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FEDERAL PREEMPTION AND STATE ANTI-“GM” FOOD LAWS

By

Eric Lasker

For thousands of years, humans have used selective breeding to attempt to improve the genetic makeup of crops and livestock. With modern biotechnology, those often-crude efforts have given way to targeted genetic modifications that carry the promise of significant advances for public health and welfare and the environment. As the American Medical Association Counsel on Scientific Affairs explained in December 2000, genetic modification (“GM”) technology “has the potential to increase the production of food, improve the efficiency of production and the nutritional quality of food, reduce the environmental impact of traditional agriculture, and with cooperative efforts, provide access to this technology for small-scale farmers.”¹ First approved for sale in the U.S. market in the 1990s, up to forty-five percent of major crops grown in the United States are now genetically modified and much of the nation’s livestock are now raised with growth hormones or fed GM foods.² While there have been a handful of well-publicized events involving cross-pollination or commingling of GM and non-GM seeds, to date, there has not been a single demonstrated instance of a consumer being harmed by a GM crop (or food containing GM crops) or of any adverse environmental consequence of GM technology.³

Although GM technology had been strongly endorsed by the federal government, many state and local legislatures over the past five years have considered laws that would restrict its use.⁴ This LEGAL BACKGROUNDER discusses the conflict between favorable federal law and various restrictive state legislative

¹American Medical Association, Featured CSA Report, *Genetically Modified Crops and Foods* (1-00) (Dec. 2000), available at <http://www.ama-assn.org/ama/pub/category/print/13595.html> (hereinafter AMA Statement).

²Carl R. Galant, *Labeling Limbo: Why Genetically Modified Foods Continue to Duck Mandatory Disclosure*, 42 Hous. L. Rev. 125 (2005).

³See AMA Statement, *supra* note 1; see also Galen (2005), at 133-36.

⁴Lawrence A. Kogan, *Exporting Precaution: How Europe’s Risk-Free Regulatory Agenda Threatens American Free Enterprise*, Washington Legal Foundation Monograph (2005), at 80-82; see also Pew Initiative on Food and Biotechnology Legislation Tracker 2004 at <http://pewagbiotech.org/resources/factsheets/legislation> (last visited Sept. 15, 2005).

Eric Lasker is a partner in the Washington, D.C. law firm, Spriggs & Hollingsworth.

initiatives and explores whether the proposed state laws might be precluded on grounds of federal preemption.⁵

Federal Regulation of GM Technology. In 1986, the federal Office of Science and Technology Policy issued the Coordinated Framework for Regulation of Biotechnology.⁶ Under the Coordinated Framework, GM technology is regulated by the FDA, USDA, and EPA within the existing statutory and regulatory framework.

The FDA regulates GM foods (i.e., GM crops or foods containing ingredients made with GM technology) pursuant to provisions under the Food, Drug and Cosmetics Act (“FDCA”) governing adulterated food, food additives, and food labeling. *See* 21 U.S.C. §§ 321(n), 331(a), 342, 343 & 348 (2000). In 1992, FDA issued a Statement of Policy in which it concluded that GM technology was simply an extension of traditional agricultural methods and that GM foods were the equivalent of existing products and thus presumed to be “Generally Recognized as Safe” (“GRAS”).⁷ FDA stated that the use of GM technology need not be disclosed in food labeling.⁸ In 2001, FDA issued a Draft Guidance for Industry in which it again concluded that GM foods were GRAS and that the use of GM technology need not be indicated on the food label. FDA further cautioned that voluntary labels stating that foods were non-GM might be false and misleading under federal law if they imply that the food is superior because it has not been bioengineered.⁹ FDA’s regulation of GM foods is at least partially covered by an express preemption provision in the Nutritional Labeling and Education Act of 1990, 21 U.S.C. § 343-1, which provides that “no State or political subdivision may directly or indirectly establish” requirements regarding (a) federally mandated “standards of identity” for certain types of foods or (b) nutritional or other labeling as set forth in other sections of the Act.

The USDA and EPA have comparatively smaller roles in the regulation of GM products. USDA regulates the development and field-testing of GM products through the Animal and Plant Health Inspection Service, 7 U.S.C. §§ 7701-72, and regulates the labeling of all meat and poultry products under the Federal Meat Inspection Act (“FMIA”), 21 U.S.C. 601, et seq. and the Poultry Products Inspection Act (“PPIA”), 21 U.S.C. § 451, et seq. The MPIA and PPIA contain express preemption provisions precluding state law requirements for “marking, labeling, packaging, or ingredients ... in addition to, or different than, those made under” those Acts. 21 U.S.C. §§ 467e & 678.

