DIFFERENTIATING FOOD PRODUCTS: ORGANIC LABELING PROVISIONS FACILITATE CONSUMER CHOICE

Terence J. Centner[1] and Kyle W. Lathrop[2]

I. INTRODUCTION

Americans' concern about food quality and safety has led to an extensive array of laws, rules, and regulations to provide for safe quality food[3] and infor-

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1. Professor, The University of Georgia, College of Agricultural and Environmental Sciences; LL.M. 1982, University of Arkansas; J.D. 1976, SUNY at Buffalo; B.S. 1973, Cornell University.

2. Temporary Instructor, The University of Georgia, College of Agricultural and Environmental Sciences; LL.M. expected June, 1996, University of Arkansas; J.D. 1992, University of Iowa; B.S. 1987, University of Wyoming.

3. The Government Accounting Office reports that thirty-five federal laws cover items involving food safety and quality. *See* GENERAL ACCOUNTING OFFICE, GAO/RCED-92-152, FOOD SAFETY AND QUALITY: UNIFORM, RISK-BASED INSPECTION SYSTEM NEEDED TO ENSURE SAFE FOOD SUPPLY (1992) (hereinafter GAO 92-152). Major legislation includes the Agricultural Marketing Act of 1946, 7 U.S.C. §§ 1621—1623 (1994); Agricultural Marketing Agreement Act of 1937, 7 U.S.C. §§ 601, 602, 608a—608e, 610, 612, 614, 671—674 (1994); Egg Products Inspection Act, 21 U.S.C. §§ 1031—1056 (1994); Federal Anti-Tampering Act, 18 U.S.C. § 1365 and 35 U.S.C. § 155A (1994); Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301—395 (1994); Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. §§ 136—136y (1994); Federal Meat Inspection Act, 21 U.S.C. §§ 601—695 (1994); Import Milk Act, 21 U.S.C. §§ 141—149 (1994); Infant Formula Act of 1980, 21 U.S.C. § 350a (1994); Magnuson Fishery Conservation and Management Act, 16 U.S.C. §§ 1801—1882 (1994); Pesticide Monitoring Improvements Act, 21 U.S.C. §§ 1401—1403 (1994); Poultry Products Inspection Act, 21 U.S.C. §§ 451—470 (1994); Public Health Service Act, 42 U.S.C.A. §§ 201—237 (1994 and Supp. 1995); Safe Drinking Water Act, 42 U.S.C.A. §§ 300f—300j(25) (1994 and Supp. 1995); Toxic Substances Control Act, 15 U.S.C. §§ 2601—2629 (1994); and United States Grain Standards Act, 7 U.S.C. §§ 71—87k (1994). Moreover, twelve federal agencies are involved, including the Agricultural Marketing

mation for consumers to differentiate products. Longstanding trademark and trade name provisions, food safety laws, and misbranding prohibitions have been supplemented by recent federal labeling legislation that helps consumers learn more about attributes of products being considered for purchase. While food safety is of paramount concern, many of the food safety provisions are part of a continuum of instruments that differentiate products by providing consumers additional information about varying characteristics. Concern about the safety and wholesomeness of food products has been met with a flurry of activity by the General Accounting Office,[4] as well as suggestions for reform.[5] Furthermore,

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Service, Agricultural Research Service, Animal and Plant Health Inspection Service, Customs Service, Environmental Protection Agency, Food and Drug Administration, Federal Grain Inspection Service, Food Safety and Inspection Service, Federal Trade Commission, Health and Human Services' Centers for Disease Control, National Marine Fisheries Service and the Treasury Department's Bureau of Alcohol, Tobacco, and Firearms. GAO 92-152, *id.*

4. GENERAL ACCOUNTING OFFICE, GAO/RCED-94-223, FOOD SAFETY: A UNIFIED, RISK-BASED FOOD SAFETY SYSTEM NEEDED (1994) (hereinafter GAO 94-223); GENERAL ACCOUNTING OFFICE, GAO/RCED-94-192 FOOD SAFETY: CHANGES NEEDED TO MINIMIZE UNSAFE CHEMICALS IN FOOD (1994); GENERAL ACCOUNTING OFFICE, GAO/RCED-94-158, FOOD SAFETY: USDA'S ROLE UNDER THE NATIONAL RESIDUE PROGRAM SHOULD BE REEVALUATED (1994) (hereinafter GAO 94-158); GENERAL ACCOUNTING OFFICE, GAO/RCED-94-71 FOOD SAFETY: A UNIFIED RISK-BASED SYSTEM NEEDED TO ENHANCE FOOD SAFETY (1993); GENERAL ACCOUNTING OFFICE, GAO/RCED-94-30, FOOD SAFETY: A UNIFIED RISK-BASED NUTRITION: BETTER GUIDANCE NEEDED TO IMPROVE RELIABILITY OF USDA'S FOOD COMPOSITION DATE (1993); GENERAL ACCOUNTING OFFICE, GAO/RCED-94-23 NUTRITION MONITORING: PROGRESS IN DEVELOPING A COORDINATED PROGRAM (1994); GENERAL ACCOUNTING OFFICE, GAO/RCED-94-1 PESTICIDES: LIMITED TESTING FINDS FEW EXPORTED UNREGISTERED PESTICIDE VIOLATIONS ON IMPORTED FOOD (1993); GENERAL ACCOUNTING OFFICE, GAO/RCED-93-142 FOOD SAFETY AND QUALITY: INNOVATIVE STRATEGIES MAY BE NEEDED TO REGULATE NEW FOOD TECHNOLOGIES (1993); GENERAL ACCOUNTING OFFICE, GAO/RCED-93-55, STATUS OF FDA'S EFFORTS TO IMPROVE IMPORT MONITORING AND ENFORCEMENT (1993); GENERAL ACCOUNTING OFFICE, GAO/RCED-93-22 FOOD SAFETY: BUILDING A SCIENTIFIC, RISK-BASED MEAT AND POULTRY INSPECTION SYSTEM (1993); GENERAL ACCOUNTING OFFICE, GAO/RCED-92-77 PESTICIDES: 30 YEARS SINCE SILENT SPRING—LONG-STANDING CONCERNS REMAIN (1992); GENERAL ACCOUNTING OFFICE, GAO/RCED-92-152, FOOD SAFETY AND QUALITY: UNIFORM, RISK-BASED INSPECTION SYSTEM NEEDED TO ENSURE SAFE FOOD SUPPLY (1992); GENERAL ACCOUNTING OFFICE, GAO/OCG-93-15TR, FOOD AND AGRICULTURE ISSUES (1992).

5. See GENERAL ACCOUNTING OFFICE, GAO/RCED-92-152, FOOD SAFETY AND QUALITY: UNIFORM, RISK-BASED INSPECTION SYSTEM NEEDED TO ENSURE SAFE FOOD SUPPLY (1992); W.M. Layden, *Food Safety: A Patchwork System*, 15 GEN. ACCT. J. 48 (1992). The major issue is not the lack of safe food, but whether a more effective and efficient system could better provide consumers with wholesome and healthy foodstuffs. AMERICAN CHEMICAL SOCIETY, FOOD SAFETY ASSESSMENT 26-27 (John W. Findley, ed. 1992). Reform is complicated by two major consumer beliefs about risk and nutrition. First, many Americans believe that food can be risk-free and that it is the function of legislation to achieve this goal. In contrast, scientists and public health officials advance a definition of safe food as posing a minimal threat to health while providing maximum nutrition and quality. *Id.* Educational efforts are proceeding to help consumers share a common and more realistic view of safe food, rather than seeking risk-free food products. Second, Americans believe that consumers should be able to select food items based on health concerns so that all food products should be appropriately labeled. The agenda of nutritional information of food products has resulted in major new food labeling regulations by the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA). In response to the Nutrition Labeling and Education Act of 1990 (Pub. L. No. 101-535, 104 Stat. 2353 (1990)) (codified as amended in scattered sections of 21 U.S.C. §§ 301—393 (1994)), several new regulations have been advanced to foster three objectives:

