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United States Food Law Update

by

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UNITED STATES FOOD LAW UPDATE

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I. INTRODUCTION

This update summarizes significant changes and developments in food law over the first half of 2005. Not every change in national food law for the first half of 2005 is included; instead, this update is limited to significant changes in national law. New developments in state law, while certainly important and deserving of attention, are beyond the scope of this update.

These updates provide a starting point for scholars, practitioners, food scientists, and policymakers determined to understand the shaping of food law in modern society. Tracing the development of food law through these updates also builds an important historical context for the overall development of food law.

II. RECENT CASE DECISIONS

A. Obesity Litigation Revived

In January 2005, the United States Second Circuit revived the hopes of those intent on making the food industry liable for the growing epidemic of obesity by reversing a district court's dismissal of claims in the case of *Pelman v. McDonald's Corporation*.[1] Statistics substantiate the magnitude of the problem of obesity in the United States: 97 million persons are overweight or obese and each year obesity contributes to the death of 300,000 people.[2]

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1. *See* Pelman v. McDonald's Corp., 396 F.3d 508, 512 (2d Cir. 2005).

2. *See* NAT'L INST. OF HEALTH, CLINICAL GUIDELINES ON THE IDENTIFICATION, EVALUATION, AND TREATMENT OF OVERWEIGHT AND OBESITY IN ADULTS: THE EVIDENCE REPORT, NIH Publication No. 98-4083 at vii, *available at* http://www.nhlbi.nih.gov/guidelines/obesity/ob_gdlns.pdf; Surgeon General's Call to Action to Prevent and Decrease Overweight and Obesity, 2001, United States Dep't Health and Human Services, *available at* http://www.surgeongeneral.gov/topics/ obesity/calltoaction/_0.htm.

1. Background

The case began in August 2002, when the parents of two minor children filed a class action lawsuit in state court against McDonald's Corporation, McDonald's of New York, and two New York City fast food restaurants (referred to collectively as McDonald's).[3] The lawsuit was brought on behalf of all New York minors who had purchased and consumed McDonald's products.[4] The suit alleged that McDonald's engaged in deceptive practices, violated state consumer protection laws, and claims of negligence and failure to warn of harmful health effects of consuming McDonald's products.[5] Finding deficiencies in the allegations, the court dismissed every count in the complaint, but granted leave to amend.[6] The court expressly stated that it was guided by the general principle that it was not the place of the law to protect people who knew, or ought to have known, of the dangers of eating such food.[7]

The plaintiffs then filed an amended complaint, alleging four causes of action.[8] The first three causes of action were for deceptive acts and advertisements in violation of two sections of the New York General Business Law: Section 350, which prohibits false advertising, and Section 349, which prohibits "deceptive acts or practices in the conduct of any business, trade, or commerce or in the furnishing of any service."[9] The fourth claim, which alleged negligence by McDonald's because of its

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3. *See* Pelman v. McDonald's Corp.*,* 237 F. Supp. 2d 512, 519 (S.D.N.Y. 2003). Although the original complaint named several local franchisees, the notice of appeal named only McDonald's Corporation. *See Pelman*, 396 F.3d at 510 n.2. Thus, the Second Circuit Court did not address whether the McDonald's franchises should be liable for the alleged misconduct and, if so, indemnified by their franchisor.

4. *See Pelman*, 237 F. Supp. 2d at 520.

5. *See id.*

6. *See id.* at 543. However, Count I (deceptive advertising and failure to warn) and Count II (inducement of minors through deceptive marketing) of the complaint were dismissed with prejudice to the extent they were based on the New York City administrative code. *Id.*

7. *See id.* at 517. The author of the opinion, the Honorable Robert W. Sweet, revealed in a footnote that he had publicly opposed the criminalization of drugs and that his logic for doing so applied in the situation of fast food: as long as consumers have adequate knowledge about even harmful substances, they should be entitled to purchase them. *See Pelman*, 237 F. Supp. at 517 n.2.

8. *See* Pelman v. McDonald's Corp., No. 02-Civ.-7821, 2003 WL 22052778, at *2 (S.D.N.Y. Sept. 3, 2003) *vacated in part*, 396 F.3d 508 (2d Cir. 2005).

9. *See id.* at *4.

failure to warn plaintiffs of the dangers and adverse health effects of eating processed foods from McDonald's, was voluntarily dropped by the plaintiffs.[10]

The district court dismissed the amended complaint principally for two reasons: first, plaintiffs failed to plead an adequate causal connection between the consumption of McDonald's food and their alleged injuries, and second, certain alleged misrepresentations in advertisements regarding McDonald's french fries and hash browns were objectively non-deceptive and therefore not actionable.[11] Refusing to grant leave a second time to amend the complaint, the district court dismissed the complaint with prejudice.[12]

2. Second Circuit Reversal

On appeal, the Second Circuit reversed the district court and reinstated some of plaintiffs' claims.[13] The plaintiffs did not appeal the dismissal of their Section 350 claims for false advertising, so the Second Circuit considered only the dismissal of the Section 349 claims of deceptive acts or practices which dismissal rested entirely on the district court's conclusion that plaintiffs failed to properly allege causation.[14] The claims of deceptive acts or practices were as follows: first, that the combined effect of McDonald's various promotional representations created the false impression that its "food products were nutritionally beneficial and part of a healthy lifestyle;" second, that McDonald's failed to disclose its use of additives and how its processes of products rendered those products "substantially less healthy than represented;" and, third, that McDonald's deceptively promoted the availability of nutritional information in its stores.[15]

The Second Circuit found that the district court erred by determining that the statutory claim of deceptive acts or practices was subject to the pleading-with-particularity requirements of Rule 9(b) of the Federal Rules of Civil Procedure.[16] Referring to the bare bones notice-pleading requirements of Rule 8(a) of the Federal Rules of Civil Procedure, the Second Circuit determined that the statutory

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10. *See id.* at *2.

11. *See id.* at *11-14.

12. *See id.* at *14.

13. *See Pelman*, 396 F.3d at 512.

14. *See id.* at 511.

15. *See id.* at 510.

16. *See id.* at 511.

claim of deceptive acts or practices has a lower pleading standard.[17] Information, such as the amount plaintiffs exercised, family medical history, and the other components of plaintiffs' diet could be obtained in discovery, rather than constitute what the district court believed requisite for plaintiffs to state a claim.[18] Thus, the Second Circuit determined that the amended complaint was properly pleaded.[19]

3. Bills Barring Obesity-Related Lawsuits and Public Policy Debate[20]

An interesting outcome of the *Pelman* decision by the Second Circuit is that it may be seized upon by some as evidence of the need for protecting the food industry against obesity-related lawsuits. Two bills introduced in Congress seek to prevent lawsuits against manufacturers, distributors, and sellers of food and non-alcoholic beverages rising from obesity claims—the proposed Personal Responsibility in Food Consumption Act of 2003 and the proposed Commonsense Consumption Act of 2003, also known as "cheeseburger bills."[21] Similar legislation has also received considerable attention in state legislatures. As of May 2005, such legislation reportedly became law in eighteen states, with another twenty-seven states considering the legislation.[22]

Suggestions that the food industry may follow the tobacco industry as the next target for massive class-action lawsuits have sparked the National Restaurant Association and allied groups to push for these laws.[23] The issue certainly has caught the attention of many legal, political, and social commentators who debate issues such as the role of courts in determining the complexities of the

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17. *See id.*

18. *See Pelman*, 396 F.3d at 511-12.

19. *See id.*

20. This update discusses such legislation relevant only to the first half of 2005. During the second half of 2005, the U.S. House of Representative passed the Personal Responsibility in Food Consumption Act of 2005. Further discussion of this legislation will be addressed in subsequent versions of this update.

21. *See* Personal Responsibility in Food Consumption Act, H.R. Res. 339, 108th Cong. (2003); Commonsense Consumption Act of 2003, S. Res. 1428, 108th Cong. (2003).

