with how the agrifood chain will be reconfigured in the future. Key technology races are occurring at this time that will define the position of biotechnology players for years to come. Large amounts are being spent on genomic research to establish strong intellectual property positions in the second- and third-generation biotechnologies. If such races result in multiple, overlapping ownerships of patents that cannot be successfully consolidated, additional vertical M&As in relevant downstream markets will likely occur. It is important that such possibilities are analyzed and policy initiatives that reduce market friction and maximize social welfare are identified.

Regulations

Since 1986, biotechnology products in the United States have been regulated under the Coordinated Framework for Regulation of Biotechnology. The Coordinated Framework operates under the assumption that existing legislation provides sufficient regulatory coverage for all biotechnology products. Under the Coordinated Framework, provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA) are used to regulate novel substances in foods and feeds on the basis of dietary risk. Provisions of the Federal Plant Pest Act (FPPA) provide for the regulation of newly developed plant varieties on the basis of ecological risk. Provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provide for regulation of microbial and other pesticidal substances on the basis of human health and ecological risk. Provisions of the Toxic Substances Control Act (TSCA) provide for regulation of novel microorganisms on the basis of environmental risk. The Food and Drug Administration (FDA) enforces FFDCA for all substances except pesticidal ones, which are assigned to the U.S. Environmental Protection Agency (EPA). USDA's Food Safety and Inspection Service (FSIS) administers the Federal Meat Inspection Act (FMIA) and the Poultry Product Inspection Act (PPIA), including ancillary regulations and policies concerning agricultural biotechnology related to food animals. The USDA's Animal and Plant Health Inspection Service (APHIS) enforces FPPA, and FSIS enforces FMIA and PPIA. Finally, the EPA enforces FIFRA, TSCA, and FFDCA as it applies to pesticidal substances.

This regulatory system has had the effect of providing reasonable assurances of public safety and environmental protection while allowing the research, development, and commercialization of the products of agricultural biotechnology to go forward. But the system is not fully compatible with regulatory systems of our major trading partners. In Europe biotechnology regulation is focused on the process, not the products, of biotechnology. This has led some governments to consider extending regulatory consideration beyond safety, efficacy, and quality to questions such as "Do we need it?" This "fourth criterion" has been strongly resisted in the United States as inappropriate to our system of regulatory authorities. But it remains a contentious trade issue.

Product Labeling

To deal with differences in consumer acceptance of agricultural biotechnology products, some have argued for food labeling as the means of informing the public about the process (i.e., agricultural biotechnology) by which a food has been created. This strategy has become standard in Europe and is under review in the United States.

The Food and Drug Administration established the current U.S. labeling policy in 1992 after extensive hearings and protracted consideration. That FDA policy states, in essence, that foods developed through biotechnology will be labeled only if they have been changed in some material way. For example, labels need to state whether the nutritional content has been changed in a significant way or if food safety concerns (e.g., an allergen) have been introduced. This current labeling policy is now under review by the FDA and Congress. In fact, the FDA has held three public meetings to gain input from industry and consumers about the most effective ways to provide consumers with information, including the viability of alternative labeling strategies.

The current discussion about the need for labeling is explicitly based upon "consumer preferences" rather than identified lapses in food safety or environmental safety. Some consumers may prefer to avoid foods produced through biotechnology for ethical, environmental, or social reasons. But because the current FDA policy is based on the end product rather than the process, previous guidelines for food labeling are not applicable.

In this regard, labeling should be seen as part of a larger movement to monitor and control production processes instead of products per se in commerce. Similar examples of labeling as a consumer choice issue include requests for labeling cosmetics developed without animal testing, labeling clothing or shoes made without sweatshop labor, and labeling fabrics made without child labor.

ISSUES:

Definitions of what is being labeled: The understanding of what constitutes "agricultural biotechnology" or what is a "genetically modified organism" (GMO) varies greatly from one group to another. Some definitions of biotechnology tend to be very broad, typically including the use of all technology or living organisms to modify plants or foods. There must be general acceptance of common definitions and agreement as to what aspects of biotechnology might trigger labeling. For most groups who are calling for mandatory labeling, this criterion appears to be the introduction of any genetic material from outside the species through recombinant DNA techniques (i.e., the production of genetically engineered plants or animals). Research has shown that consumers tend to have much less need for labels on processed food items than they do on whole produce items.