Congress responded in 1990 with two sets of health-based provisions for differentiating food products: the Nutrition Labeling and Education Act of 1990[6] and the Organic Food Production Act of 1990 (OFPA).[7]

OFPA complements other legislation and rules to facilitate consumer knowledge of attributes of food products. OFPA ensures that products marketed as organic satisfy minimum requirements and is expected to negate problems created by varying state regulatory systems. The provisions stipulate requirements for domestic producers[8] and provide additional provisions to facilitate the handling, monitoring, and enforcement of the use of the term 'organic' in connection with all foodstuffs.[9]

Firms marketing organically produced food offer consumers the option of buying food that is produced without the use of synthetic fertilizers and pesticides.[10] The specialized organic food market, once thought to be the domain of alternative-culture food cooperatives, is growing rapidly and experts predict that it will continue its pace.[11] One recent study estimated that the U.S. market for organically produced food was $2.3 billion in 1994, up from $1 billion in 1990.[12] This market growth may be propelled by two major trends in consumer interests: heightened concerns about food safety and new regard for the impact of agricultural production on the environment.[13] As the demand grows, it is anticipated that

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> [a] To make available nutrition information that can assist consumers in selecting foods that can lead to healthier diets, [b] to eliminate consumer confusion by establishing definitions for nutrient content claims that are consistent with the terms defined by the Secretary [of Health and Human Services], and [c] to encourage product innovation through the development and marketing of nutritionally improved foods.

58 Fed. Reg. 2302 (1993).

6. Nutrition Labeling and Education Act of 1990. Pub. L. No. 101-535, 104 Stat. 2353 (1990) (codified as amended in scattered sections of 21 U.S.C. §§ 301—393 (1994)).

7. 7 U.S.C. §§ 6501—6522 (1994). The Organic Food Production Act of 1990 (hereinafter OFPA) was passed in 1990 after earlier legislative attempts to regulate organic food production had failed. *See* Kyle W. Lathrop, *Preempting Apples with Oranges: Federal Regulation of Organic Food Labeling*, 16 J. CORP. L. 885, 894 (1991) (noting that three organic food bills were introduced in 1989 following initial federal resistance to regulating organic food production).

8. 7 U.S.C. § 6505(a)(1994).

9. *Id.* §§ 6501—6522.

10. *Id.* § 6502(14) (defining "organically produced" foods). *See also* Terence J. Centner, *Organically produced Food Products: Regulations From the European Union and the United States Set the Stage for Imports*, 7 J. INT'L FOOD & AGRIBUSINESS MARKETING 41 (1996) (contrasting organic production provisions of the United States and the European Union); John Bell Clark, *Impact and Analysis of the U.S. Federal Organic Food Production Act of 1990 with Particular Reference to the Great Lakes*, 26 U. TOL. L. REV. 323, 328 (1995) (defining "organic" and discussing confusion with other terms); Gordon G. Bones, *State and Federal Organic Food Certification Laws: Coming of Age?*, 68 N.D. L. REV. 405, 437-39 (defining "organic" according to federal labeling provisions); Lathrop, *supra* note 7, at 886 (defining organic food production).

11. Carole Sugarman, *In for the Long Haul; Organic Produce Isn't Small Potatoes Anymore*, WASH. POST, Sept. 13, 1995, at E1 (reporting that the increased number of retail stores carrying organically produced foods has been a catalyst in the rapid growth of the market).

12. Barbara De Lollis, *Organic Farmers Debate Coming Regulation; USDA to Issue National Standards for Growing Industry*, S.F. EXAMINER, Oct. 23, 1995, at B-4. *See also* Sugarman, *supra* note 11, at E1 (reporting that 1994 retail sales were up more than 32% over 1993 sales).

13. *See* Sugarman, *supra* note 11, at E1 (also finding that sophistication of the industry and expansion of large natural food chains have helped boost sales).

there will be a corresponding increase in international trade of organic food products, including imports to the United States that comport with the requirements of OFPA and exports of U.S. produced organic products.

The trend toward increased product differentiation is not without problems. For example, OFPA may not be completely effective in fostering international trade in organic foods because it predates the North American Free Trade Agreement (NAFTA)[14] and the new GATT/WTO agreement.[15] A second potential problem stems from the federal government's delay in promulgating regulations to implement OFPA.[16] The initial language of OFPA generously allowed 540 days for the U.S. Department of Agriculture (USDA) to issue and implement regulations, recognizing the difficulty in arriving at the intricate details necessary to regulate the many types of organic food farming and processing systems.[17] Owing to lack of funding, continuing controversies about the technical details of organic food production, and a general lack of initiative, the rules for OFPA are still not in place.[18]

This article will review the numerous regulatory devices that provide consumers with information to be used in selecting and differentiating food products. In the first section of the article, safety features followed by safety enforcement measures and sanctions for violations show a massive federal regulatory scheme in place for food products. The second section enumerates additional devices including trademark law, marketing orders, and health claim regulations to illustrate familiar and innovative devices that convey significant information to consumers. With this foundation, the third section examines key components of OFPA, commencing with labeling requirements. Consideration of the exceptions for substances placed on the National List of approved synthetic substances and prohibited natural substances establish critical parameters governing the production of organic products. Next, a framework for certification and compliance is described under OFPA's reporting requirements. Issues for organically produced imports are also presented. The OFPA provisions show a detailed approach to the production, handling, certification, and marketing of organically produced products that forms a significant addition to the regulatory devices available for the differentiation of food products. Furthermore, understanding the regulatory framework that affects domestic and international trade of organic food will highlight many of the difficulties facing the next trend in food production: biotechnologically-produced foodstuffs.

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14. North American Free Trade Agreement Implementation Act, Pub. L. No. 103-182, 107 Stat. 2057 (1993) (codified at 19 U.S.C. §§ 3301—3473 (1994)) (containing U.S. legislative approval and implementation of negotiated NAFTA provisions).

15. Marrakesh Agreement Establishing World Trade Organization, Apr. 15, 1994, art. III, para. 3, *reprinted in* GATT SECRETARIAT, THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS: THE LEGAL TEXTS 6, 7 (1994), 33 I.L.M. 1144, 1145. *See also* Uruguay Round Agreements Act, Pub. L. No. 103-465, 108 Stat. 4809 (1994) (codified at 19 U.S.C. §§ 3501—3624 (1994)) (including U.S. approval and adoption of World Trade Organization (WTO) provisions). *See also* Terence J. Centner, *The United States Organic Foods Production Act: Does the Small Farmer Exception Breach the United States' Obligations Under GATT?*, 28 TULSA L.J. 715, 715 (1993).

16. Clark, *supra* note 10, at 331-33 (detailing the many developments that have delayed the promulgation of regulations).

17. 7 U.S.C. § 6521(a)(1994).

18. Clark, *supra* note 10, at 332.

II. DIFFERENTIATION THROUGH SAFETY PROVISIONS

Food safety regulations provide such a basic service in differentiating wholesome products from others that they may be overlooked as product-differentiation regulations. For example, food adulteration, misbranding and mislabeling, pesticide residues, cancer-causing additives, and other issues are addressed by this legislation. An overview of safety enforcement measures and sanctions illuminates the regulatory apparatus to guarantee consumers that these safety regulations are followed, and provides much of the background for analyzing the OFPA provisions.

A. *General Food Safety Provisions*

The major food safety law, the Federal Food, Drug and Cosmetic Act (FFDCA),[19] covers the general subject of food quality with the Food and Drug Administration (FDA) having the primary authority to oversee its provisions.[20] The two major components that differentiate products are provisions concerning adulterated and misbranded products. A food is adulterated if it contains substances that "may render it injurious to health."[21] A food is misbranded if information required by law does not clearly appear on the label or if the label is false or misleading.[22] Moreover, a product is misbranded if its label statement is misleading in any particular,[23] including a statement, word, design, device, or failure to reveal a fact material in the light of any representation.[24]

The FFDCA also prescribes regulations to limit pesticide residues and cancer-causing substances. Under the FFDCA, pesticide tolerance levels are established for foods.[25] The controversial anti-cancer statement known as the "Delaney Clause" prohibits carcinogenic food additives or color additives from being added to food destined for interstate commerce, without allowing consideration of

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19. 21 U.S.C. §§ 301—392 (1994) (containing statutory provisions and regulatory authorizations under the Federal Food Drug and Cosmetic Act (FFDCA)).