22. *See* Jeffrey Gilbert, *Senate OKs Obesity Bill that Limits Lawsuits*, Houston Chronicle.com, May 26, 2005, *at* http://www.chron.com/cs/CDA/ssistory.mpl/ special/05/legislature/3198692 (last visited Nov. 5, 2005).

23. *See* Hank Shaw, *Democrats Say No to Limiting Fatty Food Suits*, THE RECORD, May 4, 2005, *available at* 2005 WLNR 7001270.

nation's expanding waistline, the social responsibility of the food industry, and the role of personal responsibility and individual autonomy.[24]

B. Organic Rules Examined

In January 2005, the United States First Circuit Court of Appeals addressed in the case of *Harvey v. Veneman*,[25] possible conflicts between the National Organic Program (Final Rule)[26] and the Organic Foods Production Act of 1990 (OFPA).[27]

1. Organic Foods Production Act of 1990

OFPA establishes national standards governing the marketing of organically produced food products.[28] The purpose of the Act is two-fold: "to assure consumers that organically produced products meet a consistent standard" and to "facilitate interstate commerce" in organically produced food.[29] These purposes are advanced by the establishment of a national certification program for producers and handlers of organic products and by the regulation of the labeling of organic products.[30] To bear the United States Department of Agriculture's (USDA) organic seal, a food product must be produced and handled without the use of synthetic substances and in accordance with an organic plan agreed to by an accredited certifying agent and by the producer and handler of the food product.[31] Synthetic substances that are exceptions to this general prohibition against such use are to be listed on a National List following notice and comment and are subject to review.[32]

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24. *See*, *e.g.*, Richard C. Ausness, *Tell Me What You Eat, And I Will Tell You Whom to Sue: Big Problems Ahead for "Big Food"?*, 39 GA. L. REV. 839, 893 (2005) (suggesting that while legislative action may be warranted if the food industry does not act on its own, anti-obesity litigation, among other things, undermines personal autonomy).

25. 396 F.3d 28 (1st Cir. 2005).

26. *See* 7 C.F.R. pt. 205 (2005).

27. *See* Organic Foods Production Act of 1990 (OFPA), 7 U.S.C. §§ 6501-6522 (2000).

28. *See id.* at 7 U.S.C. § 6501 (Supp. 2005).

29. *Id.*

30. *See id.* at §§ 6503(a), 6504, 6505(a)(1)(A) (Supp. 2005).

31. *See id.* at § 6504 (Supp. 2005).

32. *See* OFPA, 7 U.S.C. §§ 6517(a), (d), (e); 6518(k), (l), (m) (Supp. 2005).

2. Lawsuit

Plaintiff Arthur Harvey brought a suit against the Secretary of USDA in his multiple capacities as a producer and handler of organic crops, an USDA-accredited certified inspector, and a consumer of organic products.[33] Harvey sought declaratory and injunctive relief under the Administrative Procedure Act and under OFPA, alleging that certain provisions of the Final Rule were inconsistent with OFPA and diluted organic standards.[34] Largely adopting a magistrate judge's recommended decision, the district court granted summary judgment to the Secretary on nine claims asserted by Harvey.[35]

3. Appeal

On appeal, seven of Harvey's original nine claims were brought before the First Circuit.[36] The First Circuit affirmed the district court's granting of summary judgment in favor of the Secretary on four of the seven claims. These four claims asserted that the following provisions in the Final Rule contravened the purposes of OFPA: allowing use of a private certifier's seal on products containing less than ninety-five percent organic ingredients, excluding certain wholesalers and distributors from coverage under OFPA, prohibiting advice from certifying agents regarding certification standards for compensation, and imposing uniform standards on private certifiers.[37] Rejecting these claims, the First Circuit found these four provisions to be consistent with the purposes of OFPA.[38]

The First Circuit ruled, however, in favor of Harvey on three of the claims on appeal, reversing on two of the claims and remanding on the third claim. On the first reversed claim, the First Circuit held that the Final Rule allowing a converting herd to be fed a diet of only eighty percent organic feed for a period of nine months for newly converting herds violated the OFPA provision requiring all organic dairy animals to receive organic feed for twelve months prior to sale of milk or milk products.[39] On the second reversed claim, the First Circuit held that the Final Rule allowing the listing of synthetics for

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33. *Harvey*, 396 F.3d at 32.

34. *Id.*

35. *See Harvey v. Veneman*, 297 F. Supp. 2d 334, 334-35 (D. Me. 2004). Harvey's claim that the Secretary of Agriculture failed to implement a provision of OFPA survived. *Id.* at 335.

36. *Harvey*, 396 F.3d at 33.

37. *See id.* at 36-45.

38. *See id.*

39. *Id.* at 44; *see also* OFPA, 7 U.S.C. § 6509(e)(2); 7 C.F.R. § 205.236(a) (2005).

use in the handling of products labeled organic contravened the OFPA provision that bars synthetics in processed foods.[40] On the third claim, the First Circuit remanded for declaratory judgment as to whether the Final Rule establishes a blanket exemption to the National List requirements for non-organic products that are not commercially available.[41] The First Circuit directs that such a blanket exemption would controvert the OFPA requirements for the National List.[42]

C. Court Rules in Favor of Ephedra

In April 2005, the United States District Court of Utah ruled against the Food and Drug Administration (FDA) on a summary judgment motion that served as a crucial test of the FDA's power to ban questionable over-the-counter health products under the Dietary Supplement Health and Education Act (DSHEA).[43]

1. Dietary Supplement Health and Education Act of 1999

DSHEA was enacted in 1994 as an amendment to the Federal Food, Drug and Cosmetic Act of 1938 (FDCA), as amended.[44] Under DSHEA, dietary supplements are regulated as a subset of foods unless claims are made that bring the supplements within the definition of a drug.[45] As a food product, dietary supplements are not subject to pre-market approval as are drugs, meaning that evidence of product safety and efficacy prior to marketing is not required for dietary supplements.[46] Nor are dietary supplements subject to post-market activity as are drugs, meaning that product safety monitoring and reporting specifications are not required for dietary supplements.[47] Instead, as a food product, dietary supplements may be banned if found by FDA to be adulterated. [48] DSHEA provides

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40. *Harvey*, 396 F.3d at 40; *see also* OFPA, 7 U.S.C. § 6509(e)(2); 7 C.F.R. §§ 205.600(b) (2005), 205.605(b) (2005).

41. *Harvey*, 396 F.3d at 36.

42. *Id.*

43. *See* Nutraceutical Corp. v. Crawford, 364 F. Supp. 2d 1310, 1321 (D. Utah 2005).

44. *See* DSHEA, Pub. L. No. 103-417, 108 Stat. 4325 (1994).

45. *See* 21 U.S.C. § 321(ff) (Supp. 2005) ("[A] dietary supplement shall be deemed to be a food within the meaning of [the act].").

46. *Nutraceutical Corp.*, 364 F. Supp. 2d at 1312.

