

# The Obstacles of Outsourcing Imported Food Safety to China

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## Introduction

Approximately 60% of fresh fruits and vegetables<sup>1</sup> and 80% of seafood<sup>2</sup> consumed in the United States are imported. On average, 15% of the overall U.S. food supply by volume comes from foreign countries.<sup>3</sup> In 2007, the United States imported \$85.4 billion worth of agricultural and seafood products.<sup>4</sup> China was the third largest food exporter to the United States, after Canada and Mexico.<sup>5</sup> China is also the largest exporter of

1. U.S. FOOD AND DRUG ADMIN. (FDA), DEP'T OF HEALTH AND HUMAN SERV. (HHS), FOOD PROTECTION PLAN: AN INTEGRATED STRATEGY FOR PROTECTING THE NATION'S FOOD SUPPLY 8 (2007), available at <http://www.fda.gov/downloads/aboutfda/centeroffices/oc/officeofoperations/ucm121761.pdf> [hereinafter FDA FOOD PROTECTION PLAN].

2. U.S. FOOD AND DRUG ADMIN. (FDA), IMPORT ALERT NO. 16-131, FDA IMPORT ALERTS (2010), available at [http://www.accessdata.fda.gov/cms\\_ia/importalert\\_33.html](http://www.accessdata.fda.gov/cms_ia/importalert_33.html) [hereinafter FDA IMPORT ALERTS].

3. See FDA FOOD PROTECTION PLAN, *supra* note 1, at 8.

4. GEOFFREY S. BECKER, CONG. RESEARCH SERV. (CRS), FOOD AND AGRICULTURAL IMPORTS FROM CHINA 5 (updated Sept. 26, 2008), available at Order Code RL34080.

5. *Id.*

seafood to the United States,<sup>6</sup> and made up 21% of the total imported seafood coming into the United States in 2007.<sup>7</sup>

The Food and Drug Administration (FDA) regulates approximately 80% of the nation's food supply,<sup>8</sup> yet it inspects only 1% of imported foods.<sup>9</sup> The threat of increasing food imports and an inadequate inspection rate has portended a serious and growing risk for food-borne illness outbreaks in the United States.

In early 2007, the recall of melamine tainted pet foods imported from China brought significant public attention to the efficacy of the U.S. food safety regulatory system.<sup>10</sup> Critics asserted that the current system was broken and incapable of protecting American consumers.<sup>11</sup> Growing public concern about food safety, particularly over foodstuffs made in or sourced from China, has prompted several legislative proposals to overhaul the U.S. food safety system.<sup>12</sup> Under this pressure, the FDA has pursued various measures aimed at better protecting America's food supply, one of which is the Action Plan for Import Safety.<sup>13</sup>

The U.S. government concedes that the FDA cannot afford to adequately inspect food imports at the over 300 U.S. ports of entry.<sup>14</sup> In

6. *Id.* at 5-6.

7. Food & Water Watch, *Import Alert: Government Fails Consumers, Falls Short on Seafood Inspections* (2007), available at <http://documents.foodandwaterwatch.org/ImportAlertJuly2007-1.pdf>.

8. LISA SHAMES, DIR., NAT'L RES. AND ENV'T, U.S. GOV'T ACCOUNTABILITY OFFICE (GAO), TESTIMONY BEFORE THE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS, COMMITTEE ON ENERGY AND COMMERCE, HOUSE OF REPRESENTATIVES, GAO-08-435T, FEDERAL OVERSIGHT OF FOOD SAFETY: FDA'S FOOD PROTECTION PLAN PROPOSES POSITIVE FIRST STEPS, BUT CAPACITY TO CARRY THEM OUT IS CRITICAL I (Jan. 29, 2009), available at <http://www.gao.gov/new.items/d08435t.pdf>.

9. See GEOFFREY S. BECKER, CONG. RESEARCH SERV. (CRS), U.S. FOOD AND AGRICULTURAL IMPORTS: SAFEGUARDS AND SELECTED ISSUES I (Dec. 16, 2009), available at 7-5700 RL34198; Alexei Barrionuevo, *Food Imports Often Escape Scrutiny*, N.Y. TIMES, May 1, 2007, at C1.

10. See Kelly Chen & Rosa Dunnegan-Mallat, H.R. 3610, *the Food and Drug Import Safety Act of 2007*, 42 INT'L L. 1339, 1339-40 (2008) (discussing the "enormous" media attention given to tainted foods, including pet food, and the impact of the scandals on FDA legislation); Sharon B. Jacobs, *Crises, Congress, and Cognitive Biases: A Critical Examination of Food and Drug Legislation in the United States*, 64 FOOD & DRUG L.J. 599, 616-17 (2009) (discussing the pet food scandal as a crisis that led to legislation regarding the FDA); Kate Paulman, Comment, *See Spot Eat, See Spot Die: The Pet Food Recall of 2007*, 15 ANIMAL L. 113, 126 (2008) (discussing the impact of the pet food scandal on the FDA and the public's concern).

11. See Caroline Smith DeWaal & David Plunkett, *Building a Modern Food Safety System for FDA Regulated Foods 3-4* (2009) (a white paper for the Ctr. for Sci. in the Pub. Interest), available at <http://www.cspinet.org/new/pdf/fswhitepaper.pdf>.

12. See generally Food Safety Enhancement Act of 2009, H.R. 2749, 111th Cong. (2009); Food Safety Modernization Act of 2009, H.R. 875, 111th Cong. (2009); Food and Drug Administration Globalization Act of 2009, H.R. 759, 111th Cong. (2009); Safe Food Enforcement, Assessment, Standards, and Targeting Act of 2009, H.R. 1332, 111th Cong. (2009); FDA Food Safety Modernization Act, S. 510, 111th Cong. (2009); see also Part I, 1.3 B of this article.

13. See *infra* Part III, 3.1 of this article.

14. See STEVE SUPPAN, INST. FOR AGRIC. AND TRADE POLICY, *IMPORT FOOD SAFETY IN THE TWILIGHT OF THE BUSH ADMINISTRATION* 5 (May 2008) (noting the difficulty in assessing

searching for alternatives to physical inspections, the FDA calls for “capacity building” of foreign food safety regulatory regimes.<sup>15</sup> That is, through bilateral agreements with China and other nations that contribute to the bulk of food imports to the United States, the FDA intends to shift the burden of securing the U.S. food supply onto the regulatory systems in exporting countries.<sup>16</sup> In essence, these measures propose to outsource the food safety regulatory power from the United States to China and other foreign governments.

This article argues that outsourcing regulatory power through a bilateral agreement with China is unlikely to ensure the safety of imported food for two primary reasons. First, shifting the regulatory burden does not present a feasible alternative to the traditional enforcement tools of outcome-based and production-based inspections and sanctions. With the extensive evolution of food safety law in the United States over the past one hundred years, these traditional tools have, for the most part, proven effective in safeguarding the American food supply.<sup>17</sup> Moving away from physical inspections in the United States, therefore, will not only eliminate a proven method for ensuring food safety but will also send the wrong message to both importers and foreign manufacturers.

Second, China’s burgeoning food safety regime, based on an entirely different culture and legal system, provides little incentive for Chinese food manufacturers to increase production costs to comply with U.S. standards. A mere bilateral agreement will not alter existing Chinese production practices in the absence of heightened scrutiny from the United States. Despite the Chinese government’s genuine efforts, many factors hamper its capacity to secure food safety, such as corruption, lack of a developed regulatory framework, environmental degradation, and the zealous pursuit of economic miracles.

Part I of the article examines the regulatory framework for the safety of U.S. made food, particularly the development of the Food, Drug and Cosmetic Act (FD&C Act), the FDA, and the traditional enforcement tools. Part II addresses the weakened U.S. enforcement of food safety measures in the context of food imports. Part III considers the proposed outsourcing of food safety regulatory power to the Chinese government. Part IV analyzes the inherent problems of China’s evolving food safety regime. The article concludes that outsourcing regulatory power to China is unwise and will be ineffective in protecting U.S. consumers.

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regulation costs and the challenges in gathering data on specific importers), *available at* <http://www.iatp.org/iatp/publications.cfm?accountID=451&refID=102785>.

15. INTERAGENCY WORKING GROUP ON IMP. SAFETY, REPORT TO THE PRESIDENT, ACTION PLAN FOR IMPORT SAFETY: A ROADMAP FOR CONTINUAL IMPROVEMENT 24 (Nov. 2007), *available at* <http://importsafety.gov/report/actionplan.pdf> [hereinafter ACTION PLAN FOR IMPORT SAFETY].

16. See *infra* Part III of this article.

17. Critics of the current food safety regulatory framework mainly focus on institutional flaws that hinder the efficiency of enforcement tools. See Part I, 1.3 of this article.

## I. Regulatory Framework for the Safety of U.S. Made Food

### A. The Development of the Regulatory Framework

#### 1. *The Pure Food and Drug Act of 1906*

In the late 19th Century, scandals involving food contamination plagued the American food industry.<sup>18</sup> The transition from a predominantly agricultural society to an industrial nation led to a newly urbanized population with an insatiable appetite for cheap processed foods.<sup>19</sup> Facing growing demand, big business took advantage of new technologies to adulterate food products.<sup>20</sup> Food manufacturers invented various ways of deceiving consumers by adding chemicals to make deleterious foods appear fresh and desirable.<sup>21</sup> For years, legislators deliberated over federal regulation of the food industry until scenes of appalling and grossly unsanitary working conditions in meat packing factories, depicted in Upton Sinclair's *The Jungle*, shocked the public's conscience.<sup>22</sup> In response, lawmakers enacted the Pure Food and Drug Act (PFDA) and the Meat Inspection Act (MIA) in 1906.<sup>23</sup> The current U.S. food safety regulatory framework can be traced to these two laws.<sup>24</sup>

The PFDA prohibited the use in food of "any added poisonous or other added deleterious ingredient which may render such article injurious to health."<sup>25</sup> To enforce the law, the PFDA granted the Secretary of the United States Department of Agriculture (USDA) the authority to inspect foods<sup>26</sup> and report violations to the proper U.S. District Attorney.<sup>27</sup> The PFDA also provided criminal penalties for introducing adulterated or misbranded foods and drugs into interstate commerce.<sup>28</sup> Similarly, the MIA granted the USDA authority to inspect meat consumed in the U.S.<sup>29</sup>

Although Sinclair's exposé sparked outrage that was instrumental to the passage of the MIA, commentators widely credited passage of the PFDA to the much publicized experiment of Dr. Harvey Wiley.<sup>30</sup> Wiley's group of volunteers—called the "poison squad"—consumed doses of chemicals identical to those found in food preservatives.<sup>31</sup> Dr. Wiley's work raised

18. See BEE WILSON, *SWINDLED: THE DARK HISTORY OF FOOD FRAUD, FROM POISONED CANDY TO COUNTERFEIT COFFEE*, ch. 4, *Pink Margarine and Pure Ketchup* 152-212 (2008).

19. See *id.* at 153.

20. See *id.*

21. *Id.*

22. See *id.* at 190.

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

24. See *id.*

25. Pure Food and Drug Act, ch. 3915, § 7, 34 Stat. 768 (1906) [hereinafter Pure Food and Drug Act]; see *id.*

26. See Merrill & Francer, *supra* note 23, at 79.

27. Pure Food and Drug Act, *supra* note 25, § 4.

28. *Id.* ch. 3915.

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

30. Note, *Reforming the Food Safety System: What if Consolidation Isn't Enough?* 120 *HARV. L. REV.* 1345, 1348 (2007). For a detailed account of Dr. Wiley's experiment, see WILSON, *supra* note 18, at 188-90.

31. See WILSON, *supra* note 18, at 182-86.

public awareness of the harm in adulterated and misbranded foodstuffs.<sup>32</sup> As a result, the PFDA was also commonly referred to as the Wiley Act.<sup>33</sup> In 1907, Dr. Wiley became the head of the Bureau of Chemistry of the USDA,<sup>34</sup> which became the Food and Drug Administration.<sup>35</sup>

## 2. *The Federal Food, Drug & Cosmetic Act of 1938*

Even though proponents hailed the PFDA as an important breakthrough, many doubted its effectiveness due to its vague language on key requirements.<sup>36</sup> In 1938, Congress passed the Federal Food, Drug and Cosmetic Act (FD&C Act) which overhauled the regulatory framework created under the PFDA.<sup>37</sup> The passage of the 1938 Act resulted from the

32. *Reforming the Food Safety System*, *supra* note 30, at 1348.

33. *Id.*

34. See U.S. Dep't of Health and Human Serv., Food and Drug Admin, Harvey Washington Wiley, M.D., <http://www.fda.gov/AboutFDA/CommissionersPage/PastCommissioners/ucm113692.htm> (last visited Mar. 16, 2010).

35. *Id.*; see also Merrill & Francer, *supra* note 23, at 82 (discussing the development of the FDA). The Bureau later changed its name to the Food, Drug and Insecticide Administration and, in 1931, reorganized as the Food and Drug Administration (FDA). Jordan Paradise, Alison W. Tisdale, Ralph F. Hall & Efrosini Kokkoli, *Evaluating Oversight of Human Drugs and Medical Devices: A Case Study of the FDA and Implications for Nanobiotechnology*, 37 J.L. MED. & ETHICS 598, 599 (2009); see *Reforming the Food Safety System*, *supra* note 30, at 1348. In 1940, President Roosevelt incorporated the FDA into the Federal Security Agency. *Id.* Over a decade later, the FDA was moved under the Department of Health, Education, and Welfare (HEW). *Id.* In 1980, the HEW was split into two departments: the Department of Health and Human Services (HHS) and the Department of Education. The FDA has remained a part of the HHS ever since. Despite the historical shifts from one department to another, the FDA's ambition has consistently been "to assure that the products it regulates are safe and truthfully labeled." Max Sherman, *Developing a Labeling Compliance Program*, in *THE MEDICAL DEVICE INDUSTRY: SCIENCE, TECHNOLOGY, AND REGULATION IN A COMPETITIVE ENVIRONMENT* 399, 399 (Norman F. Estrin ed., 1990). Throughout its over one hundred year history, however, the FDA's ambition has often met setbacks and defeats, especially in the regulation of imported food and drugs.

36. See, e.g., *U.S. v. Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914). The government asserted that the respondent adulterated its flour in violation of § 7 of the PFDA by using nitrogen peroxide gas treatments to conceal the flour's inferior quality. *Id.* at 405. When the government sought to condemn the flour, however, the court denied its petition. *Id.* Interpreting the PFDA narrowly, the Court reasoned that, if Congress intended to prohibit *all* foods containing added poisonous or deleterious ingredients, it would have done so in explicit terms. *Id.* at 410-11. Thus, the Court stated that the Act "placed upon the Government the burden of establishing . . . that the added poisonous or deleterious substances must be such as may render such article injurious to health." *Id.* at 411. Because the government failed to prove the treated flour was actually injurious to a person's health, the Court held that "such flour, though having a small addition of poisonous or deleterious ingredients, may not be condemned under the [A]ct." *Id.* Thus, the PFDA required the government to prove in court that a particular ingredient was harmful in order to prevail in each case. See *id.* at 410-11 (referring to the fifth subdivision of § 7). This onerous burden significantly hindered the government's ability to maintain even an image of high standards for food and drugs.

37. See Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-399 (2000)) [hereinafter Federal Food, Drug, and Cosmetic Act]; PETER BARTON HUTT, RICHARD A. MERRILL, & LEWIS A. GROSSMAN, *FOOD AND DRUG LAW: CASE AND MATERIALS* (3d ed. 2007) at 12-13; Merrill & Francer, *supra* note 23, at 81.

reported deaths of over one hundred people who had taken an untested elixir drug, which appeared to be harmless but was in fact contaminated with fatal substances.<sup>38</sup> To avoid similar occurrences, the FD&C Act required drug manufacturers to prove the safety of any new drug and to receive FDA approval before placing it in interstate commerce.<sup>39</sup> It also expanded the FDA's power to regulate food safety, by authorizing FDA inspections of food manufacturing facilities and products,<sup>40</sup> establishing safety tolerances for unavoidable contaminants, and creating labeling standards.<sup>41</sup> Most importantly, the FD&C Act required courts to focus on the character of added substances and the conditions under which a product was manufactured.<sup>42</sup> Thus, the Act greatly enhanced the FDA's enforcement power by eliminating the government's burden to prove in food safety cases the causal link between added substances and injuries to human health.

