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Food for Thought: Consistent Protocol Could Strengthen Food Supply Security Measures

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FOOD FOR THOUGHT: CONSISTENT PROTOCOL COULD STRENGTHEN FOOD SUPPLY SECURITY MEASURES

When Americans buy food at their hometown grocery stores or frequent favorite restaurants, it is unlikely that much thought is given to whether any of the food consumed may ultimately cause their demise. They should.[1]

I. INTRODUCTION

A. *Food*[2] *Safety Focus Since September 11, 2001*

Food safety laws are an integral part of the domestic food supply and have been for most of this century.[3] The attack on America on September 11, 2001 forced government officials,[4] producers,[5] and consumers[6] to seek out and bolster any potential weak spots in national security.[7] The domestic food supply is one such area of concern.[8] The

1. *See* Food Safety Office, *at* http://www.cdc.gov/foodsafety (Feb. 7, 2004) (stating that in the United States, foodborne illnesses result in an estimated seventy-six million illnesses and five thousand deaths annually) (on file with the Texas Wesleyan Law Review); DANIEL L. GALLAGHER ET AL., U.S. DEP'T OF AGRIC., DRAFT FSIS RISK ASSESSMENT FOR *Listeria* in Ready-to-eat Meat and Poultry Products 2 (2003), *available at* http://www.fsis.usda.gov/ophs/lmrisk/draftlm22603.pdf (on file with the Texas Wesleyan Law Review); *see also* Telephone Interview with Ann Shaw, Manager in Charge of Labeling and Research Records, Morningstar Foods, Inc. (Feb. 3, 2003) (on file with the Texas Wesleyan Law Review) (recommending for anyone who frequents restaurants to get inoculated against Hepatitis A and B because food is only as clean as were the hands of its server).

2. *See* United States v. Blue Ribbon Smoked Fish, Inc., 179 F. Supp. 2d 30, 42 (E.D.N.Y. 2001) (citing the Food, Drug, and Cosmetic Act's definition of "food" as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." (quoting 21 U.S.C. § 321(f))).

3. Roger Roots, *A Muckraker's Aftermath:* The Jungle *of Meat-Packing Regulation After a Century*, 27 WM. MITCHELL L. REV. 2413, 2419–21 (2001); JAMES L. VETTER, PH.D., FOOD LAWS AND REGULATIONS 1–17 (Elizabeth Brock ed., 1996); *see* Carey Gillam, *US Food Safety Efforts Struggle Amid Death, Illness*, REUTERS, Oct. 7, 2002, *at* http://story.news.yahoo.com/news?tmpl=story&ncid=594&e=8&cid=594&u=/nm/20021007/hl_nm/food_safety (on file with the Texas Wesleyan Law Review).

4. *See, e.g.*, Homeland Security Act of 2002, Pub. L. No. 107-296, § 101(a)–(b), 116 Stat. 2135, 2142 (enacted to address terrorism).

5. *See, e.g.*, *Second International Conference and Expo To Address Food Safety and Quality*, FOOD TECH., Dec. 2001, at 28 (announcing a conference to address public and industry concerns about the integrity of the food supply).

6. *See id.*

7. *See* Homeland Security Act of 2002 § 101(a)–(b).

8. *See* Ctr. for Food Safety & Applied Nutrition, U.S. Food & Drug Admin., *Frequently Asked Consumer Questions About Food Safety and Terrorism*, *at* http://www.cfsan.fda.gov/dms/fsterrqa.html (Nov. 15, 2001) (on file with the Texas Wesleyan

recent passage of the Public Health Security and Bioterrorism Preparedness Act of 2002 validates the concern that the food supply is at risk for possible terrorist activity.[9] While the terrorist aspect of food safety regulation is most prominent,[10] another more pervasive area of concern gaining regulatory attention is biological, not necessarily terrorist, activity.[11] This Comment explores current food safety laws and practices and suggests that more consistent safety protocol throughout every link in the "farm-to-table"[12] chain could bolster the integrity of the domestic food supply in the post-September 11th environment against both intentional and negligent harm risks.

B. *A Complex Food Regulation System*[13]

As recommended by pending legislation, the Safe Food Act of 2001,[14] the first suggestion for bolstering food safety is to simplify the regulatory system that oversees the domestic food supply.[15] The current food regulation system is complex and should be streamlined under one general regulating body for efficiency in maintaining a safe domestic food supply for the long term.[16]

According to the United States Department of Agriculture (USDA) and the Food and Drug Administration (FDA), the domestic

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Law Review); *see also* James N. Klapthor, *Food Security and Food Safety: Today's Topics of News Media*, FOOD TECH., Dec. 2001, at 20.

9. *See* Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594; Steven C. Bahls, *AALA Presidential Address: September 11, 2001, and Agricultural Law*, 7 DRAKE J. AGRIC. L. 1, 3 (2002); Emily Gersema, *Experts Warn on Food Supply Attack*, ASSOCIATED PRESS, Sept. 23, 2002, *at* http://story.news.yahoo.com (on file with the Texas Wesleyan Law Review).

10. *See* Public Health Security and Bioterrorism Preparedness and Response Act of 2002 § 1.

11. *See generally* GALLAGHER ET AL., *supra* note 1. The pathogen *L. monocytogenes*, which causes about 500 foodborne listeriosis deaths annually, naturally occurs in the environment where food is grown or further processed; an estimated one to three percent of all "ready to eat" (RTE) meat and poultry foods such as prepackaged luncheon meats, deli meats, and hot dogs are contaminated with *L. monocytogenes*. *Id.* at 2, 29.

12. "Farm-to-table" chain link members are regulators, producers, and consumers. *See* U.S. FOOD & DRUG ADMIN., U.S. DEP'T OF AGRIC., A DESCRIPTION OF THE U.S. FOOD SAFETY SYSTEM at II.C, *at* http://www.foodsafety.gov/~fsg/fssyst2.html (Mar. 3, 2000) [hereinafter A DESCRIPTION OF THE U.S. FOOD SAFETY SYSTEM] (on file with the Texas Wesleyan Law Review) (an interagency paper prepared for submission to the Organization for Economic Cooperation and Development).

13. VETTER, *supra* note 3, at 31; *see* Michael R. Taylor, *Preparing America's Safety System for the Twenty-First Century—Who Is Responsible for What When It Comes to Meeting the Food Safety Challenges of the Consumer-Driven Global Economy?*, 52 FOOD & DRUG L.J. 13, 14–20 (1997) (discussing the "fragmented" domestic food system).

14. H.R. 1671, 107th Cong. (2001).

15. *See id.* For more detail regarding H.R. 1671, see Connecticut Congresswoman Rosa L. DeLauro's web site, *at* http://www.house.gov/delauro/safe_food.html (last visited Feb. 4, 2004) (on file with the Texas Wesleyan Law Review).

16. *See* H.R. 1671.

"food safety system is based on strong, flexible, and science-based federal and state laws and [the] industry's legal responsibility [is] to produce safe food."[17] The largest federal food governing bodies are the USDA and the Department of Health and Human Services (HHS).[18]

The USDA enforces its food regulations such as (1) the Federal Meat Inspection Act,[19] (2) the Poultry and Poultry Products Inspection Act,[20] and (3) the Egg Products Inspection Act[21] for the meat and poultry industries respectively, through the Food Safety and Inspection Service (FSIS).[22] The USDA oversees the Animal and Plant Health Inspection Service, which is responsible for "protect[ing] against plant and animal pests and diseases."[23] The USDA also oversees the Agricultural Research Service, which provides "[r]esearch programs and technical assistance to federal agencies."[24]

The HHS oversees the FDA, which regulates most other food industries through the Federal Food, Drug, and Cosmetic Act (FDCA).[25] Through the FDCA, the FDA ensures that food is pure and properly labeled.[26] The HHS also oversees the federal Centers for Disease Control and Prevention (CDC), which "monitors the occurrence of illness in the United States attributable to the food supply"[27] and "investigat[es] . . . specific outbreaks of illness[es] when invited to do so by the health department of the state in which the outbreak occurred."[28] The HHS also oversees the National Institutes of Health, which is a "steward of medical and behavioral research for the nation."[29]

Other key agencies are: (1) the Environmental Protection Agency, which works with the USDA and the FDA in regard to regulating tolerances for pesticide residues in food;[30] (2) the Department of Trea-

17. A DESCRIPTION OF THE U.S. FOOD SAFETY SYSTEM, *supra* note 12, at I.
18. *See id.* at II.
19. 21 U.S.C. §§ 601–695 (2000).
20. 21 U.S.C. §§ 451–471 (2000).
21. 21 U.S.C. §§ 1031–1056 (2000).
22. *See* Taylor, *supra* note 13, at 18.
23. A DESCRIPTION OF THE U.S. FOOD SAFETY SYSTEM, *supra* note 12, at II.
24. *See* VETTER, *supra* note 3, at 39; A DESCRIPTION OF THE U.S. FOOD SAFETY SYSTEM, *supra* note 12, at II.
25. 21 U.S.C. §§ 301–395 (2002); *see* VETTER, *supra* note 3, at 39; Taylor, *supra* note 13, at 15.
26. *See* A DESCRIPTION OF THE U.S. FOOD SAFETY SYSTEM, *supra* note 12, at II.
27. *Food Safety and Security: Hearing Before the Comm. on Governmental Affairs, Subcomm. on Oversight of Gov't Mgmt., Restructuring, and the D.C.*, 107th Cong. (2001) (statement of Bernard A. Schwetz, D.V.M., Ph.D.), 2001 WL 26186923 [hereinafter *Hearing*].
28. Taylor, *supra* note 13, at 19.
29. *About NIH*, National Institutes of Health, U.S. Dep't of Health & Human Servs., *at* http://www.nih.gov/about (last reviewed Feb. 6, 2003) (on file with the Texas Wesleyan Law Review); *see* A DESCRIPTION OF THE U.S. FOOD SAFETY SYSTEM, *supra* note 12, at II.
30. A DESCRIPTION OF THE U.S. FOOD SAFETY SYSTEM, *supra* note 12, at II; Taylor, *supra* note 13, at 18.

sury's Customs Service, which "detain[s] imports based on guidance provided";[31] (3) the Cooperative State Research, Education, and Extension Service;[32] (4) the Agricultural Marketing Service;[33] (5) the Economic Research Service;[34] (6) the Grain Inspection, Packers and Stockyard Administration;[35] (7) the U.S. Codex Office;[36] and (8) the Department of Commerce's National Marine Fisheries Service.[37] Lastly, the states oversee some localized food safety programs.[38]

These federal and state bodies promulgate regulations and guidelines regarding safe food handling and food quality standards for human consumption, as well as how foodstuffs are labeled.[39] Government officials routinely make inspections to ensure proper producer compliance with these regulations, but because some industries are less regulated than others, producers are often self-monitoring.[40]

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31. A DESCRIPTION OF THE U.S. FOOD SAFETY SYSTEM, *supra* note 12, at II.

32. CREES provides "research and education information about many subjects." *Program Information*, Cooperative State Research, Education, and Extension Service, U.S. Dep't of Agric., *at* http://www.reeusda.gov/1700/programs/programs.htm (last updated Jan. 29, 2003) (on file with the Texas Wesleyan Law Review).

33. The Agricultural Marketing Service provides "standardization, grading and market news services for" "six commodity programs—Cotton, Dairy, Fruit and Vegetable, Livestock and Seed, Poultry, and Tobacco." *See An Overview of AMS Programs and Services*, Agric. Mktg. Serv., U.S. Dep't of Agric., *at* http://www.ams.usda.gov/admin/overview.htm (last visited Feb. 4, 2004) (on file with the Texas Wesleyan Law Review).

34. The Economic Research Service is an economic research arm of the USDA that aids decision making "on economic and policy issues related to agriculture, food, natural resources, and rural development." *See About ERS*, Econ. Research Serv., U.S. Dep't of Agric., *at* http://www.ers.usda.gov/abouters (last updated Sept. 30, 2002) (on file with the Texas Wesleyan Law Review).

35. The Grain Inspection, Packers and Stockyards Administration "facilitates the marketing of livestock, poultry, meat, cereals, oilseeds . . . and promotes fair and competitive trading practices for the overall benefit of consumers and American agriculture." *See GIPSA Backgrounder*, Grain Inspection, Packers & Stockyards Admin., U.S. Dep't of Agric., *at* http://www.usda.gov/gipsa/aboutus/background.htm (last visited Feb. 19, 2003) (on file with the Texas Wesleyan Law Review).

36. The *Codex Alimentarius Commission* "provides a forum . . . used by countries to facilitate trade." *See Codex Mission & Activities*, Food Safety and Inspection Serv., U.S. Dep't of Agric., *at* http://www.fsis.usda.gov/oa/codex/mission.htm (last visited Feb. 19, 2003) (on file with the Texas Wesleyan Law Review).