Methods for determining content: Labels must be based on clear and consistent guidelines for the procedures for determining biotechnology product content. Assays of introduced DNA are unambiguous, but many purified foods, such as seed oils, contain no DNA. New methods just over the horizon, such as chimeroplasty, present the prospect of foods that have been genetically modified without introducing any foreign DNA. Standardized methods of monitoring such materials are needed. It also is likely that some form of identity preservation will be needed so that it is possible to track and verify the production, storage, and shipment of grain through every step in the food value chain. The questions of certification/verification and preservation are a substantial challenge.

Threshold concentrations for labeling: A zero tolerance standard is unachievable. Therefore, labeling standards must be adopted that are achievable and that meet the public's need to have accurate labels that avoid misinformation. A related point is whether it is necessary to label meat or milk products when the animals have been fed plant materials developed through biotechnology. In this case it is unlikely that there will be any detectable differences in the meat or milk from cows that have been fed such plant materials or feed. To require labeling for such situations would make any verification system much more complex.

Positive versus negative labeling: There are two different approaches to identifying whether a whole food product has been produced through biotechnology, or whether it contains ingredients that have been genetically modified. One approach is referred to as positive labeling. When products of biotechnology and non-biotechnology product streams have not been segregated and the proportion of each is unknown, a positive label would state that the whole product might contain biotechnology products. This type of label is uninformative and does not help the consumer make intelligent choices. In another instance, especially when biotechnology has enhanced the consumer appeal of the product, the label could state that it does contain ingredients derived from modern biotechnology. Positive labeling may become more commonplace as food producers start using ingredients derived from biotechnology that provide tangible consumer benefits (although only the benefit may be stated—such as lower saturated fat—rather than the fact that biotechnology was used).

The second approach is to develop a system of negative labeling. In this case, the label on the product would indicate that the food does not contain any ingredients derived from modern biotechnology. This would be analogous to the "organic" food designation that emphasizes that the crops were grown without the use of pesticides or in ways that are viewed as beneficial to the environment. Under this approach, foods would be produced and marketed as being "biotechnology-free" or "not developed with biotechnology." This type of label is much clearer than a default positive label, which is based on lack of knowledge of the product's composition. However, "does not contain" labeling requires a system of product handling and certification that has not been developed. Minimizing the possibility of unintended mixing of biotechnology-produced and biotechnology-free products will require considerable restructuring of the current food processing system.

Segregated product streams: Labeling, especially negative labeling, requires segregation of product from harvest to table. The infrastructure and the technology are not currently in place to achieve this goal. Both need to be developed and optimized, and this will likely prove costly. Nonetheless, a negative approach to labeling would likely prove to be more efficient and effective. A premium price could be paid to all groups within the food production and processing system to offset the costs of segregation and verification. Models for identity preservation already exist for organic food and certain specialty products, such as the soybeans used to make tofu.

The difficulty and cost of segregation will vary from one commodity to another, depending on the size and the diversity of the standard "processing unit." For example, a standard bale of cotton represents the product from less than one acre of land and could be labeled according to type fairly easily within existing processing and distribution channels. The contents of a grain elevator, however, are aggregated from many farms, and segregation would be much more difficult without major structural changes in the distribution system.

Voluntary versus mandatory labeling: The current FDA approach requires mandatory labeling only when there is a definitive safety or nutritional change. Some consumer groups are calling for mandatory, positive labels that would indicate whether a processed food contains any ingredients derived from biotechnology. Recognizing the importance of consumer choice, the U.S. agricultural and food industries are now considering voluntary labeling as an alternative. A coalition of about 40 groups recently wrote a letter to President Clinton supporting such an approach. This preference is also reflected in the testimony given at the FDA public meetings by organizations such as the American Farm Bureau Federation and the Grocery Manufacturers of America.

All surveys over the past decade have found that between two-thirds and three-quarters of U.S. consumers are quite positive about food biotechnology. However, about 10 to 15 percent of the respondents were clearly opposed to the use of biotechnology. The best way to meet the needs of that group would be to provide a system of voluntary negative labeling for foods **not** produced through biotechnology that is truthful, informative, and non-misleading. Then if the demand is strong enough,the market will grow similarly to the growth of the organic niche market. In this way meaningful choice can be provided to the concerned minority without imposing costs on or denying benefits to the majority of consumers, who are generally quite supportive of biotechnology.

