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United States Food Law Update

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I. INTRODUCTION

Michael T. Roberts and Margie Alsbrook noted in the *Journal's* inaugural *Food Law Update* that "[t]he one constancy about food law in the United States is change, especially in a rapidly-developing food industry."[1] This observation holds true today and also augurs a change in authorship of this section of the *Journal.* I hope to follow my colleagues' lead and provide timely and cogent updates of the federal (and occasionally state) statutes, regulations, and judicial decisions impacting food law and policy. It is both an honor and a duty, as food and its legal implications remain in many respects "the world's most important subject."[2]

This update summarizes significant changes and developments in food law throughout the second half of 2006. 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.

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1. Michael T. Roberts & Margie Alsbrook, *United States Food Law Update,* 1 J. FOOD L. & POL'Y 187, 187 (2005).

2. *Id.* (quoting FELIPE FERNANDEZ-ARMESTO, NEAR A THOUSAND TABLES: A HISTORY OF FOOD ix (2002)).

II. RECENT FEDERAL ADMINISTRATIVE ACTIONS

A. FDA: Produce Safety Initiatives

With the possible exceptions of the ongoing war in Iraq, the mid-term elections, and the Cruise-Holmes celebrity wedding, food law, specifically issues of food safety, captured the nation's attention in the second half of 2006.[3]

On September 14, 2006, the Food and Drug Administration (FDA) and Center for Disease Control and Prevention (CDC) issued alerts regarding fifty instances of illness nationwide associated with the deadly *E. coli* O157:H7 pathogen.[4] In an abrupt departure from the government's repeated urging to eat more produce as part of a healthy diet,[5] the two agencies warned consumers to immediately

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3. *See, e.g.*, Michael Pollan, *The Vegetable-Industrial Complex*, N.Y. TIMES MAGAZINE, Oct. 15, 2006, at 14 (discussing food safety in the context of industrial-scale production); *see also* CBS News, *E. coli Outbreak Source Located*, Sept. 16, 2006, http://www.cbsnews.com/stories/2006/09/15/health/printable2012579.shtml (last visited Sept. 20, 2007).

4. Press Release, Centers for Disease Control & Prevention (CDC), CDC Health Alert: Multiple States Investigating a Large Outbreak of E. coli O157:H7 Infections (Sept. 14, 2006), http://www2a.cdc.gov/HAN/ArchiveSys/ViewMsgV.asp?=AlertNum=00249 (last visited Sept. 20, 2007); Press Release, Food & Drug Administration (FDA), FDA Warning on Serious Foodborne E. coli O157:H7 Outbreak (Sept. 14, 2006), http://www.fda.gov/bbs/topics/NEWS/2006/NEW01450.html (last visited Sept. 20, 2007).

> Currently, there are four recognized classes of enterovirulent *E. coli* (collectively referred to as the EEC group) that cause gastroenteritis in humans. Among these is the enterohemorrhagic (EHEC) strain designated *E. coli* O157:H7. *E. coli* is a normal inhabitant of the intestines of all animals, including humans. When aerobic culture methods are used, *E. coli* is the dominant species found in feces. Normally *E. coli* serves a useful function in the body by suppressing the growth of harmful bacterial species and by synthesizing appreciable amounts of vitamins. A minority of *E. coli* strains are capable of causing human illness by several different mechanisms. *E. coli* serotype O157:H7 is a rare variety of *E. coli* that produces large quantities of one or more related, potent toxins that cause severe damage to the lining of the intestine. These toxins [verotoxin (VT), shiga-like toxin] are closely related or identical to the toxin produced by *Shigella dysenteriae*.

FDA, CENTER FOR FOOD SAFETY & APPLIED NUTRITION (CFSAN), FOODBORNE PATHOGENIC MICROORGANISMS AND NATURAL TOXINS HANDBOOK: ESCHERICHIA COLI O157:H7 (2001), http://www.cfsan.fda.gov/~mow/chap15.html (last visited Sept. 20, 2007). *See also* CDC, *Escherichia coli O157:H7*, http://www.cdc.gov/ncidod/dbmd/diseaseinfo/escherichiacoli_g.htm (last visited Sept. 20, 2007).