37. A DESCRIPTION OF THE U.S. FOOD SAFETY SYSTEM, *supra* note 12, at II; *see* Nat'l Marine Fisheries Serv., Nat'l Oceanic & Atmospheric Admin., *at* http://www.nmfs.noaa.gov (last visited Feb. 20, 2004) (on file with the Texas Wesleyan Law Review) (the NMFS (NOAA Fisheries) is "dedicated to the stewardship of living marine resources through science-based conservation and management, and the promotion of healthy ecosystems"); Nat'l Marine Fisheries Serv., Nat'l Oceanic & Atmospheric Admin., *Seafood Inspection Program*, *at* http://seafood.nmfs.noaa.gov (last visited Feb. 19, 2003) (on file with the Texas Wesleyan Law Review) (the National Oceanic and Atmospheric Administration (NOAA) provides voluntary seafood inspection services to the fish industry).

38. Taylor, *supra* note 13, at 19.

39. *See id.*; *Hearing*, *supra* note 27 (testimony of Bernard A. Schwetz, D.V.M., Ph.D.).

40. HACCP is only mandatory for meat, fish, and poultry producers. *See* Taylor, *supra* note 13, at 14.

C. *Safe Food Supply Is the Goal*

With the number of groups involved, it is no surprise that experts consider the United States's food supply among the cleanest in the world for consumers.[41] However, considering that an estimated "[seventy-six] million people get sick, more than 300,000 are hospitalized, and 5,000 Americans die each year from food borne illness,"[42] the domestic food supply is "safe" only in relative terms.[43] Undoubtedly, a fail-safe food supply is a critical goal for policy makers[44] because the current system is inefficient[45] and poses an ill-defined foundation upon which to risk the domestic food supply for the long term. Food safety is compromised not only by the complexity of the system, but also by regulators imposing mere guidelines[46] instead of regulations, or by outright ineffective regulations.[47] For some of the key regulations, inconsistent inspection protocol further exacerbates the problem.[48] Therefore, more consistent regulation inspection protocol should strengthen food safety measures within the United States.[49]

This Comment focuses on the current status of the United States' food safety law in a post-September 11th environment. First, in Part II, the food safety focus of this Comment will define and differentiate naturally occurring food safety problems from intentionally created food safety problems. Second, in Part III, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002[50] will be

41. VETTER, *supra* note 3, at 181; *see Hearing*, *supra* note 27 (testimony of Bernard A. Schwetz, D.V.M., Ph.D.).

42. *See* Food Safety Office, *at* http://www.cdc.gov/foodsafety (Feb. 7, 2004) (on file with the Texas Wesleyan Law Review).

43. *Compare* VETTER, *supra* note 3, at 181 (stating that the food supply is one of the safest in the world), *and Hearing*, *supra* note 27 (testimony of Bernard A. Schwetz, D.V.M., Ph.D.), *with* Food Safety Office, *at* http://www.cdc.gov/foodsafety (Feb. 7, 2004) (on file with the Texas Wesleyan Law Review).

44. *See* Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, § 301, 116 Stat. 594, 662.

45. *See* discussion *supra* Part I.B (regarding the complexity of the current regulatory system); *see also* Taylor, *supra* note 13, at 18 (describing the "Fragmented Federal Food Supply System"); discussion *infra* Part III.A. (noting interagency coordination requirements built into the Public Health Security and Bioterrorism Preparedness and Response Act).

46. *See* CTR. FOR FOOD SAFETY AND APPLIED NUTRITION, U.S. DEP'T OF HEALTH & HUMAN SERVS., FOOD PRODUCERS, PROCESSORS, TRANSPORTERS, AND RETAILERS: FOOD SECURITY PREVENTATIVE MEASURES GUIDANCE, (Jan. 9, 2002), *at* http://www.cfsan.fda.gov/~dms/secguid.html [hereinafter FOOD SECURITY PREVENTATIVE MEASURES GUIDANCE] (on file with the Texas Wesleyan Law Review).

47. *See* U.S. GEN. ACCOUNTING OFFICE, PUB. NO. GAO-02-902, MEAT AND POULTRY: BETTER USDA OVERSIGHT AND ENFORCEMENT OF SAFETY RULES NEEDED TO REDUCE THE RISK OF FOODBORNE ILLNESSES, 4–6 (2002); Roots, *supra* note 3, at 2414; *see also* Allison M. Sgroi, *Federal Food and Drug Act Violations*, 39 AM. CRIM. L. REV. 609, 615–17 (2002) (noting difficulties in applying "criminal liability on a corporate officer" in an FDCA related action).

48. *See* U.S. GEN. ACCOUNTING OFFICE, *supra* note 47, at 4–6.

49. *See id.*

50. Pub. L. No. 107-188, 116 Stat. 594.

evaluated and then compared to current Hazardous Analysis and Critical Control Points (HACCP) programs.[51] Third, in Part IV, a suggested protocol will be offered. Finally, in Part V, conclusions will be drawn and offered as food for thought for each of the stakeholders—regulatory, supply chain, or consumer—in their collective development of comprehensive post-September 11th food safety protocol.

II. DEFINING THE PROBLEM

Existing food supply risk factors include both naturally occurring and artificially created food hazards.[52] For illustration, pitted cherry requirements are an example of a naturally occurring food hazard.[53] The USDA allows up to two pits in any twenty ounce sample unit of cherries in its standards for "pitted" cherries, which are utilized by domestic fruit base manufacturers.[54] The purpose behind the USDA standard is to enhance the marketability of cherries and similar crops.[55] "As in the case of other standards for grades of processed fruits and vegetables, these standards are designed to facilitate orderly marketing by providing a convenient basis for buying and selling, for establishing quality control programs, and for determining loan values."[56] The USDA purports that these specifications are an acceptable quality baseline for producers.[57] Yet in practice, USDA standards are not as rigorous as what cautious fruit base manufacturers would require in order to maintain their customer base,[58] and although deemed "pitted" by the USDA, these manufacturers would likely further screen these cherries before processing them.[59] Other-

51. *See* Taylor, *supra* note 13, at 14.

52. *See, e.g.*, *Grocery Worker Indicted in Meat-Poisoning Case*, HOUS. CHRON., Feb. 14, 2003 (reporting intentional harm to food supply where disgruntled employee is indicted for poisoning beef sold to grocery store's customers); Associated Press, *FDA Renews Sprout Warning*, THE SACRAMENTO BEE, Oct. 2, 2002, http://www.sacbee.com/24hour/healthscience/story/559740p-4407991c.html (on file with the Texas Wesleyan Law Review) (warning that raw sprouts may cause food poisoning for *E. coli* or *salmonella*).

53. *See* Ingredient Specification 5 + 1 Elliot Pitted Red Tart Cherries (May 16, 2000) (indicating limit of 1 pit per 320 ounce sample) (provided courtesy of Mike Mulhausen, President, California Custom Fruits and Flavors, Inc.) [hereinafter Ingredient Specification] (on file with the Texas Wesleyan Law Review); Product Information Black Cherry Yogurt Fruit (Jan. 9, 2003) (indicating 1 pit per 800 ounce sample) (provided courtesy of Mike Jacobs, President, Pacific Fruit Processors, Inc.) [hereinafter Product Information] (on file with the Texas Wesleyan Law Review).

54. *See* U.S. Standards for Grades of Frozen Red Tart Pitted Cherries, 7 C.F.R. §§ 52.807(c), 52.810 tbl.1 (2003).

55. U.S. Standards for Grades of Frozen Red Tart Pitted Cherries, 39 Fed. Reg. 23,234, at Introduction (June 27, 1979).

56. *Id.*

57. *See id.*

58. *See* Ingredient Specification, *supra* note 53; Product Information, *supra* note 53.

59. *See* Ingredient Specification, *supra* note 53; Product Information, *supra* note 53.

wise, the manufacturer unnecessarily exposes itself to tort liability and loss of reputation if the cherry pit ultimately ends up in a finished product such as yogurt, and the consumer inadvertently breaks a tooth on the pit.[60] Thus, in this scenario, the USDA's allowable level of particulate for pitted cherries, as a category, is probably unacceptable for both the fruit base supplier and the ultimate consumer.

This cherry pit illustration describes a simple, naturally occurring food safety hazard that is easily avoidable by a manufacturer insisting on tighter than USDA recommended standards[61] from its suppliers. The USDA should tighten up its specifications to reduce the amount of extraneous matter allowed[62] and, consequently, reduce the possibility of harming consumers. Mandating tighter USDA specifications[63] is one suggestion for regulators to better protect the domestic food supply. The balance of this Comment focuses on food safety issues that are less easily ameliorated.

A. *Food Pathogens*

Foodborne pathogens[64] are a natural part of the food supply, and when the count of certain pathogens is high enough, foods are considered unsafe for human consumption.[65] Often, proper handling and preparation of foods at the consumer level is enough to destroy these pathogens.[66] But when the pathogens are not destroyed prior to consumption, typically the "immuno-compromised,"[67] or people with weakened immune systems, such as the elderly or very young, can become ill or in some instances, die.[68]

A frequent remedy for removing food products containing intolerable amounts of dangerous pathogens is a recall.[69] With over 7,600

60. *See* Product Information, *supra* note 53.

61. *See* U.S. Standards for Grades of Frozen Red Tart Pitted Cherries, 7 C.F.R. §§ 52.807, 52.810 (2003).

62. *See id.*

63. *See id.*

64. A "pathogen" is an agent, like a bacterium or virus, which causes disease. MERRIAM WEBSTER'S COLLEGIATE DICTIONARY 852 (10th ed. 1994).

65. *See, e.g.*, United States v. Blue Ribbon Smoked Fish, Inc., 179 F. Supp. 2d 30, 38 (E.D.N.Y. 2001) (indicating "zero tolerance" for *L. monocytogenes*).

66. *See Consumer Food Safety Behavior: Overview*, Econ. Research Serv., U.S. Dep't of Agric., *at* http://www.ers.usda.gov/briefing/consumerfoodssafety/overview.htm (last updated May 23, 2002) (on file with the Texas Wesleyan Law Review).

67. *Hearing*, *supra* note 27 (testimony of Bernard A. Schwetz, D.V.M., Ph.D.).

68. *See Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d at 37; Food Safety Office, *at* http://www.cdc.gov/foodsafety (Feb. 7, 2004) (on file with the Texas Wesleyan Law Review).

69. *See* FOOD SAFETY & INSPECTION SERVICE, U.S. DEP'T OF AGRIC., DIRECTIVE 8080.1 REVISION 3: RECALL OF MEAT AND POULTRY PRODUCTS at I (Jan. 19, 2000), *at* http://www.fsis.usda.gov/foia/dir/8080.htm (on file with the Texas Wesleyan Law Review). According to the FSIS, a "recall is a firm's voluntary removal of product from trade or consumer channels . . . to protect the public from consuming adulterated or misbranded products" and can be an alternative to a FSIS initiated action. *Id.* at V.

FSIS inspectors overseeing the meat, egg, and poultry processors, these industries are more directly federally regulated than other food industries in regard to inspection and reporting of food pathogens.[70] Consequently, many of the publicly announced recalls fall into the meat, egg, or poultry industries.[71] For example, in the fall of 2002, Pilgrim's Pride and Jack Lambersky Poultry Company recalled over twenty-seven million pounds of ready to eat poultry products that were "fingerprinted" to an outbreak of listeriosis that killed eight people.[72]

B. *Misbranded or Adulterated Food*

The FDCA prohibits distribution into interstate commerce of any misbranded or adulterated food.[73] "Misbranded" refers to food packaging labels that are "inaccurate, false, or misleading."[74] The FDCA describes adulterated food in a variety of ways including: (1) having "[p]oisonous, insanitary . . . ingredients";[75] (2) "[a]bsence, substitution, or addition of constituents";[76] (3) unsafe "[c]olor additives";[77] (4) "[c]onfectionery containing alcohol or nonnutritive substance";[78] (5) "[o]leomargarine containing filthy, putrid, etc., matter";[79] (6) a "[d]ietary supplement" that poses "an unreasonable risk of illness or injury"[80] to its consumer; (7) a "[d]ietary supplement" that "has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations";[81] and (8) an "article of food imported or offered for import into the United States . . . [that

70. *See* 21 C.F.R. pt. 123 (2003) (citing regulations for fish and fishery products); *Protecting the Public from Foodborne Illness: The Food Safety and Inspection Service*, Food Safety and Inspection Service, U.S. Dep't of Agric., *at* http://www.fsis.usda.gov/oa/background/fsisgeneral.htm (Apr. 2001) (on file with the Texas Wesleyan Law Review).

71. *See* Recall, Market Withdrawals and Safety Alerts, *at* http://www.fda.gov/opacom/7alerts.html (Feb. 7, 2004) (on file with the Texas Wesleyan Law Review) (listing recent food recalls).

