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## Food Safety and Security: What Tragedy Teaches Us about Our 100-Year-Old Food Laws

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# Food Safety and Security: What Tragedy Teaches Us about Our 100-Year-Old Food Laws

Caroline Smith DeWaal\*

## ABSTRACT

*The United States food safety system is antiquated and failing. The laws that form the foundation of our food protection and govern the United States Department of Agriculture (USDA) and the Food and Drug Administration (FDA) were enacted over 100 years ago.<sup>1</sup> While some new powers were given to FDA with the Bioterrorism Act of 2002, funding has not kept pace.<sup>2</sup> Safe Food International (SFI), a coalition of consumer organizations from around the world, created a set of guidelines outlining an ideal national food safety program.<sup>3</sup> The current system in the United States falls short of that goal. The outbreaks in 2006 and 2007 are simply the latest symptom of our outdated and failing food-safety system.<sup>4</sup> We need to modernize our food laws and create a strong, science-based Food Safety Administration. The Safe Food Act of 2007, introduced by Senator Durbin and Representative DeLauro, requires the development of a single food-safety agency with the power to recall food, inspect foreign food plants, and work to prevent both intentional and unintentional contamination of the U.S. food supply.<sup>5</sup>*

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1. James Harvey Young, *The Long Struggle for the 1906 Law*, FDA CONSUMER, June 1981, available at <http://www.cfsan.fda.gov/~lrd/history2.html>.

2. Public Health Security and Bioterrorism Preparedness and Response (Bioterrorism) Act of 2002, Pub. L. No. 107-188, 116 Stat. 594 (codified in scattered sections of 7, 21, 29, and 42 U.S.C.) (2002).

3. Caroline Smith DeWaal & Gonzalo R. Guerrero Brito, *Safe Food International: A Blueprint for Better Global Food Safety*, 60 FOOD & DRUG L.J. 393, 398-405 (2005).

4. See, e.g., Scott Kilman, *Consumers are Urged to Avoid Bagged Spinach Amid Illnesses*, WALL ST. J., Sept. 15, 2006, at A8.

5. Safe Food Act of 2007, S. 654, H.R. 1148, 110th Cong. (2007).

## TABLE OF CONTENTS

I.	THE FOUNDATION OF FOOD LAW.....	922
A.	<i>The 1906 Laws</i> .....	922
B.	<i>The Need for Food Protection Recognized</i> .....	924
C.	<i>The Formation of Safe Food International</i> .....	925
II.	ONGOING OUTBREAKS UNDER A BROKEN SYSTEM.....	928
III.	GAPING HOLES IN THE FOOD SAFETY NET .....	931
IV.	THE SAFE FOOD ACT: A MODERN SOLUTION .....	933

Americans live in a fast-paced global economy. They snack on raspberries from Guatemala and mangos from the South Pacific, unaware that the safety of these foods is subject to a patchwork of oversight, both here and in foreign countries. In many parts of the world, underfunded food safety agencies do not have the ability to regulate food entering the global market.<sup>6</sup> The same holds true in the United States, where the laws governing food safety were enacted in 1906.

This Article will discuss the gaps in our safety net and the steps needed to address these deficiencies through a reexamination of both the statutory and fiscal underpinnings of the U.S. food safety infrastructure. Building a more effective food safety and security program requires updated food laws implemented by a unified food safety authority and built on a strong foundation of public health and science. This new agency must have strong regulatory and enforcement powers that are sufficient to address both man-made and natural threats to the food supply.

## I. THE FOUNDATION OF FOOD LAW

A. *The 1906 Laws*

The food safety laws of the United States were adopted in 1906 in response to Upton Sinclair's shocking exposé novel, *The Jungle*.<sup>7</sup> Congress enacted the Pure Food and Drug Act and the Federal Meat Inspection Act (FMIA), and they were signed into law by President Theodore Roosevelt.<sup>8</sup> Under FMIA, meat was for the first time

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6. WORD HEALTH ORGANIZATION [WHO], HEALTHY FOOD MARKETS (2006) available at [http://www.who.int/entity/foodsafety/publications/capacity/healthymarket\\_brochure.pdf](http://www.who.int/entity/foodsafety/publications/capacity/healthymarket_brochure.pdf).

7. Young, *supra* note 1.

8. *Id.*

subject to continuous federal inspection by the United States Department of Agriculture (USDA). FMIA ensured meat safety by requiring inspectors to inspect and stamp all meat products with USDA's mark: "Inspected and passed."<sup>9</sup> Poultry products were added to the program in 1957, and subject to the same legal requirement as beef: carcass-by-carcass inspection at slaughter, and continuous inspection of processing plants.<sup>10</sup> The meat and poultry inspection programs today employ over 7,000 inspectors who visit meat plants daily.<sup>11</sup>

The vast majority of foods are subject to much more passive oversight by the Food and Drug Administration (FDA). The Pure Food and Drug Act, also passed in 1906, forbade the marketing of any food containing "any added poisonous or other added deleterious ingredient which may render such article injurious to health."<sup>12</sup> Thus, Congress provided FDA with limited authority to act only when foods were adulterated or misbranded. Today, the FDA is responsible for regulating and inspecting about eighty percent of the U.S. food supply, including many imported foods, using this startlingly weak statutory structure.<sup>13</sup>

