

FOOD SAFETY IN THE UNITED STATES:
IS THE FOOD SAFETY MODERNIZATION ACT ENOUGH TO
LEAD US OUT OF THE JUNGLE?

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I. INTRODUCTION

The earliest call to action to improve food safety in the United States occurred in 1906 when Upton Sinclair's *The Jungle* described to the nation in vivid detail what was in their sausage.¹ First, there was the rotting ham

1. Adam Cohen, *100 Years Later, the Food Industry Is Still 'The Jungle'*, N.Y. TIMES (Jan. 2, 2007), <http://www.nytimes.com/2007/01/02/opinion/02tue4.html>.

that could no longer be sold as ham.² Added to that were rat droppings, rat poison, and even whole rats.³ Even more disturbing “were the unnamed things ‘in comparison with which a poisoned rat was a tidbit.’”⁴ The public was outraged, and readers bombarded President Theodore Roosevelt with letters.⁵ Reluctantly, the President sent his Labor Commissioner and Assistant Treasury Secretary to Chicago to investigate Sinclair’s allegations.⁶ Much to the nation’s surprise, Sinclair’s images were not an exaggeration.⁷ The reports published by Roosevelt’s team included images like “workers using privies without soap or toilet paper and returning ‘directly from these places to plunge their unwashed hands into the meat.’”⁸ These reports led directly to the passage of the first food safety laws in the United States.⁹ More than 100 years later, it is unclear how far out of *The Jungle* the United States has progressed. According to the Department of Health and Human Services, each year more than 300,000 Americans are hospitalized and 5,000 die after consuming contaminated foods and beverages.¹⁰

Moreover, the United States has recently been stricken with a string of highly publicized foodborne illness outbreaks that have made clear the shortcomings of current food safety laws. It began in 2006 when an outbreak of E. coli associated with the consumption of tainted spinach grown in California resulted in confirmed illnesses and deaths.¹¹ This was followed by widespread outbreaks of Salmonella that occurred from contaminated peanut butter and tomatoes.¹² The most recent outbreak occurred in May 2010, when a Salmonella outbreak led to the recall of 380 million eggs in the United States.¹³

In response to concerns generated by these high-profile outbreaks, the FDA Food Safety Modernization Act, which amends the Federal Food,

2. *Id.*

3. *Id.*

4. *Id.* (quoting UPTON SINCLAIR, *THE JUNGLE* (1906)).

5. *Id.*

6. *Id.*

7. *Id.*

8. *Id.*

9. *Id.*

10. DEPT. OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., OEI-02-08-00080, FDA INSPECTIONS OF DOMESTIC FOOD FACILITIES (Apr. 2010) [hereinafter FDA INSPECTIONS], available at <http://oig.hhs.gov/oei/reports/oei-02-08-00080.pdf>.

11. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-08-794, *FOOD SAFETY: SELECTED COUNTRIES’ SYSTEMS CAN OFFER INSIGHTS INTO ENSURING IMPORT SAFETY AND RESPONDING TO FOODBORNE ILLNESS*, 1–2 (June 2008) [hereinafter *SELECTED COUNTRIES*].

12. *Id.*

13. Steven Reinberg, *Nationwide Recall of Eggs Linked to Salmonella Expanded*, BUSINESSWEEK (Aug. 19, 2010), <http://www.businessweek.com/lifestyle/content/healthday/642286.html>.

Drug, and Cosmetic Act, was passed by the legislature and signed into law by President Obama on January 4, 2011.¹⁴ This Act has been called “the most comprehensive reform of our nation’s food safety laws in more than 70 years”¹⁵ and is celebrated by its supporters as an act that will protect consumers from contaminated food and respond to outbreaks more efficiently.¹⁶ Supporters tout the Act’s provisions increasing the regulatory authority of the Food and Drug Administration (FDA) as “landmark legislation” that “provides FDA with the resources and authorities the agency needs to help strengthen our nation’s food safety system.”¹⁷ But failure of agencies to inspect and regulate the food safety system is often treated as the entire problem, and increased agency authority and funding is treated as the whole solution. However, such a one-dimensional approach is unlikely to be enough to significantly improve food safety in the United States.

This note will discuss the shortcomings of the increased regulatory powers granted in the Food Safety Modernization Act, suggesting that the solution lies in creating a more dynamic approach. It will first discuss the rather random development of food safety laws in the United States and the current balkanized agency structure that is designed to enforce these laws. Next, it will discuss how the Food Safety Modernization Act adds to the regulatory powers of the current agency structure, both in terms of prevention of foodborne illness as well as response to outbreaks that might occur. It argues that, though the Act does make progress toward faster and more efficient responses to outbreaks of foodborne illness, its provisions dealing with prevention of outbreaks do little more than increase the workload of an already over-worked agency. Finally, it argues that the solution lies not in more spending or agency authority, but in creating a dynamic approach to food safety. Success of food safety reform in other countries demonstrates that shifting more of the burden to producers of food rather than regulators can improve the food safety system in the United States. Producers should be held accountable not only for ensuring safety but also for informing consumers about their food safety protocols. Only by providing producers at every stage of production with incentives to ensure food safety will our food safety system find its way out of “the Jungle” and into a safer, healthier future.

14. Helena Bottemiller, *Historic Food Safety Bill Signed into Law*, FOOD SAFETY NEWS (Jan. 5, 2011), <http://www.foodsafetynews.com/2011/01/historic-food-safety-bill-signed-into-law/>.

15. *Id.*

16. Sen. Harry Reid, *Food Safety Modernization Act: Why Its Passage Matters*, THE HUFFINGTON POST (Nov. 30, 2010, 5:25 PM), http://www.huffingtonpost.com/sen-harry-reid/food-safety-modernization_b_790069.html.

17. *See* Bottemiller, *supra* note 14.