72. Press Release, Media Relations, Center for Disease Control, Update: Listeria Outbreak Investigation (Nov. 21, 2002), *at* http://www.cdc.gov/od/oc/media/pressrel/r021121.htm (on file with the Texas Wesleyan Law Review).

73. 21 U.S.C. § 33(a) (2000); *see also* United States v. Dotterweich, 320 U.S. 277, 284 (1943).

74. VETTER, *supra* note 3, at 49; *see* 21 U.S.C.A. § 343 (West 1999 & Supp. 2003).

75. 21 U.S.C. § 342(a) (2000).

76. *Id.* § 342(b).

77. *Id.* § 342(c).

78. *Id.* § 342(d).

79. *Id.* § 342(e).

80. 21 U.S.C.A. § 342(f) (West 1999 & Supp. 2003).

81. 21 U.S.C. § 342(g) (2000).

has] previously been refused admission."[82] "Adulteration" is essentially to cause something to be less pure.[83]

Related to misbranding and adulteration is nutritional labeling, a seemingly quiet area of the law[84] but which has significant consumer ramifications in regard to food safety. In 1990, the Nutritional Labeling and Education Act (NLEA) was enacted so consumers could be more informed in their food choices.[85] The NLEA "mandated nutrition labeling for FDA regulated foods. Although not required by law, the U.S. Department of Agriculture promulgated nutrition labeling regulations for meat and poultry products . . . [that were] very similar to the requirements promulgated by [the] FDA."[86] Primarily, the federal government is responsible for ensuring proper labeling,[87] but often, unless tipped off by a consumer watchdog group, a consumer who has suffered harm, or a company's competitor, mislabeled foods go undetected.[88]

Because "each year, roughly 30,000 individuals require emergency room treatment and 150 individuals die because of allergic reactions to food," changing the FDCA to include allergen labeling requirements has been proposed in the Senate to take effect in 2006.[89] If the proposed labeling requirements come to fruition, then lack of allergen declaration on labels would be considered misbranding or adulteration.[90] Would anyone suspect that an undeclared addition of peanut oil[91] was intentional? Realistically, the cost of creating a food company in order to harm the occasional consumer through improper labeling makes it unlikely. However, the possibility that a wrongdoer decides to work at a food company in order to tamper with the prod-

82. 21 U.S.C.A. § 342(h) (West 1999 & Supp. 2003).

83. *See* BLACK'S LAW DICTIONARY 41 (abridged 7th ed. 2000); *see, e.g.*, United States v. Union Cheese Co., 902 F. Supp. 778, 787 (N.D. Ohio 1995) (ordering injunction for adulterated food).

84. *See* Pearson v. Shalala, 130 F. Supp. 2d 105, 120 (D.D.C. 2001) (holding that "the FDA's refusal to authorize the Folic Acid Claim [on the label] violated the First Amendment").

85. *See* VETTER, *supra* note 3, at 87.

86. *Id.* "The detailed requirements for declaring nutrition information may be found in 21 CFR 101.9 for FDA regulated foods, 9 CFR 317 for meat products, and 9 CFR 381 for poultry products." *Id.* at 88.

87. *See id.* at 100.

88. *See, e.g.*, *Food Irradiation Information*, Public Citizen, *at* http://www.citizen.org/cmep/foodsafety/food_irrad/ (last visited Feb. 17, 2003) (on file with the Texas Wesleyan Law Review); *Stop Food Irradiation Project*, Organic Consumers Ass'n, *at* http://www.organicconsumers.org/irrad/science.cfm (updated Dec. 17, 2002) (on file with the Texas Wesleyan Law Review).

89. Food Allergen Labeling and Consumer Protection Act, S. 3001, 109th Cong. (2002).

90. *See* S. 3001 § 3(a)(t)(1)(A)–(B).

91. *See* S. 3001 § 2(2)(A) (listing major allergen food groups: "milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans"); *Peanut Allergy from Playing Cards a Losing Hand*, REUTERS, Sept. 12, 2002, *at* http://story.news.yahoo.com (on file with the Texas Wesleyan Law Review).

ucts is more likely and should be considered when policy makers are deciding how to screen employees.[92]

C. *Food Tampering*

For the purpose of differentiation, this Comment will use "tampering" to refer to adulteration of a product with the intent to harm its ultimate consumer.[93] For example, on September 9, 1982, seven people died as a result of consuming Tylenol that had been deliberately laced with cyanide.[94] As a result of the Tylenol tampering, tamper evident packaging materials became the norm for domestic packaged food and pharmaceuticals.[95] These packaging materials do not make the food inside impregnable, but they do hinder a terrorist's ability to tamper with the product and will be further discussed in the proposed protocol section of this Comment.

Tampering and bioterrorism are directly related. The Department of Homeland Security refers to "terrorism" as an intentional act that is "dangerous to human life or potentially destructive of critical infrastructure or key resources" for the purpose of "intimidat[ing] or coerc[ing] a civilian population."[96] One example is tampering with the water supply to poison an entire city.[97] For the purposes of this Comment, bioterrorism refers to one's tampering with any link in the food supply chain to intentionally harm consumers for presumably political purposes.[98]

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92. *See* Steven Grover, *Food Safety and Food Security Issues Before and After September 11, 2001*, SG104 A.L.I.-A.B.A. 143, 149–50 (2002), http://www.westlaw.com (suggesting food safety and employee screening methodology); Douglas L. Archer & Fred H. Degnan, *Impact of Bioterrorism Threat*, FOOD TECH., Dec. 2001, at 21 (recommending "background checks for *all* personnel" as part of the post-September 11, 2001 protocol for producers); *see, e.g.*, United States v. Lewis, 797 F.2d 358, 362–63 (7th Cir. 1986) (describing facts about the 1982 Chicago Tylenol cyanide tampering case).

93. *See Lewis*, 797 F.2d at 362.

94. *Id.*

95. *See* Interview with Don Klein, Vice President of Purchasing, Morningstar Foods, Inc., in Dallas, Tex. (Jan. 18, 2002) (on file with the Texas Wesleyan Law Review).

96. *See* Homeland Security Act of 2002, Pub. L. No. 107-296 § 2(15), 116 Stat. 2135, 2141.

97. *See* Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, sec. 401, § 1433(a)(1), 116 Stat. 594, 682; *see also* Letter from Joseph A. Levitt, Ctr. for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, (July 17, 2002), *at* http://www.cfsan.fda.gov/~dms/sec-ltr.html (on file with the Texas Wesleyan Law Review) (summarizing the FDA's responsibilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002).

98. *See supra* notes 93–97 and accompanying text.

III. The Current State of Food Safety Law

A. *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*[99]

On June 12, 2002, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Act) became law.[100] The purpose of the Act is "[t]o improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies."[101] The Act has five titles: "Title I—National Preparedness for Bioterrorism and Other Public Health Emergencies," "Title II—Enhancing Controls on Dangerous Biological Agents and Toxins," "Title III—Protecting Safety and Security of the Food and Drug Supply," "Title IV—Drinking Water Security and Safety," and "Title V—Additional Provisions."[102] Food safety primarily falls within Title II and Title III, but it is also touched upon throughout the first four titles.[103] This Act, which is a response to the September 11th terrorist attacks,[104] is a good start toward ensuring a safe domestic food supply; however, it reads more like a plan to make "recommendations" rather than an enactment to address potential bioterrorism today.[105] The following comments are intended to further strengthen the effectiveness of the food safety aspect of this Act.

1. Title II of the Act Inefficiently Duplicates the Efforts of the FDA and USDA

In Title II, the Act mandates that the FDA, by regulation, identify and list potential biological toxins and agents that severely threaten "public health and safety"[106] and separately charges that the USDA, by regulation, identify those toxins and agents that "pose a severe threat to animal or plant health, or to animal or plant products."[107] The Act also requires that the FDA and USDA separately create regulations covering the transfers, proper handling, limited access, research, possession and use, registration, and inspection for each department's respective identified list of biological agents and toxins.[108]

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99. Pub. L. No. 107-188, 116 Stat. 594.

100. Letter from Joseph A. Levitt, *supra* note 97.

101. Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 116 Stat. at 594 (quoting introductory note for H.R. 3448).

102. Public Health Security and Bioterrorism Preparedness and Response Act of 2002 § 1.

103. *See id.*

104. *See id.* sec. 143, § 1135(b).

105. *See id.* sec. 101, § 2801(a)–(b).

106. *Id.* sec. 201(a), § 351A(a)(1)(A).

107. *Id.* § 212(a)(1)(A).

108. *Id.* sec. 201(a), § 351A(b)–(f); *id.* § 212(b)–(f).

The mandate for separate, yet virtually duplicate, regulations is inefficient.[109] This inefficiency may be explained by the Act's mandate that each department establish criteria for the agents and toxins as they relate to that department's respective area of expertise—the FDA for human health and the USDA for plant and animal health.[110] However, the Act recognizes that some "overlap agents and toxins" will clearly fall into both departments' regulatory jurisdiction[111] and has added "Interagency Coordination" procedures which include a mandate to coordinate efforts to minimize inefficiency and ensure that the "overlap" toxins and agents—toxins and agents that could be classified under either the FDA or USDA—are listed in both databases.[112] The Act requires that the Secretary of Health and Human Services and the Secretary of Agriculture enter into a "Memorandum of Understanding" regarding these "overlap" toxins and agents so that a possessor or user of them is only required to register one time to be in compliance and also so that the information can then be shared, inspected, and enforced by both departments.[113] Furthermore, the Act calls for "Joint Regulations" to be issued within eighteen months of the enactment.[114]

Rather than harmonize regulations post-implementation,[115] clearly the Act could be more efficient if it required both the FDA and USDA to consult *pre*-implementation regarding which criteria are required to ensure that the entire food supply is represented and then promulgate a single set of regulations that are applicable to any food source. The likely benefit of such simplification would be clarity in communication and understanding of what producers and inspectors must do to comply with the Act regardless of the end food produced—better serving the Act's purpose of protecting the food supply.[116]

2. Exemptions Create Inherent Weakness in the Act's Potential Effectiveness

According to the FDA Center for Food Safety and Applied Nutrition (CFSAN), the Act mandates that domestic food facilities and importers of food processed completely outside of the United States must register with the FDA by December 12, 2003.[117] However, the Act curiously exempts "farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or

109. *See id.* sec. 201, § 351A(b)–(f); *see also id.* § 212(b)–(f).
110. *See id.* sec. 201, § 351A(a)(1)(B)(i)(I–III); *see also id.* § 212(a)(1)(B)(i)(I–IV).
111. *See id.* § 221.
112. *See id.*
113. *See id.* § 221(c).
114. *See id.* § 221(d).
115. *But see id.*
116. *See id.* (citing Introductory note for HR 3448).
117. Letter from Joseph A. Levitt, *supra* note 97.

served directly to the consumer; or fishing vessels . . . ."[118] Other than a Representative Buyer's assertion that it is "common sense" to exclude farms from the Act,[119] the Act's legislative history does little in clarifying *why* the exemptions are in place.[120] Research indicates that the states are likely responsible for overseeing some of these exempted food establishments,[121] but the level of food safety inspection requirements varies significantly by state.[122] In California for example, the Los Angeles County Department of Health Services (LACDHS) provides an excellent system for food establishment inspection and reporting.[123] LACDHS publishes, via its web site, a comprehensive food inspection guide detailing food safety requirements for food service establishments.[124] The web site has a "Food Facility Closure List" that details alphabetically the restaurants that inspectors have closed, the length of time of the closure, and the reason for the closure.[125] The web site further provides a useful "Restaurant Rating Search Help" section so consumers can research a particular food establishment's rating online[126] and has a toll-free "Food Hotline Program Number" available for public comment.[127] LACDHS also

118. Public Health Security and Bioterrorism Preparedness and Response Act of 2002 sec. 305(a), § 415(b)(1); *see also* Letter from Joseph A. Levitt, *supra* note 97, at A (providing synopsis of FDA's responsibilities under the Act).

119. *See* 147 CONG. REC. H9195 (debating the introduction of HR 3448, which was the main outline for the Bioterrorism Act).

120. *But see* Bioterrorism Preparedness Act of 2001, H.R. 3448, 107th Congress, § 534 (2001) (Engrossed Senate Amendment), *available at* http://www.counterterrorism.org/pdf/bioterrorismpreparednessact2001.pdf (last visited Feb. 27, 2004) (on file with the Texas Wesleyan Law Review) (providing possible explanation in the Senate's amendments to H.R. 3448 indicating that farms and food establishments are exempt from registration because their registration is considered unnecessary for the Act to be effective).

121. *See, e.g.*, Kellogg Co. v. Mattox, 763 F. Supp. 1369, 1378 (N.D. Tex. 1991).

