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An Agricultural Law Research Article

## **United States Food Law Update**

by

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## UNITED STATES FOOD LAW UPDATE

*Michael Tingey Roberts\**

### I. INTRODUCTION

This update summarizes significant changes and developments in food law during the second half of 2005. An update of developments in United States food law is published in each issue of the *Journal of Food Law & Policy*. Each update of United States food law follows the same organization: an update of recent case and administrative decisions; federal statutes, regulations, and agency guidelines; and interesting developments and pending legislation. This framework has limits. Not every change in national food law for the second 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. Judicial Challenge to the Enforcement of the Bovine Spongiform Encephalopathy (BSE) Final Rule*

In August 2005, the United States Court of Appeals in the Ninth Circuit held that the district court in Montana erred in issuing a preliminary injunction prohibiting the implementation of a final rule known as the BSE final rule.<sup>1</sup> Bovine Spongiform Encephalopathy (BSE), commonly known as “mad cow disease,” is a “degenerative, fatal disease affecting the nervous system in cattle.”<sup>2</sup> Published in January 2005 by the United States

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

2. See Geoffrey S. Becker, *Mad Cow Disease: Agricultural Issues for Congress*, CRS Issue Brief for Congress, CRS-1, Mar. 24, 2005, available at <http://kuhl.house.gov/UploadedFiles/madcow.pdf>.

Department of Agriculture (USDA) and effective in March 2005, the BSE final rule reversed a USDA ban of imports of cattle and edible bovine products from Canada.<sup>3</sup> This May 2003 ban was in response to the first case of BSE native to North America being diagnosed in a cow in Alberta, Canada.<sup>4</sup> The BSE final rule reversing the ban has been the subject of controversy due to ill-timed BSE episodes before and after publication and this well-publicized lawsuit in Montana that sought to enjoin its enforcement.<sup>5</sup>

### 1. Background of Case

Six days after USDA published the BSE final rule, the Ranchers-Cattlemen Action Legal Fund, United Stockgrowers of America (R-CALF)<sup>6</sup> filed suit against USDA, seeking to enjoin the rule's implementation.<sup>7</sup> In early March 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.<sup>8</sup> The court found the BSE final rule to be arbitrary and capricious in violation of the Administrative Procedures Act (APA).<sup>9</sup> 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."<sup>10</sup> USDA then filed an appeal with the Ninth Circuit to reverse the district court decision.<sup>11</sup>

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3. 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). USDA published the BSE final rule through its branch, the Animal and Plant Health Inspection Service, commonly known as APHIS. *Id.*

4. The ban was effectuated when 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. *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). Under the USDA regulations, the Emergency Order effectively banned all imports of live ruminants or ruminant meat products from Canada. *See* 9 C.F.R. §§ 93.401, 94.18 (2005).

5. *See generally* Michael T. Roberts, *United States Food Law Update*, 1 J. FOOD L. & POL'Y 517, 530-32 (2005) (outlining the chronology of four mad cows found in the United States and the regulatory response and implications).

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

7. *Id.* at 1090.

8. *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).

9. *Id.* at 1069.

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

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

## 2. Ninth Circuit's Decision

The Ninth Circuit found that the district court failed under APA to defer to the USDA's judgment and expertise.<sup>12</sup> For example, the Ninth Circuit faulted the district court for rejecting the USDA's calculation in assessing the prevalence of BSE in the Canadian herd and in accepting the prevalence rate provided by R-CALF's expert, completely without explanation.<sup>13</sup> The Ninth Circuit attributed the district court's failure of deference to its misreading of the Animal Health Protection Act (AHPA),<sup>14</sup> the statute under which the BSE Final Rule was promulgated.<sup>15</sup> The Ninth Circuit noted that it was this misreading that led the district court to erroneously interpret AHPA to require the USDA regulation to remove *all* risk of BSE entering the United States.<sup>16</sup>

The Ninth Circuit did not stop at finding that the district court failed to defer to the expertise of USDA.<sup>17</sup> 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.<sup>18</sup> The court relied on what it described as "multiple, interlocking safeguards" within the regulatory system that minimize the risk of BSE to livestock and consumers in the United States.<sup>19</sup> These interlocking safeguards include the low incidence of BSE in Canadian cattle, Canada's feed ban and other measures to ensure that this low BSE incidence rate is decreasing, and the USDA's age restriction against imported cattle over thirty months of age.<sup>20</sup> The Ninth Circuit relied on the USDA's scientific evidence that Canadian cattle less than thirty months of age are less likely to be in the advanced stages of BSE.<sup>21</sup> Further safeguards inside the United States referred to by the Ninth Circuit that limit the spread of BSE include (i) the USDA requirement that Canadian cattle be immediately slaughtered or fed and then slaughtered before they reach the age of thirty months, (ii) the feed ban by the United States Food and Drug Administration (FDA) that ensures that the slaughtered animals are not then fed to other cattle, and (iii) the natural, biological defense of humans being less likely to contract the disease so easily.<sup>22</sup>

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12. *Id.* at 1093.