5. United States Dep't of Agric. (USDA), *Dietary Guidelines*, http://www.mypyramid.gov/guidelines/index.html (last visited Sept. 20, 2007)

cease consumption of bagged fresh spinach.[6] By October 6th, the CDC identified 199 cases of *E. coli*-induced illness (three of which resulted in the victim's death) across twenty-six states.[7] On October 12th, the FDA and the State of California announced the results of a joint investigation that traced back the particular outbreak strain of *E. coli* O157:H7 to cattle feces on a ranch in California's Central Valley.[8]

Less than two months later, the CDC and the FDA warned the public about another *E. coli* O157:H7 outbreak associated with fresh produce.[9] In this instance, the agencies traced seventy-one illnesses to lettuce from Taco Bell restaurants in four northeastern states.[10] During this same November-December time period, yet another *E. coli* outbreak linked to iceberg lettuce injured eighty-one patrons of Taco John's restaurants in Minnesota, Iowa, and Wisconsin.[11] As of this writing, the source of the tainted lettuce in the Taco Bell incidents has yet to be officially determined, but health officials in California, Minnesota, Iowa, and Wisconsin have matched the DNA of the *E. coli* associated with the Taco John's outbreak with samples gathered from dairy farms near lettuce fields in the Central Valley.[12]

Though the public's awareness of the association between *E. coli* and fresh lettuce peaked in the second half of 2006, the FDA

(stating that a healthy diet should emphasize fruits and vegetables); FDA, CFSAN/OFFICE OF PLANT AND DIARY FOODS, PRODUCE SAFETY FROM PRODUCTION TO CONSUMPTION: 2004 ACTION PLAN TO MINIMIZE FOODBORNE ILLNESS ASSOCIATED WITH FRESH PRODUCE CONSUMPTION (Oct. 2004), http://www.cfsan.fda.gov/~dms/prodpla2.html (last visited Sept. 20, 2007) [hereinafter PRODUCE SAFETY ACTION PLAN].

6. Press Release, FDA, supra note 4; Press Release, CDC, supra note 4.

7. Press Release, FDA, FDA Statement on Foodborne E. coli O157:H7 Outbreak in Spinach (Oct. 6, 2006), http://www.fda.gov/bbs/topics/NEWS/2006/NEW01486.html (last visited Sept. 20, 2007).

8. Press Release, FDA, FDA Statement on Foodbourne E. coli O157:H7 Outbreak in Spinach (Oct. 12, 2006), http://www.fda.gov/bbs/topics/NEWS/2006/NEW01489.html (last visited Sept. 20, 2007).

9. Press Release, FDA, FDA Investigating E. coli O157:H7 Infections Associated with Taco Bell Restaurants in Northeast (Dec. 6, 2006), http://www.fda.gov/bbs/topics/NEWS/2006/NEW01517.html (last visited Sept. 20, 2007).

10. Press Release, FDA, Update: FDA Narrows Investigation of E. coli O157:H7 Outbreak at Taco Bell Restaurants (Dec. 13, 2006), http://www.fda.gov/bbs/topics/NEWS/2006/NEW01525.html (last visited Sept. 20, 2007).

11. Press Release, FDA, FDA and States Closer to Identifying Source of E. coli Contamination Associated with Illnesses at Taco John's Restaurants (Jan. 12, 2007), http://www.fda.gov/bbs/topics/NEWS/2007/NEW01546.html (last visited Sept. 20, 2007).

12. *Id.*

has long expressed concern about the number of foodborne illnesses associated with fresh produce, including lettuce.[13] In 2004, the FDA initiated the Produce Safety Action Plan with the goal of minimizing the incidence of foodborne illness associated with consumption of fresh produce[14] via contamination prevention, minimizing the public health impact when contamination occurs, improving communication about foodborne illness from farm to fork, and supporting research relevant to fresh produce safety.[15]

Specific Produce Safety Action Plan steps included development of commodity-specific and practice-specific guidance for the production, packing, processing, transportation, distribution, and preparation of fresh produce.[16] Education efforts focused on the promotion of Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs), as well as raising consumer awareness via the media and broader use of the internet.[17]

In response to recurring outbreaks of *E. coli* O157:H7 associated with fresh and fresh-cut lettuce, but before the disruptions described above, the FDA launched a Lettuce Safety Initiative (LSI) in August 2006.[18] Scheduled to commence during the Fall 2006 harvest, the LSI has four primary objectives: (1) to assess current industry practices and, if appropriate, encourage improvements in lettuce safety; (2) to respond rapidly and alert consumers in the event of an outbreak; (3) to develop or refine guidance to minimize contamination; and (4) to consider regulatory action in the event of conditions that could lead to contamination.[19] Initial steps by the FDA consisted of working with California's Department of Health Services and Department of Food and Agriculture to visit and inspect farms and processing facilities to assess existing GAPs and

13. PRODUCE SAFETY ACTION PLAN, *supra* note 5 ("Because most produce is grown in a natural environment, it is vulnerable to contamination with pathogens . . . . The fact that produce is often consumed raw without any type of intervention that would reduce, control, or eliminate pathogens prior to consumption contributes to its potential as a source of foodborne illness.").