Following September 11, 2001, Congress recognized that FDA's programs were inadequate to prevent bioterrorism. Secretary Tommy Thompson from the Department for Health and Human Services told Congress, "Am I satisfied with the [food] inspections we're doing? No, I am more fearful about this than anything else."<sup>14</sup> Following the terrorist attacks of September 11, 2001, Congress recognized the need to increase U.S. regulatory programs to better protect the security of the food supply. Accordingly, it passed the Public Health Security and Bioterrorism Response Act of 2002.<sup>15</sup> While the new law has been beneficial, recent outbreaks of contamination in spinach, lettuce, peanut butter, and pet food

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9. Federal Meat Inspection Act, 21 U.S.C. § 604 (2000).

10. Poultry Products Inspection Act, Pub. L. No. 85-172, 71 Stat. 441 (1957) (codified at 21 U.S.C. §§ 451-71).

11. Backgrounder, Food Safety & Inspection Serv. [FSIS], U.S. Dep't of Agric. [USDA], Protecting the Public from Foodborne Illness: The Food Safety and Inspection Service (Apr. 2001) <http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OA/background/fsisgeneral.htm>.

12. Federal Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768, 770 (repealed 1938).

13. Information Sheet, Food & Drug Administration [FDA], U.S. Dep't of Health & Human Servs., Keeping the Nation's Food Supply Safe: FDA's Big Job Done Well (Feb. 2002), <http://www.fda.gov/opacom/factsheets/justthefacts/2cfsan.pdf>.

14. Julian E. Barnes & Keith Bradsher, *Concerns that U.S. Food Supply is Vulnerable to Terrorist Attacks*, N.Y. TIMES, Oct. 24, 2001, at B9.

15. Bioterrorism Act of 2002, Pub. L. No. 107-188, 116 Stat. 594 (codified in scattered sections of 7, 21, 29, and 42 U.S.C.).

demonstrate that the law has not reduced the threat from natural contaminants in the food supply.<sup>16</sup>

### B. *The Need for Food Protection Recognized*

The Bioterrorism Act gave FDA several significant new food safety authorities, along with \$100 million for improvements in inspection and counterterrorism programs.<sup>17</sup> The agency was given authority to register domestic and foreign food firms, detain suspect food items, and require prior notice on all imported food shipments.<sup>18</sup> In addition, recordkeeping rules allowed FDA to require the “creation and maintenance of records needed to determine the immediate previous sources and immediate subsequent recipients of food,” the so-called “One-up/One-down Rule.”<sup>19</sup> Food companies responded by developing systems to trace food, allowing for easier recall in the event of a bioterrorist threat or foodborne illness outbreak.<sup>20</sup> These new systems improve upon the antiquated system of voluntary food recalls, but the problems are far from solved.

The Bioterrorism Act focused on food security and preventing intentional contamination, but it fails to address basic food safety. *Salmonella*, *E. coli* O157:H7, *Campylobacter*, and many other foodborne hazards regularly show up in the food supply, causing illnesses and deaths.<sup>21</sup> According to the World Health Organization (WHO) report *Terrorist Threats to Food*, “Outbreaks of both unintentional and deliberate foodborne disease can be managed by the same mechanisms. Sensible precautions, coupled with strong surveillance and response capacity, constitute the most efficient and

16. See, e.g., Press Release, FDA, FDA Warns Consumers Not to Eat Certain Jars of Peter Pan Peanut Butter and Great Value Peanut Butter (Feb. 14, 2007), available at <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01563.html>; Press Release, FDA, FDA Warns Consumers Not to Use Wild Kitty Cat Food Due to *Salmonella* Contamination (Feb. 13, 2007), available at <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01562.html>; Press Release, FDA, FDA Issues Advice to Consumers to Reduce Risk of Foodborne Illness from Fresh Produce (Nov. 2, 2006), available at <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01503.html>.

17. Bioterrorism Act of 2002 § 302.

18. *Id.* §§ 303, 305, 307.

19. See CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, WHAT YOU NEED TO KNOW ABOUT ESTABLISHMENT AND MAINTENANCE OF RECORDS (2004), available at <http://www.cfsan.fda.gov/~acrobat/fsbtrec.pdf> (informing U.S. food producers about record-keeping regulations).

20. See, e.g., Andria Cheng, *Food Companies Work to Improve Safety – and Rebuild*, INVESTOR'S BUS. DAILY, Aug. 30, 2007, available at <http://www.investors.com/breakingnews.asp?journalid=58919276> (detailing U.S. food companies' efforts to improve product tracking through technology).

21. CAROLINE SMITH DEWAAL, KENDRA JOHNSON & FARIDA BHUIYA, CTR. FOR SCI. IN THE PUB. INTEREST [CSPI], OUTBREAK ALERT!: CLOSING THE GAPS IN OUR FEDERAL FOOD-SAFETY NET (2006), [http://www.cspinet.org/foodsafety/outbreak\\_alert.pdf](http://www.cspinet.org/foodsafety/outbreak_alert.pdf).

effective way of countering all such emergencies, including food terrorism.”<sup>22</sup> As WHO’s report made clear, food safety and security go hand-in-hand.