13. *See id.* at 1093-94.

14. 7 U.S.C. §§ 8301-8321 (Supp. 2004).

15. *Ranchers Cattlemen*, 415 F.3d at 1095 (stating that the district court's misinterpretation of the statute resulted in a "fundamentally flawed" analysis of the Final Rule's compliance with APA).

16. *Id.*

17. *See id.* at 1094.

18. *Id.* at 1095-1104.

19. *Id.* at 1095.

20. *Id.* at 1095-96.

21. *See id.* at 1096.

22. *Id.*

The Ninth Circuit concluded that based on these interlocking safeguards and the administrative record, the USDA's reopening of the border to Canadian ruminants would not pose a serious risk and satisfied the requirements of AHPA.<sup>23</sup>

The Ninth Circuit's decision took the wind from the sails of the district court's decision. The district court issued an order to cancel a scheduled hearing to consider whether or not to issue a permanent injunction on Canadian cattle imports.<sup>24</sup> As of the end of 2005, the district court had not rendered a final decision. In October 2005, the Ninth Circuit denied R-CALF's request for a rehearing.<sup>25</sup> In light of the scope of the Ninth Circuit's decision, it is difficult to conceive of how the district court could make findings to support permanent injunctive relief.

### III. RECENT FEDERAL STATUTES

#### A. *Rider Amending Organic Foods Production Act*

In October 2005, Congress approved a rider to the 2006 agriculture appropriations bill that amends the Organic Foods Production Act of 1990 (OFPA).<sup>26</sup> The rider amendment was in response to *Harvey v. Veneman*, a decision made in January 2005 by the United States Court of Appeals in the First Circuit.<sup>27</sup>

#### 1. Background

OFPA establishes national standards governing the marketing of food products that qualify for the "organic" United States Department of Agriculture (USDA) label.<sup>28</sup> To bear the USDA's "organic" seal, a food product must be at least ninety-five percent organic and produced and handled without the use of synthetic substances in accordance with an organic plan agreed to by an accredited certifying agent and by the producer and handler of the food product.<sup>29</sup> Synthetic substances that are exceptions to this gen-

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23. *Id.* at 1104.

24. *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). Docket.

25. *Ranchers Cattlemen*, 415 F.3d at 1078, Docket.

26. *See* OFPA, 7 U.S.C. §§ 6501-6523 (2000), *amended by* Pub. L. No. 109-97 (Nov. 10, 2005).

27. *See* 396 F.3d 28 (1st Cir. 2005).

28. *See* 7 U.S.C. § 6501.

29. *Id.* § 6504. Food labeled "100% organic" cannot contain non-organic ingredients or processing aids. 7 C.F.R. §§ 205.301(a), 205.33 (2005).

eral prohibition against such use are to be listed on a National List following notice and comment and are subject to review.<sup>30</sup>

*Harvey* held that certain provisions in the National Organic Program Final Rule<sup>31</sup> contravened OFPA.<sup>32</sup> Initially, the First Circuit first held that 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 that required all organic dairy animals to receive organic feed for twelve months prior to sale of milk or milk products.<sup>33</sup> The First Circuit also held that the Final Rule allowing the listing of synthetics for use in the handling of products labeled organic contravened the OFPA provision that prohibits synthetics in processed foods.<sup>34</sup> The First Circuit also 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.<sup>35</sup> The First Circuit directs that such a blanket exemption would controvert the OFPA requirements for the National List.<sup>36</sup>

## 2. Rider

The rider to the 2006 agriculture appropriations bill amends OFPA and modifies the outcome in *Harvey*.<sup>37</sup> The rider allows organic dairy animals to be fed “transitional” organic feed during all of the twelve months of the conversion year.<sup>38</sup> This change in essence allows milk to be sold as organic as soon as the land qualifies as organic.<sup>39</sup> The rider does not allow, however, the twenty percent conventional feed as did the final rule reversed by *Harvey*.<sup>40</sup> In addition, the rider reverses the holding in *Harvey* prohibiting synthetic ingredients in handling by amending OFPA to remove restrictions on synthetic ingredients in post-handling, provided that

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30. 7 U.S.C. §§ 6517(a), (d), (e); 6518(k), (l), (m).

31. 7 C.F.R. pt. 205 (2005).

32. *See* 396 F.3d at 45-46.

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

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

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

36. *Id.*

37. *See* Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 2006, Pub. L. No. 109-97, § 724, 119 Stat. 2120, 2153 (2005).

38. *See* 7 U.S.C. § 6509(e)(2)(B). (Supp. 2005), *amended by* Pub. L. No. 109-97 (Nov. 10, 2005).

39. *See id.* (stating that “crops and forage from land included in the organic system plan of a dairy farm that is in the third year of organic management may be consumed by the dairy animals of the farm” during the twelve month period before the sale of organic milk and milk products).

