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Issue Report

Opportunities and challenges for crop biotechnology

The widespread introduction and adoption of Roundup Ready®* soybeans and insect-resistant "Bt" corn and cotton just over a decade ago has reshaped the global food system, affecting everything from the production tools of farmers to consumer food choices. These and other biocrops are responsible for increasing yields of important field crops, creating international trade issues and generating heated discussions regarding their safety for human and animal consumption.

Biocrops, a term that includes transgenic crops and genetically modified (GM) crops, have become an important part of agriculture in a variety of crops, and are grown in at least 22 countries around the world. Biocrops are one tool for addressing production problems that have not been solved by more traditional technologies. Biocrops are a contribution, not a solution.

At the conference, *Second Decade of Crop Biotechnology: Opportunities and Challenges for the Food System*, industry, government and academic leaders explored how the lessons learned from the first decade of crop biotechnology will shape future strategies (see *The Source*, page 4). To address the opportunities and challenges facing food, feed, fiber and biofuels production, while preserving the environment and minimizing negative climate changes, better understanding is needed of the costs and benefits of crop biotechnology, alternative production strategies and consumer choices.

What we know

Farmer adoption: Farmer adoption of biocrops has been faster and more extensive than anyone anticipated. Introduced to the market 12 years ago, herbicide tolerant soybeans are now planted on more than 90% of U.S. soybean acreage. In 2006, more than 250 million acres of biocrops were planted in 22 countries across the globe.

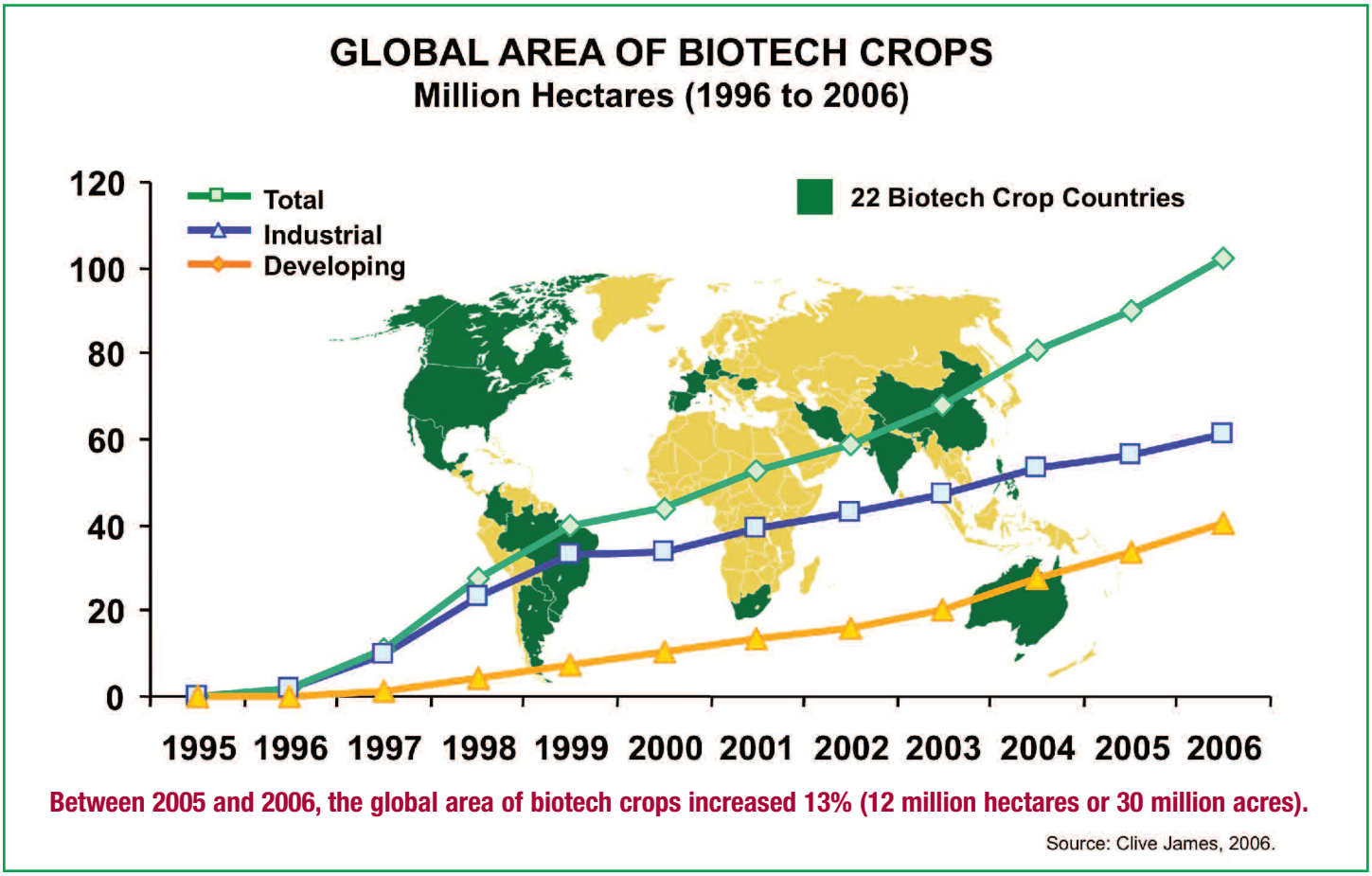
Benefits of biocrop use: To date, most of the benefits of biocrops have been aimed at farmers: increased yields; increased net returns; management time savings; and reduced pesticide use, cost and exposure. The benefits vary depending on the specific crop and GM characteristic. Insect-resistant cotton has provided both increased yields and net returns to farmers. Herbicide tolerant soybeans have, in general, not resulted in increased yields or higher net returns; rather, savings have been realized in management time, which may allow off-farm employment. Additional benefits of herbicide tolerant soybeans are the use of more benign herbicides and the adoption of no-till or reduced-tillage farming practices that help conserve soils.