### C. *The Formation of Safe Food International*

In June 2005, a coalition of consumer organizations from around the world gathered in Geneva, Switzerland, to develop standardized international guidelines for national food safety infrastructures.<sup>23</sup> Representatives of the WHO, the Food and Agriculture Organization of the United Nations (FAO), and 32 consumer organizations created the Safe Food International (SFI) principles for strong national food-safety programs, which include: (1) Food Laws and Regulations; (2) Food Control Management; (3) Inspection Services; (4) Foodborne Disease Surveillance and Investigation; (5) Recall and Tracking Systems; (6) Food Monitoring Laboratories; (7) Information, Education, Communication, and Training; and (8) Funding and Affordability of the National Food Safety Programs.<sup>24</sup>

Food control management begins with a national food safety authority that manages the entire “farm-to-table” process.<sup>25</sup> In 2003, the FAO, in conjunction with the WHO, released guidelines for national food safety control systems.<sup>26</sup> The paper discussed the benefits of a unified food safety agency, including: “[u]niform application of protection measures; [the] ability to act quickly to protect consumers; [i]mproved cost efficiency and more effective use of resources and expertise; . . . [the] [c]apacity to quickly respond to emerging challenges . . . ; and [t]he provision of more streamlined and efficient services.”<sup>27</sup> One of the major responsibilities of the national food safety authority is the development and use of risk analysis, a three stage process that includes risk assessment, risk management, and risk communication.<sup>28</sup>

Risk assessment should be carried out “openly and transparently,” ensuring adequate communication between scientists

22. FOOD SAFETY DEP’T, WHO, TERRORIST THREATS TO FOOD: GUIDANCE FOR ESTABLISHING AND STRENGTHENING PREVENTION AND RESPONSE SYSTEMS 1 (2002), <http://www.who.int/foodsafety/publications/general/en/terrorist.pdf>.

23. Safe Food Int’l [SFI], *Guidelines for Consumer Organizations to Promote National Food Safety Systems*, at 3 (2005), [http://safefoodinternational.org/guidelines\\_for\\_consumer\\_organizations.pdf](http://safefoodinternational.org/guidelines_for_consumer_organizations.pdf) [hereinafter SFI, *Guidelines*].

24. *Id.*

25. *Id.* at 10.

26. U.N. FOOD & AGRIC. ORG. [FAO] & WHO, ASSURING FOOD SAFETY AND QUALITY: GUIDELINES FOR STRENGTHENING NATIONAL FOOD CONTROL SYSTEMS (2003), available at [http://www.who.int/foodsafety/publications/capacity/en/Englsih\\_Guidelines\\_Food\\_control.pdf](http://www.who.int/foodsafety/publications/capacity/en/Englsih_Guidelines_Food_control.pdf).

27. *Id.* at 15.

28. SFI, *Guidelines*, *supra* note 23, at 7.

and consumer groups.<sup>29</sup> The national food safety authority will also be responsible for setting standards and regulations, participating in international food-control activities, approving new food ingredients and novel technologies, and developing and managing a food safety inspection system.<sup>30</sup>

Modern food laws and regulations, which provide the backbone of a successful food safety program, “should provide a framework for an integrated and coordinated food safety system.”<sup>31</sup> The international guidelines recommend creating national food laws that govern inspection authority, promote the development of preventative programs for foodborne disease, and ensure adequate tracking and recall authority should hazards develop.<sup>32</sup> In addition, as the modern farm-to-fork food chain involves many people and offers many opportunities for contamination, food laws must be actively updated to ensure that each step along the food chain has adequate oversight to prevent foodborne illness resulting from both intentional and unintentional hazards.

The SFI guidelines call for the national food safety agency to manage food inspections and require sampling at many points on the farm-to-table chain.<sup>33</sup> Government inspectors will observe practices on farms, in processing plants, and at all types of retail venues, ensuring that Hazard Analysis and Critical Control Point (HACCP) systems are developed and food production complies with national laws and regulations.<sup>34</sup> According to the WHO’s *Terrorist Threats to Food*, HACCP-like systems, coupled with routine inspection, can greatly reduce the likelihood of both inadvertent and deliberate food contamination.<sup>35</sup> Well-trained inspectors and publicly available inspection reports are the most effective way to ensure the successes or failures of the national food safety system.

SFI’s participants recognized that, although prevention is critical, total elimination of food contamination problems is unlikely; therefore, adequate surveillance, tracking, and recall systems must be in place.<sup>36</sup> Identifying foodborne illness is an important part of this process. According to the WHO, “Effective control of foodborne disease must be based on evaluated information about foodborne hazards and the incidence of foodborne disease.”<sup>37</sup> Food attribution

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29. *Id.*

30. *Id.*

31. *Id.* at 4.

32. *Id.* at 4–5.

33. *Id.* at 9.

