Agricultural Biotechnology Regulation

Gregory Conko

For conventionally 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. They are not subject to any government premarket review, and regulation of conventionally derived food products amounts to little more than monitoring the marketplace for contaminated or misbranded products. Numerous scientific bodies have concluded that there is no scientific reason for holding bioengineered and conventional crops to different regulatory standards. However, despite this long-standing consensus of the scientific community,[1] biotech-derived plants are subject to very strict government oversight in the United States and abroad.

In a 1989 report, the National Research Council (NRC) concluded, "Information about the process used to produce a genetically modified organism is important in understanding the characteristics of the product. However, the nature of the process is not a useful criterion for determining whether the product requires less or more oversight."[2] Another NRC panel repeated this conclusion in a 2004 report.[3] And an expert

1. See the policy brief titled "Agricultural Biotechnology Overview" for a description of agricultural biotechnology.

2. National Research Council, *Field Testing Genetically Modified Organisms: Framework for Decisions* (Washington, DC: National Academies Press, 1989), 14–15.

3. National Research Council, *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects* (Washington, DC: National Academies Press, 2004).

committee of the Institute of Food Technologists (IFT) concluded unequivocally that neither existing empirical data nor theoretical considerations support more stringent safety standards than those that apply to conventional foods. According to the IFT, the evaluation of bioengineered organisms and the food derived from them "does not require a fundamental change in established principles of food safety; nor does it require a different standard of safety, even though, in fact, more information and a higher standard of safety are being required."[4]

For thousands of years, human hands have used both crude and sophisticated techniques to generate both subtle and gross genetic changes in the food crops on which we rely. All of the known risks of biotechnology are also known to exist in conventional plant breeding methods. In almost all cases, these risks can be managed easily and effectively without any need for government oversight. Consequently, the disproportionate attention paid to biotechnology ignores the lessons of both biology and the history of agriculture.[5]

In some cases, certain products of conventional or biotech modification might pose substantial risk and therefore could warrant heightened government oversight. However, focusing only on recombinant DNA (deoxyribonucleic acid) techniques, and treating all bioengineered products as if they are uniquely risky, is counterproductive. Instead, regulatory efforts should be redirected to focus oversight on new organisms that express characteristics likely to pose significant risk, regardless of the methods used in their development, while leaving relatively low-risk traits of both conventional and recombinant DNA modification unburdened by costly regulation.[6]

Introducing any new living organism into the environment or the food supply cannot be said to be risk-free, but assessment of the risks of bioengineered organisms should focus on the nature of the organism and of the environment into which the organism is to be introduced, independent of the breeding method used.[7] Whether an organism is bioengineered, conventionally bred, or unmodified, safety evaluations should be based on three considerations: familiarity, or the sum total of knowledge about the traits of the organism and the new environment; the ability to confine or control the organism; and the likelihood of harmful effects if the organism should escape control or confinement.

Naturally, with conventional and biotech modification, breeders must be vigilant to ensure that newly introduced plants do not pose human health problems, become invasive, or injure natural biodiversity as a result of intentional or accidental genetic changes. But neither the introduction of one, two, or several genes, judged against the background of tens or hundreds of thousands of the host organism's own genes, nor the transformation process itself creates any risk that is novel, unique, or in some way difficult to manage.

How novel is a corn plant, for example, that contains a newly inserted gene for a bacterial

4. Institute of Food Technologists, *IFT Expert Report on Biotechnology and Foods* (Chicago: Institute of Food Technologists, 2000), 23.

5. Kent J. Bradford, Allen Van Deynze, Neal Gutterson, Wayne Parrott, and Steven H. Strauss, "Regulating Transgenic Crops Sensibly: Lessons from Plant Breeding, Biotechnology, and Genomics," *Nature Biotechnology* 23, no. 4 (2005), 439–44.

6. See, for example, Henry I. Miller and Gregory Conko, *The Frankenfood Myth: How Protest and Politics Threaten the Biotech Revolution* (Westport, CT: Praeger, 2004), and Bradford et al., "Regulating Transgenic Crops Sensibly."

7. National Research Council, *Field Testing Genetically Modified Organisms*, and National Research Council, *Safety of Genetically Engineered Foods*.

protein that is toxic only to certain insect larvae when one considers that every crop plant already has hundreds or thousands of its own natural pest-resistance genes? How novel is a gene-spliced canola plant enhanced to withstand a particular herbicide, given that conventional herbicide-tolerant canola plants have been produced and used commercially for more than two decades?