Since its passage, Congress has amended the FD&C Act numerous times.<sup>43</sup> Many of the updates attempted to strike a balance between food safety and the food industry's pursuit of economic efficiency.<sup>44</sup> For example, with growing public concern over the use of pesticides in agricultural production, the 1954 Pesticide Chemicals Amendment to the Act set tolerance levels for their use instead of completely prohibiting the use of pesticides.<sup>45</sup> Similarly, the 1938 Act prohibited even trace levels of chemicals, which were deleterious in the absolute sense but relatively harmless when in the proper amount.<sup>46</sup> The Amendment of 1958 rolled back the 1938 Act's harsh treatment of food additives and made way for advancements in food preservation.<sup>47</sup>

38. SCHUMANN, ET AL., Food Safety Law 7 (1997); see Merrill & Francer, *supra* note 23, at 81.

39. SCHUMANN, ET AL., *supra* note 38, at 7; Merrill & Francer, *supra* note 23, at 81-82.

40. Merrill & Francer, *supra* note 23, at 81-82.

41. *Id.* at 82.

42. See, e.g., U.S. v. Ewig Bros. Co., 502 F.2d 715 (7th Cir. 1974). The government sought an injunction against the distributors of smoked fish containing the residues of *dichloro diphenyl trichloroethane* (DDT), a synthetic pesticide. See *id.* The defending distributors argued that the government could not prevail unless it proved that the DDT residues in its smoked fish made their product unfit for human consumption or otherwise injurious to health. See *id.* at 724 & n.29. The court held that DDT residues in the smoked fish were a "food additive" and that because the fish were not protected by any established tolerance for the inclusion of DDT, the fish were adulterated as a matter of law. See *id.* at 723-24. On appeal, the Court affirmed the order granting a permanent injunction in favor of the government. See *id.* at 726.

43. JAMES T. O'REILLY, 1 FOOD AND DRUG ADMINISTRATION § 3:5 (3d ed. 2007).

44. See *id.* § 3:5, at 3-19 ("Whether this supposition is true, the presence of the detail suggests anxiety about arbitrary administrative practice on the part of the FDA, a lingering suspicion growing out of the 1938 Act's encounter with the apple-growing industry.").

45. *Id.*

46. See Federal Food, Drug, and Cosmetic Act.

47. See Food Additives Amendment, Pub. L. No. 85-929, 72 Stat. 1784, 21 U.S.C. § 348 (1958); O'REILLY, *supra* note 43, § 3:6, at 3-20 ("After extensive hearings revealed a need to improve the regulatory process in the food-additive area, preapproval testing before marketing additives was the means selected.").

### 3. Other Laws and Agencies that Regulate Food Safety

This article primarily focuses on the FDA because it is the main U.S. party to the food safety agreement with the Chinese government.<sup>48</sup> The FDA “is responsible for ensuring the safety of roughly 80 percent of the U.S. food supply, including \$417 billion worth of domestic food and \$49 billion in imported food annually.”<sup>49</sup> In addition to the FDA, fifteen other federal agencies are responsible for different aspects of food safety mandated by thirty principal laws.<sup>50</sup> The following three agencies are worth mentioning:

- a) The United States Department of Agriculture Food Safety and Inspection Service (FSIS) regulates the nation’s commercial supply of meat, poultry, and egg products.<sup>51</sup>
- b) The Centers for Disease Control and Prevention (CDC) “leads federal efforts to gather data on foodborne illnesses, investigate foodborne illnesses and outbreaks, and monitor the effectiveness of prevention and control efforts in reducing foodborne illnesses. CDC also plays a key role in building state and local health department epidemiology, laboratory, and environmental health capacity to support foodborne disease surveillance and outbreak response.”<sup>52</sup>
- c) The Environmental Protection Agency (EPA) regulates the use of pesticides.<sup>53</sup> It is responsible both for pre-market registration of new pesticides and for “re-registration of older pesticides to ensure that they meet current scientific standards.”<sup>54</sup> Authorized by the Food Quality Protection Act of 1996, the EPA has undertaken “a comprehensive review of tolerances for pesticide residues in food, with an emphasis on increasing protection for infants and children as well as other vulnerable groups.”<sup>55</sup>

### B. The Enforcement Tools that Keep U.S. Made Food Safe

In practice, the enforcement of the FD&C Act consists of two general approaches: the outcome-based approach and the production-based

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48. See *infra* Part III of this paper.

49. SHAMES, *supra* note 8, at 1.

50. *Id.* at 1; ROBERT A. ROBINSON, MANAGING DIR., NAT’L RES. AND ENV’T, U.S. GOV’T ACCOUNTABILITY OFFICE (GAO), TESTIMONY BEFORE THE SUBCOMMITTEE ON THE FEDERAL WORKFORCE AND AGENCY ORGANIZATION, COMMITTEE ON GOVERNMENT REFORM, HOUSE OF REPRESENTATIVES, GAO-05-549T, OVERSEEING THE U.S. FOOD SUPPLY: STEPS SHOULD BE TAKEN TO REDUCE OVERLAPPING INSPECTIONS AND RELATED ACTIVITIES 3 (May 17, 2005), available at <http://www.gao.gov/new.items/d05549t.pdf>.

51. See U.S. Dep’t of Health and Human Services, Selected Federal Agencies with a Role in Food Safety, <http://www.foodsafety.gov/about/federal/index.html> (last visited Mar. 17, 2010).

52. *Id.*

53. See Env’tl Prot. Agency, Pesticides: Topical & Chemical Fact Sheets, <http://www.epa.gov/pesticides/factsheets/securyt.htm> (last visited Apr. 20, 2010).

54. *Id.*

55. *Id.*



approach.<sup>56</sup> When feasible, the FDA uses the outcome-based approach to screen the end results of production. Primarily under this approach, all end products that pass FDA inspection would be safe for consumption, assuming that the FDA could adequately inspect all end products and also effectively test for all major safety problems. Outcome-based enforcement tools also include the use of criminal prosecutions, disbarment, seizures, injunctions, voluntary recalls, warning letters, and negative publicity. In addition, the FDA applies the production-based approach to focus on key steps in a product's manufacturing process. This approach depends on a presumption that end products will be safe if producers follow FDA designated and proven-safe procedures. Production-based enforcement tools consist of Good Manufacturing Practices (GMP) and Hazard Analysis and Critical Control Point (HACCP).

### 1. *Factory Inspections*

In the context of regulating U.S. made food, most remedial measures are taken following FDA inspection of food factories.<sup>57</sup> Therefore, the FDA's power to conduct factory inspections is crucial to securing food safety. The FD&C Act authorizes FDA personnel to enter and conduct an inspection of a food manufacturer's warehouse, factory, or other location.<sup>58</sup> The FDA has wide discretion to decide when and how to conduct inspections.<sup>59</sup> In fact, courts rarely interfere with the FDA's inspection power unless the inspected firm can demonstrate unreasonableness.<sup>60</sup>

The coverage of an FDA inspection may vary to suit its particular purpose.<sup>61</sup> If the FDA has reason to believe that an article of food is adulter-

56. See *infra* Part I, 1.2(A)-1.2(G); see generally WILSON, *supra* note 18 (discussing various enforcement tools that the FDA uses).

57. Federal Food, Drug, and Cosmetic Act § 704, 21 U.S.C. § 374 (2009): § 374 Inspection:

(a) Right of agents to enter; scope of inspection; notice; promptness; exclusions. (1) For purposes of enforcement of this chapter, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein.

See also U.S. Food and Drug Admin., Investigation Operations Manual (2009), available at <http://www.fda.gov/ICECI/Inspections/IOM/ucm124442.htm> ("Mission: Protecting consumers and enhances [sic] public health by maximizing compliance of FDA-regulated products and minimizing risk associated with those products.").

58. Federal Food, Drug and Cosmetic Act § 704(a)(A).

59. O'Reilly, *supra* note 43, § 20:6, at 20-22.

60. *Id.*

61. *Id.* § 20:4, at 20-17 ("There are three principal types of FDA inspections; comprehensive, abbreviated, and directed inspections. The types of inspection conducted vary according to their purpose.").

ated and presents a serious health threat to humans or animals, an inspection can extend to all records related to the manufacturing, processing, packing, distribution, receipt, holding, or importation of the article, in any format (including hardcopy and electronic), and at any location.<sup>62</sup>

The FDA usually does not have to present a warrant and normally conducts an inspection with the consent of the inspected firm.<sup>63</sup> Refusal of entry, however, can result in serious consequences.<sup>64</sup> Upon refusal, an FDA official would certainly obtain a warrant to complete the inspection.<sup>65</sup> If the owner then refuses a warranted search, the U.S. Marshals can arrest him on the scene.<sup>66</sup> According to § 374(a), refusing a legitimate inspection request is a criminal violation of the FD&C Act punishable with up to one year of imprisonment and a fine of up to \$1,000.<sup>67</sup> In addition, the FDA can use the refusal as the basis for a civil action against the owner, which may result in seizure or an injunction.<sup>68</sup> Forcible actions against inspectors can also lead to criminal punishment.<sup>69</sup>

## 2. Criminal Sanctions

Criminal enforcement of the FD&C Act is the least utilized sanction.<sup>70</sup> The threat of imposing criminal sanctions, however, can provide a level of deterrence and thus secure food quality and safety.<sup>71</sup> Given the complexity of modern food making processes, imposing criminal liability depends on the underlying theory that consumers cannot protect themselves even by exercising the utmost of care. Thus, public interest in the purity of food justifies the idea that food manufacturers must be held to the highest standards of care.<sup>72</sup> Hence, in theory, criminal liability can force food makers to conform to the FD&C Act even when they are not under constant FDA oversight. This idea is consistent with the notion of industry self-regulation.<sup>73</sup> With limited resources, the FDA cannot realistically monitor the increasingly massive and sophisticated food industry; therefore, the possi-

62. Federal Food, Drug and Cosmetic Act § 414(a), 21 U.S.C. § 350c.

63. See O'REILLY, *supra* note 43, § 20:1, at 20-3.

64. See *id.*

65. *Id.* § 20:12, at 20-32.

66. *Id.* § 20:1, at 20-4.

67. See 21 U.S.C. §§ 331(f), 333(a)(1), 374(a); O'REILLY, *supra* note 43, § 20:14, at 20-34.

68. See O'REILLY, *supra* note 43, § 20:1, at 20-3.

69. *Id.* § 20:12, at 20-32.

70. *Id.* § 8:1, at 8-2.

71. See, e.g., Sam D. Fine, *The Philosophy of Enforcement*, 31 FOOD DRUG. COSM. L.J. 324, 325-26 (1976) (illustrating how after criminally prosecuting two pecan shellers, an independent sheller approached Mr. Fine saying, "Tell me what I have to do, Mr. Fine—I don't want to go to jail.").

72. *U.S. v. Park*, 421 U.S. 658, 671 (1975) ("The public interest in the purity of its food is so great as to warrant the imposition of the highest standard of care on distributors.") (quoting *Smith v. California*, 361 U.S. 147, 152 (1959)).

73. See, e.g., Luke McFarland, *Insufficient FDA Resources: Leveling the Playing Field and Reducing Fraud by Altering Incentives* 22-24 (2001) (unpublished manuscript, on file with author), available at <http://leda.law.harvard.edu/leda/data/372/McFarland.pdf>.

bility of imposing criminal liability remains an indispensable means of enforcement.

“Most violations of the FD&C Act potentially carry criminal penalties.”<sup>74</sup> Not every such violation, however, actually requires criminal liability. The FDA has discretion to decide whether to prosecute a particular violation.<sup>75</sup> In deciding whether to pursue criminal charges, the FDA usually considers the following factors: “continuing violations of law (e.g., continuing insanitary conditions in a food plant); violations of an obvious and flagrant nature (e.g., food warehouse overrun with rodents, birds and insects, which contains plainly contaminated products); and intentionally false or fraudulent violations.”<sup>76</sup>

One distinctive feature of criminal liability under the FD&C Act is its standard of “strict liability.”<sup>77</sup> That is, a person in charge of a food manufacturer that violates certain provisions of the Act can be held criminally liable without the government proving the *mens rea* “typically required in Anglo-American criminal law.”<sup>78</sup> In this context, strict liability applies where the person in charge had a “responsible relation” to a violation of the FD&C Act.<sup>79</sup> In *U.S. v. Park*,<sup>80</sup> the Court explained the reason why individuals who had a “responsible relationship” to the regulated products should be held to the highest standard of care:

The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them.<sup>81</sup>

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74. HUTT, MERRILL & GROSSMAN, *supra* note 37, at 1310.

75. *Id.* at 1319.

76. *Id.*

77. See Joseph E. Cole, *Environmental Criminal Liability: What Federal Officials Know (or Should Know) Can Hurt Them*, 54 A.F.L. REV. 1, 6-7 (2004) (“For statutes concerned with public health, safety, and welfare, however, courts have taken a different view. Generally, a public welfare statute without a standard for culpability will require the government to only prove the defendant had the responsibility and had either the authority to prevent or the ability to remedy a violation; the government does not have to show that the individual had the intent to violate the law or even any knowledge of the violation.”).

78. HUTT, MERRILL & GROSSMAN, *supra* note 37, at 1310.

79. *Id.*

80. See *U.S. v. Park*, 421 U.S. 658, 671 (1975). In this case, the FDA inspections revealed that Acme Markets had persistent problems with rat infestations in food storage areas. The FDA repeatedly urged the company’s CEO, Mr. John R. Park, to correct the violations. Mr. Park directed his subordinates to address the issues, which they did, but the infestations continued. At trial, Mr. Park was criminally fined \$250. Mr. Park appealed the decision asserting that he could not have done anything more than what his subordinates had done. Affirming the trial court’s decision, the Court concluded that “[Mr. Park] had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so.” *Id.* at 673-74.

81. *Id.* at 672.

Like the Sword of Damocles, the criminal “responsible relationship” test—albeit rarely used—exists as “a formidable tool” for FDA enforcement.<sup>82</sup> The criminal penalties for a single offense under the FD&C Act may consist of a year in jail and a \$100,000 fine.<sup>83</sup> If the violation caused death, the fine may reach \$250,000.<sup>84</sup> If the defendant is also convicted of wire fraud, mail fraud, or conspiracy, additional sanctions may apply. In fact, the maximum fine for multiple counts from a single event may reach \$500,000.<sup>85</sup> Additionally, the court may order the offender to cover the FDA’s investigation expenses.<sup>86</sup>

### 3. Seizures

Another FDA enforcement tool is government seizure of adulterated or misbranded food products.<sup>87</sup> Like criminal sanctions, seizure provides leverage for the FDA to pressure a firm to take appropriate actions to eliminate or prevent foodborne harm to the public.<sup>88</sup> To avoid seizure proceedings, firms usually opt for voluntary recalls of their potentially harmful products.<sup>89</sup>

During an FDA site inspection, the FDA may seize products because the FDA believes that the manufacturer’s products possess an immediate injury potential.<sup>90</sup> To initiate a seizure, the FDA works with a local U.S. attorney to file a complaint against the suspect products in federal district court.<sup>91</sup> After a court clerk signs the complaint, the FDA can then send U.S. Marshals to seize the property.<sup>92</sup>

A seizure action is more drastic than a regular civil action because it is executed according to admiralty procedures rather than standard civil procedures.<sup>93</sup> As a result, a seizure action may be conducted *in rem* against the defective products themselves and not against the owner of the prod-

82. O’REILLY, *supra* note 43, § 8:5, at 8-16.

83. See 21 U.S.C. § 333; *Id.* § 8:25, at 8-42.

84. O’REILLY, *supra* note 43, § 8:25, at 8-42.

85. *Id.*

86. *Id.* § 8:26, at 8-44.

