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United States Food Law Update

by

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UNITED STATES FOOD LAW UPDATE

*By Michael T. Roberts & Margie Alsbrook**

I. INTRODUCTION

The one constancy about food law in the United States is change, especially in a rapidly-developing food industry.[1] Innovations in food technology, shifts in popular culture and tastes, concerns of safety and nutrition, pressures from international markets, all contribute to the changing landscape of food law. These changes are reflected in new federal statutes, regulations, administrative decisions, and judicial decisions.

The purpose of this update is to summarize significant changes and developments in food law over the last half of 2004. An update of developments in United States food law will be published in each issue of the *Journal of Food Law & Policy*. As the *Journal* will be published bi-annually, the update will appear twice a year and will cover the last six months of the calendar year immediately preceding its publication.

These updates provide a starting point for scholars, practitioners, scientists, and policy-makers determined to understand the shaping of food law in modern society.[2] Tracing the development of food law through these updates will also serve a useful historical purpose. As stated by the acclaimed food historian, Felipe Fernández-Armesto, food "has a good claim to be considered the world's most important subject. It is what matters most to most people for most of the time.

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1. *See* Peter Barton Hutt, *Food Law & Policy: An Essay*, 1 J. FOOD L. & POL. 1, 11-15 (2005).

2. *See, e.g.*, REAY TANNAHILL, FOOD IN HISTORY 371 (rev. ed. 1998) (underscoring the importance of this starting point by noting "[c]omplacency is something that neither governments nor scientists can afford, because whatever the shape of the future, the role of food in it will be every bit as decisive as it has in the past").

Yet food history remains relatively underappreciated. Most academic institutions still neglect it."[3] These updates represent a modest effort to building historical context for the development of food law.

It should be noted that this scholarly framework has limits. Not every change in national food law will be included in the update; instead, these updates will be limited to significant changes in national food law. Also, new developments in state law, while certainly important and deserving of attention, are beyond the scope of this update.[4]

II. Recent Federal Statutes

A. The Child Nutrition and WIC Reauthorization Act of 2004

On June 30, 2004, President George W. Bush signed into law the Child Nutrition and WIC Reauthorization Act.[5] Congress had passed the Act earlier in the same month.[6] The new Act took effect immediately on July 1, 2004, and has been heralded as "an important step toward improving the health and well-being of our nation's children."[7]

1. Reauthorization of Federal Legislation

The Child Nutrition and WIC Reauthorization Act reauthorizes for five years both the National School Lunch Act[8] and the Child Nutrition Act of 1996.[9] The Act also amends the existing child nutrition programs and the Special Supplemental Nutrition program for Wo-

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3. Felipe Fernández-Armesto, Near a Thousand Tables: A History of Food, at ix (2002).

4. *See* Nat'l Assoc. of State Depts. of Agric. & Nat'l Center for Agric. Law Research & Information, Food Safety State and Federal Standards and Regulations, *available at* http://www.nasda.org/nasda/nasda/Foundation/foodsafety/index.html.

5. Child Nutrition and WIC Reauthorization Act of 2004, Pub. L. No. 108-265, 118 Stat. 729 (2004) (to be codified in scattered sections of 42 U.S.C.).

6. *See* Child Nutrition and WIC Reauthorization Act (stating the Act was passed in the U.S. Senate on June 23, 2004 and in U.S. House of Representatives on June 24, 2004).

7. U.S. Newswire, *American Dietetic Association Commends U.S. Government for New Child Nutrition and WIC Reauthorization Act* (July 1, 2004), *available at* 2004 WL 78580731.

8. Richard B. Russell National School Lunch Act, 42 U.S.C. §§ 1754-1769 (2004) (originally enacted as the National School Lunch Act, June 4, 1946, c. 281, 60 Stat. 230).

9. Child Nutrition Act, 42 U.S.C. §§ 1771-1791 (originally enacted as the Child Nutrition Act of 1966, Oct. 11, 1966, 80 Stat. 885); Child Nutrition and WIC Reauthorization Act (amending 42 U.S.C. § 1761 to extend the effectiveness date of the statutes to Sept. 30, 2004).

men, Infants, and Children (WIC).[10] These programs are administered by the United States Department of Agriculture (USDA).[11]

(a) National School Lunch Act

The National School Lunch Act was passed in 1946 to "safeguard the health and well-being of the Nation's children" and to "encourage the domestic consumption of nutritious agricultural commodities and other food."[12] The National School Lunch Program today helps feed over 26 million school children in almost 100,000 public and private schools around the nation.[13]

(b) Child Nutrition Act and WIC

The Child Nutrition Act was passed in 1966 to reach more effectively children in economically poor areas.[14] The Child Nutrition Act was designed to complement the National School Lunch Act, and in fact shares the same two-fold purpose.[15] Several ambitious programs were instituted by the Child Nutrition Act, including a Special Milk Program and an experimental School Breakfast Program.[16] The

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10. *See* Child Nutrition and WIC Reauthorization Act, Pub. L. No. 108-265, § 116, 118 Stat. 729 (2004) (amending, in scattered sections, 42 U.S.C. § 1786 (2005)).

11. *See* Child Nutrition and WIC Reauthorization Act (granting, in various scattered passages, the Secretary of Agriculture the power to administer the programs authorized in the Act).

12. *See* Clint G. Salisbury, *Make an Investment in Our School Children: Increase the Nutritional Value of School Lunch Programs*, 2004 BYU EDUC. & L. J. 331, 333 (2004); 42 U.S.C. § 1941 (2005); *see also* National School Lunch Act, 42 U.S.C. §§ 1751-1769 (2005) (originally enacted as the National School Lunch Act, June 4, 1946, c. 281, 60 Stat. 230).

13. U.S. Dep't. of Agric. Food and Nutrition Serv., *Nutrition Program Facts: National School Lunch Program, available at* http://www.fns.usda.gov/wic/WIC-Fact-Sheet.pdf.

14. *See* Child Nutrition Act of 1966, Pub. L. No. 89-642, 80 Stat. 885-890 (1966) (codified as amended at 42 U.S.C. §§ 1771-1790 (2005)); *amended by* Child Nutrition and WIC Reauthorization Act of 2004, Pub. L. No. 108-265, § 116, 118 Stat. 729 (2004) (to be codified in scattered sections of 42 U.S.C.).

15. *See* Child Nutrition Act, 42 U.S.C. § 1771 (2005) (explaining the Child Nutrition Act was passed in recognition of the success of the National School Lunch Act, and in the anticipation that the new act would strengthen and expand the government's ability to meet its twin goals of increasing the health of the nation's children and encouraging the domestic consumption of agriculture).

16. *See* Child Nutrition Act, 42 U.S.C. §§ 1771-1785 (2004); *see also* Special Milk Program for Children, 7 C.F.R. §§ 215.1-215.17 (2005) (giving the rules and regulations for administering the Special Milk Program); School Breakfast Program, 7 C.F.R. §§ 220.4-220.21 (2005) (giving the rules and regulations for administering the School Breakfast Program).

Child Nutrition Act also established WIC,[17] which today serves over 7.4 million low income and nutritionally at-risk people each month by providing nutrition counseling, healthcare referrals, and checks or vouchers designed to help purchase specific foods.[18]

2. Addresses Child Nutrition Needs

Consistent with previous child nutrition legislation, the Child Nutrition and WIC Reauthorization Act was intended to help resolve a particular problem—in this case, the problem of child obesity.[19] The Act strives to decrease obesity by increasing the availability of nutritious foods. For example, school administrators are encouraged to make milk available in schools whenever possible, which is expected to combine with recent flavored-milk offerings to increase childhood milk consumption.[20] It also expands a pilot program that offers free apples, bananas, raisins, and other forms of produce to children in

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17. *See* Special Supplemental Program for Women, Infants and Children, 42 U.S.C. § 1786 (2005).

18. *See* U.S. Dep't. of Agric. Food and Nutrition Serv., *Nutrition Program Facts: National School Lunch Program*, *available at* http://www.fns.usda.gov/wic/WIC-Fact-Sheet.pdf.

19. *See Encouraging Healthy Choices for Healthy Children: Hearing on H.R. 2227 Before the House Comm. on Educ. and the Workforce Subcomm. on Educ. Reform*, 108th Cong. (2004) (opening statement of Rep. Michael N. Castle, Chairman, House Comm. on Educ. and the Workforce Subcommittee on Educ. Reform).

> As we all know, childhood obesity has become a major health problem in the United States, and studies suggest that overweight children are significantly more likely to become overweight or obese adults. This is a matter of great concern to us as a Committee, and to society in general.
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> According to a report by the National Institute for Health Care Management, the number of overweight and obese young Americans doubled between 1990 and 2000. As a result, children are increasingly suffering from conditions traditionally associated with adulthood, including Type 2 diabetes, insulin resistance, high cholesterol, high blood pressure, sleep apnea, orthopedic complications, and are troubled by other effects such as low self-esteem. *See id.*

20. *See* National School Lunch Program: Requirement for Variety of Fluid Milk in Reimbursable Meals, 69 Fed. Reg. 70,871 (Dec. 8, 2004) (to be codified at 7 C.F.R. pt. 210) (giving schools more flexibility in the types of milk they are allowed to offer students); *see also* Raquel Rutledge, *Milk is Fresh: Beverage Gets Flashy Makeover For Fast Food Restaurants*, MILWAUKEE J. SENTINEL, Nov. 21, 2004, at 1 (explaining that school districts often increase their financial resources by signing exclusive contracts with soft drink companies, but those contracts often prevent schools from offering milk in school vending machines; proponents hope the Act will nullify those clauses in the contracts, since schools who make flavored milks available or who install milk vending machines often see significant increases in milk sales).

impoverished school districts.[21] Another expanded pilot program allows school districts to buy increased amounts of fresh and locally grown foods.[22] The Act also requires and provides limited funding for schools to incorporate a nutrition and physical education component into their curriculums by 2006.[23]

The Act also strives to improve the efficiency of the school lunch program. A new direct certification process through the Food Stamp Program permits all the children in a household to apply at one time for certification eligibility (certification is valid for an entire school year).[24] Runaway, homeless, and migrant children automatically are eligible for meals.[25] Also, active duty military housing allowances will no longer be counted in the determination of eligibility.[26]

An interesting feature of the Act is its new requirements concerning irradiated food products.[27] Irradiated food products can be sent only to states and school districts that request it.[28] The program will not increase reimbursements to schools that request irradiated food products, which may discourage schools from ordering such products as irradiated meat.[29] Also, companies that send schools irradiated food products must keep them completely separate from other food products, and schools that serve them are encouraged to offer stu-

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21. *See* Michelle R. Davis, *Bush Signs School Lunch Reauthorization*, EDUC. WK., July 14, 2004, at 29 (noting the Act allows for funds for healthier snacks, as well as meals, in some school districts).