Only when an identifiable high-risk trait is involved should formal government oversight be required. Fortunately, recombinant DNA (rDNA) techniques actually make it easier to identify such risky traits.

The Current Regulatory Scheme

When the early research on plant biotechnology was being conducted in the 1980s, the White House Office of Science and Technology Policy coordinated efforts of various regulatory agencies to outline a regulatory framework that aligned with scientific recommendations. Because conventional and biotech breeding methods pose the same kinds of risks, no new regulatory apparatus was thought to be needed. Existing federal agencies would regulate bioengineered organisms on the basis of their characteristics, not the method of production.[8] At least in theory, bioengineered organisms would not require extra scrutiny simply because rDNA methods were used to produce them. Instead, individual products would be subject to heightened scrutiny only if they expressed characteristics that posed some conceptually heightened risk.

This coordinated framework for the regulation of biotechnology divided regulatory jurisdiction among agencies already involved in agricultural, food, and environmental regulation. These agencies include the U.S. Department of Agriculture (USDA), the U.S. Environmental Protection Agency (EPA), and the U.S. Food and Drug Administration (FDA). Although each of these agencies considers the characteristics of individual products in their regulation, only the FDA follows the general scientific thinking that bioengineered and conventional products should be regulated similarly. Both the USDA and the EPA automatically subject all bioengineered plants as a class to premarket approval requirements not ordinarily applied to conventionally bred plants.

More important, the supposed justification for special regulation is that the process of inserting a novel gene into a crop plant, not just the presence of a novel gene, could be uniquely risky. This supposition has been debunked,[9] but each time a particular gene is put into a particular plant variety, the resulting "transformation event" is regulated as a unique product. If a single researcher puts one particular gene (conferring insect resistance, for example) into four different corn plants, all four are considered to be individual transformation events. Each event is regulated separately, and, in general, safety studies conducted on any one of the plants are not used in the review of the others.

Department of Agriculture

The USDA's primary concerns are the creation of weeds, the spread of plant and animal pathogens, and ecological disruption that would interfere with American agriculture. The department regulates the release of all bioengineered plants under statutes giving the Animal and Plant Health

8. Office of Science and Technology Policy, "Coordinated Framework for Regulation of Biotechnology; Announcement of Policy and Notice for Public Comment," *Federal Register* 51 (June 26, 1986): 23302–50.

9. Bradford et al., "Regulating Transgenic Crops Sensibly."

Inspection Service (APHIS) of USDA authority to control plants that may be or may become weeds or other nuisances—what the statutes call "plant pests."[10] Although the rules apply in a general sense to novel or exotic varieties of both bioengineered and conventional plants, APHIS typically requires field testing of conventional plants only if they are new to a particular U.S. ecosystem (transplanted from another continent, for example) or if the plant itself is known to be a problematic weed or to harbor a plant disease.

When the introduction of conventionally bred or new but unmodified plants is being considered, the species is subject to regulation only if it appears on a list of known plants pests. If the plant species in question is not on the proscribed list, it is exempt from all USDA regulation. However, this straightforward approach is risk-based in that the organisms required to undergo case-by-case governmental review are a known enhanced-risk group.

APHIS treats all new bioengineered plants as presumptive plant pests, no matter how safe or hazardous individual varieties may be.[11] Each new bioengineered variety (or transformation event) is considered to be a "regulated article" that requires repeated and often redundant field testing until the agency decides that it is not a plant pest, at which time it may be deregulated. Consequently, a new variety of wheat produced with conventional or wide-cross hybridization or mutation breeding[12] requires no government-mandated field testing—even though wide-cross hybridization introduces thousands of unknown and uncharacterized genes into the crop and despite the fact that mutation breeding randomly scrambles the DNA of a crop plant in unpredictable ways. But all new varieties of bioengineered wheat are subject to government-mandated field testing, even though there is no logical reason for the regulatory disparity.

For most bioengineered plants, APHIS requires the company producing the plants to submit notice detailing the gene or genes that have been inserted, the place where the plants will be tested, and other relevant characteristics of the plant before receiving permission to conduct the field trials. A new permit is needed whenever the size of a field trial is increased or a new site is added. Once the company completes field testing, APHIS reviews the results and makes a determination on whether the product should be deregulated and can be released into the market.[13] Because of the added time and expense of waiting for permits and conducting often unnecessary tests, APHIS regulations can make testing a bioengineered plant 10 to 20 times more costly than testing a conventionally bred plant.[14]

10. 7 CFR §§340.3 et seq.

