POLICY FORUM: GENETIC TECHNOLOGIES

Bioengineered Food—Safety and Labeling

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Bills proposing to amend the Federal Food, Drug, and Cosmetic Act (FFDCA) to address the safety and labeling of bioengineered foods have been introduced in both houses of the U.S. Congress. The *Genetically Engineered Food Safety Act* (GEFSA) would make all transgenic components of bioengineered foods subject to premarket review as food additives (*1*). The *Genetically Engineered Food Right to Know Act* (GEFRKA) would require labeling of food that "contains a genetically engineered material, or was produced with a genetically engineered material" (*2*). Many aspects of these bills are inconsistent with well-established principles of food regulation.

Food Safety and GEFSA

Food additives are defined in the FFDCA as substances that are intended to become components of food, but are not "generally recognized as safe" (GRAS) through laboratory testing or long-standing use in food (*3*). Manufacturers must submit data on the technical effects and safety of food additives to the Food and Drug Administration (FDA), and approval takes as much as 6 years (*4*, *5*). The FDA has not generally characterized transgenes and other bioengineered substances such as proteins, carbohydrates, fats, or oils as food additives, because they are ubiquitous in living organisms and comparable to substances in foods already on the market and are therefore GRAS. However, if a bioengineered substance is not GRAS, the FDA can regulate it as a food additive (*6*). Indeed, the FDA approved bioengineered aminoglycoside 3′-phosphotransferase as a food additive (*7*).

Since 1994, the FDA has held more than 40 voluntary consultations with manufacturers to assess many of the same factors that would be considered in a safety evaluation required by the GEFSA, including possible allergenicity, toxicity, and changes in nutrient levels (*6*, *9*). The FDA recently announced that it will propose regulations requiring manufacturers to notify it of their plans to sell bioengineered foods at least 120 days before marketing and to submit information that the FDA would evaluate to determine whether additional regulatory steps should be taken (*8*). The GEFSA would be unnecessarily burdensome, because it would regulate all bioengineered components of foods as food additives, regardless of qualities or composition.

Regulate it, but not inappropriately.

In addition, the GEFSA is unnecessary, because most transgenic components of food have been evaluated for safety by the Environmental Protection Agency (EPA), under standards similar to those for food additives. Because nearly all of today's transgenic crops are either pest-resistant or herbicide-tolerant (*10*), the bioengineered components of most crops have been evaluated for safety (*11*) under legal standards that originally applied to pesticide chemicals and their inert ingredients (*12*). Approval of pesticides and food additives is based on a determination of reasonable certainty that no harm will result from cumulative dietary exposure (*12*, *13*). In addition, for pesticides the safety determination must apply to sensitive subgroups such as infants and children, as well as the general population (*12*). When evaluating bioengineered plant-incorporated protectants (PIPs) (*14*), the EPA generally considers the same factors that would be required by the GEFSA for all bioengineered components, including allergenicity and toxicity (*1*, *15*, *16*).

The EPA concluded that bioengineered PIPs are safe for human consumption at any anticipated level of dietary exposure (*11*, *15–17*). Indeed, bioengineered PIPs such as *Bt*, an insecticidal protein derived from *Bacillus thuringiensis,* offer a benefit by replacing riskier chemical pesticides (*18*). On the basis of *Bt*'s history of safe usage, rapid degradation by simulated gastric fluid in vitro, lack of acute oral toxicity in rodents, and lack of potential for allergenicity, the EPA approved bioengineered variants of *Bt* for human consumption (*15–17*). However, the EPA limited the approval of the Cry9C variant to use in animal feed, because of inconclusive results in tests designed to assess its potential allergenicity (*19*).

Bioengineered enzymes that make plants herbicide-tolerant have also been evaluated for food safety, because they are considered inert ingredients of pesticides when used as selectable markers for PIPs such as *Bt* (*20*). The EPA determined that the major herbicide tolerance–conferring enzymes were not toxic to rodents, were rapidly digested in a gastric environment, and showed no evidence of allergenicity. Thus, the EPA approved them and concluded that no maximum allowable level is necessary to protect the public health (*21–23*).

The EPA's evaluations of PIPs and their inert ingredients have affirmed their safety. Moreover, the FDA's new premarket notification policy should give the agency ample information to decide when transgenic components of bioengineered foods should be regulated as food additives. Although recent reports of taco shells containing a small percentage of corn expressing the Cry9C variant of *Bt* (*24*) indicate that limited use in feed should be permitted only if the segregation of such products can be ensured, food additive review under the GEFSA would not have prevented this contamination. Indeed, the EPA's review of Cry9C was particularly thorough, including an evaluation by a scientific advisory panel (*25*). Accordingly, premarket approval of all bioengineered foods as food additives is unwarranted and inconsistent with established principles of food regulation.