22. *See id.*

23. *See id.* (explaining additional Act provisions, which expand the school lunch program to the summer months in some areas and provide various provisions that attempt to reduce the paperwork burden on schools and administrators). *See also* Proclamation No. 7831, 69 Fed. Reg. 61,141 (Oct. 14, 2004) (proclaiming the week of Oct. 10-16, 2004 to be "National School Lunch Week").

24. *See* Child Nutrition and WIC Reauthorization Act of 2004, Pub. L. No. 108-265, § 104, 118 Stat. 729 (2004) (to be codified in scattered sections of 42 U.S.C.).

25. *See* Child Nutrition and WIC Reauthorization Act § 104.

26. *See* Child Nutrition and WIC Reauthorization Act § 107.

27. *See* Child Nutrition and WIC Reauthorization Act § 118.

28. *See* Child Nutrition and WIC Reauthorization Act § 118 (requiring that policies and procedures created by the Secretary of Agriculture ensure that "irradiated food products are made available only at the requests of States and school authorities").

29. *See* Child Nutrition and WIC Reauthorization Act of 2004, Pub. L. No. 108-265, § 118, 118 Stat. 729 (2004) (to be codified in scattered sections of 42 U.S.C.); *see also* Emily Gersema & Chris Clayton, *States Reject Irradiated Beef Over Cost, Nebraska and Minnesota Cancel Orders for Schools and Day Care Centers,* OMAHA WORLD-HERALD, Sept. 8, 2004, at 1B (Iowa ed.) (stating that irradiated beef can cost schools up to seventy-five cents more per pound than non-irradiated beef).

dents other alternatives.[30] While schools are not required to disclose on menus or signage that the food products are irradiated, schools must prominently display the fact of irradiation on the container.[31] Finally, schools are required to implement a food safety program that complies with the hazard analysis and critical control point (HACCP) system used by USDA.[32]

These new rules for irradiated food products are designed to address consumer concerns about the safety of such products especially irradiated meat, despite science's general attestation of the safety of irradiated meat products.[33] They follow on the heels of the USDA announcement in 2003 that the agency was beginning to educate school administrators about the availability of irradiated beef.[34] Time will tell what effect these new rules will have on the usage of irradiated meat products in schools.[35]

B. Food Allergen Labeling and Consumer Protection Act

On August 3, 2004, the Food Allergen Labeling and Consumer Protection Act ("Food Allergen Act") was signed into law.[36] The Food Allergen Act will take effect January 1, 2006 and will be administered by the Food and Drug Administration ("FDA").[37] The Food Allergen Act is widely celebrated by consumer groups and parents, who hope

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30. *See* Child Nutrition and WIC Reauthorization Act § 118 (stating that "irradiated food products must not be commingled with food products that are not irradiated" and including the language encouraging alternatives to irradiated foods).

31. *See* Child Nutrition and WIC Reauthorization Act § 118 (requiring irradiated food products distributed through the national school lunch program be clearly labeled with a symbol or other printed notice that "indicates the product was irradiated and is prominently displayed in a clear and understandable format on the container").

32. *See* Child Nutrition and WIC Reauthorization Act § 111.

33. *See* Carole Sugarman, *Irradiation, HACCP Included in Child Nutrition Act*, Food Chem. News, July 5, 2004, at 24 (discussing the various provisions of the Act); *see also* Gersema & Clayton, *supra* note 29 (discussing the concerns of parents and consumer groups who worry that there have been no long-term studies looking into the potential effects of eating irradiated beef).

34. Press Release, U.S. Dep't. of Agric., USDA Releases Specifications for the Purchase of Irradiated Ground Beef in the National School Lunch Program (May 29, 2003), *available at* http://www.fns.usda.gov/cga/PressReleases/2003/PR-0172.htm.

35. *See* Gersema & Clayton, *supra* note 29 (noting that since the passage of the Act, Texas has chosen not to order irradiated beef for its school lunch programs).

36. Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, 118 Stat. 891 (2004) (to be codified as 21 U.S.C. § 343).

37. *See* Food Allergen and Consumer Protection Act § 203.

the new law will make it easier to identify potentially harmful or deadly substances.[38]

1. Background and Development of the Food Allergen Act

Approximately two percent of adults and five percent of infants and young children in the United States suffer from food allergies.[39] Each year, nearly 30,000 individuals require emergency room treatment and 150 individuals die because of allergic reactions to food.[40] A recent study showed that prior to the passing of the Food Allergen Act, many parents of children with a food allergy were unable to correctly identify in each of several food labels the ingredients derived from major food allergens.[41]

Previous regulations did not prevent some manufacturers from using a wide variety of terms to describe the same type of ingredient.[42] For example, milk might be listed as whey, casein, or a variety of other words that may be equally unclear to consumers.[43] As a result, consumer and patient advocacy groups worked collaboratively with the food industry, medical community, and members of Congress in order to provide clear, consistent, and reliable ingredient label information concerning allergens.[44]

2. Food Allergen Act Requirements

The Food Allergen Act requires that food labels display prominently in layman's terms the eight most commonly allergenic substances: milk, eggs, fish, shellfish, tree nuts, wheat, peanuts, and soybeans.[45] The food label is to include the word "contains," followed by any of these eight allergens.[46] Food ingredient labels are to appear

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38. *See, e.g., President Bush Signs Bill That Will Benefit Millions With Food Allergies*, OBESITY, FITNESS & WELLNESS WK., Sept. 4, 2004, at 39.

39. *See* Food Allergen and Consumer Protection Act § 201.

40. *See* Food Allergen and Consumer Protection Act § 201.

41. *See* Food Allergen and Consumer Protection Act of 2004, Pub. L. No. 108-282, § 201, 118 Stat. 891 (2004) (to be codified as 21 U.S.C. § 343).

42. *See, e.g.*, *President Bush Signs Bill*, *supra* note 38.

43. *See, e.g.*, *id.* (reporting that one medical study showed that less than seven percent of parents with children who have milk allergies were able to correctly identify products that contain milk).

44. *See, e.g.*, Press Release, Food Allergy and Anaphylaxis Network, President Bush Signs Food Allergen Labeling and Consumer Protection Act, Historic Day for the Eleven Million Americans With Food Allergies (Aug. 3, 2004), *available at* http://www.foodallergy.org/press_releases/falcpasign.html.

45. Food Allergen Labeling and Consumer Protection Act §§ 202-03.

46. *See* Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, § 202-03, 118 Stat. 891 (2004) (to be codified as 21 U.S.C. § 343).

in a print size, type, and format that is easier to read than that required by previous regulations.[47] Food ingredient statements must identify food allergens used in spices, natural or artificial flavorings, additives, and colorings.[48]

The Food Allergen Act also requires various entities to perform certain activities. Food manufacturers are required to increase protections against cross-contamination in the food manufacturing process.[49] United States Department of Health and Human Services (DHHS) is required to conduct an extended study on allergens.[50] FDA, an agency within the DHHS,[51] is to maintain its authority to regulate the safety of certain products bioengineered to contain proteins that cause allergic reactions.[52] Centers for Disease Control, also an agency within DHHS,[53] is required to track food-allergy-related deaths.[54]

Finally, the Food Allergen Act also orders DHHS to develop regulations allowing for foods to be labeled "gluten free" within two years.[55] This is to address concerns of people with celiac disease, who can be harmed by exposure to gluten.[56] The new regulations will need to coincide with previously existing rules that require labels to identify whether gluten is corn or wheat based.[57]

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47. *See* Food Allergen Labeling and Consumer Protection Act §§ 202-03.

48. *See* Food Allergen Labeling and Consumer Protection Act § 203(d) (stating companies have until January 1, 2006 to implement the changes). Highly refined oils derived from these eight ingredients are exempt from the labeling requirements. *See* Food Allergen Labeling and Consumer Protection Act § 201(qq)(2)(A).

49. *See* Food Allergen Labeling and Consumer Protection Act § 205.

50. *See* Food Allergen Labeling and Consumer Protection Act § 208.

51. *See* U.S. Dep't. of Health and Human Serv., *HHS: What We Do*, *at* http://www.hhs.gov/about/whatwedo.html/ (last visited Mar. 7, 2005).

52. *See* Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, § 203, 118 Stat. 891 (2004) (to be codified as 21 U.S.C. § 343).

53. *See* U.S. Dep't. of Health and Human Serv., *HHS: What We Do*, *at* http://www.hhs.gov/about/whatwedo.html/ (last visited Mar. 7, 2005).

54. *See* Food Allergen Labeling and Consumer Protection Act § 207.

55. *See* Food Allergen Labeling and Consumer Protection Act § 206.

56. *See, e.g.*, Frederick H. Degnan, *The Food Label and the Right to Know*, 52 FOOD & DRUG L.J. 49, 53 n.31 (1997).

57. *See id.* (citing Corn Gluten, 24 C.F.R. § 184.1321 (2004) and Wheat Gluten, 24 C.F.R. § 184.1322 (2004)).