11. APHIS, "Introduction of Organisms and Products Altered or Produced through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," *Federal Register* 52 (June 16, 1987): 22892–915; APHIS, "Genetically Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status," *Federal Register* 58 (March 31, 1993): 17044–59; and APHIS, "Genetically Engineered Organisms and Products; Simplification of Requirements and Procedures for Genetically Engineered Organisms," *Federal Register* 62 (May 2, 1997): 23945–58.

12. For a description of these methods, see the policy brief titled "Agricultural Biotechnology Overview."

13. Donna Vogt and Mickey Parish, "Food Biotechnology in the United States: Science, Regulation, and Issues," Congressional Research Service, Washington, DC, June 2, 1999, http://fpc.state.gov/fpc/6176.htm.

14. Susanne L. Huttner and Henry I. Miller, "USDA Regulation of Field Trials of Recombinant-DNA-Modified Plants: Reforms Leave Severe Flaws," *Trends in Biotechnology* 15, no. 10 (1997): 387–89.

Environmental Protection Agency

The EPA draws its authority to regulate most bioengineered plants from the Federal Insecticide, Fungicide, and Rodenticide Act, which encompasses pesticides, growth modulators, and related substances.[15] In 1994, EPA first proposed a rule for the regulation of bioengineered plants altered to mediate "host plant resistance" to pests or diseases, treating such plants as if they were the same as chemical pesticides.[16] Any bioengineered plant that either produces a substance directly used to protect the plant from pests—such as a protein that makes the plant resistant to insects, viruses, or fungi—or facilitates other pest management practices—such as a trait for herbicide tolerance—were dubbed "plant pesticides" and covered by the regulation.[17] It is worth noting that, to agronomists, even weeds are considered pests. Thus, a plant that is bioengineered to help farmers facilitate weed control is regulated by EPA under the pesticide statute.

When the EPA rule was first proposed, it was widely criticized by scientific bodies and individual scientists as scientifically indefensible.[18] Many scientists "argued that EPA should not be in the business of regulating genetically engineered plants at all."[19] Consequently, the agency revised its proposal several times and did not finalize the regulation until 2001.[20] When the final regulation was published, the agency changed the term *plant pesticide* to *plant-incorporated protectant* (PIP) but left the substance of the original proposal essentially unchanged. Bioengineered pest-protected plants must be approved by the EPA before commercialization in much the same way that chemical pesticides are. The submission required for EPA's regulatory review includes copious data on the parental plant, the genetic construction and behavior of the test plant, and so on.

During the course of research and development on a bioengineered plant variety that contains a PIP, the EPA conducts repeated case-by-case reviews—before the initial trial, again when trials are scaled up to larger size or to additional sites (even if minor changes

15. 7 USC §§136–36(u).

16. EPA, "Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Rule," *Federal Register* 59 (November 23, 1994): 60496–547; see also, EPA, "Plant-Pesticides; Supplemental Notice of Proposed Rulemaking," *Federal Register* 62 (May 16, 1997): 27131–42.

17. Ibid.

18. American Institute of Biological Sciences, American Phytopathological Society, American Society for Horticultural Science, American Society for Microbiology, American Society of Agronomy, American Society of Plant Physiologists, Crop Science Society of America, Entomological Society of America, Institute of Food Technologists, Society of Nematologists, and Weed Science Society of America, "Appropriate Oversight for Plants with Inherited Traits for Resistance to Pests," Institute of Food Technologists, Chicago, July 1996. See also, Council for Agricultural Science and Technology, "The Proposed EPA Plant Pesticide Rule," Council for Agricultural Science and Technology, Ames, IA, October 1998.

19. Larry D. Schulze, "Eleven Societies Oppose EPA Regulating Plant Pesticides," *Label* 8, no. 8 (1996), http://pested.unl.edu/thelabel/tlaug96.htm.