20. *Id.* §§ 371-379d (listing general administrative provisions for the FDA).

21. *Id.* § 342.

22. *Id.* § 343(a). This includes information that is not prominently placed, is not conspicuous, or is not likely to be read and understood by an ordinary person. *Id.*

23. *Id.* The statute "...condemn[s] every statement, design and device which may mislead or deceive." United States v. Ninety-Five Barrels More or Less Alleged Apple Cider Vinegar, 265 U.S. 438, 442-43 (1924).

24. 21 U.S.C. § 321(n) (1994). The failure to reveal facts material to the representation may violate the misbranding provision. *Id.* The Supreme Court found that a statement that apple cider vinegar was made from selected apples was misleading when the vinegar was made from the juice of dehydrated apples. United States v. 95 Barrels (More or Less) Alleged Apple Cider Vinegar, 265 U.S. 438, 444-45 (1924). In United States v. An Article of Food Labeled Nuclomin, 482 F.2d 581 (8th Cir. 1973), the government brought a misbranding action under the FFDCA. The circuit court noted that although the label was technically accurate and met the regulatory disclosure requirements, it needed to also comply with the FFDCA misbranding requirement that it not be misleading. *Id.* at 584. The listing of several ingredients that were of no nutritional value or in quantities so minute as to not enhance the nutritional value of the product created an ambiguity that meant the label "could persuade a purchaser that the product possessed greater nutritional value than it actually did ...." This ambiguity caused the label to be false and misleading. *Id.* at 582, 586.

25. 21 U.S.C. § 346a (1994) (setting tolerances for pesticide chemicals in or on raw agricultural commodities).

risk versus benefit.[26] Other provisions that differentiate food products deal with safety and quality aspects in emergency situations of potential health significance because of microorganism contamination,[27] tolerances for poisonous ingredients in food,[28] pesticide chemicals,[29] food additives,[30] requirements for infant formulas,[31] and certification for color additives.[32]

In addition to the FDA, federal legislation authorizes the United States Department of Agriculture (USDA) to play an active role in governing food safety for specific commodities. The USDA's Food Safety and Inspection Service has the responsibility to oversee safety and labeling regulations concerning meat and poultry products.[33] The Grain Inspection, Packers and Stockyards Administration oversees the quality of grain commodities,[34] while grading programs for other products are checked by the Agricultural Marketing Service.[35] Federal agencies may condemn foods, stop processing operations, obtain records, and withhold approval of labels.[36] Individual states also may have agencies that primarily oversee state food safety issues.[37]

B. *Safety Enforcement Measures*

As might be expected, numerous provisions concerning inspections and investigations provide the federal government with various mechanisms to enforce regulations that convey information to consumers regarding food quality and safety. The FFDCA provides the authority for the FDA to conduct inspections of food items,[38] with the exception of meat and poultry products.[39] The FDA has

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26. *Id.* §§ 348(c)(3)(A), 379e(b)(5)(B). No food "additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal. ..." *Id.* § 348(c)(3)(A).

27. *Id.* § 344.

28. *Id.* § 346.

29. *Id.* § 346a.

30. *Id.* § 348.

31. *Id.* § 350a.

32. *Id.* § 379e. *See* GAO 92-152, *supra*, note 3 at 14.

33. 21 U.S.C. §§ 451—470 (1994) (inspection of poultry products); §§ 601—695 (inspection of meat). *See* GAO 92-152, *supra* note 3 at 14.

34. 7 U.S.C. §§ 71—87k (1994). *See* GAO 92-152, *supra* note 3, at 16-17.

35. 7 U.S.C. §§ 1622, 1624 (1994); 7 C.F.R. §§ 51.1—51.6005 (1995) (listing regulatory provisions for inspection and certification standards). This includes eggs. *See* GAO 92-152, *supra* note 3, at 15-16.

36. Imported animal and plant products are regulated at U.S. entry points with the assistance of the Customs Service. *See generally* 21 U.S.C. §§ 101—136a (1994) (specifying cooperative efforts with other federal agencies).

37. About 45 states conduct food inspections to enforce federal laws in conjunction with the FDA. David A. Kessler, *Remarks by the Commissioner of Food and Drugs at the Association of Food and Drug Officials' Annual Conference*, 46 FOOD DRUG COSM. L. J. 773, 775 (1991). Moreover, there are agreements between federal and state agencies in many instances. For example, the FDA may approve a state inspection program that meets federal requirements. 21 U.S.C § 661 (1994). Other examples are agreements between the USDA and state agencies dealing with poultry and meat inspection. *E.g.*, 21 U.S.C. §§ 454, 661. These cooperative agreements insure that meat inspection levels are at least equal to the federal program. 21 U.S.C. § 661 (1994).

38. 21 U.S.C. §§ 372-374 (1994) (authorizing inspections and investigations).

39. In 1991 the agency employed 1094 investigators. Kessler, *supra* note 37, at 773.

the responsibility to ensure that domestic and imported foods are safe, nutritious, wholesome, and properly labeled. FDA inspectors can conduct unannounced inspections under reasonable conditions at food processing and handling facilities, and they can also collect samples of products from the marketplace to check for compliance.[40] Moreover, inspections are carried out at ports of entry into the U.S. and can include inspection of accompanying paperwork, physical inspection of the product, or laboratory analysis of the item.[41]

The USDA operates inspection programs for many other food products.[42] For meat and poultry products, the Food Safety and Inspection Service inspects animals and birds prior to slaughter, and the inspection continues through processing and handling of the product.[43] Also, labels of approval are required for all meat products.[44] The Agricultural Marketing Service has broad inspection powers over eggs and various fruit and vegetable products.[45]

Federal agencies have enumerated policies concerning investigations to ascertain compliance and to further statutory objectives. For infractions under the FFDCA, a FDA inspector files a written report after an inspection of a food processing facility with the appropriate regional office.[46] This report also reaches the FDA Headquarters in Washington, D.C. The corrective action taken varies with the severity of the problem. Some corrective action is initiated through the use of written notices. For problems which are not serious enough to warrant immediate corrective action but are sufficient to warrant a written notice, a notice of adverse findings is sent to the company. Usually, thirty days are allowed for the company to respond to a notice of adverse findings. For situations which warrant immediate action, the FDA issues a regulatory letter. Usually the company is given ten days in which to respond by detailing corrective actions.[47]

C. *Sanctions Regarding Breaches of Safety*

Individual laws specify the civil and criminal penalties that may be invoked for violations. For example, the FFDCA specifies details concerning imprisonment or monetary fines that may be applied to violators.[48] Sanctions imposed by the FDA illustrate the major possible enforcement mechanisms.[49] First, there

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40. 21 U.S.C. §§ 371-379d (1994) (listing general administrative provisions for the FDA).

41. *Id.* § 372(a), (b), (e).

42. *See* GAO 92-152, *supra* note 3, at 14-17.

43. In 1992, the USDA spent $30 million on its National Residue Program to prevent contamination from chemical residues in meat and poultry. GAO 94-158, *supra* note 4, at 10. In 1991, the Food Safety and Inspection Service oversaw 4,630 processing plants, 400 slaughtering plants and 1070 combination slaughtering and processing operations. GAO 92-152, *supra* note 3, at 15.

44. GAO 92-152, *supra* note 3, at 14.

45. GAO 92-152, *supra* note 3, at 15-16; 7 C.F.R. pt. 51 (1995). In 1991, the Agricultural Marketing Service inspected 1150 egg-packing plants, 475 hatcheries, and 82 egg-product plants. GAO 92-152, *supra* note 3, at 15.

