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## United States Food Law Update: Labeling Controversies, Biotechnology Litigation, and the Safety of Imporeted Food

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# UNITED STATES FOOD LAW UPDATE: LABELING CONTROVERSIES, BIOTECHNOLOGY LITIGATION, AND THE SAFETY OF IMPORTED FOOD

A. Bryan Endres\*

## I. INTRODUCTION

This update summarizes significant changes and developments in food law throughout the first half of 2007. Out of necessity, not every change is included; rather, this update is limited to significant changes in national law. This series of updates provides 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 the discipline.

Significant regulatory developments within the context of three broad categories warrant discussion in this version of the *Food Law Update*: food labeling, agricultural biotechnology, and the safety of imported food. The *E. coli* outbreaks, discussed in the previous update,<sup>1</sup> alerted the public to the vulnerability of not only the meat and poultry supply to foodborne pathogens, but also the most wholesome of products, fresh produce. This unprecedented outbreak led to the questioning of the government's ability to oversee the food supply for its citizens. A series of problems involving contaminated imported food further shook the public's confidence in the food

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1. A. Bryan Endres, *United States Food Law Update*, 3 J. FOOD L. & POL'Y 103 (2007).

safety system and prompted President Bush to form a task force to identify and resolve systemic regulatory challenges. The government also suffered two significant setbacks related to its policy of biotechnology regulation, headlined by the inability to identify the source of rice contamination and the court ordered de-commercialization of a previously approved genetically engineered alfalfa variety. Many in the organic and non-genetically engineered food supply chain considered the alfalfa litigation an important step in recognizing the impact of genetic engineering on their economic welfare. Finally, two particular types of labeling claims were the subject of considerable attention during the first half of 2007. Food manufacturers, in their drive to differentiate their goods on the commodity grocery shelves and satisfy the desire of consumers for healthy, functional foods, succeeded in acquiring another qualified health claim with marginal scientific support. Meanwhile, other food processors stepped up challenges to the government's refusal to finalize rules for the ubiquitous use of the "natural" claim on food labels.

## II. FOOD LABELING

### A. FDA Industry Guidance for Labeling Claims

Although many consumers demonstrate a high degree of awareness of the use of food labels as a means to improve health through diet, general consumer comprehension of the details of food labels remains mixed.<sup>2</sup> To clarify the regulatory position of the

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2. *Winning the Claim Game: Confused by Label Claims for Health Benefits for Everything from Walnuts to Corn Oil? Here's How to Read the Fine Print*, 25 TUFTS UNIV. HEALTH & NUTRITION LETTER S1 (Aug 1, 2007) (discussing the health-labeling system that, according to some experts, has spun out of control); Susan Bora, *Consumer Perspectives on Food Labels*, 83 AM. J. CLINICAL NUTRITION 1235S, 1235S (2006 Supp.), available at <http://www.ajcn.org/cgi/reprint/83/5/1235S.pdf> (finding high consumer awareness of nutrition labels but confusion regarding percent daily value information and labels overall as too confusing); Andreas C. Drichoutis et al., *Consumers' Use of Nutritional Labels: A Review of Research Studies and Issues*, 9 ACAD. OF MKTG. SCI. REV. 1, 1 (2006), available at <http://www.amsreview.org/articles/drichoutis09-2006.pdf> (finding that nutritional labels affect purchasing behavior for consumers seeking to avoid negative nutrients in food products, although health claims may have mixed purchasing results); Sanjiv Agarwal et al., *Nutritional Claims for Functional Foods and Supplements*, 221 TOXICOLOGY 44, 44-48 (2006) (describing provisions to communicate healthfulness of a food product to consumers); J. Craig Rowlands & James E. Hoadley, *FDA Perspectives on Health Claims for Food Labels*, 221 TOXICOLOGY 35, 35 (2006) (noting that consumers may

Food and Drug Administration (FDA) with respect to the various categories of labeling claims—health claims,<sup>3</sup> structure/function claims,<sup>4</sup> nutrient content claims,<sup>5</sup> and dietary guidance<sup>6</sup>—the Center for Food Safety and Applied Nutrition issued a guidance letter to conventional food manufacturers and distributors reminding them of their responsibilities to ensure accurate food labeling information.<sup>7</sup> The agency also clarified its position that information disseminated via the Internet, by or on behalf of a regulated company, could constitute “labeling” under the Federal Food, Drug, and Cosmetic Act.<sup>8</sup> For example, a “labeling” would include information relating to a product promoted on and available for purchase directly from the company’s website.<sup>9</sup> In addition, a statement on a product referring consumers to a specific website with additional information regarding a claim for the product likely would constitute “labeling.”<sup>10</sup> Accordingly, the FDA advised all manufacturers and distributors to review their respective Internet sites for compliance with FDA regulations.<sup>11</sup>

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not be able to distinguish between a nutrient content claim and a health claim); Food & Drug Admin. (FDA), *Questions and Answers, Qualified Health Claims in Food Labeling, Report on Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims*, <http://www.cfsan.fda.gov/~dms/qhc-qa.html> (last visited Jan. 29, 2008) (discussing results of an FDA study regarding consumer confusion about qualified health claim labels) [hereinafter *FDA Questions and Answers*].

3. 21 C.F.R. § 101.14(a)(1) (2007) (defining “health claim” as a statement describing a relationship between a food or food substance and a disease or health-related condition).

4. *Id.* § 101.93(f) (defining “structure/function claim” as a statement describing the role of a nutrient intended to affect the structure or function of humans); see also FDA, *Structure/Function Claims*, <http://www.cfsan.fda.gov/~dms/labstruc.html> (last visited Jan. 29, 2008) (describing the FDA’s review of structure/function claims for conventional foods).

5. 21 C.F.R. § 101.13 (2007) (defining “nutrient content claim” as a description of the level of a nutrient in a particular food in comparison to another food or as a descriptive term such as free, high, or low).

6. See General Requirements for Health Claims for Food, 58 Fed. Reg. 2,478, 2,487 (Jan. 6, 1993) (codified at 7 C.F.R. pts. 20 and 101) (distinguishing health claims and dietary guidance statements).

7. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, GUIDANCE FOR INDUSTRY AND FDA, DEAR MANUFACTURER LETTER REGARDING FOOD LABELING (January 2007), available at <http://www.cfsan.fda.gov/~dms/flguid.html> [hereinafter *FDA Food Labeling Letter*].

8. *Id.*; see also 21 U.S.C. § 321(m) (1994) (defining “labeling” as “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article”).

9. FDA Food Labeling Letter, *supra* note 7.

10. *Id.*

11. *Id.*

### B. *Qualified Health Claims*

Health claims accompanying conventional food products intended for human consumption “characterize a relationship between a substance (a specific food component or a specific food) and a disease or health-related condition, and are supported by scientific evidence.”<sup>12</sup> Government sanctioned health claims arose from the Nutritional Labeling and Education Act of 1990.<sup>13</sup> While not requiring unanimity, the FDA requires unqualified health claims to be supported by “significant scientific agreement” among experts in the area.<sup>14</sup> For several years, the FDA rejected outright all health claims that failed to meet the significant scientific agreement standard.

The FDA’s eventual authorization of “qualified” health claims developed, in part, in response to constitutional challenges to the significant scientific agreement standard. In *Pearson v. Shalala*,<sup>15</sup> the United States Court of Appeals for the District of Columbia held that the agency infringed upon the petitioner’s First Amendment rights when it refused to consider whether a disclaimer might eliminate consumer confusion relating to the proposed health claim that has some scientific support but was disallowed because the claim lacked significant scientific agreement.<sup>16</sup> As a result, the FDA, in December 2002, announced its intention to allow on conventional foods health claims with qualifying statements regarding the degree of scientific certainty.<sup>17</sup> In July 2003, the FDA issued further indus-

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12. *FDA Questions and Answers*, *supra* note 2.

13. See Nutritional Labeling and Education Act of 1990, Pub. L. No. 101-535, § 301, 104 Stat. 2,353 (1990). For implementing regulations, see General Requirements for Health Claims for Food, 58 Fed. Reg. 2,478 (Jan. 6, 1993) (codified at 21 C.F.R. pts. 20 and 101).

14. FDA, GUIDANCE FOR INDUSTRY, SIGNIFICANT SCIENTIFIC AGREEMENT IN THE REVIEW OF HEALTH CLAIMS FOR CONVENTIONAL FOODS AND DIETARY SUPPLEMENTS (Dec. 22, 1999), available at <http://www.cfsan.fda.gov/~dms/ssaguide.html>.

15. See generally *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999).

16. See *id.* at 657-58. For a more thorough discussion of *Pearson*, see Martin Hahn, *Functional Foods: What are They? How are they Regulated? What Claim can be Made?*, 31 AM. J.L. & MED. No. 2-3, 305, 320-22 (2005); and Amber K. Spencer, Note, *FDA Knows Best . . . or Does It? First Amendment Protection of Health Claims on Dietary Supplements: Pearson v. Shalala*, 15 B.Y.U. J. PUB. L. 87 (2000) (discussing *Pearson* and advocating a policy of more rather than less information when confronted with scientific uncertainty).

17. See Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements; Availability, 67 Fed. Reg. 78,002 (Dec. 20, 2002) (providing guidance for industry for qualified health claims in the labeling for food and dietary supplements).

try guidance including procedures and criteria for exercise of the agency's enforcement discretion for qualified claims.<sup>18</sup>

Under the current rules, the agency classifies proposed health claims into one of four categories. Category "A" claims meet the significant scientific agreement standard<sup>19</sup> and may be used without qualification.<sup>20</sup> Claims in which the agency has a "moderate or good level of comfort"<sup>21</sup> are category "B" and require qualifying language such as "although there is scientific evidence supporting the claim, the evidence is not conclusive."<sup>22</sup> Category "C" and "D" claims have "a low level of comfort" or "an extremely low level of comfort,"<sup>23</sup> respectively, and stronger accompanying disclaimers.<sup>24</sup> As of this writing, the FDA has approved fifteen petitions for qualified health claims.<sup>25</sup>

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18. FDA, GUIDANCE FOR INDUSTRY, INTERIM PROCEDURES FOR QUALIFIED HEALTH CLAIMS IN THE LABELING OF CONVENTIONAL HUMAN FOOD AND HUMAN DIETARY SUPPLEMENTS, available at <http://www.cfsan.fda.gov/~dms/hclmgui3.html> [hereinafter FDA INTERIM PROCEDURES].