20. EPA, "Regulations under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant-Pesticides)," *Federal Register* 66 (July 19, 2001): 37772–817; EPA, "Exemption from the Requirement of a Tolerance under the Federal Food, Drug, and Cosmetic Act for Residues of Nucleic Acids That Are Part of Plant-Incorporated Protectants (Formerly Plant-Pesticides)," *Federal Register* 66 (July 19, 2001): 37817–830; and EPA, "Exemption from the Requirement of a Tolerance under the Federal Food, Drug, and Cosmetic Act for Residues Derived through Conventional Breeding from Sexually Compatible Plants of Plant-Incorporated Protectants (Formerly Plant-Pesticides)," *Federal Register* 66 (July 19, 2001): 37830–54.

are made in the genetic construct), and again at commercial scale. Biotech products face substantial regulatory hurdles, even though PIPs developed through conventional breeding are exempt from these requirements.[21]

EPA also regulates other organisms—such as bioengineered microbes used for bioremediation or "bio-rational" pesticides—under the Toxic Substances Control Act, which provides oversight of "non-natural" and "new" substances, and mixtures of substances, intended for use in commerce and that are not regulated elsewhere.[22] Because research with bioengineered microorganisms is subject to very heavy regulatory burdens with highly uncertain approval standards, the U.S. bioremediation industry has largely restricted itself to research on naturally occurring and conventionally modified organisms that are essentially exempt from the regulations. Today the use of biotech organisms for bioremediation or to develop microbial pesticides is almost nonexistent.

Food and Drug Administration

The FDA is responsible for ensuring that food items, including foods derived from bioengineered plants, are safe to eat. Under various statutes, including the Food, Drug, and Cosmetics Act, the FDA regulates food additives (such as artificial sweeteners and preservatives) through a premarket review process. The vast majority of what we eat, however, including both fresh and processed foods, is not subject to premarket testing, review, or inspection by the FDA. Instead, the agency simply polices the marketplace. Food products found to be *adulterated* (containing any addition "which may render [them] injurious to health") or *misbranded* (falsely or misleadingly labeled) may be removed from commerce.[23]

Following the general regulatory framework that emphasizes product regulation rather than process regulation, the FDA rightly does not treat foods derived from bioengineered plants as inherently unsafe.[24] Food producers are not required to seek premarket approval from the FDA unless there is a substantive reason to believe that the novel trait or traits in the food pose a safety question.[25] As in the case of conventionally bred food crops, the initial determination of safety is left to the producer.[26] However, the FDA has encouraged producers to consult with agency scientists before marketing a food produced with biotechnology to ensure that the appropriate determination is made. In 2001, the FDA published a proposed rule that would require producers to notify the agency

21. Staff of the Subcommittee on Basic Research of the Committee of Science, 106th Congress, 2nd Session, "Seeds of Opportunity: An Assessment of the Benefits, Safety, and Oversight of Plant Genomics and Agricultural Biotechnology," U.S. House of Representatives, Washington, DC, 2000.

22. 40 CFR Parts 700, 720, 721, 723, and 725; EPA, "Microbial Products of Biotechnology; Final Regulation under the Toxic Substances Control Act," *Federal Register* 62 (April 11, 1997): 17910–58.

23. 21 USC §§342–43.

24. FDA, "Statement of Policy: Foods Derived from New Plant Varieties," *Federal Register* 57 (May 29, 1992): 22984–3005.

25. The 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 FDA, "Statement of Policy."

26. FDA, "Statement of Policy," 22986–88. For example, the 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.

at least 120 days before marketing a new bioengineered crop plant,[27] but the proposal was later withdrawn. Instead, the FDA published a guidance document that advised crop breeders to seek voluntary safety evaluations of the new proteins produced by bioengineered plants before the plants were grown in field trials.[28] If the safety of such proteins could be determined before the field trial stage, there would be no reason for concern if an experimental crop were accidentally introduced into the food supply.

Finally, the FDA requires labeling of foods derived from biotechnology only when their composition differs significantly from that of their conventional counterparts. Such differences would need to be risk-related factors, including the presence of a substance that was completely new to the food supply, an allergen presented in an unusual or unexpected way, changes in the levels of major dietary nutrients, increased levels of natural plant-produced toxins normally found in foods, or even a change in the expected storage or preparation characteristics of the food.[29]

Labeling

Some activists argue that the government should mandate labeling of all bioengineered foods. They assert that consumers have a right to know how their foods have been altered and point to public opinion surveys in which majorities of respondents agree that labeling would be a good idea.[30]

Biotechnology advocates have argued against mandatory labeling because such requirements raise food costs—something that mostly harms low-income Americans and those on fixed budgets. Perhaps more important, while biotech products are not substantially different from other products, special labels would likely make consumers think they were more dangerous.[31] Hence, rather than serving educational or right to know purposes, such labels promise simply to confuse consumers.