III. Recent Federal Regulations

A. USDA Issues New Rule Related to Country of Origin Labeling

In October 2004, USDA issued its interim final rule[58] regarding country of origin labeling (COOL) requirements for fish and shellfish.[59] Under the rule, fish and shellfish sold in retail venues must have labels that identify both the country of origin of the fish and shellfish and the method in which they were raised (the rule gives the example of identifying wild verses farm-raised salmon).[60] Fish and shellfish that are included as ingredients in processed food products, however, are excluded from the COOL requirements. Processed food products include those that have been combined with other ingredients, pre-cooked or "undergone a change."[61] Food service establishments, such as restaurants, lunchrooms, cafeterias, food stands, bars, lounges, and similar enterprises are exempt from mandatory COOL.[62] The COOL requirements for fish and shellfish are currently not scheduled to take effect until April 4, 2005.[63] Notwithstanding the issuance of the interim final rule, the future of COOL for fish and shellfish, as with all commodities covered by the labeling program, is uncertain.[64]

COOL was introduced in the Farm Security and Rural Investment Act of 2002 (2002 Farm Bill), which amended the 1946 Agricultural

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58. The term interim final rule refers to a rule that is issued by an agency without going through the traditional pre-issue comment period. With an interim final rule, the agency in question will take comments and suggestions from the public during the first few months that the rule is in place. Later the agency may (or may not) choose to adopt these suggestions when the final version of the rule is adopted. *See, e.g.*, Michael Asimow, *Interim Final Rules: Making Haste Slowly*, 51 Admin. L. Rev. 703 (1999).

59. *See* Country of Origin Labeling for Fish and Shellfish, 7 C.F.R. §§ 60.101-.400 (2004) (Dep't of Agric. Oct. 5, 2004).

60. *See* 7 C.F.R. § 60.119.

61. *See* 7 C.F.R. § 60.119.

62. *See* Country of Origin Labeling: Definitions, 7 U.S.C. § 1638 (2005) (exempting food service establishments from the country of origin labeling requirements and defining a food service establishment as "a restaurant, cafeteria, lunch room, food stand, saloon, tavern, bar, lounge, or other similar facility operated as an enterprise engaged in the business of selling food to the public").

63. *See* 7 C.F.R. § 60.119.

64. *See* Jacquelyn Trussell, Note, *The Birth Place of Food Products: Do You Know Where Your Food Comes From?*, 16 Loy. Consumer L. Rev. 285, 285-88 (2004) (detailing recent COOL legislation and subsequent congressional postponements of the legislation's effective date).

Marketing Act (AMA).[65] COOL was to become mandatory in September 2004.[66] On October 30, 2003, USDA's Agriculture Marketing Service (AMS) published a proposed rule to implement the mandatory COOL program.[67] The regulation requires "a retailer of a covered commodity" to inform consumers "at the final point of sale of the covered commodity to consumer, of the country of origin of the covered commodity."[68] Covered commodities include beef, lamb, pork, fish, and perishable agricultural commodities such as peanuts.[69]

COOL has since been beset by congressional postponement. On January 23, 2004, Congress passed an omnibus appropriations bill, which included a provision amending the AMA.[70] This provision, Section 749 of Division A, Title VII, of the AMA, delayed the mandatory application of COOL until September 2006 for all products covered under that law, except for "'farm-raised fish' and 'wild fish.'"[71]

COOL is also under threat of repeal. In June 2004, efforts were made to pass a separate law that would completely repeal any COOL requirements present in the 1946 AMA and replace them with a voluntary country-of-origin program, dubbed as the VCOOL program.[72] Given this tumultuous history in the short life of COOL, the future for COOL is anything but certain.

B. Agencies Issue Proposals for Preventing the Spread of BSE

In July 2004, USDA and DHHS jointly issued three important announcements related to efforts to prevent the spread of bovine spon-

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65. *See id.*; *see also* Farm Security and Rural Investment Act of 2002, Pub. L. No. 107-171, 116 Stat. 134 (2002) (codified in scattered sections of 7 U.S.C.).

66. *See* Notice of Country of Origin, 7 U.S.C. § 1638a (2004).

67. *See* Mandatory Country of Origin Labeling of Beef, Lamb, Pork, Fish, Perishable Agricultural Commodities, and Peanuts; Proposed Rule, 68 Fed. Reg. 61,944 (Oct. 30, 2004) (to be codified at 7 C.F.R. pt. 60).

68. *See* 7 U.S.C. § 1638a.

69. *See* 7 U.S.C. § 1638a.

70. *See* Consolidated Appropriations Act of 2004, Pub. L. No. 108-199, 118 Stat. 3 (2004) (codified at 16 U.S.C. § 1638d).

71. *See* Consolidated Appropriations Act of 2004.

72. *See* H.R. Res. 4576, 108th Cong. (2004); *see also Country of Origin Labeling Must Go*, DAILY TRIBUNE-HERALD (Grand Prairie, Alberta), Nov. 18, 2004, at 12 (stating that VCOOL is preferred by large segments of the food industry); *Country-of-Origin Labeling Amendment Left Out of Omnibus*, NAT'L J.'S CONG. DAILY, Nov. 19, 2004 (explaining how Congressional leaders removed the COOL repeal provision from a November 2004 spending bill vote when public concern about food safety spiked due to an unrelated incident).

giform encephalopathy (BSE),[73] also known as "Mad Cow Disease,"[74] in the United States.[75] The Food Safety and Inspection Service (FSIS), under USDA, is responsible for the safety of meat and poultry.[76] FDA, under DHHS, is responsible for regulating animal feed.[77]

The first announcement was the issuance of an interim final rule[78] prohibiting the use of specific cattle parts in human food, cosmetics, and dietary supplements.[79] These prohibited parts include specific risk materials that are known to harbor concentrations of the infectious agent for BSE, such as the brain, skull, eyes, and spinal cord of cattle thirty months of age or older, and a portion of the small intestine and tonsils from all cattle, regardless of their age.[80] Prohibited parts under the interim final rule also include material from non-ambulatory disabled cattle, cattle that are not inspected and passed for human consumption, and mechanically separated beef.[81] This final interim rule is consistent with the recent interim final rule issued by USDA declaring these materials to be unfit for food and prohibiting their use as human food.[82]

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73. *See* CHUCK CULVER, GLOSSARY OF AGRICULTURAL PRODUCTION, PROGRAMS AND POLICY – FOURTH EDITION, *available at* http://www.nationalaglawcenter.org/glossary (defining Bovine spongiform encephalopathy (BSE), as a "[a] chronic, degenerative, fatal disease affecting the central nervous system of cattle").

74. *See* Note, *Challenging Concentration of Control in the American Meat Industry*, 117 HARV. L. REV. 2643 (2004).

75. *See* Press Release, U.S. Dep't of Agric. Food Safety and Inspection Serv., USDA and HHS Strengthen Safeguards Against Bovine Spongiform Encephalopathy (July 9, 2004), *available at* http://www.usda.gov/Newsroom/0280.04.html; Federal Measures to Mitigate BSE Risks: Considerations for Further Action; Proposed Rule, 69 Fed. Reg. 42,288 (July 14, 2004).

76. *See* U.S. GENERAL ACCOUNTING OFFICE, MAD COW DISEASE: IMPROVEMENTS IN THE ANIMAL FEED BAN AND OTHER REGULATORY AREAS WOULD STRENGTHEN U.S. PREVENTION EFFORTS (2002).

77. *See id.*

78. *See supra* note 58.

79. *See* Use of Material Derived from Cattle in Human Food and Cosmetics, 69 Fed. Reg. 42,255-74 (July 14, 2004) (to be codified at 21 C.F.R. pt. 189, 21 C.F.R. pt. 700) (including a more complete discussion of the reasons for the rule and explanation of the various banned cattle parts).

80. *See* USDA and HHS Strengthen Safeguards, *supra* note 75.

81. *See id.*

82. *See* Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle, 69 Fed. Reg. 1,862-01 (Jan. 12, 2004); *see also* Bovine Spongiform Encepalopathy Teaching Workshops, 69 Fed. Reg. 4,106 (Jan. 28, 2004). The initial proposed rule was later revised and broadened. *See* Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle; Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR)

The second announcement was an advanced notice of proposed rulemaking (ANPR)[83] action regarding proposals to increase efforts to prevent mammalian proteins in animal foods.[84] Although FDA issued a ban on these proteins in 1997,[85] there has been some evidence that the ban has not been entirely effective, and that not all animal facilities are compliant.[86] There is also concern that the ban does not address the common practice of feeding cattle by-products to chickens, who produce litter that is then added to the feed of cattle.[87] This announcement also called for comments on potential regulatory shifts, including the idea of implementing a national animal identification system, changing the rules for interacting with countries who import and export meat with the United States, and preventing nonambulatory disabled cattle from being used in animal feed.[88]

The third announcement was a proposed rule to require that manufacturers and processors of human food and cosmetics containing cattle-derived material establish and maintain records showing that prohibited materials are not used in their products.[89] This announcement is intended to help ensure compliance with the prohibitions in the interim final rule.[90]

Systems; Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter; Bovine Spongiform Encepalopathy (BSE) Surveillance Program, 69 Fed. Reg. 18,245 (Apr. 7, 2004) (to be codified in scattered sections of 9 C.F.R.). USDA's Food Safety and Inspection Service recently announced it would review these rules due to their "significant economic impact." *See* Regulatory Flexibility Act; Amended Plan for Reviewing Regulations Under Section 610 Requirements, 70 Fed. Reg. 4,047 (Jan. 28, 2005).

83. RICHARD J. PIERCE ET AL., ADMINISTRATIVE LAW & PROCESS 321 (3d. ed. 1999) ("The agency's notice of proposed rule making starts the process of framing the issues in a rule making by giving interested members of the public a target for critical comments.").

84. *See* USDA and HHS Strengthen Safeguards, *supra* note 75.

85. *See* Animal Proteins Prohibited in Ruminant Feed, 21 C.F.R. § 589.2000 (2004).

86. *See, e.g.*, Michael B. Abramson, *Mad Cow Disease: An Approach to Its Containment*, 7 J. HEALTH CARE L. & POL'Y 316, 334-37 (2004) (noting the various ways in which organizations in the United States are still not compliant with the ban).

87. *See Challenging Concentration of Control, supra* note 74.

88. *See* USDA and HHS Strengthen Safeguards, *supra* note 75.