14. *See id.* ("The plan's scope included fresh fruits and vegetables, both in unpeeled, natural form and raw products that have received some minimal processing (such as peeling, chopping, or trimming).") The plan did not include frozen fruits or vegetables or juices. *Id.*

15. *Id.*

16. *Id.*

17. *See id.*

18. FDA, CFSAN, LETTUCE SAFETY INITIATIVE (Aug. 23, 2006), http://www.cfsan.fda.gov/~dms/lettsafe.html (last visited Sept. 20, 2007).

19. *Id.*

GMPs.[20] Future FDA actions include continuing outreach along all points of the supply chain and facilitating lettuce safety research.[21]

On November 15, 2006, the FDA and the CDC appeared before the Senate Committee on Health, Education, Labor and Pensions to discuss the Fall 2006 *E. coli* outbreak in spinach.[22] Both agencies noted the persistent problem of foodborne illness associated with fresh produce, especially ready-to-eat products.[23]

Due to its recent adoption, the effectiveness of the LSI remains to be seen, and the Fall 2006 outbreaks may not indicate an inherent weakness with the LSI. Rather, the events amplify the need to direct increased attention toward produce safety. Although the FDA will assume the lead in the federal effort to improve produce safety, the agency acknowledges that obtaining significant results will require collaboration with the CDC, the United States Department of Agriculture (USDA), and counterparts at the local, state, and international level, as well as with the private sector and academia.[24] Not surprisingly, Congress reacted to the increased public awareness of food safety with the introduction of several food-related bills, a topic for a future update in 2007.[25]

B. USDA: Meat and Poultry Inspection Programs

Although certainly not of the same public profile as the spinach/lettuce *E. coli* issues that arose in Fall 2006, the USDA's Office of Inspector General (OIG) issued an Audit Report criticizing the

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20. *Id.*

21. *Id.*

22. *CDC Food Safety Activities and the Recent E. coli Spinach Outbreak: Hearings Before the Committee on Health, Education, Labor and Pensions*, Nov. 15, 2006 (testimony of Lonnie J. King, Sr. Veterinarian, CDC), *available at* http://www.hhs.gov/asl/testify/t061115.html; *Ensuring Food Safety: FDA's Role in Tracking and Resolving the Recent E. coli Spinach Outbreak: Hearing Before the Committee on Health, Education, Labor and Pensions*, Nov. 15, 2006 (testimony of Robert E. Brackett, Ph.D., CFSAN Director), *available at* http://help.senate.gov/Hearings/2006_11_15/Brackett.pdf.

23. Testimony of Lonnie J. King, *supra* note 22, at 5-6; testimony of Robert E. Brackett, *supra* note 22.

24. *See* PRODUCE SAFETY ACTION PLAN, *supra* note 5.

25. *See generally* GEOFFREY S. BECKER, CONGRESSIONAL RESEARCH SERVICE, CRS REPORT FOR CONGRESS, FOOD SAFETY: SELECTED ISSUES AND BILLS IN THE 110TH CONGRESS (2007), Order Code RL34152, *available at* http://www.nationalaglawcenter.org/assets/crs/RL34152.pdf.

Food Safety and Inspection Service's (FSIS) state meat and poultry inspection program.[26]

The FSIS is responsible for inspecting all meat and poultry products sold in interstate and foreign commerce.[27] It accomplishes this goal, in part, by entering into cooperative agreements with states to enforce standards that are "at least equal to" federal laws and regulations.[28] Twenty-eight states have implemented "at least equal to" meat and poultry inspection (MPI) programs.[29] Federal guidelines apply in the remaining twenty-two states.[30] In response to concerns regarding the adequacy of state-inspected facilities, the 2002 Farm Bill directed the Secretary of Agriculture to review state MPI programs and report the findings to Congress.[31] Accordingly, the FSIS instituted a comprehensive review system in October 2003 to recertify state programs under new, more secure guidelines.[32]

The OIG found that the FSIS failed to complete the reviews in a timely manner (only eight of twenty-eight on-site visits were completed over a twenty-one-month period) and of the twenty-four reviews started through April 2006, eleven initial determinations as to compliance with the "at least equal to" standard were either "deferred" or found to have significant concerns or worse.[33] In addition, the OIG noted that for the four state reviews that the FSIS completed, the agency failed to fully document or justify its conclusions.[34] For example, three states were found to be "at least equal to" federal standards although 100%, 100%, and 77% of the sampled establishments had deficiencies.[35] In contrast, the fourth state, of

26. *See generally* USDA, AUDIT REPORT: FOOD SAFETY AND INSPECTION SERVICE—STATE MEAT AND POULTRY INSPECTION PROGRAMS, REPORT NO. 24005-1-AT (2006), *available at* http://www.usda.gov/oig/webdocs/24005-01-AT.pdf [hereinafter FSIS AUDIT].

27. *See* Federal Meat Inspection Act, 21 U.S.C. § 661(a)(1)-(2) (2007); *see also* Poultry Products Inspection Act, 21 U.S.C. § 455(a)(1) (2006).