34. *Id.*

35. FOOD SAFETY DEP’T, WHO, *supra* note 22, at 14.

36. SFI, *Guidelines*, *supra* note 23, at 6.

37. WHO, WHO GLOBAL STRATEGY FOR FOOD SAFETY: SAFER FOOD FOR BETTER HEALTH 9 (2002), [http://www.who.int/entity/foodsafety/publications/general/en/strategy\\_en.pdf](http://www.who.int/entity/foodsafety/publications/general/en/strategy_en.pdf).

data is critically important to the food safety system. It allows for annual trend analysis of foodborne illness and the identification of potentially hazardous foods.<sup>38</sup> Disease surveillance and investigation systems are also essential to recognize illnesses and disease outbreaks because they allow officials to notify the public more quickly about food contamination.<sup>39</sup>

During an outbreak, recall and tracking systems can be activated to ensure that tainted food is removed from the market. Food recalls can be initiated by the food industry, the national food safety agency, or consumer organizations; however, in order for a recall system to be truly effective, mandatory national food tracking systems must be in place.<sup>40</sup> Tracking systems should include animal identification, labels on produce with the farm and lot number where it originated, and numbers on all packaged food to allow for identification. These tracking and recall systems would allow for the prompt removal of any contaminated or mislabeled food products.

Adequate surveillance and tracking systems depend on a system of government laboratories to monitor the health of their citizens and recognize potential foodborne illnesses.<sup>41</sup> The WHO recommends a laboratory system based on sentinel sites and regional and/or international laboratory networks.<sup>42</sup> Government laboratories with a range of analytical capabilities are essential, as is the establishment of quality assurance criteria.<sup>43</sup> Laboratory analysis is critical for identifying contaminated foods and confirming the safety of domestic food products.<sup>44</sup>

The integrity and effectiveness of food control operations and activities depends on the perception of consumers.<sup>45</sup> Thus, the food safety administration must develop its policies in a transparent manner to ensure consumer confidence.<sup>46</sup> Authorities, industry, and consumers need up-to-date information about foodborne illness and ways to prevent the transmission of foodborne disease. Government authorities and industry experts should also receive training on effective systems to prevent possible food contamination.<sup>47</sup> Consumer education—from media releases to educational programs—is critically important. Information should be presented in a manner

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38. See, e.g., SFI, *Guidelines*, *supra* note 23, at 6 (recommending the use of surveillance systems to collect attribution data).

39. *Id.*

40. SFI, *Guidelines*, *supra* note 23, at 11.

41. See generally FOOD SAFETY DEP'T, WHO, *supra* note 22 (providing guidance to Member States on establishing and strengthening food terrorism detection systems).

42. *Id.* at 24.

43. SFI, *Guidelines*, *supra* note 23, at 12.

44. *Id.*

45. FAO & WHO, *supra* note 26, at 11.

46. *Id.*

47. *Id.*



that informs and educates the public without causing unnecessary fear or alarm.

Finally, SFI promotes full funding for food safety agencies that protect the public while also ensuring that food production systems are still accessible and affordable to small farmers and producers.<sup>48</sup> If agency funding depends on licensing or taxing the food industry, it must be carefully managed.<sup>49</sup> Any costs passed to the food industry will eventually be paid by the consumer, a trickle-down effect that most often affects the poorer sectors of society.<sup>50</sup> Further, funding must not compromise the independence and integrity of the agencies, and “[f]unds must be utilized efficiently to maximize public health protection with accountability to the public.”<sup>51</sup>

## II. ONGOING OUTBREAKS UNDER A BROKEN SYSTEM

Congress worked quickly to enact the Bioterrorism Act of 2002 in an effort to ensure food security. The closing months of 2006, however, demonstrated that many gaps remain in the U.S. food-safety net. In August and September 2006, an outbreak of *E. coli* O157:H7 sickened 204 people in 26 states, killing at least three.<sup>52</sup> FDA warned consumers not to eat fresh, bagged spinach, which was the source of this devastating outbreak.<sup>53</sup> Another produce outbreak occurred later that fall, when *Salmonella* in tomatoes sickened restaurant patrons across the country.<sup>54</sup> This time 183 people fell ill in 21 states.<sup>55</sup> *E. coli* O157:H7 appeared in produce again before the year’s end, when shredded lettuce at Taco Bell<sup>56</sup> and Taco John’s<sup>57</sup> restaurants sickened 152 individuals.

These outbreaks dominated the news, raising consumer fears about whether it was safe to eat fresh produce. The media and angry

48. SFI, *Guidelines*, *supra* note 23, at 14.

49. FAO & WHO, *supra* note 26, at 16.

50. *Id.*

51. SFI, *Guidelines*, *supra* note 23, at 14.

52. *Wild Pigs Eyed as Source of Deadly Bacteria that Contaminated Spinach with E. coli*, INT’L HERALD TRIB., Oct. 26, 2006.

53. Press Release, FDA, FDA Statement on Foodborne *E. coli* O157:H7 Outbreak in Spinach (Sept. 15, 2006), available at <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01451.html>.

