

# FOOD-BORNE ILLNESSES STRIKE U.S. FOOD SUPPLY:

## A DISCUSSION OF INADEQUATE SAFETY PROCEDURES AND REGULATIONS IN THE U.S. AND ABROAD

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### INTRODUCTION

Globalization of the food trade industry has led to substantial increases in the number of food products traveling across the United States' borders.<sup>1</sup> This increase can be attributed to recent public information campaigns encouraging Americans to consume more fruits and vegetables.<sup>2</sup> Americans are now eating more fresh produce than ever before and desire its availability year round.<sup>3</sup> In certain seasons, over 75% of fresh produce in the U.S. market is imported.<sup>4</sup> The heightened demand for these products has led to an increase in the number of shipments the United States receives from countries with lenient sanitary standards.<sup>5</sup> Additionally, globalization of the food trade allows American food manufacturers to acquire products from less developed countries at lower prices.<sup>6</sup> Specifically, in 2002, 23.3% of fresh fruit and vegetables consumed by Americans were imported.<sup>7</sup> As a result, the United States' food supply has become particularly vulnerable to contamination as these food products travel from their countries of origin to U.S. food processing centers.<sup>8</sup>

The Center for Disease Control ("CDC") estimates that food-borne

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1. F. K. Käferstein, *Foodborne Disease Control: A Transnational Challenge*, 3 EMERGING INFECTIOUS DISEASES No. 4, at para. 15 (Oct.-Dec. 1997), available at <http://www.cdc.gov/ncidod/eid/vol3no4/kaferste.htm>.

2. *Id.*

3. Marian Burros, *Produce Becoming Increasing Source For Food Illnesses*, N.Y. TIMES, Nov. 23, 2003, at para. 4 available at <http://query.nytimes.com/gst/fullpage.html?res=9A04E1D6133BF930A15752C1A9659C8B63&scp=1&sq=produce+becoming+increasing+source+for&st=nyt>.

4. Käferstein, *supra* note 1, at para. 15.

5. Burros, *supra* note 3, at para. 4.

6. Alexei Barrionuevo, *Food Imports Often Escape Scrutiny*, N.Y. TIMES, May 1, 2007, at para. 7, available at <http://www.nytimes.com/2007/05/01/business/01food.html?res=1&scp=1&sq=Food+imports+escape+scrutiny&st=nyt>.

7. Burros, *supra* note 3, at para. 18.

8. Eric M. Goldstein, *Infecting the Hands that Feed Us: Requiring U.S. Quality For All Imported Foods*, 7 WASH. U. GLOBAL STUD. L.R. 137, 138 (2008).

illnesses of all types sicken 76 million Americans and cause 5,000 deaths annually.<sup>9</sup> While in the public's eye, food-borne illness outbreaks are generally linked to meat and seafood products, recent contamination problems have been connected to a variety of food sources that are not typically perceived as high risk.<sup>10</sup> In fact, Americans are now more likely to get sick from eating contaminated produce than from any other food source.<sup>11</sup> Of the 3,000 outbreaks that occurred between 1990 and 2003, contaminated produce was the source of the greatest number of individual illnesses, more incidents than those linked to eggs and beef combined.<sup>12</sup> Over this short period of time, the Center for Science in the Public Interest ("CSPI") found that fresh produce was linked to 428 outbreaks resulting in 23,857 illnesses.<sup>13</sup> The CSPI further stated that this data represents only the tip of the iceberg because food poisoning is vastly under-reported.<sup>14</sup>

The manner in which produce is consumed has contributed to the large number of outbreaks associated with fruits and vegetables, and is one of the difficulties of tackling contamination problems involving produce. Unlike meat, fresh produce is particularly susceptible to contamination because produce is often consumed raw.<sup>15</sup> This presents a unique food safety challenge because there is no cooking or "kill step" to rid the produce of bacteria.<sup>16</sup> In addition, consumers may fail to take additional steps such as washing the fruits and vegetables to eliminate pathogens.<sup>17</sup> The manner in which produce is often consumed is likely to have contributed to the large number of outbreaks associated with fruits and vegetables and presents one of the difficulties of tackling contamination problems involving produce.

As a result of the recent outbreaks of food-borne illnesses, the American public has become increasingly concerned with food safety.<sup>18</sup>

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9. Press Release, Ctr. For Sci. in the Pub. Interest, Contaminated Produce Top Food Poisoning Culprit (Apr. 1, 2004) [hereinafter CSPI] (on file with CSPI Newsroom).

10. Matthew Kohnke, *Reeling in a Rogue Industry: Lethal E. Coli in California's Leafy Green Produce & the Regulatory Response*, 12 DRAKE J. AGRIC. L. 493, 498 (2007).

11. CSPI, *supra* note 9.

12. Kohnke, *supra* note 10, at 498-99 (citing Daniel Akst, *Big Farms Will Keep Spinach on the Table*, N.Y. TIMES, Oct. 15, 2006, available at <http://www.nytimes.com/2006/10/15/business/yourmoney/15cont.html>).

13. CSPI, *supra* note 9.

14. *Id.* at 2.

15. Kohnke, *supra* note 10, at 500 (citing Marian Burros, *E. Coli Fears Inspire a Call for Oversight*, N.Y. TIMES, Dec. 9, 2006, at B1, available at <http://www.nytimes.com/2006/12/09/nyregion/09produce.html>).

16. Anny Shin, *Outbreaks Reveal Food Safety Net's Holes*, WASH. POST, Dec. 11, 2006, at A01, available at <http://www.washingtonpost.com/wp-dyn/content/article/2006/12/10/AR2006121000903.html>.

17. Kohnke, *supra* note 10, at 500 (citing Robert E. Brackett, Dir., Ctr. For Food Safety & Applied Nutrition, Statement to the Committee on Health, Education, Labor and Pensions (Nov. 15, 2006), available at <http://www.fda.gov/NewsEvents/Testimony/ucml10926.htm>).

18. Kohnke, *supra* note 10, at 499.

According to recent surveys performed by the Food Marketing Institution, consumer confidence in the safety of food purchased in stores and restaurants has declined by 16%, and furthermore, 61% of consumers were concerned about food products imported from the country of Mexico.<sup>19</sup> These concerns are not surprising based on the number of serious outbreaks of food-borne illnesses that have occurred over the past twelve years. In 2003, contaminated green onions from Mexico served in a Pennsylvania restaurant sickened over 555 people and caused three deaths.<sup>20</sup> Preliminary investigations by the Food and Drug Administration (“FDA”) indicated that the contamination occurred because the green onions were grown under conditions that allowed the crops to be exposed to human waste.<sup>21</sup> From 2000 to 2002, three multi-state Salmonella outbreaks linked to Mexican-grown cantaloupe were identified.<sup>22</sup> The FDA determined that there were several possible sources of this contamination problem, including “sewage-contaminated irrigation water; processing (cleaning and cooling) with Salmonella-contaminated water; poor hygienic practices of handlers; pests in packing facilities; and inadequate cleaning and sanitizing of equipment that came in contact with the cantaloupe.”<sup>23</sup> Another incident occurred in the spring and summer of 1996, when Guatemalan raspberries contaminated with *Cyclospora* resulted in more than 1,465 illnesses.<sup>24</sup> After researching the distribution system for the raspberries, the CDC concluded that the contamination most likely occurred at the farming stage.<sup>25</sup>

The most recent major contamination incident occurred in the summer of 2008, when jalapeno and serrano peppers grown on farms in Mexico caused an outbreak of Salmonella that caused two deaths and sickened 1,442 people between April and August.<sup>26</sup> This outbreak was the largest reported incident of food-borne illnesses in the past ten years.<sup>27</sup> The CDC stated that the cause of this outbreak was the use of contaminated water to irrigate a batch of the peppers.<sup>28</sup> Both the CDC and the FDA

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19. Press Release, Center For Science In The Public Interest, Crisis and Consensus: Modernizing U.S. Food Safety Law (Sept. 25, 2007) (on file with House Committee on Appropriations).

20. *Id.*

21. *Id.*

22. *Id.*

23. *Id.*

24. Linda Calvin, *Response to U.S. Foodborne Illness Outbreaks Associated with Imported Produce*, in INTERNATIONAL TRADE AND FOOD SAFETY: ECONOMIC THEORY AND CASE STUDY 74, 80 (Jean C. Buzby ed., 2003), available at <http://www.ers.usda.gov/publications/aer828/aer828g.pdf>.

25. *Id.*

26. Amanda Gardner, *FDA Faulted for Lack of Produce Oversight*, WASH. POST, Sept. 29, 2008, at para. 5, available at <http://www.washingtonpost.com/wp-dyn/content/article/2008/09/26/AR2008092602505.html>.