19. FDA Questions and Answers, *supra* note 2.

20. See FDA INTERIM PROCEDURES, *supra* note 18.

21. FDA Questions and Answers, *supra* note 2.

22. FDA INTERIM PROCEDURES, *supra* note 18.

23. FDA Questions and Answers, *supra* note 2.

24. See generally FDA INTERIM PROCEDURES, *supra* note 18. Level "C" claims require the following disclaimer: "[s]ome scientific evidence suggests . . . however, FDA has determined that this evidence is limited and not conclusive." *Id.* Level "D" claims, the lowest category allowed by the FDA, require the following disclaimer: "[v]ery limited and preliminary scientific research suggests . . . FDA concludes that there is little scientific evidence supporting this claim." *Id.*

25. FDA, *Qualified Health Claims*, available at <http://www.cfsan.fda.gov/~dms/lab-qhc.html>. The first petition for a qualified health claim arose from a court order in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), directing the FDA to reconsider a proposed health claim that folic acid reduced the risk of neural tube defects. In an October 10, 2000 letter of enforcement discretion, the agency stated its intention to consider the exercise of its enforcement discretion with regard to the proposed qualified health claims in dietary supplement labeling. FDA, LETTER REGARDING DIETARY SUPPLEMENT HEALTH CLAIM FOR FOLIC ACID WITH RESPECT TO NEURAL TUBE DEFECTS, available at <http://www.cfsan.fda.gov/~dms/ds-ltr7.html>. The second and third petitions also arose from litigation. See *Whitaker v. Thompson*, 248 F. Supp. 2d 1 (D.D.C. 2002). In a May 15, 2001 letter of enforcement discretion and a November 28, 2000 letter, the FDA agreed to exercise enforcement discretion over the proposed qualified claims that folic acid, vitamin B<sub>6</sub>, and vitamin B<sub>12</sub> decrease the risk of vascular disease. FDA, *Settlement Reached for Health Claim Relating B Vitamins and Vascular Disease*, available at <http://www.cfsan.fda.gov/~dms/ds-hclbv.html>; FDA, LETTER REGARDING DIETARY SUPPLEMENT HEALTH CLAIM FOR FOLIC ACID, VITAMIN B<sub>6</sub>, AND VITAMIN B<sub>12</sub> AND VASCULAR DISEASE, available at <http://www.cfsan.fda.gov/~dms/ds-ltr12.html>. In a letter of enforcement discretion dated April 1, 2003, the FDA also agreed to con-

sider exercising enforcement discretion over a qualified health claim that the consumption of antioxidant vitamins may reduce the risk of certain forms of cancer. FDA, LETTER REGARDING DIETARY SUPPLEMENT HEALTH CLAIM FOR ANTIOXIDANT VITAMINS AND RISK OF CERTAIN CANCERS, *available at* <http://www.cfsan.fda.gov/~dms/ds-ltr34.html>.

The Tree Nut Council Research and Education Foundation and the California Walnut Commission, in 2002, filed the fourth set of petitions, seeking authorization for a qualified health claim about the relationship between nuts and coronary heart disease. The FDA responded with a July 14, 2003 letter and a March 9, 2004 letter, in which the agency agreed to exercise enforcement discretion over a qualified health claim linking consumption of walnuts to a reduced risk of coronary heart disease. FDA, QUALIFIED HEALTH CLAIMS: LETTER OF ENFORCEMENT DISCRETION—NUTS AND CORONARY HEART DISEASE (2003), *available at* <http://www.cfsan.fda.gov/~dms/qhcnuts2.html>; FDA, QUALIFIED HEALTH CLAIMS: LETTER OF ENFORCEMENT DISCRETION—WALNUTS AND CORONARY HEART DISEASE (2004), *available at* <http://www.cfsan.fda.gov/~dms/qhcnuts3.html>.

Dr. Kyl Smith filed the fifth successful petition for a qualified health claim in 2002 relating to the relationship between phosphatidylserine and cognitive function and dementia. In its letter of enforcement discretion dated November 24, 2004, the FDA reaffirmed its decision in its May 13, 2003 letter, exercising enforcement discretion for the requested claims. FDA, LETTER UPDATING THE PHOSPHATIDYLSERINE AND COGNITIVE FUNCTION AND DEMENTIA QUALIFIED HEALTH CLAIM (2004), *available at* <http://www.cfsan.fda.gov/~dms/ds-ltr39.html>; FDA, PHOSPHATIDYLSERINE AND COGNITIVE DYSFUNCTION AND DEMENTIA (QUALIFIED HEALTH CLAIM: FINAL DECISION LETTER) (2003), *available at* <http://www.cfsan.fda.gov/~dms/ds-ltr36.html>.

Wellness Lifestyles, Inc. filed the sixth successful claim. In an April 28, 2003 letter of enforcement discretion, the FDA agreed to consider extending enforcement discretion over a qualified health claim that selenium may reduce the risk of certain cancers. FDA, SELENIUM AND CERTAIN CANCERS (QUALIFIED HEALTH CLAIM: FINAL DECISION LETTER), *available at* <http://www.cfsan.fda.gov/~dms/ds-ltr35.html>. Wellness Lifestyles, Inc. and Martek Biosciences Corporation filed the seventh set of petitions seeking FDA authorization of a health claim for the consumption of omega-3 fatty acids and a reduced risk of coronary heart disease. On September 8, 2004, FDA responded to both petitions with two letters of enforcement discretion. FDA, LETTER RESPONDING TO HEALTH CLAIM PETITION DATED NOVEMBER 3, 2003 (MARTEK PETITION): OMEGA-3 FATTY ACIDS AND REDUCED RISK OF CORONARY HEART DISEASE, *available at* <http://www.cfsan.fda.gov/~dms/ds-ltr37.html>; FDA, LETTER RESPONDING TO HEALTH CLAIM PETITION DATED JUNE 23, 2003 (WELLNESS PETITION): OMEGA-3 FATTY ACIDS AND REDUCED RISK OF CORONARY HEART DISEASE, *available at* <http://www.cfsan.fda.gov/~dms/ds-ltr38.html>.

The eighth petition for a qualified health claim, filed by Nutrition 21, Inc. in 2003, involved the relationship between chromium picolinate and a reduced risk of insulin resistance and therefore type two diabetes. In an August 25, 2005 letter of enforcement discretion, the FDA concluded there was very limited credible evidence for the qualified health claim, but agreed to consider the exercise of its enforcement discretion for the requested claim. FDA, QUALIFIED HEALTH CLAIMS: LETTER OF ENFORCEMENT DISCRETION—CHROMIUM PICOLINATE AND INSULIN RESISTANCE, *available at* <http://www.cfsan.fda.gov/~dms/qhccr.html>.

Marine Bio USA, Inc. filed the ninth successful petition for qualified health claims in 2003. The petition involved the relationship between consumption of calcium and a reduced risk of hypertension. The FDA responded with a letter of enforcement discretion dated October 12, 2005. FDA, QUALIFIED HEALTH CLAIMS: LETTER OF ENFORCEMENT DISCRETION—CALCIUM AND HYPERTENSION; PREGNANCY-INDUCED HYPERTENSION; AND PREECLAMPSIA, *available at* <http://www.cfsan.fda.gov/~dms/qhcca3.html>. Marine Bio USA, Inc. also succeeded in acquiring the tenth qualified health claim for the relationship between calcium and certain cancers. In its 2003 petition, Marine Bio requested that the agency authorize a health claim that calcium may reduce the risk of prostate, colorectal, colon, rectal, and breast cancers as well as recurrent colon polyps. In a letter of enforcement discretion dated October 12, 2005, the FDA concluded that there is no credible evidence to support qualified health claims about calcium and breast or prostate cancer, but that the FDA would consider exercising enforcement discretion over qualified health claims about calcium and colon/rectal cancer and colon/rectal polyps. FDA, QUALIFIED HEALTH CLAIMS: LETTER REGARDING CALCIUM AND COLON/RECTAL, BREAST, AND PROSTATE CANCERS AND RECURRENT COLON POLYPS, *available at* <http://www.cfsan.fda.gov/~dms/qhcca2.html>.

In 2003, the North American Olive Oil Association filed the eleventh successful qualified health claim petition regarding the consumption of monounsaturated fatty acids from olive oil and a reduced risk of coronary heart disease. In a letter dated November 1, 2004, the FDA stated its intention to consider exercising enforcement discretion over the requested qualified health claim. FDA, LETTER RESPONDING TO HEALTH CLAIM PETITION DATED AUGUST 28, 2003: MONOUNSATURATED FATTY ACIDS FROM OLIVE OIL AND CORONARY HEART DISEASE, *available at* <http://www.cfsan.fda.gov/~dms/qhcolive.html>.

Fleminger, Inc. submitted the twelfth successful petition for a qualified health claim in 2004, requesting the FDA to authorize a claim linking the consumption of green tea with a reduced risk of cancer. After a scientific review, the agency issued a letter of enforcement on June 30, 2005, stating that there is no credible evidence to support qualified health claims for green tea consumption and a reduced risk of gastric, lung, colon/rectal, esophageal, pancreatic, ovarian, and combined cancers. The FDA, however, agreed to consider exercising enforcement discretion as to claims specifically for green tea and breast and prostate cancer. FDA, LETTER RESPONDING TO HEALTH CLAIM PETITION DATED JANUARY 27, 2004: GREEN TEA AND REDUCED RISK OF CANCER HEALTH CLAIM, *available at* <http://www.cfsan.fda.gov/~dms/qhc-gtea.html>.

