

USDA-APHIS's 7 CFR Part 340 Regulations Governing Plant Biotechnology

Frequently Asked Questions

October 6, 2008

1. **What is agricultural biotechnology?**

Agricultural biotechnology is an advanced technology that allows plant breeders to make precise genetic changes to impart beneficial traits to the plants we rely on for food, fuel and fiber.

For centuries, farmers and plant breeders have worked to improve crop plants. Traditional breeding methods include selecting and sowing the seeds from the strongest, most desirable plants. By selecting and breeding plants with characteristics such as resistance to pests and herbicides, farmers can grow healthier plants with fewer pesticide applications, and even increase their plant yields on less land.

2. **Is biotechnology fundamentally different from other breeding techniques?**

No. Biotechnology is a refinement of breeding techniques that have been used to improve plants for thousands of years. The 20th century, in particular, saw the development and application of many new techniques to transfer genes between related and even unrelated species for crop improvement. Biotechnology is the latest in a long line of increasingly powerful tools for enhancing crops.

3. **What are examples of agricultural biotechnology products currently available?**

Crops designed to resist insects and viral pests or tolerate broad-spectrum herbicides account for most of the biotechnology crops available commercially.

Bt corn and cotton incorporate select genes from the widely used biological control agent *Bacillus thuringiensis* to resist the European corn borer and pink boll worm, respectively. Bt sprays have been used to combat these pests for many years. The Bt genes allow the crop to produce the pesticide safely within the plant, eliminating the need to spray for these pests.

Important commercial plants that have been modified to resist viral infection include potato, squash, cucumber, watermelon, and papaya, among others. These plants resist viruses, allowing farmers to grow these plants with fewer pesticide applications to control virus-carrying insects.

Soybean, corn, canola and other crop plants have been modified to tolerate safe, broad-spectrum herbicides. Herbicide tolerance allows farmers to use weed controls more selectively. Rather than applying herbicides before planting, farmers can wait until after the crop emerges to apply herbicides only where and in the quantities needed. With enhanced weed control, more of the soil nutrients are available for the crop rather than the weed.

Scientists are also looking to use biotechnology to fortify some food plants with higher nutritional content and to produce pharmaceuticals in plants affordably and efficiently.

USDA-APHIS's 7 CFR Part 340 Regulations Governing Plant Biotechnology Frequently Asked Questions

4. **What are examples of agricultural biotechnology products in development?**

Future crops will be designed to tolerate environmental stresses, such as salty or toxic soils, drought, and freezing temperatures. Other advances include a promising array of products that will offer more efficient use of nitrogen fertilizers, improved yields, enhanced nutrition, medicinal properties and vaccines, healthier cooking oils, extended shelf life, renewable resources and industrial feedstocks, and other desirable products. These new varieties of plants could open new markets to farmers and provide enhanced food products to consumers.

Safety

1. **Does biotechnology pose any unique risks?**

No. In a 1987 report, the National Academy of Sciences (part of what is now called the National Academies) determined that “There is no evidence that unique hazards exist either in the use of r-DNA techniques or in transfer of genes between unrelated organisms. The risks associated with the introduction of r-DNA organisms are the same in kind as those associated with the introduction in the environment of unmodified organisms and organisms modified by other genetic techniques.” Subsequent reports by the National Academies and other scientific bodies have reaffirmed this view. This scientific consensus continues to inform the U.S. regulatory policy, which focuses primarily on the characteristics of the new crop variety, not the method used to produce it.

2. **Are crops developed using biotechnology as safe for the environment as crops developed using traditional breeding practices?**

Yes. Extensive scientific evaluation worldwide has not found any examples of ecological damage from biotechnology crops. Many published studies—from the National Academies, the Organization for Economic Cooperation and Development, the Council on Agricultural Science and Technology, and others—have arrived at the same conclusion: Biotechnology-derived crops pose no unique risks to the environment compared with similar crops produced using traditional techniques.

Each plant variety is subject to extensive field-testing under the oversight of the U.S. Department of Agriculture (USDA) and the Environmental Protection Agency (EPA). To date, there have been no instances of a biotechnology-derived plant approved for field-testing either creating an environmental hazard or exhibiting any unpredictable behavior compared with similar crops modified using traditional methods.

3. **Are foods produced using biotechnology as safe to eat as foods produced using traditional breeding practices?**

Yes. Federal regulatory agencies ensure the safety of foods derived from biotechnology. To date, no approved foods derived from biotechnology has harmed human health.

For over two decades, the products of biotechnology have been assessed for safety using science-based regulatory and nonregulatory mechanisms developed over the last half century for all crop plants. Biotechnology plants are among the most tested in history.