47. *Id.*

48. *See* 21 U.S.C. § 342(f)(1) (Supp. 2005).

that FDA may deem a dietary supplement adulterated in three situations: first, if a dietary supplement presents a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling; second, if a dietary supplement presents a significant or unreasonable risk of illness or injury under ordinary conditions of use; and, third, if the Secretary of the Department of Health and Human Services (DHHS) finds that the dietary supplement poses an imminent hazard to public health or safety.[49] Within this regulatory framework, dietary supplements have soared in popularity: the result is a $20 billion dietary supplement industry with over 1,000 manufacturers marketing 29,000 dietary supplement products, being used by approximately one-fifth of Americans.[50]

2. Ephedra

Ephedrine alkaloids (EDS) used in dietary supplements are naturally occurring stimulant compounds.[51] Proponents of EDS promote the supplement as an aid to weight loss, an enhancer of athletic performance, and a booster of energy levels.[52] Critics of EDS, on the other hand, link the supplement to numerous deaths, including the death of twenty-three-year-old Baltimore Orioles pitcher Steve Belcher in 2003.[53]

Concerns over the safety of EDS, countered by the general popularity of dietary supplements, provide vexing problems for FDA to formulate an effective regulatory approach. In February 2004, FDA published a final rule, known as the Ephedra Rule, which mandates that dietary supplements containing EDS are adulterated under DSHEA.[54] The premise for the rule is that use of EDS does not

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49. *See id.*

50. *See* Justin Gillis, *Herbal Remedies Turn Deadly for Patients*, WASH. POST, Sept. 5, 2004, at A01, *available at* http://www.washingtonpost.com/wp-dyn/articles/A62671-2004Sep4.html; Rob Stein, *Alternative Remedies Gaining Popularity*, WASH. POST, May 28, 2004, at A01, *available at* http://www.washingtonpost.com/wp-dyn/articles/A61657-2004May27.html.

51. *See Nutraceutical*, 364 F. Supp. 2d at 1311-12.

52. *Id.* at 1314.

53. *See* Gardiner Harris & Jay Schreiber, *Judge's Decision Lifts Ban on Sale of Ephedra in Utah*, N.Y. TIMES, Apr. 15, 2005, *available at* http://www.nytimes.com/2005/04/15/health/15ephedra.html?ex=1138078800&en=0c10e1e92fe48108&ei=5070.

54. *See* Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk, 69 Fed. Reg. 6788 (Feb. 11, 2004) (to be codified at 21 C.F.R. pt. 119).

provide a benefit sufficient to outweigh the substantial risks of EDS—heart attack, stroke, and death.[55] Thus, FDA concluded that all EDS pose an unreasonable risk and are adulterated under DSHEA.[56]

3. Court Ruling

Nutraceutical International Corporation (Nutraceutical)[57] filed suit against FDA contesting the Ephedra Rule.[58] The issue was whether the Ephedra Rule banning all EDS violates the adulteration provision of DSHEA.[59] To resolve this issue, the court addressed whether the FDA's use of a risk-benefit analysis is appropriate under DSHEA and whether FDA provided sufficient evidence to support its conclusion that any dose of EDS presents a significant or unreasonable risk of illness or injury.[60]

Determining that the FDA's use of a risk-benefit analysis was not appropriate under DSHEA, the court relied on the statute's distinction between drugs and food.[61] Unlike drugs, dietary supplements as a food product under DSHEA are not subject to a risk-benefit analysis.[62] Also, as a food product, no requirement exists that a benefit be established for dietary supplements prior to sale.[63] The court further noted that requiring producers of EDS to demonstrate a benefit as a precondition to sale via a risk-benefit analysis specifically contradicts congressional intent.[64] As quoted by the court, "21 U.S.C.

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55. *See Nutraceutical*, 364 F. Supp. 2d at 1313 (citing Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk.)

56. *See id.* (citing Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk.)

57. Nutraceutical is a nutritional supplement manufacturer located in Park City, Utah, the self-described "Silicon Valley of the supplement industry," where 80 to 100 companies operate a $2.5 billion business. *Ephedra Ban Lifted by Judge in Utah*, SALT LAKE TRIB., Apr. 15, 2005, *available at* 2005 WLNR 5925365.

58. *Nutraceutical*, 364 F. Supp. 2d at 1310.

59. *See id.* at 1316.

60. *See id.*

61. *See id.* at 1319.

62. *See id.*

63. *See Nutraceutical*, 364 F. Supp. 2d at 1319.

64. *See id.*

§ 342(f) [provides that] 'the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated.'"[65]

In reviewing the FDA's evidence, the court held that the agency's negative inference that a safe level of intake for EDS cannot be determined does not satisfy the agency's burden to prove that any dose amount of EDS poses a significant or unreasonable risk of illness or injury.[66] Thus, the court lifted the FDA ban and sent the matter back to the agency for further evaluation.[67]

4. Implications

The scope of the court's ruling should not be overstated. The court's ruling is limited to rejecting the evidentiary process employed by FDA to ban EDS, and does not address whether EDS at any dose is safe or effective.[68] As the continual threat of litigation, lack of insurance coverage, and the low-carbohydrate dieting trend all portend against a revival of ephedra supplements, it is unlikely that the ruling will boost the legitimacy of ephedra.[69] The ruling could, however, motivate Congress to revisit DSHEA in order to give FDA more regulatory power.[70]

D. "Bivens" Case Dismissed Against Federal Meat Inspectors

In February 2005, the United States Court of Appeals for the Eighth Circuit dismissed a "*Bivens*" action brought by the operator of a meat processing facility against federal meat inspectors in the case of *Nebraska Beef Ltd. v. Greening*.[71] A *Bivens* remedy allows tort actions against federal officials and employees directly under the Constitution.[72] In this case, the operator, Nebraska Beef Ltd. (Nebraska Beef) initiated a *Bivens* action against the inspectors, claiming that the inspectors

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65. *Id.*

66. *See id.* at 1321.

67. *See id.*

68. *See generally Nutraceutical*, 364 F. Supp. 2d at 1310.

69. *See* Glen Warchol, *Ephedra Decision Leaves Questions*, SALT LAKE TRIB., Apr. 16, 2005, *available at* 2005 WLNR 6124346; Christopher Snowbeck, *Court Ruling Unlikely to Bring Back Ephedra*, PITTSBURGH POST-GAZETTE, Apr. 16, 2005, *available at* 2005 WLNR 5939524.

70. *See* Harris & Schreiber, *supra* note 53.

71. 398 F.3d 1080 (8th Cir. 2005).

72. *See generally* Bivens v. Six Unknown Named Agents of Fed. Bureau of Narcotics, 403 U.S. 388 (1971).

maliciously issued additional noncompliance records in contravention of a previous consent decree.[73] The inspectors filed a motion to dismiss, arguing that the plaintiff's action was barred because a *Bivens* remedy was not available to Nebraska Beef.[74] The federal district court denied the inspectors' motion, and the inspectors appealed to the Eighth Circuit.[75]

The Eighth Circuit held that a *Bivens* remedy was not available to Nebraska Beef on three grounds.[76] First, Congress had not explicitly created any direct right of action against the USDA employees alleged to have committed constitutional violations.[77] Second, USDA has promulgated a comprehensive regulatory scheme that includes the right to judicial review under the Administrative Procedures Act.[78] Third, Congress has created a stringent exhaustion requirement for grievances filed against the USDA employees that further evidences its intent to have grievances aired to and addressed by the agency prior to judicial review.[79] The Eighth Circuit concluded that these three factors, combined with the United States Supreme Court's caution against extending *Bivens* remedies to new contexts, precluded a *Bivens* action for Nebraska Beef.[80]

E. Trans Fat Litigation Settled

In February 2005, McDonald's Corporation (McDonald's) settled two trans fat lawsuits.[81] Produced through the partial hydrogenation of vegetable oil, trans fat has been linked to as many as 100,000 deaths a year from coronary heart disease.[82] In response to these and other dire statistics, a number of food companies, including McDonald's, have announced attempts to reduce the levels of

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73. *See Nebraska Beef*, 398 F.3d at 1081-82.

74. *See id.*

75. *See id.*

76. *See id.* at 1084.

77. *See id.*

78. *See Nebraska Beef*, 398 F.3d at 1084.

79. *See id.*

80. *See id.* at 1084.

81. *See* Press Release, BanTransFats.com, Inc., Plaintiffs' Press Release on Settlement of McDonald's Trans Fat Litigation (Feb. 11, 2005), *available at* http://www.bantransfats.com/mcdonalds.html [hereinafter BanTransFats Press Release].