122. *See, e.g.*, DEL. CODE ANN. tit. 24, § 1503 (1997); FLA. STAT. ANN. § 509.032(2)(a) (West 2002); Aldridge v. Georgia Hospitality & Travel Ass'n, 304 S.E.2d 708, 709 (Ga. 1983); County of Macon v. Bd. of Educ. of Decatur Sch. Dist. No. 61, 518 N.E.2d 653, 656 (Ill. App. Ct. 1987).

123. *See Establishment Rating List*, LA. Dep't of Health Servs., *at* http://www.lapublichealth.org/rating (last visited Feb. 21, 2004) (on file with the Texas Wesleyan Law Review) (giving a comprehensive retail food inspection guide); *see also* Telephone Interview with Ann Shaw, *supra* note 1 (recommending the Los Angeles County Health Department's A, B, C establishment rating system).

124. *See Retail Food Inspection Guide*, LA. Dep't of Health Servs., *at* http://www.lapublichealth.org/eh/rfig/index2.html (on file with the Texas Wesleyan Law Review) (giving a comprehensive retail food inspection guide).

125. *See Food Facility Closure List*, LA. Dep't of Health Servs., *at* http://lapublichealth.org/phcommon/public/eh/closure/restall1.cfm (last visited Feb. 21, 2004) (on file with the Texas Wesleyan Law Review).

126. *See Restaurant Rating Search Help*, LA. Dep't of Health Servs., *at* http://www.lapublichealth.org/eh/resthelp.htm (last visited Feb. 21, 2004) (on file with the Texas Wesleyan Law Review).

127. *See Food Facility Closure List*, LA. Dep't of Health Servs., *at* http://lapublichealth.org/phcommon/public/eh/closure/restall1.cfm (last visited Feb. 21, 2004) (on file with the Texas Wesleyan Law Review).

requires that all food establishments publicly post their inspection ratings based on an "A," "B," or "C" grading system so that consumers can make informed choices about whether to patronize that restaurant.[128] "A Establishments" have the highest scores, while "B Establishments" and "C Establishments" have lower inspection scores respectively.[129] Because consumers are more likely to choose an "A Establishment" over a "B" or a "C," this public grading system should cause all food establishments to strive to improve their letter ratings, and hence overall food safety, in order to attract and maintain customers.[130] Thus, provided the inspectors conduct fair and accurate inspections and do not taint their inspections with personal bias,[131] the LACDHS protocol for inspections likely ensures that food establishments in LACDHS's jurisdiction provide safe foods to consumers.[132]

Other state food establishment inspection programs are much less comprehensive than Los Angeles County's. In Hawaii, for example, the state recognizes that "foods . . . may contain foodborne disease microorganisms that can cause severe sickness to large numbers of people at the same time," but nevertheless established a "*non*-enforcement program within the department of health to provide voluntary food safety surveillance and control."[133] The South Dakota program is not significantly more comprehensive in that it requires a minimum of only one to two inspections every *five* years for food handlers and servers in school food service programs.[134] In Delaware, restaurants and food service establishments are subject to surprise state inspections.[135] In Florida, the state "shall adopt and enforce sanitation rules . . . to ensure the protection of the public from foodborne illness in [food service] establishments."[136] Florida also may inspect any "public food service establishment at any reasonable time"[137] and "may stop the sale . . . of any food . . . that . . . represents a threat to the public safety or welfare."[138] Clearly, this random sampling of states' food establishment inspection requirements illustrates that the spectrum of state food safety requirements is broad; some

128. *See Establishment Rating List*, LA. Dep't of Health Servs., *at* http://lapublichealth.org/rating (last visited Feb. 21, 2004) (on file with the Texas Wesleyan Law Review).

129. *See id.*

130. *See id.*

131. *See, e.g.*, Contreras v. City of Chicago, 119 F.3d 1286, 1291 (7th Cir. 1997) (describing Chicago restaurant's unsuccessful claim that inspector's racial animosity was basis for temporary shut down).

132. *See Establishment Rating List*, LA. Dep't of Health Servs., *at* http://lapublichealth.org/rating (last visited Feb. 21, 2004) (on file with the Texas Wesleyan Law Review).

133. HAW. REV. STAT. ANN. § 321–401 (Michie 2000) (emphasis added).

134. S.D. CODIFIED LAWS § 13-35-7 (Michie 2002).

135. DEL. CODE ANN. tit. 24, § 1503 (1997).

136. FLA. STAT. ANN. § 509.032(2)(d) (West 2002).

137. *Id.* § 509.032(2)(b).

138. *Id.* § 509.032(4).

states' food supplies are inherently at more risk than others.[139] Thus, exempting these food establishments from the Act poses an unnecessary risk to the food supply. In order to ensure all food that ultimately reaches the consumer in the domestic food supply is safe, the Act should not exempt food service establishments from its regulations.[140]

Hypothetically, a terrorist group could tamper with the food in these exempted establishments in various parts of the country and create havoc with the food supply. If the tampering style varied by location, then tying any pattern or series of tampering problems to a given group could be quite cumbersome, if possible at all. Although the likelihood of this type of scenario taking place is remote, lawmakers should consider these issues if the Bioterrorism Act is to be more complete and effective. Thus, regulators should not exempt any entity that delivers food directly to consumers in order to bolster the likelihood of creating an effective anti-terrorism act.

However, since these exempted food service establishments are likely purely state responsibility,[141] the Act may not have any jurisdiction over them. Enhanced communication between state and federal regulators and health services[142] may be the best way to close this potential federalism loophole[143] and strengthen the integrity of the food supply long term. A centralized web-based system in which all food safety related concerns funnel into one database could bridge communication gaps between regulating entities and provide clear parameters for both inspectors and consumers.[144] Because of LACDHS's clear communication style, the FDA should consider implementing a program modeled after Los Angeles County's comprehensive food

139. *See* DEL. CODE ANN. tit. 24, § 1503 (1997); FLA. STAT. ANN. § 509.032(2)(d) (West 2002); HAW. REV. STAT. ANN. § 321–401 (Michie 2000); S.D. CODIFIED LAWS § 13-35-7 (Michie 2002); *Establishment Rating List*, LA. Dep't of Health Servs., *at* www.lapublichealth.org/rating (last visited Feb. 21, 2004) (on file with the Texas Wesleyan Law Review) (giving a comprehensive retail food inspection guide); *see also* Telephone Interview with Ann Shaw, *supra* note 1 (recommending the Los Angeles County Health Department's A, B, C establishment rating system).

140. *See* DEL. CODE ANN. tit. 24, § 1503 (1997); FLA. STAT. ANN. § 509.032(2)(d) (West 2002); HAW. REV. STAT. ANN. § 321–401 (Michie 2000); S.D. CODIFIED LAWS § 13-35-7 (Michie 2002); *Establishment Rating List*, LA. Dep't of Health Servs., *at* www.lapublichealth.org/rating (last visited Feb. 21, 2004) (on file with the Texas Wesleyan Law Review) (giving a comprehensive retail food inspection guide); Telephone Interview with Ann Shaw, *supra* note 1.

141. *See, e.g.*, Kellogg Co. v. Mattox, 763 F. Supp. 1369, 1378 (N.D. Tex 1991).

142. *See, e.g.*, Office of Regulatory Affairs, U.S. Food & Drug Admin., *State Food Safety Task Forces: A Compilation of Progress Reports III* (Summer 2002), *at* http://www.fda.gov/ora/fed_state/food_safety/state_progressreports.htm (on file with the Texas Wesleyan Law Review).

143. *See Kellogg*, 763 F. Supp. at 1378–81.

144. For examples of useful web site databases, see for example, *Federal-State Relations*, Office of Regulatory Affairs, U.S. Food & Drug Admin., *at* http://www.fda.gov/ora/fed_state/default.htm (last edited July 30, 2002) (on file with the Texas Wesleyan Law Review); LA. Dep't of Health Servs., *at* http://www.lapublichealth.org (last visited Feb. 21, 2004).

service inspection and reporting system.[145] Therefore, in order to better communicate food safety issues in a standardized format amongst all state and local food regulating bodies, lawmakers should create a centralized web-accessible database.[146]

3. "One Up, One Down"[147] Record Keeping Regulations[148]

The Act also requires the FDA to issue one upstream, one downstream record keeping regulations[149] to most domestic food producers by December 2003, such that "the immediate previous sources and the immediate subsequent recipients of food" can be determined.[150] According to the Act, this paper trail should aid in confirming whether a suspect facility's "food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals."[151]

However, a paper trail is not impervious to tampering. Inexpensive technology has made documentation forgery a viable threat that a terrorist could exploit.[152] Hypothetically, a terrorist could create documents that would satisfy the one upstream, one downstream requirement, yet place adulterated foods into the food supply that do not conform to their associated documentation. Inspection of the documentation alone would not reveal any misconduct because on paper, the terrorist appears to have placed normal foods into the food sup-

145. *See Establishment of Rating List*, LA. Dep't of Health Servs., *at* http://www.lapublichealth.org/rating (last visited Feb. 21, 2004) (on file with the Texas Wesleyan Law Review).

146. *See, e.g.*, *id.*; *Federal-State Relations*, Office of Regulatory Affairs, U.S. Food & Drug Admin., *at* http://www.fda.gov/ora/fed_state/default.htm (last edited July 30, 2002) (on file with the Texas Wesleyan Law Review).

147. Food & Drug Admin., U.S. Dep't of Health & Human Servs., *Plans for Developing Bioterrorism-Related Food Regulations*, *at* http://www.fda.gov/oc/bioterrorism/titleiii.html (last visited Feb. 20, 2004) (on file with the Texas Wesleyan Law Review).

148. *See* Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, sec. 306(a), § 414(a), 116 Stat. 594, 669.

149. *See id.* sec. 306(a), § 414(b).

150. *See id.*; *see also* Interview with Don Klein, *supra* note 95 (explaining that because all of the members of the supply chain are visibly documented, a valid paper trail intact from the point of origin to the final consumer, should reduce the risk of tampering). This section of the Act also excludes farms and other restaurants from the record keeping requirement. Public Health Security and Bioterrorism Preparedness and Response Act of 2002 sec. 306(a), § 414(b).

151. Public Health Security and Bioterrorism Preparedness and Response Act of 2002 sec. 306(a), § 414(a).

152. *See, e.g.*, United States v. Garrido-Ortega, No. IP02-68-CR-1H/F, 2002 WL 31741468, at *1 (S.D. Ind. Nov. 15, 2002) (showing the "INS recovered a typewriter, a laminating machine, and paper and plastic stock suitable for making counterfeit documents"); United States v. Martinez-Vasquez, No. 01-50049, 2002 WL 460253 (9th Cir. Mar. 11, 2002) (not designated for publication) (seizing 1,055 counterfeit documents); News Release, Immigration & Naturalization Serv., U.S. Dep't of Justice, INS Agents Arrest Individuals for Manufacture and Sale of Counterfeit Identification Documents (May 9, 2002), *at* http://www.ins.usdoj.gov/graphics/publicaffairs/newsrels/counter.htm (on file with the Texas Wesleyan Law Review).

ply.[153] However, the Act itself may provide a solution to this hypothetical.[154] The Act has a provision funding research for efficient detection methods for adulteration of imported foods.[155] If this provision also applied domestically, provided the efficient field tests become available,[156] inspectors could physically test any retained samples to verify whether the foods indeed match their associated paperwork. Randomly testing the retained samples associated with the documentation for adulteration[157] would likely provide an additional terrorist deterrent in that these tangible food samples may be more difficult to create than paper documentation.[158]

Currently, the Act does not require any retained samples for testing against the one upstream, one downstream documentation for domestic foods; the Act could be strengthened by requiring physical sample testing to ensure that the foods actually conform to their purported paperwork. By incorporating physical sample tests into inspection protocol for domestic, as well as imported documentation, the integrity of the food supply could be strengthened. Therefore, if the Act's provision to fund research for efficient detection methods for adulteration is fruitful,[159] then the Act should be amended to require food sample tests to accompany documentation inspection for both domestic and imported foods.

4. Imported Food Shipment Notification

The Act requires that the FDA must be notified prior to the import of any food shipments or the "article of food imported or offered for import without such notice . . . shall be refused admission into the United States."[160] The Act, however, is silent in regard to what form of notice importers must give the FDA.[161] Lawmakers should clarify the language of this section to detail the type of notice that the FDA will accept by adding words such as "written notice" to the text. The

153. *See* Interview with Don Klein, *supra* note 95; *see, e.g.*, *Garrido-Ortega*, 2002 WL 31741468, at *1.

154. *See* Public Health Security and Bioterrorism Preparedness and Response Act of 2002 § 302(d)–(f) (funding research for tests that "rapidly detect the adulteration of the food").