46. The FDA reported nearly 14,000 inspections in 1993, down from more than 17,000 in 1991. GAO 94-223, *supra* note 4, at 15.

47. 21 C.F.R. § 108.25 (1995).

48. 21 U.S.C. § 333 (1994). Similar provisions are described in laws such as the Federal Meat Inspection Act and the Poultry Products Inspection Act. 7 U.S.C. §§ 461, 467a—467f (poultry products), 671—679 (meat products) (1994).

49. The FDA reports more than 1000 food enforcement actions per year for 1992 and 1993. GAO 94-223, *supra note* 4, at 15.

are civil remedial actions which may be performed without involving the Department of Justice.[50] These remedies include: 1) import detentions, 2) voluntary recalls, 3) voluntary corrections, and 4) warning letters.[51] A company in violation of a provision may voluntarily remove the product from the marketplace and destroy it. When the company does not take corrective action, the FDA can have U.S. Marshals seize products that remain on the market in violation of orders obtained from the U.S. District Court.[52] In civil seizure cases, the FDA refers proposed actions to the U.S. Attorney and to the FDA Office of Consumer Litigation.[53] The government commences the litigation by "filing a complaint seeking condemnation" of the offending products, and generally requests seizure of the goods to keep them from reaching consumers.[54]

Injunctive proceedings against violators can be sought through the federal courts.[55] Relief becomes available after a "federal judge grants the government's motion."[56] Criminal actions are also possible, and may be coordinated by FDA's Office of Consumer Litigation and the Department of Justice. Such actions may also be brought without FDA involvement.[57] Responsibility for prosecution between the FDA Office of Consumer Litigation, the FDA Chief Counsel's Office and the U.S. Attorney's Office may vary greatly depending on the type of case, judicial district, and workloads of the U.S. Attorneys.[58]

The USDA can seek similar corrective actions through voluntary recalls, seizures, and injunctions.[59] Concerning meat products, for example, Food Safety and Inspection Service inspectors can take certain immediate corrective action, such as condemning a carcass.[60] In addition, the USDA may opt to withdraw inspection approval under the Federal Meat Inspection Act[61] or the Poultry Products Inspection Act[62] in situations where the recipient is deemed unfit to engage in commerce requiring inspection. The consequence of this action is that a meat processing plant may be shut down until the alleged defect is corrected.

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50. John R. Fleder, *The Role of the Department of Justice in Enforcement Matters Relating to the Food and Drug Administration*, 46 FOOD DRUG COSM. L. J. 781, n. 17 (1991).

51. *Id.* at 788, n.17. *See also* Kessler, *supra* note 37, at 773 (discussing the manner in which warning letters address enforcement issues).

52. *See* Fleder, *supra* note 50, at 788-89; 21 U.S.C. § 334 (1994) (discussing seizure of adulterated or misbranded articles).

53. Fleder, *supra* note 50, at 784.

54. *Id.* at 784. The federal court clerk, rather than a judge, issues the warrant allowing for the seizure of the goods. *Id.*

55. *Id.* at 785; 21 U.S.C. § 332 (1994). These actions may progress more slowly than seizure, because the Office of Consumer Litigation must review the case before sending it to a U.S. Attorney. Fleder, *supra* note 50, at 785.

56. This is generally after notice to defendants and a hearing. Fleder, *supra* note 50, at 785.

57. *Id.* at 788-89.

58. *Id.* at 789.

59. *See*, for example, 21 U.S.C. § 673 (1994) (authorizing seizure actions under the Federal Meat Inspection Act).

60. *Id.* §§ 673(b), 455(c).

61. *Id.* § 671.

62. *Id.* § 467.

III. ADDITIONAL DIFFERENTIATION PROVISIONS

A. *Trademarks and Other Appellations*

Federal and state legislation employs brand names,[63] marks,[64] trademarks,[65] trade names,[66] certification marks,[67] collective marks,[68] and service marks[69] under trademark law to differentiate products for consumers.[70] Although most trademark issues are resolved under federal trademark law, state trademark law and common law are used to protect appellations denoting quality. Trademark law allows for the registration of marks,[71] and once a mark is registered, others may be precluded from adopting a similar mark in the same geographic market.[72] Thus, trademarks facilitate product differentiation and protect consumers against confusing, deceiving, or misleading names.

B. *Marketing Orders*

Marketing orders are another aspect of federal and state regulatory schemes that differentiate food products. Marketing orders are designed to regulate food quality and quantity, ensuring that a high quality and constant supply of a particular commodity is available. The producers and producer associations are responsible for approving the actual marketing agreement.[73] A significant reason for adopting federal marketing orders was to provide minimum standards on maturity, grading, and other quality measures.[74] Quality control measures include minimum grade and/or size requirements, the preclusion of harvesting before an established date, market allocation programs, reserve pools, producer allotments, and market flow regulations.[75] Individual states may enact state marketing orders for similar purposes.

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63. *See generally,* 15 U.S.C. § 1127 (1994). Brand names are colloquial terms generally used for trademarks.

64. *Id.* The term "mark" includes "any trademark, certification mark, service mark, collective mark, or certification mark." *Id.*

65. *Id.* Trademarks are any "word, name, symbol, or other device, or any combination thereof used by a person ...to identify and distinguish his or her goods...." *Id.*

66. *Id.* Tradenames "mean any name used by a person to identify his or her business or vocation." *Id.*

67. *Id.* A certification mark is "any word, name, symbol, or device, or any combination used by a person other than its owner ...to certify regional or other origin, material, mode of manufacture, quality, accuracy, or other characteristics of such person's goods or services or that work or labor on the goods or services was performed by members of a union or other organization." *Id.*

68. *Id.* Collective marks are trademarks or service marks used by the members of a collective group.

70. *Id.* Service marks cover services rather than goods.

71. *See generally* 15 U.S.C. §§ 1051—1072 (1994). *See* Terence J. Centner, *Trademark Law for Specialty Fruits and Vegetables*, 10 J. AGRIC. TAX'N & L. 3 (1988) (discussing use of a certification mark for a specialty crop).

72. 15 U.S.C. § 1127 (1994).

73. *Id.* §§ 1051, 1091 (1994).

74. 7 U.S.C. § 608c (1994).

75. *Id.*

76. *Id.*; 7 C.F.R. §§ 900-999 (1995) (containing regulatory provisions of agricultural marketing orders for fruits, vegetables, and nuts).

Although designed to assist with product differentiation, federal marketing orders and agreements may present an obstacle to importing organic foods. As authorized by the Agricultural Marketing Agreement Act of 1937 (AMAA), marketing orders and agreements are commodity-specific mechanisms that regulate the quality and quantity of fruits and vegetables.[76] In addition to specifying standards for food quality and quantity, the marketing orders and agreements may regulate the type of packaging and the promotion and advertising of the food. Marketing orders may also provide for research and development for the specific commodity.[77] These orders and agreements reach beyond the producers to encompass handlers and processors of the covered fruits and vegetables.[78] Currently there are forty-two active marketing orders in the United States for fruits, vegetables, and specialty crops,[79] and most of the commodities covered by marketing orders and agreements can be grown using organic production methods.

Section Eight of the AMAA specifies that imported fruits and vegetables are covered by the applicable marketing order or agreement.[80] Any imported fruit or vegetable to be sold within the same market as a domestically produced fruit or vegetable is subject to the same quality and quantity standards.[81] Arguably, this requirement presents a barrier to imported organic food because the order specifies characteristics that the imported food may not meet. The net result may be a marketing order that excludes imported organic food. Conversely, U.S. marketing orders and agreements do not specify separate treatment of imported fruits and vegetables.[82] Instead, provisions require that the same standards of the marketing order be applied to domestic and imported fruits and vegetables. At a minimum, imported organic food should be on the same footing as domestically produced food.

Some discussion in NAFTA negotiations with Mexico to regulate imported fruits and vegetables questioned whether U.S. marketing orders and agreements create an illegal barrier to trade.[83] As the United States moved closer toward free trade with Mexico, the provisions of the AMAA came under scrutiny to determine if they were non-tariff trade barriers.[84] However, resolution of this conflict may

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77. 7 U.S.C. § 608c(1) (1994). This statutory provision enumerates the jurisdictions and commodities for which marketing orders shall be applicable. *Id.* § 608c(2).