A number of prestigious U.S. and international scientific bodies – such as the U.S. National Academies of Science, the United Nations Food and Agriculture Organization, the World

USDA-APHIS's 7 CFR Part 340 Regulations Governing Plant Biotechnology Frequently Asked Questions

Health Organization, the Organization for Economic Cooperation and Development, the American Medical Association, the American Dietetic Association, the Council on Agricultural Science and Technology, the Institute for Food Technologists, the International Council for Science and the British Medical Association – have determined that biotech crops are as safe as similar crops improved through traditional and organic breeding methods.

4. **Do foods produced using biotechnology require special labeling?**

No. The U.S. Food and Drug Administration (FDA) applies the same labeling standards to foods produced through biotechnology that are applied to all foods produced using traditional methods. Federal law requires labeling of a new food to inform consumers when there are significant changes in nutrition, safety or usage, or if the common name of the food no longer applies.

The FDA's evaluation of a food derived from biotechnology focuses on its characteristics, not the method used to develop it. A new biotechnology product that is “substantially equivalent,” meaning it has a similar composition and nutritional value to similar varieties currently on the market, would not require a special label because it would not provide the consumer with meaningful information on the new food's safety or nutritional value.

However, the FDA may require extensive premarket testing and special labeling if the source of the genetic change has not been previously consumed in the diet or is from a common allergen. For example, any product that used a gene from a peanut, which is a potential allergen, would be subject to testing and labeling requirements.

BIO strongly supports the existing food labeling policy of the FDA. To require the labeling of foods that are indistinguishable from foods produced through traditional methods would mislead consumers by falsely implying differences where none exist. It also risks diverting attention from important safety and nutritional information. BIO agrees with the FDA that labeling standards should be science-based to give consumers meaningful information about the foods that they buy and eat.

Regulation

1. **Are the products of agricultural biotechnology regulated?**

Yes. The U.S. regulatory system, which enjoys a high degree of public confidence, employs rigorous scientific reviews within a transparent decision-making framework open to public participation. This regulatory approach provides full access to documents on which decisions are based and is carried out completely in the public eye as required by law.

Biotechnology products in the United States are regulated according to a system, the Coordinated Framework, established by the Office of Science and Technology Policy in 1986. Deriving its mandate from existing laws regulating food safety and agriculture, the Coordinated Framework assigns lead responsibility for biotechnology products to the appropriate regulatory agency and sets out principles for cooperative reviews in areas where responsibilities or authorities overlap.

The regulation of agricultural biotechnology products is handled by three agencies:

USDA-APHIS's 7 CFR Part 340 Regulations Governing Plant Biotechnology Frequently Asked Questions

- 1) **The U.S. Department of Agriculture Animal and Plant Health Inspection Service (USDA APHIS)** - APHIS oversees the field-testing of biotechnology-derived plants as “regulated articles” to ensure that the environment is protected. A petition for nonregulated status must be granted by APHIS prior to commercial growth and sale of any bioengineered crop.
- 2) **The U.S. Food and Drug Administration (FDA) Center for Food Safety and Nutrition** - The FDA imposes on foods developed through biotechnology the same regulatory requirements FDA uses to safeguard all foods in the marketplace. The FDA has both premarket and postmarket authority to regulate the safety and labeling of all foods and animal feed. Foods from biotechnology are judged on their individual safety and nutrition, not the methods used to produce them. Under federal law, the producer of a food has the legal obligation to ensure its safety to consumers, and FDA may pull from the market any foods found to be unsafe. Since 1992, FDA has used a voluntary review process for biotechnology foods. Over 50 such products have been reviewed, and none has been found to pose a safety concern.
- 3) **The U.S. Environmental Protection Agency (EPA)** - The EPA is responsible for ensuring that pest-resistant biotech varieties are safe to grow. It regulates environmental exposure to these crops to ensure there are no adverse effects to the environment or any beneficial, nontarget insects and other organisms. The agency also regulates bioengineered microorganisms under the Toxic Substances Control Act.

2. Why does USDA-APHIS want to revise its 340 regulations governing plant biotechnology?

To address the latest science, increase flexibility, and address changes in the global marketplace, APHIS has proposed several revisions to its rules. These proposals, and other alternatives not selected by APHIS, were thoroughly discussed and analyzed in a draft programmatic Environmental Impact Statement, published in 2007. Briefly, APHIS proposes to make the following changes in the regulations:

- Expand the scope of organisms and non-living genetically engineered material that APHIS regulates;
- Increase the flexibility and transparency of both the permitting and deregulation processes;
- Address low-level presence of regulated material in commodity crops; and
- Address the importation of genetically engineered commodity crops from other countries.

3. How long will USDA-APHIS take comments on its revised 340 regulations?

The public will have opportunity to provide input during a 45-day comment period. This assures transparency which BIO believes is essential within the regulatory process.