40. *See id.*

they are listed on the National List.<sup>41</sup> Finally, the rider amends OFPA to permit the USDA Secretary to develop emergency procedures to designate for the National List agricultural products not commercially available in organic form for a maximum one year period.<sup>42</sup> Presumably these emergency procedures would be subject to notice and comment rulemaking under APA.

### *B. Sanitary Food Transportation Act of 2005*

In August 2005, President George W. Bush signed into law the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users.<sup>43</sup> This act contains the Sanitary Food Transportation Act of 2005 (SFTA).<sup>44</sup> SFTA streamlines regulatory jurisdiction over the safe transportation of food and requires the establishment of safety transportation procedures to prevent the adulteration of food during transportation.<sup>45</sup>

Effective October 1, 2005, SFTA amends the Federal Food, Drug, and Cosmetic Act (FDCA) to assign the regulatory authority for food transportation to the United States Department of Health and Human Services (DHHS).<sup>46</sup> SFTA provides the Secretary of DHHS access to required food transportation records.<sup>47</sup> SFTA also requires the Secretary of the Department of Transportation (DOT), in consultation with DHHS and USDA, to establish procedures for transportation safety inspections to ensure that food is not adulterated during transportation by rail or motor vehicle.<sup>48</sup> SFTA further requires the Secretary of DOT to train DOT personnel in the appropriate use of the procedures and to notify DHHS or USDA of any instances of potential food contamination or adulteration of a food product identified during transportation safety inspections.<sup>49</sup> To ensure a working relationship between these three agencies under SFTA, the three agencies plan to enter into a memorandum of understanding.<sup>50</sup>

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41. *See id.* §§ 6510(a)(1), 6517(c)(B)(iii).

42. *See id.* §6517(d)(6) OFPA, 7 U.S.C. § 6517(d)(6), *amended by* Pub. L. No. 109-97 (Nov. 10, 2005)..

43. Pub. L. No. 109-59, 119 Stat. 1144 (2005).

44. SFTA, Pub. L. No. 109-59, § 7201, 119 Stat. 1144, 1911 (2005).

45. *See id.* § 7202.

46. *Id.* §§ 7201, 7202, 7204.

47. *Id.* § 7202.

48. *Id.* § 7203.

49. *Id.*

50. *See* Safeguarding Food From Contamination During Transportation, 70 Fed. Reg. 76,228, 76,228-76,229 (Dec. 23, 2005).

## IV. RECENT FEDERAL REGULATIONS

A. *The FDA Amendments to Feed Ban Rule*

In October 2005, Food and Drug Administration (FDA) published a proposed feed ban rule to amend the agency's regulations to prohibit the use of cattle origin materials in the food or feed of *all* animals.<sup>51</sup> As BSE is transmitted to cattle when cattle eat BSE-infected tissue, the proposed rule is intended to shore up the FDA regulatory protection by keeping the BSE-causing agent out of the animal food and feed supply.<sup>52</sup>

The proposed FDA feed ban prohibits the use in the food of all animals the following high risk cattle materials: brains and spinal cords from cattle thirty months of age and older, brains and spinal cords from cattle of any age not inspected and passed for human consumption, entire carcass of cattle not inspected and passed for human consumption if the brains and spinal cords have not been removed, tallow that is derived from the materials prohibited by the proposed rule if the tallow contains more than 0.15 percent insoluble impurities, and mechanically separated beef that is derived from materials prohibited by the proposed rule.<sup>53</sup> All of these proposed prohibitions, except for those related to tallow, have already been banned from cattle feed since 1997.<sup>54</sup>

This FDA feed ban proposal is also notable for what it does not do.<sup>55</sup> It does not ban from non-ruminant feed some of the "specified risk materials" that are now banned by USDA from human food, such as distal ileum, tonsils, and other nervous tissue.<sup>56</sup> The proposal also does not ban from ruminant feeds the use of cattle blood and blood products, plate waste, and poultry litter.<sup>57</sup>

Further context for the overall effectiveness of FDA feed regulation is provided by a February 2005 report from the Government Accountability

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51. Substances Prohibited From Use in Animal Food or Feed, 70 Fed. Reg. 58,570 (Oct. 6, 2005) (to be codified at 21 C.F.R. pt. 589).

52. FDA News, *FDA Proposes Additional "Mad Cow" Safeguards*, Oct. 4, 2005, available at <http://www.fda.gov/bbs/topics/news/2005/new01240.html> [hereinafter FDA News]; see also Substances Prohibited From Use in Animal Food or Feed, 70 Fed. Reg. at 58,578-58,580.

53. Substances Prohibited From Use in Animal Food or Feed, 70 Fed. Reg. at 58,580-58,581.

54. FDA News, *supra* note 52.

55. See Geoffrey S. Becker, *Bovine Spongiform Encephalopathy (Mad Cow Disease): Agricultural Issues for Congress*, Nov. 7, 2005, at 8, available at <http://www.nationalaglawcenter.org/assets/crs/IB10127.pdf> (outlining the criticisms of the FDA feed rule).