82. *See* Kim Severson & Melanie Warner, *America's Oil Change: Losing Trans Fats; Fat Substitute, Once Praised, Is Pushed Out of the Kitchen*, N.Y. TIMES, Feb. 13, 2005, *available at* 2005 WLNR 2041305.

trans fat in their food products.[83] In a September 3, 2002 press release, McDonald's announced that it intended to change the cooking oil for its fried foods by February 2003, thereby effectively reducing the level of trans fat in its food.[84] The trans fat lawsuits alleged that McDonald's failed to adequately disclose that it had delayed its plan announced in the September 2002 press release.[85] In exchange for a broad release of claims, McDonald's agreed to pay $7,000,000 to the American Heart Association to finance a campaign educating consumers about trans fats and to spend $1,500,000 to inform the public about the delay in changing the cooking oil.[86]

III. RECENT ADMINISTRATIVE DECISIONS

The Federal Trade Commission (FTC) announced a new initiative in November 2004 aimed at fighting deceptive advertising efforts regarding weight-loss products. [87] The initiative targets companies who create the advertisements. FTC has named the program "Operation Big Fat Lie," launching its campaign by filing actions against six companies in courts around the country.[88] The announcement came during a time when FTC expressed increasing interest in false or deceptive claims.[89]

As a part of the "Operation Big Fat Lie" campaign, FTC filed charges against AVS Marketing, Inc. (AVS).[90] According to FTC, AVS deceptively marketed a dietary supplement called "Himalayan Diet Breakthrough."[91] FTC alleged that AVS claimed the product

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83. *See id.* (quoting James A. Skinner, McDonald's Chief Executive Officer, "We remain committed to reduce trans fats").

84. *See id.*

85. *See McDonald's Hit With Lawsuit Over French Fries*, Signon San Diego.com, July 8, 2004, *available at* http://www.signonsandiego.com/news/business/20048708-1751-ca-mcdonalds-fries.html.

86. *See* BanTransFat Press Release, *supra* note 81.

87. The FTC new initiative to fight deceptive advertising efforts regarding weight-loss products is summarized more fully in the *United States Food Law Update* in the first issue of this journal. *See* Michael T. Roberts & Margie Alsbrook, *United States Food Law Update*, 1 J. FOOD L. & POL'Y 187, 214-16 (2005).

88. *See* Press Release, FTC, 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 [hereinafter 2004 FTC Press Release].

89. *See FTC Goes on Offensive Against Overblown, Weight Loss Claims*, DRUG INDUS. DAILY, Nov. 12, 2004 (noting FTC has been steadily increasing in its oversight of the dietary supplement industry).

90. *See* 2004 FTC Press Release, *supra* note 88.

causes rapid and substantial weight loss without dieting or exercise; causes users to lose substantial weight while still consuming unlimited amounts of food; causes substantial weight loss by preventing the formation of body fat; causes substantial weight loss for all users; and enables users to lose as much as 37 pounds in eight weeks safely.[92]

In June 2005, AVS Marketing and its president agreed to pay $400,000 to settle the FTC charges.[93] A stipulated final judgment and order prohibits AVS from making false or unsubstantiated claims about weight-loss products or other products in the future.[94] The order contained a judgment for more than $4,900,000—the total amount of sales for the product at issue—however, because AVS was unable to pay full redress, the order suspended the judgment upon payment of $400,000 to FTC.[95]

IV. RECENT FEDERAL REGULATIONS

A. The Saga of the Bovine Spongiform Encephalopathy (BSE) Final Rule

USDA, through its branch the Animal Plant and Health Inspections Services (APHIS), published in January 2005, a final rule (BSE Final Rule) that reversed a May 2003 ban of imports of cattle and edible bovine products from Canada.[96] Effective March 7, 2005, the BSE Final Rule has been the subject of controversy due to ill-timed BSE episodes before and after publication and a well-publicized lawsuit that sought to enjoin its enforcement.[97]

1. Chronology of Four Mad Cows

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91. Press Release, FTC, Defendants Who Deceptively Marketed the "Himalyan Diet Breakthrough" Settle FTC Charges: Agree to Pay $400,000 in Consumer Redress (June 20, 2005), *available at* http://www.ftc.gov/opa/2005/06/avsmarketing.htm [hereinafter 2005 FTC Press Release].

92. *Id.*

93. *Id.*

94. *See id.*

95. *Id.* The stipulated final judgment stated that if it is found that AVS misrepresented its financial condition, the full $4.9 million will become due immediately. *See* 2005 FTC Press Release, *supra* note 91.

96. *See* Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities, 70 Fed. Reg. 460 (Jan. 4, 2005) (to be codified at 9 C.F.R. pts. 93-96).

97. *See generally* Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. United States Dep't of Agric., 415 F.3d 1078, 1085-87 (9th Cir. 2005).

First Mad Cow: After the first case of BSE native to North America was diagnosed in a cow in Alberta, Canada, on May 20, 2003, the Secretary of USDA issued an emergency order adding Canada to the list of regions where BSE was known to exist.[98] BSE, commonly known as "'mad cow disease,' is a degenerative, fatal disease affecting the nervous system in cattle."[99] Following the detection of BSE in Great Britain in 1986, it was discovered that by consuming cattle contaminated with BSE, people could be infected with a new-variant Creutzfeldt-Jakob disease (vCJD), a rare but fatal human disease.[100] Under the USDA regulations, the emergency order effectively banned all imports of live ruminants or ruminant meat products from Canada.[101] An easing of the ban was first made nearly five months later when, on August 8, 2003, the Secretary announced that she would begin allowing certain "low-risk" ruminant products to be imported into the United States from Canada.[102] On November 4, 2003, the Secretary published notice of a proposed rule to allow the importation of live ruminants and ruminant products from regions that present a minimal risk of introducing BSE into the United States.[103] Canada would be the only region designated as a minimal risk.[104]

Second Mad Cow: Shortly after the publication of the notice of the proposed rule, on December 23, 2003, a cow that was born in Canada and imported into Washington State in 2001 was diagnosed with BSE.[105] The fact that the cow was born before a feed ban prohibiting the feeding of ruminant protein to other ruminants that went into effect in Canada in 1997 led USDA to determine that the BSE infection was likely caused by contaminated feed available prior to the Canadian ban.[106] On the heels

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98. *See* Change in Disease Status of Canada Because of BSE, 68 Fed. Reg. 31,939 (May 29, 2003) (to be codified at 9 C.F.R. pts. 93-94).

99. *See* Geoffrey S. Becker, *Mad Cow Disease: Agricultural Issues for Congress*, CRS Issue Brief for Congress at CRS-1, June 14, 2005, *available at http://kuhl.house.gov/UploadedFiles/madcow.pdf*.

100. *See id.* at CRS-2.

101. *See* 9 C.F.R. §§ 93.401, 93.418 (2003).

102. *See* Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities; Partial Delay of Applicability, 70 Fed. Reg. 460, 536 (Jan. 4, 2005).

103. *See* Bovine Spongiform Encephalopathy: Minimal Risk Regions and Importation of Commodities, 68 Fed. Reg. 62,386 (Nov. 4, 2003) (to be codified at 9 C.F.R. pts. 93-95).

104. 68 Fed. Reg. at 62,387.

105. *See* Bovine Spongiform Encephalopathy: Minimal Risk Regions and Importation of Commodities, 69 Fed. Reg. 10,634 (Mar. 8, 2004) (to be codified at 9 C.F.R. pts. 93-95).