Regulatory systems have been challenged: Protecting the quality and safety of food is an important public concern and a key role for governments, along with maintaining public confidence, facilitating trade and identifying broader environmental risks. The introduction of biocrops presented new challenges for regulatory systems to understand the new crop products and to develop appropriate and science-based regulatory systems.

Most of the important field biocrops produced in the United States are also exported to foreign markets. The industry has learned that approval in the United States is not enough to avoid trade disruptions; simultaneous regulatory approvals in key markets are essential.

Approvals for biocrops have been difficult and expensive to obtain, particularly in Europe. Approvals in Europe are complicated

* Roundup Ready is a trademark of the Monsanto Company.



by the multi-country system and consumer response to the technology. Different issues have greater salience in Europe, such as traceability and labeling (required for biocrop products).

Unintended Consequences: With the introduction of any technology, unintended consequences can be expected. To date, there has been little or no observed impact on human or animal health from biocrops. Most of the impact has been on trade, especially when biocrops have been found where they were not intended ("adventitious presence"). There will likely be future unforeseen consequences of the deployment of biocrops, despite extensive efforts by regulatory agencies and industry to identify what such consequences might be.

What is changing

Globalization of biocrop development: Farmer adoption of biocrops is spreading globally. Significant growth in acreage is expected in Asia and Brazil, while slow to moderate growth is expected to continue in Africa and the European Union. To date, seed suppliers have sought to leverage products developed for the U.S. market by introducing them to international markets. In the future, expanded development of products addressing the needs of local markets or regions, such as insect-resistant eggplant in India, is expected.

New traits and crops: New traits and crops are being developed. Continued "stacking" of multiple traits in individual biocrops is anticipated as farmers come to expect multiple advantages in the seeds they purchase. Some of the new traits expected include:

- Additional herbicide tolerance and insect resistance
- Quality traits of interest to processors and consumers, such as healthier oils or better taste
- Environmental stress tolerance, such as drought tolerance
- Plant disease resistance
- Enhanced nutrient utilization efficiency, especially nitrogen
- Biofuels applications, such as increased levels of starch and oils, or increased value of co-products
- Production of pharmaceutical and industrial products and biomaterials in plants

Biofuels development: The growing biofuels market has generated opportunities in crop biotechnology. Yield increases have and will continue to be an important goal. Research is being pursued not only in conventional biofuels crops, such as corn and soybeans, but in forest species and perennial grasses. This potential market has boosted crop biotechnology, especially investments in product development firms.