54. Press Release, FDA, FDA Notifies Consumers that Tomatoes in Restaurants Linked to *Salmonella* Tiphimurium Outbreak (Nov. 3, 2006), available at <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01504.html>.

55. *Id.*

56. Press Release, Centers for Disease Control and Prevention [CDC], Multistate Outbreak of *E. coli* O157 Infections, November-December 2006 (Dec. 14, 2006), available at <http://www.cdc.gov/ecoli/2006/december/121406.htm>.

57. Press Release, FDA, FDA and States Closer to Identifying Source of *E. coli* Contamination Associated with Illnesses at Taco John’s Restaurants (Jan. 12, 2007), available at <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01546.html>.

consumers repeatedly raised questions regarding who bore responsibility, both for the outbreak and for its resulting confusion.<sup>58</sup> The farmers who grew the affected produce were accused, as were nearby cattle ranchers.<sup>59</sup> Several federal agencies came under fire for a chaotic response: the Centers for Disease Control and Prevention (CDC), which investigate outbreaks; the Food and Drug Administration, which nominally regulates produce; the Environmental Protection Agency (EPA), which monitors water quality and other environment conditions; and the USDA, which has responsibility for animal health.<sup>60</sup> In testimony before the United States House of Representatives, former FDA Commissioner David Kessler stated, "Currently, FDA has no mandate for leadership on prevention of food safety problems, no funding to do important research to find ways to prevent food-bourne illness . . ." <sup>61</sup>

The Center for Science in the Public Interest (CSPI) tracks foodborne disease with its database, *Outbreak Alert!*, and publishes yearly reports on outbreak trends.<sup>62</sup> There has been a marked increase in the number of produce outbreaks reported since the late 1990s, due in part to better surveillance and reporting by state health departments and the CDC.<sup>63</sup> Produce has surpassed all other food categories as a cause of illness, including beef, poultry, and seafood.<sup>64</sup> Produce outbreaks have an average number of 49 victims, compared with 30 for poultry outbreaks and 10 for seafood outbreaks.<sup>65</sup> Americans are also eating more fresh produce than ever before. While nutritionists want to encourage this trend towards healthy eating, outbreaks are depressing consumer confidence in fresh produce.<sup>66</sup> Dr. David Acheson, FDA's First Assistant Commissioner

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58. See, e.g., Marion Burros, *Growing Peril on Path From Field to Plate*, N.Y. TIMES, Dec. 7, 2006, at B8; John Schmeltzer, *Food-safety Fears Revived as Taco Bell Pulls Onions*, CHI. TRIB., Dec. 7, 2006, at 1.

59. See, e.g., Brandon Bailey, *Unnamed Ranch Scoured for E. Coli Clues*, MERCURY NEWS, Oct. 14, 2006, at B1.

60. BENJAMIN ONYANGO ET AL., FOOD RECALLS AND FOOD SAFETY PERCEPTIONS: THE SEPTEMBER 2006 SPINACH RECALL CASE (2007), available at <http://ageconsearch.umn.edu/bitstream/123456789/26885/1/sp07on01.pdf> (reporting that food outbreaks have shaken consumer trust in food regulatory agencies).

61. *FDA's Critical Mission and Challenges for the Future: Before the H. Comm. on Oversight and Government Reform*, 110th Cong. 4 (2007) (statement of Dr. David Kessler, Dean, University of California, San Francisco, School of Medicine), available at <http://oversight.house.gov/documents/20070501193354.pdf>.

62. DEWAAL ET AL., *supra* note 21.

63. *Id.*

64. *Id.*

65. *Id.*

66. See, e.g., CARA CUI TE ET AL., FOOD POLICY INST., RUTGERS UNIV., PUBLIC RESPONSE TO THE CONTAMINATED SPINACH RECALL OF 2006 (Feb. 5, 2007), available at [http://www.foodpolicyinstitute.org/docs/reports/FPI\\_Spinach\\_Recall\\_Report.pdf](http://www.foodpolicyinstitute.org/docs/reports/FPI_Spinach_Recall_Report.pdf) (finding that the spinach contamination incidents have likely amplified consumer concerns about eating fresh produce that typically was viewed as healthy before the incidents).

for Food Protection and former director of FDA's Office of Food Defense, said he would not be surprised if there were future outbreaks involving produce: "Why should 2007 be any different, unless some changes are made? I hope not, but I'm a pragmatist."<sup>67</sup>

These outbreaks demonstrate the importance of rapid investigations and the quick release of information to consumers to lessen public health impacts. After spinach was identified as the vehicle in the August/September *E. coli* outbreak, the FDA promptly issued a public notice to avoid spinach and continually updated their information as more specifics became available.<sup>68</sup> One month after the FDA received notice of the outbreak, it traced the exact strain of *E. coli* bacteria causing the outbreak to the farm where the spinach was grown, and found the bacteria in nearby manure piles, a creek, and even a wild pig.<sup>69</sup> These findings definitively proved that the *E. coli* contamination originated on the farm.