87. See *U.S. Marshals Seize Sanitizer for Bacteria Problems*, ABC NEWS, Aug. 2, 2009, [http://news.yahoo.com/s/ap/20090802/ap\\_on\\_go\\_ot/us\\_sanitizer\\_seizure](http://news.yahoo.com/s/ap/20090802/ap_on_go_ot/us_sanitizer_seizure) (giving a recent example of the FDA’s seizure of medical devices).

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

89. See Eugene I. Lambert, *Recalls, Regulatory Letters and Publicity*, 31 FOOD DRUG COSM. L.J. 360, 360 (1976) (“Recalls perhaps can be characterized as do-it-yourself seizure actions.”).

90. See O’REILLY, *supra* note 43, § 7:4, at 7-15-16 (recognizing that another possible reason for seizure is dispute over nomenclature for ingredients).

91. *Id.*

92. *Id.* § 7:4, at 7-16.

93. See Federal Food, Drug and Cosmetic Act § 304(b), 21 U.S.C. § 334 (2006): § 334(b) Procedure; multiplicity of pending proceedings:

The article, equipment, or other thing proceeded against shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except

ucts.<sup>94</sup> Accordingly, a seizure action involves no party in opposition to the FDA. Additionally, procedures for these cases require no pre-seizure hearing, nor do they entitle the owner to any prior judicial finding of probable cause.<sup>95</sup> Instead, cases have held that a post-seizure hearing is sufficient.<sup>96</sup> Courts tend to accord the FDA great deference and often resolve challenges of seizures in the FDA's favor.<sup>97</sup>

#### 4. *Voluntary Recalls*

A recall is a means of removing consumer products from the market that violate the FD&C Act.<sup>98</sup> However, the FD&C Act does not explicitly authorize the FDA to conduct recalls of food products, except baby formula.<sup>99</sup> In practice, the FDA acquired the power to facilitate recalls by threatening to use other statutorily authorized enforcement methods, such as seizures and injunctions, to force manufacturers and distributors to remove their harmful food products from the market.<sup>100</sup> Thus, voluntary recalls are essentially "do-it-yourself seizure actions."<sup>101</sup>

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that on demand of either party any issue of fact joined in any such case shall be tried by jury.

94. See O'REILLY, *supra* note 43, § 7:5, at 7-22 ("Once the claimant [the owner of the seized goods] files the claim, the legal jurisdiction of the court changes from *in rem* jurisdiction over the product into *in personam* jurisdiction over the person or company who made the claim.")

95. See *id.* § 7:3, at 7-9.

96. *Id.*

97. *Id.*

98. 21 C.F.R. § 7.40(a) (2009):

Recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the Food and Drug Administration. Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective.

See also O'REILLY, *supra* note 43, § 21:1; Lambert, *supra* note 89, at 360.

99. Through later amendments, the FDA acquired authority to conduct mandatory recalls in certain areas. FD&C Act § 535(f) gives the FDA power to mandate the repurchase, repair, or replacement of radiation-emitting electronic products. 21 U.S.C. § 360ll(f) (2006). FD&C Act § 315(d) gives the FDA the power to order recall of a biological product that presents an imminent or substantial hazard to public health. 21 U.S.C. § 262(d) (2006). The Infant Formula Act of 1980 added current FD&C Act § 412(f), directing the FDA to prescribe the scope and extent of recalls of infant formulas. 21 U.S.C. § 350a(f) (2006). FD&C Act § 518(e) requires the FDA to order cessation of the distribution of medical devices in situations where there is a "reasonable probability that a device intended for human use would cause serious, adverse health consequences or death." 21 U.S.C. § 360h(e) (2006); see also HUTT, MERRILL & GROSSMAN, *supra* note 37, at 1304 (describing in detail the FDA's statutory power to conduct recalls).

100. See O'REILLY, *supra* note 43, § 21:1 at 21-3 (An FDA commissioner described the development of food recall this way: "There were some episodes of poisoning. We put out a public warning about them, and the next question was to the company: Are you going to get it off the market or shall we seize it? And from that beginning the recall system grew.") (quoting *Recall Procedures of the Food and Drug Administration: Hearings Before Subcomm. on Intergovernmental Relations, House Governmental Operations Comm.*, 91st Cong. (2d Sess. 1971)).

101. Lambert, *supra* note 89, at 360.

In 1978, the FDA issued guidelines on recall policy, procedures and industry responsibility.<sup>102</sup> Under the current guidelines, recalls take two forms: firm initiated or FDA initiated recalls.<sup>103</sup> A firm initiated recall occurs any time a firm voluntarily removes its product from the market on its own initiative or upon FDA request.<sup>104</sup> The FDA does not consider such an action a recall, however, if a firm merely retrieves its products for reasons other than violating the FD&C Act, or if the recall is due to a “minor or technical violation of the laws which the FDA administers.”<sup>105</sup> This distinction is important because the FDA issues public alerts for most recalls, which can negatively impact a firm’s reputation.<sup>106</sup> Alternatively, an FDA initiated recall occurs only in urgent situations or when a firm refuses to initiate a recall upon FDA request.<sup>107</sup> In either type of recall, the FDA assumes the supervisory role<sup>108</sup> and the recalling firm assumes primary responsibility for removing the unsafe products.<sup>109</sup>

During the consideration or administration of a recall, the FDA evaluates the product’s potential health hazard.<sup>110</sup> According to the seriousness

102. See 21 C.F.R. §§ 7.41–7.59 (2009) (incorporating the guidelines with the most recent updates and amendments).

103. 21 C.F.R. § 7.40(b) (2009).

104. *Id.* § 7.40(a).

105. O’REILLY, *supra* note 43, § 21:2, at 21-6.

106. See 21 C.F.R. § 7.50 (2009) (also stating that under certain circumstances, the FDA “will intentionally delay public notification of recalls of certain drugs and devices where the agency determines that public notification may cause unnecessary and harmful anxiety in patients and that initial consultation between patients and their physicians is essential.”); see also O’REILLY, *supra* note 43, § 21:2, at 21-7 (discussing the potential implications of the term “recall”).

107. 21 C.F.R. §§ 7.40(b), 7.45 (2009).

108. *Id.* § 7.46(b).

109. See O’REILLY, *supra* note 43, § 21:2, at 21-6 (“A *recall* is the removal or correction of a marketed product by a responsible firm.”).

110. 21 C.F.R. § 741(a) (2009):

An evaluation of the health hazard presented by a product being recalled or considered for recall . . . will take into account, but need not be limited to, the following factors:

- (1) Whether any disease or injuries have already occurred from the use of the product.
- (2) Whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.
- (3) Assessment of hazard to various segments of the population, e.g., children, surgical patients, pets, livestock, etc., who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.
- (4) Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed.
- (5) Assessment of the likelihood of occurrence of the hazard.
- (6) Assessment of the consequences (immediate or long-range) of occurrence of the hazard.

of the health hazard posed to the public, the FDA “assign[s] the recall a classification, i.e., Class I, Class II, or Class III, to indicate the relative degree of health hazard.”<sup>111</sup> Additionally, either the agency in an FDA initiated recall, or the recalling firm in a firm initiated recall, must develop a detailed strategy and submit it for FDA approval.<sup>112</sup> Along with a general assessment of the violation and the approaches the firm will take to resolve the food-borne threat, the strategy must specify how the firm will relay important information to the public and how it will conduct checks on the recall’s effectiveness.<sup>113</sup> Moreover, recalling firms must keep the FDA informed regarding the recall’s status.<sup>114</sup> Because public awareness is essential in preventing further harm, the FDA will ordinarily issue public warnings to alert consumers about the health hazard.<sup>115</sup> The FDA will also post public notifications of recalls in its weekly FDA Enforcement Report on the FDA website, providing a descriptive listing of each new recall according to its classification.<sup>116</sup>

### 5. *Good Manufacturing Practices Regulation (GMP)*

Good Manufacturing Practices (GMP) provide operational guidance to FDA regulated industries through the dissemination of systems-oriented requirements information for quality control and compliance.<sup>117</sup> GMP represents a shift from a system of discovering unsafe products after production to a system of monitoring the production process proactively to prevent violations and ensure safe results.<sup>118</sup> In the 1960s, the FDA began to standardize production procedures in certain industries.<sup>119</sup> To institute GMP—much like it instituted facilitated recalls—the FDA leverages statutorily authorized tools to effectively induce industries to self-regulate.<sup>120</sup>

The FDA’s rule making authority made it possible for a broad interpretation of the FD&C Act regarding the prohibition of “insanitary conditions.” Section 402(a) states: “A food shall be deemed to be adulterated . . . (4) if it has been prepared, packed, or held under *insanitary conditions* whereby it may have become contaminated with filth, or whereby it may

111. *Id.* § 7.41(b).

112. *Id.* § 7.46(a).

113. *See generally id.* § 7.42.

114. *See id.* § 7.46(a).

115. *See id.* § 7.50.

116. *See id.*

117. *See* 21 U.S.C. § 371(a) (2009) (“The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is vested in the Secretary [of Health and Human Services (HHS)].”); 21 U.S.C. § 342(a) (2006) (“A food shall be deemed to be adulterated . . . (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health . . . .”); 21 C.F.R. pt. 110.5 (2008).

118. *See* O’REILLY, *supra* note 43, § 23:1, at 23-2.

119. *See* O’REILLY, *supra* note 43, § 23:1, at 23-2 (“GMPs gained their first statutory power from the 1962 drug amendments, and the FDA later received full and detailed authority over medical device manufacturing practices in the 1976 Medical Device Amendments.”).

120. *See id.* § 23:1, at 23-3.

have been rendered injurious to health . . . .”<sup>121</sup> Congress, however, fell short of defining within the Act what exactly “insanitary condition” meant.<sup>122</sup> Construing the provision in its favor, the FDA seized the opportunity to define the term “insanitary conditions” by promulgating detailed GMP regulations.<sup>123</sup> As codified in 21 C.F.R. Part 110, the GMP regulations standardize production procedures in certain industries.<sup>124</sup> Essentially, any given GMP provides an FDA inspection benchmark to measure for an insanitary condition. From an enforcement point of view, GMP benefits both the FDA and the regulated industries. By checking production processes, GMP enables the FDA to find violations at an early stage and thus prevent the public from being injured in the first place. From an industry perspective, GMP provides certainty by specifying what to expect from an FDA inspection.

Although the FD&C Act does not specifically authorize GMP, courts have generally supported the FDA’s interpretation of “insanitary conditions” in light of the compelling interest in public safety. In *United States v. Nova Scotia Food Products Corp.*,<sup>125</sup> the defendant challenged the FDA’s authority to enforce GMP. The court held that “[t]he public interest will not permit invalidation simply on the basis of a lack of delegated statutory authority in this case.”<sup>126</sup>

## 6. Tort Litigation

No provisions in the FD&C Act expressly authorize a private cause of action, and “the Supreme Court declared that only the federal government may enforce the FD&C Act.”<sup>127</sup> Thus, a citizen cannot function as a private attorney general to supplement enforcement of the FD&C Act.<sup>128</sup> A private party injured by unsafe food, however, can bring a common law tort claim against the manufacturer.<sup>129</sup> As a result, tort litigation provides another important tool to compel industries to ensure food safety.<sup>130</sup> The threat of tort litigation is akin to an outcome-based enforcement approach because tort liability can only be imposed after the harm has occurred.

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121. Federal Food, Drug, and Cosmetic Act § 402(a)(4), 21 U.S.C. 342(a)(4) (2006) (emphasis added).

122. See O’REILLY, *supra* note 43, § 23:2, at 23-6.

123. See 21 C.F.R. pt. 110

124. *Id.*

125. *U.S. v. Nova Scotia Food Prod. Corp.*, 568 F.2d 240 (2d Cir. 1977).

126. *Id.* at 248.

127. HUTT, MERRILL & GROSSMAN, *supra* note 37, at 1467.

128. *Id.* at 1464.

129. See generally DAVID G. OWEN, PRODUCTS LIABILITY LAW 460-64 (2005).

130. See James T. O’Reilly, *Are We Cutting the GRAS? Food Safety Perceptions are Diminished by Dysfunctional Bureaucratic Silos*, 59 FOOD & DRUG L.J. 417, 421 (2004) (“Liability litigation avoidance is an important, disciplining factor in the safety decisions made by food processors.”).



## II. Reforming the Food Safety System

### A. The Scope of the Problem

Each year, there are approximately seventy-six million cases of food-borne illnesses resulting in 325,000 hospitalizations and 5,000 deaths in the United States.<sup>131</sup> As a result, the FDA has been under constant criticism for its failure to reduce outbreaks.<sup>132</sup> Some commentators, however, point out that the blame is largely misplaced because the FDA is substantially underfunded.<sup>133</sup> While the FDA's responsibility continues to expand, its budget actually decreases in relevant terms.<sup>134</sup> An FDA analysis indicated that, "[a]s long as the resources available to FDA do not keep up with the realities of increasing costs . . . it is increasingly difficult for FDA to perform in a way that meets public expectations."<sup>135</sup> Due to this lack of funding, the number of inspections of domestic food processing facilities has dropped from 50,000 in 1972 to less than 10,000 in 2006, a drop of more than 80%.<sup>136</sup> Even with the assistance of states, the FDA can only inspect 9% of the 210,000 food establishments each year.<sup>137</sup> With decreasing inspection rates, outbreaks of food-borne illnesses have increased rapidly.<sup>138</sup>

### B. The Food Safety Enhancement Act of 2009

In response to recent food poisoning epidemics, the legislature has proposed several bills to improve food safety.<sup>139</sup> On July 30, 2009, the U.S. House of Representatives passed the Food Safety Enhancement Act (FSEA), which is currently pending in the U.S. Senate.<sup>140</sup> The FSEA proposes major amendments to the FD&C Act.<sup>141</sup>

131. CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC), DEP'T OF HEALTH AND HUMAN SERV., *FOODBORNE ILLNESS: FREQUENTLY ASKED QUESTIONS 5* (2005), available at [http://www.cdc.gov/ncidod/dbmd/diseaseinfo/files/foodborne\\_illness\\_FAQ.pdf](http://www.cdc.gov/ncidod/dbmd/diseaseinfo/files/foodborne_illness_FAQ.pdf); see also REP. HENRY A. WAXMAN, RANKING MINORITY MEMBER, COMM. ON GOV'T REFORM, H.R., *FACT SHEET: WEAKNESSES IN FDA'S FOOD SAFETY SYSTEM 1* (Oct. 30, 2006), available at <http://oversight.house.gov/images/stories/documents/20061101115143-67937.pdf>.

132. See, e.g., DeWaal & Plunkett, *supra* note 11 (criticizing the FDA and calling for reform).

133. See William Hubbard, *Wrongly Blaming the FDA*, WASH. POST, May 8, 2006, at A19.

134. Ricardo Alonso-Zaldivar, *Spinach Scare's Larger Warning: Tight FDA Budgets Have Cut Produce Inspection. Compliance with Safety Rules is Voluntary*, L.A. TIMES, Sep. 22, 2006, at A1.

135. *Id.*

136. See WAXMAN, *supra* note 131, at 2; Hubbard, *supra* note 133.

137. See WAXMAN, *supra* note 131, at 3.

138. See DeWaal & Plunkett, *supra* note 11.

139. See Food Safety Modernization Act of 2009, H.R. 875, 111th Cong. (2009); Food and Drug Administration Globalization Act of 2009, H.R. 759, 111th Cong. (2009); Safe Food Enforcement, Assessment, Standards, and Targeting Act of 2009, H.R. 1332, 111th Cong. (2009); FDA Safety Modernization Act, S. 510, 111th Cong. (2009).

140. See Food Safety Enhancement Act of 2009, H.R. 2749, 111th Cong. (2009).

141. See COMM. ON ENERGY AND COMMERCE, H.R., 111TH CONG., SECTION-BY-SECTION SUMMARY OF H.R. 2749, THE FOOD SAFETY ENHANCEMENT ACT OF 2009 (July 2009), available at [http://energycommerce.house.gov/Press\\_111/20090729/hr2749\\_sectionsummary.pdf](http://energycommerce.house.gov/Press_111/20090729/hr2749_sectionsummary.pdf).