56. See *id.*

57. See *id.*

Office (GAO).<sup>58</sup> The GAO report concluded that while FDA had improved its management of the feed ban, program weaknesses continued to limit its effectiveness, placing United States cattle at risk of spreading BSE.<sup>59</sup> These reported program weaknesses include a variety of inspection, labeling, and communication problems.<sup>60</sup>

*B. The FDA Amendments Allowing Use of Certain Cattle-Derived Materials in Human Foods and Cosmetics*

In September 2005, FDA published several amendments to a July 2004 interim final rule on the use of materials derived from cattle in human food and cosmetics.<sup>61</sup> The interim final rule prohibits the use of cattle-derived materials that can carry the infectious agent for Bovine Spongiform Encephalopathy (BSE) in human foods, dietary supplements, and cosmetics.<sup>62</sup> After reviewing the comments received on the interim final rule, FDA decided to make some changes and clarifications prior to the expiration of the comment period.<sup>63</sup> The amendments to the interim final rule became effective in October 2005.<sup>64</sup>

The September 2005 amendments to the interim rule consist of three changes. First, the amendments allow use of the small intestine, provided that the cow's digestive tract, called the distal ileum, has been removed.<sup>65</sup> According to the scientific information provided to FDA during the interim rule's comment period, the distal ileum can be consistently and effectively removed from the other sections of the small intestine.<sup>66</sup> Thus, the entire small intestine is no longer designated as a prohibited cattle material.<sup>67</sup>

Second, the amendments clarify that milk and milk products, hides and hide-derived products, and tallow derivatives are not prohibited for use in human food and cosmetics.<sup>68</sup> Third, the amendments approve the use of

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58. See GAO, *Mad Cow Disease, FDA's Management of the Feed Ban Has Improved, But Oversight Weaknesses Continue to Limit Program Effectiveness*, GAO-05-101, Feb. 2005, available at <http://www.gao.gov/new.items/d05101.pdf>.

59. *Id.* at 5.

60. *Id.* at 16-30.

61. See Use of Materials Derived From Cattle in Human Food and Cosmetics, 70 Fed. Reg. 53,063 (Sept. 7, 2005) (to be codified at 21 C.F.R. pts. 189 and 700).

62. Use of Materials Derived From Cattle in Human Food and Cosmetics, 69 Fed. Reg. 42,256 (July 14, 2004) (to be codified at 21 C.F.R. pts. 189 and 700).

63. Press Release, Food & Drug Admin., FDA Amends Interim Final Rule "Use of Materials Derived from Cattle in Human Food and Cosmetics," (Sept. 6, 2005), available at <http://www.fda.gov/bbs/topics/news/2005/NEW01229.html>.

64. Use of Materials Derived From Cattle in Human Food and Cosmetics, 70 Fed. Reg. At 53,063.

65. *Id.* at 53,065.

66. *Id.* at 53,064-65.

67. See *id.* at 53,065.

68. See *id.* at 53,065-66.

a particular method for testing for impurities in tallow that is less costly and requires less specialized equipment than previous methods.<sup>69</sup>

*C. The FSIS Amendments Allowing Use of Certain Specified Risk Materials for Human Food*

In September 2005, on the same day FDA published its amendments to the FDA July 2004 interim final rule regarding the use of materials derived from cattle in human food and cosmetic, USDA through its branch agency the Food Safety and Inspection Service (FSIS) published a similar notice.<sup>70</sup> The FSIS amendments amended a January 2004 FSIS interim final rule prohibiting the use of specified risk materials for human food and imposing requirements for the disposition of non-ambulatory cattle.<sup>71</sup> The FSIS amendments permit beef intestine, excluding the distal ileum, to be used for human food and includes methods for removing the distal ileum from the small intestine.<sup>72</sup> The FSIS amendments also require foreign countries exporting meat products to the United States to comply with the same requirements in the amended regulation.<sup>73</sup>

*D. The FDA Food CGMP Modernization Recommendations*

In November 2005, a “Modernization Working Group” published a number of new recommendations for the FDA’s Current Good Manufacturing Practice (CGMP) regulations.<sup>74</sup> The working group was formed in 2002 by the FDA’s Center for Food Safety and Applied Nutrition (CFSAN) specifically to examine the CGMP regulations and determine whether the regulations were in need of modernization.<sup>75</sup> The CGMP regulations were last modified in 1986.<sup>76</sup>

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69. *See id.* at 53,066 (crediting the creation of the approved method as being devised and used by the American Oil Chemist Society).

70. *See* Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle, 70 Fed. Reg. 53,043 (Sept. 7, 2005) (to be codified at 9 C.F.R. pts. 310 and 318).

71. *Id.*; *see also* Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle, 69 Fed. Reg. 1862 (Jan. 12, 2004) (to be codified at 9 C.F.R. pts. 309, 310, 311, 318, and 319).

