

AGRICULTURAL BIOTECHNOLOGY

OVERVIEW

Every year, millions of people worldwide die from starvation and nutritional deficiencies. Although these challenges remain significant, we are making some progress. Agricultural technologies have increased caloric intake on a per-capita basis in nearly every nation of the world.¹ Continued technological development — particularly in the area of agricultural biotechnology — is crucial if we want to further reduce malnutrition and starvation and meet the needs of growing populations.

Unfortunately, misperceptions about biotechnology have led to activist movements to slow down, if not eliminate, this critical technology via government regulation. In the United States, the advancement of biotech crops has slowed down because of attempts to regulate them differently than conventionally grown foods. In Europe, antibiotech movements are much stronger, and international bureaucrats are pushing various international agreements and trade restrictions. While Western nations may be able to absorb the costs of such policies, people in the developing world will pay a higher price as many continue to suffer from starvation.

What Exactly Is Biotechnology?

For centuries breeders have improved plants through selective breeding and crossbreeding different types of plants. Agricultural biotechnology — also referred to as “genetic engineering” or “genetic modification” (GM) — is a more sophisticated and precise means of modifying plant genes. Instead of transferring thousands of genes as traditional crossbreeding does, biotechnology enables the transfer of only a few select plant genes. Breeders essentially cut the desirable traits out of one plant’s DNA and paste them into another — a process called “gene splicing.” In addition, undesirable traits can be targeted and removed. Using biotechnology, plant breeders can produce better crops.

Biotechnology’s Critical Benefits

More affordable, higher quality food surely benefits people in developed nations, but those benefits pale in comparison to what biotech promises for the developing world.

- Biotechnology promises to reduce world hunger and disease by improving local productivity by adapting crops to local climates and soils; increasing yield by making plants stronger and more pest-resistant; making plants more nutritious by creating plants with higher vitamin and protein content; and making produce more affordable on the world market.²

¹ Dennis Avery, “Saving the Planet with Plastics and Pesticides,” in *True State of the Planet*, ed. Ronald Bailey (New York: The Free Press, 1995), 53.

² For some of the possibilities of genetically engineered plants see Freeman Dyson, *The Sun, the Genome and the Internet: Tools of Scientific Revolutions* (New York: Oxford University Press, 1999).



- For example, Cornell University researchers are developing a rice variety that yields 20 percent to 40 percent more food per acre and a tomato that produces 48 percent higher yields per acre.³
- Biotechnology promises to play a critical role in reducing blindness caused by vitamin A deficiencies. Every year in Southeast Asia, one quarter of a million children go blind because of a lack of vitamin A in their diets. Worldwide, 124 million children suffer from vitamin A deficiency. Increasing the intake of vitamin A could prevent one to two million deaths per year and eliminate numerous health problems.⁴ Poverty and lack of infrastructure make the traditional methods of vitamin consumption (a varied diet or supplements) impossible. Agricultural biotechnology, however, can help to address the problem of childhood blindness and death by ensuring that people get this nutrient in the key staple of their diet, rice. Researchers have spliced into the genome of rice, the beta-carotene gene from a daffodil to create “golden rice” — rice high in beta-carotene, which the human body converts into vitamin A.⁵ This is among the most well-known examples of biotechnology’s benefits. Countless other genetically engineered crop varieties are being developed to address similar problems of poor nutrition or productivity.⁶

How Agricultural Biotechnology Improves Plant Safety

Many biotechnology skeptics contend that such engineering is unsafe because it is “unnatural.” Ironically, biotechnology is actually an improved method for plant breeding. Most of what we eat today has already undergone gene manipulation under the traditional breeding methods. The traditional methods and biotechnology differ in that traditional methods are cruder because they do not give researchers control over all the genes they crossbreed. Some desirable characteristics might result with such methods, but undesirable ones might as well. It could take a long time of continual breeding to eliminate the most problematic traits and focus on the best ones.