89. *See id.*; Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, Or Otherwise Containing, Materials from Cattle, 69 Fed. Reg. 42,275 (July 14, 2004) (codified at 21 C.F.R. §§ 189, 700 (2004)).

90. Use of Materials Derived From Cattle in Human Food and Cosmetics; and Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle; Final Rule and Proposed Rule, 69 Fed. Reg. 42,255, 42,263 ("We believe that records documenting the absence of prohibited cattle materials in human food and cosmetics are critical . . . to

C. *FDA Establishes Rules for Keeping Records Under the Bioterrorism Act*

On December 9, 2004, FDA published in the Federal Register a final rule implementing the recordkeeping provisions of the Public Health Security and Bioterrorism Preparedness Act, commonly referred to as the Bioterrorism Act.[91] The rule was passed to help address concerns about the vulnerability of the United States' food supply.[92] The recordkeeping rule is the fourth rule in a series of regulations issued by FDA under the Bioterrorism Act.[93]

The final rule is effective February 7, 2005.[94] The final rule, however, extends the time period for firms to comply. Most firms have one year after the final regulations are published to comply (i.e., December 9, 2005), which is double the six months originally proposed.[95] Small businesses, those businesses with 500 or fewer full-time

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ensure compliance with the prohibitions on the use of prohibited cattle materials in this interim final rule.").

91. Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188 (codified in scattered sections of 42 U.S.C.); Press Release, Food and Drug Admin., FDA Issues Final Rule on the Establishment and Maintenance of Records to Enhance the Security of the U.S. Food Supply Under the Bioterrorism Act; FDA Also Issues Draft Guidance Regarding Records Access (Dec. 6, 2004), *available at* http://www.fda.gov/bbs/topics/news/2004/NEW01143.htm.

92. *See, e.g.*, John Blanchard, *The Bioterrorism Act: The Cost of Compliance: With the Final Rules Yet to Come, Food and Beverage Processors are Gearing Up For the Expected Requirements While Implementing the Systems They Hope Will Make Them Compliant*, FOOD ENGINEERING, Sept. 1, 2004, at BT1.

93. *See* FDA Issues Final Rule, *supra* note 91; s*ee also* Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,894 (Oct. 10, 2003) (to be codified at 21 C.F.R. pt. 1, 20) (requiring domestic and foreign facilities that manufacture, process, produce, pack, or hold food for human or animal consumption in the United States to register with the FDA); Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,974 (Oct. 10, 2003) (to be codified at 21 C.F.R. pt. 1) (requiring that entities provide prior notice of all foods for human or animal consumption before they enter the United States); Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 69 Fed. Reg. 25,242 (June 4, 2004) (to be codified at 21 C.F.R. pt. 1, 16) (providing procedures for the seizure of foods meant for animal or human consumption).

94. *See* Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Establishment and Maintenance of Records for Foods; Notice of Public Meeting; Availability of Draft Guidance for Records Access Authority; Final Rules and Notice, 69 Fed. Reg. 71,561-62 (Dec. 9, 2004) (to be codified at 21 C.F.R. pt. 1, 11).

95. *Compare* Establishment and Maintenance of Records, 69 Fed. Reg. at 71,562, *with* 68 Fed. Reg. 25,188, 25,190 (May 9, 2003) (offering the original proposed rule for public comment).

employees, have eighteen months from the publication date to comply (i.e., June 9, 2006), which is up from the twelve months originally proposed.[96] Very small businesses, those businesses with ten or fewer full-time employees, have two years to comply (i.e., December 9, 2006), which is up from the originally proposed eighteen months.[97]

The agency's recordkeeping rule applies to all those who manufacture, process, pack, transport, distribute, receive, hold, or import food.[98] Farms, restaurants, and foreign persons (other than persons who transport food in the United States), and certain other entities are excluded from the rule, which also allows for special exceptions for the makers of food contact substances.[99] The proposed regulations had contemplated covering foreign persons.[100] Exempting foreign persons in the final rule's requirements to maintain and provide access to records, except for foreign transporters hauling commodities or food into the United States, eliminates a potential burden for foreign producers.[101] It still may be prudent, however, for exempt foreign persons to maintain a recordkeeping system in order to respond appropriately to inquiries at the time of entry from either Customs and Border Protection or FDA.[102]

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96. *Compare* Establishment and Maintenance of Records, 69 Fed. Reg. at 71,562, *with* 68 Fed. Reg. 25,188, 25,190 (May 9, 2003).

97. *Compare* Establishment and Maintenance of Records, 69 Fed. Reg. at 71,562, *with* 68 Fed. Reg. 25,188, 25,190 (May 9, 2003).

98. *See* FDA Issues Final Rule, *supra* note 91 (noting that records kept by persons who transport foods do not need to be kept for longer than one year).

99. *See* Establishment and Maintenance of Records, 69 Fed. Reg. at 71,563; *see also Final Recordkeeping Rule Does Not Require Lot # On Retail Level*, FDA Wk., Nov. 10, 2004 (explaining that some groups were concerned that industry lobbying efforts had weakened the effectiveness of the record keeping requirements); *Recordkeeping Rule a Step Towards Relying on Foreign Sister Agencies*, FDA Wk., Nov. 10, 2004 (explaining some of the reasons FDA chose to exempt foreign companies who export to the United States from the record keeping requirements).

100. *See generally* 69 Fed. Reg. 25,188 (including foreign facilities throughout the requirements of the proposed rule).

101. The comments to the proposed rule argued that attempting to impose such requirements on foreign facilities could have triggered challenges within the World Trade Organization (WTO) and subjected U.S. companies to the same treatment by foreign governments. *See* Establishment and Maintenance of Records, 69 Fed. Reg. at 71,569.

102. *See, e.g.*, Persons Required to Maintain Records, 19 C.F.R. § 163.2 (Bureau of Customs and Border Prot., Dep't of Homeland Sec. 2004); Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,974 (FDA Oct. 10, 2003) (to be codified at 21 C.F.R. pt. 1) (requiring that entities provide prior notice of all foods for human or animal consumption before they enter the United States); Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism

Firms subject to the final rule must keep records of all food they receive and release.[103] The records must contain information as to the identity of the food, the immediate supplier of the food, and the immediate consumer for the food.[104] This information in general includes the names of the relevant entities, address, telephone number, fax number, e-mail address, description of the food, date the food was received, the lot or code number for the food, quantity of food, and how the food was packaged.[105] The requirements differ slightly for transporters versus non-transporters.[106]

All records must be kept at the establishment where these activities take place or at a reasonably accessible location.[107] Records related to animal and pet foods must be kept for at least one year. Records related to human foods must be kept for six months to two years, depending on the shelf life of the foods in question.[108] These records are to be made available to FDA within twenty-four hours of a proper agency request.[109] FDA may request these records only when it has a reasonable belief that the food is adulterated and poses a "threat of serious adverse health consequences or death."[110] Failure to produce the requested records within the mandatory twenty-four hour production period can result in civil and/or criminal penalties.[111]

D. Qualified Health Claims

In the last quarter of 2004, FDA announced approval of two new qualified health claims. A health claim is considered a labeling claim

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Preparedness and Response Act of 2002, 69 Fed. Reg. 25,242 (FDA June 4, 2004) (to be codified at 21 C.F.R. pt. 1, 16) (providing procedures for the seizure of foods meant for animal or human consumption).

103. *See* Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 69 Fed. Reg. 71,561, 75,562 (Dec. 9, 2004) (to be codified at 21 C.F.R. pt. 1, 11).

104. *See* Establishment and Maintenance of Records, 69 Fed. Reg. at 71,562-63.

105. *See* Establishment and Maintenance of Records, 69 Fed. Reg. at 71,563-64.

106. *See* Establishment and Maintenance of Records, 69 Fed. Reg. at 71,564.

107. *See* 69 Fed. Reg. 25,188, 25,190 (May 9, 2003).

108. *See id.*

109. *See* Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 69 Fed. Reg. 71,561, 75,564 (Dec. 9, 2004) (to be codified at 21 C.F.R. pt. 1, 11). Previously, the agency proposed to require that companies provide access to records within four hours if requested on a weekday and eight hours on a weekend. *See* 68 Fed. Reg. 25,188, 25,190 (May 9, 2003).

110. *See* Establishment and Maintenance of Records, 69 Fed. Reg. at 71,562-63.

111. *See* Establishment and Maintenance of Records, 69 Fed. Reg. at 71,562 (Dec. 9, 2004) (stating that failure to comply with the provisions of the regulation will be a violation of the Federal Food, Drug & Cosmetics Act).

that characterizes the relationship of a substance to a disease or health-related condition.[112] The first of these new qualified health claims was announced in September 2004, allowing food companies to make a qualified health claim concerning the benefits of omega-3 fatty acids.[113] The second announcement came in November 2004, allowing a qualified health claim related to the benefits of consuming olive oil.[114] These two new qualified health claims signify a new era in FDA's treatment of health claims and are lauded as providing instructive information to consumers.[115] Critics worry, however, that these new qualified health claims make consumer education for health-conscious consumers too complicated[116] and that isolating the benefits of one food will detract from the importance of an overall healthy diet.[117]

1. Background

Prior to the 1980s, few health claims were made for food products.[118] FDA treated health claims for food as bringing that food within FDA's definition of a drug ("intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease").[119] When firms

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112. *See* Health Claims: General Requirements, 21 C.F.R. § 101.14(a)(1) (2005).

113. *See* Press Release, Food and Drug Admin., FDA Announces Qualified Health Claims for Omega-3 Fatty Acids (Sept. 8, 2004), *available at* http://www.fda.gov/bbs/topics/news/2004/NEW01115.html.

114. *See* Press Release, Food and Drug Admin., FDA Allows Qualified Health Claim to Decrease Risk of Coronary Heart Disease (Nov. 1, 2004), *available at* http://www.fda.gov/bbs/topics/news/2004/NEW01129.html.

115. *See* Press Release, Food and Drug Admin., FDA Announces Initiative to Provide Better Health for Consumers (Dec. 18, 2002), *available at* http://www.fda.gov/bbs/topics/NEWS/2002/NEW00859.html.