## 1. *Enhancing Production-based Enforcement Tools*

The FSEA emphasizes production-based supervision. First, the FSEA would require that food facilities register with the FDA and pay a \$500 annual registration fee.<sup>142</sup> In addition, the FSEA would obligate food facilities to provide contact information, the primary purpose of their establishments, and all the trade names under which their facilities conduct business.<sup>143</sup> It would authorize the FDA to suspend registration if a food manufacturer has violated the law in a way that is likely to cause a serious health hazard or death.<sup>144</sup> Second, the FSEA would require food facilities to develop and implement a food safety plan. Food facilities would be required to conduct a hazard analysis and take preventative measures to ensure food safety.<sup>145</sup> The law would require the FDA to identify and publish the “most significant food-borne contaminants and the most significant resulting hazards” every two years.<sup>146</sup> Third, the FSEA would set a risk-based inspection schedule and authorize the FDA to gain access to food facility records.<sup>147</sup> It would mandate that the FDA randomly inspect high-risk (category 1) facilities every six to twelve months; low risk (category 2) facilities every eighteen to thirty-six months; and facilities that hold food (category 3) every five years.<sup>148</sup> The FDA would be required to make an annual report to Congress on the inspections of food facilities.<sup>149</sup> Furthermore, the FSEA would require the FDA to establish a tracing system that would keep track of the origin and distribution history of every food product it regulates.<sup>150</sup> In the context of imports, the FSEA would mandate that imported foods be accompanied by a valid certificate verifying that the foods comply with the FD&C Act.<sup>151</sup>

## 2. *Enhancing Outcome-based Enforcement Tools*

Additionally, the FSEA addresses outcome-based enhancements. First, it would authorize the FDA to conduct mandatory recalls of adulterated or misbranded products.<sup>152</sup> In addition, the FSEA would increase detention of foods suspected of being adulterated or misbranded from thirty days to sixty days.<sup>153</sup> Second, the FSEA would increase prison terms from one to ten years for knowing violations of the FD&C Act’s provisions concerning misbranded or adulterated food.<sup>154</sup>

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142. *Id.* at 3.

143. Food Safety Enhancement Act of 2009, H.R. 2749 § 101(b)(3).

144. *Id.* §§ 101(b)(4)-101(b)(5).

145. *Id.* § 102.

146. *Id.* § 103(b).

147. *Id.* § 106.

148. *Id.* § 105(a).

149. *Id.* § 105(b).

150. *Id.* § 107.

151. *Id.* § 109.

152. *Id.* § 111(b).

153. See 21 U.S.C. § 334(h) (2006); *Id.* § 132.

154. See 21 U.S.C. § 333; Food Safety Enhancement Act of 2009, H.R. 2749 § 134.

While it is unclear whether the U.S. Senate will pass the FSEA, or other proposed bills on food safety, these efforts show that lawmakers are concerned with the effect inadequate funding is having on the application of traditional outcome-based and production-based enforcement tools. With over a hundred years of practice, the two enforcement tools, when properly funded, have proven relatively effective in ensuring food safety.

### III. The FDA's Weakened Enforcement in the Context of Food Imports

Although the public is frustrated with the enforcement of the FD&C Act in the domestic food context, it is even more enraged that enforcement for imported foods is even weaker.<sup>155</sup> The following section explores the hurdles that have prevented both outcome-based and production-based enforcement from producing a deterrent effect on foreign food manufacturers.

#### A. FDA's Refusal of Entry

Theoretically, the FDA "has broad power to inspect, detain, and refuse entry to imported products"<sup>156</sup> within its jurisdiction.<sup>157</sup> Since the FDA need not prove that goods are actually adulterated, only that they appear to be adulterated, the standard to justify refusal is low.<sup>158</sup> The FDA may set terms for the relabeling or reconditioning of goods and may even order owners to destroy their goods.<sup>159</sup> Legal challenges to FDA refusals of entry are difficult and courts usually "decline to intrude on [the FDA's] discretion."<sup>160</sup>

#### B. Weakened Enforcement

Ironically, the FDA's broad power to regulate foreign products does not result in safe imports.<sup>161</sup> In practice, the FDA is unable to fully utilize either the outcome-based or production-based tools to regulate imported food due to lack of resources.<sup>162</sup>

##### 1. Weakened Outcome-based Tools

Over the last decade, the United States experienced a rapid increase in the import of agricultural and seafood products. From 1997 to 2007, the import value of these products increased by 94%, growing in overall value

155. See DeWaal & Plunkett, *supra* note 11, at 3.

156. O'REILLY, *supra* note 43, § 28:1, at 28-1.

157. See Federal Food, Drug, and Cosmetic Act § 801(a), 21 U.S.C. 381(a); O'REILLY, *supra* note 43, § 28:3, at 28-3.

158. See Federal Food Drug and Cosmetic Act § 801(a); O'REILLY, *supra* note 43, § 28:3, at 28-3.

159. See O'REILLY, *supra* note 43, § 28:2, at 28-3.

160. *Id.* § 28:3, at 28-3.

161. See, e.g., Elizabeth Williamson, *FDA Was Aware of Dangers to Food*, WASH. POST, Apr. 23, 2007, at A1.

162. See generally WAXMAN, *supra* note 131.

from \$43 billion to \$83.6 billion.<sup>163</sup> By volume, the increase was 35% during the same period.<sup>164</sup> Despite the dramatic increase of imported agricultural and seafood products, the FDA's budget has not increased proportionally.<sup>165</sup> In 2007, the FDA had only 450 inspectors scattered over 300 ports of entry.<sup>166</sup> As a result, the FDA was only able to conduct physical inspections of just over 1% of food imports.<sup>167</sup> A Congressional study revealed that FDA inspectors in San Francisco have an average of only thirty seconds to decide whether they should subject a particular shipment from abroad to further intensive investigation.<sup>168</sup> Without adequate inspections, the outcome-based tools, such as seizure and injunction, simply cannot be relied on to deter foreign producers from sending harmful food to the United States.

## 2. Weakened Production-based Tools

Production-based tools are even further weakened in the context of imports. Without regular periodic audits, foreign factories are not likely to take the GMP or the HACCP processes seriously because compliance with these procedures requires additional costs.<sup>169</sup> The appallingly low inspection rate at ports of entry has further emboldened foreign firms to cut corners without worrying about detection.<sup>170</sup> Even if the FDA acquires the right, mainly through bilateral agreements with foreign governments, to inspect foreign food manufacturers, it cannot realistically afford to inspect them as frequently as it inspects U.S. firms due to limited resources.<sup>171</sup> In addition, cultural and linguistic barriers add to the difficulties the FDA faces in conducting efficient inspections of foreign manufacturers. In 2008, in response to deaths caused by Heparin, a blood thinner, the FDA inspected a plant in China that they believed produced the faulty products.<sup>172</sup> It later turned out that the FDA had inspected the wrong plant,

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163. BECKER, *supra* note 9, at 1.

164. *Id.*

165. See WAXMAN, *supra* note 131, at 1.

166. BECKER, *supra* note 9, at 4.

167. *Id.*

168. See *Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply?: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 110th Cong. 377 (2007); Renea Merle & Michael Abramowitz, *FDA Faulted in Safety Lapse: White House Orders Study of Imports*, WASH. POST, July 18, 2007, at D1.

169. See, e.g., *The Heparin Disaster: Chinese Counterfeits and American Failures: Before the Subcomm. on Oversight and Investigation of the House Comm. on Energy and Commerce*, 110th Cong. 4 (2008) [hereinafter *The Heparin Disaster*] (describing how more frequent inspections and audits of Chinese factories could have prevented the Heparin Disaster).

170. FDA SCIENCE BOARD, SUBCOMM. ON SCIENCE AND TECHNOLOGY, *FDA SCIENCE AND MISSION AT RISK* 21 (2007).

171. See DeWaal & Plunkett, *supra* note 11, at 4, 12 (describing the FDA's lack of resources as well as proposed and pending legislation calling for inspection of foreign plants).

172. See *The Heparin Disaster*, *supra* note 169, at 2.

which bore a name similar to that of the real perpetrator.<sup>173</sup>

Furthermore, unannounced audits or inspections of foreign facilities are almost impossible to conduct because the FDA can only access the facilities with the “permission of the foreign government.”<sup>174</sup> During the pet food scandal of 2007, the FDA intended to inspect the suspected factories in China.<sup>175</sup> The Chinese government deliberately delayed the FDA inspectors’ visas.<sup>176</sup> One report stated that when the inspectors finally reached the two suspected plants in southern China, one plant had already been bulldozed and the other one was deserted.<sup>177</sup> According to another report, the owner of the factory not only bulldozed the building, but also deeply plowed the ground to ensure that U.S. inspectors would not find any trace of melamine.<sup>178</sup>

### C. Challenges of Suing Chinese Manufacturers in the United States

U.S. tort litigation does not provide effective deterrence to Chinese food manufacturers for several reasons. First, it is difficult to identify the manufacturer that produced the faulty food products.<sup>179</sup> The Chinese food industry is highly fragmented, with numerous small firms scattered around the country.<sup>180</sup> Market transactions in China are often conducted on a cash basis, which makes it impossible to trace the origin of products.<sup>181</sup> Many imports coming into the United States bear only “Made in China” labels without specifying the name of the manufacturer.<sup>182</sup> Identifying a Chinese manufacturer can be a time consuming and expensive undertaking, especially for a private party.<sup>183</sup>

Second, even if the plaintiff is able to identify the Chinese food manufacturer, he may find that obtaining evidence in China is a daunting task. Rule 28(b) of the U.S. Federal Rules of Civil Procedure spells out a number

173. Marc Kaufman, *FDA Says it Approved the Wrong Drug Plant*, WASH. POST, Feb. 19, 2008, at A1.

174. See, e.g., BECKER, *supra* note 9, at 5.

175. See Michael Rogers, Answers at FDA Press Conference on the Pet Food Recall (Apr. 19, 2007), at 5-6 (discussing the FDA’s intention to inspect factories in China and the attendant difficulties).

176. See SUBCOMM. ON OVERSIGHT AND INVESTIGATIONS, 110TH CONG., STAFF TRIP REPORT: FOOD FROM CHINA: CAN WE IMPORT SAFELY? 7 n.10 (2007), available at [http://energycommerce.house.gov/Press\\_110/110-rpt.100407.ChinaTripReport.pdf](http://energycommerce.house.gov/Press_110/110-rpt.100407.ChinaTripReport.pdf).

177. *Id.*

178. Gong Jing, Sanjuqing’an Qianke: Chongwu Duliang Zhi Mei Shushi Chongwu Siwang Shangqian Chongwu Huan Shenbing [A Criminal Record of Melamine: Poisonous Pet Food Kills Dozens of Pets and Thousands of Pets Gets Kidney Disease in the United States], CAIJING, Sept. 12, 2008, available at <http://finance.baidu.com/fengbao/2008-09-12/111432189932.html>.

179. Frank Greve & Grace Chung, *Chinese Makers of Shoddy Goods Rarely Face U.S. Sanctions*, McClatchy Newspapers, June 30, 2009, available at [http://www.mcclatchydc.com/staff/frank\\_greve/v-print/story/70986.html](http://www.mcclatchydc.com/staff/frank_greve/v-print/story/70986.html).

180. See *infra* Part IV 4.4 of this article.

181. See, e.g., U.S. DEP’T. OF COMMERCE, OFFICE OF INSPECTOR GENERAL, INSPECTION REPORT NO. IPE-10915, US&FCS CHINA IS MEETING THE DEMANDS OF ITS CLIENT, BUT INTERNAL OPERATIONS NEED ATTENTION 20 (Sept. 1999).

182. Greve & Chung, *supra* note 179.

183. *Id.*

of ways to take depositions in a foreign country.<sup>184</sup> China, however, has greatly restricted the ability of foreign parties to take depositions.<sup>185</sup> Currently, China allows only foreign diplomatic personnel to conduct depositions in China under limited circumstances.<sup>186</sup> Even though China and the United States are both parties to the Hague Convention on Taking Evidence Abroad,<sup>187</sup> China has an official reservation to adopting Articles Sixteen through Twenty-two of the Convention.<sup>188</sup> As a result, “[t]aking evidence in China for use in foreign courts is problematic.”<sup>189</sup> Any violation may result in the arrest or detention of the U.S. citizen participating in the deposition.<sup>190</sup>

Third, even if the plaintiff overcomes these procedural hurdles and wins damages, he may find it difficult to enforce a U.S. judgment in China, particularly because the defendant will likely lack attachable assets in the United States.<sup>191</sup> In order to enforce a foreign judgment in China, Article 265 of the Chinese Civil Procedure Law<sup>192</sup> requires the existence of a

184. FED. R. CIV. P. 28(b):  
In a Foreign Country.

(1) In General.

A deposition may be taken in a foreign country:

(A) under an applicable treaty or convention;

(B) under a letter of request, whether or not captioned a “letter rogatory”;

(C) on notice, before a person authorized to administer oaths either by federal law or by the law in the place of examination; or

(D) before a person commissioned by the court to administer any necessary oath and take testimony.

(2) Issuing a Letter of Request or a Commission.

A letter of request, a commission, or both may be issued:

(A) on appropriate terms after an application and notice of it; and

(B) without a showing that taking the deposition in another manner is impracticable or inconvenient.

(3) Form of a Request, Notice, or Commission.

When a letter of request or any other device is used according to a treaty or convention, it must be captioned in the form prescribed by that treaty or convention. A letter of request may be addressed “To the Appropriate Authority in [name of country].” A deposition notice or a commission must designate by name or descriptive title the person before whom the deposition is to be taken.

185. See U.S. DEP’T. OF STATE, BUREAU OF CONSULAR AFFAIRS, CHINA JUDICIAL ASSISTANCE (2010), [http://travel.state.gov/law/info/judicial/judicial\\_694.html](http://travel.state.gov/law/info/judicial/judicial_694.html) [hereinafter CHINA JUDICIAL ASSISTANCE].

186. See *id.*

187. Convention on the Taking of Evidence Abroad in Civil or Commercial Matters, Nov. 8, 1972, 23 U.S.T. 2555, 847 U.N.T.S. 241.

188. See CHINA JUDICIAL ASSISTANCE, *supra* note 185.

189. *Id.*

190. See *id.*

191. Greve & Chung, *supra* note 179.

192. Zhonghua Renmin Gonghe Guo Min Shi Susong Fa (2007 Xouzheng) [The Law of Civil Litigation Procedure of the People’s Republic of China (as amended in 2007)] (promulgated by the Standing Comm. Nat’l People’s Cong., Apr. 9, 1991) (P.R.C.) [hereinafter Chinese Civil Procedure Law], translated at <http://www.lawinfochina.com/>.

Article 265: If a legally effective judgment or ruling made by a foreign court seeks the recognition and enforcement of a people’s court of the People’s Repub-

treaty of reciprocity. Currently there is no bilateral or multilateral treaty between the United States and China that obligates China to recognize and enforce U.S. judgments.<sup>193</sup>

#### D. Challenges of Suing U.S. Retailers

Given the difficulties associated with suing Chinese manufacturers, consumers might naturally assume they will be able to sue the U.S. retailers of Chinese-made products. Unfortunately, they will be disappointed to find that a growing number of states have enacted statutes, with some complicated exceptions, that shield such retailers from strict liability.<sup>194</sup>

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lic of China, the party may directly apply to the intermediate people's court of the People's Republic of China that has the jurisdiction over the case for the recognition and enforcement, or the foreign court may, according to the provisions of the international treaties concluded or acceded to by the People's Republic of China or based on the principle of reciprocity, request the recognition and enforcement of a people's court.