27. *Id.*

28. Mike King, *Sick Food-Safety System*, THE ATLANTA J. CONST., Aug. 1, 2008, at para 2, available at <http://www.ajc.com/opinion/content/opinion/stories/2008/08/01/fdaed.html>.

advised consumers to avoid consuming raw peppers from Mexico.<sup>29</sup> The issuance of this warning was delayed because food safety officials incorrectly targeted the tomato industry as the source of the outbreak.<sup>30</sup> Industry representatives stated that the erroneous warnings prompted tomato growers to plow crops and destroy millions of tons of produce ready for sale.<sup>31</sup> In a congressional hearing, the representatives testified that the industry lost 300 million dollars because of the misidentification.<sup>32</sup> This outbreak represents a failed test of the U.S. food safety system.<sup>33</sup> In July, people were still consuming contaminated peppers even though some health departments had evidence that the crop was the true source of the outbreak, and tomatoes were still being destroyed because of the erroneous warnings.<sup>34</sup> The mishandling of this outbreak and the economic losses associated with the CDC's misidentification of the contamination's source illustrate the seriousness of food contamination issues and the need for a food safety system that will prevent contamination and limit the scope of damages if an outbreak occurs.

The purpose of this Note is twofold. The first initiative is to raise awareness of the susceptibility of the United States' food supply to contamination from imported produce. These contaminations result from poor agricultural practices, relaxed regulations in foreign nations, and the diminishing capabilities of U.S. regulating agencies. Secondly, this Note illustrates how the failures of our current food safety system can be remedied through the adoption of stricter food safety procedures by foreign nations and the enactment of domestic legislation to increase the capabilities of regulatory agencies by requiring stricter standards for food safety. Part I of this Note will outline the foundation of our food safety system and the respective jurisdictions of the regulating agencies. This part will also examine how imported fruits and vegetables are handled upon their entry into the United States and the protocols followed by each agency. It particularly focuses on the differences between the two government agencies that regulate food products, the Food Safety and Inspection Service ("FSIS") and the FDA, based on their jurisdiction, level of authority, and standard safety procedures. This analysis will illustrate the inability of the FDA to regulate fresh produce because of the agency's limited budget, limited personnel, and lack of statutory authority to fully enforce U.S. safety standards and procedures upon foreign nations.<sup>35</sup>

Part II of this Note will analyze the 2002 bioterrorism bill that was enacted after September 11, 2001, to strengthen the United States' safety

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29. *Id.*

30. *Id.* at para. 3.

31. *Id.*

32. *Id.*

33. *Id.* at para. 9.

34. *Id.*

35. *See generally* Goldstein, *supra* note 8, at 147-49.

regulations and protect the nation's food supply from a bioterrorism attack.<sup>36</sup> This part will discuss the purpose of the bill, which contained provisions that would have required more stringent inspection and record-keeping procedures, and the actual effect of the passed legislation, which was watered down by the Bush Administration.<sup>37</sup> Part II will also examine the influence of the food industry's resistance to changes in the regulations regarding safety procedures and enforcement tools.<sup>38</sup>

Part III of this Note will discuss the agricultural practices and regulations that are followed in foreign nations from which the United States receives its produce. In particular, Part III will focus on the food safety procedures that were adopted in Guatemala to overcome the multiple outbreaks of *Cyclospora* that plagued the country's raspberry crop.<sup>39</sup> This part will discuss the success of Guatemala's new regulations and the potential for other nations to implement similar food safety programs.

Part IV of this Note will discuss the repercussions of contamination problems that have resulted in a growing number of outbreaks linked to imported fresh produce. In particular, this part will focus on the economic losses that are suffered by the industry of the contaminated product or an industry that has been identified as a possible source of the outbreak.<sup>40</sup> The main concern addressed in this part is the detrimental results of the food safety system's lack of an efficient trace-back system that prevents the source of an outbreak from being quickly identified and removed from the market.<sup>41</sup> This shortcoming exacerbates the damage that these outbreaks can cause, including continued consumption of unidentified contaminated products and severe economic losses due to false reports of product contamination.<sup>42</sup>

Part V of this Note will present several recommendations for preventing the contamination of produce, quickly managing any contamination problems that do occur, and creating and enforcing legislation that would require the implementation of stricter controls on the global food safety system. The first of these recommendations entails strengthening the capabilities of the FDA by increasing funding for the agency and enacting legislation that would give the agency "equivalency

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36. Press Release, Chris Richard, Voice of Am., U.S. Food Indus. Gears Up for Tougher Inspections in Fight Against Terror (Nov. 26, 2003) (on file with Voice of America), available at <http://www1.voanews.com/english/news/a-13-a-2003-11-26-12-US.html>.

37. *Id.*

38. See Robert Pear, *Food Industry's Resistance Stalls Bill to Protect Food*, N.Y. TIMES A22, Apr. 16, 2002, available at <http://query.nytimes.com/gst/fullpage.html?res=9A03E1DA113CF935A25757C0A9649C8B63&scp=1&sq=Food+Industry%27s+Resistanc e+Stalls&st=nyt>.

39. Calvin, *supra* note 24, at 80.

40. See King, *supra* note 28, at para. 3; Calvin, *supra* note 25, at 81-82.

41. See King, *supra* note 28, at para. 6-9.

42. *Id.*, *supra* note 28.

authority” to enforce the United States’ safety standards on foreign nations.<sup>43</sup> This section will also explain the need for a reliable trace-back system that would allow the source of an outbreak to be quickly identified and removed from the market, while allowing erroneously targeted items to be eliminated as a suspects.<sup>44</sup> The second recommendation is directed at foreign nations who export food products to the United States, requiring these countries to improve their agricultural practices to ensure that the produce grown is safe for consumption.<sup>45</sup> Finally, this Note recommends that these changes be implemented during the Obama Administration through federal legislation modeled after the Government Accountability Office’s (“GAO”) food safety recommendations discussed in its report released on June 12, 2008, and the Safe Food Act, which was proposed at the committee level of Congress in 2007.<sup>46</sup>

#### PART I: AN EXPLANATION OF THE UNITED STATES’ FOOD SAFETY SYSTEM AND ITS TWO REGULATING AGENCIES

The FSIS and the FDA work side by side to ensure the safety of the United States’ food supply, but can hardly be considered equal partners in accomplishing this task. The FDA has been denied the resources and authority delegated to the FSIS and consequently does not have the capability to protect consumers from contaminated food.<sup>47</sup> This disparity makes the FDA unable to sufficiently monitor the food supply and is partially to blame for recent outbreaks in the United States associated with contaminated food products.<sup>48</sup>

##### A. *FSIS and the FDA*

The responsibility of ensuring the safety of the United States’ food supply is delegated to two government agencies: the FSIS, which operates under the U.S. Department of Agriculture (“USDA”), and the FDA.<sup>49</sup> The FSIS provides regulations for meat, poultry, and some egg products, while the FDA has jurisdiction over all other food sources.<sup>50</sup> As a result, the FDA

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43. Press Release, U.S. Gov’t Accountability Office, Federal Oversight of Food Safety: FDA Has Provided Few Details on the Resource and Strategies Needed to Implement its Food Protection Plan (June 12, 2006) [hereinafter GAO] (on file with author); Goldstein, *supra* note 8, at 141.

44. King, *supra* note 28, at para 1-2.

45. CSPI, *supra* note 9.

46. Press Release, Ctr. For Sci. in the Pub. Interest, Testimony of Caroline Smith DeWaal, Crisis and Consensus: Modernizing U.S. Food Safety Law (Sept. 25, 2007) (on file with author); GAO, *supra* note 43.

47. See Goldstein, *supra* note 8.

48. *Id.*

49. *Id.* at 139.

50. *Id.*

is responsible for the quality of 80% of the United States' food supply, including all fruits and vegetables.<sup>51</sup> Both the FSIS and the FDA must ensure that shipments under their jurisdiction entering the United States comply with our nation's standards for safety and wholesomeness.<sup>52</sup> In order to mandate the compliance of foreign nations, the FSIS uses its legislatively granted "equivalency authority."<sup>53</sup>

According to the U.S. Government Accountability Office ("GAO"), equivalency authority allows the FSIS to ensure compliance with U.S. standards by requiring that "foreign food production systems operate under standards equivalent to those enforced domestically before a country may export its food to the United States."<sup>54</sup> As a result of this regulating power, in 2006, only thirty-two countries were authorized to export meat and poultry to the United States.<sup>55</sup> But, the FDA has not been granted equivalent authority and food products under its jurisdiction, such as fresh produce, can be exported from any country without FDA approval of their safety standards.<sup>56</sup> The FDA's lack of authority to force compliance with U.S. standards is one of the several ways in which the FSIS and the FDA differ and has been recognized as one of the FDA's major deficiencies.<sup>57</sup>

The FSIS and the FDA have different protocols for handling food shipments that arrive at U.S. borders. These differences stem largely from the FDA's lack of both equivalency authority and necessary resources to sufficiently monitor incoming food products.<sup>58</sup> When a shipment is received under the jurisdiction of the FSIS it must be delivered to one of the agency's warehouses for re-inspection.<sup>59</sup> The FSIS refers to this stage in the processing of the shipment as re-inspection because essentially the first inspection occurs when the FSIS conducts an investigation of the exporter's facilities to ensure they meet U.S. safety standards.<sup>60</sup> At the warehouses, FSIS inspectors visually examine every shipment to determine that the products are not damaged and their documentation and labeling is accurate.<sup>61</sup> If a shipment fails this inspection, it is stamped with the words "U.S. Refused Entry" and is returned to the exporter, destroyed, or possibly turned into animal food, within forty-five days.<sup>62</sup> The importer and customs

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51. *Id.*

52. *Id.* (citing U.S. GOV'T ACCOUNTABILITY OFFICE, REP. NO. GAO/RCED-98-103, FEDERAL EFFORTS TO ENSURE THE SAFETY OF IMPORTED FOODS ARE INCONSISTENT AND UNRELIABLE 47 (1998), available at <http://www.gao.gov/archive/1998/rc98103.pdf>).