155. *See id.*

156. *See id.*; *see also* Linda Milo Ohr, *Real Time Testing*, Prepared Foods, *at* http://www.preparedfoods.com/cda/articlearchivesearch/1,1226,,00.html (posted on Nov. 21, 2003) (on file with the Texas Wesleyan Law Review) (listing pathogen tests that are currently available).

157. *See* Public Health Security and Bioterrorism Preparedness and Response Act of 2002 § 302(d)–(f) (funding research for tests that "rapidly detect the adulteration of the food").

158. *See, e.g.*, *Garrido-Ortega*, 2002 WL 31741468, at *1 (describing the operation of a counterfeiter in Indiana).

159. *See* Public Health Security and Bioterrorism Preparedness and Response Act of 2002 § 302(d)–(f).

160. *Id.* sec. 307(a), § 801(m)(1).

161. *See id.*

notice section requires that the importer detail the food being imported, its manufacturer and grower if available, the country of origin, and the food's expected domestic port of entry.[162] Through advance notification, knowledge of what is being imported is imputed to the FDA.[163] The FDA could then verify that what was scheduled to arrive indeed arrived,[164] or the FDA could take other appropriate action before the arrival, such as alerting states about the shipment to ensure its refusal into the United States when necessary.[165] Thus, by requiring advance notification, this section seems a reasonable way to address the risk of materials coming into the United States through standard importation points.[166]

a. Administrative Detention[167]

Once given, if this notice is clearly communicated to inspectors, then alerting inspectors about what food imports to anticipate in advance of the shipment's arrival should strengthen the "Administrative Detention" section of the Act, which authorizes certain inspectors to detain any foods that they suspect are adulterated.[168] Through a "memorandum of understanding between" the federal agencies, the Act authorizes the FDA to commission and train inspectors from other federal agencies.[169] However, the Act's detention process could be more streamlined if, after uniform training, *all* of the inspectors rather than just designated officials were empowered to detain suspect imported foods.[170]

b. Debarment for Repeated or Serious Food Import Violations

A second benefit that advance notification of imports provides is the knowledge necessary for enforcement of the Act's authorization to refuse imports from persons that have been debarred by their previous importation of adulterated foods into the United States.[171] However, the Act is silent in regard to which officials within the FDA have the authority to enforce debarments;[172] for clarity, lawmakers should list exactly which officials the Act authorizes to enforce these debarments.

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162. *See id.*
163. *See id.*
164. *See id.* sec. 307(a), § 801(2)(A).
165. *See generally id.* §§ 307–310 (regarding notices to states when the FDA deems necessary to protect the human or animal health).
166. *See id.* § 307.
167. *Id.* § 303.
168. *See id.* sec. 303, § 304(a)(h)(1) (specifying that detention by inspectors is limited by whether an approved official has approved the detention).
169. *See id.* sec. 314, § 702(a)(2)(a).
170. *See id.* §§ 303, 314.
171. *See id.* §§ 304, 307. Debarring can occur for either a conviction for importing adulterated foods or for a pattern of doing such adulterated imports. *Id.* § 304.
172. *See id.* §§ 304(e), 307.

c. Articles Marked Refused Entry into the United States[173]

The third benefit where advance notice could apply is pursuant to the Act's authorization for inspectors to refuse entry to products, labeling them "UNITED STATES: REFUSED ENTRY."[174] Here, the advance notice could alert inspectors at any domestic port to watch for importers that may attempt to merely repackage foods that have previously been denied entry into the United States.[175]

In summary, the Act's advance notice section is a practical measure that imputes to the FDA knowledge about what foods are being imported.[176] If the FDA effectively communicates this knowledge to appropriate federal and state food import inspectors, then those inspectors should be better armed against repeat importers of adulterated foods.[177]

5. Is Eighteen Months an "Ambitious" Timeline?

While CFSAN describes this December 12, 2003 deadline as "ambitious,"[178] an eighteen month window from inception of the Act in June 2002 to its deadline simply to *establish* the regulations seems unnecessarily slow, especially considering that the Act, in regard to food safety, revamps food supplier and manufacturer paper trails and little more.[179] Until December 2003, the Act mainly funded research[180] but did not have any teeth in regard to mandates on practical food safety protocol.[181]

Part of the problem may be that food safety responsibilities span too many governing bodies to be efficient.[182] The "overlap"[183] of these departments risks putting unnecessary holes in the food protection safety net because each department may focus on its own narrow field of regulation, ignoring those that it considers another agency's

173. *Id.* § 308.
174. *See id.*
175. *See id.* §§ 308–309.
176. *See* discussion *supra* Part III.A.4.
177. *See* discussion *supra* Part III.A.4.
178. *See* Letter from Joseph A. Levitt, *supra* note 97; Food & Drug Admin., U.S. Dep't of Health & Human Servs., *Plans for Developing Bioterrorism-Related Food Regulations, at* http://www.fda.gov/oc/bioterrorism/titleiii.html (last visited Feb. 20, 2004) (on file with the Texas Wesleyan Law Review); *see also* VETTER, *supra* note 3, at 164 (describing as "short" the five month time frame between FDA's proposed and final good manufacturing practice rule).
179. *See* discussion *supra* Part III.A.3.
180. *See, e.g.*, Public Health Security and Bioterrorism Preparedness and Response Act of 2002 §§ 301–302 (appropriating $750,000 for "Food Safety and Security Strategy" and $100,000,000 for "Assessment of Threat of Intentional Adulteration of Food").
181. *See* discussion *supra* Part III.A.3.
182. *See* Safe Food Act of 2001, H.R. 1671, 107th Cong. § 2(b)(1) (2001); VETTER, *supra* note 3, at 31; Taylor, *supra* note 13, at 14–20.
183. *See* discussion *supra* Part III.A.1 (discussing departmental "overlap" inefficiency).

responsibility.[184] As part of the September 11th legislation, lawmakers realized a potential gap and added a section to the Bioterrorism Act specifically to address departmental "overlap."[185]

Conversely, because of the complexity and newness of bioterrorism, slowly and rationally debated regulations made with input from many departments and lobbies may prove more effective than quickly made regulations[186] and are necessary protocol in order to adhere to the tenets of Executive Order 12866 (EO).[187] This EO requires, *inter alia*, efficiency, extensive cost-benefit analysis, agency coordination, alternatives to proposed regulations, and budgetary review before creating new regulations.[188] However, when emergencies arise, this EO may not necessarily be enforced.[189] For example, the first United States case of Bovine Spongiform Encephalopathy (BSE), commonly known as "mad cow" disease, was discovered in a "downer cow" from sample test results obtained twelve days after its slaughter at a Washington meat packing plant on December 9, 2003.[190] Not following the EO,[191] the USDA sprang into action in order to protect the food supply, promulgating new safeguards that became effective on January 12, 2004.[192] Here, the very real threat of bioterrorism[193] urges similar

184. *See* discussion *supra* Part III.A.1 (discussing departmental "overlap" inefficiency).

185. *See* discussion *supra* Part III.A.1 (discussing departmental "overlap" inefficiency).

186. *See* Letter from Joseph A. Levitt, *supra* note 97, at B.

187. *See* Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Sept. 30, 1993).

188. *See id.*

189. *See, e.g.*, Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle, 69 Fed. Reg. 1862, 1871 (Jan. 12, 2004) (to be codified at 9 C.F.R. pts. 309, 310, 311, 318, 319) (stating that "[t]he emergency situation surrounding this rulemaking makes timely compliance with Executive Order 12866 . . . impracticable").

190. *'Mad Cow' in U.S.*, PREPARED FOODS.COM E-NEWSLETTER, (Prepared Foods, Bensenville, Ill.) Jan. 6, 2004, *at* http://preparedfoods.com/files/html/pf _newsletter4 (on file with the Texas Wesleyan Law Review).

191. *See, e.g.*, Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle, 69 Fed. Reg. at 1871 (stating that "[t]he emergency situation surrounding this rulemaking makes timely compliance with Executive Order 12866 . . . impracticable").

192. The USDA promulgated four interim rules effective January 12, 2004:

(1) 9 C.F.R. § 309.3 (2004) (prohibiting "non-ambulatory disabled cattle" as a source of human food);

(2) Meat produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems, 69 Fed. Reg. 1874 (Jan. 12, 2004) (to be codified at 9 C.F.R. pts. 301, 320) (prohibiting non-ambulatory cattle as source of human food);

(3) 9 C.F.R. § 313.15 (prohibiting "bolt stunners that deliberately inject compressed air into the cranium" of cattle); and

(4) Bovine Spongiform Encephalopathy Surveillance Program, 69 Fed. Reg. 1892 (Jan. 12, 2004) (announcing that the "FSIS will no longer allow these carcasses to be marked 'Inspected and passed' until the sample testing has been completed, and the result is negative").

emergency *pro*-activeness.[194] Thus, eighteen months merely to *establish* a food safety plan[195] leaves the food supply at unnecessary risk.

6. Concluding Comments Regarding the Act

The Act is a proactive measure that has the opportunity to bolster the safety of the domestic food supply; however, some improvements could strengthen its effectiveness. Although likely unpopular with food supply chain members because mandates are more enforceable and more predictable than mere guidelines, the FDA should focus on mandating requirements to members of the supply chain rather than merely providing guidelines.[196] First, the Act should eliminate inefficiency by authorizing one body to promulgate food safety regulations.[197] Second, the Act should eliminate compliance loopholes by not exempting any member of the domestic food supply chain.[198] Third, because technology risks the integrity of the paper trail, the Act should add a mandate for physical testing procedures to tie the paper trail with the actual foodstuffs.[199] Fourth, because the Act authorizes ample time for the USDA and FDA to consider various perspectives in creating their safety protocols they should do so, but they should not lose sight of the goal to create sustainable food safety measures now.[200] Lastly, the keys to whether the Act will be effective lie in whether the forthcoming joint USDA and FDA requirements are (1) enforceable and (2) uniformly enforced.[201] As a guide to the USDA and FDA, the following HACCP[202] section is an example of a concep-

See also News Release, Food Safety & Inspection Serv., U.S. Dep't of Agric., USDA Issues New Regulations to Address BSE (Jan 8, 2002), *at* http://www.fsis.usda.gov/oa/news/2004/bseregs.htm (on file with the Texas Wesleyan Law Review) (summarizing the new BSE regulations). Ironically, these regulations became effective less than a month after a petitioner won an appeal from a 1998 denial of standing to sue the USDA in an attempt to ban downed livestock from the human food supply. *See* Baur v. Veneman, 352 F.3d 625, 625–31, 643 (2d Cir. 2003).

193. *See* News Release, The White House: Press Secretary Briefings, Homeland Security Threat Level Raised to Orange (Feb. 7, 2003), *at* http://www.whitehouse.gov/news/releases/2003/02/20030207-6.html (on file with the Texas Wesleyan Law Review) (reporting that in February 2003, the United States was under a "Level Orange" or "high risk of terrorist attacks" alert); Emily Gersema, *Experts Warn on Food Supply Attack*, ASSOCIATED PRESS, Sep. 23, 2002, *at* http://story.news.yahoo (on file with the Texas Wesleyan Law Review).

194. *See, e.g.*, Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle, 69 Fed. Reg. at 1871 (stating that "[t]he emergency situation surrounding this rulemaking makes timely compliance with Executive Order 12866 . . . impracticable").

195. *See* discussion *supra* Part III.A.5.

196. *See, e.g.*, FOOD SECURITY PREVENTIVE MEASURES GUIDANCE, *supra* note 46.

197. *See supra* notes 182–85 and accompanying text.

198. *See* discussion *supra* Part III.A.2.

199. *See* discussion *supra* Part III.A.3.

200. *See* discussion *supra* Part III.A.4–III.A.4(a).

201. *See* U.S. GEN. ACCOUNTING OFFICE, *supra* note 47, at 4–6.

202. *See, e.g.*, United States v. Blue Ribbon Smoked Fish, Inc., 179 F. Supp. 2d 30, 34 (E.D.N.Y. 2001); 21 C.F.R. § 123.6 (2003) (describing fish HACCP plans).

tually good food safety strengthening program that was rendered ineffective by poor inspection procedures and lax enforcement protocol.[203]

B. *HACCP*

Because the USDA is not able to continuously inspect all of the food supply members in its jurisdiction, the Hazardous Areas and Critical Control Points (HACCP) program has become recent methodology for sharing food safety responsibility among the food supply chain members.[204] It is mandatory for beef, fish, and poultry processors;[205] however, it is discretionary for other food suppliers and producers.[206] Essentially, HACCP programs first define what hazards are within a facility; second, they address the "critical control points," which are the areas in the facility where those hazards might contact food; third, they establish limits for those points; fourth, they monitor those points; fifth, they include a corrective action plan if the limits are exceeded and a hazard could be introduced; sixth, they include a written record keeping system; and seventh, they include a periodic verification procedure.[207] In theory, the program identifies hazardous areas within each process as food moves through a plant.[208] Common HACCP areas of concern are incoming raw materials, work in process, storage conditions, product and materials handling, and outgoing processes.[209]

1. The Mandatory Program Is Insufficient To Ensure Food Safety

In 1996, the USDA published a rule requiring implementation of HACCP for all "meat and poultry processors."[210] The implementation of this purportedly "huge cultural shift" and "hugely successful effort by [the] industry" was complete for all 6,500 plants in 2001.[211] However, in 2002, the General Accounting Office (GAO) submitted a scathing report about the current inspection protocol for the meat and

203. *See* U.S. GEN. ACCOUNTING OFFICE, *supra* note 47, at 4–6.