II. BACKGROUND: THE WINDING PATH TO U.S. FOOD SAFETY LAWS

A. *Early Calls to Action*

The current regulatory framework for food safety in the U.S. can be traced to two laws enacted in 1906—the Meat Inspection Act and the Pure Food and Drug Act.¹⁸ The passage of these laws and the resulting regulatory framework is due in large part to historical accident.¹⁹ In fact, the earliest call to action to improve food safety was itself an accident.²⁰ Upton Sinclair intended *The Jungle* to be a labor exposé to improve working conditions for laborers.²¹ But readers were much more appalled by what they learned about their food than they were by Sinclair’s account of working conditions.²² As a result, the Meat Inspection Act (MIA) was passed in 1906.²³ The MIA granted the United States Department of Agriculture (USDA) authority to inspect meat consumed in the U.S.²⁴ The USDA’s Bureau of Animal Industry was assigned the responsibility of administering the MIA.²⁵ Moreover, it established a program of continuous examination by resident federal inspectors in meat processing facilities that still exists today.²⁶

The other major piece of legislation, the Pure Food and Drug Act (PFDA), is widely credited by commentators to the work of Dr. Harvey Wiley.²⁷ Dr. Wiley conducted a highly publicized experiment in which a group of volunteers that called themselves the “poison squad” consumed doses of chemicals identical to those found in food preservatives.²⁸ This work raised public awareness of the harm caused by misbranded or adulterated food products, and as a result, the PFDA was commonly referred to as the Wiley Act.²⁹ The PFDA prohibited the use in food of “any added poisonous or other added deleterious ingredient which may

18. Richard A. Merrill & Jeffrey K. Francer, *Organizing Federal Food Safety Regulation*, 31 SETON HALL L. REV. 61, 79 (2000).

19. Note, *Reforming the Food Safety System: What If Consolidation Isn’t Enough?* 120 HARV. L. REV. 1345, 1350 (2007) [hereinafter *Reforming the Food Safety System*].

20. See Cohen, *supra* note 1.

21. *Id.*

22. *Id.* “I aimed at the public’s heart,” Sinclair famously stated, “and by accident I hit it in the stomach.” *Id.*

23. Merrill & Francer, *supra* note 18, at 79.

24. *Id.*

25. See ARTHUR D. HERRICK, *FOOD REGULATION AND COMPLIANCE* 35 (1944).

26. Merrill & Francer, *supra* note 18, at 79.

27. Chenglin Liu, *The Obstacles of Outsourcing Imported Food Safety to China*, 43 CORNELL INT’L L.J. 249, 253 (2010).

28. BEE WILSON, *SWINDLED: THE DARK HISTORY OF FOOD FRAUD, FROM POISONED CANDY TO COUNTERFEIT COFFEE*, 182–86 (2008).

29. *Reforming the Food Safety System*, *supra* note 19, at 1348.

render such article injurious to health.”³⁰ It granted authority to the Secretary of Agriculture to examine food for possible adulteration and directed the Secretary to report potential violations to the Department of Justice.³¹ Moreover, the PFDA provided criminal penalties for introducing adulterated or misbranded foods and drugs into interstate commerce.³² The USDA’s Bureau of Chemistry was responsible for implementing the PFDA.³³ The Bureau of Chemistry later broke away from the USDA and formed a separate agency that is now the FDA.³⁴

The regulatory framework established by the PFDA was overhauled in 1938 by the Federal Food, Drug, and Cosmetic Act (FDCA), which established the framework that still exists today.³⁵ Like its predecessors, the FDCA’s passage was also largely the result of historical accident.³⁶ In 1937, elixir of sulfanilamide, which contained a poisonous solvent, killed 107 people, many of whom were children.³⁷ This tragedy led to public outcry to enact pending food safety laws.³⁸ While the FDCA focused primarily on ensuring that new drugs be tested for safety before marketing, it also enlarged the authority of the FDA to ensure food safety.³⁹ Under the Act, the FDA was authorized to inspect factories,⁴⁰ create identity and quality standards,⁴¹ and establish safety tolerances for unavoidable poisons.⁴² Moreover, it required manufacturers to label food ingredients.⁴³

B. The Current Regulatory Structure

Due to the patchwork of laws and historical accidents that created the foundation for the current regulatory scheme, there is no unified “food safety” counterpart to modern federal regulatory laws such as the Clean Air

30. Pure Food and Drug Act, ch. 3915, § 7, 34 Stat. 768 (1906), *repealed by* Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–399 (2006)).

31. *See id.*

32. *Id.*

33. HERRICK, *supra* note 25, at 35.

34. *Id.*

35. Liu, *supra* note 27, at 254–55.

36. Merrill & Francer, *supra* note 18, at 81.

37. *Significant Dates in U.S. Food and Drug Law History*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/Milestones/ucml28305.htm> (last visited Mar. 20, 2012).

38. *Id.*

39. Merrill & Francer, *supra* note 18, at 81.

40. *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 374 (2006).

41. *See id.* § 341.

42. *See id.* § 346.

43. *See id.* § 343(q).

Act or the Occupational Safety and Health Act.⁴⁴ The current U.S. food safety system is comprised of thirty main statutes⁴⁵ and fifteen different federal agencies that are responsible for food safety.⁴⁶ Among these agencies, primary authority for food safety is bifurcated between the USDA and the FDA.⁴⁷ The USDA is responsible for the safety of meat, poultry, and certain egg products.⁴⁸ The FDA is responsible for almost all other foods, including milk, seafood, fruits, and vegetables.⁴⁹ Moreover, responsibility for food safety is further divided among the states.⁵⁰ There is no formal mechanism for granting power to state regulatory bodies, nor is there any system for coordinating their efforts.⁵¹

C. Current Enforcement Tools and Their Limits

1. Inspections

The primary tool available to agencies to prevent outbreaks of foodborne illness is the authority to conduct inspections. Under the FDCA, the FDA is responsible for ensuring the safety of almost all food products sold in the United States, except for meat, poultry, and some egg products that are regulated by the USDA.⁵² Under the Act, the FDA inspects food facilities that manufacture, process, pack, and store food.⁵³ Nineteen district offices conduct these inspections according to guidelines provided by the FDA, and the FDA sometimes contracts with States to conduct the inspections.⁵⁴ Once an inspection is completed, the FDA will assign a facility one of three classifications: official action indicated (OAI), voluntary action indicated (VAI), or no action indicated (NAI).⁵⁵ An OAI

44. COMM. TO ENSURE SAFE FOOD FROM PROD. TO CONSUMPTION, INST. OF MEDICINE, NAT'L RESEARCH COUNCIL, ENSURING SAFE FOOD FROM PRODUCTION TO CONSUMPTION 85 (Nat'l Academy Press 1998) [hereinafter ENSURING SAFE FOOD].

45. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-05-549T, OVERSEEING THE U.S. FOOD SUPPLY: STEPS SHOULD BE TAKEN TO REDUCE OVERLAPPING INSPECTIONS AND RELATED ACTIVITIES 1 (2005).

46. SELECTED COUNTRIES, *supra* note 11, at 2.

47. *Id.* This bifurcation can be traced to the MIA, which gave regulatory authority to the USDA, and the PFDA, which granted regulatory authority to the Bureau of Chemistry, which was part of the USDA at that time. The Bureau of Chemistry's name was changed to the FDA in 1930 and was moved from the USDA to the Federal Security Agency in 1940. It was then transferred to what became the Department of Health and Human Services, where it currently resides.

48. *Id.*

49. *Id.*

50. *Id.*

51. ENSURING SAFE FOOD, *supra* note 44, at 85. In fact, many state agencies are also divided along the USDA-FDA jurisdictional line.

52. FDA INSPECTIONS, *supra* note 10, at 2.

53. See 21 U.S.C. § 374; see also *id.* § 372.

54. FDA INSPECTIONS, *supra* note 10, at 2.

55. *Id.* at i.

classification signifies that the inspector found the most significant types of violations.⁵⁶ These violations include objectionable conditions in the food facility that “warrant regulatory action.”⁵⁷ The VAI classification means that the inspector “found violations that are serious enough to record but do not cross ‘the threshold for regulatory action.’”⁵⁸ Finally, the NAI classification “signifies that the inspector found either no violations of Federal law or violations that were so insignificant that no action is warranted.”⁵⁹ When a facility receives an OAI classification, FDA guidance requires that some type of regulatory action be recommended.⁶⁰ This action may either be advisory action, which allows an opportunity for the facility to voluntarily correct violations, or enforcement action, which is usually initiated in court and the facility is required to correct the violations.⁶¹ The FDA uses a variety of approaches to determine whether violations have been corrected, including re-inspecting the facility and reviewing evidence provided by the facility that describes its corrective actions.⁶² In general, there are no specific guidelines governing the frequency of inspections.⁶³ Instead, the district offices, along with FDA headquarters, develop annual priorities for inspection that may change based on emerging issues, such as outbreaks of foodborne illness.⁶⁴

While the theory behind the FDA’s regulatory program is sound, a report issued in April 2010 by the Department of Health and Human Services’ Office of Inspector General highlights many of the problems with the FDA inspections of domestic food facilities. First, the report indicated that on average, the FDA inspects less than one-fourth of food facilities each year, and that the number of facilities inspected has declined over time.⁶⁵ Moreover, the report noted that 56% of food facilities have gone five or more years without an inspection.⁶⁶ In terms of the actual inspections, the report notes that the number of facilities that received OAI classifications indicating the most severe violations of food safety laws has declined over time.⁶⁷ Most disturbingly, the study found that the FDA took regulatory action against only 46% of the facilities with OAI

56. *Id.* at 3.

57. *Id.*

58. *Id.*

59. *Id.*

60. *Id.* at i.

61. *Id.*

62. *Id.*

63. *Id.* at 2.

64. *Id.*

65. *Id.* at ii.

66. *Id.*

67. *Id.*

classifications.⁶⁸ For the remainder, the FDA re-classified 29% and took no regulatory action for the other 25% of facilities.⁶⁹ These weaknesses are no doubt the product of significant decreases in FDA staffing for its food program.⁷⁰ In fiscal year 2003, the “FDA had 3,167 full-time equivalent employees . . . responsible for the oversight of food facilities.”⁷¹ By fiscal year 2007, the number of full-time equivalent employees had decreased to 2,569.⁷² Due to concerns about staffing shortages, Congress increased funding in fiscal year 2009 for the FDA’s food program to a level that would support an estimated 3,019 full-time employees.⁷³

The Food Safety and Inspection Service (FSIS) of the USDA is responsible for ensuring that meat and poultry products are “safe, wholesome, and correctly marked, labeled, and packaged if they move into interstate or international commerce.”⁷⁴ The FSIS shares responsibility with the FDA for inspecting eggs and egg products.⁷⁵ Because of statutorily mandated continuous inspection requirements,⁷⁶ approximately 7,400 FSIS inspectors are responsible for inspecting 6,200 meat and poultry slaughtering and processing plants.⁷⁷ The FSIS inspection process includes a “continuous carcass-by-carcass inspection during slaughter as well as [a] full daily inspection during processing.”⁷⁸ Because of these statutory requirements, the “FSIS’s inspection budget is about four times that of [the] FDA.”⁷⁹

Because authority for food safety is split between the FDA and the USDA based on the type of commodity, there is some overlap of authority for some food products that seem similar.⁸⁰ The most common example is pizza.⁸¹ Pizza “is regulated by [the] FDA unless it is topped with 2 percent or more of cooked meat or poultry, in which case it is [regulated by the USDA.]”⁸² Therefore, inspection at pizza production facilities must be

68. *Id.*

69. *Id.* at ii–iii.

70. *Id.* at 2.

71. *Id.*

72. *Id.*

73. *Id.* at 3.