In 2004, American Longevity, Inc. and the Lycopene Health Claim Coalition petitioned the FDA for qualified health claims that lycopene from tomatoes reduces the risk of certain types of cancer, such as prostate cancer. On November 8, 2005, the FDA issued two letters of enforcement discretion, stating that the current scientific evidence for the proposed qualified health claims relating to the consumption of tomatoes and/or tomato sauce and reduced risk of cancer is appropriate for consideration as a qualified health claim, but that claims about the relationship between the consumption of lycopene and cancer did not have a sufficient scientific basis to support a qualified health claim. FDA, QUALIFIED HEALTH CLAIMS: LETTER REGARDING TOMATOES AND PROSTATE, OVARIAN, GASTRIC AND PANCREATIC CANCERS (AMERICAN LONGEVITY PETITION), *available at* <http://www.cfsan.fda.gov/~dms/qhclyco.html>; FDA, QUALIFIED HEALTH CLAIMS: LETTER REGARDING



On March 26, 2007, the agency, despite what some critics contend is little scientific evidence in support,<sup>26</sup> approved a qualified health claim for corn oil.<sup>27</sup> Specifically, the qualified health claim relates consumption of unsaturated fatty acids from corn oil in substitution for saturated fatty acids while not increasing caloric intake to a reduced risk of coronary heart disease.<sup>28</sup> The FDA approved the qualified claim under its category "D" criteria with relatively strong limiting language.<sup>29</sup>

The controversy arising from the recent approval of a qualified health claim for corn oil illustrates the current debate among nutrition policy experts,<sup>30</sup> and within the FDA,<sup>31</sup> regarding the effectiveness of the disclaimers and concerns that a proliferation of very

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TOMATOES AND PROSTATE CANCER (LYCOPENE HEALTH CLAIM COALITION), *available at* <http://www.cfsan.fda.gov/~dms/qhclcyco2.html>.

The U.S. Canola Association, in 2006, filed the fourteenth successful petition for a qualified health claim involving consumption of unsaturated fatty acids in canola oil and a reduced risk of coronary heart disease. On October 6, 2006, the FDA responded with a letter of enforcement discretion stating that it would consider extending enforcement discretion for the proposed qualified health claim. FDA, QUALIFIED HEALTH CLAIMS: LETTER OF ENFORCEMENT DISCRETION—UNSATURATED FATTY ACIDS FROM CANOLA OIL AND REDUCED RISK OF CORONARY HEART DISEASE, *available at* <http://www.cfsan.fda.gov/~dms/qhccanol.html>.

ACH Food Companies, Inc. submitted the fifteenth and most controversial request for a qualified health claim in 2006, for corn oil and a reduced risk of heart disease. The FDA responded in a March 26, 2007 letter of enforcement discretion concluding that sufficient scientific evidence existed to warrant enforcement discretion over the requested qualified health claim. FDA, QUALIFIED HEALTH CLAIMS: LETTER OF ENFORCEMENT DISCRETION—CORN OIL AND CORN OIL-CONTAINING PRODUCTS AND A REDUCED RISK OF HEART DISEASE, *available at* <http://www.cfsan.fda.gov/~dms/qhccorno.html>. For further discussion of the corn oil health claim, see *infra* notes 27-32 and accompanying text.

26. See Karen Ravn, *Corn Oil—Good for You?*, L.A. TIMES, April 16, 2007, at F3 (quoting Marion Nestle, professor of nutrition at New York University).

27. FDA, QUALIFIED HEALTH CLAIMS: LETTER OF ENFORCEMENT DISCRETION—CORN OIL AND CORN OIL-CONTAINING PRODUCTS AND A REDUCED RISK OF HEART DISEASE, *supra* note 25.

28. *Id.*

29. *Id.*

30. See *Winning the Claim Game*, *supra* note 2 (noting that in the consumer's mind, the fine distinctions between disclaimers are often blurred and add to the confusing maze of health labeling rules, and quoting Professor Tillotson's concerns that the public will regard the claims as "nothing more than product puffery" with those firms making a valid attempt at high level research and development to provide worthwhile health benefits eventually losing out).

31. FDA *Questions and Answers*, *supra* note 2 (discussing the FDA's findings that qualifying statements were "not understood by consumers" and even when understood as intended, resulted in "unexpected effects on consumers' judgments about the health benefits and overall healthfulness of the product").

weak claims, even if accompanied by legalistic disclaimers, may eventually “crowd out” the effectiveness of unqualified, category “A” health claims and those qualified health claims with higher levels of scientific support. Although the “corn oil” claim engendered a fair amount of public criticism this past spring, the FDA is unlikely to further address this issue via rulemaking in the near term. Rather, the agency will continue to scrutinize proposed claims, rejecting those wholly lacking in scientific support.<sup>32</sup>

Concerns regarding qualified health claims relate to the larger issue of products marketed as “functional foods.”<sup>33</sup> The Institute of Food Technologists (IFT) defines “functional foods” as “food and food components that provide a health benefit beyond basic nutrition . . . .”<sup>34</sup> The FDA regulates additives and labeling claims made for functional foods under the existing regulatory framework for conventional foods.<sup>35</sup> The IFT, as well as the Government Accountability Office, recommended that the FDA develop and promulgate regulations or industry guidance to address specifically functional foods.<sup>36</sup> On December 5, 2006, the FDA held a public hearing to gather information regarding regulation of conventional food marketed as functional foods<sup>37</sup> and later extended the comment period to March 5, 2007.<sup>38</sup> Future updates will track the agency’s progress with respect to functional food regulation.

### *C. Defining “Natural” in USDA and FDA Regulated Food Products*

For more than three decades, various federal agencies have grappled with regulating the term “natural” on food labels. Advances in technology, including new uses for additives otherwise deemed “natural,” pose challenges to existing policies. Consumers have become increasingly interested in food additives and labels,

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32. As of this writing, the FDA has issued letters of denial for at least fifteen petitions for qualified health claims. See FDA, *Qualified Health Claims*, *supra* note 25.

33. Conventional Foods Being Marketed as “Functional Foods”; Public Hearing; Request for Comments, 71 Fed. Reg. 62,400, 62,401 (Oct. 25, 2006).

34. *Id.* at 62,401.

35. *Id.* Moreover, FDA does not consider “functional foods” to be dietary supplements. *Id.*

36. *Id.* at 62,403 (Government Accountability Office recommendation); *id.* at 62,405 (Institute of Food Technologists recommendation).

37. *Id.* at 62,400 (providing notice of meeting date).

38. Conventional Foods Being Marketed as “Functional Foods”; Extension of Comment Period, 72 Fed. Reg. 694 (Jan. 8, 2007) (extending comment period for functional food proposed regulations).

and the food industry seeks to exploit consumers' willingness to pay for what they perceive as a more wholesome product. Recognizing this new market paradigm, the United States Department of Agriculture (USDA) Food Safety Inspection Service (FSIS) is reconsidering its twenty-five-year-old policy and has initiated a formal rulemaking process for "natural" labels for meat and poultry products. The history of foot-dragging at developing a regulation may not repeat itself, however. The USDA faces an industry lawsuit for its failure to develop a consistent policy for "natural" claims, including allegations that recent policy changes have favored less-innovative competitors. The FDA also has not been immune to recent controversy surrounding "natural" claims. Pending before the FDA are two industry petitions requesting that the FDA work jointly with the FSIS to develop a uniform policy concerning the term "natural."

## 1. The History of "Natural" Claim Rulemaking

The Federal Trade Commission (FTC) was the first agency to attempt regulation of "natural" label claims in the 1970s.<sup>39</sup> The agency terminated its rulemaking in 1983, however, concluding that "natural" claims would continue to be evaluated on a case-by-case basis.<sup>40</sup> The Bureau of Alcohol, Tobacco and Firearms followed suit in 1985.<sup>41</sup> The FDA also attempted to define the term through a rule in the early 1990s,<sup>42</sup> but ultimately concluded that resource limitations and other agency priorities precluded rulemaking at that time.<sup>43</sup>

In 1982, the FSIS established guidance for "natural" label claims on meat and poultry products, based in part on the FTC recommendations stemming from its aborted rulemaking process of the early 1980s. Under the guidance system, manufacturers submit la-

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39. Proposed Trade Regulation Rule, 39 Fed. Reg. 39,842 (Nov. 11, 1974); Proposed Trade Regulation Rule, 40 Fed. Reg. 23,086 (May 28, 1975); Final Notice Regarding Proposed Trade Regulation Rule, 41 Fed. Reg. 8,980 (Mar. 2, 1976).

40. Termination of Proposed Trade Regulation; Rule on Food Advertising, 48 Fed. Reg. 23,270 (May 24, 1983).

41. Use of "Natural" in the Labeling and Advertising of Alcoholic Beverages, 50 Fed. Reg. 906, 960-61 (Jan. 8, 1985) (withdrawing the "natural" issue from notice of proposed rulemaking).

42. Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60,421, 60,466 (Nov. 27, 1991).

43. Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2,302, 2,407 (Jan. 6, 1993).

bels bearing “natural” claims to the FSIS Labeling and Consumer Protection staff before applying the labeling to products. The FSIS determines the appropriateness of the label on a case-by-case basis. As the process evolved, the FSIS developed guidance memos incorporated into the FSIS Food Standards and Labeling Policy Book.<sup>44</sup> One of these memos—Policy Memorandum 055 (Policy Memo 055)—governs the pre-market approval process for “natural” labels on meat and poultry products.<sup>45</sup> Guidance is not contained in formal regulations.