78. *See* USDA AGRICULTURAL MARKETING SERVICE, MARKETING AGREEMENTS AND ORDERS 6-8, (Program Aid No. 1095, 1987) (describing the allowable functions for marketing orders) [hereinafter USDA Agricultural Marketing Service]. The AMAA also provides the authority for the orders and agreements to regulate unfair practices and unfair competition. *Id.* at 8.

79. *Id.*

80. 7 C.F.R. §§ 900-999 (1995) (including active marketing orders for fruits, vegetables, and nuts).

81. 7 U.S.C. § 608c (1994).

82. *Id.*; *See also* 7 C.F.R. §§ 944.28-944.605 (1995) (specifying import regulations and safeguard procedures for avocados, limes, oranges, grapefruit, kiwifruit, olives, table grapes, and Tokay grapes); 7 C.F.R. §§ 999.1-999.500 (1995) (specifying import regulations and special safeguards for specialty crops including dates, walnuts, prunes, raisins, and filberts)

83. *See, e.g.*, 7 C.F.R. §§ 916.1 to .356. (1995) (providing rules for California nectarine marketing order).

84. Robert G. Chambers and Daniel H. Pick, *Marketing Orders as Nontariff Trade Barriers*, 76 AM. J. AGRIC. ECON. 47 (1994).

85. *Id.* This question is especially important because Mexico sought to export six fruits, three vegetables, and five specialty crops that are covered by U.S. marketing orders and agreements.

be possible without great difficulty. The ultimate authority for enforcement and modification of marketing orders is the USDA, but most of the operational management is left to the local administrative committee.[85] These committees consist of the producers and handlers affected by the particular order. Any processor or handler that seeks to import produce could appeal to the marketing order committee and the local administrative agency for modification of the order so that the organic food imports could be marketed successfully.

Potential precedent does exist for modification of marketing orders to accommodate organic produce, as in 1990 when the USDA Agricultural Marketing Service amended the rules for the California pear marketing order to accommodate organically grown pears.[86] The grade requirements for the California marketing order are based on the appearance of the pears.[87] This standard posed a problem under organic pear production techniques, because the non-use of certain chemicals causes russetting of the organic pears.[88] The local committee acknowledged this difference, and the USDA relaxed the grading requirements so that organic producers would not be penalized by the operation of the marketing order.[89]

Id. Any quantity restrictions or shipping holidays imposed under marketing order provisions appear to act as non-tariff trade barriers because they have the same effect as quotas. By keeping out Mexican fruits and vegetables or limiting the amounts that can be imported, it is likely that the marketing order would be valid in light of the GATT and NAFTA. However, it is still questionable in legal and economic terms whether such quality standards violate the GATT national-treatment requirements. *Id.* One economist defines a true non-tariff trade barrier as "any measure (public or private) that causes internationally traded goods and services or resources devoted to the production of these goods and services to be allocated in such a way as to reduce potential real world income." *Id.* at 48 (citing R.E. BALDWIN, NONTARIFF DISTORTIONS OF INTERNATIONAL TRADE 5 (1970)). This definition sets out a quantifiable result to determine if a measure has the effect of a barrier to trade. In this context, a recent economic study found that minimum quality standards imposed by U.S. marketing orders can produce this result. *Id.*

86. *See, e.g.*, USDA Agricultural Marketing Service, *supra* note 78, at 11 (describing the daily operations of a marketing order). *See also,* Modification of Grade Requirements for Organically Grown Pears in 1990, 55 Fed. Reg. 25,956 (codified at 7 C.F.R. § 917.461 (1995)). For purposes of this provision, "organic pears" are defined as:

> pears which are produced, harvested, distributed, stored, processed and packaged without application of synthetically compounded fertilizers, pesticides, or growth regulators. In addition, no synthetically compounded fertilizers, pesticides, or growth regulators shall be applied by the grower to the field or the area in which the pears are grown for 12 months prior to the appearance of flower buds and throughout the entire growing and harvesting season for pears.

7 C.F.R. § 917.461(a)(1)(1995). Note that this definition does not match the statutory standards for organic food production in the federal system. *Cf.* 7 U.S.C. § 6504 (1994) (listing the national standards for organic food production, including a three year withdrawal period for all synthetic fertilizers, pesticides and growth regulators).

87. 7 C.F.R § 917.461 (1995).

88. *Id.* Russetting is a harmless brown roughening of the pear skin that does not affect the flavor or quality. *Id.*

89. *Id.*

C. *Health Claims*

Health claims on food products are another form of product differentiation and have been subjected recently to closer governmental scrutiny. Especially in the realm of organic foods, this is problematic for two reasons. First, there are no means to document that organic food is compositionally different from conventionally produced food. Therefore, any claims on organic food labels must not assert that the food is somehow different in its quality compared to conventional foods. Second, the strict regulation of health claims may be a problem for importing organic food if the labels violate proscriptions against making health claims. The United States recently implemented new statutory provisions to regulate food health claims.[90] Recent problems with health claims about food moved the government to restrict the type of information that can appear in conjunction with food labeling.[91] These changes in U.S. law narrow the scope of allowed label information that can appear relating to nutrient content and to health claims.[92] Because part of the consumer appeal of certified organic food is the nutrient content and supposed health benefits, labeling imported organic food should be approached cautiously.[93]

Presumably the final U.S. regulations for organic food labeling will provide specific guidance for allowable label information. Regardless of those rules, any organic food labeling must still conform with the Nutrition Labeling and Education Act of 1990.[94] Any organic food imported from another country should be labeled so that it does not violate these types of regulations.[95]

IV. ORGANIC FOOD PRODUCTION ACT

The United States prohibits selling or labeling a product as organically produced except in accordance with the organic production and handling provisions

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90. *See generally* Elizabeth Toni Guarino, *Nutrient Descriptor and Disease Claims for Foods Under the New FDA and USDA Rules,* 48 FOOD DRUG L.J. 665 (1993) (describing the new USDA and FDA rules for nutrient descriptors and disease claims made on food labels).

91. *Id.*; *See also* Mara A. Michaels, *FDA Regulation of Health Claims Under the Nutrition Labeling and Education Act of 1990: A Proposal for a Less Restrictive Scientific Standard,* 44 EMORY L.J. 319, 319-322 (1995) (describing the background of problems that led to the revised law to regulate food labeling information).

92. Michaels, *supra* note 91, at 321 (stating what information can now appear on food labels).

93. *See, e.g.,* Julie Cromer, *Recent Developments: Sanitary and Phytosanitary Measures: What They Could Mean for Health and Safety Regulations Under GATT,* 36 HARV. INT'L L.J. 557, 563-66 (1995) (describing how provisions of the FFDCA may violate new GATT provisions against trade barriers); Joan Jacobs Levie, *Health Claims in Wine Labeling and Advertising: Is Government Regulation Taking the Veritas Out of the Vino?,* 4 SAN JOAQUIN AGRIC. L. REV. 97, 126-31 (1994) (arguing that the proscriptions against health claims on wine labels violate the First Amendment).

94. Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (1990) (codified as amended in scattered sections of 21 U.S.C. §§ 301-393 (1994)).