204. *See id.* at 1–2; VETTER, *supra* note 3, at 172–73.

205. *See* VETTER, *supra* note 3, at 177, 179. HAACP is mandatory for USDA governed facilities and discretionary for FDA governed facilities. *See, e.g.*, *Blue Ribbon Smoked Fish, Inc.*, 170 F. Supp. 2d at 34; 21 C.F.R. § 123.6 (describing fish HACCP plans).

206. *See* VETTER, *supra* note 3, at 177–78.

207. *Id.* at 173–76; *see also* Delilah Dill Schuller, Comment, *Pathogen Reduction Through "HACCP" Systems: Is Overhaul of the Meat Inspection System All It's Cut Out to Be?* 8 SAN JOAQUIN AGRIC. L. REV. 77, 88 (1998) (listing the seven main areas of an HACCP program).

208. *See* VETTER, *supra* note 3, at 177.

209. *See id.* at 173.

210. *See id.* at 179.

211. Margaret O'K. Glavin, *HACCP: We've Only Just Begun*, 56 FOOD & DRUG L.J. 137, 137–38 (2001).

poultry industries.[212] Although the report was specific to these industries, an implication is that inadequate inspection training and inconsistent rule enforcement is a likely area of concern for other domestic food manufacturers.[213] The report emphasized that the HACCP plans for these plant inspections were not followed consistently on a plant to plant basis.[214] The inspectors' training and experience were inconsistent.[215] When a plant was reported out of compliance, it was often put on an extended probationary period rather than directed to correct the problem according to the regulation's requirements.[216] Although the HACCP regulation allowed for injunctive measures, inspectors rarely imposed them, and consequently, non-compliant plants continued operating.[217]

A recent news report stated that one Colorado meat processing plant that slaughtered on average about 5,500 cattle daily was "cited more than 300 times for violating federal food safety regulations in the last three years," including thirty-three citations in the first six months of 2002.[218] In 2001, this same plant recalled almost nineteen million pounds of *E. coli* contaminated beef that was linked to "[twenty-seven] illnesses and one death."[219] Certainly, this example of grossly inadequate enforcement of food safety regulations should in no way allow for one commentator's characterization of the six year HACCP implementation as "hugely successful."[220] Unless the government's protocol is radically reformed such that its inspectors consistently enforce regulations, adding more FSIS inspectors, as suggested in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002,[221] will not address food supply safety.

212. *See* U.S. GEN. ACCOUNTING OFFICE, *supra* note 47, at 4–6.
213. *See id.*
214. *See id.* at 10–11.
215. *See id.* at 16.
216. *See id.* at 27–30.
217. *See id.*
218. *USA: Former ConAgra Beef Plant Broke Food Safety Regulations Before Recall*, JUST-FOOD.COM, Jan. 20, 2003, *at* http://just-food.com/news_detail.asp?art=52886&app=1 (on file with the Texas Wesleyan Law Review).
219. *Id.*; Gillam, *supra* note 3.
220. *See* Glavin, *supra* note 211, at 137.
221. *See* Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, § 332, 116 Stat. 594, 679 (allocating money to expand FSIS activities).

2. The Discretionary Program[222] Poses Additional Risk to Food Safety

The government has suggested "guidelines"[223] but mandates little for most food companies within the food supply chain.[224] Certainly, if the industries that have government inspectors in their plants daily for testing cannot control the situation through the current testing methods,[225] how can the government expect less regulated food processors to self-police their plants? Three main problems arise with discretionary HACCP self-policing programs. First, given the option, many producers would likely choose in designing its HACCP program to *not* test for very serious pathogens in order to side-step attracting government scrutiny.[226] This is a substantial food safety protocol gap that needs to be addressed because, otherwise, regulators cannot impute knowledge to producers for knowingly placing unsafe foods into the marketplace.[227] Furthermore, this gap risks inviting bioterroristic activity because, hypothetically, a producer's introduction of listeria into food without knowledge could be deemed accidental; however, the same act with knowledge of the introduction should be deemed terroristic.[228] Thus, in order to properly impute knowledge about the safety of the products the producers are holding out to the marketplace, regulators should impose mandatory testing requirements in all food producers' HACCP programs.

A second problem is that the FSIS allows for a producer to rely on its supplying vendor to have an HACCP program through listing this requirement in the producer's purchase order specifications for in-

222. *See* VETTER, *supra* note 3, at 178.

223. *See id.* at 161–62, 177–80.

224. *See id.* at 177–80; *see, e.g.*, United States v. Blue Ribbon Smoked Fish, Inc., 179 F. Supp. 2d 30, 34 (E.D.N.Y. 2001); 21 C.F.R. § 123.6 (2003) (describing fish HACCP plans).

225. *See, e.g.*, Randy Fabi, *Most US Meat Plants Violate Food Safety Rules—USDA*, REUTERS, Feb. 4, 2003, *at* http://www.biz.yahoo.com (on file with the Texas Wesleyan Law Review) (reporting that approximately "[sixty] percent of the largest U.S. meat plants failed to meet federal food safety regulations for preventing the *E. coli* bacteria in their products"). *See generally* U.S. GEN. ACCOUNTING OFFICE, *supra* note 47, at 4–6 (noting poor inspection and enforcement protocol across survey of plants currently under HACCP regulatory inspection).

226. *See* GALLAGHER ET AL., *supra* note 1, at 4 (stating that whether to test food contact surfaces for listeria depended on the plant's designation of its critical control points); *see also* Telephone Interview with Ann Shaw, *supra* note 1 (noting that some plant surfaces, and not the food products themselves, are tested for listeria contamination).

227. *See, e.g.*, United States v. Park, 421 U.S. 658, 676 (1975) (stating the Federal Food Drug and Cosmetic Act "imposes the highest standard of care" upon "corporate officials who, in light of this standard of care, have the power to prevent or correct violations of its provisions").

228. *See* Homeland Security Act of 2002, Pub. L. No. 107-296, § 2(15), 116 Stat. 2135, 2141 (defining "terrorism").

coming raw materials.[229] For the reasoning discussed in the "one up, one down" section listed above,[230] relying exclusively on a paper trail is unduly risky and should not be allowed by the FSIS. Instead, the FSIS should mandate that the producer test materials to ensure that the documentation matches the actual incoming raw materials. The producer should either personally audit its suppliers, or where that is infeasible, have an independent third party[231] inspect the supplier to ensure that what the supplier claims is its protocol is what actually occurs.

A third problem presented by the discretionary program is the lack of a proper penalty provision. In support of self-policing, however, basic supply and demand economics plays a larger role than regulations.[232] In order to compete, producers must self-regulate.[233] Losing consumer confidence means losing consumer dollars.[234] Producers who want to sustain a consumer base cannot afford the negative publicity associated with putting shoddy products into the marketplace.[235] For government food regulations to be effective without incurring the huge costs in adding FSIS personnel for more frequent inspections,[236] adding a penalty provision requiring non-compliant producers to televise public notices of their non-compliance may be more effective than merely putting them on probation.[237]

In summary, HACCP is a good procedural start but not a guarantee for food safety. For effectiveness, regulators should mandate uniformly designed industry HACCP programs.[238] When hazards exceed control standards, plants should follow the established procedure, shutting down production when necessary.[239] Producers should test

229. *E. Coli* O157:H7 Contamination of Beef Products, 67 Fed. Reg. 62,325, 62,329–330 (Oct. 7, 2002) (to be codified at 9 C.F.R. pt. 417).

230. *See* discussion *supra* Part III.A.3.

231. *See, e.g., Integrated Quality System Gold Standard Certification Programs*, American Institute of Baking, *at* http://www.aibonline.org/qualitycertprograms/gold.html (last visited March 2, 2004) (on file with the Texas Wesleyan Law Review); *Lab Services: General Information*, Silliker, Inc., *at* http://www.silliker.com/html/labservices_general.php (last visited Feb. 27, 2004) (on file with the Texas Wesleyan Law Review) (providing "microbiological, chemical, biotechnology, and physical testing needs").

232. *See, e.g., Pilgrim's Pride to Face Listeria Lawsuit*, REUTERS, Nov. 1, 2002, *at* http://biz.yahoo.com (on file with the Texas Wesleyan Law Review) (stating an example of the negative impact of putting listeria contaminated poultry into the marketplace).

233. *See, e.g., id.*

234. *See, e.g., id.*

235. *See generally id.*

236. *See* Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, § 332, 116 Stat. 594, 679 (allocating money to expand FSIS activities).

237. *See* U.S. GEN. ACCOUNTING OFFICE, *supra* note 47, at 22 (inspecting non-compliance often resulted in no penalty for producer).

238. *See* discussion *supra* Part III.B.

239. *See* discussion *supra* Part III.B.1.

incoming raw materials for purity and not merely rely on the accuracy of any purchase order paper trail from upstream suppliers.[240] Furthermore, to encourage producers to self-police, regulators should consider publicizing non-compliance as a penalty.[241]

IV. SUGGESTED PROTOCOL

This Comment suggests food safety protocol and responsibility for each link in the domestic food supply chain. First, in Section A, the proposed Regulatory Protocol is discussed; Section B follows with Producer suggestions; and lastly, in Section C, the Consumer Protocol is recommended.

A. *Regulatory Protocol*

The current food regulation system is overly complex;[242] and rather than perpetuate this convoluted system, the government should unify its food safety oversight[243] under one general agency's umbrella[244] to which the FDA, the USDA, and their respective agencies[245] will report.[246] Ideally, this general agency would eliminate the duplication of effort overlap[247] between the FDA and USDA, streamline the information flow among members of the food chain, and establish a concise and understandable policy such that regulations can be uniformly followed throughout the food chain. By consolidating the reporting function, the various department expertise could still be tapped from the local level and yet be funneled to one main department for interpretation, evaluation, and response.[248]

Recently, a presidential directive was announced mandating that the Secretary of Homeland Security coordinate with the Secretaries of Agriculture and HHS, and the EPA in developing a comprehensive plan "to respond quickly and effectively to a terrorist attack, major

240. *See supra* notes 229–31 and accompanying text.

241. *See, e.g.*, Randy Fabi, *USDA Closes Troubled Colorado Beef Plant*, REUTERS, Nov. 15, 2002, *at* http://biz.yahoo.com (on file with the Texas Wesleyan Law Review) (stating an example of negative publicity for food safety violations).

242. *See* VETTER, *supra* note 3, at 31; Taylor, *supra* note 13, at 14–20.

243. *See* discussion *supra* Part I.B.

244. *See* Safe Food Act of 2001, H.R. 1671, 107th Cong. (2001) (suggesting unifying the food safety oversight to one regulatory department). For more detail regarding H.R. 1671, see Connecticut Congresswoman Rosa L. DeLauro's website at http://www.house.gov/delauro/safe_food.html (last visited Feb. 4, 2004).

245. *See* discussion *supra* Part I.B.

246. Because the HHS currently oversees the Center for Disease Control, the National Institute of Health, and the FDA, the HHS presumably understands the interrelationship between food, disease, and health; thus, the HHS would likely be a suitable candidate if an umbrella agency encompassing all food regulation were created. *See supra* notes 25–29 and accompanying text.

247. *See* discussion *supra* Part III.A.1 (discussing departmental "overlap" inefficiency).

248. *See* H.R. 1671.

disease outbreak, or other disaster affecting the national agriculture or food infrastructure."[249] The directive does not put food oversight completely under the HHS's umbrella as suggested above,[250] nor does it change the complexity of the oversight of the food supply as it is currently divided among the USDA and the HHS;[251] but it does make a great stride toward identifying safety gaps in the food chain.[252] The directive mandates that *one* department, Homeland Security, is ultimately responsible for the coordination among the various departments for the development of food safety protocol as it relates to "protection of the critical infrastructure and key resources of the United States."[253] The directive requires that the Secretary of Homeland Security make timely reports and recommendations to the President regarding risk awareness and "vulnerability assessments."[254] Certainly one of the recommendations should be to eliminate the complexity of the number of agencies involved in the current system;[255] thus, eliminating potential safety gaps in the farm-to-table chain.