Policy Memo 055 states that products may bear the “natural” label if: “(1) the product does not contain any artificial flavor or flavoring, coloring ingredient, or chemical preservative (as defined in 21 C.F.R. § 101.22), or any other artificial or synthetic ingredient; and (2) the product and its ingredients are not more than minimally processed.”<sup>46</sup> Minimal processing includes traditional methods of processing or preserving such as “smoking, roasting, freezing, drying or fermenting,” or physical processes that “do not fundamentally alter the raw product” or which only separate parts from the whole (e.g., grinding meat or pressing fruit to make juice).<sup>47</sup>

Manufacturers must explain on the label near the “natural” claim that the product is considered natural because “it contains no artificial ingredients, and is minimally processed . . . .”<sup>48</sup> Policy Memo 055 allows for exceptions on a case-by-case basis if the proposed ingredient “would not significantly change the character of the product to the point where it could no longer be considered a natural product.”<sup>49</sup> But, manufacturers must conspicuously identify the excepted ingredient on the label.<sup>50</sup> The FSIS judges the “natural” claim on a contextual basis as well. For example, a “turkey roast” cannot be called a natural *product* if it contains beet coloring, but can still bear the statement “all natural ingredients.”<sup>51</sup>

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44. See Food Safety Inspection Serv. (FSIS), Transcript of Public Meeting, Product Labeling: Definition of the Term “Natural” 19-20 (Dec. 12, 2006), *available at* [http://www.fsis.usda.gov/PDF/Natural\\_Claims\\_Transcripts.pdf](http://www.fsis.usda.gov/PDF/Natural_Claims_Transcripts.pdf). [hereinafter FSIS Transcript].

45. FSIS, FOOD STANDARDS AND LABELING POLICY BOOK (Aug. 2005), *available at* [http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling\\_Policy\\_Book\\_082005.pdf](http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_Policy_Book_082005.pdf) [hereinafter LABELING POLICY BOOK]. This version contains an explanation of the policy that was in place prior to the August 2005 changes.

46. *Id.* at 116.

47. *Id.*

48. *Id.*

49. *Id.*

50. LABELING POLICY BOOK, *supra* note 45, at 116.

51. See FSIS Transcript, *supra* note 44, at 24.

In August 2005, the FSIS modified Policy Memo 055 by adding what quickly became a very controversial addendum. The additional language stated that “[s]ugar, sodium lactate (from a corn source), natural flavorings from oleoresins or extractives are acceptable for ‘all natural’ claims.”<sup>52</sup> The new policy also referred to the National Organic Program’s (NOP) National List of Allowed and Prohibited Substances<sup>53</sup> for a list of acceptable ingredients allowed for “all natural” claims.

## 2. The October 2006 Hormel Petition

In response to the August 2005 changes, Hormel Foods Corporation filed a petition with the FSIS in October 2006 requesting that the agency initiate rulemaking procedures to define the term “natural” and the circumstances under which it can be used.<sup>54</sup> In the petition, Hormel advocated placing a formal definition of “natural” in the FSIS’s false or misleading labeling regulations.<sup>55</sup> Hormel argued that in the absence of a regulation, consumer confusion will continue to grow.<sup>56</sup> Hormel cited industry and citizen group efforts to prevent misleading “natural” claims that result from ambiguous policies, including the Sugar Association’s petition<sup>57</sup> before the FDA and the Center for Science in the Public Interest’s (CSPI) requests for enforcement actions and threatened lawsuits.<sup>58</sup>

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52. See LABELING POLICY BOOK, *supra* note 45; see also Product Labeling: Definition of the Term “Natural,” 71 Fed. Reg. 70,503, 70,504 (Dec. 5, 2006).

53. 7 C.F.R. §§ 205.601-606 (2007).

54. Hormel Foods Corporate Services, LLC Petition to FSIS, Re: Issuance of a Rule Regarding Natural Label Claims (October 9, 2006), *available at* [http://www.fsis.usda.gov/PDF/Petition\\_Natural\\_Label\\_Claims1.pdf](http://www.fsis.usda.gov/PDF/Petition_Natural_Label_Claims1.pdf) [hereinafter Hormel Petition].

55. See *generally id.*; see also 9 C.F.R. § 317.8 (2007) (meat) and § 381.129 (poultry).

56. Hormel Petition, *supra* note 54, at 5-8.

57. Sugar Ass’n Petition to FDA, Re: Definition of the Term “Natural” For Making Claims on Food and Beverages Regulated by the Food and Drug Administration (February 28, 2006), *available at* [http://www.cspinet.org/new/pdf/sugar\\_fda\\_petition.pdf](http://www.cspinet.org/new/pdf/sugar_fda_petition.pdf) [hereinafter Sugar Ass’n Petition]. For a more thorough discussion of the sugar industry’s petition, see *infra* notes 86-94 and accompanying text.

58. The Center for Science in the Public Interest (CSPI) sued Kraft for its “natural” claim on Capri Sun drinks sweetened with high-fructose corn syrup, an ingredient the CSPI alleged was not “minimally processed” under the 1982 Policy. Kraft eventually agreed to drop the claim. See Complaint, Linda Rex v. Kraft Foods, Inc. (Fla. Palm Beach County Ct. Jan. 8, 2007), *available at* <http://cspinet.org/new/pdf/complaint.pdf>. Cadbury Schweppes also agreed to drop a similar “all natural” claim after the CSPI threatened suit. See Press Release, CPSI, CPSI to Sue

Hormel's petition identified internal inconsistencies in the new FSIS policy. Hormel noted that while one part of the policy states that "natural" foods cannot contain any artificial flavors or flavorings, coloring ingredient, or chemical preservatives, newly added language allowed ingredients from the NOP National List.<sup>59</sup> Therefore, it is unclear whether "natural chili" could be labeled as such if it was colored with an ingredient on the NOP list such as beet powder.<sup>60</sup> Hormel further argued that allowing the use of synthetic ingredients from the National List was inconsistent with the prohibition against artificial flavor or color.<sup>61</sup> Hormel concluded by arguing that sodium lactate is a chemical preservative, and its inclusion as an allowable ingredient in products labeled as "natural" was inconsistent with previous policies.<sup>62</sup>

### 3. Formal Rulemaking Process for "Natural" Claims

In December 2006, the FSIS announced that it would remove the sodium lactate provision from Policy Memo 055 due to the controversy it caused within the regulated community.<sup>63</sup> The FSIS added language to Policy Memo 055 indicating that sodium lactate would be judged on a case-by-case basis pending a final rule on the term "natural."<sup>64</sup> The reference to the NOP National List was also removed. The FSIS explained that it only added the reference to the NOP National List to help manufacturers locate sources for ingredients that could be used in "natural" products, but that the statement confused manufacturers by implying that all organic ingredients could be used in "natural" products—a situation that the FSIS states is not allowed.<sup>65</sup>

The FSIS concluded that it would initiate formal rulemaking in an attempt to resolve the sodium lactate and other escalating controversies stemming from Policy Memo 055 and the August 2005

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Cadbury Schweppes Over "All Natural" 7-Up (May 11, 2006), <http://www.cspinet.org/new/200605111.html> (last visited Feb. 20, 2008).

59. Hormel Petition, *supra* note 54, at 9.

60. *Id.*

61. *Id.*

62. *Id.* at 11-12.

63. Product Labeling: Definition of the Term "Natural," 71 Fed. Reg. 70,503, 70,504 (Dec. 5, 2006) (providing notice of the Hormel petition and requesting public comments).

64. LABELING POLICY BOOK, *supra* note 45.

65. *Id.*

changes.<sup>66</sup> The FSIS also acknowledged several allegations contained in the Hormel petition, including arguments that the August 2005 policy changes made it difficult for manufacturers to maintain a level playing field, and that some manufacturers would take advantage of perceived inconsistencies in the policy and manipulate exceptions in a way that would undercut the effectiveness of the “natural” label and regulatory intent.<sup>67</sup>

The FSIS held a public meeting<sup>68</sup> to discuss certain issues raised by the Hormel petition, including consumer expectations of a “natural” label, the types of food processing methods commonplace today versus twenty-four years ago when the policy on “natural” claims was established, and whether a “minimally processed” standard should remain a requirement of the “natural” label.<sup>69</sup> The public hearing also sought to address whether ingredients or processes that would otherwise disqualify a product from bearing the “natural” label but would enhance food safety—for example, sodium lactate or high pressure processing—should be excepted.<sup>70</sup> The FSIS also solicited public comment through January 2007, and later extended the comment period through March 5, 2007.<sup>71</sup>

The FSIS has yet to issue any further statement or rule regarding the hearing and public comments. Some written comments and oral testimony focused on the value to the regulated community of transparency and consistency in the FSIS determinations,<sup>72</sup> and on the fact that case-by-case determinations have resulted in varied meanings of the word “natural.”<sup>73</sup> Other comments have noted the emphasis in existing policy on processing methods and ingredients, despite growing consumer awareness and concern over how animals

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66. 71 Fed. Reg. at 70,504.

67. *Id.*

68. The hearing was held on December 12, 2006. See FSIS Transcript, *supra* note 44.

69. 71 Fed. Reg. at 70,504.

70. *Id.*

71. Product Labeling: Definition of the Term “Natural,” 72 Fed. Reg. 2,257 (Jan. 18, 2007). The comments can be found at <http://www.fsis.usda.gov/OPPDE/Comments/2006-0040/> (last visited Mar. 26, 2008).

72. See Sara Lee Food & Beverage Corp., Citizen Petition: requesting the Food Safety & Inspection Service to Develop requirements for the Use of the Term “Natural” Consistent with the Food & Drug Administration, Mar. 5, 2007, *available at* <http://www.fsis.usda.gov/OPPDE/Comments/2006-00400?2006-0400-24.pdf>.