International harmonization on labeling: A number of countries, particularly in the European Union, have recently chosen to not follow the FDA labeling policy. They are moving toward mandatory labeling, although it is unclear whether the preferred approach will be positive or negative. This move requires attention to all the segregation and verification issues discussed above. It also poses a number of significant challenges to the established system of storing and shipping commodities in North America and elsewhere. The end result of forced labeling of substantially equivalent products will generally be higher costs and greater complexity to producers, processors, retailers, and consumers.

Calculating and distributing the full costs of labeling: Labeling based on the process of biotechnology where no nutritional or safety concerns are evident will involve costs to consumers and everyone else in the food production and processing system. The costs associated with identity preservation and verification for "biotech-free" foods could be significantly higher than for foods produced through bulk commodities, as is true with "organic" foods. There also are opportunity costs associated with biotechnology product labeling because there is only limited space on the label (i.e., other types of information will be left off). There also are psychological costs to consumers related to their having to learn about the use of biotechnology, adding another factor to their already complex food decision-making process.

Benefits and costs of labeling: Labeling foods made with biotechnology products is often put forward as a simple matter of providing information that would allow consumers to make better choices. But labeling is costly; thus, requiring labeling will be sound public policy only if the benefits of labeling exceed its costs. Little is known about either the benefits or the costs of labeling. On the cost side, more information is needed about the costs of segregating genetically modified crops and maintaining that segregation throughout the marketing chain. More information is also needed about the costs of monitoring compliance. For example, in some cases the presence of biotechnology crops in foods or feed cannot be detected by chemical analysis. In such cases, enforcing compliance with labels may require continuous monitoring at all stages of the marketing chain. On the benefit side, labeling is valuable only to the extent that it allows consumers to make informed choices.

Some would argue that labels are best suited to protecting consumers' rights to know and allowing them to choose products based on their own values. Others would argue that labeling is only useful in allowing economic choice and therefore better consumer purchasing and should only be used when the benefits of labeling exceed the costs.

Studies of demand for reduced pesticide residues on food suggest that consumer markets may be segmented; some consumers want purely "natural" products while others care only about whether their food meets reliable standards

for safety. If non-genetically engineered products can be certified and labeled and if they are more expensive, consumers will be able to "vote with their pocketbooks," seeking out their preferences in the marketplace. Whether the cost of food is higher or lower, the market will ensure that benefits will exceed the costs.

Values

There is considerable variance in the way that individuals and cultural groups interpret the significance of food biotechnology and in the standards that they would apply in evaluating its acceptability. As recent controversy attests, some people object to gene transfer technology in the strongest possible terms, while others pay little heed. Survey research has documented the range and distribution of public opinion on food biotechnology, and focus groups provide some insight into the bases for consumer opinion. However, the bases for variation in consumer acceptance of food biotechnology remain somewhat conjectural. Having a better understanding of the values that spawn opposition to food biotechnology will provide a better basis for understanding the criticisms and concerns and for responding to them. Three key areas bear on this issue.

Religious Studies and Freedom of Conscience: Many of the world's religions stipulate dietary rules as a part of religious practice, and some contain specific injunctions against crossing species lines. Religious doctrines about food consumption and preparation, including procedures for holidays and special events, may be interpreted to preclude genetically engineered foods. Religious groups vary with respect to the way that the interpretive judgment is made. Some churches have central hierarchies, while others delegate final authority to the spiritual leader of an individual congregation. There is, thus, the possibility that widespread dispersal of genetically engineered foods could limit religious believers' practice of their faith and that regulatory agencies working with one group of spiritual leaders will effectively disenfranchise others.

In addition, Constitutional protection of religious liberties is generally interpreted so as to protect individuals' rights to judge and act on the basis of their personal belief system, at least in their actions to not harm others or endanger public safety. Religion is just one basis for the formation of a belief system. Some individuals will act from belief systems grounded more on skepticism than faith, and their right to act on the basis of their skepticism is also protected. It is thus important to understand secular attitudes toward the consumption of genetically engineered foods and to accommodate the widest possible divergence of personal and religious values.