53. Goldstein, *supra* note 8, at 139.

54. *Id.* at 140.

55. *Id.*

56. *Id.* at 140.

57. *Id.* at 148-49.

58. *Id.* at 143.

59. *Id.* at 144.

60. *Id.*

61. *Id.*

62. *Id.*

are also notified that the particular shipment did not pass its inspection and the product is not released from the warehouse unless documentation is produced showing that arrangements for the product's disposal have been made.<sup>63</sup> If a shipment passes inspection, it is stamped as having been reviewed by the USDA and is released to the importer for market distribution.<sup>64</sup>

### *B. The Significance of Equivalency Authority*

A product imported under the jurisdiction of the FDA is handled in a much different manner than shipments received under the jurisdiction of the FSIS. The FDA electronically screens all the shipments that arrive at the U.S. border; however, the FDA releases a majority of these shipments without conducting an inspection.<sup>65</sup> In 2001, less than 1% of FDA-regulated shipments arriving in the United States were physically inspected.<sup>66</sup> Five years later, FDA inspectors examined just 20,662 shipments out of the 8.9 million shipments that arrived at U.S. borders.<sup>67</sup> This equals 0.23% of all inspected products. This minimal scrutiny can be partially explained by the FDA's lack of statutory authority to hold the imported food products in FDA-controlled warehouses for inspection.<sup>68</sup> It can also be explained by the FDA's lack of equivalency authority which forces the agency to spread its resources thin because it cannot shift the burden of compliance onto the exporting nations and must solely shoulder the burden of inspecting the products at the border.<sup>69</sup> This responsibility would be alleviated if the exporting nation was required, under equivalency authority, to ensure that its facilities and exported food products met U.S. quality standards.<sup>70</sup> This is what allows the FSIS to focus on inspecting the shipments for proper labeling and superficial transport damage, as opposed to quality issues.<sup>71</sup> The FDA does not have this capability, which results in FDA-regulated shipments arriving at the border without any information regarding how the products were grown, produced, handled or shipped.<sup>72</sup> Therefore, the FDA is forced to make quick determinations and decide if the food is safe for consumption.<sup>73</sup>

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63. *Id.*

64. *Id.* at 144-45.

65. *Id.* at 145.

66. *Id.* (citing John D. Dingell, Ranking Member, House Committee on Energy and Commerce, Remarks Before the Consumer Federation of America's 25<sup>th</sup> Annual National Food Policy Conference: Food Safety and the Bioterrorism Legislation (Apr. 23, 2002).

67. Barrionuevo, *supra* note 6, at para 3.

68. Goldstein, *supra* note 8, at 145.

69. *Id.* at 147.

70. *Id.* at 148.

71. *Id.*

72. *Id.* at 148-49.

73. *Id.* at 149.

### C. Budget and Personnel Concerns

Another hurdle the FDA must overcome to protect the nation's food supply is a limited budget that has led to reductions in staff and a limited number of inspections that can be performed.<sup>74</sup> According to a report written by three members of the FDA's advisory board, "[O]ver the last two decades, the agency's public health responsibilities have soared while its appropriations have barely budged. The result is that the FDA is falling farther and farther behind in carrying out its responsibilities . . . ."<sup>75</sup> Although the FDA oversees 80% of the nation's food supply, the agency receives only 38% of the federal food safety budget.<sup>76</sup> Of this budget, the FDA estimates that only 3% of its funding is spent on regulating fresh produce.<sup>77</sup> In addition, according to the GAO's report, "The FDA has no formal program devoted exclusively to fresh produce and has not consistently and reliably tracked its fresh produce spending . . . ."<sup>78</sup>

The FDA's budget limitations force the agency to operate understaffed at the expense of food safety. In the past three years, the FDA has reduced its science staff by 20% and has cut 600 food safety inspectors.<sup>79</sup> According to Caroline Smith DeWaal, Food Safety Director for the CSPI, "The reality of [the] FDA's situation is they don't have the basic inspectors to inspect the food supply they're in charge of . . . ."<sup>80</sup> In 2007, the FDA employed only 1,750 food inspectors who were responsible for all U.S. ports and domestic food processing plants.<sup>81</sup> There are so few inspectors that most domestic food plants receive only one visit every five to ten years.<sup>82</sup> And in 2001, the FDA employed only 150 inspectors who were responsible for monitoring 207 U.S. ports, while the FSIS employed 9,000 inspectors to oversee food products under its jurisdiction.<sup>83</sup> The FDA's budget prevents the adequate examination of imported food products because if no inspector is present at the port when a shipment arrives, the food passes through to the market unchecked.<sup>84</sup> And even if an inspector is present, it has been estimated that inspectors only have thirty seconds to

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74. See Barrionuevo, *supra* note 6, at para 15; Shin, *supra* note 16.

75. Gardiner Harris, *Advisers Say F.D.A.'s Flaws Put Lives at Risk*, N.Y. TIMES, Dec. 1 2007, at para. 4, available at <http://www.nytimes.com/2007/12/01/washington/01fda.html>.

76. Goldstein, *supra* note 8, at 146-47 (citing U.S. GOV'T ACCOUNTABILITY OFFICE, REP. NO. GAO-05-549T, OVERSEEING THE U.S. FOOD SUPPLY: STEPS SHOULD BE TAKEN TO REDUCE OVERLAPPING INSPECTIONS AND RELATED ACTIVITIES 8 (2005), available at <http://www.gao.gov/new.items/d05549t.pdf>).

77. Gardner, *supra* note 26, at para. 6.

78. *Id.* (quoting a GAO report).

79. *Id.* at para. 15.

80. Shin, *supra* note 16.

81. Goldstein, *supra* note 8, at 150.

82. Barrionuevo, *supra* note 6, at para. 11.

83. Goldstein, *supra* note 8, at 150.

84. *Id.*

determine whether hundreds of shipments meet quality standards.<sup>85</sup> It is difficult to understand why an agency that oversees products which account for 25% of every U.S. dollar spent by consumers is so poorly equipped handle this large burden; however, it is clear that this process is insufficient to ensure the safety of the nation's food supply and must be changed.<sup>86</sup>

The problems caused by the FDA's low budget are exacerbated by the agency's lack of equivalency authority. Equivalency authority could relieve the already stretched FDA staff of some of the responsibility for determining the safety of the large numbers of imported food products that arrive at U.S. borders. Additionally, FDA inspectors would be able to spend less time examining each shipment because they would already have information regarding the food product when it arrives.<sup>87</sup> According to John Swann, FDA historian, this would enable the FDA to inspect more shipments each year by "ameliorating the pressure to conduct exhaustive inspections by providing a presumptive assurance of safety and quality."<sup>88</sup> Equivalency authority is also beneficial because visual inspections at ports are often ineffective at detecting contaminated products, and inspection of the production facilities in the foreign nations would be more effective at guarding against contamination problems.<sup>89</sup> Without equivalency authority, the FDA will continue to have difficulties ensuring the safety of imported products and preventing contaminated food sources from entering the market.

Another problem experienced by the FDA is the agency's lack of the basic resources needed to record and monitor food products under its jurisdiction.<sup>90</sup> The computer systems used by the FDA are aging and breaking down. The inspectors' reports are still handwritten, and the system for regulating imported produce is unable to communicate with U.S. customs and other government systems.<sup>91</sup> This information was revealed in a report written by three members of the FDA's Science Board, and according to one of the report's authors, "[t]his was the first time that a group of people got together and really looked at all the areas that the F.D.A. has to cover. . . [w]e were shocked at the scope of its responsibilities, we were shocked at how little its resources have increased, and we were surprised at the conditions those in the F.D.A. had to work under."<sup>92</sup>

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85. *Id.* at 145.

86. John Swann, *History of the FDA*, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm124403.htm>, (last visited April 23, 2010). Bad link, I think I replaced it with the correct one.

87. *Id.*

88. *Id.*

89. *Id.*

90. See Harris, *supra* note 75.

91. *Id.* at para. 9-10.

92. *Id.* at para. 8.