106. *See id.*

of this discovery of a second mad cow, USDA reopened the comment period for its proposed rule for an additional thirty days, extending it until April 7, 2004.[107] On April 19, 2004, USDA moved, without public notice, to expand the types of ruminant products eligible to be imported.[108]

Third Mad Cow: On January 2, 2005, another cow in Alberta, Canada, was diagnosed with BSE. Since this Alberta cow was also born before Canada's feed ban, USDA once again attributed the infection to contaminated feed manufactured before Canada's feed ban went into effect.[109] Two days later, on January 4, 2005, after having considered 3,379 comments from interested parties, USDA published its BSE Final Rule to reopen the border to Canadian ruminants and ruminant products.[110] The BSE Final Rule also allows the importation of Canadian cattle over thirty months of age provided the cattle were immediately slaughtered or fed and then slaughtered.[111] The thirty-month age is specified because BSE infection levels are believed to rise as cattle grow older.[112]

Fourth Mad Cow: Shortly after publication of the BSE Final Rule, on January 11, 2005, the fourth "mad cow"—another Alberta cow—was diagnosed with BSE.[113] This cow was born shortly after Canada's feed ban, but USDA once again attributed the infection to contaminated feed manufactured before Canada's feed ban went into effect.[114] USDA indefinitely suspended, however, the implementation of the portion of its BSE Final Rule that permitted the importation of beef products from cattle over thirty months of age.[115]

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107. *See id.* at 10,633.

108. *See Ranchers Cattlemen*, 415 F.3d at 1089.

109. *See* Bovine Spongiform Encephalopathy: Minimal Risk Regions and Importation of Commodities: Finding of No Significant Impact and Affirmation of Final Rule, 70 Fed. Reg. 18,252, 18,258 (Apr. 8, 2005) (to be codified at 9 C.F.R. pts. 93-95, 98).

110. *See* Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities; Partial Delay of Applicability, 70 Fed. Reg. 460, 469 (Jan. 4, 2005).

111. *See* 70 Fed. Reg. 460, 548.

112. *See Ranchers Cattlemen*, 415 F.3d at 1088 n.7.

113. *See* Bovine Spongiform Encephalopathy: Minimal Risk Regions and Importation of Commodities: Finding No Significant Impact and Affirmation of Final Rule, 70 Fed. Reg. at 18,254.

114. *See id.* at 18,255.

115. *See* Bovine Spongiform Encephalopathy: Minimal Risk Regions and Importation of Commodities: Partial Delay of Applicability, 70 Fed. Reg. 12,112 (Mar. 11, 2005) (to be codified at 9 C.F.R. pts. 94-95).

2. Judicial and Legislative Challenges to the BSE Final Rule

Six days after USDA published the BSE Final Rule, the Ranchers Cattlemen Action Legal Fund United Stockgrowers of America (R-CALF)[116] filed suit against USDA, seeking to enjoin the rule's implementation.[117] On March 2, 2005, the federal District Court of Montana granted R-CALF's motion for a preliminary injunction to prevent the BSE Final Rule from taking effect.[118] The court found the Final Rule to be arbitrary and capricious in violation of the Administrative Procedures Act (APA).[119] The court's principle concern was that USDA "ignoring its statutory mandate to protect the health and welfare of the people of the United States, established its goal of re-opening the border to the importation of live beef from Canada and thereafter attempted to work backwards to support and justify this *goal*."[120] One day later, on March 3, 2005, the Senate approved a joint resolution to overturn the BSE Final Rule.[121] A similar resolution was introduced in the House of Representatives.[122] During the March vote in the Senate, however, it was announced that the Administration strongly opposed Senate passage of the resolution and would veto the bill.[123]

In March 2005, USDA filed an appeal with the United States Court of Appeals in the Ninth Circuit to reverse the district court decision.[124] In August 2005, the Ninth Circuit held that the district court

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116. R-CALF is a non-profit cattle association that represents cattle producers, cattle backgrounders, and independent feedlot operators on matters of international trade and marketing. *See Ranchers Cattlemen*, 415 F.3d at 1090 n.12.

117. *Id.* at 1090.

118. *See* Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. United States Dep't of Agric., 359 F. Supp. 2d 1058, 1074 (D. Mont. 2005) *rev'd*, 415 F.3d 1078 (9th Cir. 2005).

119. *Id.* at 1069.

120. *Id.* at 1066 (emphasis in original).

121. *See* S.J. Res. 4, 109th Cong. (2005).

122. *See* H.J. Res. 23, 109th Cong. (2005).

123. *See Senate Passes Resolution to Kill Border Rule*, 47 FOOD CHEM. NEWS 11, Mar. 7, 2005.

124. *See Ranchers Cattlemen*, 415 F.3d at 1092.

erred in issuing a preliminary injunction prohibiting the implementation of the BSE Final Rule.[125] The Ninth Circuit found that the district court failed under APA to properly defer to the USDA's judgment and expertise.[126] The Ninth Circuit further found an adequate basis in the administrative record for the USDA's conclusion that the risks for reopening the border were acceptable.[127]

B. New Health-Conscious Labels for Meat and Poultry

In June 2005, the USDA's Food Safety Inspection Service (FSIS) issued a final rule allowing nutrient content claims for certain meat and poultry products.[128] The rule establishes a general definition and standard of identity for standardized meat and poultry products that have been modified to qualify for use of an expressed nutrient-content claim in the product names.[129] These qualifying products may be identified by an expressed nutrition content claim such as "fat free," "low fat," and "light" in conjunction with an appropriate standardized term, such as "low fat bologna."[130] The final rule replaces two interim policy memoranda that already allowed modified versions of standardized meat and poultry products formulated with less fat to use the nutrient-content claims.[131] The rule still prohibits the direct fortification of meat and poultry products.[132] The rule does provide, however, that water and fat-replacers may be added, along with textured vegetable protein, to replace fat.[133]

The express purposes of the final rule are to promote healthy dietary practices by providing meat and poultry products that have reduced levels of unhealthy constituents such as fat, cholesterol, and

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125. *See id.* at 1093.

126. *See id.*

127. See id. at 1095-110 (Because the Ninth Circuit's decision was issued after the time period covered in this update, a more complete summary of the decision and an update on the status of this case will be included in the next issue of this journal).

128. *See* Food Standards: Requirements for Substitute Standardized Meat and Poultry Products Named By Use of an Expressed Nutrient Content Claim and a Standardized Term, 70 Fed. Reg. 33,803, 33,804 (June 10, 2005) (to be codified at 9 C.F.R. pts. 319, 381).

129. *See* 70 Fed. Reg. at 33,804, 33,814.

130. *See* 70 Fed. Reg. at 33,804, 33,814.

131. 70 Fed. Reg. at 33,804.

132. 70 Fed. Reg. at 33,805-06.

133. 70 Fed. Reg. at 33,809, 33,814.

sodium; increasing regulatory flexibility and support meat and poultry product innovation; and helping provide an informative nutrition labeling system.[134]

The effective date for the final rule is January 1, 2008,[135] although food establishments may begin to make nutrient-content claims for their meat and poultry products in compliance with the final rule at any time.[136]

V. RECENT GUIDELINES

A. Guidance for Mandatory COOL for Fish and Shellfish

In March 2005, one month prior to the effective date for mandatory country of origin labeling (COOL) for fish and shellfish,[137] USDA issued a "Notice to the Trade" (Notice).[138] Mandatory COOL requires that fish and shellfish sold in retail venues must have labels that identify both the country of origin of the product and the method in which it was raised (the rule gives the example of identifying wild verses farm-raised salmon).[139]

Issued in response to inquiries and comments from retailers and their suppliers, the Notice clarified the final rule's documentation and recordkeeping requirements.[140] USDA noted two parts of

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134. 70 Fed. Reg. at 33,804.

135. In March 2005, FDA issued a final rule establishing January 1, 2008, as the uniform compliance date for any food labeling regulations issued between January 1, 2005 and December 31, 2006. *See* Uniform Compliance Date for Food Labeling Regulations, 69 Fed. Reg. 74,405 (Dec. 14, 2004) (to be codified at 9 C.F.R. pts. 317, 381).

136. *See* 70 Fed. Reg. at 33,804.