The EPA regulates GM crops with pesticide properties, primarily under FIFRA.¹⁰ FIFRA’s express preemption provision states that a “State shall not impose any requirements for labeling or packaging in addition to or different from those required under” FIFRA. 7 U.S.C. § 136v(b).

⁵While beyond the scope of this LEGAL BACKGROUNDER, the proposed state laws may also be legally vulnerable under the commerce clause or, to the extent they would mandate warning labels without evidence of health risks, the First Amendment. *See International Dairy Foods Ass’n v. Amestoy*, 92 F.3d 67 (2d Cir. 1996) (state law requiring labeling of products from cows treated with growth hormone violated First Amendment); *Kraft Foods North America, Inc. v. Rockland County Dept. of Weights and Measures*, No. 01 Civ. 6980, 2003 WL 554796, at * 8-10 (S.D.N.Y. 2003) (state food labeling law unduly burdened interstate commerce); *Lever Bros. Co. v. Maurer*, 712 F. Supp. 645, 651-54 (S.D. Ohio 1989) (state food labeling law violated First Amendment and Commerce Clause).

⁶Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (proposed June 26, 1986).

⁷Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, at 22990 (May 29, 1992).

⁸*Id.*, at 22991.

⁹Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4839, 4840 (Jan. 18, 2001).

¹⁰7 U.S.C. §§ 136-136v. The EPA also has more limited federal oversight over GM products under TSCA and the FDCA.

State Legislative Initiatives Regarding GM Technology. While many states have considered and enacted legislation that favors GM technology (including legislation that preempts contrary local ordinances), there have been a number of developments in the other direction. Recent state and local legislative efforts to restrict the production and/or sale of GM foods has taken three primary forms: (1) voluntary or mandatory labeling requirements; (2) special rules governing legal bases for liability; and (3) moratoria on production.¹¹

Over the past several years, legislators in some sixteen states have sought to introduce bills that would either require or allow food labels to indicate whether the foods were produced, in whole or in part, using GM technology (Alaska, Colorado, Connecticut, Florida, Hawaii, Iowa, Maine, Massachusetts, Michigan, Minnesota, New Hampshire, New York, Oregon, Rhode Island, Vermont, Washington). In 2004, Vermont enacted the first law to require labeling of GM seed. In 2005, Alaska passed legislation requiring labeling of transgenic fish.

Some state legislators also have sought to create special legal liability rules for alleged health, environmental, or “cross-pollination” claims brought against producers or sellers of GM products (specifically, legislators in Hawaii, Iowa, Massachusetts, Minnesota, Missouri, Montana, North Dakota, New York, South Dakota, and Vermont). In the 2004-2005 session, legislators in Montana, North Dakota and Vermont considered legislation that would impose strict liability on GM seed producers. None of these initiatives were enacted.

Finally, legislators in California, Colorado, Hawaii, Iowa, Idaho, Massachusetts, Maryland, Michigan, Montana, North Dakota, New York, Oregon, South Dakota, Texas, and Vermont sought to impose moratoria on the production or sale of certain GM products. California and Maryland have enacted statutes restricting or prohibiting the production of transgenic fish. In Vermont, a number of towns passed non-binding resolutions calling for moratoria on the production of GM crops.

Arguments for Federal Preemption of State GM Food Legislation. Over ninety years ago, in *McDermott v. Wisconsin*, 228 U.S. 114, 133-34 (1913), the United States Supreme Court held that state food labeling laws are preempted if they conflict with federal law:

Conceding to the state the authority to make regulations consistent with the Federal law for the further protection of its citizens against impure and misbranded food ... we think to permit such regulation ... is to permit a state to discredit and burden legitimate Federal regulations of interstate commerce, to destroy rights arising out of the federal statute ... and to impair the effect of a Federal law.

In recent years, numerous courts have struck state laws regarding food labeling on either express or implied preemption grounds.¹² Although a full preemption analysis of the many differing proposed state statutes on GM technology is beyond the scope of this LEGAL BACKGROUNDER, many of these statutes, if enacted, would likely fail on preemption grounds.

¹¹The information herein regarding state law initiatives on GM food (and more) can be found at <http://pewagbiotech.org/resources/factsheet/legislation>.

