U.S. DEPARTMENT OF STATE
INTERNATIONAL INFORMATION PROGRAMS

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United States Department of State

Biotech FAQ

Frequently Asked Questions about Biotechnology

1. What is biotechnology, and how is it different from traditional plant breeding?

Biotechnology is the use of modern scientific techniques, including genetic engineering, to improve or modify plants, animals, and microorganisms.

In agriculture, crop improvement is not new. For centuries, farmers, nurserymen, and others have crossbred (intermingled the genes of) various plants in an effort to produce more and better foods. Using advanced scientific methods, biotechnology greatly expands our capabilities to introduce new traits into food crops.

Traditional breeding techniques typically involve the repeated mixing of thousands of genes over several years and many generations of plants to achieve a desired trait. Thanks to science, biotechnology accelerates this lengthy process by allowing scientists to insert selected genes directly into a plant. This brings about the desired results much more efficiently. Although traditional breeding has been able to overcome some natural barriers to crossbreeding plants of different species, and sometimes even of different genera, biotechnology greatly expands that capability.

2. Beyond increased yields, what are some of the benefits of biotech products?

The first genetically engineered products were medicines designed to combat human diseases. Insulin, used to treat diabetics, and blood clot-reducing enzymes for heart attack victims are now produced easily and cheaply as a result of biotechnology. In agriculture, first generation biotechnology products have traits that result in reduced pesticide use or higher yields due to reduced pest losses. Bt cotton, for example, is a widely grown biotech crop that kills several important cotton pests. These products provide indirect benefits for consumers and the environment through lower agricultural chemical usage.

Every day, more and more seed varieties with potential direct benefits for consumers are being field tested in the United States under approvals from U.S. regulatory agencies. Some of the products of this research are already appearing on grocery shelves in the United States and in the European Union, such as cheeses, yogurts, and new cooking oils derived from soybeans. Products in development also include those with improved nutritional value. For example, a new rice variety developed in Switzerland under a Rockefeller Foundation grant provides vitamin A. Each year nearly 1 million child deaths and 14 million children with blindness and other eye problems have been linked to vitamin A deficiency. Another variety of rice will soon provide twice the iron as currently available rice varieties. Also in development are soybeans with enhanced nutrient

content for use in animal feed and corn that contains phosphorus in a form more easily absorbed by livestock. This latter product could reduce the use of supplements while at the same time helping the environment by lowering the amount of phosphorous in animal waste.

Biotechnology developments also have tremendous benefit for developing countries where almost a billion people live in poverty and suffer from chronic hunger. Seventy percent of those people are poor farmers who face huge crop productivity losses owing to insects, drought, and low soil fertility. New varieties of grains, many of which provide a stable calorie source for developing country populations, are being developed that can grow on land that is currently unsuitable for cultivation. The fact is that land under cultivation worldwide simply is no longer sufficient to feed the growing global population. Biotechnology can improve agricultural production for subsistence farmers, driving rural economic development and increased food security. Using biotechnology to grow crops in poor soil, rather than seeking increased yields through more irrigation, fertilizers and chemicals, or by bringing new lands into cultivation, would be the environmentally more responsible approach.

In addition to creating better foods and feeds, biotechnology helps fiber producers and manufacturers, too. For example, cotton varieties are being developed that will produce sturdier, wrinkle-resistant or fire-retardant fibers.

Biotechnology also can contribute to the development of new products that would be otherwise unavailable and products that could replace nonrenewable petroleum-based chemicals with renewable, agriculturally based specialty oils and chemicals for use by industry.

3. Is biotechnology safe?

Yes, if properly regulated, as is the case with all foods.

Many international organizations - such as the Food and Agriculture Organization of the United Nations, the World Health Organization, and the Organization for Economic Cooperation and Development - have recognized that biotechnology, when properly used, does not affect the safety of a product. In the United States, foods developed through biotechnology face the same regulatory requirements that the Food and Drug Administration uses to safeguard other foods and food ingredients in the marketplace. There is no evidence that biotech foods currently on the market present a risk to human health.

Biotechnology is regulated in the United States under a risk-based system that focuses on the end product and its uses. Over the years, Federal agencies with authority to regulate agriculture, the environment, and the nation's food and drug supply have developed regulations and oversight processes for biotechnology. Under this regulatory framework, USDA's Animal and Plant Health Inspection Service (APHIS) ensures that new biotech plant varieties are as safe to use in agriculture as conventional varieties. The Food and Drug Administration consults with developers of transgenic plants to ensure that the new crops and foods produced from them are as safe to consume as conventional foods. The Environmental Protection Agency (EPA) conducts extensive scientific reviews to ensure public health and environmental protection of new plant-pesticidal substances (i.e., genes that work as a pesticide in a plant, for example, the Bt gene in corn or cotton) introduced into plants or new uses of herbicides in conjunction with transgenic plants.

Under the safety guidelines imposed by APHIS and the other regulatory agencies, thousands of field tests with genetically engineered crops have been conducted since the mid 1980s. Resulting products have been grown commercially since the early 1990s and currently account for over 40 varieties and comprise a large percentage of the acreage of corn, soybeans, and cotton. Our system of regulatory oversight has contributed to there being no known cases of harm to humans or the environment resulting from the development and use of these plants.