116. *See, e.g.*, Sally Squires, *Omega-3 Foods Can Put Benefits on Label, FDA Says*, WASH. POST, Sept. 9, 2004, at A4 (quoting the director of the Center for Science in the Public Interest as saying qualified health claims are not in the best interests of consumers because "[t]he tenet of consumer education is to keep it simple. The FDA is making it quite complicated for health-conscious consumers who are trying to improve their diets.").

117. *See id.*; *see also* MARION NESTLE, FOOD POLITICS 315 (2003) (criticizing the use of health claims and noting that since all foods and beverages contain some ingredients that are essential for life, almost any food has the potential for being marketed for its health benefits).

118. *See, e.g.*, Clement Dimitri Pappas, *Maintaining a Level Playing Field: The Need for a Uniform Standard to Evaluate Health Claims for Foods and Dietary Supplements*, 57 FOOD & DRUG L.J. 25, 27 (2002) (implying the FDA faced intense pressure in the 1980s as more scientific studies began to show a connection between diet and chronic disease).

119. *See* Federal Food, Drug & Cosmetics Act, Definitions; Generally; 21 U.S.C. § 321 (2004).

began making health claims for foods without requesting FDA approval,[120] FDA published in 1987 a proposed rule addressing health claims.[121] In 1990, FDA published a proposed regulation to establish rules for health claims for foods that was published again by FDA in 1990.[122]

Shortly after the 1990 proposed rule, Congress passed the Nutrition Labeling and Education Act of 1990 (NLEA), authorizing FDA to allow certain health claims to appear in food labeling.[123] Pursuant to the Act, FDA was to evaluate health claims using a standard of significant scientific agreement, which required that a sufficient body of sound, relevant scientific evidence show consistency across different studies and among different researchers.[124]

In 1999, the United States Court of Appeals for the District of Columbia held in *Pearson v. Shalala* that FDA's denial of four health claims on dietary supplements violated the First Amendment.[125] The court held that FDA was required, under commercial speech doctrine, to consider whether inclusion of appropriate disclaimers would negate the potentially misleading nature of health claims.[126] The court also found that FDA's failure to define the phrase "significant scientific agreement" in its regulation governing the authorization of health claims violated the Administrative Procedure Act.[127] Despite urging from the food industry to apply the *Pearson* decision to conventional foods, FDA implemented the *Pearson* decision only with respect to dietary supplements.[128] This dichotomy effectively created different standards for foods and dietary supplements, subjecting FDA to some pointed criticism.[129]

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120. *See, e.g.*, Pappas, *supra* note 118 (discussing the successful efforts of Kellogg Company to get permission from the Federal Trade Commission and the National Cancer Institute to list the health benefits of consuming bran on its cereal packaging, a move that was against FDA regulations at the time and helped lead to the agency's increased willingness to consider the allowance of qualified health claims).

121. *See* Food Labeling: Public Health Messages on Food Labels and Labeling, 52 Fed. Reg. 28,843 (proposed Aug. 4, 1987).

122. Food Labeling; Health Messages and Statements; Reproposed Rule, 55 Fed. Reg. 5,176 (proposed Feb. 13, 1990, codified at 21 C.F.R. § 101 (2005)).

123. Nutrition Labeling and Health Education Act of 1990, Pub. L. 101-535, 104 Stat. 3562 (codified as amended in scattered sections of 21 U.S.C.).

124. *See* 21 U.S.C. § 343 (2004).

125. *See* 164 F.3d 650 (U.S. App. D.C. 1998).

126. *See id.* at 655-60.

127. *See id.* at 660-61.

128. *See* Public Meeting Concerning Implementation of Pearson Court Decision and Whether Claims of Effects on Existing Diseases May Be Made as Health Claims, 65 Fed. Reg. 14,219 (Mar. 16, 2000).

129. *See generally* Pappas, *supra* note 118.

In December 2002, FDA changed its policy. The agency announced that it was updating its approach to implementing the *Pearson* decision to include conventional foods, in addition to dietary supplements.[130] FDA also announced that it would evaluate health claims for dietary supplements and conventional foods using a weight-of-the-scientific-evidence standard, which is less stringent that the significant-scientific-standard.[131] FDA also established a task force to help determine how the agency should evaluate scientific evidence for qualified health claims and to develop an overall framework for the regulations.[132]

Six days after the announcement of FDA's change in policy, the U.S. District Court for the District of Columbia in *Whitaker v. Thompson* held that in interpreting *Pearson*, the "credible evidence" standard, an even lower standard than the weight-of-the-scientific-evidence standard, was the appropriate standard for FDA to apply in evaluating qualified health claims.[133] As in *Pearson*, the *Whitaker* case on its facts specifically involved dietary supplements, not conventional food.[134]

In July 2003, in a notice published in the Federal Register, FDA announced the availability of the task force report and the availability of two guidance documents that stated in light of *Whitaker*, the weight-of-the-evidence standard set forth in the December guidance "must be tempered by the test of credible evidence."[135] The July guidance also asserts FDA's authority to permit a qualified health claim for conventional food where supported by credible evidence.[136] As of September 2003, FDA has implemented on an interim basis an evidence-based-ranking system and a set of procedures for qualified health claims, suggested by the task force report identified in the earlier July guidance.[137] The evidence-ranking system assigns a final rank to the

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130. *See* Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements; Availability, 67 Fed. Reg. 78,002 (Dec. 20, 2002).

131. *See, e.g.*, Release of Task Force Report; Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data; Interim Procedures for Health Claims on the Labeling of Conventional Human Foods and Human Dietary Supplements; Availability, 68 Fed. Reg. 41,387 (July 9, 2003).

132. *See id.*

133. *See* 248 F. Supp. 2d 1, 10 (D.C. 2002).

134. *See id.*

135. *See* Release of Task Force Report, 68 Fed. Reg. at 41,388-89.

136. *See id.*

137. *See* Health Claims: General Requirements, 21 C.F.R. § 101.14 (2004); Petitions for Health Claims, 21 C.F.R. § 101.70 (2004).

evidence in support of the health claim and accommodates the use of disclaimers and clarifying language.[138]

This new rule is not uniformly endorsed. The Federal Trade Commission, as well as numerous health and consumer groups have raised concerns about the clarity of these new rules.[139] The FDA's rule changes are also being challenged in a law suit filed by two consumer groups: the Center for Science in the Public Interest (CSPI)[140] and Public Citizen.[141] In September 2003, CSPI and Public Citizen filed a complaint, alleging that the NLEA requires health claims on food to be backed up by the significant-scientific-agreement standard.[142] The suit alleges also that FDA is ignoring laws requiring the agency to respond to public comments and to justify its decisions regarding new health claims.[143]

In April 2004, walnuts became the first conventional food for which FDA formally approved a qualified health claim.[144] FDA determined that the walnut claim could be stated as follows:

> Supportive but not conclusive research shows that eating 1.5 oz. (a little more than a handful) of walnuts per day as part of a low saturated fat and low cholesterol diet, and not resulting in increased

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138. *See* Release of Task Force Report, 68 Fed. Reg. 41,387, 41,389.

139. *See, e.g.*, Press Release, Fed. Trade Comm'n, FTC Staff Provides FDA With Comment on Permitting Health Claims for More Foods (July 30, 2004), *available at* http://www.ftc.gov/opa/2004/07/fdacomment.htm; *How Qualified Are Health Claims for Food?*, HARV. HEALTH LETTER, Dec. 1, 2004.

140. The Center for Science in the Public Interest (CSPI) is a non-profit consumer education and advocacy organization that conducts research and represents consumer interests in food safety and nutrition before Congress and federal government agencies. *See, e.g.*, Center for Science in the Public Interest, *About CSPI*, *at* http://www.cspinet.org/about/index.html (last visited Mar. 8, 2005); Complaint for Declaratory and Injunctive Relief, CSPI et. al. v. FDA, No. CV-01962 (D. D.C. filed Sept. 23, 2003), *available at* http://www.citizen.org/documents/compl-3.8xx.pdf.

141. Public Citizen is a non-profit consumer advocacy organization that promotes consumer health and safety through research and public education on matters including food, drugs, and health care delivery systems. *See* Public Citizen, *About Public Citizen*, *at* http://www.publiccitizen.org/about/; Complaint for Declaratory and Injunctive Relief, CSPI et. al. v. FDA, No. CV-01962 (D. D.C. filed Sept. 23, 2003), *available at* http://www.citizen.org/documents/compl-3.8xx.pdf.

142. *See* Complaint for Declaratory and Injunctive Relief, CSPI et. al. v. FDA, No.CV-01962 (D. D.C. filed Sept. 23, 2003), *available at* http://www.citizen.org/documents/compl-3.8xx.pdf.

143. *See id.*

144. *See* Letter from Laura Tarantino, Acting Director, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition, FDA, to Sarah E. Taylor, Covington & Burling (Mar. 9, 2004), *available at* http://www.cfsan.fda.gov/%7Edms/qhcnuts3.html.

> caloric intake, may reduce the risk of coronary heart disease. See nutrition information for fat (and calorie) content.[145]

This first qualified health claim was heralded by food marketers, especially those in the walnut industry, who claimed that "[w]alnuts are a powerful weapon in the battle against heart disease."[146] Critics were troubled not necessarily by the walnut qualified health claim itself, but by the fear that health claims "for which there are limited data and inconclusive evidence, will start appearing."[147]

2. Two New Qualified Health Claims: Omega-3 Fatty Acids and Olive Oil

(a) Omega-3 Fatty Acids

In September 2004, FDA formally approved a second qualified health claim.[148] FDA announced that it would allow producers of foods containing omega-3 fatty acids to make qualified health claims on food labels.[149] The new rule allows the makers and marketers of foods that contain eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) omega-3 fatty acids to add labels making qualified health claims stating these acids may reduce the risk of coronary heart disease.[150] FDA's approved phrasing states that "supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of heart disease. One serving of [x] food provides [x] grams of EPA and DHA omega-3 fatty acids."[151] In 2000 FDA allowed a similar health claim to be added to the labels of dietary supplements containing EPA and DHA omega-3 fatty acids.[152]

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145. *See id.*; *see also* Squires, *supra* note 116.