73. N. Am. Natural Casing Ass’n, Comments, Docket No. FSIS-2006-0400: Product Labeling: Definition of the term “Natural,” Mar. 5, 2007, *available at* <http://www.fsis.usda.gov/OPPDE/Comments/2006-0040-25.pdf>.

are raised.<sup>74</sup> One commenter noted that the FSIS should work with the Agricultural Marketing Service (AMS) for claims involving naturally-raised livestock.<sup>75</sup> Many commenters expressed concern that Hormel's claim—that sodium lactate is a chemical preservative because it is not minimally processed or because it results in food preservation—might result in future preclusion of other ingredients that the FSIS has previously allowed as preservatives for naturally-labeled food.<sup>76</sup>

#### 4. The Hormel Foods Lawsuit

Despite the FSIS's initial attempts to redefine "natural," in September 2007, Hormel Foods Corporation filed a complaint in the U.S. District Court for the District of Columbia alleging that the USDA has failed to rescind approval of "natural" label claims on certain meat and poultry products marketed by Hormel's competitors that contain sodium lactate and potassium lactate, even after issuing letters indicating the contrary.<sup>77</sup> Hormel claimed that the USDA's failure to rescind approval of "natural" claims results in misbranding<sup>78</sup> under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), and contravenes the

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74. See, e.g., Farm Sanctuary, Inc., Comments, Docket No. FSIS-2006-0400: Product Labeling: Definition of the term "Natural," Jan. 10, 2007, *available at* <http://www.fsis.usda.gov/OPPDE/Comments/2006-0040-11.pdf>.

75. See, e.g., Am. Ass'n of Meat Processors, Comments, Docket No. FSIS-2006-0400: Product Labeling: Definition of the term "Natural," Jan. 11, 2007, *available at* <http://www.fsis.usda.gov/OPPDE/Comments/2006-0040-13.pdf>.

76. Nat'l Meat Ass'n, Comments, Docket No. FSIS-2006-0400: Product Labeling: Definition of the term "Natural," Dec. 12, 2006, *available at* <http://www.fsis.usda.gov/OPPDE/Comments/2006-0040-17.pdf>.

77. See *generally* Complaint, Hormel Foods Corp. v. USDA, No. 07-1724 (D.D.C. Sept. 26, 2007) [hereinafter Hormel Complaint]. At the same time that the FSIS announced that it was rescinding the note to Policy Memo 055 regarding sodium lactate, it sent letters to thirty members of the regulated community regarding the use of lactates in their products. *Id.* at 15-17. The FSIS requested that users of lactates show, within sixty days, that use of lactates below the 2% threshold was only for flavoring purposes and that lactates in their product do not function as preservatives. *Id.* at 16. Thirty members of the industry responded. *Id.* at 17. The FSIS has stated that it will not rescind any natural label permissions that have been issued for products containing sodium lactate or potassium lactate, and will instead pursue resolution through the rulemaking process. *Id.* at 17-18.

78. "Misbranding" under the Federal Meat Inspection Act or Poultry Products Inspection Act occurs if a label "bears or contains any artificial flavoring, artificial coloring, or *chemical preservative*, unless it bears labeling stating that fact . . . ." 21 U.S.C. § 601(h)(11); § 458(n)(11) (2000) (emphasis added).



FSIS's Policy Memo 055, because products bearing the claim: (1) contain less than 2% of sodium lactate and potassium lactate for preservative purposes, (2) do not display the fact that the product contains preservatives on the label, and (3) are not minimally processed.<sup>79</sup> Hormel further asserted that the USDA "act[ed] arbitrarily, capriciously, or contrary to law" under the Administrative Procedure Act (APA) by not rescinding the "natural" label approvals according to its own findings, even though it stated that it would do so in letters to the regulated community.<sup>80</sup> Hormel contended that the USDA further violated the APA by failing to conduct notice and comment rulemaking before making its decision not to rescind the "natural" labels.<sup>81</sup> Hormel also argued that the USDA's failure amounts to abdication of its statutory responsibilities under the FMIA and the PPIA.<sup>82</sup>

Hormel sought a declaration from the court that the USDA has approved "natural" labels for products that contain sodium or potassium lactate acting as a chemical preservative and, moreover, that the agency must require a disclaimer in these instances acknowledging use of the chemical preservatives and that the product is not "minimally processed."<sup>83</sup> Hormel also sought a declaration that the USDA violated the APA by failing to provide the rationale for acting inconsistently with its prior determination that products labeled as "natural" cannot contain sodium lactate or potassium lactate for preservative purposes, for its failure to rescind approval of such labels, and for failing to conduct notice and comment rulemaking before making the decision to grant an exemption from what Hormel claims is misbranding under the governing statutes.<sup>84</sup> Hormel asked the court to enjoin the USDA from approving such products for sale without a label stating that they are preserved using sodium lactate or potassium lactate, and that existing approvals be rescinded.<sup>85</sup>

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79. Hormel Complaint, *supra* note 77, at 20.

80. *Id.* at 21.

81. *Id.* at 22.

82. *Id.*

83. *Id.* at 22-23.

84. Hormel Complaint, *supra* note 77, at 23.

85. *Id.* at 23-24.

## 5. Petitions Before the FDA Regarding “Natural” Claims

As of this writing, two petitions are pending before the FDA requesting action relating to use of the term “natural” on food labels. The first petition was filed by the Sugar Association on February 28, 2006, requesting that the FDA Commissioner “establish rules and regulations governing the definition of ‘natural’ before a natural claim can be made on food and beverages regulated by the FDA.”<sup>86</sup> The Sugar Association asked the FDA to “maintain consistency across Federal agencies and define the term ‘natural’ based on the definition provided in the United States Department of Agriculture (USDA) *Food Standards and Labeling Policy Book*,” and proposed a policy mirroring that of Policy Memo 055.<sup>87</sup> The petition noted that even though consumer interest in natural labels has grown, the lack of a concise FDA rule regarding the claim has “engendered a great deal of ambiguity.”<sup>88</sup> The petition further explained that the explosion of food technologies since the FDA last attempted to address the “natural” claim issue in the early 1990s warrants “strict [FDA] guidelines that ensure that ‘natural’ claims do not mislead the growing number of consumers who value and wish to purchase natural products.”<sup>89</sup>

The Sugar Association petition focused on the “minimally processed” standard contained in Policy Memo 055 and how starch-based sweeteners are so fundamentally altered as to disqualify their use in products labeled as “natural.”<sup>90</sup> The Association contended that this should be true regardless of whether the transformation process is triggered through enzymatic or chemical means, or whether the resulting substance otherwise exists in nature.<sup>91</sup> The Sugar Association cited three cases decided by the National Advertising Division of the Better Business Bureau in which “natural” claims were found misleading, thus evidencing the vulnerability of consumers and the importance of regulatory bodies in preventing misleading claims.<sup>92</sup> The FDA docket<sup>93</sup> for the Petition indicated that

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86. Sugar Ass’n Petition, *supra* note 57.

87. *Id.* at 1-2.

88. *Id.* at 3.

89. *Id.* at 4.

90. *Id.* at 4-5.

91. Sugar Ass’n Petition, *supra* note 57, at 6-7.

92. *Id.* at 7-8.

93. USDA, *Docket No. 2006P-0094: Define the term natural before a natural claim can be made on foods and beverages regulated by the FDA*, <http://www.fda.gov/ohrms/dockets/dockets/06p0094/06p0094.htm> (last visited Jan. 28, 2008).

as of August 2006, the FDA had taken no action on the Petition because of resource limitations and competing agency priorities.<sup>94</sup>

On April 9, 2007, the Sara Lee Corporation filed a Petition with the FDA requesting that the agency work jointly with the FSIS to adopt a uniform policy for “natural” claims.<sup>95</sup> The Petition noted that recent FSIS changes to Policy Memo 055 have created uncertainty, particularly for products containing sodium lactate.<sup>96</sup> Sara Lee argued that use of sodium lactate is consistent with “natural” claims, and that the FDA should adopt a policy that maximizes food safety.<sup>97</sup> Sara Lee advocated against formal rulemaking, arguing that flexibility is necessary to judge the context in which an ingredient is used. The FDA docket, as of this writing, did not indicate that any action has been taken on the Petition.<sup>98</sup>

With the FDA allocating resources to other priorities such as food safety,<sup>99</sup> the agency may choose once again to ignore the issue. This may, unfortunately, not be the best strategy. Due to the expanding market presence of “natural” products and increasing scientific complexity of natural-derived ingredients, food regulatory agencies, as well as the FTC, should coordinate their efforts now to finalize a workable standard that will facilitate industry compliance and eliminate consumer confusion.

### III. BIOTECHNOLOGY

#### *A. Genetically Engineered Rice Commingles with Rice Intended for Human Consumption*

In December 1998, Aventis CropScience commenced field testing of a new genetically engineered rice variety, LLRice601, resistant

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94. Letter from Barbara Schneeman, Dir. of Nutritional Products, Labeling, & Dietary Supplements Office of the FDA, to Andrew Briscoe, CEO of the Sugar Ass'n (Aug. 3, 2006), *available at* <http://www.fda.gov/ohrms/dockets/dockets/06p0094/06p-0094-let0001-vol2.pdf>.

95. Sara Lee Corp., Citizen Petition Requesting the FDA to Develop Requirements for the Use of the Term “Natural” Consistent with the USDA’s Food Safety and Inspection Service (April 9, 2007), *available at* <http://www.fda.gov/ohrms/dockets/dockets/07p0147/07p-0147-cp00001-toc.htm>.

96. *Id.* at 8-9.

97. *Id.* at 10.

98. See USDA, Docket No. 2007P-0147: Develop Requirements for the use of the Term Natural Consistent with USDA’s Food Safety and Inspection Serv., <http://www.fda.gov/ohrms/dockets/dockets/07p0147/07p0147.htm> (last visited Jan. 30, 2008).

99. See *infra* Section IV.

to the herbicide glufosinate, marketed under the brand name "Liberty." Although it did not seek regulatory approval for the commercial release of LLRice601, Aventis did obtain approval from the United States Department of Agriculture (USDA) Animal & Plant Health Inspection Service (APHIS) for two nearly identical genetic engineering events, LLRice06 and LLRice62.<sup>100</sup> As field trials were wrapping up, Bayer acquired Aventis and formed Bayer CropScience. Bayer, however, did not petition the USDA for deregulation of LLRice601 variety.