Article 266: After a people's court of the People's Republic of China reviews an application or pleading for the recognition and enforcement of a legally effective judgment or ruling rendered by a foreign court according to the international treaties concluded or acceded to by the People's Republic of China or based on the principle of reciprocity, if the court considers that such a judgment or ruling does not contradict the basic principles of the laws of the People's Republic of China nor violates the national, social, and public interest of China, the court may render a ruling to recognize its force. Where the enforcement is necessary, the court may issue an order to enforce a foreign judgment according to the relevant provisions of this Law. If a legally effective judgment or ruling rendered by a foreign court contradicts the basic principles of the law of the People's Republic of China or the national, social, and public interest of China, the people's court shall reject the application of recognition and enforcement.

193. Greve & Chung, *supra* note 179; see also Donald C. Clarke, *The Enforcement of United States Court Judgments in China: A Research Note 2* (George Washington Univ. Law Sch. Pub. Law Working Paper No. 236, May 27, 2004), available at <http://ssrn.com/abstract=943922>.

194. See, e.g., TEX. CIV. PRAC. & REM. CODE ANN. § 82.003(a)(6) (Vernon 2009):

Liability of Nonmanufacturing Sellers:

(a) A seller that did not manufacture a product is not liable for harm caused to the claimant by that product unless the claimant proves: [the manufacturer of the product is insolvent; not subject to jurisdiction of the court; or the seller actually knew of the defect to the product at the time the seller supplied the product, etc.].

COLO. REV. STAT. § 13-21-402 (2008):

Innocent Seller:

(1) No product liability action shall be commenced or maintained against any seller of a product unless said seller is also the manufacturer of said product or the manufacturer of the part thereof giving rise to the product liability action. . . .

(2) If jurisdiction cannot be obtained over a particular manufacturer of a product or a part of a product alleged to be defective, then that manufacturer's principal distributor or seller over whom jurisdiction can be obtained shall be deemed, for the purposes of this section, the manufacturer of the product.

IND. CODE ANN. § 34-20-2-3 (LexisNexis 2004):

Actions against sellers limited:

A product liability action based on the doctrine of strict liability in tort may not be commenced or maintained against a seller of a product that is

There used to be a bright-line rule stating that retailers were strictly liable for the defective products they sold. This strict liability doctrine originated in *Vandermark v. Ford Motor Co.*<sup>195</sup> In *Vandermark*, the plaintiff, who was injured in an automobile accident caused by defective brakes, sued both the manufacturer and the automobile dealer.<sup>196</sup> The court held that both were strictly liable for the plaintiff's injuries.<sup>197</sup> Writing for the court, Judge Traynor gave two primary reasons why retailers were subject to strict liability.<sup>198</sup> First, retailers are "an integral part of the overall producing and marketing enterprise."<sup>199</sup> Therefore, they are in a position to pressure the manufacturer and assure maximum protection for consumers.<sup>200</sup> Since the manufacturer and the retailer are involved in an on-going course of business, they are able to calculate the costs of accidents and allocate them accordingly. Second, retailers are often the only party the plaintiff can identify, and if the retailer is not held liable, the plaintiff could be left without a remedy.<sup>201</sup> "Strict liability on the manufacturer and retailer alike affords maximum protection to the injured plaintiff and works no injustice to the defendants, for they can adjust the costs of such protection between them in the course of their continuing business relationship."<sup>202</sup> Many state courts subsequently followed *Vandermark*.<sup>203</sup> The Restatement (Second) of Torts also embraced this idea in § 402A.<sup>204</sup>

With the publication of the Model Uniform Products Liability Act in 1979, some states began a trend of moving away from *Vandermark*.<sup>205</sup> Opponents of *Vandermark* proffered pro-business arguments that retailers are not in control of the production process and so are not in the position

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alleged to contain or possess a defective condition unreasonably dangerous to the user or consumer unless the seller is a manufacturer of the product or of the part of the product alleged to be defective.

N.C. GEN. STAT. § 99B-2(a) (2009):

No product liability action, except an action for breach of express warranty, shall be commenced or maintained against any seller when the product was acquired and sold by the seller in a sealed container or when the product was acquired and sold by the seller under circumstances in which the seller was afforded no reasonable opportunity to inspect the product in such a manner that would have or should have, in the exercise of reasonable care, revealed the existence of the condition complained of, unless the seller damaged or mishandled the product while in his possession; provided, that the provisions of this section shall not apply if the manufacturer of the product is not subject to the jurisdiction of the courts of this State or if such manufacturer has been judicially declared insolvent.

195. *Vandermark v. Ford Motor Co.*, 391 P.2d 168 (Ca. 1964); see OWEN, *supra* note 129, at 959.

196. See *Vandermark*, 391 P.2d at 169.

197. *Id.* at 172.

198. See *id.* at 171-72.

199. *Id.* at 171.

200. See *id.*

201. See *id.* at 171-72.

202. *Id.* at 172.

203. See OWEN, *supra* note 129, at 959.

204. See *id.*

205. See Frank J. Cavico Jr., *The Strict Tort Liability of Retailers, Wholesalers, and Distributors of Defective Products*, 12 NOVA L. REV. 213, 237-41 (1987).



to prevent the production of defective products.<sup>206</sup> Retailers lack sufficient information and thus are ill-equipped to defend themselves.<sup>207</sup> In addition, because *Vandermark* gave courts greater ability to assert personal jurisdiction over nonresident manufacturers, it became inefficient for retailers to waste resources on indemnity lawsuits against manufacturers instead of simply requiring plaintiffs to sue the manufacturers directly in the first place.<sup>208</sup>

Despite the fact that the Restatement (Third) of Torts reaffirmed *Vandermark*, a number of state statutes followed the Model Uniform Product Liability Act, which significantly limits strict liability for retailers.<sup>209</sup> These statutes typically create two major exceptions: retailers are strictly liable (1) if the manufacturer of a defective product “is not subject to the jurisdiction of the court;” or (2) if the manufacturer is insolvent.<sup>210</sup>

Unfortunately, these two exceptions generally will not provide U.S. consumers of Chinese imports with an adequate remedy. First, although the indirect and tenuous role a large number of small Chinese manufacturers play in distribution will not meet the minimum contacts test,<sup>211</sup> many Chinese manufacturers set up U.S. branch offices to promote their products, which may be sufficient to subject them to state court jurisdiction.<sup>212</sup> Thus, in many cases, a consumer will not be able to invoke the first exception to the retailer’s strict liability protection. The second exception—manufacturer insolvency—is more complicated in the context of Chinese imports. The Chinese bankruptcy law is still in its infancy, thus Chinese courts are reluctant to deal with bankruptcy cases.<sup>213</sup> When a Chinese manufacturer’s defective products cause injuries in the United States, the Chinese government tends to respond by revoking the manufacturer’s license and shutting it down rather than declaring it bankrupt.<sup>214</sup> As a result, the consumer will find it difficult to argue that the retailer should be held strictly liable because the Chinese manufacturer is not insolvent but merely shut down by the government.<sup>215</sup> Therefore, a consumer’s only feasible course of action, when injured by a Chinese-made product, will likely be to sue the Chinese manufacturer in a U.S. court. However, given that Chinese manufacturers predominately do not maintain attachable assets in the United States, a consumer who can otherwise successfully establish jurisdiction and obtain a favorable judgment will not be able to collect

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206. See Adam Feeney, *In Search of a Remedy: Do State Laws Exempting Sellers from Strict Liability Adequately Protect Consumers Harmed by Defective Chinese-Manufactured Products?*, 34 J. CORP. L. 567, 571 (2009).

207. See *id.*

208. See *id.*

209. See OWEN, *supra* note 129, at 960.

210. *Id.*

211. See Hao Huang, *Maximizing Chinese Imports’ Compliance with United States Safety and Quality Standards: Carrot and Stick from Whom?*, 18 S. CAL. INTERDISC. L.J. 131, 150–51 (2008).

212. *But cf. id.*

213. See Feeney, *supra* note 206, at 581.

214. *Id.*

215. See *id.*

domestically.<sup>216</sup> Consequently, the consumer will have to confront the legal hurdle of enforcing a U.S. judgment in China.

Finally, it's noteworthy that Georgia statutes "exempt non-manufacturers unconditionally from strict products liability in tort."<sup>217</sup> Therefore, Georgia consumers of Chinese-made products will have no way to sue U.S. retailers, even if they were somehow able to meet the above noted exceptions.<sup>218</sup> The statutory limitation on retailers' strict liability is based on the assumption that consumers can always bring a tort action against manufacturers.<sup>219</sup> This assumption is true in the context of U.S.-made products, but not imports.

In sum, although the FDA has wide discretion to refuse entry of defective imports, the agency is unable to conduct adequate inspections at every port of entry to detect defective products. Thus, the traditional outcome-based enforcement tools provide ineffective deterrence to Chinese manufacturers. Furthermore, with insurmountable legal hurdles, consumers are discouraged from resorting to litigation against Chinese manufacturers in U.S. courts.

#### IV. Outsourcing Regulatory Power to China

In response to the pet food scandal in 2007 and other high profile recalls of Chinese-made products, the Bush Administration created an Interagency Working Group (IWG) to tackle the issue of imported food safety.<sup>220</sup> The Department of Health and Human Services (HHS) also proposed its own plans to improve food safety.<sup>221</sup> Among other measures, these action plans invariably call for "capacity building" of foreign food safety regulatory regimes.<sup>222</sup> Through bilateral agreements with China and other nations, the objective of these proposals is to shift the burden of securing food safety to those countries exporting food products into the

216. See Huang, *supra* note 211, at 151.

217. OWEN, *supra* note 129, at 960.

218. See GA. CODE ANN. § 51-1-11.1 (2000):

(b) For purposes of a product liability action based in whole or in part on the doctrine of strict liability in tort, a product seller is not a manufacturer as provided in Code Section 51-1-11 and is not liable as such.

(c) Nothing contained in this Code section shall be construed to grant a cause of action in strict liability in tort or any other legal theory or to affect the right of any person to seek and obtain indemnity or contribution.

219. See Robert A. Sachs, *Product Liability Reform and Seller Liability: A Proposal for Change*, 55 BAYLOR L. REV. 1031, 1114 (2003).

220. See Exec. Order No. 13439, Establishing an Interagency Working Group on Import Safety, 72 Fed. Reg. 40,053 (July 20, 2007), available at <http://edocket.access.gpo.gov/2007/pdf/07-3593.pdf>.

221. There are major reports on import safety to the President: (1) INTERAGENCY WORKING GROUP ON IMP. SAFETY, IMPORT SAFETY - ACTION PLAN UPDATE: A PROGRESS SUMMARY (July 2008) [hereinafter ACTION PLAN UPDATE]; (2) ACTION PLAN FOR IMPORT SAFETY, *supra* note 15; (3) INTERAGENCY WORKING GROUP ON IMP. SAFETY, PROTECTING AMERICAN CONSUMERS EVERY STEP OF THE WAY: A STRATEGIC FRAMEWORK FOR CONTINUAL IMPROVEMENT IN IMPORT SAFETY (Sept. 10, 2007) [hereinafter PROTECTING AMERICAN CONSUMERS]. All three reports are available at <http://www.importsafety.gov/>.

222. See ACTION PLAN FOR IMPORT SAFETY, *supra* note 15, at 24.

Unites States.<sup>223</sup> In essence, the proposed measures seek to outsource food safety regulatory power from the United States to China and other foreign governments. This section examines the United States' action plans and legislative proposals, as well as the U.S.-China agreement on import safety.

#### A. U.S. Government's Action Plans on Import Safety

There were several government action plans on import safety under the Bush Administration. These plans have thus far continued to be in force under the Obama administration. Experts predict that the Obama Administration is unlikely to take a different approach from the previous administration.<sup>224</sup>

##### 1. *Promoting Import Safety within Existing Resources*

On July 18, 2007, President Bush issued Executive Order 13439 establishing the Interagency Working Group (IWG) on Import Safety, consisting of members from 13 federal agencies.<sup>225</sup> The stated mission of the IWG was to "identify actions and appropriate steps that can be pursued, *within existing resources*, to promote the safety of imported products . . ." <sup>226</sup>

The President assigned the IWG three tasks. First, the IWG had to review current procedures used for ensuring imported product safety. The President emphasized that the IWG should review "existing cooperation with foreign governments . . ." and verify inspections and certifications of those manufacturers that export products into the United States.<sup>227</sup> Second, the IWG had to identify best importer practices, including processes for making the right selection of foreign manufacturers, inspecting their facilities, and ensuring the traceability of imported products.<sup>228</sup> Third, the IWG had to find ways to enhance cooperation on import safety among federal agencies as well as state and local governments.<sup>229</sup>

##### 2. *The Ultimate Goal: Reduction of Physical Inspections*

In September 2007, the IWG produced its first report, in which Mr. Michael O. Leavitt, Secretary of HHS, set the basic tone of the government's approach to import safety.<sup>230</sup> He stated in the cover letter to the President that the sharp increase of imports into the United States had made it impossible for the federal government to physically inspect every imported product.<sup>231</sup> He emphasized that inspections at ports of entry would not only hinder trade flow, but also "distract limited resources from those

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223. *See id.*

224. Suppan, *supra* note 14, at 4-5.

225. *See* Exec. Order No. 13439, *supra* note 220, at 40,053.

226. *See id.* (emphasis added).

227. *Id.* at 40,053-54.

228. *Id.* at 40,054.

229. *See id.*

230. *See* PROTECTING AMERICAN CONSUMERS, *supra* note 221, cover letter.

231. *Id.*

imported goods that pose the greatest risk.”<sup>232</sup> As a general principle, the Secretary proclaimed that “we have to be smarter about what we do.”<sup>233</sup>

The Secretary characterized the physical inspections at ports of entry as “snapshots” that were inadequate to ensure import safety.<sup>234</sup> He proposed moving towards a “prevention-focused ‘video’ model,” where imports would be screened at critical points in the import life-cycle before entering the U.S. market.<sup>235</sup> In other words, foreign governments and private-sector companies should shoulder the responsibility for safeguarding the production process in foreign countries.

The “smarter” strategy that the Secretary called for encompasses three steps: prevention, intervention, and response.<sup>236</sup> As outlined, the Plan emphasizes collaboration with foreign governments at the prevention phase.<sup>237</sup> The Plan has a rather ambitious goal: through capacity building, the U.S. government helps developing nations by strengthening “their legal systems and public health infrastructure . . .” to ensure the safety of imports coming into the U.S. market.<sup>238</sup> It recommends making “product safety an important principle of our diplomatic relationships with foreign countries.”<sup>239</sup> More specifically, it requires the federal government to negotiate cooperative arrangements with foreign governments on product safety<sup>240</sup> to include measures for (1) conducting inspections in foreign countries; (2) collaborating with foreign governments to conduct joint investigations; and (3) expanding information sharing channels on product safety.<sup>241</sup>

## B. U.S.-China Agreement on Import Safety

The U.S.-China agreement on food safety is the direct result of the IWG Action Plan. The Agreement is also a culmination of multiple forces, including high-level negotiations, finger pointing, China’s vigorous defense of its product safety record and lobbying efforts by U.S. retailers to reduce inspections at U.S. ports of entry.

### 1. *The Blame Game*

In the midst of the pet food scandal and toy recalls, U.S. Treasury Secretary, Henry M. Paulson Jr., put aside his tenacious push for Chinese currency appreciation, which had been a hallmark of his tenure.<sup>242</sup> He vowed

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232. *Id.*

233. *Id.*

234. *Id.*

235. *Id.*

236. *Id.*, at 11-12.

237. *See id.*

238. *See* ACTION PLAN FOR IMPORT SAFETY, *supra* note 15, at 24.

239. *Id.*

240. *See id.*

241. *Id.* at 24-26.