Compared to these more “traditional” methods of hybridization, genetic engineering is a wonder of precision and accuracy. Genetic engineering enables scientists to pinpoint the genes that express a desirable characteristic in one plant and to insert those genes into the genome of another plant. Scientists mark the insertion point so that they know where these novel genes are located in the genome of the new plant. While there are several different methods of genetically engineering plants,⁷ these processes transfer far fewer genes than do “traditional” methods of plant breeding.⁸

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³ Michael A. Wilson, John R. Hillman, and David J. Robinson, “Genetic Modification in Context and Perspective,” in *Fearing Food: Risk, Health & Environment*, ed. Julian Morris and Roger Bate (Boston: Butterworth Heineman, 1999), 70.

⁴ Xudong Ye et al., “Engineering the Provitamin A (Beta-Carotene) Biosynthetic Pathway into (Carotenoid-Free) Rice Endosperm,” *Science* 287, no. 5451 (14 January 2000): 303-5.

⁵ Ibid.

⁶ Royal Society of London, the U.S. Academy of Sciences, the Brazilian Academy of Sciences, the Chinese Academy of Sciences, the Indian National Science Academy, the Mexican Academy of Sciences, and the Third World Academy of Sciences, *Transgenic Plants and World Agriculture* (Washington, D.C.: National Academy Press, 2000), <http://stills.nap.edu/html/transgenic/pdf/transgenic.pdf>.

⁷ For a discussion of the various processes, see Peter H. Raven, Ray F. Evert, and Susan E. Eichorn, *Biology of Plants*, 5th Edition, (New York: Worth Publishers, 1992), 565-71.

⁸ Robert M. Goodman et al., “Gene Transfer in Crop Improvement,” *Science* 236 (3 April 1987): 48-54.



AGRICULTURAL BIOTECHNOLOGY REGULATION

For traditionally bred plants, regulators rely on plant breeders to conduct appropriate safety testing and to be the first line of defense against genetic alterations that might prove dangerous. The same should be true for agricultural products developed using biotechnology.¹ There is no reason for regulators to treat biotech plants any differently than traditionally bred plants, particularly given the fact that biotechnology provides greater control over gene manipulation.

Despite fears about gene manipulation, traditional crossbreeding² has altered plant genes and improved the human diet for the past 30 years. In fact, people worldwide safely consume these plants every day.³ Examples include wheat, corn, potatoes, tomatoes, and countless other staples of the American diet.⁴ In 1984, the biotechnology industry began experimenting with “gene-spliced plants” — the more advanced approach to gene manipulation that we now call “biotechnology.”

Regulatory Scheme

At the time, the White House Office of Science and Technology Policy began crafting a framework wherein existing federal agencies would regulate genetically engineered organisms on the basis of their characteristics, not the method of production⁵ — thus wisely deferring to the scientific community’s judgment that regulation ought to address the products, not the process of biotechnology.⁶ Engineered organisms would not require extra scrutiny simply because genetic engineering produced them (the process). Instead, they would be subject to heightened scrutiny only if the individual organisms expressed characteristics that posed some conceptually heightened risk (the product).

The federal government divided regulatory jurisdiction among agencies already involved in agricultural, food, and environmental regulation. These include the United States Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA). While each of these agencies considers the characteristics of individual products in their regulation, only FDA followed the general scientific thinking that genetically engineered and non-genetically engineered products should be regulated similarly. Both USDA and EPA automatically subject all genetically engineered plants as a class to premarket approval requirements not ordinarily applied to conventionally bred plants.

Department of Agriculture

USDA regulates the release of all genetically engineered agricultural plants under statutes giving USDA’s Animal and Plant Health Inspection Service (APHIS) the authority to regulate plants that may be or may become weeds or other nuisances — what the statutes call “plant pests.”⁷ Although the rules apply in a general sense to novel or exotic varieties of both gene-spliced and conven-

¹ See “Agricultural Biotechnology Overview” in *The Environmental Source* for a description of agricultural biotechnology.

² For a description of traditional crossbreeding, see “Agricultural Biotechnology Overview,” in *The Environmental Source*.

³ See “Mutation Techniques for Plant Breeding,” <http://www.new-agri.co.uk/99-1/focuson/focuson9.html>; see also www.abs.sdstate.edu/plantsci/teachings/ps383/breeding/mumint.htm.

⁴ Robert M. Goodman et al., “Gene Transfer in Crop Improvement,” *Science* 236 (3 April 1987): 53.

⁵ *Federal Register* 51 (26 June 1986): 23,302.