28. FSIS AUDIT, *supra* note 26, at i.

29. *Id.* at 1.

30. *Id.*

31. *Id.* at 2, n.6.

32. *Id.* at 4. Hazard Analysis and Critical Control Points (HACCP) programs, Sanitation Standard Operating Procedures (SSOP), and Sanitation Performance Standards (SPS) provide guidance for state meat and poultry inspection (MPI) programs. *Id.* at 1.

33. *Id.* at 3-4. The Food Safety and Inspection Service (FSIS) deferred determinations for nine states, made one preliminary determination that there were "significant concerns," and made one preliminary finding that the state's program "did not support at least equal to." *Id.* at 3, n.7.

34. *Id.* at 8-9.

35. *Id.* at 8, Tbl. 1.

which the FSIS found 86% of the sampled establishments to be deficient, was deemed to have "significant concerns."[36]

In response to these and other criticisms identified by the OIG, the FSIS updated its Manual for State Meat and Poultry Inspection Reviews.[37] Under the revised state review procedures, the FSIS revised the two-stage determination of a state's "at least equal to" status and placed new emphasis on compliance with the Humane Methods of Slaughter Act (HMSA).[38]

During the state's examination process under the new review process, the FSIS will make independent "at least equal to" determinations for each stage of the review—state self-assessment and FSIS on-site review (including verification of the self-assessment).[39] States not scheduled for on-site review in a particular year, however, will receive a single determination based solely on the self-assessment.[40] States receiving an on-site review will receive a determination by the FSIS based on both the self-assessment and the on-site review.[41]

As part of its new emphasis on humane slaughter, the FSIS will determine compliance with the HMSA as part of the annual state self-assessment of Statutory Authority and Food Safety Regulations.[42] Previously, the FSIS assessed compliance with HMSA provisions only during on-site reviews.[43] States must demonstrate that they have either adopted the HMSA or promulgated equivalent regulations along with legal authority to enforce the rules.[44]

C. FDA and Department of Treasury: Food and Beverage Allergen Labeling

The Federal Food, Drug, and Cosmetic Act (FFDCA) and the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) address the labeling of foods that contain potential food

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36. *Id.* at 8-9 and Tbl. 1.

37. *See id.* at 11 (noting FSIS's response to OIG Recommendation 3); *see generally*, USDA, FSIS, FSIS MANUAL FOR STATE MEAT AND POULTRY INSPECTION REVIEWS (2006), *available at* http://www.fsis.usda.gov/PDF/State_Programs_Review_Manual.pdf [hereinafter FSIS MPI MANUAL].

38. FSIS MPI MANUAL, *supra* note 37, at 5-6.

39. *Id.* at 5.

40. *Id.*

41. *Id.*

42. *Id.*

43. FSIS MPI MANUAL, *supra* note 37, at 5.

44. *Id.* at 6.

allergens.[45] In October 2006, the FDA revised, for the third time, its industry guidance for food allergen labeling.[46] In a related action, the Department of Treasury, Bureau of Alcohol and Tobacco Tax and Trade (TTB) issued an interim rule for the adoption of *voluntary* labeling standards for major food allergens used in the production of alcoholic beverages.[47] A brief discussion of these two regulatory actions follows.

1. FDA Industry Guidance Regarding Food Allergens

In the FALCPA, Congress designated eight foods or food groups as "major food allergens," which comprise 90% of all known food allergens.[48] Packaged foods containing a designated "major food allergen," and labeled on or after January 1, 2006, must comply with the FALCPA's food allergen labeling requirements.[49] The FDA's October 2006 guidance revision clarified four issues for industry–the common names for nineteen tree nuts,[50] the identification of acceptable market names for imported and domestically available seafood that comply with the declaration of the "species of fish or Crustacean shellfish" requirement,[51] that the term "wheat" includes any species in the genus *Triticum* (e.g., common wheat, spelt, semolina, kamut, and triticale),[52] and that even single ingredient foods must comply with allergen declaration requirements.[53]

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45. Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C.A. § 343 (w)-(x) (2007) (addressing labeling, misbranding, and food allergens); Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), Pub. L. No. 108-282, § 201-210 (codified in scattered sections of 21 U.S.C.A.).

46. *See* FDA, GUIDANCE FOR INDUSTRY: QUESTIONS AND ANSWERS REGARDING FOOD ALLERGENS, INCLUDING THE FOOD ALLERGEN LABELING AND CONSUMER PROTECTION ACT OF 2004 (4th ed. 2006), *available at* http://www.cfsan.fda.gov/~dms/alrguid4.html [hereinafter FDA FOOD ALLERGEN GUIDANCE].