In one typical survey, for example, 70 percent of respondents agreed that "the words genetically engineered should appear on the label of a food product where one or more ingredients were genetically engineered." However, 25 percent of respondents admitted that they were "not at all familiar" with bioengineered foods, 30 percent said "not very familiar," 38 percent said "somewhat familiar," and only 5 percent said they were "extremely familiar."[32] What are we to make of largely uninformed opinions about complex public policy issues?

27. FDA, "Premarket Notice Concerning Bioengineered Foods," *Federal Register* 66 (January 18, 2001): 4706–38.

28. FDA, "Guidance for Industry; Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use," *Federal Register* 71 (June 21, 2006): 35688–89.

29. FDA, "Statement of Policy," 22991.

30. See, for example, Campaign to Label Genetically Engineered Foods website, http://www.thecampaign.org, and Center for Science in the Public Interest, "National Opinion Poll on Labeling of Genetically Modified Foods," Center for Science in the Public Interest, Washington, DC, 2001, http://www.cspinet.org/reports/op_poll_labeling.html.

31. Henry I. Miller, "Genetic Engineering: A Rational Approach to Labeling Biotech-Derived Foods," *Science* 284, no. 5419 (May 28, 1999): 1471–72; Subcommittee on Basic Research of the Committee of Science, "Seeds of Opportunity, 53–55; Gregory Conko, *Eat, Drink, and Be Merry: Why Mandatory Biotech Food Labeling Is Unnecessary* (Portland, OR: Cascade Public Policy Institute, October 2002).

32. Center for Science in the Public Interest, "National Opinion Poll on Labeling of Genetically Modified Foods."

In that same survey, 40 percent of respondents agreed that foods "made from cross-bred corn" should be labeled.[33] But virtually all the corn grown in the United States is from cross-bred, or hybrid, varieties. Labeling in this case would, therefore, convey no useful information and make absolutely no sense. It would be tantamount to labeling bottled water to inform consumers that the products contain hydrogen and oxygen. In any case, we wonder how many of the respondents who say they support biotechnology labeling know the substance of existing FDA policies for food labeling in general or biotech foods in particular.

Currently, FDA policy mandates labels on any new food products in which a "material" change has been made to a health- or safety-related characteristic.[34] This risk-based labeling requirement applies to all foods, whether they have been developed through conventional breeding methods or the more advanced bioengineering techniques, and it is therefore consistent with the scientific consensus that regulation should be based on the specific characteristics of the products that could make them more or less safe, not how they were created. Consequently, the biotech labeling policy of the FDA has been endorsed by scientific organizations such as the American Medical Association[35] and the Institute of Food Technologists.[36]

In a series of polls commissioned by the International Food Information Council (IFIC), respondents were read a summary of current FDA policy on labeling and asked if they supported or opposed it. In each survey, a majority of respondents agreed with the FDA labeling policy.[37] Because respondents were given a summary understanding of the FDA's current policy before they were asked to comment on it, the results of the IFIC surveys should be given more credence than surveys of uninformed members of the public. Given the limited level of background knowledge on which other research on public attitudes is based, there is no evidence that that the public genuinely supports mandatory labeling.

A government-mandated label on all genetically engineered foods also would raise important First Amendment free speech issues. In 1996, the U.S. Second Circuit Court of Appeals, in the case of *International Dairy Foods Association, et al. v. Amestoy*, ruled unconstitutional a Vermont statute requiring the labeling of dairy products 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."[38] In other words, to be constitutional, labeling must be confined to disclosure of information for which a legitimate governmental interest exists, such as that relevant to health or nutrition. This is decidedly not the case when it comes to generic labeling of all bioengineered foods.

33. Ibid.

34. FDA, "Statement of Policy."

35. American Medical Association, "Report 10 of the Council on Scientific Affairs (I-00): Genetically Modified Crops and Foods," American Medical Association, Chicago, 2000.

36. Institute of Food Technologists, *IFT Expert Report on Biotechnology and Foods*.

37. IFIC, "IFIC Survey: Food Biotechnology Not a Top-of-Mind Concern for American Consumers," IFIC, Chicago, June 2005, http://www.ific.org/research/upload/2005BiotechSurvey.pdf.