⁶ See, for example, U.S. National Academy of Sciences, *Introduction of Recombinant DNA-Engineered Organisms into the Environment: Key Issues* (Washington, D.C.: National Academy Press, 1987), 16; and Royal Society of London et al., *Transgenic Plants And World Agriculture* (Washington, D.C.: National Academy Press, 2000).

⁷ 7 CFR § 340.3 et seq.



tional plants, APHIS typically only requires field testing of conventional plants that are new to a particular U.S. ecosystem (transplanted from another continent, for example).

However, all genetically engineered agricultural plants face a higher regulatory bar — making it more difficult to expand the use of biotechnology. Genetically engineered crops must be field tested under APHIS regulations prior to commercialization. For example, a new variety of corn produced with conventional hybridization requires no government-mandated field testing, but all new varieties of genetically engineered corn do, even though there is no logical reason for the regulatory disparity. For most genetically engineered plants, APHIS requires the company producing the plants to submit notice detailing the gene or genes that have been inserted, where the plant will be tested, and other relevant characteristics of the plant prior to receiving permission to conduct the field trials. Once the company completes field testing, APHIS reviews the results and makes a determination on whether or not the product should be “deregulated” and can be released into the market.⁸

Environmental Protection Agency

EPA regulates plants that are modified to produce substances that act like pesticides: that is, substances used by a plant to protect itself from pests, such as insects, viruses, and fungi.⁹ EPA’s proposed rule for these “plant-incorporated protectants” is not yet finalized.¹⁰ In the interim, however, EPA has regulated such plants by applying its proposed guidelines,¹¹ which are functionally similar to rules for the registration of synthetic chemical pesticides. Again, biotech products face higher regulatory hurdles, even though plant-incorporated protectants developed through conventional breeding are exempt from these requirements.¹²

Health and Human Services: Food and Drug Administration

FDA is responsible for ensuring that food items, including foods derived from genetically modified plants, are safe to eat. Following the general regulatory framework that emphasizes product regulation rather than process regulation, FDA rightly does not treat foods derived from genetically engineered plants to be inherently unsafe.¹³ Food producers are not required to seek premarket approval from FDA unless there is a substantive reason to believe that the novel trait (or traits) in the food pose a safety question.¹⁴ The initial determination of safety is left to the producer,¹⁵ but FDA has encouraged producers to consult with agency scientists prior to marketing a food produced with biotechnology to ensure that the appropriate determination is made. Recently, FDA published a proposed rule that would require producers to notify the agency at least 120 days before marketing,¹⁶ which may be a signal that FDA could abandon its more reasonable approach in the future.

⁸ Donna Vogt and Mickey Parish, “Food Biotechnology in the United States: Science, Regulation, and Issues” (Washington, D.C.: Congressional Research Service, 2 June 1999), 11, <http://www.usinfo.state.gov/topical/global/biotech/crsfood.htm>.

⁹ 40 C.F.R. § 45(c) et seq.

¹⁰ On 17 January 2001, EPA announced its intent to publish in the *Federal Register* a final rule for the regulation of “plant-incorporated protectants,” (<http://www.epa.gov/scipoly/6057-6.pdf>). The Bush administration has postponed the rule.

¹¹ *Federal Register* 59 (23 November 1994): 60,496 and *Federal Register* 62 (16 May 1997): 27,132.

¹² Subcommittee on Basic Research on the Committee on Science, *Seeds of Opportunity: An Assessment of the Benefits, Safety and Oversight of Plant Genomics and Agricultural Biotechnology*, U.S. House of Rep. (April 2000), 26.

¹³ *Federal Register* 57 (29 May 1992): 22,984.

¹⁴ FDA has established a risk-based “decision tree” that plant developers and food manufacturers apply to all foods to determine the safety of any new product, be it genetically engineered or produced through “traditional” methods. See “Seeds of Opportunity” at 22-23.

¹⁵ *Federal Register* 57 (29 May 1992): 22,986-88. For example, FDA does require notification when the nutritional or toxicological profile of the plant is changed significantly from what a consumer would reasonably expect from the conventional equivalent, or when genes coding for the proteins of known allergenic foods such as eggs, wheat, and tree nuts are transferred.

¹⁶ *Federal Register* 66 (18 January 2001): 4,706.