74. ENSURING SAFE FOOD, *supra* note 44, at 27.

75. *Id.*

76. The USDA regulates meats under the Federal Meat Inspection Act, 21 U.S.C. §§ 601–695 (2006), and the Poultry Products Inspection Act, 21 U.S.C. §§ 451–472 (2006).

77. ENSURING SAFE FOOD, *supra* note 44, at 27.

78. *Id.*

79. *Id.*

80. *Id.*

81. *Id.*

82. *Id.*; *see also* 68 Fed. Reg. 44859-01 (July 31, 2003).

conducted simultaneously by inspectors from two different agencies using different guidelines.⁸³

Not only does the FDA–USDA jurisdictional split create overlap, it also creates inconsistencies among agencies. One example of this is the regulation of eggs, the source of the most recent Salmonella outbreak in 2010. Regulation of eggs is controlled by several agencies within the USDA and the FDA, as well as various state agencies.⁸⁴ Despite the fact that eggs are the source of 75% of all Salmonella outbreaks,⁸⁵ different agencies have different requirements for packaging and labeling that tend to confuse or mislead consumers.⁸⁶ Thus, while inspections are at the heart of the U.S. food safety system, overlap and inefficiency tend to slow the process and weigh down agencies whose resources are already stretched to their limits.

2. Tort Liability

No provisions of the FDCA expressly authorize a private cause of action to be brought under it, and the Supreme Court has rejected the notion of an implied right of action under the Act.⁸⁷ However, a private party injured by unsafe food may bring a common law tort action.⁸⁸ In cases where foods actually cause harm to an individual, the primary type of tort liability applied is strict product liability.⁸⁹ In addition, punitive damages are available when the defendant's conduct is outrageous, reckless, or malicious.⁹⁰ The success and practicality of tort actions is discussed in more detail in Part IV.C.2 *infra*.

3. Criminal Sanctions

Criminal sanctions are available under the FDCA, but they are the least used method of enforcing food safety laws.⁹¹ In fact, “[m]ost violations of the [FDCA] potentially carry criminal penalties.”⁹² The FDA has discretion

83. ENSURING SAFE FOOD, *supra* note 44, at 27.

84. U.S. GEN. ACCOUNTING OFFICE, GAO/T-RCED-99-232, FOOD SAFETY: U.S. NEEDS A CONSISTENT FARM-TO-TABLE APPROACH TO EGG SAFETY 3–4 (1999).

85. *Id.* at 1.

86. *Reforming the Food Safety System*, *supra* note 19, at 1357.

87. PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, FOOD AND DRUG LAW: CASES AND MATERIALS 1467 (3d ed. 2007).

88. *See generally* DAVID G. OWEN, PRODUCTS LIABILITY LAW 460–64 (2005).

89. Adam I. Muchmore, *Private Regulation and Foreign Conduct*, 47 SAN DIEGO L. REV. 371, 390–91 (2010).

90. *Id.* at 391.

91. JAMES T. O'REILLY, 1 FOOD AND DRUG ADMINISTRATION § 8.01 (3d ed. 2007).

92. HUTT, MERRILL & GROSSMAN, *supra* note 87, at 1310.

to determine whether to prosecute violations.⁹³ In making this decision, the FDA usually considers the following factors: “continuing violations of law (e.g., continuing insanitary conditions in a food plant); violations of an obvious and flagrant nature (e.g., food warehouse overrun with rodents, birds and insects, which contains plainly contaminated products); and intentional false or fraudulent violations.”⁹⁴ The standard for criminal liability under the FDCA is strict liability,⁹⁵ and individuals who have a “responsible relationship” to the regulated products can be liable.⁹⁶ Thus, a person in charge of a food facility that violates the Act can be criminally liable without the government proving *mens rea*.⁹⁷ Even though they are rarely used, criminal sanctions under the FDCA are still a powerful tool, as criminal penalties for a single offense may consist of one year in jail and a \$1,000 fine.⁹⁸ In addition, the fine may be up to \$250,000 if the violation causes death.⁹⁹

4. Seizures

In addition to criminal sanctions, the FDA can also seize adulterated or misbranded food products.¹⁰⁰ The power to seize, though an intrusive measure, gives the FDA leverage to force a firm to take action on its own to eliminate or mitigate the danger caused by tainted foods.¹⁰¹ If an FDA inspector believes that the facility’s products have the potential to cause immediate injury, the FDA may seize the products.¹⁰² However, like criminal sanctions, the seizure power is rarely used, as firms will usually opt for a voluntary recall of potentially harmful products.¹⁰³

93. *Id.* at 1319.

94. *Id.*

95. Liu, *supra* note 27, at 259.

96. *United States v. Park*, 421 U.S. 658, 672 (1975).

97. Liu, *supra* note 27, at 259.

98. *See* 21 U.S.C. § 333 (2006); *see also* Liu, *supra* note 27, at 260.

99. O’REILLY, *supra* note 91, § 8.07.

100. Liu, *supra* note 27, at 260.

101. *Id.*; *see also* *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594, 601 (1950) (“Congress weighed the potential injury to the public from misbranded articles against the injury to the purveyor of the article from a temporary interference with its distribution and decided in favor of the speedy, preventive device of multiple seizures.”).