#### *D. Mishandling of Contaminated Products*

The FDA's shortcomings also extend to its procedures for when a contaminated product has been identified. Unlike the FSIS, the FDA does not have a "U.S. Refused Entry" stamp or a comparable marking to identify a shipment that has been deemed unacceptable.<sup>93</sup> When a food product does not pass inspection, the FDA sends out a notice to both U.S. Customs and the importer.<sup>94</sup> Thereafter, the importer has ten days to produce evidence that the shipment is admissible.<sup>95</sup> If the FDA rejects this testimony, the importer is given another chance to show that the product meets U.S. standards by having a sample of their product examined in a laboratory.<sup>96</sup> If the FDA is still not satisfied that the shipment meets quality standards, the importer must return the product to U.S. customs for re-export or destruction.<sup>97</sup> Unlike the protocol of the FSIS, under FDA regulations, the shipment remains in the control of the importer throughout the inspection process.<sup>98</sup> This is due to the FDA's lack of authority to mandate the use of FDA-controlled storage facilities.<sup>99</sup> This inability makes the FDA's system vulnerable to manipulation because the importer is allowed to select the sample of its product for re-inspection and decide in which laboratory to conduct the testing.<sup>100</sup> This control could potentially enable importers to substitute a safe product for an unsafe one during the testing process.<sup>101</sup>

Finally, this protocol allows products that were rejected by the FDA to find their way into the stream of commerce.<sup>102</sup> This occurrence is often the result of communication breakdowns between the FDA and U.S. customs.<sup>103</sup> In some cases, the FDA's decision to reject a shipment is not made until the agency receives the laboratory test results from a product that had arrived days, possibly weeks, earlier.<sup>104</sup> By the time the product is deemed unsafe by the FDA, the importer may have already released the product into the market or simply refused to re-export the shipment.<sup>105</sup> In the customs surveillance operation "Bad Apple," it was noted that "about 40 percent of the imported foods [the] FDA checked and found in violation of U.S. standards were never redelivered to Customs for disposition. These

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93. Goldstein, *supra* note 8, at 145.

94. *Id.* at 146.

95. *Id.*

96. *Id.*

97. *Id.*

98. *Id.* at 145.

99. *Id.*

100. *Id.* at 151.

101. *Id.*

102. *Id.* at 152.

103. *Id.*

104. *Id.*

105. *Id.*

foods were not destroyed or exported as required and presumably were released into U.S. commerce.”<sup>106</sup>

The inability of the FDA to close this hole within the nation's food safety system has produced disastrous results for both sides of the food trade industry. Consumers have lost trust in the regulating agencies to protect the nation's food supply from contamination, and the food industries, both foreign and domestic, are feeling the effects of this loss of trust and the erroneous warnings that have accompanied several recent outbreaks.<sup>107</sup> Most significantly, outbreaks of food-borne illnesses linked to fresh produce have greatly increased, and the FDA is not currently equipped to handle the responsibility of protecting the nation's food supply.<sup>108</sup> According to William Hubbard, former Associate Commissioner of the FDA, “[t]he public thinks the food supply is much more protected than it is . . . If people really knew how weak the F.D.A. program is, they would be shocked.”<sup>109</sup>

## PART II: THE BIOTERRORISM ACT OF 2002: A FAILED ATTEMPT AT REFORM OF THE UNITED STATES' FOOD SAFETY SYSTEM

Although enacted to strengthen regulations governing food safety in the wake of the September 11, 2001, attacks, the Bioterrorism Act of 2002 has done little to improve the United States' food safety system. Cost concerns and resistance from the food industry caused the Act to become watered down during the lawmaking process and the relaxed standards have been unable to remedy the existing problems with the nation's food safety system.<sup>110</sup>

### A. *Post-September 11, 2001, Legislative Initiative*

The Bioterrorism Act was passed in 2002 as an aspect of the Homeland Security effort in response to the terrorist attacks of September 11, 2001.<sup>111</sup> The Act was designed to implement stringent requirements for the inspection and record-keeping of imported food products.<sup>112</sup> Under the original Act, foreign exporters had to register with the FDA and notify officials twenty-four hours in advance of when a shipment would arrive at

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106. *Id.* (citing U.S. GOV'T ACCOUNTABILITY OFFICE, Rep. No. GAO-02-47T, FOOD SAFETY AND SECURITY: FUNDAMENTAL CHANGES NEEDED TO ENSURE SAFE FOOD 7 (2001), available at <http://www.gao.gov/new.items/d0247t.pdf>).

107. Calvin, *supra* note 24, at 74.

108. Goldstein, *supra* note 8, at 147.

109. Barrionuevo, *supra* note 6, at para. 5.

110. See Richard, *supra* note 36; see Pear, *supra* note 38.

111. Richard, *supra* note 36, at para. 1; Goldstein, *supra* note 8, at 153.

112. Richard, *supra* note 36, at para. 1.

U.S. borders.<sup>113</sup> This notice requirement allows the agency to schedule inspections for products vulnerable to tampering or from areas posing terrorist threats.<sup>114</sup> In addition, farmers and shippers were required to record everyone who handles the food items from the field to the packing company.<sup>115</sup> The legislation was intended to increase the number of inspections that take place each year and allow the FDA to detain food products in their warehouses without a court order.<sup>116</sup> According to Robert Pear, this change in the regulations would have been “the most significant expansion of federal authority over the food industry in more than six decades.”<sup>117</sup>

As with many post-September 11th initiatives, the Bioterrorism Act soon lost its urgency.<sup>118</sup> Although it quickly passed through both houses of Congress, the Bill stalled during the House-Senate conference committee in the face of strong resistance from the food industry.<sup>119</sup> While the conference committee is designed to allow lawmakers to work out their differences, it largely remains a secretive part of the legislative process.<sup>120</sup> According to Senator Richard Durbin (D-IL), “Many of the food trade associations are too embarrassed to oppose this bill publicly. They wait until the conference committee meets late at night or work through Congressional staff members to oppose sensible and meaningful safety provisions.”<sup>121</sup> The National Food Processors Association, which represents companies such as Kraft, H. J. Heinz and ConAgra, argued that the legislation was not needed, citing the government’s current legal authority and enforcement mechanisms to ensure the safety of the nation’s food supply.<sup>122</sup> Another group, Lawyers for the Grocery Manufacturers of America, drafted amendments to the Bill that would limit the number of companies required to register with the government and reduce the penalties imposed for violations of the Act.<sup>123</sup> Similarly, the Food Marketing Institute, which represents grocery stores such as Safeway, Kroger and Wal-Mart, lobbied to exempt its stores from the stringent requirements of the Act.<sup>124</sup> Instead of a new broad authority for regulator agencies to monitor imported food products, industry leaders essentially wanted to narrow the focus of the Act to terrorism alone.<sup>125</sup> According to DeWaal, “Congress let

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113. *Id.* at para. 11.

114. *Id.* at para. 6.

115. *Id.* at para. 3.

116. Pear, *supra* note 38, at para. 3.

117. *Id.* at para 5.

118. *Id.* at para 2.

119. *Id.* at para 1.

120. *Id.* at para 9.

121. *Id.*

122. *Id.* at para 6.

123. *Id.* at para. 7.

124. *Id.* at para 8.

125. *Id.* at para. 9.

[the] industry set the parameters in the current debate, and the industry is trying to keep [the] F.D.A. as weak as possible.”<sup>126</sup>

On October 9, 2003, the FDA announced its revised regulations based on the decision by the Bush Administration and food industry leaders that the Bioterrorism Act as proposed would be “too cumbersome and costly.”<sup>127</sup> Industry officials cited the change as a good outcome, stating that “the government . . . significantly softened earlier proposals” and “head[ed] off what could have caused chaos for haulers of food and agricultural commodities.”<sup>128</sup> The revised regulations included less stringent registration requirements for exporters and more flexible deadlines for informing the FDA that a shipment would be arriving at the U.S. border.<sup>129</sup> The original Act required shippers to give agency officials twenty-four hours notice that a shipment was going to be arriving, but because of the industries’ protests, in 2003 this requirement was reduced to only two hours.<sup>130</sup> According to DeWaal, companies may even arrive at a different border crossing than the one the company reported to the FDA.<sup>131</sup> She stated that this is not what Congress intended with the bioterrorism bill because the:

FDA hasn’t given itself enough margin of protection to insure that they can identify all the high-risk food shipments and actually get inspectors to the ports to check them. Congress intended for the legislation to result in strong protections. But FDA, after intensive lobbying by the food industry, has significantly weakened these protections.<sup>132</sup>

In addition, under the current regulations, produce processors and distributors are only required to keep track of where their products come from and go for one step backward and forward in the process.<sup>133</sup> This requirement does not apply to restaurants or farms and the record-keeping can be done on paper in many different formats.<sup>134</sup> This protocol makes

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126. *Id.* at para. 20.

127. CSPI, *supra* note 9. Press Release, Whitt Flora, Transport Topics, U.S. Eases Border Rules (Oct. 20, 2003) (on file with Transport Topics); King, *supra* note 28, at para. 12.

128. Flora, *supra* note 127, at para. 2.

129. *Id.* at para. 5.

130. Richard, *supra* note 36, at para. 11.

131. *Id.* at para. 12.