Labeling and GEFRKA

Mandatory labeling of bioengineered food proposed by the GEFRKA is inconsistent with the historical exemption of pesticides

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from labeling requirements. Disclosure of chemical pesticide and fungicide residues in food labels was largely eliminated during a 1960's controversy that strongly resembles today's controversy over labeling (*11*). At that time, the FFDCA required disclosure in retail food labels of the residues of certain fungicides applied after harvest. The FDA supported this disclosure on the basis of consumer "right-to-know." However, insecticides and herbicides did not have to be disclosed because of the difficulty of tracking their residues from the beginning of crop production (*26–28*). Food industry and state agricultural and land-grant college officials asserted that fungicide labeling was burdensome and impractical, that detection methods for pesticide residues were inadequate, and that there would be widespread violations of the FFDCA and criminal liability. Some stores refused to accept produce treated with disputed fungicides, and there was fear of widespread economic loss (*28*). Because of these concerns, Congress amended the FFDCA to end mandatory disclosure of fungicides (*27*, *29*, *30*).

Mandatory labeling of bioengineered foods could be more burdensome than disclosure of fungicides applied after harvest. It would require segregating and tracking an inherent, minute component of food through the entire chain of food production, including planting, harvesting, shipping, processing, and retail sale. It would be perverse to require disclosure of bioengineered PIPs when no labeling is required for chemical pesticides (*11*).

More generally, the labeling provisions of the GEFRKA are contrary to well-established tenets of food labeling under the FFDCA. The FFDCA requires that labeling be truthful and not misleading (*31*) and that it reveal material facts relevant to the use of the product (*32*). In *United States* v. *95 Barrels of ... Apple Cider Vinegar*, the Supreme Court interpreted "material facts" to be facts about composition, not method of manufacture (*33*). Similarly, genetic engineering, a method of manufacture, has not been construed by the FDA as a material fact requiring labeling, just as other plant breeding methods are not required to be disclosed (*6*). The FDA has concluded that as a class, bioengineered foods cannot be distinguished compositionally from foods developed by traditional methods, and thus do not require labeling. However, if bioengineering produces a material difference, for example, through the introduction of an allergen, toxin, or novel component such as a sweet protein, labeling would be required (*6*). Accordingly, the FDA recently required labeling of bioengineered soybean and canola oils with altered fatty acid composition (*9*).

In *Stauber* v. *Shalala*, consumer advocates were unsuccessful in their effort to force FDA to require labeling of milk produced with the use of recombinant bovine somatotropin (rbST), because the milk is compositionally indistinguishable from milk produced without the hormone (*34*). The district court concluded that a labeling requirement based solely on consumer demand to know the method of manufacture would violate the FFDCA (*34*). The GEFRKA seeks to overrule *Stauber* v. *Shalala* by requiring labeling of food derived from animals injected with genetically engineered materials (*2*).

The GEFRKA may also violate the First Amendment commercial speech rights of the manufacturers of bioengineered foods by requiring labeling in the absence of health and safety concerns. In *International Dairy Foods Assoc.* v. *Amestoy*, the Court of Appeals for the 2nd Circuit held that a Vermont law requiring labeling of rbST-enhanced milk violated commercial speech rights of the dairy manufacturers, because it imposed the equivalent of a warning about method of manufacture, even though the composition of the milk was unaffected (*35*). Consumer "right-to-know" was insufficient to compel labeling in the absence of a substantial government interest, such as health or safety concerns (*35*). By this reasoning, the labeling requirement in the GEFRKA for any food that "contains a genetically engineered material, or was produced with a genetically engineered material," could also be held unconstitutional.

The GEFRKA would require labeling and tracking of bioengineered foods regardless of whether the altered characteristics of the genetically modified organism are detectable in the food (*2*). The GEFRKA would require labeling of milk or meat derived from animals that have been fed bioengineered foods, even though no evidence suggests that the milk or meat would be distinguishable from that of animals fed traditional foods (*2*, *25*). As bioengineered corn and soybeans are widely used as animal feed in the United States (*36*), this requirement could lead to the meaningless labeling of most milk and meat. These labeling provisions are extreme even as compared with those of the European Union, which does not require labeling in the absence of detectable transgenic DNA or proteins (*37*). Finally, a labeling requirement would not prevent inadvertent contamination, as recently occurred with the Cry9C variant.

