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Frequently Asked Questions On Agricultural Biotechnology

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 crop plants we rely on for food and fiber.

For centuries farmers and plant breeders have labored to improve crop plants. Traditional breeding methods include selecting and sowing the seeds from the strongest, most desirable plants to produce the next generation of crops. By selecting and breeding plants with characteristics such as higher yield, resistance to pests and hardiness, early farmers dramatically changed the genetic make-up of crop plants long before the science of genetics was understood. As a result, most of today's crop plants bear little resemblance to their wild ancestors.

The tools of modern biotechnology allow plant breeders to select genes that produce beneficial traits and move them from one organism to another. This process is far more precise and selective than crossbreeding, which involves the transfer of tens of thousands of genes, and provided plant developers with a more detailed knowledge of the changes being made.

The ability to introduce genetic material from other plants and organisms opens up a world of possibilities to benefit food production. As an example, "Bt" crops that are protected against insect damage contain selected genes found in the common soil

bacteria, Bacillus thuringiensis. The Bt genes contain information that the plant uses to produce a protein toxic to the larvae of certain plant pests but is safe for humans, animals and other insects. Pest-protected Bt plants stop these insects from eating and destroying the plant, which improves yields and reduces the need for pesticide applications, saving the farmer time and money. Organic farmers use this same Bt to protect their crops from insects.

To learn more about biotechnology techniques, click here.

Is biotechnology fundamentally different from other breeding techniques, and does it pose unacceptable risks?
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.

Many scientific groups have concluded that the risks associated with crop plants developed using biotechnology are the same as those for similar varieties developed using traditional breeding methods. 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.

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 Development and Cooperation, 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.

To ensure that the new plant is safe for the environment, extensive field-testing is conducted under USDA and EPA oversight. 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.

Agricultural biotechnology has tremendous potential to reduce the environmental impact of farming. Current crops designed to resist pests and tolerate herbicides have already cut chemical usage on farms significantly, and the herbicide-tolerance trait promotes conservation agricultural practices like no-tillage farming that reduce soil erosion, prevent water loss, and even limit release of greenhouse gases.

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 and fiber on less land. These and other traits also will allow farmers to bring currently nonarable land into production, reducing the pressure to convert threatened ecosystems, such as rainforests, to farmland. Biotechnology can also be used to produce renewable plant-based energy and industrial products and biological agents to clean up contaminated soils.

To learn more about the environmental benefits of agricultural biotechnology, click here.

Are foods produced using biotechnology as safe to eat as foods produced using traditional breeding practices?
Yes. 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 and foods 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 (FAO), the World Health Organization, the Organization for Economic Cooperation and Development (OECD), the American Medical Association (AMA), the American Dietetic Association, the Council on Agricultural Science and Technology (CAST), the Institute for Food Technologists, the International Council for Science (ICSU) and the British

Medical Association – have determined that biotech crops are as safe as similar crops improved through traditional and organic breeding methods. A 2004 report by the National Academies, for example, found that biotech crops do not pose any more health risks than do crops created by other techniques and that food safety evaluations should be based on the resulting food product, not the technique used to create it."

Indeed, because scientists know more about the changes being made using biotechnology, these foods may be even safer than conventional foods. The precision of biotechnology puts plant developers and regulators are in a better position to address safety that cannot be addressed for products of conventional breeding, which involves the uncontrolled crossing of tens of thousands of uncharacterized genes.

Federal regulatory agencies also ensure the safety of biotechnology foods. To date, no approved biotechnology food has harmed human health.

To learn more about the safety of agricultural biotechnology food products, click here.

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. The science-based U.S. regulatory system has helped ensure that biotechnology products are safe for producers, consumers, and the environment.

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:

- U.S. Department of Agriculture Animal and Plant Health Inspection Service - 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.
- The Environmental Protection Agency - The EPA is responsible for ensuring that pest-resistant biotech varieties are safe to grow and consume. It regulates environmental exposure to these crops to ensure there are no adverse effects to the environment or any beneficial, nontargeted insects and other organisms. The agency also regulates bioengineered microorganisms under the Toxic Substances Control Act.
- Food and Drug Administration, 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. To improve consumer confidence, proposed rules issued by FDA in 2001 would make premarket review of biotech foods mandatory.

To learn more about the regulations governing agricultural biotechnology, click here.

Do foods produced using biotechnology require special labeling?
No. The 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 biotechnology food focuses on its characteristics, not the method used to develop it. A new biotechnology food that is "substantially equivalent"-that is, 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 material information on the new food's safety or nutritional value.

However, the FDA may require extensive premarket testing requirements 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.