4. How open to public scrutiny is the U.S. regulatory process for biotechnology products?

The U.S. regulatory system involves the public in the decision-making process. For example, the Administrative Procedures Act (APA) requires that all federal agencies provide the public with an opportunity for "notice and comment" before adopting final regulations. In addition, APHIS, FDA, and EPA ensure "transparency" in their oversight system through the use of public meetings, Federal Register notices, and postings on the World Wide Web. Lastly, the agencies have been open to modifying their regulations based on experience with technology and scientific advancements. It should be noted that extensive scientific evaluations by USDA, EPA and FDA have identified no significant or unexpected concerns unique to products resulting from biotechnology. FDA has conducted public sessions on various aspects of biotech foods and received tens of thousands of written comments. On January 21, 2000, Secretary of Agriculture Dan Glickman announced a new Advisory Committee on Agricultural Biotechnology that will bring together individuals with a broad range of expertise to advise the U.S. government on policies related to the creation, application, marketability, trade and use of agricultural biotechnology. The Secretary formed this committee not because of concerns about products currently on the market, but to ensure that USDA is fully prepared for the future.

5. What are some of the concerns about biotechnology regarding human health and biodiversity?

Biotechnology is a tool. Like any tool, if used properly and with care, it can be safe and beneficial. Many of the concerns that have arisen regarding biotechnology stem from concerns about its potential uses. The U.S. regulatory system ensures that products that are commercially grown, sold, processed, and consumed are safe. Every biotechnology plant variety commercially grown in the United States has gone through the necessary regulatory process in USDA, the EPA (if it has a pesticide component), and the Food and Drug Administration (if it is used as a human food or animal feed). We recognize the right of every country to establish its own product evaluation system. However, we believe that such regulatory decisions must be open to public comment, predictable, and based on science.

6. Is the United States the only industrial country that has developed genetically engineered agricultural products?

The United States is not alone in developing new biotech products or in offering them for commercial production. Several European countries, including Germany and Switzerland, as well as Canada, China, Argentina, South Africa, and Japan, have already approved several biotech varieties, such as corn, soybeans, and other crops. What's more, European companies are very active in developing and offering transgenic varieties for commercial planting in the United States. For example, AgrEvo, a German company, and Novartis, a Swiss company, both have offered commercial varieties of genetically modified corn and soybean to U.S. farmers. Moreover, about one-half of the applications for approval of transgenic varieties currently pending in the EU

regulatory system are sponsored by EU companies.

7. Why is it difficult for the United States to segregate genetically engineered products from "biotech-free" products?

Some companies are attempting to maintain the identity of their biotech product from farm to manufacturer. Often these products have value-added traits that need to be preserved throughout the distribution process. This is called "identity preservation" and is normally done on a small scale. This niche market requires an entirely different and more costly marketing system than bulk agricultural trading, in which products go to market without segregating and preserving the identity of the products in each shipment.

Other companies have requested that farmers segregate transgenic crops from conventional varieties when the commodities are marketed. Some processors and importers, in turn, are specifying conventional commodities only, and sometimes paying a premium for them.

Our farms, grain storage, and transportation systems are not designed to segregate bulk, unbagged, genetically engineered agricultural products, on a large scale and with precision, from conventional varieties. Therefore, we cannot easily ship "biotech-free" corn and soybeans to individual markets. While identity preservation is taking place on a contractual basis, farmers and exporters are paid a substantial premium to keep these varieties separate from others. If customers do not want to buy biotech products, U.S. producers and exporters will try to provide an alternative -- usually at an additional cost. However, exporters of bulk agricultural commodities cannot guarantee that a given shipment will be 100-percent "biotech-free," just as they cannot guarantee that a shipment of any product in a bulk commodity will be 100-percent identity preserved. Importers will have to establish realistic tolerances and testing methodologies before "biotech-free" shipments can occur.

8. How is the United States ensuring that biotech varieties unapproved in other countries are not finding their way to export channels?

Seed companies operating in the United States - including European companies -- advise and work with farmers to channel varieties that are unapproved in potential export markets to domestic livestock feed and other uses. Some of the safeguards by seed companies include: requiring farmers to sign a grower agreement that, lacking all required international approvals, the grain will be held for domestic livestock use; maintaining lists of farmers to whom the seed was sold; helping farmers identify nearby outlets for grain in order to facilitate the proper marketing of unapproved varieties; establishing toll-free telephone numbers for farmers to call for additional information about how and where to market the corn domestically.

Also, major corn refiners have said that they will only buy corn varieties that have been approved by the EU, helping to preserve the integrity of the system. Furthermore, there are identity preservation systems in place for value-added products, such as non-biotech high-oil corn. Under this system, farmers and handlers are paid premiums at each stage of the marketing chain to keep the product apart from the other products.

The U.S. Government does not have the authority to force farmers to market their crop in one channel or another. Therefore, the U.S. Government cannot certify that certain varieties are completely absent from export channels. The USDA believes that the safeguards described above

are helpful in preventing varieties not yet approved in any country from reaching the export market, but the USDA does not monitor the companies' safeguarding efforts.

9. Does the U.S. support the development of international standards for food biotechnology?

In terms of safety assessment and scientific reviews, the United States supports the work of the CODEX Alimentarius, the international standard setting body for food safety organized under the United Nations Food and Agriculture Organization (FAO) and the World Health Organization (WHO). CODEX committees and specially organized task forces and working groups are addressing issues of standards. CODEX has the knowledge and expertise in the area of food safety and can build on work that has been done under the FAO and WHO. The FAO/WHO has drafted a report based on a meeting of experts on biotechnology and food safety in 1996, which confirmed the safety of processed food containing biotech inputs, based on rigorous scientific risk assessments.

10. Why not just stop all marketing and development of biotech products for five years, just to be safe, as some advocate?

A freeze would deny hundreds of millions of people the benefits of this technology. As more than 500 noted scientists recently wrote in a letter supporting biotechnology: "In developing countries, biotechnology advances will provide the means to overcome vitamin deficiencies, to supply vaccines for killer diseases, like cholera and malaria, to increase production and protect fragile natural resources, and to grow crops under normally unfavorable conditions." When there is no credible evidence of a risk to human health from use of biotechnology, why would anyone want to deny the world these benefits?

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