137. *See* News Release, Agricultural Marketing Service (AMS), USDA, Retail Country of Origin Labeling Becomes Effective April 4 (Mar. 25, 2005), *available at* http://www.ams.usda.gov/news/074-05.htm [hereinafter AMS News Release]; *see also* AMS, USDA, 2002 Farm Bill Provisions, *available at* http://www.ams.usda.gov/cool/ index.htm (providing the full text of the Interim Final Rule for the mandatory COOL of fish and shellfish).

138. *See* AMS, USDA, NOTICE TO THE TRADE MANDATORY COUNTRY OF ORIGIN LABELING FOR FISH AND SHELLFISH (2005), *available at* http://www.ams.usda.gov/ cool/notice.htm [hereinafter NOTICE].

139. *See* 7 C.F.R. § 60.200 (2005). 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. *See* 70 C.F.R. § 60.119 (2005).

140. *See* 7 C.F.R. § 60.400 (2005).

the recordkeeping requirements.[141] The first part of the record establishes the chain of custody of the product, which USDA anticipates retailers and their suppliers should be able to maintain through routine business documents.[142] The second part of the record establishes country of origin and method of production, and according to the notice the compliance depends on whether or not the covered product is labeled prior to being possessed by the retailer.[143] If the product is labeled prior to possession by the retailer, the label itself suffices as an adequate record while the product is in the possession of the retailer and supplier.[144] Once the pre-labeled product leaves the possession of the supplier or retailer, their recordkeeping requirements expire.[145] For covered products that are not pre-labeled, documentation must be maintained at the retail site while the product is on-hand and for a period of one year thereafter by the retailer and their suppliers.[146] The Notice clarifies that a pre-labeled product under the interim final rule does not refer to a covered product repackaged by the retailer.[147]

B. National Animal Identification Draft Strategic Plan

In May 2005, USDA announced the release of a National Animal Identification System (NAIS) Draft Strategic Plan.[148] The USDA's Draft Strategic Plan 2005 to 2009 presents the current views of USDA on how the NAIS implementation process will develop.[149] The strategy paper covers four significant issues: data confidentiallity, mandatory versus voluntary participation, data ownership, and a timeline for implementation.[150] The timeline proposes that NAIS be fully implemented and all

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141. *See* NOTICE, *supra* note 138.

142. *See id.*

143. *See id.*

144. *See id.*

145. *See id.*

146. *See* NOTICE, *supra* note 138.

147. *See id.*

148. *See* National Animal Identification System; Notice of Availability of a Draft Strategic Plan and Draft Program Standards, 70 Fed. Reg. 23,961 (May 6, 2005).

149. *See* APHIS, USDA, NATIONAL ANIMAL IDENTIFICATION SYSTEM (NAIS) DRAFT STRATEGIC PLAN 2005 TO 2009 (Apr. 25, 2005), *available at* http://animalid.aphis.usda.gov/nais/about/pdf/NAIS_Draft_Strategic_Plan_42505.pdf.

150. *See id.*

components mandatory by 2009.[151] Later in May 2005, the comment period for the strategy paper was extended to July 6, 2005, a one month extension of the original deadline.[152]

C. New Dietary Guidelines

In January 2005, for the first time in five years, DHHS and USDA issued an updated set of health and nutrition recommendations for Americans.[153] These agencies are required every five years to release new recommended dietary guidelines.[154] While the guidelines do not have any coercive effect on what foods are sold and consumed in the United States, they are subject to intense scrutiny because they influence the types of foods Americans choose to purchase and consume.[155] The new guidelines emphasize reducing calorie consumption and increasing physical activity.[156] The new guidelines also recommend an increased consumption of fruits, vegetables, whole grains, and non-fat or low-fat milk or milk products.[157] Finally, the new guidelines recommend choosing fats and carbohydrates wisely, choosing and preparing foods with little salt, drinking alcoholic beverages in moderation (if one chooses to drink), and keeping food safe to eat.[158]

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151. *See id.* at 10.

152. *See* 70 Fed. Reg. 29,269, 29,270 (May 20, 2005).

153. *See* DHS & USDA, Dietary Guidelines for Americans (2005), *available at* http://www.healthierus.gov/dietaryguidelines/dga2005/document/pdf/dga2005.pdf [hereinafter Dietary Guidelines].

154. *See* Announcement of the Availability of the Final Report of the Dietary Guidelines Advisory Committee, A Public Commend 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. § 5312 (a)(8)(B) (Supp. 2005).

155. *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 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").

156. *See* Press Release, DHHS, New Dietary Guidelines Will Help Americans Make Better Food Choices, Live Healthier Lives (Jan. 12, 2005), *available at* http://www.hhs.gov/news/press/2005pres/20050112.html.

157. *See* Dietary Guidelines, *supra* note 153, at 23-26.

158. *See id. at* 29-50.

VI. RECENT DEVELOPMENTS AND PENDING LEGISLATION

A. The Protracted Battle Over Mandatory COOL

Efforts to delay and repeal mandatory COOL continued in the first half of 2005. As reported in the previous section of this issue, mandatory COOL requirements for fish and shellfish became effective in April 2005.[159] For the other covered commodities, however, mandatory COOL appears to be dead or, at best, stalemated.

COOL was introduced in the Farm Security and Rural Investment Act of 2002 (2002 Farm Bill), which amended the 1946 Agricultural Marketing Act (AMA).[160] COOL was to become mandatory in September 2004.[161] On October 30, 2003, the USDA's Agriculture Marketing Service (AMS) published a proposed rule to implement the mandatory COOL program.[162] The statute 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."[163] Covered commodities include beef, lamb, pork, fish, and perishable agricultural commodities such as peanuts.[164] Food service establishments, such as restaurants, lunchrooms, cafeterias, food stands, bars, lounges, and similar enterprises are exempt from mandatory COOL.[165]

COOL has since been beset by congressional postponement. On January 23, 2004, Congress passed an omnibus appropriations bill, which included a provision amending AMA.[166] This provision,

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159. *See* AMS News Release, *supra* note 137.

160. *See* 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.).

161. *See* 7 U.S.C. § 1638c (b) (Supp. 2005).

162. *See* Mandatory Country of Origin Labeling of Beef, Lamb, Pork, Fish, Perishable Agricultural Commodities, and Peanuts, 68 Fed. Reg. 61,944 (Oct. 30, 2003) (to be codified at 7 C.F.R. pt. 60).

163. 7 U.S.C.§ 1638a (a)(1) (Supp. 2005).

164. *See id.* at § 1638a (a)(2).

165. *See* Country of Origin Labeling: Definitions, 7 U.S.C. § 1638a (b) (Supp. 2005) (exempting food service establishments from the country of origin labeling requirements). Food service establishments include "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." 7 U.S.C. § 1638(4) (Supp. 2005).

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

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."[167]

Whether mandatory COOL is implemented in September 2006 has yet to be determined. In June 2005, the House of Representatives approved a fiscal 2006 USDA appropriations bill that contained a provision delaying mandatory country-of-origin for meat beyond the current September 30, 2006 deadline.[168] The Senate Appropriations Committee, however, left funds in the fiscal 2006 USDA appropriations bill to implement mandatory COOL for meat.[169] Implementation of COOL will likely be a thorny issue when the House and Senate meet to reconcile the two versions of the spending bills.[170]

Making matters even more complicated, pending bills in the House and Senate would prohibit the implementation of the BSE Final Rule that reopens the border to Canadian ruminants and ruminant products,[171] unless the retail COOL is in effect.[172]

Introduced in the House of Representatives in May 2005, the Meat Promotion Act of 2005 would repeal any COOL requirements present in the 1946 AMA and replace them with a voluntary country-of-origin program, dubbed as the VCOOL program.[173] The bill would allow retailers to label beef, pork, lamb, and seafood as products of the United States if they are derived exclusively from animals, born, raised, and slaughtered in the United States.[174] USDA would administer the VCOOL program and create a unique label that retailers could use for designating country-of-origin.[175] Participants in the program would be required to maintain records enabling USDA to verify compliance with the terms

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167. *See id.* at § 749.