In addition, FDA does not require labeling of foods derived from biotechnology unless the genetic insertions so alter the food that the common name no longer describes it adequately. Examples of this phenomenon would include such alterations of the food product that would raise a safety issue or change the product's nutritional composition or its storage or preparation characteristics.¹⁷

Labeling Issues

Some activists, however, argue that the government should mandate the labeling of all genetically engineered foods. They assert that consumers have a "right to know" how their foods have been altered, and that a mandatory label would best allow consumers to choose between genetically engineered and conventional foods.¹⁸

Biotechnology advocates have argued against mandatory labeling because such requirements raise food costs — something that mostly harms lower-income Americans and people on fixed budgets. Perhaps more important, while biotech products are not substantially different from other products, special labels would likely make consumers think these products were more dangerous.¹⁹ Hence, rather than serving educational or "right to know" purposes, such labels promise to simply confuse consumers.

A government-mandated label on all genetically engineered foods also would raise important First Amendment free speech issues. In 1996, the U.S. Court of Appeals, in *International Dairy Foods Association et al. v. Amestoy*, ruled unconstitutional a Vermont statute requiring the labeling of dairy products derived from cows treated with a genetically engineered growth hormone, noting that food labeling cannot be mandated simply because some people would like to have the information. "Absent ... some indication that this information bears on a reasonable concern for human health or safety or some other sufficiently substantial governmental concern, the manufacturers cannot be compelled to disclose it."²⁰ In other words, to be constitutional, labeling mandates must be based in science and confined to requiring disclosure of information that is relevant to health or nutrition.

Furthermore, consumers need not rely on mandatory labeling of biotech foods to truly have a choice. Real-world examples show that market forces are fully capable of supplying information about process attributes (including kosher and organic production standards) that consumers truly demand. The same can be said about nonbiotech foods, and the FDA recently published proposed guidelines to assist producers in voluntarily labeling both genetically engineered and nongenetically engineered foods. Additionally, the USDA's newly published rule for organic certification necessarily excludes biotech products from organic food production.²¹ Consequently, consumers wishing to purchase nonbiotech foods need only look for certified organic products.

International Trade

While U.S. consumers do not appear to be strongly opposed to biotech foods (they, in fact, seem rather indifferent), a strong anti-biotechnology movement has arisen in several European coun-

¹⁷ *Federal Register* 57 (29 May 1992): 22,991.

¹⁸ See, for example, The Campaign to Label Genetically Engineered Foods Web site: <http://www.thecampaign.org>.

¹⁹ Henry I. Miller "A Rational Approach to labeling Biotech-Derived Foods," *Science* 284 (28 May 1999): 1471-1472. See also *Seeds of Opportunity*, 53-55.

²⁰ 92 F.3d 67 (2d Cir. 1996).

²¹ 7 C.F.R. Part 205.



tries over the last few years. The European Union (EU) has established strong restrictions on the commercial planting of genetically engineered plants, and European food processors and retailers are reluctant to import harvested agricultural products derived from biotechnology — thus jeopardizing the marketability of U.S. commodity grain exports. And the EU is now negotiating for strong restrictions on agricultural biotech products in important international agreements governing food safety and environmental protection. Very strong restrictions were included in the Biosafety Protocol, finalized in January 2000.²² Perhaps, more important, though, are the Codex Alimentarius Commission standards for food safety.²³

Without convincing scientific evidence that genetically engineered crop plants pose a heightened environmental or human health risk, restrictions on agricultural biotech imports could be challenged under the General Agreement on Tariffs and Trade and the World Trade Organization. Thus the EU has resorted to justifying its decisions on the basis of a risk-management philosophy known as the “precautionary principle,” and the EU advocates inclusion of the precautionary principle in international environmental and food safety agreements (such as the Codex Alimentarius), as well as within GATT itself. Its inclusion would give nations greater latitude in restricting imports of U.S. agricultural products.