132. *Id.*

133. Bina Venkataraman, *Amid Salmonella Case, Food Industry Seems Set to Back Greater Regulation*, N.Y. TIMES, July 31, 2008, at para. 13, available at <http://www.nytimes.com/2008/07/31/health/policy/31outbreak.html>.

134. *Id.* at para. 14.

tracing contaminated produce quite cumbersome.<sup>135</sup>

The shortfalls of the Bioterrorism Act are largely a result of the purpose of the Act, which is a security, rather than a safety, measure.<sup>136</sup> By simply focusing on the contamination of the nation's food supply through a terrorist attack, the government is ignoring the possibility of accidental contaminations, which can have the same devastating effects. The Act also fails to address issues such as the sanitation standards of foreign producers and the lack of the FDA's equivalency authority to ensure that foreign nations are in compliance with U.S. standards.<sup>137</sup> These holes in the current legislation illustrate the need for a comprehensive food safety system that will protect the nation's food supply from both terrorist attack and accidental contamination.

### PART III: FOOD SAFETY SYSTEMS IN EXPORTING NATIONS: SUCCESSES AND FAILURES

Many of the contamination problems that have plagued the United States have been linked to the poor agricultural practices used in the countries from which the United States imports its produce.<sup>138</sup> The growing practices in these nations vary greatly from farms having very deficient safety systems that are essentially unregulated to other producers adopting safety practices that are mandated by government programs.<sup>139</sup> The successes and failures that have accompanied these various systems are useful as guidance for determining how to best establish safety procedures capable of preventing contamination problems.

#### *A. Lack of Food Safety Regulations and Unsanitary Growing Conditions in Mexico Linked to Recent Outbreaks*

In 2008, an outbreak of Salmonella associated with Mexican peppers sickened at least 1,440 people and caused two deaths.<sup>140</sup> This incident can be explained by the lack of food safety regulations in Mexico and the poor growing conditions that exist on some Mexican farms and processing centers.<sup>141</sup> For example, at a processing plant for peppers in northern Mexico suspected by the FDA to be associated with the 2008 Salmonella outbreak, workers are not required to separate peppers based on the sanitary

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135. *Id.*

136. Goldstein, *supra* note 8, at 153.

137. *Id.*

138. See Mark Walsh & Olga L. Rodriguez, *Few Safeguards for Mexican Produce Heading North*, ASSOCIATED PRESS, Sept. 14, 2008, available at <http://www.commondreams.org/headline/2008/09/14>.

139. *Id.*; see Calvin, *supra* note 24.

140. Walsh, *supra* note 138, at para. 2-3.

141. *Id.* at para. 5.

conditions under which the produce was grown.<sup>142</sup>

This protocol is not unusual; neither the United States nor Mexico require Mexican produce growers and processing plants to adhere to any specific safety requirements.<sup>143</sup> Therefore, although some growers operate under good sanitary conditions, others do not and their produce is shipped to the United States regardless.<sup>144</sup> Some farms and processing plants choose to operate under better sanitary conditions so that they may sell their produce to U.S. supermarket chains that refuse to buy products that are not certified by private companies.<sup>145</sup> However, according to Cesar Frago, President of Mexico's Chili Peppers Growers Association, most growers do not bother to have their products certified because their crops are sent to distributors without knowledge of where their products will end up.<sup>146</sup> The only requirement for a Mexican company to be able to ship their products to the United States is that the company must be registered online.<sup>147</sup> This process prevents the FDA from identifying which products are at risk for contamination due to poor sanitary conditions and makes it impossible for consumers to know which products are more likely to be safe for consumption.<sup>148</sup>

In Mexico, there is a wide range in the amount and type of safety precautions that are taken at the farming level.<sup>149</sup> For example, some Mexican farms grow their crops in fenced-off fields, use fresh water to irrigate the plants, and pack the products in clean processing plants where the workers are dressed in protective gear.<sup>150</sup> Other farms operate without these precautions, allowing wildlife to roam in unfenced crop fields and use untreated, and sometimes sewage-laced, water for irrigation.<sup>151</sup> Although most major produce buyers attempt to avoid products grown under these conditions by requiring their growers to be certified through a third-party, not all buyers operate under the same rules.<sup>152</sup> According to Kathy Means, Vice President for the U.S. Produce Marketing Associations, food safety is not regulated by the government, so it is up to the individual companies to require the growers to be certified.<sup>153</sup>

The existence of a non-mandatory certification process poses a problem for those growers who adopt the safety procedures necessary to meet the qualifications for certification. Growers in their region which do

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142. *Id.* at para. 3.

143. *Id.* at para. 5.

144. *Id.* at para. 6.

145. *Id.* at para. 7.

146. *Id.* at para. 14.

147. *Id.* at para. 6.

148. *Id.* at para. 8.

149. *See id.* at para. 10.

150. *Id.* at para. 10.

151. *Id.*

152. *Id.* at para. 20.

153. *Id.* at para. 21.

not operate under proper sanitary conditions may offer contaminated crops that are then associated with the entire country.<sup>154</sup> The extent of the impact on trade when a food-borne illness is linked to a country's crop depends on how quickly the country corrects the contamination problem and their ability to convince other countries that their product does not pose a health risk.<sup>155</sup> For example, after multiple incidents of food-borne illnesses outbreaks were linked to Guatemalan raspberries in the 1990s, the United States' demand for blackberries from Guatemala decreased even though blackberries were never identified as a source of the outbreak.<sup>156</sup> This reaction may be attributed to the desire of buyers to purchase all of their berries from one region, which was not possible when Guatemala was prohibited from exporting its raspberries to the United States during the height of its contamination issues.<sup>157</sup> However, the decreased demand also illustrates how the effects of a contamination problem can extend well beyond the producer of the food product at issue affecting other areas of the country's produce industry. This wide scope of damages further illustrates the need to prevent contaminated products from entering the market and causing injury to consumers and exporters.

Produce may also become contaminated in foreign nations at the distribution level. This is particularly true given that produce often passes through several distributors before reaching the marketplace.<sup>158</sup> According to William Hubbard, former FDA official, "It is very common for distributors to receive products from numerous sources, numerous farms and in some cases multiple countries . . . . That's just the way produce moves."<sup>159</sup> This process increases the opportunities for contamination to occur and makes tracing the source of an outbreak more difficult.<sup>160</sup>

The lack of government oversight in Mexico's current food safety system illustrates the need to reform the country's safety procedures. In particular, the sanitary conditions, growing practices, and the ability to trace an item of produce back to its source, must be improved. Although the voluntary certification process appears to validate the quality of crops from some farms, not all farms receive certification and contaminated produce is still slipping through the cracks and making its way into the market. This occurrence is detrimental to consumers and producers alike and must be prevented.

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154. *See id.* at para. 27.

155. Calvin, *supra* note 24, at 74.

156. *Id.* at 82.

157. *Id.*

158. Walsh, *supra* note 138, at para. 15.

159. *Id.* at para. 16.

160. *Id.* at para. 15.

*B. Guatemala Overcomes Series of Food-Borne Illness Outbreaks Through Implementation of a Rigorous Food Safety Program*

Like Mexico, Guatemala has been associated with multiple outbreaks of food-borne illnesses resulting from its contaminated crops.<sup>161</sup> These outbreaks led to large economic losses and for a period of time ruined the country's reputation as a safe producer.<sup>162</sup> However, unlike Mexico, Guatemala was able to change its food safety system by implementing the Model Plan of Excellence ("MPE"), which involved the use of strict regulations to ensure that the country's exports were safe for consumption.<sup>163</sup> Although this reform was not perfect, the system vastly improved the quality of Guatemala's produce, and has allowed the country to somewhat overcome the devastating effects of being associated with multiple outbreaks over a short period of time.<sup>164</sup>

Guatemala's first incident involving food-borne illnesses occurred in 1996, when an outbreak of *Cyclospora* in the United States sickened more than 1,465 people.<sup>165</sup> Although the outbreak was first linked to California strawberries, it was later discovered that raspberries from Guatemala were the source of the outbreak.<sup>166</sup> By the time the raspberries were identified as the source, the growing season for the berries was over and no immediate action was taken.<sup>167</sup> The FDA and the CDC sent investigators to Guatemala to examine the raspberry farms and gain a better understanding of the local industry.<sup>168</sup> The FDA determined that the contamination likely occurred at various farms throughout the country.<sup>169</sup> The FDA recommended that the industry implement Good Agricultural Practices ("GAPs"), Good Manufacturing Practices ("GMPs"), and sanitation procedures.<sup>170</sup> The agency also provided advice and technical assistance in making these changes.<sup>171</sup> In response to the 1996 outbreaks, the Guatemalan Berry Commission ("GBC") developed a plan to categorize the berry farms based on their level of risk of contamination and only allowed certain farms to export their produce.<sup>172</sup> Despite the GBC's efforts, in 1997 another outbreak of *Cyclospora* was linked to the country's raspberries and the GBC voluntarily agreed to halt its raspberry exports mid-season.<sup>173</sup> It is

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161. See Calvin, *supra* note 24, at 80-83.