¹²*See Grocery Manufacturers of America, Inc. v. Gerace*, 755 F.2d 993 (1st Cir. 1985) (imitation cheese); *Vermont Pure Holding, Ltd. v. Nestle Waters North America Inc.*, No. Civ.A.03-11465, 2004 WL 2030254 (D. Mass. Sept. 9, 2004) (spring water); *Goya de Puerto Rico Inc. v. Santiago*, 49 F. Supp. 2d 274 (D.P.R. 1999) (pigeon peas); *Lever Bros Co. v. Maurer*, 712 F. Supp. 645 (S.D. Ohio 1989) (dairy spread); *Committee for Accurate Labeling and Marketing v. Brownback*, 665 F. Supp. 880 (D. Kan. 1987) (artificial dairy products); *Cohen v. McDonald's Corp.*, 808 N.E.2d 1 (Ill. App. 2004) (McDonalds' Happy Meal®); *see also Hillside Dairy Inc. v. Lyons*, 539 U.S. 59 (2003) (noting possibility of preemption of state law labeling requirement on reduced fat milk prior to enactment of specific federal savings clause).

State Labeling Statutes. State legislative efforts regarding labeling of GM foods raise clear preemption problems. As noted above, express preemption provisions in the FDCA, FMIA, PPIA, and FIFRA may preclude state law requirements regarding GM food labeling, particularly where they differ from federal law or regulation. FDA has squarely considered whether GM foods should be labeled and repeatedly has determined that such labeling is inappropriate.¹³ Moreover, FDA has explained that voluntary labeling of non-GM food by manufacturers or grocers is likely to be deemed false and misleading under federal law, because of the implicit adverse representations such labels would make concerning GM foods. FDA's pronouncements have been set forth in a policy statement and a draft guidance, and numerous courts have relied on such interpretive documents in finding a preemptive conflict between federal and state law. *See, e.g., Gerace*, 755 F.2d at 1002 (“[t]he distinctions between formal rules and interpretive rules or general statements of policy are often vague” and the latter are “entitled to deference”); *Kraft Foods North America*, 2003 WL 554796, at *5-*6 (relying on federal food inspection handbook in holding state packaging law preempted).

State Laws Regarding Liability of GM Food Producers and Sellers. To the extent state statutes would impose liability based on the failure to adequately label GM foods, they would be subject to the same preemption arguments as state labeling laws.¹⁴ Preemption of other types of statutory liability provisions will likely turn on the extent to which FDA or other federal regulatory agencies can be shown to have specifically considered the issues in question. *Compare Bates v. Dow Agrosciences, LLC*, 125 S. Ct. 1788 (2005) (design defect, negligent testing/marketing and warranty claims not preempted where EPA had not considered product efficacy claims at issue) with *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861 (2000) (state law claims against car manufacturers for failure to equip automobile with side air bags impliedly preempted where DOT had specifically rejected regulation requiring same). FDA's repeated conclusion that the use of GM technology does not create special health or environmental risks creates a significant preemption hurdle for states seeking to impose special liability rules, particularly rules that would hold GM food producers alone strictly liable. *See Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166 (D.D.C. 2000) (“FDA has determined that foods produced through rDNA techniques do not ‘present any different or greater safety concerns than foods developed by traditional plant breeding ... [t]hat determination ... is entitled to deference”).¹⁵

State Moratoria on GM Foods. While State law moratoria likely will face serious challenges on Commerce Clause grounds, these moratoria would not appear to come within the scope of any of the statutory preemption provisions discussed above. Accordingly, preemption arguments would center on the conflict between the federal policy favoring GM technology and any state law efforts to block this technology. *See, e.g., Grocery Manufacturers of America v. Gerace*, 581 F. Supp. 658, 668 (S.D.N.Y. 1984) (state law preempted where it conflicts with FDA purpose to encourage development of nutritious foods), *aff'd* 755 F.2d 993 (2d Cir. 1985).

Conclusion. After careful deliberation, the federal government has squarely rejected arguments that GM foods are unsafe or that labeling of GM foods should be required or is appropriate. States that enact statutes that single out GM products or producers for adverse treatment – burdening their operations through labels or liability rules or barring their operations altogether – may find these laws to be unenforceable as contrary to federal law.

¹³In addition to the regulatory materials discussed above, FDA voiced its opposition to GM-food labeling statutes in an October 4, 2002 letter from then-Deputy Commissioner Lester M. Crawford to Oregon Governor Kitzhaber. (The text of Chairman Crawford's letter is available at <http://www.bio.org/local/foodag/Kitzhaber.pdf>).

¹⁴The possible preemption arguments that might be made regarding claims of cross-pollination or commingling are beyond the scope of this LEGAL BACKGROUNDER.

¹⁵For a discussion of how insurance policies apply to alleged physical damage, economic losses, and personal injury stemming from GM materials, *see* Marc Mayerson, *Insurance Recovery Losses from Contaminated or Genetically Modified Foods*, 39 TORT TRIAL & INS. PRAC. J. 837 (2004).