

Lecture

BEYOND FOOD AND EVIL

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The mass marketing of foods derived from organisms modified through recombinant DNA (rDNA) technology (genetically modified, or GM foods) has put extreme pressure on the interpretation and implementation of the United States' basic food safety law, the venerable Food, Drug & Cosmetic Act (FD&CA).¹ In its classic form, the FD&CA reflects its Progressive and New Deal roots. It vests enormous trust in a specialized agency, the Food and Drug Administration (FDA), which is presumed to have nonpareil expertise over food safety. The political reality of GM foods, however, has placed the FD&CA and its implementation by the FDA in severe tension with the Organic Foods Production Act² and with commercial speech doctrine.

Although proponents of rDNA-based food technology tout dream products such as Golden Rice,³ most commercially viable GM crops are aimed at modifying the characteristics of plants with respect to agricultural production rather than retail consumption. GM crops tend to fall into two categories, either herbicide resistant (as in Roundup Ready soybeans) or pesticidal in their own right (as in Bt-enhanced corn). These crops raise at least five distinct concerns:

1. These crops may be unsafe for human consumption.
2. Herbicide resistant GM crops may confer this trait on wild relatives and create “weedy” strains.

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1. 21 U.S.C. §§ 301–399 (2000).
2. 7 U.S.C. §§ 6501–6522 (2000).
3. See generally Golden Rice Project Home Page, <http://www.goldenrice.org> (last visited Apr. 1, 2007) (describing Golden Rice, a genetically modified line of rice high in vitamin A).

3. The widespread deployment of any pesticide enables target organisms to acquire resistance.
4. Pesticidal GM crops may harm nontarget organisms (as Bt corn has allegedly done to the monarch butterfly).
5. Economic pressure to adopt GM technology may squeeze out economically marginal farmers.

The FD&CA offers almost nothing in direct response to these concerns. The second, third, and fourth objections—weediness, resistance, and harm to nontarget organisms—trigger a host of statutory authorities within the jurisdiction of the Environmental Protection Agency and the Department of Agriculture, such as the National Environmental Policy Act (NEPA),⁴ the Endangered Species Act,⁵ and the Federal Insecticide, Fungicide, and Rodenticide Act.⁶ The fifth objection, that of economic harm to individuals or even entire classes of business enterprises, has long been held to fall outside the scope of NEPA.⁷

The only concern that the FD&CA can address is objection 1—safety for human consumption. The FD&CA provides the FDA with three basic statutory tools for safeguarding this interest: (1) an outright ban, (2) targeted mandatory labeling, and (3) accommodation of voluntary labeling. The FD&CA provides fairly clear guidance on bans and on targeted mandatory labeling. Voluntary labeling, on the other hand, coexists very uncomfortably with this statute. The trouble arises in the interplay of the FD&CA with two other sources of law pertinent to the marketing of foods produced with and without rDNA technology: the Organic Foods Production Act of 1990 (OFPA)⁸ and the First Amendment's commercial speech doctrine.

It is useful to distinguish between GM technology that undermines the safety of all food developed with it, on one hand, and GM technology that would affect only a small population (as it might by directing the production of a protein to which unsuspecting consumers would be allergic). In the former case, the appropriate remedy under the FD&CA is an outright ban. The FDA would have

4. 42 U.S.C. §§ 4321, 4331–4335, 4341–4347 (2000).

5. 16 U.S.C. §§ 1531–1544 (2000).

6. 7 U.S.C. §§ 136–136y (2000).

7. *See, e.g.,* *Metro. Edison Co. v. People Against Nuclear Energy*, 460 U.S. 766, 776 (1983).

8. 7 U.S.C. §§ 6501–6522 (2000).

the authority—indeed, the responsibility—under § 402(a)(1) of the FD&CA to ban all adulterated food and under § 409 to ban all nonapproved food additives.⁹ The applicability of a labeling remedy therefore appears to be confined to the special case of a GM food that is generally safe for consumption by the broader public, but peculiarly unsafe for some segment of the population, such as consumers allergic to a particular food (as in the instance of nuts). The FD&CA thus readily accommodates two of the three basic statutory options open to the FDA: an outright ban and targeted mandatory labeling.

Voluntary labeling, by contrast, raises severe statutory difficulties. Under §§ 201(n) and 403(a)(1) of the FD&CA, food is “misbranded” if “its labeling is false or misleading in any particular.”¹⁰ This misbranding provision serves two distinct purposes. First, the prohibition on misbranding reinforces the statute’s anti-adulteration provisions by preventing the consumption of foods (or, for that matter, drugs) in excess or in the wrong combination. Second, the misbranding provision also serves a strong consumer protection purpose. Misbranding thus constitutes a form of false (and therefore proscribable) advertising.

For this reason, the inclusion of a claim on a label that a food is not produced using rDNA technology is highly problematic. The FDA having concluded that a particular food satisfies § 402 and that its rDNA-produced food additive satisfies § 409, a contrary claim that another food, not produced with this technology, has superior value or even confirms affirmative health benefits represents an arguably incipient violation of § 403.