162. *Id.*

163. *Id.* at 82.

164. *Id.*

165. *Id.* at 80.

166. *Id.*

167. *Id.*

168. *Id.*

169. *Id.*

170. *Id.*

171. *Id.*

172. *Id.* at 81.

173. *Id.*

estimated that stopping the shipment of raspberries in the middle of the growing season resulted in a ten million dollar loss for the industry.<sup>174</sup>

With two consecutive years of contamination problems, the GBC and the government of Guatemala realized stricter controls and enforcement measures had to be implemented.<sup>175</sup> In the fall of 1997, the Guatemalan government developed a commission to head the initiative and gave the GBC enforcement power that was critical for the success of the export plan.<sup>176</sup> Despite the changes, the FDA was not convinced that Guatemala had resolved its contamination problems. It required all shipments from the country to be detained without physical examination (“DWPE”) and denied the shipments entry into the United States.<sup>177</sup> This procedure was an unusual response, generally only exercised when all other means of regulating the product have proved ineffective.<sup>178</sup>

In 1999, the United States began to allow shipments of raspberries produced under the MPE to enter the country.<sup>179</sup> The MPE is a joint program of the Guatemalan government and the GBC.<sup>180</sup> Under the program, farmers that wish to participate must comply with specific food safety practices and pass government inspections and FDA audits.<sup>181</sup> The safety procedures required by the MPE include filtering the water used for irrigation and creating better worker hygiene facilities.<sup>182</sup> The MPE also requires each clamshell of raspberries to be coded, allowing the product to be traced back to its farm of origin in case of a contamination problem.<sup>183</sup> This capability makes it possible for the MPE to revoke export authority from specific farms that have food safety issues, which helps maintain the program’s integrity.<sup>184</sup>

The trace-back ability created by the MPE has been successful in limiting the spread of food-borne illnesses and helping correctly identify the source of an outbreak.<sup>185</sup> In 1999, several *Cyclospora* outbreaks in the United States and Canada were linked to raspberries; however, the GBC was able to show, by utilizing the tracking feature of the MPE, that Guatemalan raspberries were not the source of the outbreak.<sup>186</sup> In 2000, two outbreaks were linked to Guatemalan raspberries and were traced to a

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174. *Id.*

175. *Id.*

176. *Id.*

177. *Id.* at 82.

178. *Id.*

179. *Id.*

180. *Id.*

181. *Id.*

182. *Id.*

183. *Id.*

184. *Id.*

185. *Id.*

186. *Id.*

specific farm that was then removed from the MPE program.<sup>187</sup> Since this outbreak, there have been no further incidents involving Guatemalan raspberries.<sup>188</sup> The success of the MPE program in remodeling Guatemala's food safety system and halting the contamination problems associated with the country's raspberry crop illustrates the potential for other countries to similarly reform their safety regulations and resolve their contamination problems.

#### PART IV: ECONOMIC CONSEQUENCES OF REOCCURRING OUTBREAKS

Over the past twelve years, outbreaks of food-borne illnesses have been frequent and severe.<sup>189</sup> These contamination problems have not only sickened many people but also have led produce growers to experience huge economic losses.<sup>190</sup> Furthermore, the repeated occurrences of these outbreaks, and the erroneous warnings that often accompany them, have led American consumers to distrust the ability of the FDA to protect the nation's food supply.<sup>191</sup>

For example, in the summer of 2008, an outbreak of Salmonella was initially identified by U.S. food safety officials to be linked to tomatoes.<sup>192</sup> However, on June 17, 2008, the FDA lifted its warning about contaminated tomatoes and identified jalapeno peppers from Mexico as the true source of the outbreak.<sup>193</sup> This second warning did not come in time to prevent the fear of tainted tomatoes which prompted growers to destroy their crops, and ruined millions of tons of produce that was ready to be sent to the market.<sup>194</sup> Meanwhile, jalapeno peppers, the true source of the outbreak, were still being consumed in July of 2008 even though some state and local health departments had evidence the peppers were contaminated.<sup>195</sup> Industry representatives estimated that the false identification of tomatoes as the source of the 2008 Salmonella outbreak resulted in a loss of 300 million dollars.<sup>196</sup> Similarly, in 1996, California strawberries were misidentified as the source of an outbreak of Cyclospora, which led to a sixteen million dollar loss in revenue for strawberry growers in the month of June alone.<sup>197</sup> According to Representative Dennis Cardoza of California, "You can describe our current food safety system as 'outbreak roulette.'"<sup>198</sup> The

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187. *Id.*

188. *Id.*

189. *See supra* INTRODUCTION.

190. *See generally* Part IV.

191. *See id.*

192. King, *supra* note 28, at para. 3.

193. *Id.* at para. 4.

194. *Id.* at para. 3.

195. *Id.* at para. 9.

196. *Id.* at para. 3.

197. Calvin, *supra* note 24, at 80.

198. King, *supra* note 28, at para. 5.

current uncertainties in the FDA's announcements must be resolved in order to prevent the devastating effects of erroneous warnings and having contaminated products remain unidentified in the market. The FDA serves an important role in preventing contaminated products from reaching consumers. This position is far too significant to allow these inaccuracies to persist.

#### PART V: RECOMMENDATIONS FOR REMODELING THE GLOBAL FOOD SAFETY SYSTEM

Taking measures to protect the global food supply must begin on the farms of foreign nations who export produce and extend to regulatory agencies in the United States and abroad. Both the United States and foreign nations must strengthen their food safety systems through stricter regulations, more extensive monitoring by the regulatory agencies, education about safe practices, and new legislation.

This multi-tiered approach is necessary because, although the U.S. food industry has stated that it can monitor itself, the current system is clearly not working.<sup>199</sup> The creation of a revamped food safety system in the United States will involve greatly expanding the capabilities of the FDA and making substantial changes to the current legislation governing food safety procedures.

Vernon Tesh, professor of microbial and molecular pathogenesis at Texas A&M University, suggests that remodeling the United States' food safety system will essentially require a "two-pronged attack."<sup>200</sup> First, the FDA must be capable of performing better inspections, then, when a problem is detected, there must be a means for enforcing the regulations.<sup>201</sup> In order to tackle a contamination problem once it occurs, a centralized food-tracking system is needed. This trace-back ability would allow food safety officials to keep tabs on which countries the food products are coming from and where the products have been placed in the market.<sup>202</sup> This change would allow the FDA to quickly remove contaminated products from the market and limit the number of consumers affected by outbreaks of food-borne illnesses. Furthermore, the enactment of new legislation is needed to ensure that the FDA has sufficient resources to adequately monitor incoming food products and mandate compliance with the agency's regulations.

There are several aspects of the food safety systems in the foreign nations from which the United States receives produce shipments that must be addressed. Contamination problems often begin on the farms where the

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199. *Id.* at para. 6.

200. Gardner, *supra* note 26, at para. 16.

201. *Id.*

202. King, *supra* note 28, at para. 6-7.

produce is grown; therefore, it is important to examine the growing practices used at the farming level. GAPs are capable of preventing contamination problems altogether and must be adopted to prevent the spread of illness and maintain the reputation of these countries as safe producers. Secondly, the producers must be educated about these farming practices and be monitored to ensure that their agricultural practices meet the applicable standards set forth by the country's regulating agency or food safety program. This substantial change would best be implemented by legislation that would establish agencies to police the farms and ensure their cooperation with newly implemented food safety programs. Changes of this nature would significantly improve foreign countries' ability to protect its exports and would assist these nations in maintaining good trade relations with other countries. Preventing contamination problems will benefit consumers and the food industry in these countries by limiting the frequency and severity of outbreaks of food-borne illnesses.

*A. Increased Authority and Resources for the FDA.*

The FDA plays a significant role in preventing contaminated food products from entering the U.S. market. However, despite the agency's importance, it has continually been denied the authority and resources that have been granted to the FSIS.<sup>203</sup> In order to protect the nation's food supply it is imperative that the FDA be granted equivalency authority to match that of the FSIS's and be supplied more resources, primarily in the form of personnel and funding, to exercise its authority.<sup>204</sup>

Equivalency authority is the ability of a regulatory agency to require foreign countries to operate under safety standards equivalent to those required domestically before a nation may export its products to the United States.<sup>205</sup> Although the FSIS has this ability, the FDA does not.<sup>206</sup> This difference between the agencies has a large effect on the capabilities of the FDA to adequately protect the nation's food supply.<sup>207</sup> If the FDA were to receive equivalency authority through new legislation, a significant portion of the burden of ensuring compliance with U.S. food safety standards would be shifted to the exporting countries.<sup>208</sup> This change would limit the number of countries who could send their products to the United States and would relieve the FDA border inspectors of the task of determining on the spot if a shipment is safe for consumption.<sup>209</sup> Through the use of equivalency authority the FDA could operate like the FSIS and concentrate

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203. See Goldstein, *supra* note 8, at 139-40, 149-50.

204. *Id.* at 141.

205. *Id.* at 140.