95. Labeling and other printed information about the imported organic food should be prepared in light of the varied authority for regulation of label claims as discussed above. For example, a single label claim may be subject to review by the USDA, the FDA, the FTC, and relevant state consumer and/or health agencies.

of the OFPA.[96] Under this Act, a National Organic Standards Board (NOSB)[97] is in the process of developing recommendations on organic standards to be presented to the Secretary of Agriculture.[98] The Secretary will publish proposed regulations open for public comment, evaluate comments received, and promulgate final regulations to implement the organic program.[99] Following much delay and criticism, the program is expected to be implemented sometime in 1997.[100]

In the absence of more specific federal guidelines, OFPA may be analyzed to discern important features. While OFPA delineates rules for the production[101] and certification of organic products,[102] its product differentiation provision occurs by reason of labeling requirements.[103] Food products may not be labeled as being produced under organic production methods unless they meet the enumerated statutory requirements.[104]

A. *Labeling Requirements*

Labels permitted under OFPA may not refer inaccurately to the process of production.[105] Food products cannot not be labeled as "organic" if they have not been produced using specific organic methods.[106] Products imported into U.S. markets must meet the requisite labeling requirements.[107] While such provisions may be applied fairly objectively to most unprocessed agricultural crops

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96. 7 U.S.C. §§ 6503-6506 (1994). "On or after October 1, 1993, (A) a person may sell or label an agricultural product as organically produced only if such product is produced and handled in accordance with this chapter...." *Id.* § 6505(a)(1).

97. The NOSB was established pursuant to the authority of OFPA. *Id.* § 6518. The Secretary established the NOSB "to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of implementing the Act." *Id.* Procedure to Submit Names of Substances for Evaluation for Inclusion in the National List to be Included in the National Organic Program, 60 Fed. Reg. 15,744 (1995).

98. *See* 60 Fed. Reg. 15,744, 15,745 (1995).

99. A recent notice in the Federal Register invited applications (petitions) for substances to be considered for inclusion on the National List. *Id.*

100. De Lollis, *supra* note 12, at B-4 (noting that the regulations will be implemented five years after the statute mandated promulgation and two years after receiving appropriations to promulgate the regulations). *See also* Timothy J. Sullivan, *The Organic Food Production Act: Part Two - Accreditation*, FARMERS' LEGAL ACTION REP., Autumn 1994, at 3, 11-12 (noting that although the lack of funds and the high cost of accreditation have slowed the development of regulations, part of the problem stems from the complexity of the issues associated with regulating organic food production).

101. 7 U.S.C. § 6504 (1994). § 2105 delineates national standards for organic production.

102. *Id.* § 6503(d). An organic certification program is mandated by § 2104. States may also prepare and submit organic certification programs. *Id.* § 6507.

103. *Id.* § 6505.

104. *Id.* This is dependent on the Secretary of Agriculture establishing the program as mandated by the Act. *Id.* § 6503(a).

105. *Id.* The organic certification program is for "agricultural products that have been produced using organic methods." *Id.* § 6503(a).

106. *Id.* § 6505(a). Note that part of the reason for the OFPA legislation was to eliminate label confusion because food products were being labeled as "natural," "organic", or "no chemical additives." *See* Lathrop, *supra* note 7, at 890-91.

107. 7 U.S.C. § 6505(b)(1994).

under OFPA's production and certification requirements, processed products present issues that require more creative resolutions.

OFPA contains two exceptions for exempting qualifying processed foods from some of the provisions of the Act.[108] The most significant exception involves products that contain at least fifty percent organically produced ingredients.[109] This provision enables processed products containing ingredients not produced under organic methods of production to refer to ingredients produced by organic production methods, if more than fifty percent of the ingredients meet the statutory requirements.[110] For qualifying processed foods, OFPA allows the word "organic" to be used on the principal display panel to describe organically produced ingredients.[111] The appellation, however, cannot describe the product as an organically produced product; rather it simply identifies the organic production of ingredients. For processed foods containing less than fifty percent organically produced ingredients, OFPA allows the word "organic" to be used for ingredients produced organically on the ingredient listing panel.[112]

A second labeling exception is contained in the handling requirements delineated by OFPA.[113] Under this exception, up to five percent of the total weight of the finished product may consist of ingredients not organically produced, provided they are on the National List.[114] This exception relies on a National List of approved synthetic substances and prohibited natural substances which is developed and established by the Secretary of Agriculture.[115]

B. *National Lists of Approved and Prohibited Substances*

In order to obtain authorization to label products as organically produced, the basic outlines of the production standards of OFPA must be met.[116] This includes the establishment of a National List of "approved synthetic and prohib-

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108. *See* Centner, *supra* note 10 (contrasting these exceptions with the provisions of the European Union).

109. 7 U.S.C. § 6505(c) (1994).

110. *Id.* The statute anticipates a procedure whereby the Secretary of Agriculture will consult with the NOSB and the Secretary of Health and Human Services before such appellation may be used. *Id.*

111. *Id.* This may be contrasted to a requirement whereby indications of organic origin may only appear in the list of ingredients rather than the display panel, as occurs under the organic production provisions of the European Union. *See* 1 Council Regulation 2092/91, art. 5, 1991 O.J. (L 198).

112. The U.S. provisions regarding processed products consisting of organic and nonorganic ingredients may be more lenient than foreign provisions. OFPA allows the word "organic" to appear on the display panel of processed foods although nearly 50% of the ingredients may not qualify as being organically produced. In contrast, the European Union provisions relegate the word "organic" to the list of ingredients. Council Regulation 2092/91, art. 5, 1991 O.J. (L 198).

113. 7 U.S.C. § 6510(a) (1994).

114. *Id.* §§ 6510(a), 6517. This provision excludes water and salt. *Id.* § 6510(a). Presumably, the statute means that ingredients on the National List of prohibited substances may constitute up to five per cent of added ingredients. *Id.* § 6517.

115. *Id.* § 6517. OFPA requires the Secretary of Agriculture to establish a National List of approved synthetic and prohibited natural substances for organic production and handling. *Id.* This may be contrasted to provisions of the European Union which allow up to five per cent of ingredients of agricultural origin, not organically produced, if the ingredients are not produced in the European Union. Council Regulation 2092/91, art. 5, 1991 O.J. (L 198).

116. 7 U.S.C. § 6504 (1994).

ited natural substances to be included in the standards established for the organic production and handling of agricultural products."[117] The National List will prohibit the use of synthetic substances unless the substance is included on the list of approved substances.[118] Natural substances are permitted except those on the list of prohibited natural substances.[119] For plant products, the organic production standards provide that no prohibited substances may have been applied to the soil for a period of three years prior to the first harvest.[120] Only natural ingredients that have not been prohibited and synthetic chemicals that have been specifically approved may be used.[121]

Exemptions for prohibited synthetic substances are permitted if they have an active synthetic ingredient falling into certain enumerated categories.[122] A substance may also be included in the list of exemptions if it is used in handling and is non-synthetic, but not organically produced.[123] The Secretary of Agriculture may approve prohibited substances upon determination that the substances would not be harmful to human health or the environment, are necessary to the protection or handling of the product, have no substitutes, and are consistent with organic farming and handling.[124]

The NOSB is evaluating substances for inclusion in the National List using seven specified criteria.[125] As might be expected, these criteria are rather exacting and tedious, especially when applied by committee. Moreover, the National List

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117. 60 Fed. Reg. 15,744 (1995).

118. 7 U.S.C. § 6517 (1994). Clark argues that OFPA "does not allow, either in its spirit or letter, for any such adulteration" with 'adulteration' referring to the use of non-organic ingredients in organic products. Clark, *supra* note 10, at 327.

119. 7 U.S.C. § 6517(c)(2) (1994).

120. *Id.* § 6504.

121. *Id.*

122. *Id.* § 6517(c)(1)(B). If a product does not contain one of these substances, it may contain synthetic inert ingredients as long as they are not classified by the Environmental Protection Agency as "inerts of toxicological concern." *Id.*

123. *Id.*

124. *Id.* § 6517(c)(2). The Secretary, however, must consult with the Secretary of Health and Human Services and the head of the Environmental Protection Agency. *Id.*

125. 60 Fed. Reg. 15,744 (1995). These criteria include:

> (1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;
> (2) the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;
> (3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;
> (4) the effect of the substance on human health;
> (5) the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;
> (6) the alternatives to using the substance in terms of practices or other available materials; and
> (7) its compatibility with a system of sustainable agriculture.