Food manufacturers are free to make voluntary claims about whether their products contain biotechnology ingredients or not, and these must be truthful, clear, and not misleading. In January 2001, the FDA issued draft guidance for food manufacturers who wish to use voluntary labels.

The FDA's labeling policy has received broad scientific and industry support. For example, the American Medical Association noted that "there is no scientific justification for special labeling of genetically modified foods, as a class, and that voluntary labeling is without value unless it is accompanied by focused consumer education."

The biotechnology industry supports labels that convey accurate and useful information.

To learn more about the labeling issue, click here.

Can foods developed using biotechnology cause food allergies?

Developers of foods enhanced through biotechnology are mindful of the possibility, albeit unlikely, of introducing an allergen into that food. FDA regulations require companies that use genes from a known allergenic source to assume that they will produce an allergen and to perform allergenicity tests on the food product. Approximately 90 percent of food-related allergies are linked to proteins found in tree nuts, peanuts, soybeans, milk, eggs, fish, crustaceans, and wheat. Knowing this, agricultural biotechnology companies have avoided using genetic material from these foods in developing biotechnology products.

In addition, all foods enhanced through biotechnology are tested for allergenicity in comparison to its conventional counterpart before being approved for market by the FDA. According to FDA labeling guidelines, products produced through biotechnology that contain a likely allergen require a label informing consumers of this fact.

To date, no allergic reactions have been attributed to any food product of biotechnology. In fact, advanced techniques are being used to remove allergens from certain foods. Hypoallergenic rice and soybeans have already been developed, and researchers are at work on wheat. The removal of allergens from foods will open up a broader range of products for those with food allergies to enjoy.

To learn more about food allergies and agricultural biotechnology, click here.

What are examples of agricultural biotechnology products currently available?

The first effort at marketing a crop food modified through biotechnology occurred in the 1989, when Calgene Corporation sought approval for its Flavr Savr tomato, engineered to provide extended shelf life. Since then, there have been a number of crops developed offering a wide variety of enhanced traits. Crops designed to resist insect and viral pest or tolerate broad-spectrum herbicides account for most of the biotechnology crops available commercially.

Bt corn, potato, and cotton incorporate select genes from the widely used biological control agent Bacillus thuringiensis to resist the European corn borer, Colorado potato beetle 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 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 through a mechanism known as cross-protection, which is somewhat similar to immunization. Farmers growing these plants are able to reduce 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 herbicide before planting, farmers can wait until after the crop emerges to apply herbicides only where and in the quantities needed.

Likely advances include a promising array of products that will offer 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 up lucrative new markets to farmers and provide enhanced food products to consumers.

To learn more about current products and products undergoing approval, click here.

Have farmers adopted new crop varieties developed using biotechnology?
Yes. Farmers have embraced crops enhanced through biotechnology because they provide value and solve real, sometimes previously intractable, problems. U.S. farmers, in particular, have taken advantage of this new technology. USDA has estimated that in 2004, 45 percent of the corn (36.4 million acres), 76 percent of the cotton (10.4 million acres), and 85 percent of the soybeans (63.5 million acres) planted were biotech varieties. This is a remarkable level of market penetration considering that these crops were only introduced in the mid-1990s. Today, about 60 to 70 percent of the processed foods available in U.S. grocery stores contain some ingredients or oils derived from biotech crops.

Worldwide, according to the International Service for the Acquisition of Agri-biotech Applications (ISAAA), biotech crops were grown on more than 167 million acres in 2003 by 7 million farmers in 18 countries. A total of 85 percent of growers using biotech crops are small farmers in developing countries, which represents nearly one-third of the global biotech crop area. While the United States grew more than 105 million acres of biotech crops in 2003, Argentina and China each grew more than 10 million acres of biotech crops that same year; China and Brazil each grew more than 5 million acres of biotech crops in 2003.

Adoption throughout the rest of the world has been slower. The United States is fortunate in that it had a science-based regulatory policy in place to accommodate the production and use of new biotechnology varieties. As acceptance of biotechnology grows worldwide, new varieties of important staple crops, such as rice, will be readily adopted overseas.

To learn more about adoption of biotech plants by farmers, click here.

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. A recent study by the National Center for Food and Agriculture Policy (NCFAP) found that six biotech crops – canola, corn, cotton, papaya, soybean and squash – increased grower incomes by an additional $1.9 billion, boosted crop yields by 5.3 billion pounds and reduced pesticide use by 46.4 million pounds in 2003. These savings came from reduced inputs including time, labor, and wear and tear on farm equipment.