47. *See* Major Food Allergen Labeling for Wines, Distilled Spirits, and Malt Beverages, Interim Rule, 71 Fed. Reg. 42260 (July 26, 2006) (to be codified at 27 C.F.R. pts. 4, 5 and 7).

48. FDA FOOD ALLERGEN GUIDANCE, *supra* note 46. FALCPA defines a "major food allergen" as an ingredient that is one of the following five foods or food groups, or an ingredient containing a protein derived from one of the following: milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, or soybeans. 21 U.S.C. § 321(qq) (2005).

49. FDA FOOD ALLERGEN GUIDANCE, *supra* note 46.

50. *Id.* (listing tree nuts by their common and scientific names).

51. *Id.* *See also* FDA, CFSAN, *Seafood List Introduction* (2002), http://www.cfsan.fda.gov/~frf/seaintro.html (last visited Oct. 1, 2007).

52. FDA FOOD ALLERGEN GUIDANCE, *supra* note 46 (listing types of wheat).

53. *Id.*

2. TTB Interim Rule for Alcohol Beverage Food Allergen Labeling

The TTB administers the Federal Alcohol Administration Act (FAA Act),[54] which, among its other actions, regulates the labeling of wines with at least 7% alcohol, distilled spirits, and malt (alcohol) beverages. Section 105 of the FAA Act authorizes the promulgation of regulations regarding the labeling of alcohol beverages with respect to identity and quality to prevent consumer deception.[55]

Although the TTB regulations do not require full ingredient labeling for alcoholic beverages, the agency has a long-standing memorandum of understanding with the FDA to coordinate mandatory labeling of "ingredients in alcohol beverages that pose a recognized public health problem."[56] If the FDA determines that the presence of an ingredient poses a public health problem, the TTB will initiate rulemaking procedures to require indication of the ingredient on the label.[57] For example, the TTB rules require labels to indicate the use of aspartame in the production of malt beverages, the addition of FD&C Yellow No. 5, and the presence of sulfites above 10 parts per million.[58]

Acknowledging this history of cooperation between the FDA and the TTB, Congress called on the agencies to promulgate appropriate allergen labeling regulations for products under TTB jurisdiction.[59] In cooperation with the FDA, the TTB issued regulations that adopt, in large part, the FALCPA and the FDA guidance, described above.[60] As of this writing, the TTB allergen labeling regulations remain voluntary. The TTB, however, simultaneously published a

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54. *See generally* 27 U.S.C. § 201 (2006); *see also* 27 U.S.C. § 202(f) (2006) (allowing the Secretary of the Treasury to utilize other governmental agencies).

55. 27 U.S.C. § 205(e) (2006). For specific Alcohol and Tobacco Tax and Trade Bureau (TTB) regulations regarding the labeling of alcohol beverages, see 27 C.F.R. § 4-5, 7 (2007).

56. Memorandum of Understanding, 52 Fed. Reg. 45502 (Nov. 30, 1987).

57. Major Food Allergen Labeling for Wines, Distilled Spirits, and Malt Beverages, Interim Rule, 71 Fed. Reg. 42260, 42261 (July 26, 2006) (to be codified at 27 C.F.R. pts. 4, 5 and 7) (describing the Memorandum of Understanding with the FDA).

58. *Id.* (citing 58 Fed. Reg. 44131 (August 19, 1993) (codified at 27 C.F.R. pt. 7) (discussing aspartame); 48 Fed. Reg. 45549 (October 6, 1983) (codified at 27 C.F.R. pts. 4, 5 and 7) (discussing Yellow No. 5); 51 Fed. Reg. 34706 (September 30, 1986) (codified at 27 C.F.R. pts. 4, 5 and 7) (discussing sulfites)).

59. *Id.* at 42262 (citing H.R. Rep. No. 108-608, at 3 (2004)). Authority for TTB's actions, however, rests with the Federal Alcohol Administration Act, rather than the FALCPA or the FFDCA. *Id.*

60. *Id.* at 42264.

notice of proposed rulemaking and solicited comments on a proposal to make major food allergen labeling mandatory.[61]

The interim regulations provide that if an individual chooses to label any major food allergen (i.e., opt-in to the program), then the individual must declare all major food allergens used in production of the alcohol beverage.[62] Although compliance with the voluntary labeling program generally tracks the FALCPA rules for food, the alcohol beverage labeling rules do not require the identification of specific fish species due to the inability of vintners and brewers to ascertain the species when purchasing supplies.[63] In addition, an individual may petition the TTB for a labeling exemption if the use of a major food allergen in the production of a specific alcohol beverage differs from its use in food and does not cause an allergic reaction or contain an allergic protein.[64] This early petition process for exemptions may allow the regulated community time to transition to the proposed mandatory program.