72. Prohibition of the Use of Specified Risk Materials, 70 Fed. Reg. at 53,047.

73. *Id.*

74. Center for Food Safety and Applied Nutrition (CFSAN), *Food CGMP Modernization—A Focus on Food Safety*, Nov. 2, 2005, available at <http://www.cfsan.fda.gov/~dms/cgm3.html> [hereinafter CFSAN Food CGMP].

75. *Id.*; *see also* Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, 21 C.F.R. pt. 110 (2005).

76. *See* CFSAN Food CGMP, *supra* note 74.

Determining that the CGMP regulations were in need of modernization, the working group noted two important changes within the food industry since 1986—an increased market for ready-to-eat foods and an expansion of scientific understanding of foodborne illnesses, such as *Listeria monocytogenes*, *Escherichia coli* O157:H7, *Campylobacter jejuni*, *Cryptosporidium parvum*, *Cyclospora cayetanensis*, and *Norovirus*.<sup>77</sup>

The modernization recommendations made by the working group are based on two predicates. The first predicate is matching risk-based regulation to food safety outcomes.<sup>78</sup> The other key predicate is preserving for food manufacturers the flexibility to implement required controls to unique situations as they deem advisable.<sup>79</sup>

Building on these predicates and adhering to comments made to FDA in response to a series of public meetings, the working group offered seven specific modernization recommendations.<sup>80</sup> First, require “appropriate training for supervisors and workers to ensure that they have the necessary knowledge and expertise” in food and personal hygiene, food protection, and employee health.<sup>81</sup> Second, require processors of foods “containing one or more of the eight major food allergens (milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans) to have a food allergen control plan.”<sup>82</sup> Third, require processors of ready-to-eat foods that support the growth of *Listeria monocytogenes* to devise a written environmental pathogen control program.<sup>83</sup> Fourth, require food processors to develop and maintain written sanitation procedures that define the scope, objectives, management and recordkeeping responsibilities, monitoring, and corrective action associated with the sanitation procedure.<sup>84</sup> Fifth, obtain further comments about removing the exclusion from CGMP compliance for establishments engaged solely in the harvesting, storage, or distribution of raw agricultural commodities.<sup>85</sup> Sixth, require food processors to maintain critical records to be made available for review and evaluation by FDA investigators.<sup>86</sup> Seventh, obtain further comments about the use by food

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77. *Id.*

78. *See id.*

79. *See id.*

80. *See* Food; Current Good Manufacturing Practice Regulations; Public Meetings, 69 Fed. Reg. 40,312 (July 2, 2004) (to be codified at 21 C.F.R. pt. 110); Current Good Manufacturing Practice Regulations; Public Meetings, 69 Fed. Reg. 29,220, 29,222 (May 21, 2004) (to be codified at 21 C.F.R. pt. 110).

81. *See* CFSAN Food CGMP, *supra* note 74.

82. *See id.*

83. *See id.*

84. *See id.*

85. *See id.*

86. *See id.*

processors of time-temperature relationships to incorporate into regulations or guidance for proper refrigerated storage or hot holding.<sup>87</sup>

### *E. Health Claim Activity*

A health claim is considered a labeling claim that characterizes the relationship of a substance to a disease or health-related condition.<sup>88</sup> The announcement in 2004 of two new qualified health claims—omega-3 fatty acids and olive oil—signified a new era of the FDA’s treatment of health claims.<sup>89</sup> Since then, including the second half of 2005, there has been much activity concerning health claims.

#### 1. Background

Prior to the 1980s, few health claims were made for food products.<sup>90</sup> FDA treated health claims for food as bringing that food within the FDA’s definition of a drug (“intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease”).<sup>91</sup> When firms began making health claims for foods without requesting the FDA’s approval,<sup>92</sup> FDA published in 1987 a proposed rule addressing health claims.<sup>93</sup> In 1990, FDA published a proposed regulation to establish rules for health claims for foods.<sup>94</sup> 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.<sup>95</sup> Pursuant to NLEA, FDA was to evaluate health claims using a standard of significant scientific agreement, which required that a sufficient body of sound, relevant scientific evidence

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87. *See id.*

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

89. *See generally* Michael T. Roberts & Margie Alsbrook, *United States Food Law Update*, 1 J. FOOD L. & POL’Y 187, 206-08 (2005).

90. *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 that FDA faced increased pressure in the 1980s as scientific studies began to show a connection between diet and chronic disease).

91. *See* FDCA, 21 U.S.C. § 321(g)(1)(B) (2000).

92. *See, e.g.*, Pappas, *supra* note 90, at 27 (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 the FDA regulations at the time and helped lead to the agency’s increased willingness to consider the allowance of qualified health claims).

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

94. Food Labeling; Health Messages and Label Statements; Reproposed Rule, 55 Fed. Reg. 5176 (Feb. 13, 1990) (codified at 21 C.F.R. § 101 (2005)).