Comparative Politics: Some of the most obvious variations in attitudes to food biotechnology break down on national lines. Part of the variation may be the result of religious beliefs, but there are many other possible contributing factors.

- Legal Systems. Liability laws and lawsuits are a significant component of the U.S. legal system. They provide the potential for direct redress, and the threat of legal action structures business decision making. In many other countries, it is much more difficult to initiate or sustain a legal action under product liability. Consumers and government officials may place more reliance on the initial product approval process.
- Voting Rules and Political Structure. Minorities have a larger voice in the politics of nations that use proportional voting or multi-party coalitions to seat government officials. If only 5 percent of Americans opposed food biotechnology, it would cause little stir in our winner-take-all politics. Yet 5 percent would guarantee representation in the government in some countries.
- The Press. Journalists around the world operate under very different formal rules and follow very different journalistic traditions. In the United States, most science writing is done by a handful of reporters at the nation's elite news organizations (*NY Times, Washington Post*, CNN, the networks), though these stories may be carried by many local outlets. In the U.K., regular beat reporters write stories about food biotechnology. In Holland and Germany, newspapers carry extended debates on technology that demand greater technical sophistication than even U.S. science reporting.
- Consensus and Consent. The U.S. political style emphasizes individual rights and implies that a practice is acceptable as long as anyone who does not want to participate has the right to withhold consent. In many other parts of the world, political values would not typically be framed in terms of individual consent. They might, instead, stress the need for arriving at consensus as a function of national identity and cultural integrity.

Risk: Interdisciplinary research on risky technologies suggests that many features of the broader social and political context influence the way that members of the public evaluate risks. Recent or particularly memorable events, for example, lead people to increase their estimate of risk for new proposals. Furthermore, the manner in which science-based information is presented to the public affects the perception of risk. When information sources are judged to be solicitous, forthcoming, and trustworthy, the technology itself is judged to be less risky.

Human Research: Opponents of some forms of animal biotechnology appear to be concerned with the potential applications of the results to humans. This research link has historically been proven to be indisputably true, thus a better set of guidelines on where agricultural biotechnology should "draw the line" before research work on livestock is permitted is needed. In addition, there are ethical issues associated with animal research that are not dealt with in this report. These issues need to be addressed in some forum.

APPENDIX 1
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APPENDIX 2

A History of IPR

Efforts to secure legal protection for inventions related to living organisms while accounting for their self-replicating and natural origin started several decades ago. Improved plant cultivars, when propagated as clones, have been awarded protection since 1930 under the Plant Patent Act. Furthermore, Plant Breeders' Rights (PBRs) are patent-like rights for cultivated plants. PBRs were organized in 1961 under the International Union for Protection of New Varieties (UPOV), an international convention. The US adopted PBRs in 1970.

In 1980 the Supreme Court in the significant Chakrabarty decision extended the scope of utility patents to living organisms. Specific extension to plants was decided by the patent office in 1985 (Ex parte Hibberd) and to animals in 1987 (Ex parte Allen). Utility patent claims require demonstration of novelty, utility, and non-obviousness. By comparison, the tests for PBRs certificates are uniformity, stability, and distinctiveness.

PBRs and utility patents differ in some significant respects. PBRs make allowances for farmers' rights (farmer saved seed) and include a research exemption for the use of protected material in the development of new varieties. PBRs also apply to whole plants or propagating material. Typically they do not protect individual and unique characteristics of a protected variety. Accordingly, they provide no effective protection for biotechnology. Any singular bioengineered trait (e.g. a gene) can be legally copied and transferred to another distinct variety.

IPRs for living organisms are national rights and vary substantially from one country to another, both in coverage and enforcement. Patent rights for living organisms continue to be hazy in the European Union and many developing countries explicitly exclude plants and animals from patent or patent-like protection. The 1993 Uruguay Round of the GATT agreement changed this balance by recognizing that exports of industrialized countries tend to be technology-rich. As such, absence of IPRs protection in certain regions acts as a trade barrier. The Trade Related Aspects of IPRs (TRIPS) addition to the GATT agreement created a framework for increased standardization of IPRs for plants and animals around the world and the adoption of a minimum standard, in most cases PBRs.