Despite these successes, the spinach outbreak revealed the Achilles heel of the U.S. food safety system: a lack of resources to prevent outbreaks from occurring. William Hubbard, retired FDA Associate Commissioner, said, "The agency was currently so stretched that they can do little more than react to outbreaks, rather than try to prevent them."<sup>70</sup> Budget cuts have left the agency with fewer inspectors, yet the agency's workload continues to increase.<sup>71</sup> The produce outbreaks are just the latest symptom of an agency overwhelmed by responsibility but without the staff or resources to function effectively.

FDA's food program has a current funding shortfall of \$135 million, which an FDA budget official described as equivalent to a twenty-four percent budget cut.<sup>72</sup> This lack of funding has led to fewer inspections.<sup>73</sup> Since 2003, the number of FDA field staff dropped by twelve percent. Between 2003 and 2006, there was a thirty-two percent drop in federal inspections.<sup>74</sup> In fact, since 1972 inspections conducted by the FDA have declined by eighty-one percent.<sup>75</sup> In addition, funding shortfalls do not allow the FDA to

67. Dania Akkad, *Produce Still at Risk, FDA Official Says; Trade Groups Defend New Policies After E. coli Outbreak*, MONTEREY COUNTY HERALD, Mar. 21, 2007.

68. CUIE ET AL., *supra* note 66.

69. *Id.*

70. Andrew Martin, *Stronger Rules and More Oversight for Produce Likely After Outbreaks of E. coli*, N.Y. TIMES, Dec. 11, 2006, at A20.

71. Rep. Henry A. Waxman, *Fact Sheet: Weaknesses in FDA's Food Safety System*, Oct. 30, 2006, <http://oversight.house.gov/Documents/20061101115143-67937.pdf>.

72. *Id.*

73. *Id.*

74. *Id.*

75. *Id.*

explore new food safety technologies and leave the United States at a competitive disadvantage compared to other developed countries.<sup>76</sup>

The Bioterrorism Act of 2002 purportedly increased funding for the FDA to protect the nation from bioterrorism. In recent years, however, this funding has dissipated, so that the current number of inspectors has dropped below 2002 numbers.<sup>77</sup> Bioterrorism funding is no better at the state level. While the federal government gave state programs almost a billion dollars for the purpose of counterterrorism, food safety, and food security, less than 0.5% was earmarked for food safety at the manufacturing, processing, distribution, storage, and retail levels.<sup>78</sup>

### III. GAPING HOLES IN THE FOOD SAFETY NET

Following September 11, 2001, security at U.S. airports was centralized under the Department of Homeland Security.<sup>79</sup> Notably, however, the most frequent traveler across U.S. borders—imported food—is still under the supervision of a bifurcated federal system of food regulation.<sup>80</sup> According to the National Academy of Sciences, “[a]t least a dozen federal agencies implementing more than 35 statutes make up the federal part of the food safety system.”<sup>81</sup> Furthermore, states play a huge role in conducting food plant inspections for the FDA.<sup>82</sup> Though this fragmented network may play to the different needs of disparate agencies and industries, the recent outbreaks from both imported and domestic food demonstrate that such loosely connected departments can leave consumers unprotected.

The USDA inspects meat and poultry products as well as certain processed egg products.<sup>83</sup> In addition, the USDA has responsibility for marketing meat overseas, ensuring the protection of plants and animals from disease, and acting as an advocate for agricultural

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76. *Id.*

77. BIOTERRORISM REGULATIONS: RECORDS MAINTENANCE AND INSPECTION OF RECORDS FOR FOOD, <http://cspinet.org/new/pdf/bioterrorismfactsheets.pdf> (last visited Sept. 11, 2007); Waxman, *supra* note 71.

78. Press Release, Nat'l Ass'n of State Departments of Agric. [NASDA], NASDA Urges More Funding for Food Safety and Security (June 17, 2003), [http://www.nasda.org/nasda/nasda/News\\_Publications/06-17-2003.html](http://www.nasda.org/nasda/nasda/News_Publications/06-17-2003.html).

79. *Id.*

80. INSTITUTE OF MEDICINE, NATIONAL RESEARCH COUNCIL, ENSURING SAFE FOOD: FROM PRODUCTION TO CONSUMPTION 84 (National Academy Press 1998).

81. *Id.* at 26.

82. Waxman, *supra* note 71.

83. About FSIS: Structure and Organization, [http://www.fsis.usda.gov/about\\_fsis/index.asp](http://www.fsis.usda.gov/about_fsis/index.asp) (last visited Sept. 10, 2007).

interests in the U.S. Congress.<sup>84</sup> Thus, USDA shares two often-conflicting missions when it comes to food: safety and promotion.

The FDA is charged with protecting the safety of all foods not regulated by USDA.<sup>85</sup> The agency regulates about eighty percent of the nation's food supply, including such high-risk products as seafood, fruits, vegetables, and dairy products.<sup>86</sup> Although the foods that FDA regulates are responsible for two-thirds of all foodborne illness outbreaks, the agency receives only one third of the total federal food budget, with the other two thirds going to USDA for the inspection of meat and poultry products.<sup>87</sup> Hence, FDA-regulated foods—both domestic and imported—receive much less oversight and inspection than USDA-regulated foods.