95. Nutrition Labeling and Health Education Act of 1990, Pub. L. 101-535, 104 Stat. 2353 (codified as amended in scattered sections of 21 U.S.C.).

show consistency across different studies and among different researchers.<sup>96</sup>

In recent years, judicial scrutiny of the FDA regulatory treatment of health claims has pressured the agency to change its policy.<sup>97</sup> In response to the decision by the United States Court of Appeals for the District of Columbia in *Pearson v. Shalala*,<sup>98</sup> FDA adopted a weight-of-the-scientific-evidence standard in evaluating health claims, which is less stringent than the significant-scientific standard.<sup>99</sup>

In response to the holding of United States District Court for the District of Columbia in *Whitaker v. Thompson*,<sup>100</sup> FDA has adopted an even lower standard of approval by tempering the weight-of-evidence standard “by the test of credible evidence.”<sup>101</sup> As of September 2003, FDA implemented, on an interim basis, an evidence-based ranking system that assigns a final rank to the evidence in support of the health claim and accommodates the use of disclaimers and clarifying language.<sup>102</sup>

## 2. The FDA Decisions on Health Claim Petitions

In the second half of 2005, employing its evidence-based-ranking system, FDA evaluated several qualified health claims. In August 2005, FDA approved a qualified health claim for chromium picolinate and reduced risk of type 2 diabetes.<sup>103</sup> FDA denied, however, a health claim for chromium picolinate and reduced risk of cardiovascular disease when caused by (i) insulin resistance, abnormally elevated blood sugar levels, or type 2 diabetes, (ii) retinopathy when caused by abnormally high blood sugar le-

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96. See 21 U.S.C. § 343(r)(3)(B) (Supp. 2005).

97. See Roberts & Alsbrook, *supra* note 89, at 202-06.

98. 164 F.3d 650 (D.C. Cir. 1999).

99. 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 Food and Human Dietary Supplements; Availability, 68 Fed. Reg. 41,387, 41,389-90 (July 11, 2003).

100. 248 F. Supp. 2d 1 (D.D.C. 2002).

101. See 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 Food and Human Dietary Supplements, 68 Fed. Reg. at 41,388-89.

102. See *generally* Health Claims: General Requirements, 21 C.F.R. § 101.14 (2005); Petitions for Health Claims, 21 C.F.R. § 101.70 (2005); see also 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 Food and Human Dietary Supplements, 68 Fed. Reg. at 41,389.

103. CFSAN, *Qualified Health Claims: Letter of Enforcement Discretion—Chromium Picolinate and Insulin Resistance*, Aug. 25, 2005, available at <http://www.cfsan.fda.gov/~dms/qhccr.html>.

vels, and (iii) kidney disease when caused by abnormally high blood sugar levels.<sup>104</sup>

In October 2005, FDA approved a qualified health claim for calcium and reduced risk of colon/rectal cancers and recurrent colon polyps<sup>105</sup> and for calcium and reduced risk of essential hypertension, gestational hypertension, and preeclampsia.<sup>106</sup> FDA denied, however, a health claim for calcium and reduced risk of breast and prostate cancers.<sup>107</sup>

In November 2005, FDA approved a qualified health claim for tomatoes or tomato sauce and reduced risk of prostate, gastric, ovarian, and pancreatic cancers.<sup>108</sup> FDA denied, however, a health claim for tomato-based foods other than tomato sauce and prostate and ovarian cancers; for all tomato-based foods and gastric and pancreatic cancers; for tomatoes and ovarian cancer; for tomatoes or tomato-based foods and lung, colorectal, breast, cervical, and endometrial cancers; and for tomatoes and tomato products which contain lycopene and reduced risk of prostate cancer.<sup>109</sup>

In December 2005, in response to a petition by the National Barley Foods Council, FDA published an amendment to the regulation authorizing a health claim on the relationship between oat beta-glucan soluble fiber and reduced risk of coronary heart disease (CHD).<sup>110</sup> The amendment adds barley as an additional eligible source of beta-glucan soluble fiber.<sup>111</sup>

### 3. The FDA Evaluation of Effectiveness of Qualified Health Claims

In September 2005, FDA released a report on its consumer research of qualified health claims, entitled “Effects of Strength of Science Dis-

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104. *Id.*

105. CFSAN, *Qualified Health Claims: Letter Regarding Calcium and Colon/Rectal, Breast, and Prostate Cancers and Recurrent Colon Polyps*, Oct. 12, 2005, available at <http://www.cfsan.fda.gov/~dms/qhcca2.html> [hereinafter CFSAN Calcium and Colon/Rectal Letter].

106. CFSAN, *Qualified Health Claims: Letter of Enforcement Discretion—Calcium and Hypertension; Pregnancy-Induced Hypertension; and Preeclampsia*, Oct. 12, 2005, available at <http://www.cfsan.fda.gov/~dms/qhcca3.html>.