146. *See, e.g.*, Lawrence Linder, *Health Claims Rest on Inconclusive Data*, BOSTON GLOBE, Sept. 7, 2004 (quoting an official from walnut-marketer Diamond of California), *available at* http://www.boston.com/news/globe/health_science/articles/2004/09/07/health_claims_rest_on_inconclusive_data/.

147. *See id.*

148. *See* Press Release, Food and Drug Admin., FDA Announces Qualified Health Claims for Omega-3 Fatty Acids (Sept. 8, 2004), *available at* http://www.fda.gov/bbs/topics/news/2004/NEW01115.html.

149. *See id.*

150. *See id.*

151. *See id.* The label also tells consumers to look at additional nutrition information to see the total fat, saturated fat, and cholesterol content of the product. *See id.*

152. *See* FDA Announces Qualified Health Claims, *supra* note 148. FDA also recommends that no more than two grams of these acids should come from dietary supplements. *See id.* At the time, FDA also warned against consuming more than three grams of these acids every day. *See id.*

Omega-3 fatty acids are most frequently found in oily fish such as salmon, tuna, lake trout, and herring. These acids can also be found in other foods as well,[153] but the regulation forbids food producers from adding omega-3 fatty acids to otherwise unhealthy foods simply to make the health claim. Most foods must also be low in cholesterol and saturated fat before they can claim the health benefits of omega-3 fatty acids.[154]

(b) Olive Oil

In November 2004, FDA announced the allowance of an additional qualified health claim[155] related to the benefits of consuming olive oil.[156] The new claim coincided with the agency's recommendation that consumers wishing to reduce their risk of coronary heart disease replace foods high in saturated fat with the monounsaturated fat from olive oil and olive oil-containing foods.[157] FDA approved phrasing for the new labeling reads:

> Limited and not conclusive scientific evidence suggests that eating about 2 tablespoons (23 grams) of olive oil daily may reduce the risk of coronary heart disease due to the mono-unsaturated fat in olive oil. To achieve this possible benefit, olive oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product [Name of food] contains [x] grams of olive oil.[158]

While foods bearing this claim will not be held to the low fat and low saturated fat requirement applied to omega-3 fatty acid claims,[159] foods that are higher in saturated fat must direct consumers to "see nutritional information for saturated fat content."[160] Foods must

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153. *See id.*

154. *See* Squires, *supra* note 116. (noting that fish and dietary supplements are exempted from the low cholesterol and low saturated fat requirements).

155. *See supra* notes 135-38 and accompanying text.

156. *See* Press Release, Food and Drug Admin., FDA Allows Qualified Health Claim to Decrease Risk of Coronary Heart Disease (Nov. 1, 2004), *available at* http://www.fda.gov/bbs/topics/news/2004/NEW01129.html.

157. *See id.*

158. *Id.*

159. *See supra* note 154 and accompanying text.

160. *See* Letter from the Food and Drug Administration's Center for Food Safety and Applied Nutrition's Office of Nutritional Products, Labeling and Dietary Supplements, to Bob Bauer, North American Olive Oil Association, formally titled Letter Responding to Health Claim Petition dated August 28, 2003: Monounsaturated Fatty Acids from Olive Oil and Coronary Heart Disease (Nov. 1, 2004), *available at* http://www.cfsan.fda.gov/~dms/qhcolive.html.

also be relatively low in cholesterol to meet the claim's requirements.[161]

E. FDA & USDA Present Joint Effort to Combat Salmonella in Eggs

USDA and FDA combined forces in September 2004 to distribute a proposed rule for combating Salmonella Enteritidis (salmonella) in eggs.[162] Salmonella is a food borne disease that can cause severe discomfort, and in some cases death.[163] High-risk populations—the very young, the very old, or anyone with pre-existing illness or reduced immunity—are especially vulnerable.[164] The Centers for Disease Control has identified salmonella as a public health problem since 1986, when an outbreak in at least seven states sickened more than 3,000 people.[165] Since then, the number of reported salmonella incidents have either declined and increased, depending on the geographical region and period of time.[166] It is estimated that 118,000 illnesses per year are caused by consumption of salmonella-contaminated eggs.[167] Unlike past outbreaks of salmonella, evidence shows that current cases of salmonella are being transmitted through intact and healthy looking eggs. This is because the disease infects the ovaries of hens which means salmonella is entering the structures of eggs before they are formed.[168]

Federal regulation of eggs is complex. Multiple agencies and multiple laws govern the safety and quality of eggs and egg products.[169] Agencies involved in regulating eggs, from the hen to the consumer, include FDA and numerous agencies within USDA, includ-

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161. *See id.*; *see also* Specific Requirements for Nutrient Content Claims, 21 C.F.R. § 101.62(d) (2004) (giving the specific requirements for general labeling claims related to cholesterol).

162. *See* Prevention of Salmonella Enteritidis in Shell Eggs During Production, 69 Fed. Reg. 56,824 (proposed Sept. 22, 2004).

163. *See* Ctr. for Disease Control Div. of Bacterial and Mycotic Diseases, *Salmonella Enteritidis: Frequently Asked Questions*, *at* http://www.cdc.gov/ncidod/dbmd/diseaseinfo/salment_g.htm (last visited Dec. 16, 2004).

164. U.S. General Accounting Office (GAO), Food Safety: U.S. Needs a Consistent Farm-To-Table Approach To Egg Safety, at 28 (1999).

165. U.S. General Accounting Office, Food Safety And Quality: Salmonella Control Efforts Show Need For More Coordination, at 10 (1992).

166. *See* Sandra B. Eskin, *Putting All of Your Eggs in One Basket: Egg Safety and the Case for a Single Food Safety Agency*, 59 Food & Drug L.J. 441 (2004).

167. Press Release, Food and Drug Admin., FDA Proposes Further Action to Improve Farm-to-Table Shell Egg Safety (Sept. 20, 2004), *available at* http://www.fda.gov/bbs/topics/news/2004/NEW01117.html.

168. *See* Eskin, *supra* note 166, at 445-46.

169. *See id.* at 444.

ing, Animal and Plant Health Inspection Services (APHIS), Agricultural Marketing Service (AMS), and Food Safety Inspection Service (FSIS).[170] These agencies may operate under the Egg Inspection Act[171] and various federal programs and state laws.[172] Such fragmentation has exposed the nation's egg safety efforts to criticism for lacking focus and for containing gaps, inconsistencies, and inefficiencies.[173]

The joint effort by USDA and FDA is an attempt to coordinate in seeking to identify farm-to-table actions that will decrease the food safety risks associated with eggs.[174] The proposed egg safety rules would call for increased safety education, refrigeration requirements, and specific cleaning and disinfecting processes for farms that have tested positive for salmonella.[175] One of the key provisions in the proposed rule would be an increase in the testing of eggs for infection at the farm level, and another key provision requires the creation of a bio-terrorism security program for eggs to be implemented in the future.[176] The two agencies also released final versions of rules related to recordkeeping in December; these new rules will go into effect in February 2005.[177]

IV. Recent Administrative Decisions

A. FTC Settles Dispute with KFC Corporation Over False Advertising Claims

Federal Trade Commission (FTC) has primary responsibility for regulating the advertising and other marketing practices associated with FDA regulated products, including food.[178] In September 2004, FTC finalized a settlement with KFC Corporation, owner of the inter-

170. *See* Food Safety: U.S. Needs a Consistent Farm-to-Table Approach, *supra* note 164.

171. *See* Egg Products Inspection Act, 21 U.S.C. § 1031 et. seq. (2004).

172. *See* Food Safety: U.S. Needs a Consistent Farm-to-Table Approach, *supra* note 164.

173. *See id.*

174. *See* Prevention of Salmonella Enteritidis in Shell Eggs During Production, 69 Fed. Reg. 56,824, 56,832 (Sept. 22, 2004).

175. *See* Prevention of Salmonella Enteritidis in Shell Eggs During Production, 69 Fed. Reg. 56,824, 56,834 (Sept. 22, 2004).

176. *See* Prevention of Salmonella Enteritidis in Shell Eggs During Production, 69 Fed. Reg. 56,824 at 56,834-38 (Sept. 22, 2004).

177. *See generally* Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 69 Fed. Reg. 71,561 (Dec. 9, 2004).

178. *See* 15 U.S.C. §§ 52, 55 (2004).

national restaurant chain Kentucky Fried Chicken, in a dispute over health-related claims the company had made in advertisements for its food.[179] FTC claimed the advertisements in question promoted the supposed health and weight loss benefits of fried chicken in a misleading manner.[180] The agency offered evidence that KFC had stated two KFC chicken breasts contained less fat than a Burger King Whopper, and had also implied eating KFC's fried chicken was compatible with various branded diet plans and other attempts to lose weight.[181] In reality, two of the restaurant's breaded chicken breasts have slightly less fat than the Whopper but contain higher levels of trans fat, sodium, cholesterol, and calories.[182]

As part of the final settlement order KFC agreed to stop running the advertisements and not to make similar health claims in the future.[183] The settlement also barred the company from claiming its chicken has any health benefits or comparing the nutritional content of its chicken to that of other foods.[184] The agency stated the agreement was part of its cooperation with a recent government-wide effort to fight the rise of obesity in America.[185]

V. Recent Case Decisions

A. *Government Regulation of Egg Safety and Taking of Private Property*

In June 2004, the Court of Appeals for the Federal Circuit vacated and remanded a case in which the lower court held that the government's attempt to restrict the sale of contaminated eggs constituted a "taking" of private property and awarded millions of dollars in

179. *See* Press Release, Fed. Trade Comm'n, KFC's Claims That Fried Chicken is a Way to "Eat Better" Don't Fly (June 13, 2004), *available at* http://www.ftc.gov/opa/2004/06/kfccorp.htm. The settlement agreement was announced in June, and after a period of public comment it was finalized without changes on September 17, 2004.

180. *See id.*; *see also* Complaint of the U.S. Federal Trade Commission, In the Matter of KFC Corporation (F.T.C. 2004) (No. C-4118).