III. RECENT CASE DECISIONS

A. Food Safety: Criminal Convictions for Improper Food Storage

According to the Court of Appeals for the Seventh Circuit, "[t]he conditions at LaGrou's cold storage warehouse at 2101 Pershing Road in Chicago were enough to turn even the most enthusiastic meat-loving carnivore into a vegetarian."[65] Approximately two million pounds of food passed through the warehouse on a daily basis.[66] Unfortunately, the rat population was of similar scale and employee "rat patrols" tallied as many as fifty trapped rats per day.[67] Product loss due to extensive rodent damage (e.g., beef brisket chewed by rats) continued for several years with employees adopting shorthand codes such as "MM" (short for "Mickey Mouse") on shipping

61. *See* Major Food Allergen Labeling for Wines, Distilled Spirits, and Malt Beverages, Notice of Proposed Rulemaking, 71 Fed. Reg. 42329-44 (July 18, 2006) (to be codified at 27 C.F.R. pts. 4, 5 and 7).

62. Major Food Allergen Labeling for Wines, Distilled Spirits, and Malt Beverages, Interim Rule, 71 Fed. Reg. 42260, 42264 (July 26, 2006) (to be codified at 27 C.F.R. pts. 4, 5 and 7).

63. *Id.*

64. *Id.* at 42265 (discussing petitions for exemption from TTB regulation).

65. United States v. LaGrou Distribution Sys., Inc., 466 F.3d 585, 587 (7th Cir. 2006).

66. *Id.*

67. *Id.*

documents to differentiate rodent damage from other warehouse-related product loss.[68]

In May 2002, a team of United States Department of Agriculture (USDA), Food and Drug Administration (FDA), Illinois Department of Public Health, Chicago Department of Public Health, and Illinois Department of Agriculture officials inspected the Pershing Road warehouse.[69] A USDA microbiologist present at the inspection testified that the warehouse was "the 'worst case' she had seen in her 28 years with the USDA."[70] The government detained all 22 million pounds of meat, poultry, and food products at the warehouse.[71]

The corporate defendant LaGrou Distribution Systems, Inc. (LaGrou), was convicted of three felony counts[72] for (1) knowing improper storage of poultry products,[73] (2) knowing improper storage of meat products,[74] and (3) knowing improper storage of food products.[75] The trial court sentenced LaGrou to five years probation, a total fine of $2 million, and ordered $8.2 million in restitution.[76]

Although certainly an egregious example of good manufacturing practices,[77] the case warrants discussion in this Update because of the Seventh Circuit's analysis of the *mens rea* requirements for a

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68. *Id.* at 588.

69. *Id.* at 589.

70. *LaGrou*, 466 F.3d at 589. Even after the warehouse manager and twenty-eight employees spent all night cleaning in anticipation of the inspection, officials found and photographed

> rat droppings and rat nesting material throughout the warehouse, including next to and on product; rodent-gnawed meat, poultry, and other food products; live rodent sightings; blood from meat product on the floor mixed with rodent droppings and rat tail marks; dirt and debris on meat product; potential rodent access points, including open sewer drains... holes in ceilings, walls and doors; ice buildup on the ceilings directly above stored product and water dripping... onto the product; mold and filth on the walls and ceilings; several inoperable bathrooms, which forced workers to use broken toilets and "flush" them with buckets of water; and raw sewage and standing water on the floors.
>
> *Id.*

71. *Id.* at 590.

72. *Id.* at 586-87.

73. *See* 21 U.S.C. § 458(a)(3) and § 461(a) (2006).

74. *See* 21 U.S.C. § 610(d) and § 676(a) (2006).

75. *See* 21 U.S.C. § 331(b), § 333(a)(2), and § 342(a)(4) (2006).

76. *LaGrou*, 466 F.3d at 587.

77. *See generally* Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food, 21 C.F.R. § 110 (2007).

corporate criminal conviction and reasonable restitution amounts in light of *Apprendi v. New Jersey*[78] and *United States v. Booker*.[79]

1. "Knowingly" stored products under insanitary conditions.

The critical element for the criminal conviction in this case was a finding that the corporation, through its authorized agents or employees, knowingly stored products under insanitary conditions.[80] The jury instructions noted that a corporation acquires "knowledge" through its agents and "[w]here a corporate agent obtains knowledge while acting in the scope of agency" there is a presumption that the agent will report that knowledge to the corporate principal.[81] In this case, LaGrou's president, warehouse manager, and employees on the "rat patrol" were "well aware of the rodent infestation problem and other insanitary conditions ... yet persisted in storing and distributing meat, poultry, and other food products [at the Pershing Warehouse]."[82] The Seventh Circuit upheld the jury instruction and felony conviction.[83]