An increasingly strong correlation is emerging between the price of energy and the price of commodities used to produce food and biofuels. Higher energy prices impact the price of food directly through petroleum-based inputs and

transportation costs, and indirectly by competition for crops to produce biofuels.

Environmental concerns: In recent years, there has been increasing concern and research addressing the environmental consequences and sustainability of biocrops. Requirements for formal environmental impact statements have increased, even to address changes in the scope of regulatory programs. The biocrops industry has established stewardship programs to enhance food and environmental safety. Assessment and measurement tools are evolving to better identify and quantify environmental risks.

The rise of "academic capitalism": Many innovations in crop biotechnology originated in universities, usually with support from the federal government and/or industry. The legal right of universities to own and control patents relating to those innovations has provided university personnel with opportunities to generate licensing revenue and create start-up companies. This has stimulated entrepreneurship on campuses. University administrators experience new pressures to add local and regional economic development to their organizational missions, along with teaching and research. There has been some concern about the impact of industrial relationships on academia. An extensive research project found that the values and interests of academic researchers are the primary drivers of university scientists' research agendas. Industrial funding was found to be correlated with more applied university research, as might be expected.

Intellectual property protection: In crop biotechnology, there are a number of ways inventors can protect the intellectual property (IP) they create. These include plant patents, plant variety protection and utility patents, the primary means for protecting IP in crop biotechnology. In the developed world, there are likely to be layers of patent protection for any one biocrop, including patents for the trait of interest, for elements used to control how that trait is expressed in the plant, and for how crops are created and used. Obtaining "freedom to operate"—the ability to market a product without infringing another's patents—is costly and extremely difficult. It is a barrier to the development of new biocrops, particularly for small companies and for specialty crops with relatively small markets.

Some biocrop researchers are trying new approaches to IP protection, including an "open source" approach, employed initially in agriculture and more recently in some computer software development applications. This approach raises many issues, and it is too soon to assess its potential with biocrops.

In the developing world, there are different concerns regarding IP rights. Difficulty in securing and enforcing IP rights protection is often cited as a limitation on use of biocrops in the developing world. Developing countries often do not have strong laws that protect IP, and/or may not have the legal system in place to protect IP rights. Companies are often reluctant to invest in the development of technology where there is limited opportunity to obtain legal protection. As scientific capabilities grow in developing countries, it is expected that there will be increasing interest in protecting inventions, and IP systems will become more robust, especially where they can be used to protect local inventions.

Projects in the developing world: While India and China are actively developing biocrops, other developing countries are only slowly embracing the technology. A number of public-private investment approaches have been used. Collaborations among private companies, public funding organizations and local researchers are investigating ways to use the technology to address local needs. For example, genes developed by Monsanto have been provided to support development of insect-resistant eggplant in India and cowpea in Africa, with support from research organizations in developed and developing countries. Financial support has come from public sources and humanitarian organizations.

What we need to know

How to balance the needs of stakeholders in biocrops: The stakeholders in biocrops are as numerous and diverse as in the food system as a whole. Their interests are complex.

- Farmers need the best and most appropriate tools to produce agricultural products and to enhance their incomes and quality of life. Farmers desire a choice of markets, and don't want the production choices of neighboring farmers to impact the quality of their own production—for example, the appearance of transgenes in organic produce.
- Consumers want safe food and choice in food products—variety of foods, organic or conventional production, costs, and nutrition. Consumers in the developed world have relatively low food prices compared to total expenses, while consumers in the developing world pay a significant portion of their incomes for food. Significant increases in food costs will add to the economic misery of many. Alleviation of poverty will require that agricultural production technologies more than keep pace with food consumption needs.
- Developers of crops for biofuels are concerned about competition of fuel production with food, feed and fiber uses, as well as sustainability with regard to soils, wildlife and other aspects of the environment. More research is needed to understand the risks and benefits of alternative agricultural production.