Whereas there are legal impediments to mandatory labeling, the FDA is planning to issue guidelines for voluntary labeling, so that product claims will be truthful and not misleading, consistent with the requirements of the FFDCA (*8*, *38*). To ensure that labeling meets this standard, the U.S. Department of Agriculture is developing a program to certify laboratories and testing kits for the detection of bioengineered components of food (*38*, *39*).

Conclusion

Both the GEFSA and the GEFRKA are inconsistent with basic principles of food regulation, as well as current scientific knowledge about bioengineered foods. Laws addressing the safety and labeling of bioengineered food, or the regulation of any new technology, should be based on sound science.

References and Notes

1. H.R. 3883, 106th Cong. (2000); S. 2315, 106th Cong. (2000).
2. H.R. 3377, 106th Cong. (1999); S. 2080, 106th Cong. (2000).
3. 21 U.S.C. § 321(s) (1998).
4. 21 U.S.C. § 348 (1998).
5. *Delays in the FDA's Food Additive Petition Process, Hearings Before the Subcommittee on Human Resources and Intergovernmental Relations of the House Committee on Government Reform and Oversight*, 104th Cong. 16 (1995).
6. 57 Fed. Reg. 22,984 (FDA 1992).
7. 59 Fed. Reg. 26,700 (FDA 1994).
8. FDA, U.S. Department of Health and Human Services, *HHS News*, P00-10, 3 May, 2000.
9. L. Thompson, *FDA Consumer* **34**, 18 (January–February 2000).
10. D. Ferber, *Science* **286**, 1662 (1999).
11. K. A. Goldman, *Georgetown Int. Environ. Law Rev.* **12**, 717 (2000).
12. 21 U.S.C. § 346a (1998).
13. 21 C.F.R. § 170.3(i) (1999) (food additives).
14. "Plant-incorporated protectants" have been called "plant-pesticides," but the latter will be renamed in new EPA regulations. 65 Fed. Reg. 55,929 (2000).
15. 61 Fed. Reg. 40,340 (1996).
16. 62 Fed. Reg. 17,720 (1997).
17. 60 Fed. Reg. 21,725 (1995).
18. N. Smith, Subcommittee on Basic Research, Committee on Science, 106th Cong., 2d Session, Seeds of Opportunity (Committee Print 2000).
19. 63 Fed. Reg. 28,258 (1998).
20. 59 Fed. Reg. 60,496 (1994).
21. 61 Fed. Reg. 40,338 (1996).
22. 62 Fed. Reg. 52,505 (1997).
23. 62 Fed. Reg. 17,717 (1997).
24. A. Pollack, *New York Times*, 23 September 2000, p. C1.
25. EPA, *Cry9C Food Allergenicity Assessment Background Document* (2000). www.epa.gov/scipoly/sap/2000/february/12-9.pdf
26. H.R. Rep. No. 85-2119 (1958).
27. H.R. Rep. No. 86-1468 (1960).
28. *Chemical Preservatives: Hearings on H.R. 9521 Before a Subcommittee of the House Committee on Interstate and Foreign Commerce*, 85th Cong. 118 (1958).
29. 21 U.S.C. § 343(k) (1994).
30. The only exception is a requirement for disclosure of residues of pesticides applied after harvest on shipping (not retail) containers of raw agricultural commodities. 21 U.S.C. § 343(l) (1994).
31. 21 U.S.C. § 343(a)(1) (1994).
32. 21 U.S.C. § 321(n) (1994).
33. 265 U.S. 438 (1924).
34. 895 F. Supp. 1178 (1995).
35. 92 F.3d 67 (2d Cir. 1996).
36. Economic Research Service, U.S. Department of Agriculture, *Biotech Corn and Soybeans: Changing Markets and the Government's Role*, 29 March 2000, www.ers.usda.gov/whatsnew/issues/biotech-markets/governmentrole.htm
37. Commission Regulation (EC) No. 49/2000 of 10 January 2000, art. 1, 2000 O.J. (L 6/13).
38. Office of the Press Secretary, The White House, *Clinton Administration Agencies Announce Food and Agricultural Biotechnology Initiatives*, 3 May 2000.
39. U.S. Department of Agriculture, release no. 0147.00, 4 May 2000.