242. *See* Steven R. Weisman, *U.S. to Pressure China on Food and Product Safety at Coming Trade Talks*, N.Y. TIMES, Dec. 7, 2007, at C7.

to pressure China to reform its food safety system.<sup>243</sup> He claimed that “[r]ight now product and food safety is at the No. 1 issue.”<sup>244</sup> Facing a rapid decline in exports as a result of negative news reports on Chinese-made products, the Chinese government quickly fought back. It blamed the United States for lax inspections of Chinese-made products and for refusing to recognize Chinese government certifications on exports.<sup>245</sup> In retaliation, the Chinese government imposed restrictions on U.S. products exported into China.<sup>246</sup> China also accused the United States and world media of deliberately vilifying “Made in China” products. Vice Premier Wu Yi reacted strongly to the unfavorable news reports: “We disagree with biased, incomplete media reports and pure condemnation that are blind to the facts; and we are opposed to trade barriers set for food safety issues and politicizing the issues.”<sup>247</sup>

In preparation for the Beijing Olympics, the Chinese government published a “White Paper” on food safety, in which it declared that “more than 99 percent of Chinese food to the United States met the U.S. safety and quality standards.”<sup>248</sup> Chinese President Hu Jintao once told President Bush, “quality and safety questions are something that every country has to deal with.”<sup>249</sup> Apparently, President Hu was referring to safety concerns over U.S.-made products entering China.

## 2. *Scope of the Agreement*

Under the foregoing backdrop, the United States and China signed an agreement on food safety on December 14, 2007, entitled *Agreement Between the Department of Health and Human Services of the United States of America and the General Administration of Quality Supervision, Inspection and Quarantine of the People’s Republic of China on the Safety of Food and Feed* (the Agreement).<sup>250</sup> The Agreement is not merely, as some have perceived it, a demand that China improve its food safety regulatory framework. Rather, it is a mutual agreement in which the United States and China have agreed to assist each other in ensuring import safety. A major goal of the Agreement is to improve understanding and gain greater confidence in each other’s regulatory system.<sup>251</sup>

243. *See id.*

244. *See id.*

245. *See* SUBCOMM. ON OVERSIGHT AND INVESTIGATIONS, *supra* note 176, at 5–6.

246. David Barboza, *China Blocks Some Imports Of U.S. Chicken and Pork*, N.Y. TIMES, July 14, 2007, at A10.

247. STEVE SUPPAN, INST. FOR AGRIC. AND TRADE POLICY, U.S. CHINA AGREEMENT ON FOOD SAFETY: TERMS AND ENFORCEMENT CAPACITY 3 (May 2008), available at <http://www.iatp.org/iatp/publications.cfm?accountID=451&refID=102837>.

248. *Id.* at 3–4.

249. *Id.* at 4.

250. The Agreement Between the Department of Health and Human Services of the United States of America and the General Administration of Quality Supervision, Inspection and Quarantine of the People’s Republic of China on the Safety of Food and Feed, U.S.-P.R.C., Dec. 11, 2007, 8325 KAV, available at <http://www.globalhealth.gov/news/agreements/ia121107b.html> [hereinafter The Agreement].

251. *Id.* art. III(2).

The Agreement covers four types of products in the initial phase: “(a) Low-acid canned products or acidified food; (b) Pet food/pet treats of plant origin or animal origin; (c) Ingredients of food and feed, i.e., wheat gluten and rice protein; and (d) all aquaculture farming products other than molluscan shellfish.”<sup>252</sup> The Agreement allows for expansion to additional products upon future negotiation.<sup>253</sup> The Agreement’s scope seems limited, but the covered products account for a large portion of Chinese food exports to the United States. For example, China is the largest aquaculture producer in the world, accounting for 70% of total production, and the third largest exporter to the United States.<sup>254</sup>

### 3. *Controversial Provisions*

Most controversially, Article VI of the Agreement requires both China and the United States to work towards mutual reliance on each other’s registration and certification of covered products.<sup>255</sup> Essentially, the General Administration of Quality Supervision, Inspection and Quarantine of the People’s Republic of China (AQSIQ) will act as the FDA’s surrogate by inspecting exports in China before they enter U.S. ports.<sup>256</sup> If AQSIQ determines that a shipment of Chinese exports meets U.S. requirements, it will issue a certificate and electronically transmit the certificate to the FDA.<sup>257</sup> The FDA will consider AQSIQ’s registration and certification in making decisions about whether to admit entry of the Chinese imports.<sup>258</sup> In return, China will do the same.<sup>259</sup> Even though the Agreement specifically states that neither party is obligated to solely rely on each other’s registration and certification,<sup>260</sup> the FDA is unlikely to resort to its traditional border inspection of Chinese imports having the Chinese registration and certification. According to FDA officials, the goal of the Agreement is to create a “system to ultimately reduce U.S. border inspections . . . .”<sup>261</sup> The U.S. Grocery Manufacturers Association (GMA) has lobbied hard for this goal because border inspections raise regulatory costs

252. *Id.* Annex § I(B)(1).

253. *Id.* Annex § I(B)(2).

254. BECKER, *supra* note 4, at 17 (noting that the United States relies heavily for its seafood on imports; “approximately 80% of U.S. seafood consumption is from imports and that over 40% of these imports come from aquaculture operations.”).

255. The Agreement, *supra* note 250, art. VI(1):

For the purpose of using AQSIQ/CNCA [China’s quality and certification agency] registration and/or certification to inform decision-making regarding the admissibility of Covered Products for entry into the United States, both Parties shall endeavor to agree on all criteria and procedures that AQSIQ/CNCA uses to implement the registration and certification provisions of this Agreement.

256. *See id.* Annex § II(C)(1-3).

257. *See id.*

258. *Id.* art. VI(1).

259. *Id.*

260. *Id.* art. VI(3).

261. Erica Lee Nelson, *U.S.-China Food Safety Deal Could Give China Preferential Treatment*, 25 Inside Wash. Publishers, Dec. 14, 2007.

and thereby decrease profits.<sup>262</sup> Ultimately, the Agreement embodies the GMA's wishes. In Annex § II(2), AQSIQ essentially assumes the task of ensuring U.S. import safety:

Based on the success of the registration and certification programs . . . [U.S.] HHS/FDA will use registration and certification information provided to it by [China] AQSIQ to inform [U.S.] HHS/FDA import entry decisions, which may include a reduction in the rate of examination of Designated Covered Products that are part of the registration and/or certification program.<sup>263</sup>

#### 4. *Addressing U.S. Concerns*

Some provisions of the Agreement do address the FDA's concerns for transparency.<sup>264</sup> Section IV provides that the United States and China will exchange their respective laws and regulations on food and feed safety.<sup>265</sup> Each party is required to inform the other within two calendar days of significant risks to public health posed by products and gross deceptions against consumers by Covered Products.<sup>266</sup> Apparently, the Agreement reflects the FDA's great frustration over the length of time it took to figure out that melamine was the culprit causing the deaths of pets in the United States.<sup>267</sup> In China, however, it was well known that Chinese pet food, and even human food, had boosted protein counts resulting from the adding of melamine.<sup>268</sup> In addition, the two parties must promptly provide detailed contact information of covered establishments when so requested by the other.<sup>269</sup> The main purpose of this clause is to aid the United States in locating Chinese producers. In several instances the FDA has had great difficulties in identifying perpetrators among 170,000 Chinese food manufacturers.<sup>270</sup>

Additionally, the Agreement requires regulatory cooperation on food safety between the United States and China. Through training and scientific cooperation, the two parties will develop strategies to prevent harmful products from shipping to each other's country.<sup>271</sup> The two countries will focus on identifying differences in food standards, such as maximum resi-

262. See GROCERY MFRS. ASS'N, A COMMITMENT TO CONSUMERS TO ENSURE THE SAFETY OF IMPORTED FOODS: FOUR PILLARS OF PUBLIC-PRIVATE PARTNERSHIP 3 ("Moreover, it would be misguided to focus additional resources exclusively on activities at the border in a fruitless effort to 'catch' products that do not meet US standards.").

263. The Agreement, *supra* note 250, Annex § II(2).

264. See *id.*; *id.* art. III.

265. *Id.* art. IV.

266. *Id.*

267. See SUPPAN, *supra* note 247, at 3.

268. See generally Chenglin Liu, Profit Above the Law: China's Melamine Tainted Milk Scandal, 79 MISS. L.J. 371 (2009) (examining melamine-tainted milk scandal in China).

269. The Agreement, *supra* note 250, art. IV(3).

270. Ying Feihu, Wanshan Woguo Shipin Zhiliang Xinxi Chuandao Jizhi Yindui Shipin Anquan Wenti [Improvement of China's Information Exchange on Food Safety], 5 Zhengzhi Yu Falu [J. POL. & L.] 24, 26 (2007).

271. See The Agreement, *supra* note 250, art. V(1).

due levels (MRLs).<sup>272</sup> Furthermore, the two parties will work on plans to identify incidental or intentional additions of chemical, radiologic or microbiological substances to foodstuffs.<sup>273</sup> The Agreement also requires cooperation on the preventing food adulteration for illegal gains.<sup>274</sup>

### 5. *Benchmarks for Measuring Success*

The U.S. government intends to evaluate the performance of the Agreement based on two primary factors:<sup>275</sup> (1) HHS/FDA's rate of refusal of covered products from China; and (2) the frequency of recalls of covered Chinese products posing significant health hazards to U.S. consumers. The first performance evaluation factor is inherently unreliable. Since the ultimate goal is to reduce inspections at ports of entry, the FDA will heavily rely on AQSIQ's electronically transmitted certifications in deciding whether to admit imports.<sup>276</sup> Without adequate physical inspections, FDA refusal will most likely be due to insufficient paperwork rather than concerns for quality and safety.<sup>277</sup> The only concrete factor evaluating the Agreement's performance is the frequency of recalls of hazardous imports. This criterion, however, is contrary to the FDA's prevention-focused approach. This approach is also unfair to consumers because the government will take action to reevaluate the Agreement only after injuries prompt product recalls.

### 6. *Winners and Losers*

Overall, China is the unequivocal winner of the Agreement. The Chinese government gains control of the standards for exports to the United States. The GMA is another big winner. Like other industries that have shifted business overseas to cut costs, the GMA will greatly benefit from outsourcing regulatory power to the Chinese government. To some extent, the FDA perceives itself as a winner because the Agreement allows the FDA to stay "within existing resources" by reducing its "unbearable" burden of securing imported food.<sup>278</sup>

Yet, by no means has the Agreement purely created a win-win situation. The Agreement's terms on mutual recognition of certification conceded rights to China far superior to those in the North American Free Trade Agreement (NAFTA),<sup>279</sup> a surprise to both Canada and Mexico, the closest trade allies with the United States.<sup>280</sup> For years, Canada and Mex-

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272. *Id.* art. V(2)(b).

273. *Id.* art. V(2)(d).

274. *See id.* art. V(2)(e).

275. *See id.* art. VIII(2)(b) (revealing the third factor—the overall percentage of covered products from non-AQSIQ registered establishments to the U.S.—a vague factor that may need further clarification).

276. *See id.* art. VIII(2)(a); SUPPAN, *supra* note 247, at 8.

277. *See* SUPPAN, *supra* note 247, at 5.

278. *See* Exec. Order No. 13439, *supra* note 220, at 40,053.

279. *See* North American Free Trade Agreement, U.S.-Can.-Mex., Dec. 17, 1992, 32 I.L.M. 289 (1993).

280. *See* Nelson, *supra* note 261.



ico have unsuccessfully urged the U.S. government to relax border inspections on their exports.<sup>281</sup> The Agreement is likely to open the door for trade conflicts between the United States and its two close neighbors.<sup>282</sup> The Agreement could also lead other nations to seek the same preferential treatment under the Most Favored Nations Clause of the World Trade Organization (WTO).<sup>283</sup>

Most importantly, while U.S. consumers will benefit from the reduced regulatory costs, and thus lower food costs, resulting from the Agreement, they are potentially at greater risk of being exposed to adulterated and deleterious imports from China. Going forward, U.S. consumers' faith in imported food rests with the Chinese government, far away in Beijing. What remains unseen is whether the Chinese government will live up to the U.S. government's expectations.

## V. Food Safety in China

China's Food Safety Law<sup>284</sup> provides that export quality and safety are subject to the same standards and controls as domestic food products. Therefore, to answer the question whether China can secure exported food safety, examining China's domestic food safety challenges, relevant laws, and enforcement mechanisms, is necessary. The most recent Food Safety Law became effective on June 1, 2009.<sup>285</sup> The next section will analyze the new law and its implications for the safety of China's food exports.

### A. Development of Food Safety Law

Compared with the FD&C Act, China's food safety law has a much shorter history.<sup>286</sup> The development of Chinese food safety law can be traced back to the 1950s during the Korean War, otherwise known in China as the War Resisting America and Aiding Korea.<sup>287</sup> During that

281. *See id.*

282. *See id.*

283. *See* General Agreement on Tariffs and Trade (GATT) art. I(1), Oct. 30, 1947, T.I.A.S. No. 1700, 55 U.N.T.S. 194.

. . . any advantage, favour, privilege or immunity granted by any contracting party to any product originating in or destined for any other country shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties.

284. *See* Zhonghua Renmin Gonghe Gou Shipin Anquan Fa (Shi Xing) [Food Safety Law of the People's Republic of China] (promulgated by the Standing Comm. Nat'l People's Cong., Feb. 28, 2009, effective June 1, 2009), art. 89(3), (P.R.C) [hereinafter Food Safety Law], available at <http://www.fas.usda.gov/gainfiles/200903/146327461.pdf>. The Food Safety Law is discussed extensively in Part 4.3.

285. *Id.* art. 104.

286. *See* Zhang Fang, *Zhongguo Xiandai Shipin Anquan Jianguan Falu Zhidu de Fazhan Yu Wanshan* [The Development and Improvement of China's Modern Legal Framework on Food Safety], 5 Zhengzhi Yu Falu [J. POLITICS & L.] 18, 18 (2007).

287. *See* Fenghuang Luntan, Wuer Nian Quanguo Dajia Qiangbi Liang Jianshang Zhenshe Ji Shi Nian [The Execution of Two Swindlers in 1952 had Deterrence for Decades], available at <http://bbs.ifeng.com/viewthread.php?tid=3822247&extra=page3D2>.

time, a number of soldiers died of botulism after eating contaminated canned meat.<sup>288</sup> Mao ordered the immediate execution of Mr. Wang and Mr. Tian, the owners of the food factories that sold the tainted food to the troops.<sup>289</sup> Even though there were no officially promulgated regulations on food safety, the executions sent a powerful message to other private food manufacturers.<sup>290</sup> With the development of socialization, the state gradually took over privately owned food factories and transformed them into state-owned-enterprises (SOE).<sup>291</sup> The SOEs were notorious for their low productivity, but food safety was under the government's tight control. As a result, except for sanitation problems, food adulteration was not a major issue until the economic reforms in the 1980s.

In 1965, the State Council issued the first food regulation.<sup>292</sup> The regulation mainly dealt with the unsanitary conditions in which food products were stored, manufactured and transported.<sup>293</sup> It did not set forth requirements for food content because China was still recovering from a catastrophic famine, in which an estimated thirty million people died of malnutrition between 1960 and 1962.<sup>294</sup> The government's primary concern was how to maintain an adequate food supply.<sup>295</sup> In the promulgation circular, the State Council stressed that the government should be flexible in enforcing the regulation.<sup>296</sup> If food manufacturers were unable to comply with the regulation because of high costs, the government should help them overcome those economic difficulties.<sup>297</sup>

In 1983, China enacted a trial implementation of the Food Sanitation Law, in an attempt to regulate the growing number of privately owned food manufacturers and vendors emerging from the economic reforms.<sup>298</sup> Unlike the 1965 regulation, the Food Sanitation Law had greater coverage. It set forth standards for food content, additives, containers, manufacturing conditions and equipment.<sup>299</sup> The Food Sanitation Law required food ven-

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288. See *id.*

289. See *id.*

290. See *id.*

291. See CHRIS BRAMALL, CHINESE ECONOMIC DEVELOPMENT 119-21 (2009).

292. Shipin Weisheng Guanli Shixing Tiaoli [Food Sanitation Regulation (For Trial Implementation)] (promulgated by the State Council on Aug. 17, 1965), available at [http://news.xinhuanet.com/ziliao/2005-02/02/content\\_2538913.htm](http://news.xinhuanet.com/ziliao/2005-02/02/content_2538913.htm) [hereinafter Food Sanitation Regulation].