38. 92 F.3d 67 (2nd Cir. 1996).

Furthermore, consumers need not rely on mandatory labeling of bioengineered foods to truly have a choice. Real-world examples show that market forces are fully capable of supplying information about process attributes (such as kosher and organic production standards) that consumers truly demand. The same can be said about nonengineered foods. Numerous products voluntarily labeled as containing no genetically engineered ingredients can be found on grocery store shelves, and several antibiotech organizations tout their own guides to buying "non-GM" products.[39] And, in 2001, FDA published a draft guidance to assist producers in voluntarily labeling both genetically engineered foods and foods that are not genetically engineered.[40] In addition, the USDA rule published for organic certification necessarily excludes biotech products from organic food production.[41] Consequently, consumers wishing to purchase nonbiotech foods need look only for certified organic products or others specifically labeled as not developed using bioengineering techniques.

International Trade

Although U.S. consumers do not appear to be strongly opposed to biotech foods (in fact, they seem rather indifferent), a strong antibiotechnology movement has arisen in several European and Asian countries in the past decade. The European Union (EU) has established strong restrictions on the commercial planting of genetically engineered crops,[42] and European food processors and retailers are reluctant to import harvested agricultural products derived from biotechnology.

After approving two biotech varieties for commercialization in the mid-1990s, EU policymakers imposed an unofficial moratorium from 1998 to 2004 on the approval of additional biotech crops. Six EU member countries—Austria, France, Germany, Greece, Italy, and Luxembourg—banned all commercial planting and sale of bioengineered varieties. In 2006, the World Trade Organization (WTO) ruled that the moratorium and national bans violated global trade treaties.[43] However, the victory for the United States, Canada, and Argentina, which jointly filed the case, was largely symbolic because the WTO decision left the underlying regulatory policy of the European Union unchallenged. The trade panel did not object to how biotech products were regulated in the

39. Institute for Responsible Technology, "How to Buy Non-GM," Institute for Responsible Technology, Fairfield, Iowa, available at http://www.responsibletechnology.org/GMFree/AboutGMFoods/HowtoBuyNon-GM/index.cfm.

40. FDA, "Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability" *Federal Register* 66 (January 18, 2001): 4839–42.

41. 7 CFR Part 205.

42. European Parliament and the Council of the European Union, "Regulation (EC) No. 1829/2003 on Genetically Modified Food and Feed," *Official Journal of the European Union* L268 (2003): 1–23; European Parliament and the Council of the European Union, "Regulation (EC) No. 1830/2003 Concerning the Traceability and Labeling of Genetically Modified Organisms and the Traceability of Food and Feed Products from Genetically Modified Organisms and Amending Directive 2001/18/EC," *Official Journal of the European Union* L268 (2003): 24–28; European Parliament and the Council of the European Union, "Commission Regulation (EC) No 65/2004 of 14 January 2004 Establishing a System for the Development and Assignment of Unique Identifiers for Genetically Modified Organisms," *Official Journal of the European Union* L10 (2004): 5–10.

43. WTO, "European Communities—Measures Affecting the Approval and Marketing of Biotech Products: Reports of the Panel," WT/DS291/R, WT/DS292/R, WT/DS293/R, WTO, Geneva, September 29, 2006.

EU; it held only that European officials were not following their own regulations by "unduly delaying" final approval of otherwise complete applications for 25 food biotech products for transparently political reasons.[44]

EU regulatory policies, however, are themselves problematic.[45] First, there is no relationship between regulation and risk in EU biotech policies, so very safe products are held to extreme regulatory scrutiny. And, second, once biotech foods are approved for commercial use, EU policy requires both labeling and traceability. Every single bioengineered variety (or transformation event) and every food ingredient derived from it must be labeled with a unique identifier, regardless of whether it can be distinguished from conventionally produced foods. Then, every link in the vast food chain—from seed breeders to farmers, shippers, processors, wholesalers, and retailers—is required to keep detailed records identifying from whom each ingredient was received and to whom it was sent, so that every ingredient can be traced back to the farm on which it was grown.