In January of 2006, Riceland, the nation's largest rice cooperative, discovered trace amounts of genetically engineered DNA in the 2005 Midwest long-grain rice crop.<sup>101</sup> According to Bill Reed, Riceland Vice President of Public Affairs, the company initially believed that the genetically engineered material was from "residual fragments of genetically engineered corn or soybeans resulting from use of common public transportation systems."<sup>102</sup> Because the genetically engineered material was present in such small quantities, a lab was unable to determine its origin.<sup>103</sup> Riceland collected additional samples in May, and "[a] significant number tested positive for the Bayer trait."<sup>104</sup> Bayer confirmed that the genetically engineered material was the LLRice601.<sup>105</sup>

The USDA learned of the incident on July 31, 2006 and announced to the public that genetically engineered rice was present in the food supply on August 18, 2006, after conducting a safety review and approving a method to test for LLRice601.<sup>106</sup> Japan immediately banned long-grain rice imports from the United States and the European Union implemented a testing regime for all rice originating from the United States.<sup>107</sup> Within days, the first lawsuits by farmers were filed against Bayer and Riceland. On December 19, 2006, the Judicial Panel of Multi District Litigation transferred

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100. See AgrEvo USA Co., *Availability of Determination of Nonregulated Status for Rice Genetically Engineered for Glufosinate Herbicide Tolerance*, 64 Fed. Reg. 22,595 (April 27, 1999).

101. See Statement from Bill J. Reed, Vice President for Public Affairs, Riceland Foods, *Regarding Genetically Engineered Material in Rice* (August 18, 2006), available at [http://www.riceland.com/about/ge\\_docs/Statement%20Regarding%20Material%20in%20Rice%20Updated.pdf](http://www.riceland.com/about/ge_docs/Statement%20Regarding%20Material%20in%20Rice%20Updated.pdf).

102. *Id.*

103. *Id.*

104. *Id.*

105. *Id.*

106. Andrew Pollack, *Unapproved Rice Strain Found in Wide Area*, N.Y. TIMES, Aug. 22, 2006, at C2.

107. *Id.*

thirteen of the pending LLRice601 actions to the Eastern District of Missouri in St. Louis.<sup>108</sup> The court further noted the filing of six other actions and eight potential “tag along” actions not consolidated with the original thirteen, which presumably seek recovery for the price impacts attributable to lost exports.<sup>109</sup> In addition, a German food processing firm, Rickmers, filed a breach of contract action against Riceland for the delivery of rice in 2005 and 2006 that contained genetically engineered material (an alleged non-conforming good).<sup>110</sup>

Based on Bayer’s assertion of similarity to the previously deregulated LLRice06 and LLRice62, the USDA subsequently deregulated LLRice601.<sup>111</sup> Determining the cause of the contamination, however, proved to be a larger challenge for the agency and the rice industry. After discovery of the LLRice601 contamination, the USA Rice Federation commenced a seed-testing program to identify other contamination from genetic engineering. The Arkansas State Plant Board notified the USDA that up to thirty percent of the 2006 certified rice samples of CL131, a long grain rice variety, tested positive for a genetically engineered gene similar to the LL601 rice.<sup>112</sup> Subsequently identified as LLRice604, only three acres (by a single producer) were planted due to the early identification and response by APHIS.<sup>113</sup> The crop was destroyed without incident.<sup>114</sup> Despite its extensive investigation, the USDA eventually announced that it was unable to determine how the commingling occurred and declined any regulatory enforcement action against Bayer.<sup>115</sup>

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108. Transfer Order, *In re LLRice601 Contamination Litigation*, MDL Docket No. MDL-1811 (E.D. Mo. 2006), *available at* <http://www.llrice601contaminationlitigation.com/caseinformation.html#mdl>.

109. *Id.*

110. Complaint, *Rickmers Reismühle GmbH. v. Riceland Foods, Inc.*, Case No. 4-07-CV00000733-JMM (E.D. Ark. Aug. 21, 2007) (on file with the author).

111. *See* Bayer CropScience, Availability of an Environmental Assessment and a Preliminary Decision for an Extension of a Determination of Nonregulated Status for Rice Genetically Engineered for Glufosinate Herbicide Tolerance, 71 Fed. Reg. 53,076 (Sept. 8, 2006); *see also* FDA, Biotechnology Consultation, Note to the File BNF No. 00063 (Aug. 30, 2000), *available at* <http://www.cfsan.fda.gov/~rdb/bnfm063.html> (stating that the agency had no further questions regarding human consumption of genetically engineered varieties LLRice06 and LLRice62).

112. USDA, REPORT OF LIBERTYLINK RICE INCIDENTS 5, *available at* <http://www.aphis.usda.gov/newsroom/content/2007/10/content/printable/RiceReport10-2007.pdf>.

113. *See id.*

114. *Id.* at 5-6.

115. *See id.* at 1.

Many of the class action plaintiffs in the ongoing rice litigation<sup>116</sup> raise issues similar to the allegations in the Starlink corn products liability litigation,<sup>117</sup> which resulted in a significant settlement for the nation's corn growers.<sup>118</sup> Future updates in this journal will track the rice litigation and any subsequent impact on agricultural biotechnology regulation.

This is not the first legal debate regarding genetically engineered rice and coexistence concerns. On May 16, 2007, the USDA approved Ventria Bioscience's permit application for field testing of rice genetically engineered to produce a pharmaceutical compound, specifically, lactoferrin, lysozyme, or serum albumin.<sup>119</sup> The location of the approved field test is Geary County, Kansas.<sup>120</sup> At this time, there is no commercial rice production at any location in Kansas.<sup>121</sup> This is in contrast to Ventria's other proposed field trials of its genetically engineered rice. Previous permit applications for California and Missouri, two of the nation's largest commercial rice producing states, were met with stiff opposition from the rice industry due to fears of commingling with non-genetically engineered rice produced for the domestic and international markets.<sup>122</sup> Although the USDA eventually granted permits for experimental trials of the genetically engineered rice in Missouri,<sup>123</sup> public opposition moti-

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116. See *In re Genetically Modified Rice Litigation*, *Court Papers*, <http://www.bayerricelitigation.com/> (follow Court Papers hyperlink) (last visited May 23, 2008) (containing a collection of complaints filed against Riceland and Bayer CropScience alleging that Bayer had a regulatory duty (Count I) as well as a general duty (Count II) to test, grow, store, transport and dispose of the LLRice601 variety in a manner that would not result in contamination of the rice market and that Bayer allegedly breached those duties by failing to adequately oversee or control its field test growers, directly resulting in damages to plaintiffs).

117. *Kramer v. Aventis CropScience USA Holding Inc.*, 212 F. Supp. 2d 828 (N.D. Ill. 2002).

118. For a thorough discussion of the *Starlink* litigation and settlement, see Donald L. Uchtmann, *Starlink™—A Case Study of Agricultural Biotechnology Regulation*, 7 DRAKE J. AGRIC. L. 159 (2002).

119. See Availability of an Environmental Assessment and Finding of No Significant Impact for a Proposed Field Release of Rice Genetically Engineered to Express lactoferrin, Lysozyme, or Serum Albumin, 72 Fed. Reg. 27,539 (May 16, 2007).

120. *Id.* at 27,540.

121. *Id.*

122. A. Bryan Endres, *Coexistence Strategies in a Biotech World: Exploring Statutory Grower Protections*, 13 MO. ENVTL. L. & POL'Y REV. 206, 224-32 (2006) (discussing Ventria's attempts to conduct field trials).

123. Availability of Environmental Assessment and Finding of No Significant Impact for Field Tests of Genetically Engineered Rice Expressing Lysozyme, 70 Fed. Reg. 37,077 (June 28, 2005); Availability of Environmental Assessment and

vated Ventria to change locations to Kansas, thereby diffusing at least some criticism related to food purity and adding another chapter to the coexistence debate between conventional and genetically engineered agricultural products.<sup>124</sup>

### *B. Genetically Engineered Alfalfa Removed from Market*

In April 2004, Monsanto Company and Forage Genetics International submitted a petition requesting the deregulation of its glyphosate-tolerant alfalfa.<sup>125</sup> APHIS prepared an Environmental Assessment (EA) and solicited public comment on the assessment and deregulation petition.<sup>126</sup> Many comments related to possible "contamination" of organic or conventionally grown alfalfa with genetically modified varieties during pollination.<sup>127</sup> Alfalfa, unlike many commodity crops, relies on bees for pollination and therefore traditional segregation distances may not be effective.<sup>128</sup> Farmers wishing to sell conventional or organic alfalfa feared that they would be unable to meet the domestic market's contractual requirements for genetic purity or the export market's demand for only approved genetic events.<sup>129</sup> Despite these concerns, APHIS issued a determination of nonregulated status for the herbicide tolerant alfalfa,<sup>130</sup>

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Finding of No Significant Impact for Field Tests of Genetically Engineered Rice Expressing Lactoferrin, 70 Fed. Reg. 37,079 (June 28, 2005).

124. See generally USDA, DRAFT GUIDANCE FOR APHIS PERMITS FOR FIELD TESTING OR MOVEMENT OF ORGANISMS WITH PHARMACEUTICAL OR INDUSTRIAL INTENT, at 18-24 (Jan. 9, 2007), available at [http://www.aphis.usda.gov/brs/pdf/Pharma\\_Guidance.pdf](http://www.aphis.usda.gov/brs/pdf/Pharma_Guidance.pdf) (providing guidance to facilitate coexistence).

125. Petition for Determination of Nonregulated Status: Roundup Ready Alfalfa (*Medicago sativa* L.) Events J101 and J163, Petition No. 04-AL-116U, available at [http://www.aphis.usda.gov/brs/aphisdocs/04\\_11001p.pdf](http://www.aphis.usda.gov/brs/aphisdocs/04_11001p.pdf).