181. *See* KFC's Claims Don't Fly, *supra* note 179*; see also* Editorial, *KFC Blunders in 'Health' Ads*, Advertising Age, Nov. 3, 2003, at 22 (calling the ads in question "as laughable, and as damaging, as any we can imagine or recall, and [ ] should be pulled off the air immediately. In the long history of absurd, misleading and ludicrous ad claims, the campaign's positioning of KFC's breaded, fried chicken as a part of a healthy diet merits special derision").

182. *See* Complaint of the U.S. Federal Trade Commission, In the Matter of KFC Corporation (F.T.C. 2004) (No. C-4118).

183. *See* Decision and Order of the U.S. Federal Trade Commission, In the Matter of KFC Corporation (F.T.C. 2004) (No. C-4118).

184. *See id.*

185. *See* KFC's Claims Don't Fly, *supra* note 179.

damages.[186] This case poses several interesting elements of modern agriculture and food production: a family-owned business that has evolved into a highly integrated egg production enterprise, a food safety concern that has widespread health implications, and government regulation and action that significantly disrupts the enterprise.

1. Facts and Background of the Case

Rose Acre is a family-owned business, albeit one of the largest egg producers in the nation, based in Seymour, Indiana.[187] It is primarily engaged in the production of table eggs, which are raw poultry eggs sold in their shells.[188] Rose Acre is a highly integrated table-egg production business consisting of eight layer-hen farms with millions of hens.[189]

Increasing concern of Salmonella Enteritidis (salmonella) led to interim regulations in 1990 that restricted the interstate sale and transportation of eggs and poultry from flocks determined under the regulations to be salmonella-contaminated.[190] After the interim regulations took effect, salmonella outbreaks were traced to each of the three Rose Acre farms.[191] The government required that Rose Acre depopulate, clean, and disinfect the infected houses and then have those houses pass USDA inspection.[192] For a period of twenty-five months, Rose Acre was unable to sell eggs as table eggs from one or more of the three farms.[193] The trial court determined that the government action constituted a regulatory taking of the hens and awarded millions of dollars in damages, including attorney fees and expenses.[194]

2. Analysis

The issue on appeal before the Federal Circuit Court was whether under the United States Supreme Court's test in *Pennsylvania Coal Company v. Mahon*[195] the egg and poultry regulation went far enough

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186. *See* Rose Acre Farms v. United States, 373 F.3d 1177 (2004).
187. *See id.* at 1179.
188. *See id.* at 1179-80.
189. *See id.* at 1180.
190. *See, e.g.*, Salmonella Enteritidis in Eggs, 63 Fed. Reg. 27,502-11 (Food Safety and Inspection Serv.) (May 19, 1998) (to be codified at 7 C.F.R. § 59).
191. *See Rose Acre Farms,* 373 F.3d at 1182.
192. *See id.*
193. *See id.*
194. *See id.* at 1183.
195. *See* 260 U.S. 393, 413-15 (1922).

to be recognized as a taking.[196] *Pennsylvania Coal* noted that in a regulatory taking claim arising from a public program, the test is to "determine whether justice and fairness require that economic injuries caused by public action be compensated by the government, rather than remain disproportionately concentrated on a few persons."[197] A three-factor balancing test was then developed to determine whether there is a regulatory takings claim: first, the "economic impact of the regulation on the claimant;" second, "the extent to which the regulation has interfered with distinct investment-backed expectations;" and, third, "the character of the governmental action."[198]

The Federal Circuit Court held that the trial court erred in its application of the first and third factors of the regulatory-takings test that was explained in *Penn Central Transportation Company v. City of New York*.[199] The court found that the evidence cited by the trial court did not appropriately gauge the severity of the economic impact of the regulations on Rose Acre as a whole operation, as opposed to each independent hen house.[200] Thus, the fact that 57.5 million dozen of Rose Acre's eggs from each of the hen houses were, as a result of the restrictions, diverted for sale at less than Rose Acre's average total cost of production, was not enough.[201] The court noted that while some of the eggs on some of the Rose Acre farms suffered a reduction in value, the impact on its operations was relatively brief—approximately two years—after which Rose Acre reverted to its pre-regulation table-egg sales levels.[202] The court instructed the trial court to determine on remand, by combining the three farms together, whether the economic impact is best measured by a value decline or profitability decrease caused by the restrictions.[203]

The court also found that the trial court erred in its analysis of the character of the government's action.[204] The trial court had misgivings about the regulations, based on its finding that a less-burdensome egg testing scheme was feasible.[205] The court found, however, that the regulatory means of the government were consistent with the

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196. *See Rose Acre Farms*, 373 F.3d at 1183-84.
197. *See id.* at 1184.
198. *See id.*; *citing* Penn Central Transp. Co. v. City of New York, 438 U.S. 104 (1978).
199. *See Rose Acre Farms*, 373 F.3d at 1184-91.
200. *See id.* at 1188-89, 1195-98.
201. *See id.* at 1184, 1198.
202. *See id.* at 1185.
203. *See id.* at 1196.
204. *See Rose Acre Farms*, 373 F.3d at 1192-95.
205. *See id.* at 1193.

knowledge the government possessed at the time they were adopted or applied against Rose Acre.[206]

B. Location of Open-Air Field Tests of Biopharmaceutical Crops

In August 2004, a federal district court issued a ruling ordering USDA to disclose locations of open-air field tests in Hawaii of "biopharmaceutical" crops genetically modified to produce industrial chemicals and drugs.[207] Ruling that locations do not qualify as confidential business information, the court found that defendants USDA and Biotechnology Industry Organization[208] had failed to provide sufficient evidence that revealing the location of the open-field trials would cause damage specifically in Hawaii via theft of the seeds or plants by competing companies or vandalism by opponents of the biotechnology industry.[209] The court gave USDA ninety days from the date of the order to demonstrate that releasing the locations to the public would cause irreparable harm.[210]

The order raises the interesting issue of how geographic-specific the evidence must be showing irreparable harm. The court was not persuaded by evidence of past commercial arrogation and destruction of crop fields and biotechnology companies in other parts of the world.[211] In the event that disclosing the location of field-test sites leads to actual harm, it will be interesting to watch whether other courts follow the decision made by the Hawaii court in this case.

VI. Interesting Developments and Pending Legislation

A. Proposed Legislation: The National Uniformity for Food Act

The proposed National Uniformity for Food Act[212] presents several potential amendments to the Federal Food, Drug & Cosmetic Act (FDCA).[213] These amendments would strengthen the FDCA's ability to nullify state or local government food safety and labeling requirements whenever those requirements ask companies to adhere to stan-

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206. *See id.* at 1194.
207. *See* Center for Food Safety v. Veneman, No. 03-00621 (D. Haw. Aug. 3, 2004).
208. Biotechnology Industry Organization filed as an intervener in the case. *See id.* at 6.
209. *See id.* at 10.
210. *See id.*
211. *See id.* at 9.
212. *See* H.R. 2699, 108th Cong. (2004).
213. 21 U.S.C. §§ 301-399 (2004); *see also* Peter Barton Hutt & Richard A. Merrill, Food & Drug Law 10 (2d ed. 1991) (stating the FDCA establishes the basic legal framework for controlling the activities of food producers).

dards that go beyond what is required at the federal level.[214] The new act would also prohibit additional warning requirements on food products, although the proposal does provide for emergency exceptions.[215]

The proposed act allows for a lengthy petition process, during which individual states can petition the Secretary of DHHS for a waiver or lobby for FDA to adopt their food safety requirements instead.[216] While industry advocates have praised the proposed Act as another progressive step towards establishing national food safety standards,[217] some consumer groups argue the Act will significantly reduce the power of state and local health departments and food safety agencies.[218]

The Act was initially introduced in 2003 by Representative Richard M. Burr, a Republican from North Carolina. The bill listed 164 cosponsors by the end of the 108th Congress, but the congressional session ended before it was brought to a vote.[219]

B. Agencies Launch Programs Aimed at Combating False or Deceptive Claims in Weight-Loss Advertisements

FTC announced a new initiative in November that is aimed at fighting deceptive advertising efforts regarding weight-loss products. In addition to targeting companies who create the advertisements, the new initiative plans to discourage media outlets from carrying advertisements that make deceptive weight-loss claims and encourage them

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214. *See* H.R. 2699(2)(a); 21 U.S.C. § 343-1 (2004) (stating the current law, which allows for some federal preemption of state and local requirements).

215. *See* H.R. 2699(2)(b).

216. *See* H.R. 2699.

217. *See, e.g.*, White Paper, Grocery Manufacturer's of America, National Uniformity for Food Act: Background and Analysis, *available at* http://www.gmabrands.com/publicpolicy/docs/whitepaper.cfm?DocID=606; *see also* HUTT & MERRILL, *supra* note 213, at 986-94 (discussing the history of the movement for creating uniform food laws, and offering samples of various arguments related to the issue).

218. *See, e.g.*, Letter from Jean Halloran, Director, Consumer Policy Institute, to a Congressional Representative, formally titled *National Uniformity for Food Act: Uniformly a Disaster for Consumers* (Sept. 28, 2004), *available at* http://www.consumersunion.org/pub/core_food_safety/001400.html#more (worrying that "states will spend time and money wrangling with the [FDA], or worse, in court litigating, over whether or not their current laws are identical to federal laws, rather than protecting their citizens").

219. *See* H.R. 2699 (listing 164 Republicans and 38 Democrats, representing at least 39 states, among the bill's cosponsors).

to educate the public about deceptive claims.[220] FTC has named the program "Operation Big Fat Lie," launching its campaign by filing actions against six companies in courts around the country.[221]

The announcement came during a time when FTC increasingly seems to be interested in false or deceptive weight-loss claims.[222] In addition to the action taken against Kentucky Fried Chicken last summer,[223] the agency also charged three Florida companies with deceptive advertising in its marketing of Pedia Loss, a weight-loss supplement aimed at children.[224] During the six-month period covered by this update, FTC also filed complaints against numerous other companies who made false, misleading, or unsubstantiated claims related to the weight-loss benefits of their products.[225] In addition to administrative complaints, the agency also won at least one case against weight-loss companies in federal court.[226]

FTC's campaign announcement complemented a FDA announcement in November of 2004 of three major regulatory initiatives designed to further implement the Dietary Supplement Health

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220. *See* Press Release, Fed. Trade Comm'n, FTC Launches "Big Fat Lie" Initiative Targeting Bogus Weight-Loss Claims (Nov. 9, 2004), *available at* http://www.ftc.gov/opa/2004/11/bigfatliesweep.htm.