1. Mandatory Regulations

The government should impose mandatory regulations and not leave HACCP and similar programs to the creation of the members of the supply chain. Most food producers are not required to have any formalized HACCP programs,[256] and this is an odd oversight of the government that puts the domestic food supply at unnecessary risk. The self-imposed industry standards[257] are simply not sufficient.[258] Food processors may handle different types of food by industry, but commonality likely exists, at least by industry, such that a uniform code of safe handling requirements is not impossible to compose for

249. Homeland Security Presidential Directive/HSPD-9, 40 WEEKLY COMP. PRES. DOC. 185 (Feb. 3, 2004); *see also Bush Orders Protections for Food Supply*, ASSOCIATED PRESS, Feb. 3, 2004, *at* http://www.msnbc.msn.com/id/4156537 (on file with the Texas Wesleyan Law Review) (summarizing the directive); News Release, Ann M. Veneman, U.S. Dep't of Agriculture, President's Agriculture Budget Proposes Increased Funding to Protect the Nation's Food Supply and Conserve Natural Resources (Feb. 2, 2004), *at* http://www.usda.gov/newsroom/0055.04.html (on file with the Texas Wesleyan Law Review) (describing the 2005 presidential budgetary increases earmarked to fund the directive).

250. *See supra* note 246 and accompanying text.

251. *See* Homeland Security Presidential Directive/HSPD-9, 40 WEEKLY COMP. PRES. DOC. 185 (Feb. 3, 2004); *see also* Homeland Security Presidential Directive/HSPD-7, 39 WEEKLY COMP. PRES. DOC. 1818 (Dec. 17, 2003) (describing the intra-agency coordination responsibilities of the Secretary of Homeland Security).

252. *See* Homeland Security Presidential Directive/HSPD-7, 39 WEEKLY COMP. PRES. DOC. 1817 (Dec. 17, 2003).

253. *See id.*

254. *See id.* at 1817–18.

255. *See supra* Part II.A.1 (discussing departmental "overlap" inefficiency).

256. *See supra* notes 223–24 and accompanying text.

257. *See* discussion *supra* Part III.B.2.

258. *See* U.S. GEN. ACCOUNTING OFFICE, *supra* note 47, at 4–6.

that industry.[259] Basically, all food processors and manufacturers bring in food materials in some state of work in process, process it, package it, store it, and then place it into distribution channels to reach the end consumer.[260] Thus, regulators imposing mandatory HACCP program requirements by industry should be feasible.

2. Testing Requirements Should Accompany Documentation

The FSIS's allowance for food manufacturers to simply put purchase order requirements in their regulatory documentation[261] is insufficient. The purchase order specification documentation is merely a paper trail that can act as a type of evidence of the intent to comply with regulations, but it cannot be a substitute for the processor's responsibility to test its incoming materials.[262] The federal government should mandate that the processor is responsible for ensuring that the documents listed in the contracts with its suppliers can be independently proven, either upon receipt of the goods or upon surprise inspection.[263] The qualification and training of inspection personnel should also be better established, mandated, and then tested for compliance.[264]

3. Irradiation as a Method to Eliminate Some Food Pathogens

The government should enlist the media's support in educating consumers about potential food safety risks and also about the potential technology related food safety augmentation.[265] For example, the government could reduce the risk of the naturally occurring pathogens such as *E. coli* and *L. monocytogenes* though mandating the process of irradiation.[266] Irradiation is a process that renders some foods sterile

259. *See* Interview with Don Klein, *supra* note 95.

260. *See id.*

261. *See supra* notes 229–31 and accompanying text.

262. *See supra* notes 229–31 and accompanying text.

263. *See supra* notes 229–31 and accompanying text.

264. *See* U.S. GEN. ACCOUNTING OFFICE, *supra* note 47, at 31–32.

265. *See, e.g.*, *Food Irradiation*, Public Citizen, *at* http://www.citizen.org/cmep/foodsafety/food_irrad/ (last visited Feb. 17, 2003) (on file with the Texas Wesleyan Law Review); *Frequently Asked Questions About Food Irradiation*, *at* http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodirradiation.htm (Feb. 7, 2004) (on file with the Texas Wesleyan Law Review); *Stop Food Irradiation Project*, Organic Consumers Ass'n, *at* http://www.organicconsumers.org/irrad/science.cfm (updated Dec. 17, 2002) (on file with the Texas Wesleyan Law Review); *USA: Organic Acid Can Stop Listeria, Say Scientists*, JUST-FOOD.COM, Jan. 6, 2003, *at* http://www.just-food.com/news_detail.asp?art=52751&app=1 (on file with the Texas Wesleyan Law Review); Julie Vorman, *Oregano May Cut Listeria Risk—US Meat Industry*, REUTERS, Feb. 14, 2003, *at* http://foodhaccp.com/msgboard.mv?parm_func=showmsg+parm_msgnum=1007182 (on file with the Texas Wesleyan Law Review).

266. *See Frequently Asked Questions About Food Irradiation*, *at* http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodirradiation.htm (Feb. 7, 2004) (on file with the Texas Wesleyan Law Review).

and thereby eliminates the pathogens within those irradiated foods.[267] The 2002 Farm Bill makes a great stride in showing the government's support of food safety. Properly mandated to suspect food classes, irradiation would eliminate many of the foodborne pathogens and is gaining some support domestically.[268] Grocery chains are in the early stages of adding irradiated meats to their line of options for consumers, but the consumer response is wary.[269] Consumer activist groups such as Public Citizen are against irradiated foods,[270] and the European Union is also wary of adding food groups to the irradiation listing.[271] Before regulators broadly adopt irradiation as their standard for reducing the incidence of foodborne pathogens, they should address concerns that these groups have about this technology to ensure that it does not cause unexpected problems in the future.[272] Lawmakers should also limit the applications for irradiated food materials to those that pose a high risk for harmful pathogens, such as ready to eat meat and poultry.[273] Furthermore, in order for consum-

267. *See id.*; *see also* James N. Klapthor, *Food Security and Food Safety: Today's Topics of News Media*, FOOD TECH., December 2001, at 20 (describing irradiation as a way to kill anthrax in regard to the postal system).

268. *See, e.g.*, Jerry Bieszk, *U.S. Food Industry Begins to Embrace Irradiation*, REUTERS, Jan. 31, 2003, *at* http://biz.yahoo.com (on file with the Texas Wesleyan Law Review); Emily Gersema, *Irradiated Meat OK'd for Schools*, ASSOCIATED PRESS, Oct. 29, 2002, *available at* 2002 WL 102131692.

269. *See, e.g.*, Marian Burros, *Irradiated Beef: A Question In Lunchrooms*, N.Y. TIMES, Jan 29, 2003, at F3, *available at* 2003 WL 11555472; Patricia Callahan, *Supermarkets Test Appetite for Irradiated Meat*, WALL ST. J., Nov. 7, 2002, at B1; *Jewel, Dominick's Will Sell Irradiated Meat Soon*, Chicago Sun-Times, Nov. 8, 2002, at 65, *available at* 2002 WL 6478778.

270. *See* Letter from Wenonah Hauter, Director, Public Citizen's Critical Mass Energy and Environment Program & Andrew Kimbrell, Director, Center for Food Safety, to Livestock and Seed Programs Agricultural Marketing Services, U.S. Dep't of Agric. (Dec. 18, 2002), *at* http://www.citizen.org/documents/schoollunchprogram comments.pdf (on file with the Texas Wesleyan Law Review) (referring to a joint letter by Public Citizen and The Center for Food Safety concerned about the effect of irradiated foods on consumers and also concerned that irradiated foods would replace pathogen testing); *see generally Bad Taste: The Disturbing Truth About the World Health Organization's Endorsement of Food Irradiation*, Public Citizen, *at* http://www.citizen.org/publications/release.cfm?ID=7210 (last visited Feb. 17, 2003) (on file with the Texas Wesleyan Law Review); *Nuclear Lunch: The Dangers and Unknowns of Food Irradiation*, *in* FOOD IRRADIATION, AN ACTIVIST PRIMER, *at* http://www.wildmatters.org/primer/nukelunch.htm (last visited Feb. 27, 2004) (on file with the Texas Wesleyan Law Review); *Stop Food Irradiation Project*, Organic Consumers Ass'n, *at* http://organicconsumers.org/irrad/science.cfm (updated Dec. 17, 2002) (on file with the Texas Wesleyan Law Review); *Why Oppose Food Irradiation*, Public Citizen, *at* http://www.citizen.org/emep/foodsafety/food_irrad/ (last visited Feb. 28, 2004) (on file with the Texas Wesleyan Law Review).

271. *See European Parliament Committee Votes on Food Irradiation Report*, *at* http://www.euractiv.com/cgi-bin/cgint.exe/2292696-948?targ=1&204&ODIN=1504218&-home=home (July 11, 2002) (on file with the Texas Wesleyan Law Review).

272. Analogous to the genetically modified organism concern. *See* Veronica Brown, *UK Report Casts Doubt on North American GM Crops*, REUTERS, Sept. 17, 2002, *at* http://biz.yahoo.com (on file with the Texas Wesleyan Law Review).

273. *See supra* notes 271–72 and accompanying text.

ers to make informed decisions as to whether to buy irradiated foods, lawmakers should amend the NLEA to require labeling declarations for all food products that have irradiated ingredients.[274] Thus, although regulators have progressively embraced irradiation as a method to limit outbreaks of harmful food pathogens, they should continue to seek alternative innovations that further strengthen the safety of the food supply against pathogens.[275]

4. Inspector Training and Evaluation

After a five-year introductory period to indoctrinate HACCP to the meat and poultry industries,[276] suggesting "training" for inspectors about how to enforce HACCP seems counterintuitive. However, the glaring inconsistency in FSIS plant inspection and enforcement protocol discussed in the HACCP section above[277] demands that regulators mandate inspector training for all current inspectors. Post training, regulators should evaluate each inspector's performance, by surprise if necessary, to ensure that the trained inspection protocol matches the actual practice. Regulators should also determine criteria as to whether inspector infractions can be corrected through remedial training or require inspector termination. Although harsh, once regulators clearly communicate proper inspection protocol through mandatory training, regulators should establish "zero tolerance"[278] for lax inspector performance because inconsistent inspection protocol[279] risks the integrity of the food supply.[280] Thus, by properly training and evaluating inspectors, the food supply should be safer.

B. *Producer Protocol*

1. Producers Should Test Food and Not Merely Food Contact Surfaces

Because producers profit from the foods they put into the marketplace,[281] they should bear the burden of ensuring that foods are safe when the foods reach consumers.[282] The recommended protocol is

274. *See supra* notes 84–88 and accompanying text.
275. *See supra* notes 238–41 and accompanying text.
276. *See* U.S. GEN. ACCOUNTING OFFICE, *supra* note 47, at 7.
277. *See* discussion *supra* Part III.B.
278. *See* United States v. Blue Ribbon Smoked Fish, Inc., 179 F. Supp.2d 30, 38 (E.D.N.Y. 2001) (discussing an FDA "zero tolerance" policy).
279. *See* U.S. GEN. ACCOUNTING OFFICE, *supra* note 47, at 4–6.
280. *See USA: Former ConAgra Beef Plant Broke Food Safety Regulations Before Recall*, JUST-FOOD.COM, Jan. 20, 2003, *at* http://just-food.com/news_detail.asp?art=52886&app=1 (on file with the Texas Wesleyan Law Review) (noting lax enforcement for multiple plant food safety infractions).
281. *See, e.g.*, *Financials—Tyson Foods, Inc. (NYSE:TSN)*, *at* http://biz.yahoo.com/fin/l/t/tsn.html (Feb. 6, 2003) (on file with the Texas Wesleyan Law Review) (showing financial statement for Tyson Foods at $295 million in net income for 2002).
282. *See also* Archer & Degnan, *supra* note 92, at 21.

simple: *all* [283] producers should test for pathogens in the foods they place into the marketplace.[284] If any foods test positive for known pathogens, then those foods should not enter the marketplace. Producers should be as proactive about keeping food safe from potential pathogens as the industry has been since September 11th in securing food shipments against potential terrorist[285] tampering, as discussed below.

2. Tamper Evident Seals

Immediately after September 11th, many large domestic food companies reviewed and significantly revamped their security policies to address weaknesses in security and ensure that plants could not be easily accessed by outsiders.[286] Currently, food manufacturers routinely insist on having their suppliers provide their "September 11th" food safety documentation, detailing the suppliers' revamped plant safety measures utilized since that terrorist attack.[287] Tamper evidence for incoming raw materials is now a common listing on supplier food safety documentation.[288]

Tamper evident seals are commonly used in the food industry for bulk food ingredients, like liquid corn sweetener or soybean oil, which are shipped via rail car or truck from supplier to the industrial food converter.[289] These tamper evident seals in theory show whether a compartment has been tampered with during transit, as evidenced by

283. Because some producers are more regulated than others, this Comment advocates *all* producers follow the same basic protocol regardless of industry. *See* discussion *supra* Part III.B.