126. APHIS, Environmental Assessment: Monsanto Co. & Forage Genetics Int'l Petition 04-110-01p for Determination of Non-regulated Status for Roundup Ready Alfalfa Events J101 and J163 (Oct. 2004), available at [http://www.aphis.usda.gov/brs/aphisdocs/04\\_11001p\\_pea.pdf](http://www.aphis.usda.gov/brs/aphisdocs/04_11001p_pea.pdf); see also Monsanto Co. & Forage Genetics International; Availability of Petition & Environmental Assessment for Determination of Nonregulated States for Alfalfa Genetically Engineered for Tolerance to Herbicide Glyphosate, 69 Fed. Reg. 68,300 (Nov. 24, 2004).

127. *Geertson Seed Farms v. Johanns*, No. C 06-01075 CRB, 2007 WL 518624, \*2 (N.D. Cal. Feb. 13, 2007) [hereinafter *Geertson I*].

128. APHIS, Response to Comments to the Finding of No Significant Impact for the Determination of Non-regulated Status for Roundup Ready Alfalfa Events J101 and J163, at 2, available at [http://www.aphis.usda.gov/brs/aphisdocs2/04\\_11001p\\_com.pdf](http://www.aphis.usda.gov/brs/aphisdocs2/04_11001p_com.pdf) [hereinafter Comments to Alfalfa FONSI].

129. *Id.* at 1-2.

130. See Monsanto Co. & Forage Genetics Int'l; Availability Determination of Nonregulated Status, 70 Fed. Reg. 36,917 (June 27, 2005).

and farmers planted an estimated 200,000 acres of Roundup Ready alfalfa for forage and another 20,000 acres for seed in 2006.<sup>131</sup> Some alfalfa growers, the Sierra Club, and various farm and consumer organizations challenged the APHIS decision in the Northern District of California.

In pleadings before the court, APHIS acknowledged the potential coexistence problems. It reasoned, however, that stewardship efforts on the part of farmers growing conventional alfalfa could keep any commingling below the applicable thresholds.<sup>132</sup> With respect to contamination of organic alfalfa production, APHIS concluded that because organic operators already had to implement a production system that would avoid cross-pollination with neighboring, non-organic farmers, the deregulation decision would be unlikely to have a significant environmental impact.<sup>133</sup> The government, in similar agency actions, repeatedly has resolved the question of who should be responsible for preserving the integrity of a non-genetically modified (conventional or organic) harvest in favor of the farmer adopting the new, genetically engineered technology, regardless of the amount of disruption it may cause on established farming practices.<sup>134</sup>

The court in *Geertson* noted that while APHIS based its “no significant impact” decision on its conclusion that it is organic and conventional farmers who should ensure that contamination does not occur, APHIS failed to “identify a single method that an organic farmer can employ to protect his crop from being pollinated by a bee that travels from a nearby genetically engineered seed farm, even assuming the [organic] farmer maintains a ‘buffer zone.’”<sup>135</sup> In addition, the court found that the potential economic or financial impacts suffered by conventional and organic farmers directly result from the deregulation of genetically engineered alfalfa and that APHIS’s conclusion of “no significant impact” simply was not convincing.<sup>136</sup> Accordingly, the court granted the plaintiffs’ motion for

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131. See *Geertson Farms v. Johanss*, No. C 06-01075 CRB, 2007 WL 1302981, \*3 (N.D. Cal. May 3, 2007) [hereinafter *Geertson II*].

132. Comments to Alfalfa FONSI, *supra* note 128, at 2.

133. *Id.*

134. See APHIS, Decision on Monsanto Petition 04-125-01P Seeking a Determination of Nonregulated Status for Bt *cry3Bb1* Insect Resistant Corn Line MON 88017, at 18-19, available at [http://www.aphis.usda.gov/brs/aphisdocs/04\\_12501p\\_pea.pdf](http://www.aphis.usda.gov/brs/aphisdocs/04_12501p_pea.pdf) (stating that there will be no impact on organic farmers from commercialization of a new genetically engineered corn variety).

135. *Geertson I*, *supra* note 127, at \*6.

136. *Id.*



summary judgment on the NEPA claim and ordered APHIS to prepare a full Environmental Impact Statement (EIS).<sup>137</sup> On May 3, 2007, the court permanently enjoined future planting of Roundup Ready alfalfa pending completion of the EIS and a decision on the deregulation petition, but declined to enjoin the harvesting of already-planted seed and hay.<sup>138</sup> On August 13, 2007, Monsanto Company filed a notice of appeal of the injunction.<sup>139</sup>

The *Geertson* decision is a significant benchmark for further legal challenges to the express regulatory assumption that organic and conventional producers must bear the full burden of segregation to avoid undesirable commingling prior to delivery. To the extent that the government will require future petitioners seeking deregulation of genetically engineered crops to undertake coexistence measures, organic and conventional producers may experience lower production costs and fewer marketing problems related to biotechnology. Of course, these impacts may be long-term and slight, depending upon the degree of government oversight, market demands, and consumers' sustained preference for organic or conventionally produced foodstuffs.

#### IV. FOOD SAFETY DEVELOPMENTS

##### *A. Follow-Up on Fresh Produce E. coli Outbreaks*

The last update in this journal chronicled the government's response to the *E. coli* O157:H7 pathogen outbreak in fresh spinach and lettuce.<sup>140</sup> As is often the case, highly publicized events trigger not only immediate agency action, but also regulatory reaction in the form of revisions or additions to existing programs of oversight.

The Food and Drug Administration (FDA) released results of its joint investigation (conducted with the Centers for Disease Control and Prevention, the United States Department of Agriculture

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137. *Id.* at \*12. *Geertson* was decided just a few days after a ruling on another case challenging APHIS's approval of field trials of genetically engineered grass. See *Int'l Ctr. for Tech. Assessment v. Johanns*, 473 F. Supp. 2d 9 (D.D.C. 2007) (vacating APHIS's denial of a noxious weed petition for genetically engineered grass and granting summary judgment on plaintiffs' NEPA claims alleging that APHIS failed to assess properly potential impacts of the field trials).

138. See *Geertson II*, *supra* note 131.

139. Jacqui Fatka, *Monsanto to Appeal Biotech Alfalfa Ruling*, FEEDSTUFFS, August 20, 2007, at 1, available at [http://fdsmagissues.feedstuffs.com/fds/PastIssues/FDS7934/fds01\\_7934.pdf](http://fdsmagissues.feedstuffs.com/fds/PastIssues/FDS7934/fds01_7934.pdf).

140. Endres, *supra* note 1, at 104-07.

(USDA) Animal and Plant Health Inspection Service (APHIS), and various California agencies) into the causes of the 2006 *E. coli* spinach outbreak.<sup>141</sup> Although the agencies were able to identify the environmental risk factors and the farms most likely linked to the outbreak, they were unable to conclusively determine the origin of the contamination.<sup>142</sup>

The FDA also held two public hearings in the spring of 2007 to solicit data and other scientific information regarding current practices in the production and processing of fresh produce.<sup>143</sup> Despite a proliferation of FDA-issued good agricultural practices (GAPs) and good manufacturing practices (GMPs),<sup>144</sup> the agency expressed concern that outbreaks continued to occur and it sought information on the implementation and effectiveness of its prior guidance, as well as opportunities to further reduce risks of foodborne illness related to fresh produce.<sup>145</sup> In March 2007, the FDA also finalized its *Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables*.<sup>146</sup> As with all industry guidance, however, it does not set binding requirements, but outlines the agency's current perspective on the topic and recommends that firms adopt food safety practices tailored to their specific operations.<sup>147</sup> Whether the FDA's hearing will result in modification of the guidance document remains to be seen. Private litigation related to the outbreak, however, may be winding down. The *Los Angeles Times* has reported that the farm and two processing companies linked to the spinach outbreak

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141. Press Release, FDA, FDA Finalizes Report on 2006 Spinach Outbreak (Mar. 23, 2007), available at <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01593.html>.

142. *Id.*

143. FDA, Safety of Fresh Produce; Public Hearings; Request for Comments, 72 Fed. Reg. 8,750, 8,750-51 (Feb. 27, 2007) (providing notice of hearings and background information on food safety and fresh produce).

144. See *id.* at 8,752-53 (describing current GAPs and GMPs such as the Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables, FDA Food Code, current GMPs in 21 C.F.R. part 110, and the Produce Safety From Production to Consumption: 2004 Action Plan to Minimize Foodborne Illness Associated with Fresh Produce Consumption).

145. *Id.* at 8,753.

146. Draft Final Guidance for Industry: Guide to Minimize Food Safety Hazards for Fresh-Cut Fruits and Vegetables; Availability; Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request, 72 Fed. Reg. 11,364 (Mar. 13, 2007).

147. FDA, GUIDE TO MINIMIZE MICROBIAL FOOD SAFETY HAZARDS OF FRESH-CUT FRUITS AND VEGETABLES 3 (Oct. 26, 1998), available at <http://www.cfsan/fda/gov/~acrobat/prodguid.pdf>.

reached confidential settlements with families of three of the individuals who died from consuming the contaminated food.<sup>148</sup>

### *B. Imports and the Food Safety System*

In 2006, the United States exported agricultural products valued at almost \$71 billion.<sup>149</sup> During that same year, the United States imported over \$65 billion of agricultural products,<sup>150</sup> up from only \$47 billion in 2003.<sup>151</sup> This rapid growth in imported food and agricultural products has stressed the fragile food safety system. Physical inspection of every food product entering the United States would exhaust the resources of the food safety agencies and “bring international trade to a standstill.”<sup>152</sup> Striking the right balance between targeted inspections and general surveillance, however, is a difficult proposition. In early 2007, a series of problematic imports from China shocked the food safety system and prompted the President to establish an Interagency Working Group on Import Safety.<sup>153</sup>

On March 17, 2007, the FDA announced the recall of pet food manufactured by Menu Foods, Inc.<sup>154</sup> Nine cats died during routine taste trials conducted by the company and consumers reported the death of an additional five pets.<sup>155</sup> At the time of the recall, Menu Foods was unable to identify the source of the problem.<sup>156</sup> The FDA eventually identified the suspected contaminant as melamine in rice protein concentrate used as an ingredient in some pet foods.<sup>157</sup> The

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148. Mary Engel, *Lawsuits over 3 E. coli Deaths Settled*, L.A. TIMES, Apr. 23, 2007, at Metro 4.