At the time this chapter was written, it was not clear how the global commodity system would accommodate the traceability regime, but compliance was expected to be very costly. Thus, even European food processors and retailers that sold some bioengineered foods before implementation of the labeling and traceability rules were reluctant to continue selling biotech products. Consequently, the European market is no more open to bioengineered crops today than before the WTO case was decided.

In addition, the very strong restrictions included in the Cartagena Protocol on Biosafety,[46] which was finalized in January 2000, are beginning to spread European-style biotech regulation based on the precautionary principle around the world. Many less developed country governments are reluctant to approved bioengineered crops for their own farmers as long as major export markets in Europe are closed to such crops.[47] Others have been convinced by European policymakers and environmental activists that such regulation is warranted. However, while the EU continues to assert that the precautionary principle is an unbiased risk management philosophy, critics have shown that its lack of definition and evidentiary standards makes it easy to abuse for the purpose of masking trade protectionism and that its inherently flawed risk management approach may, in fact, increase net risk.[48]

---

44. Ibid. See also Gregory Conko, "New Era, or Ancien Régime, for European Biotech?" *Planet* (May 2006): 1, 3.

45. See generally Henry I. Miller and Gregory Conko, *The Frankenfood Myth*; Tony Gilland, "Trade War or Culture War? The GM Debate in Britain and the European Union," in *Let Them Eat Precaution: How Politics Is Undermining the Genetic Revolution in Agriculture*, ed. Jon Entine (Washington, DC: American Enterprise Institute, 2006); Neville Craddock, "Flies in the Soup—European GM Labeling Legislation," *Nature Biotechnology* 22 (April 2004): 383–84.

46. Secretariat of the Convention on Biological Diversity, *Cartagena Protocol on Biosafety to the Convention on Biological Diversity: Text and Annexes* (Montreal: Secretariat of the Convention on Biological Diversity, 2000).

47. Robert Paarlberg, *The Politics of Precaution: Genetically Modified Crops in Developing Countries* (Baltimore, MD: Johns Hopkins University Press, 2001); Robert Paarlberg, "African Famine, Made in Europe," *Wall Street Journal*, August 23, 2002, A12; Gregory Conko, "Rethinking the Regulation of Bioengineered Crops: Why European and American Biotechnology Rules Are Bad for Less Developed Countries," paper presented at the U.S. State Department conference on Agricultural Biotechnology and Developing Countries, Arlington, VA, May 23, 2003.

48. Gregory Conko, "Safety, Risk, and the Precautionary Principle: Rethinking Precautionary Approaches to the

Conclusion

Even as farmers in underdeveloped nations clamor for biotechnology applications, and even as countries like China continue to experiment with and use agricultural biotechnology,[49] opponents of agricultural biotechnology in the West, particularly Europe, attack it as an unnatural process that will destroy the world, not improve it. They argue that biotechnology should be heavily regulated, if not banned.

Genetically engineered plants already 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 their further research and development, 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 affect the international trade of agricultural goods and delay their introduction into the marketplace. Each of these problems could prevent the benefits of this technology from being introduced to industrial nations and, more importantly, to the developing world.

Key Experts

Gregory Conko, Senior Fellow, Competitive Enterprise Institute, gconko@cei.org

Henry Miller, Fellow, Hoover Institution, miller@hoover.stanford.edu

Recommended Reading

Miller, Henry I., and Gregory Conko. 2004. *The Frankenfood Myth: How Protest and Politics Threaten the Biotech Revolution*. Westport, CT: Praeger.

Bradford, Kent J., Allen Van Deynze, Neal Gutterson, Wayne Parrott, and Steven H. Strauss. 2005. "Regulating Transgenic Crops Sensibly: Lessons from Plant Breeding, Biotechnology, and Genomics," *Nature Biotechnology* 23, no. 4, 439–44.

Institute of Food Technologists. 2000. *IFT Expert Report on Biotechnology and Foods*. Chicago: Institute of Food Technologists.

National Research Council. 1989. *Field Testing Genetically Modified Organisms: Framework for Decisions*. Washington, DC: National Academies Press.

Regulation of Transgenic Plants," *Transgenic Research* 12, no. 6 (2003): 639–47; Henry I. Miller and Gregory Conko, "The Perils of Precaution," *Policy Review* 107 (June/July 2001): 25–39.

49. Jikun Huang and Qinfang Wang, "Agricultural Biotechnology Development and Policy in China," *AgBioForum*, 5, no. 4 (2002): 122-135.

Updated 2008.