206. *Id.*

207. See *supra* Part I.B.

208. Goldstein, *supra* note 8, at 148.

209. *Id.*

its resources on inspecting the farms and facilities used in the foreign countries, as opposed attempting to catch contaminated products at the border.<sup>210</sup>

Because food products under the jurisdiction of the FSIS arrive at the border with the guarantee that the item was produced under adequate safety standards, the FSIS is primarily concerned with detecting damaged shipments and labeling mistakes at the border, as opposed to contamination issues.<sup>211</sup> As a result, the FSIS is better able to conserve its resources and expend its funding and personnel towards monitoring potential sources of contamination.<sup>212</sup> The FDA would similarly benefit by being able to focus its limited resources on correcting contamination problems, as opposed to merely trying to catch problems before they affect the food supply.

Equivalency authority would also assist the FDA by preventing shipments from reaching the U.S. border with essentially no information regarding how the product was grown, produced, handled or shipped.<sup>213</sup> Currently, the burden of acquiring this information is on the FDA, and the agency must ascertain these facts during border inspections.<sup>214</sup> Equivalency authority would make this task unnecessary and would allow FDA inspectors to examine a larger percentage of shipments that arrive at the border.<sup>215</sup> The use of equivalency authority “would allow FDA inspectors to spend less time on each shipment, thereby allowing them to inspect more shipments each year and thus ameliorating the pressure to conduct exhaustive inspections by providing a presumptive assurance of safety and quality.”<sup>216</sup> Currently, the FDA is only capable of inspecting a small number of the shipments that arrive at U.S. borders and is only able to spend a short amount of time examining each shipment.<sup>217</sup> This process of relying heavily on hastily conducted border and port inspections is ineffective in preventing contaminated products from entering the United States.<sup>218</sup> In addition, relying solely on information provided by the exporting nations, without actually inspecting the farms and facilities in these countries, creates an opportunity for the exporting nations to manipulate the FDA’s inspection system.<sup>219</sup> Furthermore, many conditions that make food products unsafe for consumption are undetectable by visual inspections. Therefore, inspections at the farming and production level are

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210. *Id.*

211. *Id.*

212. *Id.*

213. *Id.*

214. *Id.*

215. *Id.* at 150.

216. *Id.*

217. *See supra* Part I.B.

218. Goldstein, *supra* note 8, at 150.

219. *Id.* at 150-51.

necessary to effectively guard against contamination problems.<sup>220</sup> Finally, equivalency authority would allow the FDA to operate like the FSIS by sending shipments to FDA-controlled warehouses for inspections and use a "U.S. Refused Entry" stamp on shipments that were rejected upon inspection to make sure they do not enter the market.<sup>221</sup> Granting the FDA equivalency authority through new legislation will be the best means to achieve these objectives and conserve resources.

One of the biggest problems with the FDA's lack of equivalency authority is that it requires the agency to spread its resources thin while trying to inspect the large amounts of shipments that arrive at U.S. borders every day.<sup>222</sup> Although granting the FDA equivalency authority would partially relieve the budget concerns which plague the FDA, the agency must also receive more funding in order to keep up with the increasing number of imports by hiring additional personnel to conduct inspections of farms and facilities in foreign nations and at the border.<sup>223</sup> According to a report released by the FDA's Science Board in 2007, the "FDA is not positioned to meet current or emerging regulatory needs . . . [and] does not have the capacity, such as staffing and technology, to ensure the safety of the nation's food supply."<sup>224</sup> According to the report, the "resources have not kept pace with [the FDA's] increasing responsibilities, and this disparity has made it increasingly 'impossible' for FDA to maintain its historic public health mission."<sup>225</sup> Former Associate Commissioner of the FDA, Bill Hubbard, stated that in 2007, the FDA employed only 450 inspectors who were responsible for screening almost 20 million imports, which averages to 44,000 shipments per inspector.<sup>226</sup> The inadequacy of the FDA's resources is not a secret. This problem has been identified by the FDA and other agencies, and must be resolved through legislative reform.<sup>227</sup> In order to fully protect the nation's food supply, it is estimated that the FDA's base budget will need to increase by 755 million dollars by 2013, beginning with a 128 million dollar increase in 2009.<sup>228</sup> This substantial increase can only be achieved through the enactment of legislation which forces the FDA's budget increase to become a priority.

The GAO, the CSPI, and the FDA have all expressed the need for the FDA to receive equivalency authority and increased resources.<sup>229</sup> In 2004,

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220. *Id.* at 151.

221. *Id.* at 152; see *supra* Part I.A.

222. See *supra* Part I.B.

223. See Goldstein, *supra* note 8, at 149-51.

224. Press Release, Lisa Shames, GAO, Federal Oversight of Food Safety (June 12, 2008) (on file with GAO).

225. *Id.*

226. *Id.*

227. Goldstein, *supra* note 8, at 156.

228. Shames, *supra* note 224.

229. Goldstein, *supra* note 8, at 156.

the GAO recommended that the FDA make it a priority to establish equivalency agreements with the United States' trading partners in order to shift some of the FDA's oversight burden to these countries.<sup>230</sup> In 2007, the FDA released its Food Protection Plan, which requested "Congress allow the agency to enter into agreements with exporting countries to certify that foreign producers' shipments of designated high-risk products comply with FDA standards."<sup>231</sup> As of 2008, the FDA has been unable to enter into these agreements.<sup>232</sup> Members of Congress have also recognized the need for changes in legislation, as evidenced by numerous proposed bills.<sup>233</sup> None of the bills, however, have advanced beyond the committee level.<sup>234</sup> In order to alleviate the FDA's current oversight burden and increase the productivity of the agency, legislation must be passed which will grant the agency sufficient funding and the authority to pursue the equivalency agreements with foreign nations.

Another aspect of the United States' food safety system that needs to be strengthened is the FDA's ability to trace the origin of a product once it has been identified as contaminated. This trace-back ability would enable the FDA to identify the sources of an outbreak sooner and promptly eliminate regions and products that may have been mistakenly suspected.<sup>235</sup> Early identification is becoming particularly important as the countries from which the United States receives imports move towards industrialization and produce on a larger scale.<sup>236</sup> Under the Bioterrorism Act of 2002, processors and distributors are only required to keep track of where their food products come from and are sent to for one step forward and one step backward in the process.<sup>237</sup> This procedure has limited application because "those rules do not apply to farms or restaurants. And the records can be kept on paper and in a multitude of formats, making the tracing of fresh produce, which has a short self-life, a cumbersome task."<sup>238</sup> This checkerboard process must be replaced by a more efficient, computerized system, which would consist of a single database to contain all records for food products under the jurisdiction of the FDA.<sup>239</sup> Congress must pass comprehensive legislation to accomplish these objectives. In particular, producers, distributors and retailers must be held accountable for better oversight of their products as they travel through the market, and the FDA must be given greater authority to investigate and recall contaminated food

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230. Shames, *supra* note 224.

231. *Id.*

232. *Id.*

233. Goldstein, *supra* note 8, at 156.

234. Goldstein, *supra* note 8, at 156 n.135.

235. Venkataraman, *supra* note 133, at para. 13.

236. Käferstein, *supra* note 1, at para. 12.

237. Venkataraman, *supra* note 133, at para. 14.

238. *Id.* at para. 15.

239. King, *supra* note 28, at para. 8-9.

products.<sup>240</sup>

Of the proposed bills, the Safe Food Act, which was introduced by Senator Durbin and Representative Rosa DeLauro (D-CT) in 2007, seems to have the most potential to successfully reform the nation's food safety system.<sup>241</sup> This Act would effectively streamline the food safety system by consolidating the FDA, USDA, the Center for Veterinary Medicine, the Environmental Protection Agency ("EPA") and several other agencies in order to create a unified Food Safety Administration.<sup>242</sup> The Act would also modernize the outdated inspection program and give the Administration clear authority to implement safety programs at the farming level. The Act is premised on "preventative control systems implemented by the industry and performance standards monitored and enforced by the government."<sup>243</sup> Under the Act the administration would have equivalency authority, which would allow it to certify an exporting nation's food safety system and ensure that its procedures are equivalent to the United States' standards.<sup>244</sup> The Administration would also have the authority to audit the certified countries every five years for compliance and conduct routine inspections to ensure that the exports are safe for consumption and properly labeled.<sup>245</sup> Furthermore, the Act would give the Administration authority to issue civil and criminal penalties for violating food safety regulations and provide protection to whistleblowers that reveal violations.<sup>246</sup> Overall, the Act would ensure that "foods would no longer have an 'open visa' to enter the U.S. without inspection or regulation."<sup>247</sup> The Safe Food Act should be implemented in order to remodel the United States' food safety system in a way that will provide proper government oversight and the resources necessary to maintain the safety of the nation's food supply.

The United States would not be the first country to reform its food safety system in this manner.<sup>248</sup> In 1999, the United Kingdom established a single Food Standards Agency, which has been effective in reducing the number the food-borne illness outbreaks and building consumer confidence in the country's food safety system.<sup>249</sup> Within the first three years of creating the Agency, food-borne illnesses declined by 18% and public confidence in the wholesomeness of the country's food supply increased from 44% to 60%.<sup>250</sup> The Food Standards Agency was established during a

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240. *Id.* at para. 13.