2. Restitution and Fines

On appeal, LaGrou urged the court to review the lower court's restitution order in light of the newly-issued *Apprendi* and *Booker* decisions.[84] The court rejected LaGrou's arguments and held that restitution is a civil penalty "for harm done" and is "administered for convenience by the courts," and therefore is not within the sole providence of the jury.[85] Accordingly, the Sixth Amendment, as interpreted by *Booker*, and *Apprendi*, do not apply.[86]

The court went on to review the trial court's $8.2 million order for restitution based on an abuse of discretion standard.[87] Of the approximately 22 million pounds seized, health officials salvaged over 12 million pounds at a decontamination cost of $2.7 million.[88]

78. 530 U.S. 466 (2000).
79. 543 U.S. 220 (2005).
80. *LaGrou*, 466 F.3d at 591-92.
81. *Id.* at 591.
82. *Id.* at 592.
83. *Id.* at 592, 594.
84. *Id.* at 592-93.
85. *LaGrou*, 466 F.3d at 593.
86. *Id.*
87. *Id.*
88. *Id.*

The government, however, could not recondition and therefore destroyed over 8 million pounds of customers' products with a wholesale price of $5.5 million.[89] The court found the expenses incurred for decontamination to be "reasonable," as well as the use of wholesale prices to assess the balance of the restitution amount.[90]

The trial court sentenced LaGrou to a total of $2 million in fines in accordance with the Sentencing Guidelines for corporate defendants found guilty of a felony ranging from "not more than the greater of (a) $500,000; (b) twice the gross gain; or (c) twice the gross loss."[91] The trial court sentenced LaGrou to $500,000 on count three (poultry), $500,000 on count four (meat), and $1 million on count five (food products).[92] Because the court failed to give a special interrogatory or verdict form to the jury, the statutory maximum for each count was limited to $500,000. Accordingly, the appeals court remanded for resentencing on the $1 million fine for count five.[93] Absent a jury's determination, the court held that the trial judge improperly used a preponderance of the evidence standard to determine the "loss amount" under section (c), rather than a jury standard of beyond a reasonable doubt.[94]

B. Genetic Engineering Field Trials: Environmental Assessments

In February 2004, a group of environmental and food safety interest groups filed suit alleging that the USDA's Animal and Plant Health Inspection Service (APHIS) failed to comply with the Endangered Species Act (ESA) and the National Environmental Policy Act (NEPA) when it approved permits for the open-air field testing of genetically engineered, pharmaceutical-producing plant varieties (GEPPVs) in Hawaii.[95] After protracted litigation, the district court granted in part and denied in part the parties' competing motions for summary judgment.[96] Although this case dealt specifically with

89. *Id.*

90. *LaGrou*, 466 F.3d at 593-94.

91. *Id.* at 594 (citing 18 U.S.C. § 3571(c)(3), (d)).

92. *Id.* at 594.

93. *Id.* As of this writing, the Supreme Court has further refined *Apprendi* in *Cunningham v. California*, 127 S. Ct. 856 (2007), the implication of which is beyond the scope of this paper.

94. *LaGrou*, 466 F.3d at 594.

95. *See* Center for Food Safety v. Veneman, 364 F. Supp. 2d 1202, 1205 (D. Haw. 2005) (denying motion to dismiss).

96. Center for Food Safety v. Johanns, 451 F. Supp. 2d 1165, 1171 (D. Haw. 2006).

GEPPVs, the ESA and NEPA requirements could apply to future APHIS decisions that permit open-air field testing of genetically engineered plant varieties destined for food or feed that do not otherwise qualify for APHIS's streamlined "notification" provisions for field testing.[97]

The plaintiffs argued in their motion for summary judgment, *inter alia*, that APHIS failed to evaluate properly the environmental impact of the genetically engineered crops before issuing permits for field testing.[98] Moreover, the plaintiffs alleged that the experimental use permits for the Hawaii field trials were part of a broader GEPPV program and APHIS failed to consider the environmental consequences of the program as a whole.[99] In so doing, the plaintiffs claimed that APHIS violated the ESA and NEPA.[100] APHIS countered that it fulfilled its statutory obligations and placed strict conditions on the permits at issue to ensure protection of the environment.[101]

The court concluded that APHIS violated both the ESA and NEPA in issuing the individual field testing permits and entered summary judgment for plaintiffs.[102] However, the court granted summary judgment for the government defendants with respect to ESA and NEPA compliance for APHIS's alleged GEPPV program.[103] A brief discussion of the court's decision follows.