The CDC, housed within the Department of Health and Human Services, is yet another public health agency in the U.S. food safety system. CDC works with states and local health departments to track and manage food borne illness outbreaks.<sup>88</sup> In addition, it coordinates FoodNet, a system for tracking foodborne diseases, and PulseNet, a system for genetic fingerprinting of isolates of disease agents, that has revolutionized CDC's ability to identify multi-state outbreaks.<sup>89</sup> CDC is the first federal agency that is informed of an outbreak when one exists, but it must identify a food source before the regulatory agency responsible for that food can be identified.<sup>90</sup>

Other agencies working to ensure safety in the food supply include the Environmental Protection Agency (EPA), the National Marine Fisheries Service (NOAA), and many others.<sup>91</sup> The multitude of federal food safety agencies, disparate policies, inadequate resources, and ongoing issues with both domestic and imported foods can create problems when hazards—both intentional and unintentional—arise in the food supply.

84. About USDA: Mission Statement, [http://www.usda.gov/wps/portal/!ut/p/\\_s.7\\_0\\_A/7\\_0\\_1OB?navtype=MA&navid=ABOUT\\_USDA](http://www.usda.gov/wps/portal/!ut/p/_s.7_0_A/7_0_1OB?navtype=MA&navid=ABOUT_USDA) (follow "Mission Statement" hyperlink) (last visited Sept. 10, 2007).

85. History of the FDA, <http://www.fda.gov/oc/history/historyoffda/default.htm> (last visited Sept. 10, 2007).

86. H. Comm. on Energy and Commerce, H.R. 3075, "Imported Food Safety Act of 2001": Fact Sheet, <http://energycommerce.house.gov/foodsafety/107foodfacts.shtml> (last visited Sept. 11, 2007).

87. *Id.*

88. CDC, Foodborne Illness: Frequently Asked Questions (Jan. 10, 2005), [http://www.cdc.gov/ncidod/dbmd/diseaseinfo/files/foodborne\\_illness\\_FAQ.pdf](http://www.cdc.gov/ncidod/dbmd/diseaseinfo/files/foodborne_illness_FAQ.pdf).

89. *Id.*

90. *Id.*

91. Fact Sheet, U.S. Env'tl. Prot. Agency [EPA], The EPA and Food Security, <http://www.epa.gov/pesticides/factsheets/securty.htm> (last visited Sept. 17, 2007); Nat'l Oceanic & Atmospheric Admin. [NOAA], Fisheries, <http://www.noaa.gov/fisheries.html> (last visited Sept. 17, 2007).

## IV. THE SAFE FOOD ACT: A MODERN SOLUTION

In a post-September 11 world, with risks of bioterrorism and ongoing natural hazards such as *E. coli* O157:H7, the U.S. food safety system has become an issue of national security. The existing regulatory framework is simply insufficient to handle these challenges. The Safe Food Act was introduced on February 15, 2007, by Senator Richard Durbin (D-IL) and Representative Rosa DeLauro (D-CT) as a solution to the myriad problems in the food security system.<sup>92</sup> The Act would streamline food safety at the federal level by consolidating the FDA, USDA, Center for Veterinary Medicine (CVM), EPA, and several other key food agencies to create a unified, science-based Food Safety Administration.<sup>93</sup>

In addition, the Safe Food Act would create a system of risk-based inspection, "determined by the type of food handled and the type of processing to which the food is subjected."<sup>94</sup> Food establishments would receive a rating of between one and five, based on public health considerations and strong scientific evidence, to determine the frequency and timing of inspections.<sup>95</sup> The risk-based inspection program would continue the carcass-by-carcass inspections at slaughterhouses and perform daily inspections of high-risk products.<sup>96</sup> All facilities would be inspected at least annually, with many inspected much more often.<sup>97</sup> This system of risk-based inspection would allow for the best use of department resources, while still providing safety checks along the entire farm-to-fork continuum.

Inspections are an important part of the process to prevent foodborne illness, but the best way to protect Americans is to prevent contamination. The Safe Food Act calls for the implementation of science-based process controls to ensure that food contamination is minimized throughout the production process.<sup>98</sup> The bill would require all food establishments to implement appropriate measures to control and reduce the levels of harmful contaminants in food and to meet performance standards for harmful pathogens.<sup>99</sup> The bill builds upon existing HACCP programs—a prevention-based food safety system—but would not limit the agency administrator to rely solely on this program.<sup>100</sup> The Safe Food Act authorizes the promulgation

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92. Safe Food Act of 2007, S. 654, H.R. 1148, 110th Cong. (2007).

93. *Id.*

94. Rep. Rosa DeLauro, Summary, The Safe Food Act of 2005, H.R. 1507, [http://www.house.gov/delauro/safe\\_food\\_act\\_109.html](http://www.house.gov/delauro/safe_food_act_109.html) (last visited Sept. 10, 2007).

95. Safe Food Act of 2007 § 202(b).

96. *Id.* § 205.