107. CFSAN Calcium and Colon/Rectal Letter, *supra* note 105.

108. CFSAN, *Qualified Health Claims: Letter Regarding “Tomatoes and Prostate, Ovarian, Gastric and Pancreatic Cancers (American Longevity Petition)”*, Nov. 8, 2005, available at <http://www.cfsan.fda.gov/~dms/ghclyco.html>; CFSAN, *Qualified Health Claims Letter Regarding Tomatoes and Prostate Cancer (Lycopene Health Claim Coalition)*, Nov. 8, 2005, available at <http://www.cfsan.fda.gov/~dms/ghclyco2.html>.

109. CFSAN, *Qualified Health Claims: Letter Regarding “Tomatoes and Prostate, Ovarian, Gastric and Pancreatic Cancers (American Longevity Petition)”*, Nov. 8, 2005, available at <http://www.cfsan.fda.gov/~dms/ghclyco.html>; CFSAN, *Qualified Health Claims Letter Regarding Tomatoes and Prostate Cancer (Lycopene Health Claim Coalition)*, Nov. 8, 2005, available at <http://www.cfsan.fda.gov/~dms/ghclyco2.html>.

110. Food Labeling: Health Claims; Soluble Dietary Fiber From Certain Foods and Coronary Heart Disease, 70 Fed. Reg. 76,150, 76,150 (Dec. 23, 2005).

111. *Id.*

claimers on the Communication Impacts of Health Claims.”<sup>112</sup> The purpose of the report is to provide FDA with information about consumers’ reactions to qualified health claims and to understand the most effective way to present scientifically based, truthful, and non-misleading information to consumers.<sup>113</sup> The report revealed serious questions about the effectiveness of strength of science disclaimers.<sup>114</sup> The report, as well as other related studies, was the subject of a November 2005 public meeting held by FDA to evaluate the effectiveness of qualified health claims.<sup>115</sup> Underscoring the importance of the report and future studies on the effectiveness of science disclaimers on qualified health claims is the position of the *Pearson* and *Whitaker* cases that a complete ban on a health claim, even under certain circumstances, is only appropriate when the government demonstrates with empirical evidence that science disclaimers “would bewilder consumers and fail to correct for deceptiveness.”<sup>116</sup>

#### F. Tomato Color Claim

In July 2005, FDA amended the color additive regulations to provide for the safe use of tomato lycopene extract and tomato lycopene concentrate as color additives in foods.<sup>117</sup> The term “color additive,” as defined by the United States Food, Drug and Cosmetics Act (FDCA), means any material when added to food that is capable of imparting color, except those that the Secretary of the Department of Health and Human Services (DHHS), by regulation, determines are used “solely for a purpose or purposes other than coloring.”<sup>118</sup> Under FDCA, FDA must preapprove color additives, which are subject to an extensive notice-and-comment rulemaking procedure.<sup>119</sup> To be approved, color additives must be shown with reasonable certainty to pose no risk to human health, not deceive consumers, and accomplish an intended effect.<sup>120</sup> Unlike with food additives, FDCA

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112. Brenda M. Derby & Alan S. Levy, *Working Paper: Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims* (Sept. 2005), available at <http://www.fda.gov/OHRMS/dockets/dockets/03N0496/03N-0496-rpt0001.pdf>.

113. *See id.* at 6.

114. *See id.* at 34-39.

115. *See* Assessing Consumer Perceptions of Health Claims; Public Meeting; Request for Comments, 70 Fed. Reg. 60,749, 60,751 (Oct. 19, 2005) (to be codified at 21 C.F.R. pt. 101).

116. *Pearson v. Shalala*, 164 F.3d 650, 659-60 (D.C. Cir. 1999); *Whitaker v. Thompson*, 248 F. Supp. 2d 1, 5 (quoting *Pearson*, 164 F.3d at 658).

117. Listing of Color Additives Exempt From Certification; Tomato Lycopene Extract and Tomato Lycopene Concentrate, 70 Fed. Reg. 43,043 (July 26, 2005) (to be codified at 21 C.F.R. pt. 73).

118. FDCA, 21 U.S.C. § 321(t)(1)(B) (2000).

119. *Id.* § 379e(a)(1)(A).

120. *Id.* § 379e(b).

does not exempt generally recognized as safe (GRAS) color additives or prior sanctioned color additives from the requirement for pre-approval.<sup>121</sup>

### *G. Food Labeling and Sodium Levels*

In September 2005, FDA published a final rule that amends its regulations concerning the maximum sodium levels for foods that bear the implied nutrient content claim “healthy.”<sup>122</sup> The final rule retains the current, less restrictive, “first-tier” sodium level requirements for all food categories, including individual foods (480 milligrams (mg)) and meals and main dishes (600 mg).<sup>123</sup> The final rule eliminates the “second-tier,” more restrictive, sodium level requirement for all food categories, which had been stayed until January 2006.<sup>124</sup>

The amendment responds to industry and consumer advocate concerns that implementing the second-tier sodium requirements would risk the elimination of existing “healthy” products from the marketplace because the levels were unattainable.<sup>125</sup>