A study by University of Minnesota professor C. Ford Runge found that four commercial biotech crops – corn, soybeans, cotton and canola – represented $20 billion in value in the United States in 2002, half of the total $40 billion value of the four crops. The study also found that the economic impact of plant biotechnology extends beyond the farm gate and in individual states active in biotech research and development. At least 41 of the 50 states had some type of biotech initiatives in 2001, and those that have readily adopted and invested in biotechnology are reaping the greatest economic rewards. Corn Belt states with higher adoption levels of biotech crops have a greater number of agriculture and food science jobs than those with lower levels of adoption. Additionally, the study found that these new jobs typically pay 1.5 to 2 times the average wage of workers in these states, mostly because these types of jobs require at least a Bachelor's and Master's degree, and sometimes a doctoral degree. Crop biotech also demands a variety of other high-tech, high-paying jobs, such as food scientists, microbiologists, biochemists and biophysicists.

To learn more about the benefits of biotechnology to farmers, click here.

Does pest-protected Bt corn harm monarch butterflies?
No. Bt crops incorporate genes from the common soil microbe Bacillus thuringiensis, which allows them to produce proteins (endotoxins) that protect them from certain insect pests. The protein expressed in Bt corn has long been known to be toxic to the caterpillars of butterflies, including the monarch. Laboratory studies confirming this led some outside the scientific community to claim that Bt corn posed a severe threat to the monarch.

Subsequent field studies published in the *Proceedings of the National Academy of Sciences* demonstrate that the threat to monarch populations from Bt corn is negligible. Indeed, some of the evidence suggests that Bt corn could greatly benefit monarch butterfly survival by reducing pesticide use. Scientific evidence gathered by the EPA also demonstrates that Bt corn does not harm monarch butterfly populations. Given this scientific consensus, in October 2000 EPA agreed to renew the registration for Bt crops for an additional seven years.

To learn more about Bt corn and the monarch butterfly, click here.

Has gene flow occurred between Bt corn and landraces in Mexico, and does this threaten natural biodiversity?
A November 2001 article in the journal *Nature* claimed that genetic material from Bt corn had found its way into traditional landraces in Mexico. In 1998, Mexico instituted a ban on growing corn enhanced through biotechnology.

Critiques of this study identified flawed methodology and interpretation, unprecedented assertions, and a failure to confirm results. As a result, the editors of Nature published an editorial note, saying, "In light of these discussions and the diverse advice received, Nature has concluded that the evidence available is not sufficient to justify the publication of the original paper." A review by the editors of Transgenic Research also concluded that "no credible scientific is presented in the paper to support claims made by the authors that gene flow between transgenic maize and traditional maize landraces has taken place."

Testing by the International Maize and Wheat Improvement Center has not found any trace of the promoters associated with Bt corn. However, sampling and analysis performed by Mexico's National Institute of Ecology indicated the presence of transgenes in landraces in two states, but even these results were the subject of controversy. Further testing may confirm these results, but to date, there is little reason to believe that large-scale gene flow has occurred or that is has harmed the biodiversity of landraces, which themselves have been genetically manipulated by Mexican farmers for generations.

What is "terminator" technology?
Terminator technology refers to research of seeds/plants that produce sterile seeds. While research of this technology has been conducted in conjunction with the USDA, no agricultural biotechnology company currently uses this technology. In the future, this technology could be used to prevent any gene flow between biotechnology and traditional crops.

Can biotechnology play a beneficial role in aquaculture?
Yes. Using biotechnology, developments in the field of aquaculture will allow a high-quality source of food to be brought to market more quickly, reduce the price to consumers, and eliminate the demand to overfish wild stocks. For example, AquaAdvantage® salmon, developed by Aqua Bounty Farms, can grow from egg to market size (6 to 10 pounds) in 12 to 18 months. Fish produced using conventional fish-breeding techniques normally require two to three years.

Federal regulatory agencies will require rigorous testing for food and environmental safety. New biotechnology salmon varieties could make fish farming more sustainable, decrease overfishing of wild salmon and lower consumer costs. As sterile females are used, there is little risk to wild stocks should these fish escape to the wild.

Aqua Bounty expects to introduce the AquaAdvantage® salmon within two to three years to a public for whom salmon is an increasingly popular food.

To learn more about biotechnology and aquaculture, click here (scroll down to "Aquaculture").