293. See Bian Yongmin, *The Challenges for Food Safety in China*, 53 CHINA PERSP., para. 2 (2004), available at <http://chinaperspectives.revues.org/document819.html>.

294. See BRAMALL, *supra* note 291, at 126.

295. See *id.* at 134-35.

296. See Food Sanitation Regulation, *supra* note 292.

297. See Guowu Yuan Pizhuan Shipin Weisheng Guanli Tiaoli [The State Council Notice on Promulgation of the Food Sanitary Regulation] (Aug. 17, 1965), available at [http://news.xinhuanet.com/ziliao/2005-02/02/content\\_2538913.htm](http://news.xinhuanet.com/ziliao/2005-02/02/content_2538913.htm).

298. Zhonghua Renmin Gonghe Gou Shipin Weisheng Fa (Shi Xing) [Food Sanitation Law of The People's Republic of China (trial version)] (promulgated by the Standing Comm. Nat'l People's Cong., Nov. 19, 1982, effective July 1, 1983, repealed 1995) (P.R.C.), available at <http://www.hflib.gov.cn/law/law/falvfagui2/XZF/FLFG/YYWS/1180.htm>.

299. See *id.* art. 3.

dors to register with local industrial and commercial administrations.<sup>300</sup> The law also prescribed penalties for violations of the Food Sanitation Law, ranging from fines to criminal prosecution.<sup>301</sup>

The People's Congress completely revamped the Food Sanitation Law (FSL) in 1995.<sup>302</sup> The updated FSL designated the Ministry of Health as the primary enforcement agency.<sup>303</sup> To provide detailed guidance for the food industry, the State Council and provincial governments issued over 500 regulations and rules interpreting the FSL.<sup>304</sup> Despite the improvement of the legal framework, the FSL's enforcement was rather weak. Scandals involving food adulteration repeatedly claimed lives.<sup>305</sup> As a result, the public lost confidence in the government's ability to ensure food safety.<sup>306</sup>

## B. The Food Safety Law of 2009

### 1. Government Structure and Legislative Background

On February 28, 2009, the National People's Congress passed the latest version of the FSL, which took effect on June 1, 2009.<sup>307</sup> Undoubtedly, the 2008 milk scandal hastened its passage.<sup>308</sup> To fully appreciate the new FSL and its enforcement mechanisms, understanding China's government structure and legislative process is essential.

Unlike the U.S. federal structure, China has a centralized system, which consists of the central government in Beijing and local governments across the country.<sup>309</sup> According to the Constitution, local governments are subordinate to the central government.<sup>310</sup> At the central level, the National People's Congress (NPC) is the legislature, which is at the peak of the state structure.<sup>311</sup> Below the NPC is the State Council, which is the central administration of China.<sup>312</sup> In the State Council, the Premier is the head of the cabinet, which consists of Ministries, Commissions, and

300. See *id.* art. 26.

301. See *id.* arts. 37-41.

302. See Zhonghua Renmin Gonghe Gou Shipin Weisheng Fa (Shi Xing) [Food Sanitation Law of the People's Republic of China] (promulgated by the Standing Comm. Nat'l People's Cong., Oct. 30, 1995, effective Oct. 30, 1995) (P.R.C.), available at [http://www.chinacourt.org/flwk/show.php?file\\_id=23857](http://www.chinacourt.org/flwk/show.php?file_id=23857).

303. See *id.* art. 3.

304. See Zhang, *supra* note 286, at 19.

305. See *id.*

306. See *id.*

307. See Food Safety Law, *supra* note 284, art. 104.

308. See James T. Areddy, Dairy Probe Began Almost 11 Months Before Being Disclosed, WALL ST. J., Jan. 8, 2010, A7 (discussing the scandal).

309. See XIANFA [Constitution of the People's Republic of China] arts. 95, 138 (1982) (P.R.C.) translated at <http://english.people.com.cn/constitution/constitution.html>.

310. See *id.* art. 100.

311. See *id.* arts. 2, 57-58.

312. See *id.* arts. 85, 92. Along with the State Council, three other institutions are under the NPC: the Central Military Commission (CMC), the Supreme People's Court, and the Supreme People's Procuratorate. See *id.* art. 62, §§ 6-8. The President is the head of the state. See *id.* arts. 79-80. The President nominates the State Council's Premier as well as all other Ministers. See *id.* art. 62, § 5. The State Council is China's

Administrations.<sup>313</sup> The State Council and other institutions are subject to the NPC's supervision.<sup>314</sup> The NPC approves all legislative proposals the State Council submits.<sup>315</sup> The State Council proposed the new FSL in 2004, after a series of well-publicized food poisoning incidents.<sup>316</sup> Experts often claim that it took the NPC five years to pass the new FSL.<sup>317</sup> In fact, the delay resulted from the State Council's reluctance to subject the food industry to strict food safety laws until further food and drug scandals occurred.<sup>318</sup>

At the local level, there exists a hierarchy of four levels of government (in descending order): provinces, counties, cities and townships.<sup>319</sup> Each level reports to the next higher level.<sup>320</sup> Provinces report directly to the State Council.<sup>321</sup> Even though Provinces are of the same bureaucratic level

Central Government. See *id.* art. 85. Therefore, the State President and the Premier of the State Council are the most influential figures in China's politics.

313. See *id.* art. 86. Ministries and Commissions are of equal bureaucratic rank as full ministerial level. See *id.* arts. 80, 86, 90. Administrations are of lower rank than that of Ministries. Three Administrations are related to the FSL's enforcement: the General Administration of Safety, Quality Inspection and Quarantine (AQSIQ) and the State Food and Drug Administration (SFDA) and the Industrial and Commercial Administration (SICA). In China's rigid bureaucratic structure, the administrative ranks are crucial in enforcing particular policies and laws. An agency of lower rank will find that pushing through any agenda requiring a higher agency's involvement is an extremely difficult task. As a result, the AQSIQ, SFDA and SICA will face hurdles in coordinating with the MOH, MOA and other ministries on food safety issues. In this regard, the 2007 U.S.-China Agreement on Food Safety is a mismatch. The Agreement was signed by the HHS (cabinet level in the U.S.) and the AQSIQ (not a full ministerial, or cabinet level in China). See The Agreement, *supra* note 250, pmbl. The Agreement should have been between either the HHS and MOH or between the US FDA and AQSIQ.

314. See XIANFA [Constitution of the People's Republic of China] arts. 67, 73, 92 (1982) (P.R.C.) translated at <http://english.people.com.cn/constitution/constitution.html>.

315. See *id.* art. 89, § 2.

316. See Zhang, *supra* note 286, at 19.

317. See *id.*

318. See *infra* Part V.D. of this article.

319. See XIANFA [Constitution of the People's Republic of China] arts. 95-111 (1982) (P.R.C.) translated at <http://english.people.com.cn/constitution/constitution.html> (establishing structure and function of local governments). For a further understanding of the relationship between central and local governments, see CHENGLIN LIU, Chinese Law on SARS 43 (2004):

There are twenty-three Provinces, five Autonomous regions and four large cities, Beijing, Shanghai, Tianjing and Chongqing, directly under the Central Government. Provinces and their equivalents are divided into prefectures or cities with districts. Under the prefecture or city level are counties, which are divided into townships.

The relationship of the Central Government to local governments at various levels is laid out in Article 3 of the Constitution, "The state institutions of the People's Republic of the China apply the principle of democratic centralism." The principle of democratic centralism was first developed by the CCP and has become the basic principle governing all aspects of Chinese political life. The fundamental tenet of democratic centralism is that the local governments are subordinate to the Central Government.

320. See XIANFA, *supra* note 319, arts. 95-111.

321. See *id.*

as Ministries in Beijing, they are deemed local governments according to the Constitution.<sup>322</sup> Each of the four levels of local government mimics the structure of the State Council; i.e., each local government directs various departments.<sup>323</sup>

## 2. *Central and Local Enforcement Agencies*

At the central level, the new FSL requires that the State Council establish a Food Safety Commission (FSC) to administer its provisions.<sup>324</sup> As a Commission, the FSC will acquire a ministerial rank. Since the law just became effective, the State Council has not yet defined the scope of the FSC and its jurisdiction. At this point, the prospective relationship between the FSC and other Ministries remains unclear.

The new FSL designates the Ministry of Health (MOH) as the primary agency in charge of setting food safety standards, evaluating food safety risks, issuing public notices on food safety, and investigating major food safety incidents.<sup>325</sup> In addition, it grants the MOH the authority to set standards for food certification agencies.<sup>326</sup> It further makes the AQSIQ, the State Industrial and Commercial Administration (SICA), and the State Food and Drug Administration (SFDA) responsible for the supervision of food manufacturing, distribution, and catering services.<sup>327</sup>

At the local level, the new FSL places governments at the county level and above in charge of food safety administration in their respective jurisdictions.<sup>328</sup> Within each level of local government, the FSL mandates departments of health, agriculture, quality control, industrial and commercial, and food and drug to coordinate with each other to enforce its provisions.<sup>329</sup>

Thus, local governments are on the frontline of food inspections. Notwithstanding the Central Government's power to conduct inspection tours, it is practically impossible for officials from Beijing to make regular visits to the nearly two million food manufacturers scattered around the country. Therefore, whether the new FSL succeeds in securing food safety ultimately depends on the effectiveness of local government enforcement.

In addition to government agencies, the new FSL encourages trade associations, consumer protection organizations, research institutions, and individuals to contribute to the enforcement of its requirements. Article 10 specifically grants private organizations and individuals the right to report to the government any safety violation occurring in the food production process.<sup>330</sup>

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322. *See id.* art. 95.

323. *See id.* at 95-111.

324. *See* Food Safety Law, *supra* note 284, art. 4.

325. *See id.*

326. *See id.*

327. *See id.*

328. *See id.* art. 5.

329. *Id.* art. 6.

330. *See id.* art. 10.

### 3. Food Safety Standards

In China's transition from a predominately agrarian society to an industrial society, the food industry remains extremely fragmented with 170,000 food processing firms, over 70% having fewer than ten workers.<sup>331</sup> Prior to the FSL, the government promulgated some food quality standards that were typically inconsistent, outdated, and underdeveloped.<sup>332</sup> A lack of sufficient standards is a serious problem in food safety. To remedy this issue, the FSL devotes an entire chapter to defining mandatory food safety standards.<sup>333</sup>

Under the new FSL, the MOH is responsible for determining and promulgating food safety standards except for pesticide residue levels, which the Ministry of Agriculture (MOA) sets.<sup>334</sup> Article 21 requires that the State Council and concerned Ministries establish safety standards for meat and poultry.<sup>335</sup>

According to Article 20, the FSL food safety standards are to include:

- a) Tolerance levels of pathogenic microorganisms, pesticide residues, animal drug residues, heavy metals, pollutants and other health hazardous materials;
- b) Food additives and their scope and usage;
- c) Nutritional content of infant food and foods intended for particular groups of people, such as the sick and old;
- d) Labeling related to food safety and nutrition;
- e) Sanitary conditions for food processing;
- f) Quality requirements related to food safety;
- g) Food inspection methods and procedures; and
- h) Other food safety standards.<sup>336</sup>

On January 20, 2010, the MOH established the State Food Safety Standard Assessment Committee, which is in charge of drafting a national standard on food safety.<sup>337</sup> Violation of the food safety standards will result in a fine of not more than 50,000 Yuan (\$7,000), if the sale value is less than 10,000 Yuan (\$1,400); or a fine of not more than ten times the sale value, if the sale value is more than 10,000 Yuan. Serious violations will result in revocation of the food manufacturer's license.<sup>338</sup>

To ensure food industry compliance with the new law, the MOH intends to study the consistency between the new safety standards and the existing quality and sanitary standards.<sup>339</sup> Realistically, it will take a long

331. Ying, *supra* note 270, at 26.

332. *See id.* at 25-27.

333. *See* Food Safety Law, *supra* note 284, arts. 18-25.

334. *See id.* art. 21.

335. *Id.*

336. *Id.* art. 20.

337. Weisheng Bu Chengli Diyi Jie Shipin Anquan Guojia Biaozhun Shencha Weiyuan Hui [The Ministry of Health established the first State Food Safety Standard Assessment Committee], available at <http://www.cfs.gov.cn/cmsweb/webportal/W402/A64031418.html>.

338. *See* Food Safety Law, *supra* note 284, art. 18.

339. *See id.* art. 22.

time for the Health Ministry to complete this study.

#### 4. *Enforcement Tools*

Like the U.S. FD&C Act, the new FSL provides two kinds of enforcement tools: outcome-based and production-based.

##### a) *Outcome-based Approach*

The new FSL requires that the county government departments of quality control, industrial and commercial, and food and drug conduct regular or unannounced inspections of food manufacturers.<sup>340</sup> The scope of these inspections includes site visits, sampling, auditing of contracts, and review of receipts and accounting books.<sup>341</sup> Upon finding FSL violations, the departments are authorized to seize illegal food products, materials, additives, or equipment.<sup>342</sup> The departments may also shut down food manufacturers if they deem it necessary. The new FSL also requires that the departments keep inspection records and increase inspections of repeat violators.<sup>343</sup> If an FSL violation constitutes a crime, the departments must transfer the food manufacturer's case to the public security department for a criminal investigation.<sup>344</sup>

To ensure impartial inspections and certifications, the new FSL provides administrative penalties for inspectors who violate the law. If an inspector issues a false report, the inspector will face dismissal or forced resignation, and disbarment from conducting food inspections for ten years. In addition, the government will revoke the inspection agency's practice license.<sup>345</sup>

The new FSL provides for product recall as another enforcement tool.<sup>346</sup> If a food manufacturer fails to comply with food safety standards, the manufacturer must immediately stop production and voluntarily recall illegal products already in circulation. It must also contact consumers and publicly announce the recall. The manufacturer must further inform the relevant departments of the local government. In addition, the manufacturer must take appropriate measures to destroy recalled products in order to prevent reentry into the market. If the manufacturer refuses to conduct a voluntary recall, the local government must compel it to retrieve its illegal products.

##### b) *Production-based Tools*

The new FSL encourages food manufacturers to adopt GMP or HACCP practices.<sup>347</sup> It tasks the government accreditation agency to issue certificates to qualified manufacturers and conduct follow-up audits of these accredited manufacturers. If the agency finds that a certified manufacturer

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340. *See id.* arts. 60, 77.

341. *Id.* art. 77.

342. *See id.*

343. *Id.* art. 79.

344. *See id.* art. 81.

345. *Id.* art. 93.

346. *Id.* art. 53.

347. *Id.* art. 33.

fails to meet the requirements of GMP or HACCP, the agency must revoke the certification and inform the relevant local department.<sup>348</sup> The agency must also publicly announce such revocations.

To increase traceability, the new FSL requires food manufacturers to keep records regarding the supply of raw food materials, food additives, and other food ingredients.<sup>349</sup> Manufacturers must keep these records for at least two years.<sup>350</sup> Manufacturers have a duty to check the quality of raw materials and verify supplier certifications.<sup>351</sup> Additionally, manufacturers must keep records, for at least two years, of internal quality checks conducted before their products entered the market.<sup>352</sup> Failure to maintain the required records will result in a fine of not more than 20,000 Yuan (\$3,000) for minor violations.<sup>353</sup> For serious violations, manufacturers face injunction or revocation of their production license.<sup>354</sup>

### C. Criminal Penalties

The new FSL does not directly set forth criminal penalties for serious food safety violations. Instead, the FSL only refers to application of the Criminal Law of China.<sup>355</sup> The Criminal Law imposes severe criminal sanctions on producers and sellers who produce counterfeits or substandard products that cause serious bodily injury or death.<sup>356</sup> For example, Article 140 prohibits the production of adulterated products as well as the sale of counterfeits as genuine products, substandard products as good products, or unqualified products as qualified ones.<sup>357</sup> For producers who

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348. *See id.*

349. *Id.* art. 36.

350. *Id.*

351. *Id.* art. 39.

352. *Id.* art. 37.

353. *Id.* art. 87.

354. *Id.*

355. *Id.* art. 98.