168. *See Senate Appropriations Committee Rejects COOL Delay*, 47 FOOD CHEM. NEWS 18 (June 27, 2005).

169. *See id.*

170. *See id*.

171. Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities; Partial Delay of Applicability, 70 Fed. Reg. 460, 469 (Jan. 4, 2005).

172. *See* H.R. Res. 384, 109th Cong. (2005); S. Res. 108, 109th Cong. (2005).

173. *See* H.R. Res. 2068, 109th Cong. (2005). The same legislation was also proposed in June 2004. *See* H.R. Res. 4576, 108th Cong. (2004).

174. *See* H.R. Res. 2068, 109th Cong. (2005) at § 294.

175. *See id.* at § 293.

of the program.[176] Violators of the program, such as anyone who labels meat that has not been born, raised, and slaughtered in the United States as having country-of-origin status, would be subject to a civil penalty of up to $10,000 per violation.[177]

B. WTO Regional Indications

In March 2005, a World Trade Organization (WTO) dispute panel issued a ruling addressing claims made by the United States against the European Union (E.U.) system of geographical indications.[178] The United States and E.U. both claim the panel decision a victory for its respective position.[179]

Geographical indications fall under the purview of the WTO's 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement), which establishes the minimum standards for the protection of geographical indications within the WTO member countries.[180] The TRIPs Agreement defines geographical indications as "indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin."[181] Examples of geographic food names in the United States include Florida oranges and Idaho potatoes; examples of geographic food names in Europe include Parma ham and Roquefort cheese.[182] Geographical Indications have been the source of intense disagreement between the United States and the E.U. The E.U. holds geographical indications as sources of cultural and economic wealth and view the

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176. *See id.* at § 295.

177. *See id.* at § 296 (a)(2).

178. Panel Report, *European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, WT/DS174/R (Mar. 15, 2005), *available at* http://www.wto.org/English/tratop_e/dispu_e/174r_e.pdf.

179. *See*, *e.g.*, *Both Sides Declare Final Victory in WTO Food Names Dispute*, 47 FOOD CHEM. NEWS 22 (Mar. 21, 2005).

180. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 81, 91-92 (1994).

181. *See id.* at 91.

182. *See* Press Release, Office of the United States Trade Representative, United States Wins "Food Name" Case in WTO Against EU (Mar. 15, 2005), *available at* http://www.ustr.gov/Document_Library/Press_Releases/2005/March/United_States_Wins_Food_Name_Case_in_WTO_Against_EU.html [hereinafter Office of the United Stated Trade Representative].

terms as a specific type of intellectual property.[183] In contrast, the United States generally does not care about who makes a food product or where it comes from, as long as the characteristics remain consistent with taste and consistency expectations.[184] This cultural divide has helped contribute to an international dispute over the intellectual property protection of geographic indications.[185]

The United States claimed the panel decision a victory because the panel determined under the WTO rules that the E.U. had discriminated against United States producers by excluding the United States from the same protection on geographically named products as E.U. food producers.[186] The panel also agreed with the United States that the E.U. could not, under the WTO rules, deny United States trademark owners their rights, stating that any exceptions to trademark rights for the use of registered geographical indications were narrow and limited to the actual geographical indication name as registered.[187]

The E.U. claimed victory because the panel decision upholds the integrity of the E.U. system of geographical indications.[188] The panel decision upholds the requirement for inspection structures to verify that the conditions for each geographical indication are fulfilled in order to benefit from the high level of protection against unlawful use.[189] Moreover, the panel confirmed the provision of the E.U. system that allows the coexistence of geographical indications with prior trade marks under certain circumstances.[190]

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183. *See* Frances G. Zacher, Comment, *Pass the Parmesan: Geographic Indications in the United States and the European Union–Can There Be Compromise?*, 19 EMORY INT'L L. REV. 427, 427 (2005).

184. *See id.*

185. *See id.* at 427-28.

186. *See* Office of the United States Trade Representative, *supra* note 182.

187. *See id.*

188. See Press Release, Europa, WTO Panel Upholds EU System of Protection of "Geographical Indications" (Mar. 15, 2005), available at http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/05/298&format=HTML&aged=0&language=EN&guiLanguage=en.

189. *See id.*

190. *See id.*

C. Proposal to Revamp Food Identity Standards

In May 2005, USDA and FDA issued a proposed rule to establish a set of general principles for evaluating whether to revise, eliminate, or create standards of identity for food.[191] These agencies share responsibility for ensuring that food labels are truthful and not misleading.[192] USDA through its branch agency, FSIS, regulates the labeling of meat, poultry, and processed egg products, while FDA regulates the labeling of all other foods.[193] Food standards ensure that food products sold under a particular name have the characteristics expected by the consumer.[194]

The new proposal would not modernize all existing food standards; rather, the agencies would use the new general principles in reviewing petitions filed by the food industry to change, create, or eliminate a food standard.[195] The general principles are designed to protect and promote honest and fair dealing in the interest of consumers, allow for technological advances in food production, harmonize food standards with international food standards, and expedite the use of the standards by manufacturers and enforcing agencies.[196]

The principles proposed respectively by FSIS and FDA differ in certain respects. FSIS is proposing that a food standard be based on a finished product in order to ensure easier compliance.[197] FDA does not see a need for a parallel provision in the proposed the FDA food standards principles because the essential characteristics of FDA-regulated food are based on the finished product, rather than at the point of formulation or at intermediate stages during manufacturing.[198] FSIS is also proposing that food standards identify whether the product is a ready-

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191. *See* Food Standards; General Principles and Food Standards Modernization, 70 Fed. Reg. 29,214 (May 20, 2005) (to be codified at 9 C.F.R. pt. 410 and 21 C.F.R. pt. 130).

192. *See* News Release, FDA, USDA and HHS Propose to Modernize Principles for Food Standards of Identity (May 17, 2005), *available at* http://www.fda.gov/bbs/ topics/news/2005/usda_hhs051705.html; News Release, USDA, USDA and HHS Propose to Modernize Principles for Food Standards of Identity (May 17, 2005), *available at* http://www.fsis.usda.gov/News_&_Events/NR_051705_01/index.asp.

193. *See* 70 Fed. Reg. at 29,215.

194. *See id.* at 29,220.

195. *See id.* at 29,221.

196. *Id.* at 29,223.

197. *See id. at* 29,224.

198. *See* 70 Fed. Reg. at 29,224.

to-eat item to ensure that consumer expectations are met.[199] FDA is not proposing food standards to address whether the food is ready-to-eat or not due to the basic nature of standardized foods regulated by FDA.[200]

D. Produce Labeling Proposed Rule

In April 2005, FDA reopened the comment period on a proposed rule for produce labeling.[201] Three years earlier, FDA issued a proposed rule to amend its voluntary nutrition labeling regulations by updating the names and nutrition labeling values for the twenty most frequently consumed raw fruits, vegetables, and fish.[202] Since publication of the proposed rule in 2002, FDA has received new data in comments that it intends to use to further update the nutrition labeling values.[203] The comment period, which expired June 3, 2005, allowed stakeholders to comment on the updated nutrition values and to submit new data.[204] The produce list includes apples, avocados, bananas, cantaloupe, grapefruit, honeydew melon, kiwifruit, lemon, nectarine, orange, peach, pear, pineapple, plums, strawberries, sweet cherries, tangerines, and watermelon.[205] The vegetable list includes bell pepper, broccoli, carrot, celery, cucumber, iceberg lettuce, leaf lettuce, onion, potato, radish, sweet potato, and tomato.[206] FDA also requested comments on whether Chinook salmon should be added to the list of salmon already eligible for voluntary nutrition labeling.[207]

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199. *See id.* at 29,224-29,225.