221. *See id.* (stating that complaints had been filed in California, Connecticut, Florida, Illinois, New York, and Maine against companies marketing a variety of products claiming to help consumers lose weight).

222. *See FTC Goes On Offensive Against Overblown Weight Loss Claims*, DRUG INDUS. DAILY, Nov. 12, 2004 (noting FTC has been steadily increasing its oversight of the dietary supplement industry, and the agency had banned ephedra in early 2004).

223. *See supra* notes 178-85 and accompanying text.

224. *See* Press Release, Fed. Trade Comm'n, FTC Challenges Ads for Kids' Weight Loss Pill (June 16, 2004), *available at* http://www.ftc.gov/opa/2004/06/dynamichealth.htm.

225. *See, e.g.*, Press Release, Fed. Trade Comm'n, Ads for Various Diet Supplements and Topical Gels Don't Cut the Fat, Says the FTC (June 16, 2004) (charging a Utah company and its affiliates with marketing numerous false claims, including some for products containing illegal ingredients and some aimed at children), *available at* http://www.ftc.gov/opa/2004/06/dietsupp.htm; Press Release, Fed. Trade Comm'n, FTC Continues Campaign to Halt Deceptive Advertisements & Other Scams Aimed at Hispanics (June 17, 2004) (initiating a law-enforcement action against a company that claimed its pills would cause "permanent weight loss"), *available at* http://www.ftc.gov/opa/2004/06/hispsweep.htm; Press Release, Fed. Trade Comm'n, Two Maine Dietary Supplement Marketers Pay Nearly $1 Million to Settle FTC Deceptive Advertising Complaints (Aug. 27, 2004) (announcing the punishment of companies that had marketed "carb blocker" and "fat blocker" tablets by using unsubstantiated claims and unrealistic promises of weight loss), *available at* http://www.ftc.gov/opa/2004/08/pvt.htm.

226. *See, e.g.*, Press Release, Fed. Trade Comm'n, Slim Down Solution: Problem Solved (Oct. 19, 2004), *available at* http://www.ftc.gov/opa/2004/11/slimdown.htm.

and Education Act of 1994 (DSHEA).[227] These initiatives include a regulatory strategy, an open public meeting, and a draft guidance document for the industry.[228] The initiatives are viewed as sending a message to marketers that claims about the benefits of dietary supplements must be truthful and substantiated by scientific evidence.[229] In October 2004, FDA sent eight warning letters to dietary supplement distributors that were making unsubstantiated claims for dietary supplement products promoted for weight loss over the Internet.[230] Also, on the same day it announced the initiatives, FDA sent a letter to major retailers of dietary supplements to inform them that products labeled with unsubstantiated claims are misbranded and that FDA may take enforcement action against misbranded products in their possession.[231]

C. Government Committee Prepares New Dietary Guidelines to Be Released in 2005

Every five years DHHS and USDA release new recommended dietary guidelines.[232] While the guidelines do not have any coercive effects on what foods are sold and consumed in the United States, they are subject to intense scrutiny since they influence the types of foods Americans choose to purchase and consume.[233] The thirteen mem-

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227. *See* Press Release, Food and Drug Admin., FDA Announces Major Initiatives for Dietary Supplements (Nov. 4, 2004), *available at* http://www.fda.gov/bbs/topics/news/2004/NEW01130.html.

228. *See id.*

229. *See id.* (quoting FTC Chairman Deborah Platt Majoras, who said the effort sends a clear and strong reminder to marketers that claims about the benefits of dietary supplements, wherever they appear, must be truthful and substantiated by high quality scientific evidence. Today's FDA action leaves no doubt that our two agencies are united in our efforts to combat false or unfounded claims. We look forward to continuing our close collaboration with FDA to attack deceptive and unsubstantiated claims in the dietary supplement market.).

230. *See id.*

231. *See id.*

232. *See* Announcement of the Availability of the Final Report of the Dietary Guidelines Committee, A Public Comment Period and a Public Meeting, 69 Fed. Reg. 52,697 (Aug. 27, 2004). The release of nutrition guidelines is mandated by the National Nutrition Monitoring and Related Research Act. *See* 7 U.S.C. § 5301 (2004).

233. *See* David Feder, *Building a New Food Pyramid . . . or Plate, or Whatever: The 2005 USDA Dietary Guidelines Are On Their Way With More Than the Recommended Allowance of Controversy*, FOOD PROCESSING, Oct. 1, 2004, at S14 (discussing the political process of creating the dietary guidelines); Judith Weinraub, *Redrawing the U.S. Roadmap to Health: Revised Dietary Guidelines Expected to Have Major Impact*, SUN-SENTINAL (Ft. Lauderdale, Fla.), Dec. 9, 2004, at 5 (originally published as *Coming Soon: The Government's*

ber Dietary Guidelines Advisory Committee met several times over the last two years to study data and to hear comments from industry and consumer groups who are concerned about the content of future guidelines.[234] While the final 2005 guidelines were not released until January 2005, the Committee's final report was published in late 2004 and contained nine phrases it labeled "key messages" for the future. These messages encourage people to consume a variety of foods within and among the basic food groups while staying within energy needs; control calorie intake to manage body weight, be physically active every day; increase daily intake of fruits and vegetables, whole grains and non-fat or low-fat milk or milk products; choose fats wisely for good health; choose carbohydrates wisely for good health; choose and prepare foods with little salt; if you drink alcoholic beverages do so in moderation; and keep food safe to eat.[235] In addition to the key messages, the guidelines were accompanied by a lengthy report covering detailed proposals for diet, nutrition and exercise recommendations.[236]

Revised Guidelines for Healthful Eating, WASH. POST, Dec. 1, 2004 at F1); *see also* Emily Heil, *Critics See Food Pyramid With Lobbyists at the Top*, CONG. DAILY, Sept. 21, 2004 (stating that "[f]ood lobbies representing large commodities – such as beef and sugar – swarm around the process, as a prime spot on the pyramid can be a potent marketing tool").

234. *See, e.g.*, Judy Walker, *Going with the Grain; They Came to New Orleans to Hatch a Plot: To Get at Least Three Ounces of Whole Grains into Every American's Daily Diet*, TIMES-PICAYUNE (New Orleans), Dec. 2. 2002 (discussing the efforts of the Whole Grains Council and the Oldways Provision Trust to get increased grain consumption into the 2005 dietary guidelines); Raja Mishra, *Soft Drink Industry Fighting a Possible Health Warning*, CHARLESTON GAZETTE, Dec. 1, 2004, at 12B (discussing the efforts of soft drink industry lobbyists to have the connection between sugar-sweetened beverages and weight gain removed from the proposed guidelines); Kay Ledbetter, *Have Your Steak and Eat It Too*, AMARILLO GLOBE-NEWS (Texas), Nov. 14, 2004 (previewing efforts of beef enthusiasts to promote beef as a dietary guideline-approved food); *Group Urges Government to Give Realistic Nutrition Advice*, OBESITY, FITNESS & WELLNESS WK., Oct. 23, 2004, at 985 (discussing efforts to get the committee to recommend dietary supplements in the guidelines, and add a tenth key message stating "consider a daily multivitamin"); *see also* Kim Krisberg, *Emphasis on Sugar Intake Weakened in New Dietary Guidelines*, NATION'S HEALTH, Oct. 1, 2004, at 1 (lamenting the lack of recommendation for people to "reduce" sugar intake in the current version of the guidelines).

235. *See* Dep't of Health and Human Serv. And USDA, Executive Summary, 2005 Dietary Guidelines Advisory Committee Report, *available at* http://www.health.gov/dietaryguidelines/dga2005/report.

236. *See id.* For example, the report recommends that Americans increase their intake of oily fish which some scientific evidence indicates can help combat coronary heart disease. *See id.*; *see also supra* notes 152-58 and accompanying text.

D. FDA Proposal for Draft Guidance for Industry to New Plant Varieties

In November 2004, FDA announced the availability of a draft guidance document entitled "Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use."[237] The issuance of draft guidance was proposed in August 2002 in a Federal Register Notice published by the Office of Science and Technology Policy (OSTP) as part of proposed federal actions to update field test requirements to establish early voluntary food safety evaluations for new proteins produced by bioengineered plants.[238] The draft guidance discusses the early food safety evaluation of new proteins in new plant varieties, particularly in new bioengineered varieties that are under development for possible use as food for humans or animals.[239] Under the proposal, developers would provide FDA with information about the food safety of the new protein early in the development of the crop.[240] When a developer decides to commercialize a crop, the developer would be expected to participate in FDA's voluntary premarket consultation process.[241] To date, all new plant varieties developed through biotechnology that are intended for food and feed marketed in the United States have completed the consultation process before they enter the market.[242]

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237. Draft Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use; Availability, Action Notice, 69 Fed. Reg. 68,381-01 (Nov. 24, 2004); Food and Drug Admin. & Center for Food Safety & Applied Nutrition, Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use (2004), *available at* http://www.cfsan.fda.gov/~dms/bioprgui.html; *see also* Talk Paper, Food and Drug Admin., FDA Proposes Draft Guidance for Industry for New Plant Varieties Intended for Food Use, FDA Talk Paper (Nov. 19, 2004), *available at* http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01327.html.

238. *See* Proposed Actions to Update Field Test Requirements for Biotechnology Derived Plants and Establish Early Food Safety Assessments for New Proteins Produced by Such Plants, 67 Fed. Reg. 50,578-01 (Aug. 2, 2004).

239. *See* Guidance for Industry, *supra* note 237.

240. *See id.*

241. *See id.*

242. *See id.*