102. Liu, *supra* note 27, at 260.

103. *Id.*

5. *Voluntary Recalls*

Voluntary recalls are essentially “do-it-yourself seizure actions.”¹⁰⁴ In recent years, the number of recalls has declined.¹⁰⁵ However, the quantity of meat and poultry recalled has increased sharply.¹⁰⁶ According to a report issued by the U.S. Government Accountability Office, “[m]eat and poultry product recalls declined from 125 in 2002 to 58 in 2007. However, two of the six biggest meat recalls in U.S. history occurred in a six-month period, between October 2007 and February 2008.”¹⁰⁷

Although the FDA does not currently have authority to require a recall, the FDA still publishes guidelines that establish policies, procedures, and industry responsibilities for recalls.¹⁰⁸ In general, when a firm issues a recall, the FDA assumes the supervisory role,¹⁰⁹ while the recalling firm is responsible for removing the unsafe products from the market.¹¹⁰ Once a recall is issued, the FDA will evaluate the product’s potential health hazard.¹¹¹ The FDA will then “assign the recall a classification, i.e., Class I, Class II, or Class III, to indicate the relative degree of health hazard.”¹¹² The recalling firm must also submit a strategy to the FDA that must specify the approaches that the firm will take to resolve the threat, how the firm will relay important information to the public, and how it will check the recall’s effectiveness.¹¹³ The firm must also inform the FDA regularly of the recall’s status.¹¹⁴

In addition to overseeing the recall, the FDA also issues public warnings to alert consumers to the potential health hazard.¹¹⁵ The FDA also posts public notifications of recalls in its weekly FDA Enforcement Report on its website, which gives a listing of each new recall according to its classification.¹¹⁶ In addition to their primary role of informing consumers, these notifications also serve a deterrent function because public alerts of a recall negatively impact a firm’s reputation.¹¹⁷

104. Eugene I. Lambert, *Recalls, Regulatory Letters and Publicity*, 31 FOOD DRUG COSM. L.J. 360, 360 (1976).

105. SELECTED COUNTRIES, *supra* note 11, at 2.

106. *Id.*

107. *Id.*

108. See 21 C.F.R. §§ 7.41–7.59 (2011).

109. *Id.* § 7.46(b).

110. Liu, *supra* note 27, at 262.

111. See *id.* § 7.41(a) (2011).

112. *Id.* § 7.41(b).

113. See generally *id.* § 7.42; see also *id.* § 7.46(a).

114. *Id.* § 7.53.

115. *Id.* § 7.50.

116. *Id.*

117. Liu, *supra* note 27, at 262.

6. *Production-Based Enforcement Tools*

In addition to the enforcement mechanisms discussed above, agencies also set production-based enforcement tools.¹¹⁸ One such enforcement tool in the U.S. is the use of a science-based safety system for certain food products, called Hazard Analysis and Critical Control Point (HACCP).¹¹⁹ According to a report issued by the U.S. Government Accountability Office, “[a] HACCP system is designed to improve the safety of food by having industry identify and control biological, chemical, and physical hazards in products before they enter the market.”¹²⁰ HACCP requirements for meat and poultry were established by the USDA in 1996, and the FDA implemented similar HACCP requirements for seafood in 1997 and for juice in 2002.¹²¹ “Under the HACCP system, processing firms must identify hazards that are reasonably likely to occur and must develop and implement plans to control those hazards.”¹²²

While the HACCP system is designed to protect human health from known hazards and new threats, it has limitations.¹²³ The main limitation is that the regulation begins at the point of processing, rather than on the farm itself.¹²⁴ Under both USDA and FDA regulations, HCCAP systems are required only for food processors and not for other stages of production.¹²⁵ Moreover, neither the Meat Products Inspection Act nor the Poultry Products Inspection Act address how livestock is produced, maintained, and managed.¹²⁶ Thus, there are virtually no standards regulating food production prior to the processing stage.

III. THE FOOD SAFETY MODERNIZATION ACT

The Food Safety Modernization Act, signed into law by President Obama on January 4, 2011, has been called the biggest overhaul of food safety laws since the Great Depression.¹²⁷ The Act is expected to cost \$1.4 billion dollars, most of which will be used to fund the hiring and training of more employees at the FDA.¹²⁸ The FDA is expected to increase its current

118. *Id.* at 256–57.

119. SELECTED COUNTRIES, *supra* note 11, at 11.

120. *Id.*

121. *Id.*

122. *Id.*

123. *See id.*

124. *See id.*

125. *Id.*

126. ENSURING SAFE FOOD, *supra* note 44, at 86.

127. Bottemiller, *supra* note 14.

128. Dan Flynn, *Top Food Safety Stories of 2010: No. 1*, FOOD SAFETY NEWS (Dec. 31, 2010), <http://www.foodsafetynews.com/2010/12/top-food-safety-stories-of-2010-no-1/>.

number of food safety employees from approximately 3,000 existing employees to 4,000 in 2011 and 5,000 in 2012.¹²⁹ The Food Safety Modernization Act consists of four titles.¹³⁰ Title I focuses on preventing food safety problems, while Title II deals with detecting and responding to these problems.¹³¹ Title III addresses imports and Title IV consists of miscellaneous provisions.¹³² Titles I and II, dealing with prevention and response to foodborne illness outbreaks, will be the focus of this note.

A. Title I: Preventing Food Safety Problems

Title I of the Act amends the Federal Food, Drug, and Cosmetic Act to expand the authority of the Secretary of Health and Human Services over food safety.¹³³ First, it authorizes the Secretary to inspect records related to food production.¹³⁴ Second, the Secretary is required to issue guidance documents for reducing risks caused by the most significant foodborne contaminants, and to establish minimum standards for the safe production and harvesting of fruits and vegetables based on known safety risks.¹³⁵ The Secretary also has the authority to issue exemptions and variances from these standards.¹³⁶ Finally, the Act directs the Secretary to assess and collect fees related to: (1) food facility re-inspections; (2) food recalls; (3) the voluntary qualified importer program; and (4) importer re-inspection.¹³⁷

Title I also creates new requirements for food production facilities. The Act requires owners, operators, or agents in charge of food facilities to identify and implement preventative controls in order to significantly minimize or prevent hazards that might affect food that is manufactured, processed, packed, or held by that facility.¹³⁸ However, certain establishments that sell food directly to consumers, including roadside stands, farmers markets, and participants in community-supported agriculture programs are exempted from the Act's requirements.

129. *Id.*

130. FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (to be codified in scattered sections of 21 U.S.C.).

131. *Id.*

132. *Id.*

133. *Id.* (to be codified at 21 U.S.C. § 350c(a)).