Id.

must be based on the proposed list submitted by the NOSB, and the Secretary cannot allow additional synthetic substances.[126] The USDA provided for petitions regarding substances to be included in the standards for organic production and handling.[127] Although OFPA's exceptions promote the possibility of using synthetic substances if they are deemed necessary,[128] established rules for organic agriculture may preclude any significant discretion in developing these lists.[129]

C. *Reporting Requirements*

OFPA enumerates several reporting requirements to provide a framework for certification and compliance for organically produced products.[130] Organic farms and handling operations are required to make an annual statement that all of the provisions of the Act were followed.[131] Consequently, some record will exist containing a guarantee that, if not met, could form the basis for a claim challenging a violation of the statute. Producers are required to keep records for five years including a detailed history of substances applied; names and addresses of persons applying the substances; and dates, rates, and methods of application.[132] There must also be a handling plan for organically produced products to ensure that the products remain consistent with organic standards during handling and movement to markets.[133] OFPA also anticipates annual on-site inspections.[134]

OFPA contains a distinction among the reporting and compliance requirements for qualifying small farmers.[135] The small-farmer exception provides that American producers who sell no more than $5000 annually, in value of agricultural products, do not need to meet selected compliance provisions.[136] A

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126. 7 U.S.C. § 6517(d) (1994). The lists will be reviewed at least every five years. *Id.* § 6517(e).

127. 60 Fed. Reg. 15,744 (1995).

128. These provisions may grant more leeway than the provisions of the European Union. Under EEC Council Regulations, organic production methods can entail only use of products composed of substances listed in enumerated Annexes. Council Regulation 2092/91, 1991 O.J. (L 198) (as amended by EEC Commission Regulations 207/93, 1993 O.J. (L 25) 2608/93, 1993 O.J. (L 239) and 468/94, 1994 O.J. (L 59)). The sixth Annex provides for the enumeration of substances permitted as ingredients of non-agricultural origin in processed foods, substances permitted to be used during processing and ingredients of agricultural origin. Council Regulation 2092/91, 1991 O.J. (L 198).

129. *See, e.g.*, INTERNATIONAL FEDERATION OF ORGANIC AGRICULTURE MOVEMENTS, BASIC STANDARDS OF ORGANIC AGRICULTURE (1989).

130. *See* Centner, *supra* note 10 (contrasting U.S. certification and compliance provisions with provisions of the European Union).

131. 7 U.S.C. § 6506 (1994).

132. *Id.* § 6511.

133. *Id.* § 6513.

134. *Id.* § 6506. The provisions do not prescribe the details of an inspection. *Id.* This leaves open the possibility that inspections in the United States may be more lenient than those required under the provisions of the European Union. The EU provisions require a full physical inspection. Council Regulation 2092/91, 1991 O.J. (L 198). Second, the EU provisions require samples to be taken from products where misconduct is suspected, whereas OFPA declines to specify a corresponding requirement. 7 U.S.C. § 6506.

135. 7 U.S.C. § 6505 (1994).

136. *Id.* The different treatment of products of small American producers, as opposed to the like products of small foreign producers, may violate the national treatment obligation of the

recommendation in 1994 by the NOSB may greatly reduce the marketing activities permissible under the small-farmer exception.[137] The recommendation would exempt small farmers in the United States from certification if they do not "market through exporters, wholesalers, brokers, processors, or retail chain warehouses."[138] Exempt farmers must comply with all other aspects of OFPA and complete a declaration form pronouncing that products have been produced and handled according to the requirements of OFPA.[139]

D. *Organically produced Imports*

OFPA includes provisions to accommodate imports of organically produced products from third countries. Foreign organically produced products may be imported and sold as organically produced if it is determined "that such products have been produced and handled under an organic certification program that provides safeguards and guidelines governing the production and handling of such products that are at least equivalent to the requirements of this chapter."[140]

The NOSB recently recommended a rule regarding importation of organically produced agricultural products pursuant to three methods.[141] This rule, if adopted, would be the basis for labeling any imported food products as "organic."

The first method allows the entry of foreign organically produced products if they bear the official shield, seal, or mark of a certification program or certification agent.[142] Second, if a certifying agent or U.S. state program is approved by the Secretary, foreign products may enter the United States if they bear the official shield, seal, or mark of such agent or state program.[143] Under the third method of approval, foreign organically produced products may enter the United States if they bear the official shield, seal, or mark of a certification program or agent that ensures observance of standards that are at least equivalent to those set forth by the U.S. organic certification program.[144]

The issue that arises under the NOSB recommendations is whether organic products from foreign countries will face impediments that will preclude their sale in the United States.[145] A likely barrier may be that the standards or certification program used for the production of a foreign organic product are not deemed equivalent to U.S. standards. As a result, under OFPA's provisions for imported

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GATT. *See* Centner, *supra* note 15 (identifying an exception in OFPA that may be contrary to the U.S.'s international obligations).

137. UNITED STATES NATIONAL ORGANIC STANDARDS BOARD FINAL RECOMMENDATIONS, ORGANIC CROP PRODUCTION STANDARDS (1994) (hereinafter NOSB Recommendations).

138. *Id.*

139. *Id.*

140. 7 U.S.C. § 6505(b) (1994). The Secretary of Agriculture will make the determination. *Id.*

141. NOSB Recommendations, *supra* note 137.

142. *Id.* The shield, seal, or mark would need to be regulated by a foreign sovereign, an international standards organization, or regional entity that ensures observance of standards that are at least equivalent to those set forth in U.S. law. *Id.*

143. *Id.*

144. *Id.*

145. *See* Centner, *supra* note 10 (discussing equivalency issues posed by different U.S. and European Union provisions).

goods, the goods would not qualify to enter the United States.[146] For example, the organic production provisions of the European Union allow up to five percent of a processed product to be non-organically produced if that percentage is comprised of an ingredient of agricultural origin not produced in the European Union.[147] OFPA does not provide an exception for agricultural ingredients not produced in a country or group of countries.[148] How would an organic product from the European Union with under five percent of a non-organic agricultural ingredient be treated if imported into the United States? OFPA seems to preclude the sale of such a product if it bears an organic label.[149]

Another potential equivalency issue may involve the use of a natural substance that is on the United States' National List of prohibited natural substances[150] but may be used in the production of organic products in the European Union. Will products grown or processed using such substances be precluded from being labeled as organically produced when imported into the United States? Because such products do not meet the U.S. labeling requirements for organic products,[151] they should not be able to bear a label indicating they were organically produced.[152]

Two recent food law disputes in the United States may highlight potential problems that could arise due to subtle distinctions or the administrative enforcement of regulations for organically produced products. One dispute involved food processors who sought to compel the Customs Service to enforce a U.S. labeling law for imported frozen foods.[153] The second dispute involved the validity of a proposed equivalency inspection standard when another standard existed for imported poultry products.[154] The decisions from both cases illustrate how the OFPA standards and regulations may preclude the entry of imports.

In *Norcal/Crosetti Foods, Inc. v. United States Customs Service,* [155] the plaintiffs were domestic packagers of frozen produce based in California. Competing firms packaged their imported frozen produce with the country of origin label on the back of the package. The plaintiffs asserted that the label information was not sufficiently conspicuous.[156] Fearing that Mexican frozen vegetable imports were

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146. 7 U.S.C. § 6505(b) (1994).

147. Council Regulation 2092/91, art. 5, 1991 O.J. (L 198) 3.

148. *See supra* notes 115-117 and accompanying text. Moreover, an ingredient of agricultural origin does not qualify for the National List of approved synthetic substances and prohibited substances. The agricultural ingredient would not be a synthetic and the list of natural prohibited substances is likewise inapplicable. *See* 7 U.S.C. § 6517 (1994).

149. *See* 7 U.S.C. § 6505(b) (1994).

150. *Id.* § 6517.

151. The product from the European Union is not produced under safeguards and guidelines that are "at least equivalent" to the requirements of OFPA. *Id.* § 6505(b).

152. If the production does not meet the requirements for foreign imports, *see id.*, then the product from the European Union was not produced in accordance with OFPA. *Id.* §§ 6503(a), 6505(b).

