

Benefits of Biotechnology --A United States Case Study

Edward E. Debus¹

Abstract

The commercialization of plant biotechnology products in the United States offers evidence that biotechnology will deliver solutions to our world's growing food needs. Global pressures are driving the need for genetically modified plants. The U.S. regulatory process is a model of coordination of the review of new plant biotechnology products within an existing regulatory framework. The concept of substantial equivalence -- judging plant biotechnology products to determine their nutritional, compositional and safety equivalence to foods developed through traditional plant breeding -- has been critical in the United States to the successful commercialization of products of biotechnology. This concept has been the key to the implementation of workable, effective guidelines for assessing food safety. Media and consumer acceptance have been gained through the cooperative efforts of business, government, and trade and health organizations. Similar cooperation on a global scale will help biotechnology fulfill its long-term promise of providing safe, abundant food and a healthy environment worldwide.

Introduction

For more than 15 years, many people at Monsanto have worked toward the discovery and acceptance of a number of new crop varieties improved through genetic engineering. During this period, we have learned a great deal about all aspects of biotechnology: research, development, regulatory approval, and market acceptance. We have worked long and hard to move our products from the early research phase, through field trials, seed production and now commercial sales. This year, several of our new products are commercially available for the first time. Today I am pleased to be able to share with you some of the valuable lessons we have learned about market acceptance.

While many of my comments stem from our progress and experience in North America, I believe they are relevant and applicable on a global scale. Experience is building rapidly in many areas of the world and global advances indicate that the world is ready for biotechnology. This is a key point that I will expand on throughout my presentation.

I will begin today by reviewing Monsanto's first product interests, highlighting the significant product benefits now available to growers in North America.

¹ Global Regulatory Acceptance, Ceregen, a Unit of Monsanto Company, 700 Chesterfield Parkway North St. Louis, MO 63198 USA

Next, I will summarize the regulatory progress to date, using our Roundup Ready soybeans as the model.

Then, I will turn to the focus of this presentation: lessons we have learned about product acceptance in the marketplace.

Monsanto's plant biotechnology products

Monsanto is working to harness biotechnology to meet modern growers' needs. Since the early 1980s, we have focused our research and development programs on the selection of beneficial agronomic and food quality traits in the following benefit categories:

- insect protection
- virus protection
- herbicide tolerance
- quality and functional improvements

Insect control is an ongoing challenge for growers. To meet this challenge, Monsanto has developed three new products with built-in insect protection that I would like to mention today. The first product is an improved potato plant that resists the Colorado potato beetle. Growers apply approximately one million pounds of insecticide to potato plants in the United States each year to control this devastating insect pest. Monsanto's insect-protected NewLeaf potato eliminates the need for chemical insecticide applications to control the beetle. Growers have been very receptive to the performance of the product and consumers have responded positively because of the decreased need for insecticides. The U.S. regulatory agencies granted NewLeaf potatoes approval in May 1995 and the potatoes now are in traditional market channels.

Monsanto's insect-protected cotton, called Bollgard cotton, also gained full regulatory approval and entered traditional market channels in the United States. This product, which has been genetically engineered for protection from damaging caterpillars, again reduces the need for insecticide applications.

Monsanto's YieldGard corn, genetically engineered to protect against the European corn borer, will enter the market in 1997. There are other companies with insect-protected corn products already in the marketplace today.

Viruses, another form of plant pest, are devastating to certain types of crops, such as potatoes. Monsanto expects to have a combination virus- and insect-protected potato on the market within several years. These combined traits will eliminate more than 90 % of the insecticides applied to potatoes in some areas.

In addition to the development of crops that protect against insects and viruses, Monsanto has carefully researched crop developments that control the devastation of weeds. After years of research, Monsanto has introduced herbicide-tolerant soybeans

that are genetically improved to be tolerant to glyphosate, the active ingredient in Roundup herbicide. This improvement eliminates the need for multiple herbicides to control specific types of weeds and thus reduces herbicide use. It enables growers to use Roundup herbicide, which is widely recognized as an environmentally sound and effective non-selective herbicide.

According to a 1992 study conducted by the Weed Science Society of America (Weed Science Society of America, 1992), U.S. farmers who use traditional weed-management strategies lose approximately US \$4.6 billion worth of crops each year due to weeds. A farmer planting 50 to 100 acres must control something in the order of two billion weed seeds to prevent the crop from starving to death in competition with weeds. Roundup Ready soybeans allow growers to apply Roundup herbicide over the top of the crop for improved weed control. We predict that growers who planted Roundup Ready soybeans in 1996 will reduce herbicide use by up to one-third and experience improved weed control.