284. *See* Telephone Interview with Ann Shaw, *supra* note 1 (indicating that testing for pathogens may be at the discretion of the particular producer); *see also* Archer & Degnan, *supra* note 92, at 21 (suggesting that it is a producer's burden to "assure the safety of its products").

285. *See* FOOD SECURITY PREVENTIVE MEASURES GUIDANCE, *supra* note 46; *see also* Interview with Don Klein, *supra* note 95 (mentioning tamper evident seals for truck loads); Interview with Bruce White, Vice President of Logistics, Morningstar Foods, Inc., in Dallas, Tex. (Jan. 18, 2003) (on file with the Texas Wesleyan Law Review) (discussing tamper evident seals for truck loads).

286. *See* Interview with Bruce White, *supra* note 286 (noting the CFSAN listing truck safety seals as part of its food security guidance to producers); *see also* 21 C.F.R. § 10.115 (2003).

287. *See* Interview with Don Klein, *supra* note 95; Interview with Bruce White, *supra* note 286.

288. Interview with Bruce White, *supra* note 286 (noting that CFSAN lists truck safety seals as part of its food security guidance to producers); *see* Notice of Food Security Guidance: Availability, 67 Fed. Reg. 1224 (Jan. 9, 2002) (noting that FDA is interested in tamper evident packaging); *see also* Letter from Rima Jauregui, Director of Quality Assurance & Sanitation, California Custom Fruits and Flavors, Inc., provided courtesy of Mike Mulhausen, President, California Custom Fruits and Flavors, Inc. (Dec. 21, 2001) (on file with the Texas Wesleyan Law Review) (regarding packaging security measures).

289. Interview with Bruce White, *supra* note 286.

whether it is broken or intact upon time of delivery.[290] For full truckload deliveries, these seals are efficient.[291]

A problem arises when food manufacturers rely on these seals as their evidence of potential tampering when dealing with less than truckload (LTL) quantity shipments.[292] LTL quantity shipments often cannot guarantee being enclosed in sealed trucks or railcars from point of supply origin (point A) to final delivery (point B).[293] For truckloads, deliveries from point A to point B are usually direct.[294] In comparison, for LTL's of packaged food supplies, such as bagged sugar or spice blends, the route often is more convoluted, involving more stops as other foods are added from different companies to fill out the loads.[295] Every stop poses an additional threat for potential tampering.[296] The obvious solution of shipping the LTL material by itself directly from point A to point B would be too expensive in practice because the cost of delivering the material would then be amortized over less material on the load.[297]

Producers should consider the risk associated with placing too much reliance on safety seals because they are currently designed to address full truckload shipments, not LTL shipments.[298] Therefore, producers should seek alternative methods to detect tampering with LTL shipments.

3. Innovative Packaging

A possible solution is for producers to bolster the tamper evidence of the packaging container materials themselves such that consumers could easily detect a breach in package integrity.[299] Similarly, producers should seek innovative packaging that bolsters the safety of the food inside as well.[300] For example, innovative packaging exists that shows whether the product inside is safe to eat or has spoiled.[301] Although the benefit to the consumer for this type of packaging is clear, food processors would likely be slow to adopt any new packaging that

290. *See id.*
291. *See id.*
292. *See id.*
293. *See id.*
294. *See id.*
295. *See id.*
296. *See id.*
297. *See id.*
298. *See id.*
299. *See* Interview with Kerry Hogan, National Buyer, Morningstar Foods, Inc., in Dallas, Tex. (Jan. 18, 2003); Interview with Bruce White, *supra* note 286.
300. *See* Aaron L. Brody, *Packaging to Limit Microbiological Concerns*, FOOD TECH., December 2001, at 74 (advocating that microorganism inhibiting packaging should be part of a comprehensive food safety program but not the entire program "per se"); *Plastic Disc Designed to Detect Rotten Food*, REUTERS, Oct. 2, 2002, *at* http://dailynews.yahoo.com (on file with the Texas Wesleyan Law Review).
301. *See Plastic Disc Designed to Detect Rotten Food*, REUTERS, Oct. 2, 2002, *at* http://dailynews.yahoo.com (on file with the Texas Wesleyan Law Review).

is more expensive than traditional packaging.[302] Thus, to encourage adoption for packaging materials that aid in food safety, producers should lobby lawmakers for tax incentives, or the like, to help off-set any additional costs they may incur in order to make food packages safer for consumers.[303]

C. *Consumer Food Safety Protocol*

Although American consumers typically buy the foods they eat, and thus responsibility should fall to the profiting producers to ensure that the foods are safe, due to lax producer self-policing and lax governmental enforcement of existing food safety procedures, for consumers, this Comment's recommended food safety protocol is: Buyer beware!

1. Consumer Education

Consumers should seek education[304] about food safety measures and potential risks. For example, some foods are inherently dangerous unless cooked to certain temperatures, some foods are dangerous unless stored at proper temperatures, and most foods are perishable.[305] According to the USDA's Economic Research Service (ERS), "[r]educing foodborne illness requires not only preventing contamination through improved processing and inspection, but also [through] educating consumers to avoid higher-risk consumption choices and to avoid cross-contamination while preparing food."[306] The ERS research on consumer behavior suggests that consumers are more likely to follow proper food safety guidelines when they perceive that some foods risk causing foodborne illness when not properly handled.[307]

Recently, Ohio reported forty-seven cases of *Salmonella* tied to the sale and consumption of unpasteurized milk.[308] Pasteurization of milk is the standard process utilized by dairy processors to reduce the num-

302. *See* Interview with Don Klein, *supra* note 95.

303. *See* Notice of Food Security Guidance: Availability, 67 Fed. Reg. 1224 (Jan. 9, 2002) (noting that FDA is interested in tamper evident packaging).

304. *See Briefing Room—Consumer Food Safety Behavior: Overview*, Econ. Research Serv., U.S. Dep't Agric., *at* http//www.cdc.gov/foodsafety (Feb. 7, 2004) (on file with the Texas Wesleyan Law Review).

305. FOOD & AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, FOOD BALANCE SHEETS AND FOOD CONSUMPTION SURVEYS, *at* http://www.fao.org/es/ess/consweb.asp (last visited Feb. 13, 2004) (on file with the Texas Wesleyan Law Review); *see* Econ. & Soc. Dep't, Food & Agric. Org. of U.N, *Food Balance Sheets and Food Consumption Surveys*, *at* http://www.fao.org/es/ess/consweb.asp (last visited Feb. 13, 2004) (on file with the Texas Wesleyan Law Review).

306. *Briefing Room—Consumer Food Safety Behavior: Overview*, Econ. Research Serv., U.S. Dep't Agric., *at* http//www.cdc.gov/foodsafety (Feb.7, 2004) (on file with the Texas Wesleyan Law Review).

307. *Id.*

308. *Salmonella Outbreak Linked to Unpasteurized Milk Sold at Young's Jersey Dairy*, CHEESE MARKET NEWS, Jan. 3, 2003, at 5.

ber of harmful microorganisms in the milk supply.[309] Here, the consumers were either unaware of the potential risks associated with unpasteurized milk or ignored them.[310] Considering the vast amount of information available on the Internet and through the media, consumers should readily find information about food safety if they seek it.[311] Those that are more comfortable relying on groups may choose to buy foods that have been qualified by independent sources such as a rabbinical group[312] or independent auditing firm[313] bearing a certification mark in order to ensure that manufacturers are indeed following safe manufacturing processes. Also, consumer food activist groups[314] exist so that consumers could join to help effectuate food safety change.

2. Consumer Litigation to Effectuate Producer Change

Possible tort action is another way that consumers could effectuate food safety changes.[315] Bad publicity, even if seemingly frivolous, can

309. *See* 21 C.F.R. § 131.3(b) (2003).

310. *See id.*

311. *See, e.g.*, Centers for Disease Control, *at* http://www.cdc.gov (last visited Feb. 27, 2004) (providing information about the U.S. food safety and inspection); Economic Research Service, *at* http://www.ers.usda.gov (last visited March 23, 2004); Food & Drug Admin., *at* http://www.fda.gov (last visited Feb. 27, 2004) (providing information concerning U.S. food and drug regulations, health concerns, etc.); Food Safety & Inspection Service, *at* http://www.fsis.usda.gov (last visited Feb. 27, 2004) (providing information about the U.S. food safety and inspection).

312. *See* Lisa Marsh, *Seal of Approval*, N.Y. POST, Nov. 7, 2002, *available at* 2002 WL 102526663 (on file with the Texas Wesleyan Law Review) (referring to kosher certification).

313. *See, e.g.*, *Integrated Quality System Gold Standard Certification Programs*, American Institute of Baking, *at* http://www.aibonline.org/qualitycertprograms/gold.html (last visited March 2, 2004) (on file with the Texas Wesleyan Law Review) (providing continuous improvement in supplying facilities with full integration of sanitation, safety, and quality); *Lab Services: General Information*, Silliker, Inc., *at* http://silliker.com/index.php (last visited Feb. 27, 2004) (on file with the Texas Wesleyan Law Review) (stating that Silliker is "the leading international network of accredited testing laboratories serving the food processing, retail, food service, pharmaceutical and cosmetic industries").

314. *See supra* note 271 and accompanying text.

315. *See, e.g.*, David Barboza, *McDonald's New Recipe Lowers Goo for Arteries*, NEW YORK TIMES, Sept. 3, 2002, *available at* 2002 WL 26114059; Sean Carter, *Burgers, Nuggets and Fries . . . Oh My! The Recent Suit by an Obese Man Against Fast Food Restaurants*, *at* http://writ.corporate.findlaw.com/commentary/20020808_carter.html (Aug. 8, 2002) (on file with the Texas Wesleyan Law Review); Anthony J. Sebok, *The "Big Fat" Class Action Lawsuit Against Fast Food Companies: Is It More Than Just a Stunt?*, *at* http://writ.corporate.findlaw.com/sebok/20020814.html (Aug. 14, 2002) (on file with the Texas Wesleyan Law Review); *Senate Bill Intends To Impact Obesity, Especially Among Youth: Man Sues Fast-Food Restaurants for Causing His Weight Problems*, CHEESE MARKET NEWS, Aug. 9, 2002 (tying the Senate IMPACT Act bill to recent tort action).

encourage food producer change and cause food producers to police quality.[316]

Because consumers ultimately bear the harmful effects of unsafe foods,[317] consumers are not exempt from food safety responsibility[318] and should proactively become educated about both the inherent risks in the food supply and also how to mitigate those risks.[319]

V. CONCLUSION

Domestic food safety in the post-September 11th environment is a complex issue that impacts every member of the supply chain regardless of whether a regulator, producer, or consumer.[320] The challenge for all of these groups is establishing protocol that integrates food safety measures that address both intentionally created bioterrorism hazards, as well as naturally occurring foodborne pathogen hazards, which every link along the supply chain can adopt. For regulators, focus should be on quickly mandating food safety requirements and then on training to consistently and properly enforce those requirements.[321] For producers, focus should be on proactively taking responsibility for the foods introduced into the food supply by seeking and adopting innovative processes for protecting the food supply.[322] For consumers, focus should be upon education for safe food handling and cooking processes, as well as upon ferreting out food hazards and insisting on change by tort if necessary.[323]

Thus, regulators, producers, and consumers all share responsibility for ensuring the food is safe from both bioterrorists and pathogens. And through consistent protocol,[324] each member of the farm-to-table chain has the power to make the United States food supply among the safest in the world[325] in the truest sense of "safe"[326] without any qualifiers.

Lisa Lovett

316. *See Briefing Room—Consumer Food Safety Behavior: Overview*, Econ. Research Serv., U.S. Dep't Agric., *at* http//www.cdc.gov/foodsafety (Feb. 7, 2004) (on file with the Texas Wesleyan Law Review).

317. *See* Food Safety Office, *at* http://www.cdc.gov/foodsafety (Feb. 7, 2004) (on file with the Texas Wesleyan Law Review) (stating that in the United States, foodborne illnesses result in an estimated seventy-six million illnesses and five thousand deaths annually).

318. VETTER, *supra* note 3, at 208.

319. *See supra* notes 305–06 and accompanying text.

320. *See supra* notes 4–7 and accompanying text.

321. *See* discussion *supra* Part IV.A.4.

322. *See* discussion *supra* Part IV.B.

323. *See* discussion *supra* Part IV.C.

324. *See* discussion *supra* Part IV.

325. *See* VETTER, *supra* note 3, at 181.

326. *See id.* at 161; *supra* note 12 and accompanying text.