134. *Id.*

135. *Id.* (to be codified at 21 U.S.C. § 2201).

136. *Id.* (to be codified at 21 U.S.C. § 350g).

137. *Id.* (to be codified at 21 U.S.C. § 379j-31).

138. *Id.* (to be codified at 21 U.S.C. § 350g).

B. Title II: Detecting and Responding to Food Safety Problems

One of the biggest innovations touted by supporters of the Act is that it finally grants authority to the FDA to order a mandatory recall of contaminated foods.¹³⁹ The Act also requires the Secretary to establish a product tracing system to track food that was either produced in the U.S. or imported, which will allow the FDA to quickly determine where food came from and prevent it from reaching consumers.¹⁴⁰ The Act also addresses staffing shortages by requiring the Secretary to allocate resources to inspect facilities and imports according to the known safety risks of the facilities and the particular food product.¹⁴¹ In addition, the Act requires the Secretary, acting through the Director of the Centers for Disease Control and Prevention, to enhance foodborne illness surveillance systems in order to enhance the collection, analysis, reporting, and usefulness of data on foodborne illnesses.¹⁴²

IV. THE FDA FOOD SAFETY MODERNIZATION ACT: AN INCOMPLETE SOLUTION?

The Act's passage has been praised by industry, public health, and consumer groups.¹⁴³ Pam Bailey, president and CEO of the Grocery Manufacturers Association, praised the bill as providing the FDA "with the resources and authorities the agency needs to help strengthen our nation's food safety system by making prevention the focus of our food safety strategies, and [helping] restore the public's faith in the safety and security of the food supply."¹⁴⁴ In addition, Richard Wolford, the CEO of Del Monte Foods, stated that he was "proud of the food industry for its support of landmark food safety legislation and our efforts to protect consumers and provide them a safe food supply."¹⁴⁵

Though the Act is being touted as one that makes "prevention the focus of our food safety strategies,"¹⁴⁶ it is unclear whether the Act will be enough to prevent the types of outbreaks that have become increasingly common in our food supply. An analysis of the provisions of Titles I and II shows that while the Act makes a big step toward faster and more efficient responses to food safety crises, the provisions addressing prevention of

139. *Id.* (to be codified at 21 U.S.C. § 350l).

140. *Id.* (to be codified at 21 U.S.C. § 2223).

141. *Id.* (to be codified at 21 U.S.C. § 2224).

142. *Id.* (to be codified 42 U.S.C. § 280g-16).

143. Bottemiller, *supra* note 14.

144. *Id.*

145. *Id.*

146. *Id.*

such crises do little more than pile additional work on an already-overburdened agency.

A. Response Mechanisms

The provisions of Title II that address response to outbreaks of foodborne illness have the potential to significantly increase the speed and efficiency of authorities to respond to a food safety crisis. A study by the Government Accountability Office on food safety laws in other countries (including Canada, Germany, Ireland, Japan, the Netherlands, and the United Kingdom) reported that the selected countries cited three elements of their food safety systems as critical in helping them respond to outbreaks of foodborne illness.¹⁴⁷ These elements are “traceback procedures, cooperative arrangements between government veterinarians and public health officials, and mandatory recall authority.”¹⁴⁸ While the Food Safety Modernization Act does not address arrangements between veterinarians and public health officials, it does require the Secretary of Health and Human Services to develop traceback procedures and gives the FDA mandatory recall authority. Therefore, the Act, if vigorously implemented, will represent a big step toward faster and more efficient responses to food safety crises.

B. Prevention Mechanisms

The provisions of Title I of the Act that deal with prevention of foodborne illness promise to be much less effective. First, the Act only addresses part of the problem. By amending the Federal Food, Drug, and Cosmetic Act, the Food Safety Modernization Act expands the authority of the FDA. However, as discussed in Part II, the FDA does not have regulatory authority over the entire food supply. In fact, the FDA’s authority only extends to approximately 80% of the U.S. food supply.¹⁴⁹ Thus, 20% of our food supply is completely unaffected by this bill, including meat, poultry, and eggs, which are all within the jurisdiction of the USDA. This means that production and distribution of eggs are not affected at all by the Act, even though a *Salmonella* outbreak caused by tainted eggs was one of the primary events causing public outcry for more effective food safety laws.

Second, the Act has the potential to create bad incentives for food producers. Title II authorizes the Secretary of Health and Human Services

147. SELECTED COUNTRIES, *supra* note 11, at 23.

148. *Id.*

149. Bottemiller, *supra* note 14.

to inspect records related to food. However, the Act does not set any mandatory record-keeping requirements. Thus, if producers know they could be criminally or civilly liable based on records that may be inspected by the Secretary, they may be less likely to keep records that are completely accurate and some may not keep records at all.

Third, while the Act promises more funding for inspections and increased regulatory authority for the FDA, it is unclear how effective these provisions will be. As discussed above, the current FDA inspection levels are grossly lacking. The FDA currently inspects less than one-fourth of all domestic food facilities each year.¹⁵⁰ Therefore, even if the Act doubles the current FDA inspection force as promised, it is still unlikely that this beefed-up staff would be able to inspect all domestic food facilities each year. Based on the Government Accountability Office's report on current FDA inspection levels, this increased staff could, at best, inspect approximately half of all food production facilities each year.¹⁵¹ Moreover, it is far from certain whether the increased funding to the FDA will actually be achieved. Supporters of the bill face a tough battle ahead to get funding in a "contentious budgetary landscape."¹⁵² Furthermore, as Rep. Rosa DeLauro (D-CT), a longtime advocate of food safety reform has noted, "[w]ithout appropriate funding levels, the FDA Food Safety Modernization Act would not be as effective in protecting our food supply and saving lives."¹⁵³

Finally, while the Act does attempt to place more responsibility on producers by requiring owners, operators, or agents in charge of a food facility to identify and implement preventive controls to minimize or prevent hazards that could affect the food produced or processed in that facility, this requirement also has the potential to create bad incentives. As the Act currently reads, producers are responsible for setting their own standards by determining what preventative controls will reduce hazards; they are also responsible for implementing these controls. Producers may be tempted to set the standards for preventative controls at a low level in order to avoid the cost of implementing new preventative controls. Thus, while the Act initially appears to require more producer responsibility and accountability, this attempt will likely fall short due to the bad incentives it creates.