No single definition exists for the precautionary principle, but its general meaning is that when an activity raises threats of harm to human health or the environment, regulatory measures should be taken to prevent or restrict the activity even if the risks have not been demonstrated scientifically.²⁴ Although the EU asserts that the precautionary principle is an unbiased risk-management philosophy, critics have noted that its lack of definition and evidentiary standards makes it all too easy to abuse for the purpose of masking trade protectionism, and that its very approach to risk management is inherently flawed and may, in fact, increase net risk.²⁵ Nevertheless, the precautionary principle has already been included in several international environmental treaties, including the Convention on Biological Diversity²⁶ and the Biosafety Protocol.²⁷

²² Subcomm. on Basic Research, *Seeds of Opportunity*, 61. See also Gregory Conko, “From Montreal to Miami: Trade in Genetically Modified Organisms after the Biosafety Protocol,” Speech given at The Institute of Economic Affairs, London, UK, 10 October 2000, <http://www.cei.org/RemarksReader.asp?ID=1246>.

²³ The Codex Alimentarius Commission is an international forum for the harmonization of food safety regulations and is jointly administered by the UN’s Food and Agriculture Organization and World Health Organization (see <http://www.fao.org/waicent/faoinfo/economic/esn/CODEX/Default.htm>). Codex member nations are not bound by Codex standards, but all restrictions permitted under Codex standards are permissible under the General Agreement on Tariffs and Trade and the World Trade Organization dispute settlement mechanisms. Thus if the European Union succeeds in adding strong biotechnology restrictions to the Codex Alimentarius standards, countries will no longer be able to rely upon the WTO for legal recourse against rules that are not based upon a scientifically valid demonstration of a legitimate risk.

²⁴ See EC (2000): Communication from the Commission on the Precautionary Principle (Brussels: 2 February) COM (2000) 1, http://www.europa.eu.int/comm/off/com/health_consumer/precaution_en.pdf; and see also Gregory Conko, “Throwing Precaution to the Wind: The Perils of the Precautionary Principle,” *CEI Update* 13, no. 5 (August/September 2000): 1, <http://www.cei.org/UpdateReader.asp?ID=1195>.

²⁵ Conko, “Throwing Precaution to the Wind.”

²⁶ Convention on Biological Diversity, <http://www.biodiv.org/chm/conv/default.htm>.

²⁷ Cartagena Protocol on Biosafety to the Convention on Biological Diversity, <http://www.biodiv.org/biosafe/protocol/Protocol.html>.



Conclusion

Even as underdeveloped nations clamor for biotechnology applications, and as countries like China continue to experiment with and use agricultural biotechnology,²⁸ opponents of agricultural biotechnology in the West, particularly Europe, attack it as an unnatural process that will destroy the world, not better it. They argue that biotechnology should be heavily regulated, if not banned.²⁹

Already, however, genetically engineered plants are subject to strict regulatory oversight that is equal to or greater than that advocated by the vast majority of scientific specialists. Additional regulation will slow down research and development of genetically engineered crops, keep beneficial products off the market, and raise the cost of products that do make it to consumers. Furthermore, the inclusion of similar restrictions — or inclusion of the precautionary principle — in international agreements will greatly impact the international trade of agricultural goods and delay their introduction into the marketplace. Each of these problems could prevent this technology's benefits from being introduced to industrialized nations and, more important, the developing world.

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Recommended Readings

McHughen, Alan. *Pandora's Picnic Basket: The Potential Hazards of Genetically Modified Foods*. New York: Oxford University Press, 2000.

Nuffield Council of Bioethics. *Genetically Modified Crops: The Ethical and Social Issues*. London: Nuffield Council, 1999, <http://www.nuffieldfoundation.org/bioethics/publication/pub0000000310.html>.

Wilson, Michael A., John A. Hillman, and David J. Robinson. "Genetic Modification in Context and Perspective." *Fearing Food: Risk, Health & Environment*. Edited by Julian Morris and Roger Bate. Boston: Butterworth Heinemann, 1999, 58-77.

²⁸ Qifa Zhang, "China: Agricultural Biotechnology Opportunities to Meet the Challenges of Food Protection," in *Agricultural Biotechnology and the Poor*, ed. G. J. Persley and M. M. Lantir (Washington, D.C.: Consultive Group on International Agricultural Research, 1999), <http://www.cgiar.org/biotech/rep0100/zhang.pdf>.

²⁹ For example, see Greenpeace's anti-biotechnology Web page, <http://www.greenpeace.org/-geneng>.