97. *Id.*

98. DeLauro, *supra* note 94.

99. *Id.*

100. *Id.*

of regulations to address the development of preventative processing controls, sanitation standards, performance standards for contaminants, adequate recordkeeping to monitor compliance, and a sampling program to ensure that the process controls are effective.<sup>101</sup>

Imported food consumption in the United States continues to rise exponentially, and the Safe Food Act recognizes and addresses this important component of the food supply.<sup>102</sup> Due to limited resources, the FDA currently inspects only about one percent of food entering the United States and does little to evaluate foreign food safety systems or inspect foreign plants.<sup>103</sup> The Safe Food Act gives the Food Safety Administration the authority to evaluate and certify another country's food safety program to ensure that it is "at least equivalent to standards applicable to food produced in the United States."<sup>104</sup> The Administration would have the authority to audit the certified countries and would ensure continued compliance at least every five years.<sup>105</sup> The proposed law also requires routine inspections of foreign food imports to ensure that the food is safe and properly labeled.<sup>106</sup> Under the Safe Food Act, foods would no longer have an "open visa" to enter the United States without inspection or regulation.

Preventing all threats to the food supply—both intentional and accidental—is unlikely, so the Act gives the Food Safety Authority sufficient tools to respond in an emergency. According to the WHO, "[t]racing systems and market recalls are thus critical in responding to food contamination, whether deliberate or inadvertent."<sup>107</sup> Today, however, both USDA and the FDA rely on voluntary company tracking and recall systems.<sup>108</sup>

The Safe Food Act further mandates the establishment of a national system for "tracing food and food producing animals from point of origin to retail sale."<sup>109</sup> The Act would allow companies to issue voluntary recalls should their product be deemed unsafe, but also grants authority for the Food Safety Administration to issue a

101. Safe Food Act of 2007, S. 654, H.R. 1148.

102. ALBERTO JERARDO, U.S. DEP'T. OF AGRIC. [USDA], THE IMPORT SHARE OF U.S.-CONSUMED FOOD CONTINUES TO RISE (2002), [http://usda.mannlib.cornell.edu/usda/ers/FAU/2000s/2002/FAU-07-03-2002\\_Special\\_Report.pdf](http://usda.mannlib.cornell.edu/usda/ers/FAU/2000s/2002/FAU-07-03-2002_Special_Report.pdf).

103. *Food Safety: Overview of Food Safety and Inspection Service and Food and Drug Administration Expenditures: Hearing Before the S. Comm. on Agric., Nutrition, and Forestry*, 106th Cong. 3 (2000) (statement of Lawrence J. Dyckman, Director, Food and Agriculture Resources, Community, and Economic Development Division), available at <http://www.gao.gov/archive/2000/rc00300t.pdf>.

104. Safe Food Act of 2007 § 208.

105. *Id.*

106. *Id.*

107. FOOD SAFETY DEP'T, WHO, *supra* note 22, at 16.

108. Caroline Smith DeWaal, *Rising Imports, Bioterrorism, and the Food Supply*, 59 FOOD & DRUG L.J. 433, 437 (2004).

109. Safe Food Act of 2007 § 210.

mandatory recall if the company fails to do so.<sup>110</sup> This will ensure quick removal of contaminated products from the market and increase consumer confidence in the food supply.

Understanding of foodborne illness is constantly evolving, and the Safe Food Act recognizes the importance of outbreak investigations and scientific research to improve the safety of the food supply. The legislation requires the CDC and state health departments to share outbreak investigation information with the Food Safety Administration.<sup>111</sup> The bill also gives the Food Safety Administration the responsibility to maintain an “epidemiological system dedicated to food-borne illness identification, outbreaks, and containment.”<sup>112</sup> Detailed food attribution data is critical for risk assessments and also for the identification of emerging foodborne pathogens that could pose a risk to the public.

The Safe Food Act creates a single food agency with the necessary authority to fulfill its mission to ensure safe food on U.S. tables. The Administration can detain imported food and recall tainted food from the market.<sup>113</sup> It provides the necessary authority to penalize persons or organizations for violating food safety laws, allowing both civil and criminal penalties, and also provides whistleblower protection for individuals who disclose food safety violations.<sup>114</sup>

The Safe Food Act works to prevent foodborne illness and bioterrorism without grand schemes or an inflated budget. Instead, it ensures a strong national program, outbreak surveillance, and effective, honest public communication. The food industry remains the first line of defense, but the Act recognizes that effective industry programs require government monitoring and oversight.

U.S. food safety laws are more than a century old and were not designed to deal with modern issues such as bioterrorism, antibiotic resistance, or mad cow disease. The September 11, 2001 terrorist attacks demonstrated the need for enhanced national security, and the recent outbreaks serve as a reminder that much more must be done to protect the food supply. Safe Food International created guidelines for the development of a strong national food safety system. The Safe Food Act draws from these recommendations and creates a program that puts public health at the forefront of food safety in America.

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110. DeLauro, *supra* note 94.

111. Safe Food Act of 2007 § 301.

112. *Id.* § 301(a)(4).

113. *Id.* §§ 402–403.

114. DeLauro, *supra* note 94.



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