1. Endangered Species Act Claims

APHIS did not dispute that the issuance of the individual field testing permits was "agency action" sufficient to implicate the ESA. APHIS argued, however, that once it determined that the proposed field trials would not affect listed species or critical habitat, a formal consultation with the United States Fish and Wildlife Service (FWS)

97. *See* Introduction of Organisms and Products Altered or Produced through Genetic Engineering, 7 C.F.R. § 340.3 (2007). For a description of the streamlined "notification" procedures and genetically engineered plants eligible for this process, see USDA, Animal and Plant Health Inspection Service (APHIS), *Biotechnology Notifications*, http://www.aphis.usda.gov/biotechnology/notifications.shtml (last visited Sept. 25, 2007); and USDA, APHIS, BIOTECHNOLOGY REGULATORY SERVICES USER'S GUIDE (DRAFT GUIDANCE), Chapter 6 (2007), *available at* http://www.aphis.usda.gov/brs/pdf/brs_userguide_6_Notification.pdf.

98. *Center for Food Safety*, 451 F. Supp. 2d. at 1171.

99. *Id.*

100. *Id.*

101. *Id.*

102. *Id.*

103. *Center for Food Safety*, 451 F. Supp. 2d. at 1171.

and the National Marine Fisheries Service (NMFS) was not required.[104] The court held that regardless of whether a formal consultation may or may not eventually be required, APHIS failed to take the initial step of requesting information about listed species and critical habitats from the FWS and the NMFS.[105] The initial procedural requirement to request information is a necessary first step.[106] Accordingly, APHIS must request information from the FWS and the NMFS regarding listed species and critical habitats before determining whether to engage in formal consultation or issuing further field testing permits in Hawaii.[107]

2. National Environmental Policy Act Claim

Because avoidance of environmental impacts is built into the agency action when issuing some permits,[108] APHIS regulations provide for a categorical exclusion for the preparation of an environmental assessment (EA) or an environmental impact statement (EIS) for "confined field releases of genetically engineered organisms."[109] APHIS argued that each of the GEPPV permits in this case involved confined or controlled field tests.[110] Accordingly, APHIS asserted that its approval of the permits did not require a separate EA or EIS.[111] The court agreed with APHIS's reasoning, but refused to defer to the agency's *post hoc* explanation because the administrative record for each permit was devoid of any reference to consideration of environmental consequences as required by NEPA.[112] Moreover, APHIS failed to document in the administrative record that it considered whether an exception to the categorical exclusions applied.[113]

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104. *Id.* at 1181-82.

105. *Id.* at 1182 (interpreting 16 U.S.C. § 1536(c)(1) and Interagency Cooperation–Endangered Species Act, 50 C.F.R. § 402.12).

106. *Id.* at 1182 (noting that "[e]ven if APHIS is ultimately correct in its assertion that no listed species or habitats have been harmed, APHIS's actions are nevertheless tainted because APHIS failed to comply with a fundamental procedural requirement").

107. *Id.* at 1181-82. Hawaii has 329 endangered and threatened species. *Id.* at 1170. Yet, the mild climate and year-round growing conditions are ideal for experimental field trials. *Id.* at 1211 (noting the long history of field trials in Hawaii).

108. *Center for Food Safety*, 451 F. Supp. 2d at 1184.

109. National Environmental Policy Act Implementing Procedures, 7 C.F.R. § 372.5(c)(3)(ii) (2007).

110. *Center for Food Safety*, 451 F. Supp. 2d at 1184.

111. *Id.*

112. *Id.*

113. *Id.* at 1185-86.

Despite these deficiencies with the individual permits, the court found that APHIS's internal procedures and protocols for approving GEPPV permits as part of a general program did not violate NEPA or the ESA.[114] Although the cumulative effect of the permits may constitute an organized method of issuing GEPPV permits, there was no "final agency action" that would require a broader programmatic EIS under NEPA,[115] or "agency action" to trigger the ESA's procedural requirements.[116] The court, accordingly, entered summary judgment for APHIS on the programmatic issues.[117]

With the plaintiffs' consent, the court entered only declaratory relief on the ESA and NEPA claims related to the individual permits.[118] Because the field tests were complete and injunctive relief ordering APHIS to comply with the ESA and NEPA would be superfluous, the court declined to order further action such as an environmental study of the effects of the open-air tests.[119] Despite the limited relief, this case provides important guidance for APHIS internal operating procedures for future permitting decisions.

IV. CONCLUSION

Food safety issues (e.g., *E. coli*, state meat and poultry inspection programs, warehouse sanitation) dominated the news and federal judicial and administrative actions for the second half of 2006. Concerns related to the production, storage, and distribution of safe food in this increasingly globally connected world will remain preeminent issues for all involved in the food supply chain. Greater consumer awareness and agency interaction with the public via the internet and other distribution channels will ensure the focus of continued political attention to this important aspect of food law. In addition, the introduction of enhanced technology (e.g., genetic engineering, cloning) into the food supply promises to engender significant passion and present challenges for the food industry.

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114. *Id.* at 1190.
115. *Center for Food Safety*, 451 F. Supp. 2d at 1189.
116. *Id.* at 1190.
117. *Id.* at 1192.
118. *Id.* at 1195.
119. *Id.*