200. *See id.*

201. *See* Food Labeling; Guidelines for Voluntary Nutrition Labeling of Raw Fruits, Vegetables, and Fish; Identification of the 20 Most Frequently Consumed Raw Fruits, Vegetables, and Fish; Reopening of the Comment Period, 70 Fed. Reg. 16,995 (Apr. 5, 2005) (to be codified at 21 C.F.R. pt. 101).

202. *See* Food Labeling; Guidelines for Voluntary Nutrition Labeling of Raw Fruits, Vegetables, and Fish; Identification of the 20 Most Frequently Consumed Raw Fruits, Vegetables, and Fish, 67 Fed. Reg. 12,918 (Mar. 20, 2002).

203. *See* 70 Fed. Reg. 16,995.

204. *See id.*

205. *See id.* at 16,996-16,999.

206. *See id.* at 17,000-17,002.

207. *See id.* at 16,996.

E. Homeland Security Report

A report issued by the General Accounting Office (GAO) in March 2005 examined the efforts by government agencies in managing the risks of agroterrorism.[208] The agencies examined include USDA, DHHS, and the Department of Homeland Security (DHS).[209] Since the terrorist attacks of 2001, the roles and responsibilities of federal government agencies have been modified to protect against agroterrorism.[210] The report notes important steps taken by federal agencies to better manage the risks of agroterrorism, including the development of a National Response Plan that details how these agencies would work together in the event of a terrorist attack on agriculture and the adoption of standard protocols that include establishing emergency operation centers and a chain of command.[211] While acknowledging these important steps, the report also documents challenges and problems that remain, especially for the livestock and poultry industries.[212] The report recommends several additional steps that the agencies could take to manage the risks of terrorism, including that USDA examine the costs and benefits of developing stockpiles of ready-to-use vaccines and that DHS and USDA determine the reasons for declining agricultural inspections.[213] Agricultural inspections at ports of entry have declined over the past two years, while imports have increased.[214]

F. Single Food Agency Proposal

In April 2005, the Safe Food Act of 2005, which would establish a federal single food safety agency, was proposed in both the Senate and House.[215] While the proposal for a single food safety agency is not new or novel, the timing of the April bill is noteworthy given the backdrop of three reports issued in the first half of 2005 by GAO that recommend the consolidation of food safety agencies into a single food safety agency or, short of reorganization, the reduction of overlapping

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208. *See* UNITED STATES GEN. ACCOUNTING OFFICE (GAO), HOMELAND SECURITY: MUCH IS BEING DONE TO PROTECT AGRICULTURE FROM A TERRORIST ATTACK, BUT IMPORTANT CHALLENGES REMAIN, GAO-05-214, 3 (Mar. 2005), *available at* http:// www.gao.gov/New.items/d05214.pdf [hereinafter GAO HOMELAND SECURITY REPORT].

209. *See id.* at 4.

210. *See id.* at 13-21.

211. *See id.* at 21-27.

212. *See id.* at 27-55.

213. *See* GAO HOMELAND SECURITY REPORT, *supra* note 208, *at* 56-57.

214. *See id.* at 40-46.

215. *See* S. Res. 729, 109th Cong. (2005); H.R. Res. 1507, 109th Cong. (2005).

federal inspections and related activities.[216] It is doubtful that the proposed legislation will gain much attention, as the Bush administration has openly stated its opposition to consolidating food safety agencies into a single food safety agency.[217] The rationale for opposition to a single food safety agency is generally premised on the assertion that the current food safety system is working, and dramatic changes will create confusion, thus leading to short-term greater food safety risks.[218]

The proposed Safe Food Act of 2005 has some noteworthy features within its four sections. The first section establishes a food safety administration headed by an Administrator of Food Safety, appointed by the President.[219] The Administrator would be required to enforce food safety laws, serve as a representative to international food safety interests, promulgate safety regulations, and oversee all food safety activities.[220] The first section would also transfer numerous federal agencies and functions to the proposed new Food Safety Administration.[221]

The second section would require the Administrator to administer a national safety program to protect public health.[222] Most likely in response to the recent mad cow disease incidents, the section also requires the Administrator to develop a national food traceability plan.[223]

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216. *See* GAO, OVERSEEING THE U.S. FOOD SUPPLY: STEPS SHOULD BE TAKEN TO REDUCE OVERLAPPING INSPECTIONS AND RELATED ACTIVITIES, GAO-05-549T (May 2005), *available at* http://www.gao.gov/New.items/d05549t.pdf; GAO, OVERSIGHT OF FOOD SAFETY ACTIVITIES: FEDERAL AGENCIES SHOULD PURSUE OPPORTUNITIES TO REDUCE OVERLAP AND BETTER LEVERAGE RESOURCES, GAO-05-213 (Mar. 2005), *available at* http://www.gao.gov/New.items/d05213.pdf; GAO, FOOD SAFETY: EXPERIENCES OF SEVEN COUNTRIES IN CONSOLIDATING THEIR FOOD SAFETY SYSTEMS, GAO-05-212 (Feb. 2005), *available at* http://www.gao.gov/New.items/d05212.pdf [hereinafter GAO FOOD SAFETY].

217. *See* GAO, FOOD SAFETY, *supra* note 216, at 58 (referring to a DHHS letter setting forth the Bush Administration's position in 2002 toward the issue of consolidating food safety agencies).

218. *See id.*; *see also generally* Stuart M. Pape, Paul D. Rubin & Heili Kim, *Food Security Would Be Compromised By Combining the Food and Drug Administration and the U.S. Department of Agriculture Into a Single Food Agency*, 59 FOOD & DRUG L.J. 405, 406 (2004) (arguing that the primary problem is the absence of statutory authority for FDA and USDA for food regulation and enforcement).

219. Safe Food Act, H.R. Res. 1507, 109th Cong. §§ 101-103 (2005).

220. *See id.* at § 101 (b)(1)-(4).

221. *See id.* at § 102.

222. *Id.* at § 201 (a).

223. *See id.* at § 201 (c)(7).

The third section would require the Administrator to coordinate with the Director of the Centers for Disease Control (CDC) to establish a research and education program.[224] The Administrator would also coordinate with the Director of CDC in the maintaining of an active surveillance system for foodborne illness that would be used to assess the frequency and sources of food safety illness in the United States.[225]

The fourth section would grant the Administrator with broad enforcement powers.[226] Food producers would be required to include a code on their products so they are easily traceable in the event of a foodborne illness outbreak.[227] Voluntary recalls would continue so long as they are effective; otherwise, the Administrator may institute a mandatory recall.[228] Consumers would also be notified as to where the food was sold to minimize product consumption.[229] Persons may be assessed a penalty of up to $10,000 for violating a food safety law, and individuals who commit a violation with the intent to defraud or mislead may be imprisoned for up to three years, fined up to $100,00 or both.[230]

G. FDA Asking For Comment on Food Label Changes

In April 2005, FDA asked for public comment on two proposals to give more prominence to calories on food labels.[231] The proposals are in response to recommendations in the FDA's Obesity Working Group report entitled "Calories Count" that addresses the problem of obesity.[232] The comment period expired June 20, 2005.[233]

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224. *See* Safe Food Act, H.R. Res. 1507, 109th Cong. §§ 301-303 (2005).

225. *See id.* at § 301 (a)(2).

226. *See id.* at §§ 401-409.

227. *See id.* at §§ 401 (5), 205 (h)(3)(F).

228. *See id.* at §§ 403 (a)(2), (b)(1).

229. *See* Safe Food Act, H.R. Res. 1507, 109th Cong. § 403 (b)(3).

230. *See id.* at §§ 405 (a)(1), (b)(2).

231. *See* Food Labeling; Prominence of Calories, 70 Fed. Reg. 17,008 (Apr. 4, 2005) (to be codified at 21 C.F.R. pt. 101).

232. *See id.* at 17,009.

233. *See id.* at 17,008.