Food, Drugs, and Consumer Products

6

GENETICALLY ENGINEERED FOODS

The safety of genetically engineered (GE) organisms has been studied extensively by dozens of the world's leading scientific bodies. Every one of them has concluded that the techniques give rise to no new or unique risks compared with conventional breeding methods, and that the ability to move individual genes between organisms actually makes the characteristics of genetically engineered products more precise and predictable, and therefore safer, than comparable products developed with more conventional breeding methods. Furthermore, the consensus among scientists who have studied genetic engineering—also known as biotechnology and gene-splicing techniques—holds that the evaluation of those products "does not require a fundamental change in established principles of food safety; nor does it require a different standard of safety" than those that apply to conventional foods. (See Institute of Food Technologists, *IFT Expert Report on Biotechnology and Foods*, Chicago: Institute of Food Technologists, 2000, p. 23.)

Nevertheless, genetically engineered plants and animals, and foods derived from them, have been subject to extensive regulatory requirements imposed by three different agencies in the United States: the U.S. Department of Agriculture (USDA), Environmental Protection Agency (EPA), and Food and Drug Administration (FDA). Essentially all new genetically engineered crop plants must undergo rigorous testing and be vetted by the agencies before they are put on the market, even as conventionally bred plants with identical characteristics are subject to no regulation at all.

Congress should reform the USDA approval process for genetically engineered plants to require that only those with known high-risk traits and those whose risks are unknown be approved before commercial use. The expensive and lengthy review process is scientifically unjustified and adds millions of dollars to the development costs of each new GE variety. The cost and complexity of complying with those regulatory strictures have concentrated GE product development in the hands of six major seed companies, and has made it uneconomical to use genetic engineering to develop improved varieties of all but major commodity crops, such as corn and soybeans. Small startup firms and university researchers simply cannot afford the regulatory costs associated with bringing a new GE crop to market.

Despite the overwhelmingly positive record of environmental and human safety, and the substantial burden of mandatory testing and regulatory review, some critics have demanded special labeling for GE foods. They argue that, even if GE foods are safe and nutritious, consumers want the additional information. Current FDA policy reserves mandatory labeling for food products whose characteristics have been changed in a way that affects safety and nutrition. Where a food product has been changed in a material way—such as an increase or decrease in vitamins, the addition of an allergen, or some other change that affects safety or nutritional value—the product label must note the specific change.

Labeling advocates have been unable to persuade the FDA, but they have had some success at the state level. Connecticut, Vermont, and Maine have enacted legislation that would require certain GE foods to be labeled as containing genetically engineered ingredients. Those laws, if fully implemented, would needlessly raise the cost of *all* foods, whether they contain GE ingredients or not. They are also unnecessary because a thriving market for voluntarily labeled non-GE foods has developed, providing those who wish to avoid genetically engineered ingredients plentiful choice in the marketplace. State labeling mandates are also unconstitutional, and they may be preempted by the Federal Food, Drug, and Cosmetic Act. Congress should clarify that act to clearly preempt state GE labeling mandates.

Regulation of Genetically Engineered Plants and Foods

Dozens of scientific organizations, including the U.S. National Academies, American Association for the Advancement of Science, and Institute of Food Technologists, have carefully studied the safety of genetic engineering for consumers and the environment. All have concluded that the use of modern biotechnology, or gene-splicing techniques, gives rise to no new or unique risks compared with more conventional forms of breeding. In fact, say the experts, because the tools of genetic engineering are more precise and predictable, GE plants and foods derived from them will in many cases be safer than their conventionally bred counterparts.

Congress should:

- Reform the U.S. Department of Agriculture's approval processes for genetically engineered plants to require that only genetically engineered plants with high-risk traits be approved before commercial use.