150. FDA INSPECTIONS, *supra* note 10, at ii.

151. *Id.*

152. Bottemiller, *supra* note 14.

153. *Id.*

C. Lessons from Abroad: Increased Food Safety Through a Dynamic Approach

Some solutions for filling in the gaps in the Food Safety Modernization Act can be found by looking to approaches that have been successful abroad. In addition, effective regulatory strategies under other statutes in the United States, such as the Clean Water Act, can provide guidance. In particular, the Food Safety Modernization Act needs more comprehensive coverage, stricter informational requirements, and separation of risk assessment from risk management in order to achieve a dynamic food safety system that is more efficient and effective.

1. More Comprehensive Coverage

Commentators have long recognized the inefficiency of the current agency structure that is responsible for ensuring food safety in the United States.¹⁵⁴ Several other countries, including Canada, Denmark, Germany, Ireland, the Netherlands, New Zealand, and the United Kingdom, have all recently consolidated food safety responsibilities.¹⁵⁵ However, as at least one commentator has argued, it may simply be too late in the day to consolidate food safety responsibilities under one unified agency.¹⁵⁶ In any event, more comprehensive legislation is needed to address the inefficiencies that exist among agency responsibilities, such as the joint FDA–USDA jurisdiction over eggs, discussed in Part II. Until legislation with more comprehensive coverage is passed, U.S. food safety laws will continue to have gaping holes. Recent events such as the Salmonella outbreak linked to eggs demonstrate that the Act’s overhaul of food safety laws will continue to be incomplete until products like eggs and meat are also addressed.

Another inefficiency that should be addressed through a more comprehensive approach is the existing funding plan. As discussed in Part II, the USDA’s budget for inspections is currently four times that of the FDA’s, even though the USDA is only responsible for approximately 20% of the U.S. food supply. This is the result of statutes that require each and every carcass to be physically inspected. These statutes were appropriate when passed nearly a century ago in the world of Upton Sinclair’s *The Jungle*, a time when the most serious hazards could be identified by sight,

154. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-05-549T, OVERSEEING THE U.S. FOOD SUPPLY: STEPS SHOULD BE TAKEN TO REDUCE OVERLAPPING INSPECTIONS AND RELATED ACTIVITIES I (2005).

155. SELECTED COUNTRIES, *supra* note 11, at 10.

156. See *Reforming the Food Safety System*, *supra* note 19, at 1351 (arguing that the expense of consolidating food safety responsibility might outweigh the benefits to be derived from consolidation).

smell, and feel.¹⁵⁷ However, the hazards that pose the biggest threat today are microbiological and chemical contamination that cannot be identified by a physical inspection.¹⁵⁸ Thus, it is time for Congress to reassess the current allocation of resources among food safety agencies, as the current system is channeling a large amount of resources to fund inspections that may no longer be necessary. An effective re-allocation can be achieved only through a comprehensive approach that addresses resource allocation among all agencies that are responsible for food safety. Even if Congress is unwilling to follow the lead of other developed nations and consolidate agency responsibility for food safety, a more complete approach could still be achieved through legislation that is more comprehensive. The scope of the Food Safety Modernization Act, which only addresses the responsibilities of the FDA, is simply too narrow. Only by drafting legislation that deals with food safety laws comprehensively can Congress streamline agency responsibilities and better allocate resources.

2. Stricter Informational Requirements

Food safety issues often create an information problem.¹⁵⁹ This problem arises because “[c]onsumers cannot readily distinguish *ex ante* between safe or unsafe food, and have some trouble identifying unsafe food *ex post*.”¹⁶⁰ Since consumers cannot distinguish between safe and unsafe food *ex ante*, the incentive effect of market pricing is diminished because producers of safe food are unable to capture a price premium for this characteristic.¹⁶¹ In addition, the incentive effect of tort liability is reduced by the information problem.¹⁶² This occurs because “[w]ith the exception of a few identifiable illnesses, such as *E. coli* and hepatitis A, that are sufficiently severe to capture the attention of food safety authorities, consumers can rarely establish with any degree of certainty which of several food items they ate on a particular day made them sick.”¹⁶³ As a result, consumers are unable to prove in a tort action that unsafe food caused a particular injury.¹⁶⁴ For example, Barbara Kowalcyk, a food safety advocate and mother whose son died after eating a hamburger tainted with *E. coli* 0157:H7, told her story in the documentary *Food, Inc.* According to Kowalcyk, it took over two years and a private attorney just to find out that

157. ENSURING SAFE FOOD, *supra* note 44, at 86.

158. *Id.*

159. Muchmore, *supra* note 89, at 391.

160. *Id.*

161. *Id.*

162. *Id.*

163. *Id.* at 391–92.