153. Norcal/Crosetti Foods, Inc. v. United States Customs Service, 758 F. Supp. 729 (Ct. Int'l Trade 1991), *rev'd,* 963 F.2d 356 (1992), *vacated,* 790 F. Supp 302.

154. Mississippi Poultry Ass'n v. Madigan, 31 F.3d 293 (5th Cir. 1994).

155. 758 F. Supp. 729 (Ct. Int'l Trade 1991), *rev'd,* 963 F.2d 356 (1992), *vacated,* 790 F. Supp 302 (1992).

156. *Id.* at 732. The plaintiffs also believed the lack of conspicuous country of origin labeling was even more deceptive because the imported frozen produce was often marketed under well-known brand names, including Green Giant® and Bird's Eye®. *Id.* at 731.

reducing their market share, the plaintiffs sought to compel compliance with a legal provision[157] that requires all foreign products to carry a conspicuous label indicating country of origin.[158] The Customs Service initially denied plaintiffs' request, stating in a Letter Ruling that the back panel labeling was not actionable.[159] The Customs Service maintained that the marking requirement set forth in U.S. law was satisfied by the industry practice of placing the country-of-origin marking in close proximity to the expiration date and nutritional information.[160] The U.S. court of international trade reached a contrary conclusion. In deference to the congressional purpose of the law, the court found that the country of origin markings were not in a conspicuous place.[161] Such markings needed to be located on the front or the most prominent panel of the package.[162] Such a ruling may force imported organic food to carry extra information related to the foreign certification agency.

Inconsistencies between a proposed inspection standard and an existing provision of the Poultry Products Inspection Act[163] formed the basis of a challenge in *Mississippi Poultry Ass'n v. Madigan.*[164] A regulation promulgated by the Secretary of Agriculture would allow the entry of poultry imports whenever the foreign inspection standards were "at least equal to" U.S. standards.[165] This proposed regulation was slightly different from the applicable provision of the Poultry Products Inspection Act which required that "...imported poultry products be subject to *the same* ...standards applied to products produced in the

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157. 19 U.S.C. § 1304(a) (1994). This provision states:

> Marking of articles. Except as hereinafter provided, every article of foreign origin (or its container ...) imported into the United States shall be marked in a conspicuous place as legibly, indelibly, and permanently as the nature of the article (or container) will permit in such a manner as to indicate to the ultimate purchaser in the United States the English name of the country of origin of the article. . . .

Id. Note that this provision originally appeared as part of the Tariff Act of 1890 and has been included in U.S. trade and tariff law ever since. See Norcal/Croscetti Foods, Inc. v. United States Customs Service, 758 F. Supp. 729, 735-37 (Ct. Int'l Trade 1991) (discussing the legislative history of 19 U.S.C. § 1304).

158. 758 F. Supp. at 731. Promulgated regulations for 19 U.S.C. § 1304 are found at 19 C.F.R. § 134.41(b) (1995). This regulation requires the label to meet a certain level of permanence and visibility, stating:

> The degree of permanence should be at least sufficient to ensure that in any reasonably foreseeable circumstance, the marking shall remain on the article (or its container) until it reaches the ultimate purchaser unless it is deliberately removed. The marking must survive normal distribution and store handling. The ultimate purchaser in the United States must be able to find the marking easily and read it without strain.

Id.

159. Norcal/Crosetti Foods, Inc., 758 F. Supp. at 731.
160. *Id.* at 731.
161. *Id.* at 738.
162. *Id.* at 741.
163. 21 U.S.C. §§ 451-70 (1994).
164. 31 F.3d 293 (5th Cir. 1994).
165. *Id.* at 295 (citing 21 U.S.C. § 454 (1994)).

United States."[166] The issue posed by the proposed regulation was whether the Poultry Products Inspection Act's language of identically precluded the proposed language of equivalency.[167] After considering the congressional directives and the North American Free Trade Agreement Implementation Act,[168] the Court concluded that language of identically was the statutory requirement.[169] Consequently, the proposed equivalency standard allowing poultry products that have been inspected under standards "at least equal to" U.S. standards was found to be invalid.[170]

The significance of the *Norcal/Crosetti Foods* and *Mississippi Poultry Ass'n* cases is that subtle distinctions between regulations may be construed as barriers to trade. The courts' findings raise questions about whether a distinction between U.S. organic food provisions and other systems could mean that imported foreign organic products will not be permitted to bear labels denoting organic production. The earlier example, in which organic processed products of the European Union may contain up to five percent of agricultural ingredients not organically produced in the European Union,[171] illustrates guidelines that are not "at least equivalent" to those set forth in U.S. law.[172]

V. CONCLUDING COMMENTS

The plethora of provisions regulating food products discloses a complicated and detailed regulatory approach to provide safe food products and identify differentiating characteristics so that consumers may select a specific product. Although the legislation tends to be consumer friendly, selected concerns detract from its effectiveness. First, the regulatory system is archaic, too complex, and some particular provisions and consumer proposals may be too costly. For example, the Delaney Clause zero tolerance level precludes the use of some safe substances.[173] Next, compliance with international agreements may mean that some of the provisions need to be altered or some governmental procedures need to be ended. Some of the consumer-oriented legislation on food safety seems to disregard or circumvent international conventions and commitments.[174] The Delaney Clause[175] is one example, and the National List of approved synthetic

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166. *Id.*

167. *Id.* at 305.

168. Pub. L. No. 103-182, § 361(e), 107 Stat. 2123-24 (1993) (codified at 21 U.S.C. § 466 (1994)).

169. Mississippi Poultry Ass'n, 31 F.3d at 305. Standards that are "at least equal to" U.S. standards are not "the same" standards. *Id.*

170. *Id.* at 310.

171. *See supra* notes 147-49 and accompanying text.

172. *Compare* 7 U.S.C. § 6505(b) (1994) *with* Council Regulation 2092/91, 1991 O.J. (L 198).

173. Elizabeth Poliner, *The Regulation of Carcinogenic Pesticide Residues in Food: The Need to Reevaluate the Delaney Clause*, 7 VA. J. NAT. RES. L. 111, 135-36 (Fall 1987) (providing examples of how the Delaney Clause results in greater risks for some food products).

174. *See* Beth Sanders, Note, *International Trade—Possible Undermining of U.S. Pesticide and Food Safety Laws by the Draft Text of the Uruguay Round of GATT Negotiations*, 22 GA. J. INT'L & COMP. L. 233, 244 (1992). Sanders notes that the Delaney Clause and some of the provisions of the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. §§ 136—136y (1994) are not always based on scientific considerations.

175. 21 U.S.C. § 348(c)(3)(A) (1994).

substances of OFPA may constitute a second example.[176] Care must be used to prevent overly fervid consumer ideas, that are not based on scientific facts, from being introduced into legislation dealing with food products.

The OFPA provisions regulating organically produced food products constitute an important endeavor for enabling consumers to select products not produced using pesticides or synthetic materials. Given the ambiguity of what is organic and the originality of legislated organic-production measures, problems may be expected. Moreover, as the issues noted above illustrate, developments in international trade law and differences in organic regulatory provisions of other countries must also be considered. Distinctions among beliefs on organic production and regulations employed by other countries may lead to controversies about whether a product meets the "at least equivalent" requirements established by OFPA. It remains to be seen whether the OFPA provisions will give adequate consideration to alternative safeguards and guidelines established by other countries to guarantee that products have been produced and handled in accordance with suitable organic production methods. Yet the guarantees and enforcement actions provided by OFPA should prove beneficial in facilitating the growth of markets for organic products.[177] Thereby, OFPA should assist producers that employ organic production methods and consumers who desire to purchase organically produced products.

176. 7 U.S.C. § 6517 (1994).

177. *See* Clark, *supra* note 10, at 346. Revising the overall food regulatory system may also provide consumers with a better understanding of foods produced with new biotechnology methods. *See* William K. Hallman, *Public Perceptions of Agricultural Biotechnology*, RESOURCE, Jan. 1996, 12-13 (discussing gaps in consumer understanding of biotechnologically-produced foods).