The FDA has navigated this complex statutory and administrative thicket in a series of policy statements spanning a decade. In a 1992 proceeding, *Foods Derived from New Plant Varieties*,¹¹ the FDA declined either to ban GM foods or to require across-the-board labeling of foods produced using rDNA technology. The crux of the 1992 policy statement was that GM foods are presumed “generally recognized as safe” (GRAS) in the sense of §§ 201(s) and 409 and therefore presumptively marketable. After a

9. See also § 201(s) (defining the “food additive” and “generally recognized as safe” (GRAS) exceptions to mandatory FDA approval).

10. 7 U.S.C. §§ 321(n), 343(a) (2000).

11. 57 Fed. Reg. 22,984 (May 29, 1992).

federal district court upheld the 1992 policy statement,¹² the FDA promulgated two new policies in 2001.

The first, an order styled *Premarket Notice Concerning Bioengineered Foods*,¹³ retreated to some extent from the 1992 policy statement's presumption of GRAS treatment and instituted in its place an elaborate premarket biotechnology notice (PBN) intended to address the wide variety of food safety concerns raised by the use of rDNA technology in food production. The FDA's second policy statement, *Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering*,¹⁴ provided draft guidance for vendors seeking to market their food with labels such as "GM free" or "biotech free." The agency stopped short of endorsing such a label, at least where it is not accompanied by a statement stating that foods so labeled are not superior to foods lacking such a label.

The upshot of the FDA's policies, developed from 1992 to 2001, is that (1) GM foods are presumptively marketable after completion of the PBN process, (2) they need not be labeled as containing bioengineered ingredients, and (3) non-GM foods may be labeled as "GM free" or "biotech free" only in connection with an accompanying disclaimer that such a claim implies no qualitative distinction relative to other foods. As a practical matter, the OFPA has supplied the labeling that many consumers use in order to avoid ingesting GM foods. The OFPA, unlike the FD&CA, is enforced by the United States Department of Agriculture (USDA). In 1997 the USDA retracted a notice of proposed rulemaking that would have permitted irradiated foods, foods produced using human waste as fertilizer, and bioengineered foods to satisfy the then-pending organic standard.¹⁵ The organic standard ultimately adopted in 2002 explicitly excluded GM foods. For this reason, labels permitted under the OFPA have effectively supplanted "GM free" and "biotech free" labels that were long coveted but never achieved under the FD&CA.

This solution undermines the FD&CA in two ways. First, it creates significant statutory tension between the FD&CA and the OFPA. The OFPA, for its part, does not express a consumer

12. Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166 (D.D.C. 2000).

13. 66 Fed. Reg. 4706 (Jan. 18, 2001).

14. 66 Fed. Reg. 4839 (Jan. 18, 2001).

15. See Donald T. Hornstein, *The Road Also Taken: Lessons from Organic Agriculture for Market- and Risk-Based Regulation*, 56 DUKE L.J. 1541, 1552–53 (2007).

protection agenda that is nearly as paternalistic as § 403 of the FD&CA. The OFPA does set a uniform organic standard, but it is better understood as a measure to ease the pressure of divergent organic standards on farmers rather than clarifying the meaning of organic for consumers. The term organic, in turn, does not convey any sense of superiority. It communicates nothing more than compliance with a set of production standards whose impact on the environment and on food safety have not been subjected to the sort of comprehensive premarket testing that characterizes the work of the Food and Drug Administration.

Second, the presence of a labeling solution under the OFPA places the FD&CA, particularly the most paternalistic expression of the misbranding provisions of § 403, under a palpable constitutional threat. The FD&CA was originally enacted decades before the Supreme Court subjected commercial speech to the First Amendment. In the 2002 Supreme Court case of *Thompson v. Western States Medical Center*,¹⁶ and the 1999 D.C. Circuit case of *Pearson v. Shalala*,¹⁷ speech-related provisions of the FD&CA came under withering constitutional attack. At an extreme, the rise of the OFPA, the revival of First Amendment scrutiny in the commercial sphere, and the subtle but very palpable shift from the Progressive Era's bureaucratic model of consumer protection to a more consumer- and market-oriented model may bring the misbranding provisions of the FD&CA under constitutional attack.

There are good reasons to avoid this outcome. The FD&CA and the FDA's implementation of it enjoy the protection of a host of legal doctrines. Repeals by implication are strongly disfavored,¹⁸ especially where the later OFPA evinces no legislative intent to supersede the venerable FD&CA, a bedrock of American health law. The canon against constitutional doubt counsels "saving" constructions of the FD&CA. Finally, if administrative law doctrines such as *Chevron* and *Overton Park* ever counseled judicial deference to expert administrative decisionmaking, the FDA's management of bioengineered foods represents a paradigmatic case for deference.

Fear about food is one of the most deeply seated forms of behavioral protection against the natural world. Any parent knows

16. 535 U.S. 357 (2002).

17. 164 F.3d 650 (D.C. Cir. 1999).

18. See, e.g., *Morton v. Mancari*, 417 U.S. 535, 550 (1974) ("This is a prototypical case where an adjudication of repeal by implication is not appropriate.").

that children instinctively limit their diets to avoid toxins. Prohibitions against certain foods constitute a very significant portion of entire religious traditions. It is precisely here, where food comes into contact with notions of good and evil, that the classic regulatory state must take its stand. The FDA's regulation of foods using rDNA technology upholds the best of the Progressive regulatory tradition and deserves to survive the challenge posed by the OFPA, the revived commercial speech doctrine, and contemporary consumer distrust of governmentally supervised review of science and safety.