164. *Id.* at 392.

the meat ingested by her son matched a meat recall.¹⁶⁵ Moreover, it has been noted by commentators that “even in cases when consumers are able to assign blame, it is difficult for them to recover in a tort action against a domestic producer.”¹⁶⁶

The information problem is exacerbated by the fact that many food products are sold either unbranded or weakly branded.¹⁶⁷ For example, consumer choices regarding fresh fruits, vegetables, and seafood seem to be influenced more by tangible product characteristics than by the producer’s identity or name brand.¹⁶⁸ As a result, “fresh food producers are less likely to internalize the costs of safety problems than brand-driven companies selling drugs, processed foods, or consumer products.”¹⁶⁹

Because of the information problem and the reduced incentive effects caused by it, alternative mechanisms are needed to achieve food safety. One such mechanism that is a major component of the U.S. food safety system is *ex ante* regulation under statutes such as the Federal Food, Drug, and Cosmetic Act.¹⁷⁰ However, as discussed in Part II, the FDA does not currently have the resources to monitor and frequently inspect all food production facilities. This means that other tools are needed to supplement inspections in order to provide adequate food safety. This shortage of resources is not a new phenomenon, nor is it unique to food safety. For example, in the context of environmental regulation, under-funded and under-staffed agencies such as the Environmental Protection Agency (EPA) have long struggled to force industry compliance. However, these industries have little incentive to comply with EPA regulations other than the threat of prosecution, which is a remote possibility due to the lack of inspection resources. The EPA has been particularly successful in dealing with this problem under the Clean Water Act by creating mandatory informational requirements that facilitate citizen suits. Simply put, industries subject to regulation under the Clean Water Act are required to submit periodic reports to the EPA which set out the amount of pollution that they actually discharge,¹⁷¹ and they can be subject to criminal penalties for providing false information. This information reporting requirement facilitates citizen suits under the Clean Water Act because citizens need only compare the amount of actual pollution recorded in the report to the

165. FOOD, INC. (Magnolia Pictures 2008) (documentary).

166. Muchmore, *supra* note 89, at 392.

167. *Id.*

168. *Id.*

169. *Id.*

170. *Id.* at 389.

171. WILLIAM L. ANDREEN & SHANA CAMPBELL JONES, CTR. FOR PROGRESSIVE REFORM, WHITE PAPER NO. 802, THE CLEAN WATER ACT: A BLUEPRINT FOR REFORM 43 (2008).

amount of pollution that is allowed to be discharged under their Clean Water Act permit to determine if there has been a violation.¹⁷²

Though not an exact analogy, the concept underlying the reporting requirements of the Clean Water Act can still be applied in the food safety context. Indeed, the Food Safety Modernization Act takes a step toward this type of requirement by giving the Secretary authority to inspect records. However, this provision does not go far enough. While mandatory reporting requirements in the food safety context would not necessarily be used to allow consumers to file citizen suits, these requirements would still be a powerful tool because they put a company's reputation at stake. Forcing food producers and processors to publicize information about their production processes and mechanisms for preventing hazards will make them think twice about the way they operate their business. As the recent Salmonella outbreak linked to eggs illustrates, companies are currently able to point the finger at regulators and avoid the reputational harm of failures to prevent outbreaks. News reports tend to focus on the failure of regulators to inspect, rather than the failures that take place within individual production facilities. Therefore, the FDA should set clear safety standards for food producers and then implement mandatory reporting requirements forcing producers to release information showing whether or not they are meeting those standards. This would shift more of the burden and accountability of compliance from government regulators to the producers themselves.

Japan and countries in the European Union who have recently shifted their focus to create more producer accountability have reported success in improving food safety. A study issued by the Government Accountability Office reports that an industry representative in one of the selected countries stated that "because producers are concerned with protecting their name brands, greater accountability makes them proactive."¹⁷³ Another industry representative echoed this statement, noting that "importers are bearing more responsibility for ensuring the safety of their food imports because they are aware of the damages—financial and image-related—that violations cause to their business."¹⁷⁴ A third industry representative summed it up best by saying "farmers and producers can no longer hide behind meat inspectors."¹⁷⁵ Similar success can be achieved in the United States by implementing stricter information requirements. By forcing food production facilities to disclose information about their food safety

172. *Id.*

173. SELECTED COUNTRIES, *supra* note 11, at 15.

174. *Id.*

175. *Id.*

protocols, the FDA can force these facilities to be more accountable for the food they send to consumers.

3. Separation of Risk Assessment from Risk Management

While the Food Safety Modernization Act does attempt to place more responsibility on producers by requiring them to identify and implement controls designed to reduce the risk of food safety hazards, the Act leaves too much discretion in the hands of producers by allowing them to both set the standard and implement it. An inherent conflict of interest is created by this structure since producers will likely choose less stringent control technologies in order to reduce the costs of implementing such technology. Several other countries have dealt with this conflict by separating risk assessment from risk management.¹⁷⁶ For example, some countries within the European Union allow regulatory authorities to set Hazard Analysis and Critical Control Point (HACCP) measures, and then require producers to apply these measures in their production processes.¹⁷⁷ Some countries, including the United Kingdom and Ireland, have even taken risk assessment away from their ministries of agriculture, which are perceived to favor the food industry over consumer protection.¹⁷⁸

A similar division of risk assessment and risk management is needed in order to achieve the goals of the Food Safety Modernization Act. For example, the FDA and the Centers for Disease Control should focus on assessing risks and identifying practices that will best reduce these risks. Allowing these agencies to conduct the risk assessment eliminates the conflict of interest concerns that arise when producers are allowed to make up their own safety standards. Moreover, these agencies are also better equipped to assess risks because they have much more expertise and information on foodborne illnesses than food producers or processors. Once these agencies set the standard, producers should be responsible for implementing the risk management practices identified by these agencies. Food producers would receive guidelines on reducing the risks of foodborne illness without being required to engage in expensive or complicated research to identify risks related to foodborne illness. By separating risk assessment from risk management, the conflict of interest that is currently built into the Food Safety Modernization Act can be eliminated, and the responsibilities of ensuring safe food can be allocated more efficiently.

176. *Id.*

177. *Id.* at 14.

178. *Id.* at 17.

V. CONCLUSION

While the Food Safety Modernization Act makes progress toward improving the nation's food safety laws, especially in the area of response to food safety crises, there is still more work to be done. The solution to filling the gaps, however, does not lie in more spending or in giving more regulatory responsibility to over-extended agencies. A more dynamic approach is needed that will better balance responsibility and accountability between agencies and food producers. The Food Safety Modernization Act needs more comprehensive coverage that extends beyond the FDA's jurisdiction, stricter informational requirements, and separation of risk assessment from risk management. Only then will U.S. food safety laws find their way out of *The Jungle* and into a safer future.

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