How to develop appropriate regulatory procedures: The science of risk measurement has developed in tandem with the technology, yet work is still needed to improve methods to measure risk and to communicate both risks and benefits. New types of biocrops will create new challenges for regulatory agencies. Regulatory flexibility and the ability to respond to scientific advances with new legal frameworks are important. "Conditional" or "unconditional"

approvals are one option under consideration by regulators, as are modifications to the strict event-by-event approvals—regulating separately each biocrop produced by one genetic engineering procedure. Tiered approaches with differing risk profiles are being considered. Better methods to measure and manage the presence of transgenes outside of the intended, planted crop (adventitious presence) are also important. International harmonization of regulatory procedures and data requirements will be important for managing the risks and costs of the technology. Another question is how to determine an acceptable risk/benefit ratio.

How to meet global food demands: Agricultural production will have to double to feed the nine billion people expected to inhabit the world in 2050. Increased demand is also expected for fiber and animal feed. The increasing demand for biofuels must be balanced against demands for other agricultural products. Biotechnology should be viewed as a contributing means to address these needs, not a solution for them in their entirety. Increased productivity and improved yield stability are both important to meet production needs and preserve the environment.

An important element of this is environmental management. The amount of arable land is limited and it is important to protect soils and also wilderness areas. Rather than simply maximizing yields, focus is needed on optimizing yields for greater productivity per unit of input. Such a change in focus is complex, requiring enhanced farmer education and the development of better analytical tools to aid decision-making.

How will a changing climate impact agriculture: To optimize production in a potentially more variable climate, farmers will need tools to stabilize yields. Drought tolerance and heat tolerance traits may be needed to ameliorate the effects of climate change. Awareness is also needed of the potential for new opportunities, like biofuels, to provide solutions for or to create additional climate issues.

Non-obvious impacts: Biocrops have a diverse range of impacts, including pest resistance management, liability questions and public confidence.

- Pest resistance management. Regulators are concerned about pests developing resistance to the pesticides present in biocrops and, in some cases, have required the use of refuges to prevent or slow the development of such resistance. Greater understanding is needed of when and where such pest resistance develops and of the effectiveness of current management practices.
- Liability. If pollen from a biocrop drifts to a neighbor's field where the farmer is trying to grow an organic crop, and the organic crop shows traces of the biocrop, who is liable if the crop cannot be sold as organic? If an unapproved biocrop shows up in bins of commodity crop, who is liable for the cost of destruction of the commodity crop? Better methods of detecting transgenes are needed, along with the development of systems to establish liability.
- Public confidence. Little or no material damage has been caused by the consumption of biocrops. There have, however, been containment problems reported in the media, creating issues of public confidence in the technology and its developers. What approaches are needed to educate consumers and enhance public confidence?

The Source

More than 90 leaders in agriculture, government and academia participated in the conference, *Second Decade of Crop Biotechnology: Opportunities and Challenges for the Food System*, January 16-17, 2008, in Washington, DC. Sessions addressed crop biotechnology in the food system, focusing on issues related to crop production, regulation and food safety, private and public investments, biodiversity and the environment, biofuels and global food issues. This *Issue Report* is based on closing comments by Dr. Ann Bublitz, who, with assistance from Dina Biscotti, summarized what is known, what is evolving and future information needs.

The conference was organized and sponsored by Farm Foundation, and received additional sponsorship from Jeanne M. Sullivan; USDA Animal and Plant Health Inspection Service, Biotechnology Regulatory Services; USDA Agricultural Research Service; USDA Economic Research Service; Monsanto Company; J.R. Simplot Company, AgriBusiness Group; Bayer CropScience; BASF Plant Sciences; BioTech Decisions, Inc.; and Athenix Corporation. Conference presentations are posted on the Farm Foundation Web site, *www.farmfoundation.org*.

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This publication is intended to be a vehicle to stimulate discussion and debate about challenges facing agriculture and rural America.