149. USDA, *Foreign Agricultural Trade of the United States: Monthly Summary*, <http://www.ers.usda.gov/Data/FATUS/monthlysummary.htm> (last visited Jan. 29, 2008).

150. *Id.*

151. *Id.*

152. The White House, *Fact Sheet: Import Safety Action Plan: Increasing Protection of American Consumers* (Nov. 6, 2007), available at <http://www.whitehouse.gov/news/releases/20071107-7.html> [hereinafter *Import Safety Action Plan Fact Sheet*].

153. See THE WHITE HOUSE, EXECUTIVE ORDER: ESTABLISHING AN INTERAGENCY WORKING GROUP ON IMPORT SAFETY (July 18, 2007), available at <http://www.whitehouse.gov/news/releases/2007/07/20070718-4.html>.

154. Press Release, FDA, Recall of Pet Foods Manufactured by Menu Foods, Inc. (March 17, 2007), available at <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01590.html>.

155. *Id.*

156. *Id.*

157. Press Release, FDA, FDA's Update on Tainted Pet Food (April 22, 2007), available at <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01615.html>.

source of the product was a Chinese firm, Binzhou Futian Biological Technology.<sup>158</sup> Concurrently, the California Department of Food and Agriculture announced that it had detected melamine in urine from hogs, a result of feed contamination.<sup>159</sup> The USDA and the FDA subsequently announced that swine fed the adulterated food would be prohibited from entering the food supply and offered compensation to producers for depopulation and disposal efforts.<sup>160</sup> The agencies later also tracked some melamine contamination to wheat gluten imported from China and used as feed in poultry<sup>161</sup> and aquaculture operations.<sup>162</sup>

Immediately following the pet food and animal feed contamination scares, the FDA detected toxic contaminants in toothpaste manufactured in China.<sup>163</sup> In June 2007, targeted sampling by the FDA of seafood imported from China found farm-raised seafood contaminated with drug residues from antimicrobial agents not approved for aquaculture use in the United States.<sup>164</sup> As a result, the agency imposed broader import controls on all farm-raised catfish, basa, shrimp, dace, and eel from China.<sup>165</sup> During the same month, the Chinese government closed 180 food plants after inspectors un-

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158. *Id.*

159. *Id.*

160. Press Release, FDA, Joint News Release: FDA and USDA Determine Swine Fed Adulterated Product (April 26, 2007), *available at* <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01618.html>.

161. Press Release, FDA, Joint Update: FDA/USDA Trace Adulterated Animal Feed to Poultry (April 20, 2007), *available at* <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01621.html>. During the FDA/USDA investigation, the agencies discovered that pet food was contaminated by wheat gluten and rice protein concentrate that contained melamine. Scraps of pet food were distributed later to farms and added to swine and poultry feed. Press Release, FDA, FDA/USDA Joint News Release: Scientists Conclude Very Low Risk to Humans from Food Containing Melamine (May 7, 2007), *available at* <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01629.html>.

162. Press Release, FDA, USDA Clears Swine for Processing (May 15, 2007), *available at* <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01635.html>.

163. Press Release, FDA, FDA Advises Consumers to Avoid Toothpaste from China Containing Harmful Chemical (June 1, 2007), *available at* <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01646.html> (warning consumers of the presence of diethylene glycol in several brands of toothpaste manufactured in China).

164. Press Release, FDA, FDA Detains Imports of Farm-Raised Chinese Seafood (June 28, 2007), *available at* <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01660.html>.

165. *Id.*

covered more than 23,000 food safety violations.<sup>166</sup> Much of the problem stemmed from the aggressive competitiveness of small firms using industrial chemicals, banned dyes, and other illegal ingredients to cut costs.<sup>167</sup> A culture of corruption and bribery may also permeate the Chinese food and drug industry, as the former head of the national food and drug agency recently received a death sentence for accepting bribes and approving substandard drugs.<sup>168</sup> An agricultural minister is also on trial for endorsing food products in exchange for bribes.<sup>169</sup>

In response to the recalls of various foods due to contaminated ingredients, the FDA sent a letter reminding food manufactures of their legal responsibilities regarding safe, unadulterated food.<sup>170</sup> In addition to government oversight at the border, the FDA emphasized that it remains the responsibility of the importing firms to ensure safety of their products and that they should implement verification procedures with all ingredient suppliers.<sup>171</sup>

As noted above, President Bush created the Interagency Working Group on Import Safety to coordinate the government's efforts to ensure a safe food supply and recommend regulatory modifications. On September 10, 2007, the Working Group presented the President with a Strategic Framework to increase import safety, an element of which is a three-part FDA Food Protection Plan. The plan proposed a science- and risk-based approach of prevention, intervention, and response to ensure a safe food supply.<sup>172</sup> The next edition of this update will detail the FDA's implementation of its action plan.

### C. Bovine Spongiform Encephalopathy

First identified in a cattle herd in the United Kingdom, Bovine Spongiform Encephalopathy (BSE) is a neurodegenerative disease

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166. David Barboza, *Food-Safety Crackdown in China*, N.Y. TIMES, June 28, 2007, at C1.

167. *Id.*

168. *Id.*

169. *Id.*

170. Letter from FDA to Food Manufacturers Regarding Legal Responsibilities for the Safety of Food Ingredients (May 4, 2007), available at <http://www.cfsan.fda.gov/~dms/protltr.html>.

171. *Id.*

172. See Import Safety Action Plan Fact Sheet, *supra* note 152.

that is progressive, incurable, and fatal.<sup>173</sup> Linked to a human variant of Creutzfeldt-Jacob Disease, BSE has spread from the United Kingdom to at least twenty other countries.<sup>174</sup> The discovery of a BSE-infected cow in the United States resulted in the closure of important beef export markets, including Japan and South Korea.<sup>175</sup>

Following the discovery of BSE-infected cattle in the United States, the USDA established a testing and surveillance program, as well as feeding restrictions.<sup>176</sup> The USDA adopted a policy of testing only the highest risk animals, rather than all cattle.<sup>177</sup> Due to the disease's incubation period, only rarely do cattle younger than thirty months show any signs of disease;<sup>178</sup> however, most cattle in the United States are slaughtered at less than twenty-four months old.<sup>179</sup> Therefore, the USDA asserted that any BSE testing of typical slaughter-age cattle "offers no food safety value" and is "likely to produce false negative results."<sup>180</sup>

Creekstone Premium Beef (Creekstone), a supplier of premium beef, sought to conduct its own testing of all cattle to recover its lost export markets and constructed a laboratory for BSE testing at its beef processing facility, sent its employees to France for training on testing procedures, and requested USDA approval to purchase and use the testing kits from the same company supplying test kits to the USDA, Japan, and other countries.<sup>181</sup> The USDA denied Creekstone's request, stating that the sale and use of BSE test kits would be restricted to only state- and USDA-operated laboratories.<sup>182</sup> The USDA's basis for the decision was the Virus-Serum-Toxin Act (VSTA), which requires a permit to import and places restrictions on "biological products."<sup>183</sup> Creekstone challenged the decision in the United States District Court for the District of Columbia.

In Count I of Creekstone's complaint, it argued that the inclusion of diagnostic tests as regulated biological products exceeded

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173. *Creekstone Farms Premium Beef, L.L.C. v. USDA*, 517 F. Supp. 2d 8, 10 (D.D.C. 2007).

174. *Id.*

175. *Id.*

176. See Gregory Berlowitz, Note, *Food Safety v. Promotion of Industry: Can the USDA Protect Americans from Bovine Spongiform Encephalopathy?*, 2006 U. ILL. L. REV 625 (2006) (describing the USDA's response to BSE).

177. *Creekstone*, 517 F. Supp. 2d at 10.

178. *Id.* at 11.

179. *Id.*

180. *Id.*

181. *Id.*

182. *Creekstone*, 517 F. Supp. 2d at 11 (citing APHIS notice No. 04-08).

183. *Id.*

the jurisdiction of the VSTA because such tests are neither analogous to viruses, serums or toxins, nor used in the treatment of domestic animals.<sup>184</sup> Count II asserted that even if the VSTA applied to some diagnostic tests, the BSE test kit is not subject to VSTA jurisdiction as the test is not a virus, serum, toxin, or analogous product, nor is it intended for use in the treatment of domestic animals.<sup>185</sup>

With respect to Count I, the court gave great deference to the USDA's interpretation of the statutory terms and held that the agency could regulate diagnostic tests.<sup>186</sup> The court, however, refused to defer to the agency's factual argument that "BSE test kits are used for treatment" of a disease.<sup>187</sup> As noted above, "there is no treatment for BSE and, moreover, the test kits are used only on animals that are dead."<sup>188</sup> Accordingly, the court entered an order reversing the USDA's decision.<sup>189</sup> The USDA subsequently filed a notice of appeal.

## V. CONCLUSION

Food safety issues, as in the second half of 2006, occupied significant public and agency attention through the summer of 2007, with many questioning the efficacy of the nation's import inspection system. The safety of the global food supply chain will remain a source of continued concern. In addition to safe, wholesome food, demand by American consumers for functional foods continued to grow with food processors seeking ways to differentiate their products with government sanctioned labeling claims. Continued consumer allure to these claims, however, may well depend on increased government scrutiny and vigilance among competitors to weed out frivolous labeling claims—a problem analogous to preserving the integrity (and market power) of the organic label.

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184. *Id.* at 12.

185. *Id.*

186. *Id.* at 14.

187. *Creekstone*, 517 F. Supp. 2d at 16.

188. *Id.*

189. *Id.* at 17.