In each of four studies conducted from 1989 to 2004, the National Research Council of the U.S. National Academies concluded that no scientific justification exists for regulating genetically engineered organisms any differently from conventionally bred varieties. The safety of a new plant variety has solely to do with the characteristics of the plant that is being modified, the specific traits that are added, and the local environment into which it is being introduced, regardless of whether genetic engineering or a more conventional breeding method is used to modify the plant. Nevertheless, to ameliorate public concerns about gene splicing, the U.S. Department of Agriculture and the Environmental Protection Agency each developed regulatory frameworks during the 1980s that require premarket approval for nearly all new genetically engineered plant varieties, regardless of the safety of the traits incorporated into individual plants.

Under the Plant Protection Act, the USDA treats essentially all GE plants as potential plant pests—organisms that may be injurious to agriculture—until they have been extensively tested under stringent rules, found not to be pests, and then "deregulated" by the department (7 CFR 340). Two decades of practical, commercial experience with GE crops have shown early concerns to be unwarranted, and approved varieties have an admirable record of consumer and environmental safety. Furthermore, the USDA has not once had to reject an application because the new variety was in any way unsafe. Yet instead of being comforted by that admirable safety record, the USDA's response has been to demand more testing and to lengthen the time it takes to review deregulation applications.

From 1992 to 1999, the USDA took an average of fewer than six months to deregulate 50 new GE varieties—after several years of required testing were completed for each. Regulatory review times grew steadily beginning in the 2000s, and the department now takes an average of over two full years to deregulate a new variety, despite a much smaller number of applications being submitted. (See USDA Animal and Plant Health Inspection Service, "Petitions for Determination of Nonregulated Status," http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml.) Regulatory hurdles alone add between $6 mil-

lion and $15 million to development costs for each new variety, a burden that only large seed companies can afford—and then only for high-value commodity crops. Regulatory compliance costs for GE crops can often exceed the entire market value of most fruit and vegetable species. And small startup firms and university-based researchers simply cannot afford to bring any new GE varieties to market.

The current regulatory system for genetically engineered crop varieties cannot be justified scientifically. It singles out the more precise techniques of gene splicing for added scrutiny, even as crops bred using less precise, and arguably less safe, methods—such as induced DNA mutation and forced hybridization of different plant species—go entirely unregulated. Crops bred to withstand herbicides or with added resistance to certain pests are heavily regulated if they are produced with gene-splicing techniques, but the very same traits are not regulated at all if the crop was, for example, exposed to radiation in order to mutate the plant's DNA.

What is needed is a regulatory apparatus that focuses on new plant traits, not breeding method, and increases the amount of testing and scrutiny as the riskiness of individual traits rises. Congress should instruct the USDA to exempt low-risk traits, such as herbicide tolerance, from Plant Protection Act regulation and to focus solely on traits known to pose potential hazards to humans or the environment, as well as traits that are genuinely novel, whose risks are unknown.

Expert: Gregory Conko

For Further Reading

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

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

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GE Food Labeling

The U.S. Food and Drug Administration's policy on labeling foods derived from new plant varieties, introduced in 1992, follows the advice of major scientific bodies and is premised on the view that what determines the safety, wholesomeness, and nutritional value of a food is its characteristics, not the breeding method used to develop it. (See Food and Drug Administration, "Statement of Policy: Foods Derived from New Plant Varieties," *Federal Register* 57, May 29, 1992, 22,984–23,005.)

Congress should:

- Codify the Food and Drug Administration's current labeling policy for food products, under which special labeling is necessary only when a food's characteristics have been altered in a material way, and preempt state GE food labeling requirements.

All breeding methods—from simple hybridization to the most modern biotechnology-based techniques—have the potential to introduce significant changes in the composition of foods. But well-known and easily performed testing methods are sufficient to determine a food's nutritional value and safety. Therefore, according to FDA policy, food producers have a legal obligation to ensure that new food plant varieties are safe for human and animal consumption, but special labeling specific to GE foods is not required.

Producers have a legal obligation to note on labels any time a food has been changed in a way that might be material to consumer safety and nutrition. Such changes might include a higher or lower level of vitamins or other nutrients, fats, carbohydrates, and other components beyond the normal variability present in conventional counterparts. Material changes could also include the introduction of an allergen or other potentially deleterious substance, or even a change in a food's taste, smell, texture, or its storage, handling, or preparation requirements.