BIO and its member companies are reviewing the agency's proposed revisions and will submit comments. Science-based regulations, implemented in a timely and transparent manner with adequate input from industry stakeholders, will help farmers use agriculture biotechnology to produce high quality crops to feed and fuel the world's growing population.

USDA-APHIS's 7 CFR Part 340 Regulations Governing Plant Biotechnology Frequently Asked Questions

Environmental Benefits

How can biotechnology help agriculture be more environmentally-friendly?

Future crops designed to tolerate environmental stresses, such as salty or toxic soils, drought, and freezing temperatures, will make agriculture more efficient and sustainable by producing more food, fuel and fiber on less land. Biotechnology can also be used to produce renewable plant-based energy and industrial products and biological agents to clean up contaminated soils.

In addition, agricultural biotechnology is reducing agriculture's environmental footprint by reducing fossil fuel use, soil tillage and run-off from farmer's fields. Studies show that since commercial plantings of biotech crops began in 1996, farmers have saved 551 million gallons of fuel because of reduced field operations. Worldwide, in 2006, 252 million acres of biotech crops reduced carbon dioxide emissions by nearly 15 million tons – that's equivalent to removing nearly 6.56 million cars from the road for an entire year.

Within the United States alone, biotech crop varieties eliminated the use of 70 million pounds of pesticide applications in 2005.

Economic Benefits

Does biotechnology benefit America's agricultural economy?

Yes. Farmers have adopted biotechnology products because they deliver value by reducing operating and input expenses.

Biotechnology-derived varieties of pest-protected corn, cotton, and potatoes and herbicide-tolerant soybean have significantly reduced pesticide and herbicide use, boosted yields, and saved growers tens of millions of dollars. In 2005, studies show that by growing biotech crops, American farmers increased crop production by 8.3 billion pounds, lowered crop production costs by \$1.3 billion and reduced pesticide applications by 69.7 million pounds.

Adoption

Have farmers adopted new crop varieties developed using biotechnology?

Yes. Biotech crops have been adopted by farmers worldwide at higher rates than any other agricultural practice in the history of agriculture. Since the first significant commercial plantings in 1996, acreage devoted to biotech crops has increased 60-fold. Cumulatively, farmers have planted more than 1.4 billion acres of biotech crops worldwide. In 2007, a total of 282 million acres of biotech crops were planted in 23 countries by 12 million farmers. Notably, 90 percent or 11 million are resource-poor farmers in 12 developing countries.

In the United States:

- Eighty percent of all the corn planted is a biotech variety.
- Ninety-two percent of all the soybeans planted are biotech varieties.
- Eight-six percent of all the cotton planted is a biotech variety.
- Fifty percent of all the papaya planted is a biotech variety.

Sustainability

USDA-APHIS's 7 CFR Part 340 Regulations Governing Plant Biotechnology Frequently Asked Questions

Can agriculture biotechnology assist in meeting the food demands of a growing global population?

Yes. Agricultural biotechnology can be a key element in the fight against hunger and malnutrition in the developing world.

Today, an estimated 800 million people do not have access to sufficient supplies of food. By 2030, the global population is expected to reach, if not exceed, 8 billion people, putting a further strain on food supplies. But while world population is expected to grow rapidly, particularly in developing countries, the amount of available agricultural land is limited. Only 10 percent of the world's land surface is arable, and overfarming and soil erosion are growing problems in some areas.

To overcome these dynamics, farmers will need to find ways to grow more food using less land. The National Academies and six other international scientific organizations recently issued a report discussing the role of biotechnology in meeting global food needs. It concluded that, "GM technology, coupled with important developments in other areas, should be used to increase the production of main food staples, improve the efficiency of production, reduce the environmental impact of agriculture, and provide access to food for small-scale farmers." Other groups-including the International Food Policy Research Institute, Consultative Group on International Agricultural Research, International Service for the Acquisition of Agri-biotech Applications, Pontifical Academy of Sciences and Nuffield Council on Bioethics-have issued similar findings. Biotechnology already is beginning to make a contribution.

International Impacts

What are the international trade issues affecting biotechnology food products?

While the science has repeatedly demonstrated that foods produced through biotechnology are as safe as conventional foods, approval of these foods in some overseas markets has been slow. Despite their growing acceptance and history of safe use in the United States, certain countries have been slow to authorize the use of these crops for other than animal feed.

However, it is noteworthy that in 2007, a total of 282 million acres of biotech crops were planted in 23 countries by 12 million farmers. Notably, 90 percent or 11 million are resource-poor farmers in 12 developing countries. Over 63 countries have been involved with agricultural biotechnology either in research and development or in commercial plantings of biotech crops.

For more information:

Where can I get more information about the regulation of Biotech plant products?

- Visit BIO's Web Resource Page at www.bio.org.
- Visit USDA-APHIS's Web Resource Page at www.aphis.usda.gov.