Reaction to the introduction of Roundup Ready soybeans by growers in the United States has been quite favorable. A farmer reports from trials last year on his 900-acre farm in New Madrid, Missouri: "With Roundup Ready soybeans, I had the cleanest beans I've ever had! I'd say there were less than 10 weeds in the whole 120 acres when I came through the harvest. Roundup will kill a large weed or a small weed. If your conditions are such that you can't spray on one day due to wind or weather, go ahead and wait. Roundup will still control the weeds." From a 2,500-acre farm in Ripley, Tennessee came this favorable report: "With Roundup Ready soybeans, Roundup just does its job. I don't have to worry about carryover [herbicide] damage in my rotational crops" And from a 1,000-acre farm in Marion, Arkansas, an enthusiastic farmer states that, "... Roundup Ready soybeans are just an all-around good product. ... Control was excellent. Crop safety was excellent. You have a much wider window for over-the-top weed control. They are versatile in all tillage systems. ..."

The Monsanto team also developed Roundup Ready canola varieties and have introduced them commercially in Canada this year.

Although plant developers have focused much of their work on crop pests -- insects, viruses and weeds -- they have also directed a great deal of attention to the development of crops with quality traits, such as improved taste, texture, composition, nutritional content, and new functionality. The first biotechnology plant that entered the U.S. market is an example of quality improvement. In the spring of 1994, Calgene's McGregor tomato with the Flavr Savr gene received final U.S. regulatory approval and is currently on the market, allowing us to enjoy full-flavored tomatoes in all seasons.

Insect-protected crops; virus-protected crops; herbicide-tolerant crops; and crops with quality and functional improvements -- these are just a few examples of the many different plant applications for biotechnology. But the applications cannot be used if they cannot be commercialized successfully. This brings me to the second area I want

to address today: the regulatory process for reviewing and approving plant biotechnology products.

Regulatory progress to date

Roundup Ready soybeans provide an excellent illustration of the regulatory acceptance pathway for genetically engineered crops. Glyphosate-tolerant soybeans have full approval in the United States, including approval for farmers to grow the soybeans and apply Roundup herbicide during the growing season. They have approval in the European Union for importation and processing into food and feed. The United Kingdom and the Netherlands, which have applicable food safety requirements, have likewise granted approval. Glyphosate-tolerant soybeans also have been approved in Canada and Argentina. They have been approved in Japan for importation and growing. Food and feed safety approvals still are pending, but are expected before harvest. Mexico, a major user of soybeans, has acknowledged that these soybeans will be accepted there. Approvals are advancing around the world.

Two important considerations are fundamental to regulatory approvals for glyphosate- tolerant soybeans and for all genetically improved crops.

First, the safety of genetically improved crop varieties can be confirmed by demonstrating their substantial equivalence to traditionally bred crop varieties on the market. The concept of substantial equivalence is critical to the successful commercialization of many products of biotechnology. Equivalent in this regulatory context means that there is no meaningful change in the nutritional value or composition of the improved crop variety. This concept is grounded in traditional, modern plant breeding and has been the key to implementation of workable, effective guidelines for assessing food safety.

Second, we must apply scientifically sound principles for required labelling of a new product. The U.S. Food and Drug Administration (FDA) does not require special labelling of products that are substantially equivalent to their traditional counterparts. (However, sometimes equivalence is not the goal, such as with crops designed for a specific nutrition profile.) FDA's labelling guidelines are crafted to inform and protect consumers by providing necessary information. FDA requires labelling of a genetically modified food (or a food developed by any other method) if there is a scientifically established issue of safety, such as the introduction of a known allergen; if there is a significant change in nutrients or composition; or if there is a change in identity, in which traditional names of the food do not apply. For all of our food products it is critical that we maintain these guidelines so that consumers are protected, but not overwhelmed with confusing or trivial information.

Product acceptance in the local marketplace

A science-based regulatory oversight process is crucial to marketplace acceptance of

commercial plant biotechnology products. But regulatory success is not enough. Our experience in the United States has taught us four valuable lessons about market acceptance that I want to share with you now.

First, we must continue to provide the growers with agronomic benefits and/or added value from the new crop varieties. I am pleased to report that the grower demand for our new crop varieties has been outstanding and, to date, product performance is excellent. As an example, Roundup Ready soybean seed was sold out in the United States this year.

Second, we have learned that it is important to communicate effectively about our products to business and government leaders, trade associations and other influencers -- including professionals in nutrition, dietetic and health fields -- in order to build strong coalitions for support of the products and to gain public acceptance of biotechnology.

Third, we have learned to work effectively with the media and have built long-term relationships with media leaders. This commitment includes providing the media with honest, timely information during product development and commercialization, a commitment we continue to adopt. People tend to feel uncertain about new technology. It is essential for developers of biotechnology products to dispel concerns by providing factual information. We have learned to position our company as a resource to the media both in the United States and beyond. We believe that honest communication encourages media, industry leaders, government agencies and consumers to trust our research and recognize that we are a credible voice in the biotechnology conversation.

Finally, a discussion of acceptance in the marketplace would not be complete without assessing the level of acceptance of biotechnology by consumers. Consumer research tells us that the acceptance level is growing.