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. For example:

- "Golden rice," enriched with beta carotene, will help combat vitamin-A deficiency, a major cause of blindness in the developing world. (A similar strain of rice has been enriched with iron to ward off anemia.). A "golden mustard" also may yield provitamin A-enriched cooking oil.
- New varieties of corn, sorghum and wheat are being developed to provide more lysine, an important dietary protein.
- "Pharma foods" are being developed that may help prevent or cure diseases such as cholera and diarrhea, leading causes of infant mortality in developing countries.
- Plants that resist viral pests, such as a new variety of African sweet potato that wards off the feathery mottle virus, can improve yields of important staple crops. Viral resistance also is being imparted to high-value cucurbit crops grown throughout Southeast Asia.
- Foods with extended shelf lives can reduce food losses caused by spoilage.
- Plants that resist toxic or salty soils will increase the areas available for farming in many regions of the world.

These are just a few examples of what biotechnology can do to improve the lives of people in the developing world. While not a total solution, biotechnology can play an important role in helping developing countries achieve food security.

To learn more about the role of biotechnology in meeting food challenges in the developing world, click here.

What is "golden rice" and can it be an effective means to prevent vitamin deficiency?
Vitamin-A deficiency is a serious condition that can lead to blindness and increase susceptibility to infectious agents. It affects an estimated 200 million people, primarily in developing countries where rice is a dietary staple.

Using biotechnology techniques, scientists have developed a new strain of rice, called golden rice, that naturally produces beta-carotene, the precursor to vitamin A. Golden rice can provide enough beta-carotene to make up vitamin-A deficiencies in the diets of poor children, and it can also increase the amount of vitamin A in breast milk, an important source of nutrition for infants. Further, scientists has enriched the same strain of rice with additional iron to combat anemia, which affect hundreds of millions of the world's poor.

To learn more about the role of biotechnology in meeting food challenges in the developing world, click here.

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 in coming. Despite their growing acceptance and history of safe use in the United States, certain countries-including the United Kingdom, France and other members of the European Union-have not yet approved these crops to be planted or purchased from another country.

Many variables have worked to slow the acceptance of biotech crops. For instance, Europeans have a strong cultural tie to food and resist any perceived change. Also, many countries have not enjoyed a reliable regulatory environment like that in the United States. Outbreaks of mad cow and hoof-and-mouth diseases in the United Kingdom, contaminated soft drinks in Belgium and HIV-tainted blood supplies in France are just some of the mishaps that have made citizens in other nations, especially Europe, wary of any government agency's claims that a new technology is safe. This has led some countries to reject our risk-based approach and adopt the precautionary principle, which could delay a new technology on the basis of improbable hypothetical risks. And in some instances, ostensible concern over biotechnology is being used to promote protectionist policies that aim to shut out American products from overseas markets in direct contradiction to World Trade Organization guidelines.

To learn more about agricultural biotechnology and international trade, click here.

What are the issues regarding intellectual property and agricultural biotechnology?
All new crop varieties that meet the criteria of the federal Plant Variety Protection Act-whether produced by conventional means or biotechnology-are eligible for intellectual property rights protection. To receive protection, the new variety must be distinct from other varieties and genetically uniform and stable through successive generations. The length of protection is 20 years for

most crop plants.

Researching and bringing a plant biotechnology product to market takes several years and tens of millions of dollars. As with any industry that requires such extraordinary investment, it is crucial that biotechnology companies can recoup the initial investment and continue their research and development of new products that benefit the public. Intellectual property rights also enable companies to do a better job of ensuring that their products are used responsibly.

Links to Other FAQs:

- AgBiosafety, Questions Answered
- AgBioWorld:
  - 31 Critical Questions in Agricultural Biotechnology
  - Response to GM Food Myths
- Biotech Knowledge Center, Monsanto, Frequently Asked Questions
- Center for Science in the Public Interest, Biotechnology Project, Frequently Asked Questions
- Council for Biotechnology Information, FAQs
- CropGen, Questions and Answers
- CropLife America, From Seed to Supermarket: 10 Facts About Plant Biotechnology
- DuPont, Frequently Asked Questions About Biotechnology
- Institute of Food Technologists:
  - rDNA Biotechnology
  - Human Food Safety
  - Labeling
  - Benefits and Concerns
- International Food Information Council, Agricultural Biotechnology: Myths and Facts
- International Maize and Wheat Improvement Center (CIMMYT), Answers to 10 Frequently Asked Questions About GMOs
- Syngenta, Checkbiotech.org, Basics
- World Health Organization, 20 Questions on Genetically Modified (GM) Foods
- Union of Concerned Scientists, Frequently Asked Questions about Biotechnology
- U.S. Department of Agriculture, Frequently Asked Questions, USDA and Biotechnology
- U.S. Department of State, Biotech FAQ

For more links, **click here**.

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