## V. RECENT GUIDELINES

### *A. FDA Issues Final Rule on Maintenance of Records Under Bioterrorism Act*

In November 2005, the United States Food and Drug Administration (FDA) issued a guidance document that includes answers to inquiries regarding the implementation of the FDA recordkeeping provisions of the Public Health Security and Bioterrorism Preparedness Act, commonly referred to as the Bioterrorism Act.<sup>126</sup> These recordkeeping provisions were

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121. FDCA exempts two groups of substances from the food additive approval process. The first group is substances determined safe for use by FDA or USDA in specified food products prior to the 1958 amendment. These substances are designated as prior-sanction substances. The second group is substances known as GRAS, an acronym for the phrase “Generally Recognized as Safe.” A substance is GRAS if it is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use. FDCA, 21 U.S.C. § 321(s) (2000).

122. Food Labeling; Nutrient Content Claims, Definition of Sodium Levels for the Term “Healthy,” 70 Fed. Reg. 56,828 (Sept. 29, 2005) (to be codified in 21 C.F.R. pt. 101).

123. *Id.*

124. *Id.* at 56,828-29.

125. *Id.* at 56,830.

126. CFSAN, *Questions and Answers Regarding Establishment and Maintenance of Records*, Nov. 10, 2005, available at <http://www.cfsan.fda.gov/~dms/recguid2.html>; see also Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594 (2002) (codified in scattered sections of 42 U.S.C.).

published in December 2004 by FDA in a final rule.<sup>127</sup> The rule was passed to help address concerns about the vulnerability of the country's food supply.<sup>128</sup> The recordkeeping rule is the fourth rule in a series of regulations issued by FDA under the Bioterrorism Act.<sup>129</sup> The rule applies to all those who manufacture, process, pack, transport, distribute, receive, hold, or import food.<sup>130</sup> Farms, restaurants, foreign persons (other than persons who transport food within 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.<sup>131</sup>

The guidance document is designed to help FDA field the large number of questions regarding the recordkeeping final rule.<sup>132</sup> The document follows a question-and-answer format that will periodically be updated as FDA receives and responds to additional questions.<sup>133</sup>

## VI. RECENT DEVELOPMENTS

### A. GAO Report Criticizes the FDA's BSE Feed Testing Program

In October 2005, the General Accounting Office (GAO) released a report citing several flaws in the small feed testing program the United States Food and Drug Administration (FDA) implemented in 2003.<sup>134</sup> The October 2005 GAO report acknowledged that the small feed testing program "is a small part of [the] FDA's BSE oversight effort and is one of several methods FDA uses to monitor for compliance with the feed-ban rule."<sup>135</sup> The GAO report further notes, however, that the program vies for the FDA's limited BSE oversight resources and has several weaknesses in

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

128. *Id.* at 71,562.

129. See Press Release, FDA, 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 (Dec. 6, 2004), available at <http://www.fda.gov/bbs/topics/news/2004/NEW01143.html>.

130. Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 69 Fed. Reg. at 71,562.

131. *Id.*

132. Guidance for Industry: Questions and Answers Regarding the Final Rule on Establishment and Maintenance of Records; Availability, 70 Fed. Reg. 53,728 (Sept. 12, 2005) (to be codified at 21 C.F.R. pt. 1).

133. *Id.*

134. See GAO, *Mad Cow Disease: An Evaluation of a Small Feed Testing Program FDA Implemented in 2003 with Recommendations for Making the Program a Better Oversight Tool*, GAO-06-157R, Oct. 2005, at 1-2, available at <http://www.gao.gov/new.items/d06157r.pdf>.

135. *Id.* at 3.

design and implementation that need to be addressed to improve its effectiveness.<sup>136</sup> The purpose of the small feed testing program is to “collect and analyze cattle and other types of animal feed and feed ingredients to determine whether feed that could be fed to cattle might contain material prohibited by [the] FDA’s feed-ban rule.”<sup>137</sup>

The GAO report specifically faults the program for three failures: first, not requiring the FDA district offices to document their follow-up reviews or the basis for their final determinations on samples that the laboratories identified as potentially containing banned protein products; second, taking longer than thirty days from the date the sample was collected until the date the laboratory completed its analysis for over half the samples tested, including twenty-one samples that took longer than 100 days; and third, the FDA managers not adequately overseeing the feed testing program.<sup>138</sup>

The GAO report recommends several steps for FDA to take to improve the effectiveness of the program, including implementation of an internal field management directive and an assignment memorandum, enforcement of proper periods of time for testing samples and follow-up activities, and increased oversight by headquarter managers.<sup>139</sup>

In comments included in the GAO report, FDA expressed concern with the report’s undue emphasis on “one small aspect of BSE oversight efforts.”<sup>140</sup> The GAO report did note that FDA plans to fully implement the directive and guidance issued earlier in 2005.<sup>141</sup>

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136. *See id.*

137. *Id.* at 2.

138. *Id.* at 4, 7-13.

139. *Id.* at 15.

140. *Id.*

141. *Id.*