If a new food product has been changed in any of those ways, its label must alert consumers to the modification, regardless of whether that change was made using genetic engineering or another breeding method. Importantly, it is not sufficient merely to state what *breeding method* was used to develop the product; the label must state what *change* has been made.

Ever since the first genetically engineered food products were put on the market—cheeses produced with an engineered clotting agent called chymosin in 1990 and milk from cows given an engineered version of the natural bovine growth hormone somatotropin in 1993—some critics have demanded that those products be labeled to indicate that gene splicing was used in their production. (See Center for Veterinary Medicine, U.S. Food and Drug Administration, "BST Update," *CVM Update*, March 21, 1996.) However, the FDA has resisted calls for special labeling of those genetically engineered foods that have been tested extensively for safety and have been found not to differ in any material way from their conventional counterparts. And where a food was changed in a material way, such as the introduction of a protein that could be allergenic or a modification that would produce healthier fats in cooking oils, the alteration would have to be included on the product's label.

The agency, which relies on mandatory labeling to alert consumers about important safety and nutritional changes, concluded that a mandatory GE label would falsely lead consumers to believe there is an important safety concern regarding genetic engineering when, in fact, there is none. According to the American Association for the Advancement of Science, "Legally mandating such a label can only serve to mislead and falsely alarm consumers." (See American Association for the Advancement of Science, "Statement by the AAAS Board of Directors on Labeling of Genetically Modified Foods," October 20, 2012, http://www.aaas.org/sites/default/files/AAAS_GM_statement.pdf.)

Labeling advocates respond that a large majority of consumers say they support mandatory GE labeling, and that, regardless of whether GE foods are safe, consumers have a right to choose. However, the demand for information has spawned a thriving market for voluntary labeling that indicates the absence of GE ingredients. Thousands of foods labeled "non-GE" can be found in grocery stores around the country, and both advocacy organizations and consumer groups have introduced pocket shopping guides and smartphone apps to help shoppers exercise the choice many say they want.

Finding no success with FDA, mandatory labeling advocates have turned to lobbying state governments instead. Bills and ballot initiatives to require labeling have been introduced in at least 25 states. Most have been rejected, but Connecticut, Vermont, and Maine have enacted such legislation. Those laws are unnecessary, given the availability of voluntary labeling information. If fully implemented, they will raise costs and prices for both GE and non-GE foods.

Furthermore, they are legally dubious on various grounds. They are unconstitutional because, as federal courts have concluded, satisfying consumer curiosity is not a governmental interest sufficient to overcome the producers' First Amendment rights not to include extraneous information on labels. (See *International Dairy Foods Association v. Amestoy*, 92 F.3d 67 (2nd Cir. 1996).) And state GE labeling laws may also be preempted by the Federal Food, Drug, and Cosmetic Act, as one federal court has concluded (*Briseno v. ConAgra Foods Inc.*, No. 2:11-cv-05379 (C.D. Cal., November 23, 2011)).

Because the provisions of the Federal Food, Drug, and Cosmetic Act that preempt state labeling laws are ambiguous, supporters of FDA's current policy introduced a bill in 2014 explicitly to preempt state GE labeling rules: the Safe and Accurate Food Labeling Act (H.R. 4432). To build support for the legislation, the bill would also increase the stringency of the FDA's existing safety review for new genetically engineered food products. Yet the overwhelming majority of food safety scientists agree that no scientific justification exists for regulating genetically engineered organisms any differently from conventionally bred varieties, so even FDA's existing regulatory framework is unnecessary. Congress should clarify that the Federal Food, Drug, and Cosmetic Act does preempt state GE labeling laws, but it should resist needless calls to increase the already-burdensome regulation of genetically engineered foods.

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For Further Reading

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William Lesser, "Costs of Labeling Genetically Modified Food Products in N.Y. State," Unpublished manuscript, 2014, http://dyson.cornell.edu/people/profiles/docs/LabelingNY.pdf.

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