241. CSPI, *supra* note 9.

242. *Id.* at 9.

243. *Id.* at 10.

244. *Id.*

245. *Id.*

246. *Id.*

247. *Id.*

248. *See id.* at 8.

249. *Id.*

250. *Id.*

time when the United Kingdom was experiencing food safety problems similar to those which have plagued the United States recently.<sup>251</sup> The food scares in the United Kingdom illustrated the need for change and encouraged the reaching of a compromise.<sup>252</sup> The United States should react similarly and take action now to remodel its food safety system.

### *B. Implementing Good Agricultural Practices*

Exporting food products is a major industry in Mexico and the safety of its exports is crucial to the country's continued participation in this trade.<sup>253</sup> If the country of Mexico

is not able to improve processing and self-controls, and the government does not implement the required measures for the governments of the importing countries to be confident that requirements are met, then exports will encounter difficulties to remain the same or increase, and the impact on the capital inflow, the employment rate, and the possibilities of development will be severely affected.<sup>254</sup>

In order to remain in trusting relationships with its trade partners and grow its industry, Mexico and other exporting nations must ensure that their products do not become associated with food-borne illness outbreaks.<sup>255</sup> Preventing contamination problems in these nations will require the use of GAPs, stricter sanitary procedures, and government oversight of these new measures. Furthermore, producers and distributors must be educated about these practices and the best ways to implement these new procedures at their facilities.<sup>256</sup> Through these efforts, exporting countries will be able to continue to expand their industries, meet the demands of their trade partners, and prevent the devastating effects of being identified as a producer of a dangerous product.<sup>257</sup>

A producers' first line of defense for preventing contamination problems is the adoption of GAPs.<sup>258</sup> According to the FDA, GAPs involve the use of sanitary water for irrigation and washing; controlling the potential hazards which accompany the use of manure; maintaining worker

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251. *Id.*

252. *Id.*

253. José Luis Flores Luna, *Communication and Participation: The Experience in Mexico*, in FAO/WHO GLOBAL FORUM OF FOOD SAFETY REGULATORS 194, 195 (Food and Agriculture Organization of the United Nations 2002), available at <http://www.fao.org/docrep/MEETING/004/Y2122E.HTM>.

254. *Id.*

255. *See supra* Part III.B.

256. *See* Luna, *supra* note 253, at 196.

257. *See supra* Part IV.

258. Calvin, *supra* note 24, at 89.

health and hygiene; and the use of sanitation procedures in the field, packing facilities and during the transportation process.<sup>259</sup> Although some producers in foreign nations will have adopted these practices, others have not, and their products pose a risk for contamination.<sup>260</sup> The first step in implementing GAPs is to educate farm managers and employees on the safety procedures recommended by the FDA to prevent contamination.<sup>261</sup> Education about these practices can be provided in a number of ways. For example, in 2000, a training program was held in Chile for 50 representatives from the Chilean fresh produce industry, government and academia.<sup>262</sup> The training program consisted of presentations on produce safety conducted by the United States' FDA and their Chilean counterparts and an on-site visit to a fruit packing facility and a clinic for agricultural workers.<sup>263</sup> The program primarily focused on good growing and handling practices, general principles of working hygiene and safety, quality assurance programs, safe use of pesticides and agrochemicals and new technologies in produce sanitizing.<sup>264</sup> Programs such as the one conducted in Chile should be held in every country that exports fresh fruits and vegetables and will be necessary if a country must meet U.S. safety standards under equivalency agreements.

Providing foreign countries with the training to establish GAPs is not the end of the battle. The United States, through equivalency agreements, and the governments and agencies in these countries must monitor the conditions under which their products are grown and ensure that the recommended safety standards are being followed. In Mexico, a federal produce safety law was enacted in 1994, but is rarely enforced by the government.<sup>265</sup> In addition, although some producers choose to have their safety standards certified by a third party so that they may sell to major produce buyers in the United States, the certification is not government-regulated or required.<sup>266</sup> This lack of oversight is unacceptable, and will stand in the way of improving the safety procedures in these nations.

Government oversight in these exporting countries can be provided through several means. First, the government can create a program that

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259. U.S. Department of Health and Human Services, Food and Drug Administration, Centers for Disease Control and Prevention, *Guide to Minimize Microbial Food Safety Hazards For Fresh Fruits and Vegetable*, Oct. 26, 1998, <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm064574.htm> (last visited Apr. 23, 2010).

260. See *supra* Part III.A.

261. See U.S. Department of Health and Human Services, *supra* note 259, at para. 19.

262. Daniel Trachewsky, *Report on Evaluation of Good Agricultural Practices Training Program*, at para. 1, <http://www.cfsan.fda.gov/dms/fschconf.html> (last visited Apr. 24, 2010).

263. *Id.*

264. *Id.* at para. 10-14.

265. Walsh, *supra* note 138, at para. 20.

266. *Id.* at para. 21-22.

requires the adoption of GAPs and instills consequences on farms and facilities that do not adhere to the program.<sup>267</sup> This approach was followed with successful results in Guatemala after repeated outbreaks were linked to the country's raspberry crop.<sup>268</sup> The MPE was established in Guatemala in 1999 and required growers to adhere to a detailed program of safety procedures and pass frequent inspections conducted by Guatemala's Integral Program for Agricultural and Environmental Protections and the FDA.<sup>269</sup> If a grower did not participate in the program, or it was discovered that a grower's crop was the source of the outbreak, the farm would be unable to export its product.<sup>270</sup> Furthermore, the MPE required the use of filtered water for irrigation, better worker hygiene facilities, and mandated that a code be applied to each case of raspberries so the product could be traced back to the grower in the event of a contamination problem.<sup>271</sup> Requiring a tracking code would assist regulating agencies in limiting the scope of damages once an outbreak occurs and would identify farms that are having contamination problems in order to remove their authority to export.<sup>272</sup> The mechanisms used in the MPE allowed the government of Guatemala to play an active role in the food safety system and ensure that their growers met the requirements of the program. This hands-on approach served the country of Guatemala well and could produce the same results in other countries.<sup>273</sup>

Another means a government could use to oversee its nation's food safety system is to require the country's growers to be certified through an accredited private certifying agency. In March of 2008, the House Committee on Energy and Commerce released the Food and Drug Administration Globalization Act ("FDAGA"), which would create a voluntary certification program for foreign governments, state and regional authorities, cooperatives, and other third-party agents.<sup>274</sup> These groups would be able to apply to become certifying agents who would be permitted to perform regular inspections on behalf of the FDA to determine whether facilities were in compliance with safety standards.<sup>275</sup> The FDAGA would also provide incentives to encourage growers to seek certification, such as

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267. Calvin, *supra* note 24, at 82.

268. *See id.* at 80-84.

269. Linda Calvin, Luis Flores, & William Foster, *Food Safety in Food Security and Food Trade, Case Study: Guatemalan Raspberries and Cyclospora*, INT'L FOOD POL'Y RES. INST. (2003), <http://www.ifpri.org/2020/focus/focus10.asp> (last visited Apr. 24, 2010).

270. Calvin, *supra* note 24, at 82.

271. *Id.*

272. *Id.*

273. *See supra* Part III.B.

274. David Plunkett & Caroline Smith Dewaal, *Who is Responsible for the Safety of Food in a Global Market? Government Certification v. Importer Accountability as Models for Assuring the Safety of Internationally Traded Foods*, 63 FOOD & DRUG L.J. 657, 663 (2008).

275. *Id.*

subjecting their products to less stringent laboratory testing.<sup>276</sup> This Act should be adopted to provide a means for foreign governments to be responsible for inspecting and certifying the farms and facilities in their countries. The transfer of this authority would benefit the global food safety system by shifting some of the burden of ensuring compliance with safety standards to the governments of the exporting nations and require the governments to oversee their food safety systems.

#### CONCLUSION

Outbreaks of food-borne illnesses have become a common occurrence in the global food market and have inflicted harm on consumers, the food industry, and exporting nations.<sup>277</sup> The scope of these damages is wide and the ramifications are often long-lived.<sup>278</sup> The urgency of tackling this problem cannot be ignored. The United States must join with its trade partners to improve the global food safety system by strengthening U.S. regulating agencies, providing education on good farming practices, and pushing exporting nations to take responsibility for implementing and overseeing their food safety systems.<sup>279</sup> In order to maintain and expand their food industry, the exporting nations must enter into equivalency agreements with their trade partners and hold their growers accountable for adopting better sanitation and agricultural practices.<sup>280</sup> Through these measures, the global food safety system will be strengthened and the risk of contamination problems will be minimized. As the food market further expands and the importation of products continues to increase, the necessity of a new approach to food safety will become apparent. However, the time to act is now.

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276. *Id.*

277. *See supra* INTRODUCTION.

278. *See supra* Part IV.

279. *See supra* Part V.

280. *Id.*