According to U.S. consumer surveys conducted in 1992 (United States Department of Agriculture, 1992) and again in 1994 (Grocery Manufacturers of America, 1994), consumer awareness and acceptance of biotechnology have not changed significantly despite a considerable amount of media coverage. Both studies found that consumers know very little about biotechnology. In the 1992 study, after respondents received additional information about biotechnology, two-thirds agreed that the science will personally benefit them within the next five years. Sixty-four % of these respondents supported the use of biotechnology in agriculture and food production, a value nearly identical with the level of support found in the 1994 survey (66%).

Support for specific crop improvements also varied only slightly in the two studies. About four out of five consumers said they accept most insect-protected food crops and herbicide-tolerant crops. They were less receptive to some other biotechnology improvements such as increases in the size of sport fish.

A 1995 Food Marketing Institute (FMI) survey (Food Marketing Institute, 1995), Trends in the United States: Consumer Attitudes and the Supermarket, confirmed that biotechnology is not a top-of-mind issue with consumers. On an unaided basis, fewer than 0.5 % of the more than 1,000 consumers surveyed identified biotechnology

as a perceived threat to food safety.

Fortunately, the results of consumer research conducted in the United States in the past two years indicate that most U.S. consumers accept biotechnology and welcome the benefits it brings. But what about public opinion and levels of public acceptance in other parts of the world?

In general, research from other countries indicates that while most consumers know very little about biotechnology, many of them are interested in learning more about it. And they are optimistic about its potential impact on food production. For those consumers who are familiar with the term biotechnology, the majority has not yet developed a "position" on the issue.

Let us look first at Canada. Multiple indicators support our basic premise that public attitudes about biotechnology still are in the formative stages . . . and that people are open to the idea. A 1993 Canadian Institute of Biotechnology study (Decima Research, 1993) reported that two-thirds of Canadian adults surveyed said they believe biotechnology offers "some" or "a lot of benefit". The study also reported that generally, "Biotechnology is comparably the strongest when it can replace the use of chemicals in the environment."

Consumers in the United Kingdom were surveyed in March and April of 1995. Monsanto commissioned a series of 10 focus groups and 13 individual interviews in various parts of the UK, designed to reach people who could be expected to have a specific interest in or strong attitude about food, such as parents of young children or people with dietary problems.

Across the board, most of the UK consumers surveyed were not aware of biotechnology research or its products on the horizon. Those with some level of awareness tended to have a knowledge of medicine or familiarity with farming.

After being given further explanation of what biotechnology entails, the UK participants expressed less concern about the use of technology with plants than with animals. In addition, they were generally more receptive to biotechnology food products that maintained their naturalness. For example, most participants said a new seedless grape would be acceptable because it is merely an improvement on the "original" grape.

UK respondents also indicated that biotechnology products offering positive environmental benefits, such as a reduction in pesticide use, were likely to enhance consumer acceptability.

Now I would like to tell you what we have learned about consumer acceptance in Japan. In September 1995, we commissioned a study on Japanese consumer awareness and attitudes about biotechnology. We determined that the vast majority of the Japanese consumers are very positive about the use of biotechnology in general, exceeding even support observed in the United States. For example, 93 % of the respondents in Japan believe that biotechnology will benefit them in the next five years, compared to 67 % in the United States. In fact, more than three-quarters of the Japanese consumers surveyed believe biotechnology already has benefited them or

their families.

The study also concluded that Japanese consumers react most favorably to crops with reduced need for pesticides: 73 % view it as acceptable, while another 16 % are neutral.

The single most important lesson we have learned from this worldwide research is that many consumers from many different countries share similar opinions. That is encouraging, given current food production and distribution practices. As you know, long gone are the days when food grown by a local farmer was sent to a local market to sell to local customers. The food industry today is global, complex, challenging, and interrelated.

Conclusion

Biotechnology is not just a theory any more -- it is a market reality. Fortunately, as we have learned, current consumer research on acceptance of biotechnology indicates that worldwide public acceptance is building quickly. In summarizing Monsanto's experiences, three important needs emerge as we continue to foster this acceptance:

1. The need for appropriate, knowledgeable, science-based regulatory oversight that provides timely judgment and the flexibility to learn from experience.
2. The need for food supply providers and allied food and health professionals to gain a basic understanding of biotechnology products; their benefits; safety; and the regulatory oversight in place.
3. The need to understand consumer behavior to ensure that consumers will accept plant biotechnology products, and will demonstrate their acceptance by continuing to purchase food as they have in the past.

Thank you again for letting me share our experience. Through international symposia like this, we will continue to strengthen our commitment to ensuring that biotechnology fulfills its long term promise: providing safe, abundant food and a healthy environment worldwide.

References

- 1) Commissioned by the Canadian Institute of Biotechnology (1993) : Decima Research 1993 Survey Summary. Public Attitudes Towards Biotechnology, p. 2.
- 2) Food Marketing Institute (1995) : Trends in the United States: Consumer Attitudes and the Supermarket, 1995.
- 3) Grocery Manufacturers of America (1994) : Consumer Awareness and Acceptance of Bovine Somatotropin.

- 4) United States Department of Agriculture. (1992) : Consumer Attitudes About the Use of Biotechnology in Agriculture and Food Production, July 1992.
- 5) Weed Science Society of America, (1992).