356. Liu, *supra* note 268.

357. Criminal Law of the People's Republic of China (promulgated by the Standing Comm. Nat'l People's Cong., July 1, 1979, effective Jan. 1, 1980, amended Mar. 14, 1997) (P.R.C.), available at <http://www.cecc.gov/pages/newLaws/criminalLawENG.php>. Article 140 states:

Any producer or seller who mixes impurities into or adulterates products, or passes a fake product off as a genuine one, a defective product as a high quality one, or a substandard product as a standard one, if the amount of earnings from sales is more than 50,000 yuan but less than 200,000 yuan, shall be sentenced to fixed-term imprisonment of not more than two years or criminal detention and shall also, or shall only, be fined not less than half but not more than two times the amount of earnings from sales; if the amount of earnings from sales is more than 200,000 yuan but less than 500,000 yuan, he shall be sentenced to fixed-term imprisonment of not less than two years but not more than seven years and shall also be fined not less than half but not more than two times the amount of earnings from sales; if the amount of earnings from sales is more than 500,000 yuan but less than 2,000,000 yuan, he shall be sentenced to fixed-term imprisonment of not less than seven years and shall also be fined not less than half but not more than two times the amount of earnings from sales; if the amount of earnings from sales is more than 2,000,000 yuan, he shall be sentenced to fixed-term imprisonment of 15 years or life imprisonment, and shall



violate this law and have sale amounts exceeding two million Yuan (\$280,000), Article 140 mandates a sentence of a fifteen-year, fixed-term imprisonment or life imprisonment.<sup>358</sup> In addition, the provision imposes a fine of 50% to 200% of the sale amount or a confiscation of the total amount of the illegal proceeds.<sup>359</sup>

Similarly, Article 143 imposes criminal sanctions on producers and sellers of foods that do not conform to hygienic standards.<sup>360</sup> For substandard products that cause food poisoning accidents or other severe food-borne diseases, the responsible parties face mandatory sentences ranging from several years of fixed-term imprisonment to life imprisonment, depending on the severity of the circumstances.<sup>361</sup> Violators may additionally face a fine of up to twice the total sale amount of the substandard products.<sup>362</sup>

Further, Article 144 proscribes the most severe criminal punishment for producing adulterated foods.<sup>363</sup> This article applies to those who produce or sell foods mixed with poisonous or harmful non-food materials. Under this article, committing the act itself results in a sentence of not more than five years of fixed-term imprisonment. If the act gives rise to serious harm to human health, the sentence must be not less than five years and not more than ten years. If the adulterated products cause serious bodily harm or death, however, the sentence may be the *death*

also be fined not less than half but not more than two times the amount of earnings from sales or be sentenced to confiscation of property.

358. *Id.*

359. *Id.*

360. *Id.* art. 143:

Whoever produces or sells food that is not up to hygiene standards, thus causing an accident of serious food poisoning or resulting in any serious disease caused by food-borne bacteria, shall be sentenced to fixed-term imprisonment of not more than three years or criminal detention and shall also, or shall only, be fined not less than half but not more than two times the amount of earnings from sales; if serious harm is done to human health, he shall be sentenced to fixed-term imprisonment of not less than three years but not more than seven years and shall also be fined not less than half but not more than two times the amount of earnings from sales; if the consequences are especially serious, he shall be sentenced to fixed-term imprisonment of not less than seven years or life imprisonment, and shall also be fined not less than half but not more than two times the amount of earnings from sales or be sentenced to confiscation of property.

361. *Id.*

362. *Id.*

363. *Id.* art. 144.

Whoever mixes the foods that he produces or sells with toxic or harmful non-food raw materials or knowingly sells such foods shall be sentenced to fixed-term imprisonment of not more than five years or criminal detention and shall also, or shall only, be fined not less than half but not more than two times the amount of earnings from sales; if an accident of serious food poisoning or any serious disease caused by food-borne bacteria has resulted, thus seriously harming human health, he shall be sentenced to fixed-term imprisonment of not less than five years but not more than 10 years and shall also be fined not less than half but not more than two times the amount of earnings from sales; if death is caused to another person or especially serious harm is done to human health, he shall be punished according to the provisions in Article 141 of this Law.

penalty.<sup>364</sup>

#### D. Enforcement Obstacles

On its face, the new FSL bears a close resemblance to the U.S. FD&C Act. Both laws set forth high standards for food content and manufacturing processes; both laws rely on outcome-based and production-based enforcement tools. But while the new FSL offers potential solutions to China's entrenched food safety problems, the FSL will nonetheless face serious challenges in implementation. This section examines four major obstacles the Chinese government will face in enforcing the new FSL.

##### 1. Local Protectionism and the Melamine Tainted Milk Scandal

Since the new FSL primarily depends on local governments for its enforcement, soon after its passage many Chinese experts expressed doubt about its effectiveness.<sup>365</sup> These concerns are well grounded because the new FSL does not include any mechanism to combat widespread local protectionism, which has been blamed for several major food safety scandals in China.<sup>366</sup>

Ironically, local protectionism originated from the economic reforms in the 1980s that set China on the path toward rapid economic growth.<sup>367</sup> The essence of the reform was to transition from a planned economy to a market economy though, among other strategies, decentralization.<sup>368</sup> During the decentralization process, local governments assumed the primary role of developing local economies.<sup>369</sup> Government officials at each level are actually appointed by government officials at the next higher level,

364. See *id.* arts. 141, 144. Article 141 states:

Whoever produces or sells fake medicines that are harmful enough to seriously endanger human health . . . [or] if death is caused to another person or especially serious harm is done to human health, he shall be sentenced to fixed-term imprisonment of not less than 10 years, life imprisonment or death, and shall also be fined not less than half but not more than two times the amount of earnings from sales or be sentenced to confiscation of property.

365. Zhang Ling, Shipin Anquan Reng Duotou Guanli Weiyuan Huyu Chedi Gaige [Food Safety Enforcement Still Relies on Multiple Local Agencies and Experts Have Thus Expressed Doubt About the Effectiveness of the New Food Safety Law], *Chengdu Shangbao*, Mar. 1, 2009, available at <http://news.sina.com.cn/c/2009-03-01/032315236384s.shtml>.

366. Liu, *supra* note 268.

367. See Stanley Lubman, *Bird in a Cage: Chinese Law Reform After Twenty Years*, 20 *Nw. J. INT'L L. & BUS.* 383, 395 (2000).

368. See *id.* at 386-87, 395.

369. Contrary to the western model, which promotes market economy by means of democracy, China seems to have succeeded in achieving economic growth without moving towards democracy. Therefore, the revered statesman Mr. Deng Xiaoping referred to the Chinese model as "Socialism with the Chinese Characteristics." Deng Xiaoping, Former Chairman, Central Military Commission of CCP, Speech to the Second Session of the Council of Sino-Japanese Non-Governmental Persons: Build Socialism with Chinese Characteristics (June 30, 1984), available at <http://www.wellesley.edu/Polisci/wj/China/Deng/Building.htm>.

rather than elected by the local people.<sup>370</sup> As a result, local officials became accountable only to the government officials directly above them.<sup>371</sup>

Seeking economic miracles, the central government has emphasized higher gross domestic production (GDP) disproportionately to food safety.<sup>372</sup> Compared with economic growth, food safety has rarely been a top priority except during outbreaks of major food scandals. As a result, the primary criterion for assessing the performance of local officials is their ability to increase local GDP.<sup>373</sup> Local officials, seeking reappointments and promotions, have made every effort to maintain high economic growth, even at the expense of safety and quality.

In the process, local officials have forged close ties and developed mutually beneficial relationship with local industries. Local governments expect and rely upon local enterprises to grow the local economy. In exchange, the local government gives local industries special favors including minimum safety and quality inspections.<sup>374</sup> Corruption often taints the ties between enterprises and government officials. In the Shanxi Province, for example, a number of local leaders in charge of mine safety actually held significant financial stakes in local mines with notorious safety records.<sup>375</sup>

The 2008 melamine tainted milk scandal illustrates the special relationship between local governments and local milk industries.<sup>376</sup> In September 2008, a news report first linked the death of an infant to baby formula tainted with melamine. The Sanlu Company (Sanlu) based in Shijiazhuang City, Hebei Province produced the tainted formula.<sup>377</sup> According to official estimates, at least six babies died and nearly 300,000 were sickened from drinking the tainted milk.<sup>378</sup> More than 300 children

370. This practice seems contrary to the notion envisioned in the Constitution that the local people's congress elects local government officials. See XIANFA [Constitution of the People's Republic of China] art. 101 (1982) (P.R.C.) translated at <http://english.people.com.cn/constitution/constitution.html>. In reality, however, the local people's congress consistently rubber stamps nominations by the Chinese Communist Party. Thus, the central government succeeded in designating pre-ordained officials to charge local economies. In many cases, the central government has "parachuted" officials into particular provinces without open consultation with the local congresses. Bo Zhiyue, *China's New Provincial Leaders: Major Reshuffling Before the 17th National Party Congress*, 5 CHINA: AN INT'L J. 1, 12-13 (2007).

371. In recent years, the central government has frequently shifted governors from one province to another without elections. See, e.g., *id.* at 17.

372. See Huang, *supra* note 211, at 141.

373. See *id.*

374. See *id.*

375. Zhong Ge, Meikuang Guangu Chezi "Anliu" Xiongyong Yixie Guanyuan Mingche Anchi [Some Officials Still Secretly Hold Shares in Coal Mines], Xinhua News, Oct. 28, 2005, available at <http://gov.people.com.cn/GB/46728/54337/54340/3808708.html>.

376. Liu, *supra* note 268.

377. See Loretta Chao, *Victims of Tainted Milk File Lawsuit in China's High Court*, WALL ST. J., Jan. 20, 2009, at A10.

378. Woguo Gong 29 Wan Yinger Miniao Xitong Yin Shi Wenti Naifen Chuxian Yichang [Over 290,000 Infants Suffered Urinary Abnormalities from Drinking the

were hospitalized for treatment.<sup>379</sup>

The melamine contamination was by no means an accident. The milk suppliers deliberately added melamine to diluted milk in order to deceive quality control reviewers.<sup>380</sup> In later production, milk processors only checked protein levels by measuring nitrogen concentration. As a nitrogen-rich crystalline compound, the added melamine increased the nitrogen content and made the adulterated milk appear rich in protein.<sup>381</sup> To make matters worse, some reports alleged that milk processors also added melamine to already contaminated milk in order to cut costs and increase revenue.<sup>382</sup>

A month before the scandal broke out, Sanlu actually made urgent reports to the local government about the unusually high level of melamine in its products and the numerous complaints from consumers.<sup>383</sup> According to the law, the local government had a legal obligation to promptly report the incident to the State Council in Beijing.<sup>384</sup> The local government, however, took every measure to conceal relevant information for fear of damaging the local economy.<sup>385</sup>

While the internal communications between Sanlu and the local government remain a mystery, a post-scandal public apology was quite revealing. In the apology, the local government explained the reasons for its failure to immediately report the problem to the central government.<sup>386</sup> The local government blamed itself for a lack of political sensitivity and attributed the cover-up to its failure to fully appreciate the serious political and economic consequences of the scandal.<sup>387</sup> The apology also stated that it believed that Sanlu could eventually restore its shattered image and regain public trust if it could quickly improve quality.<sup>388</sup> The local govern-

Tainted Milk], XINHUA NET, Dec. 1, 2008; see also Will Clem & Lilian Zhang, Tainted Milk Feared to have Killed Another, S. CHINA MORNING POST, Jan. 9, 2009, at 5.

379. Chao, *supra* note 377.

380. See World Health Organization, Questions and Answers on Melamine, <http://www.who.int/csr/media/faq/QAmelamine/en/> (last visited Mar. 31, 2010).

381. See *id.*

382. See David Barboza, *China's Dairy Farmers Say They Are Victims*, N.Y. TIMES, Oct. 4, 2008, at A5; see also Julie R. Ingelfinger, *Melamine and the Global Implications of Food Contamination*, NEW ENG. J. MED., Dec. 25, 2008, at 2746 ("Before the current melamine disaster, the marked dilution of infant formula in China had resulted in marasmus in some infants, which led to government directives to increase the protein content of such preparations or risk severe penalties. Thus, it is possible that the adulteration was conceived in response to a well-intentioned government directive.").

383. Ye Tieqiao, *Gongsu Jiguan Pilu Sanlu Yinman Shishi Zhi Tunai Wailiu [Sanlu's Cover-Up Caused Poisonous Milk to Enter the Market]*, ZHONGGUO QINGNIAN BAO [CHINA YOUTH DAILY], Jan. 1, 2009, available at <http://news.sina.com.cn/c/2009-01-01/050616959786.shtml>.

384. *Id.*

385. *Id.*

386. Dong Zhiyong, *Shijiazhuang Zhengfu: Sanlu Naifen Shijian Women You Buke Tuixie de Zeren [Shijiazhuang Municipality: We Are Responsible for the Milk Scandal]*, Jingji Ribao [ECON. DAILY], Oct. 4, 2008, available at [http://news.xinhuanet.com/newscenter/2008-09/30/content\\_10136125.htm](http://news.xinhuanet.com/newscenter/2008-09/30/content_10136125.htm).

387. *Id.*

388. *Id.*

ment admitted that it was concerned a revelation would damage Sanlu's reputation and result in job losses. The local government regretted that, because of its delay, the central government had missed the opportunity to control the negative impact of the scandal.<sup>389</sup>

The apology instantly drew immense public criticism. As pointed out by Zhang Qianfan, a prominent constitutional law expert at Beijing University, Sanlu was not only an important source of local revenue but also of local political legacy.<sup>390</sup> The apology revealed that the local government's first reaction was how to help Sanlu avoid bad publicity and eliminate the negative impact of a scandal. Another commentator, Mr. Shao, discerned that the apology was not actually directed to the victims but to the central government itself.<sup>391</sup> The real purpose of the apology was to beg for forgiveness from those high officials with the authority to determine the political futures of local leaders.

Depending upon governments to enforce high safety standards is illogical when those governments are willing to conceal scandals for local industries. U.S. scholars have long held concerns about the overall enforcement of laws in China due to local protectionism. Professor Lubman pointed out that "local protectionism is so strong that 'it is practically impossible for the leadership in Beijing to maintain sustained and systematic monitoring across China, with the possible exception of a handful of key issues, because enforcement costs are prohibitive.'"<sup>392</sup> Professors Liebman and Milhaupt echoed this observation stating that "[l]ocal protectionism is perhaps the single biggest problem undermining China's efforts to strengthen its legal system, and the combination of devolved authority and local protectionism frequently leads to under enforcement."<sup>393</sup>

389. *Id.*

390. Zhang Qianfan, Yi Sanlu Naifen Shijian Weili: Shipin Anquan Libukai Meiti Jiandu [Sanlu as an Example: Media Reporting is Indispensable for Ensuring Food Safety], Nanfan Ribao, Oct. 7, 2008, available at [http://news.xinhuanet.com/newmedia/2008-10/07/content\\_10159399.htm](http://news.xinhuanet.com/newmedia/2008-10/07/content_10159399.htm).

391. Shao Jian, *Shijiazhuang Shi Zhengfu Jiuqing Gai Xiang Shui Daoqian?* [Whom Did Shijiazhuang Government Owe an Apology?], Zhujiang Wanbao, Oct. 3, 2008, available at <http://news.sina.com.cn/pl/2008-10-03/090016392010.shtml>.

392. Stanley Lubman, *Looking for Law in China*, 20 COLUM. J. ASIAN L. 1, 77 (2006).

393. Benjamin L. Liebman & Curtis J. Milhaupt, *Reputational Sanctions in China's Securities Market*, 108 COLUM. L. REV. 929, 982 (2008); see also Eric Priest, *The Future of Music and Film Piracy in China*, 21 BERKELEY TECH. L.J. 795, 822 (2006) ("Local protectionism probably constitutes the largest obstacle to cracking down on piracy in China."); Srinii Sitaraman, *Regulating the Belching Dragon: Rule of Law, Politics of Enforcement, and Pollution Prevention in Post-Mao Industrial China*, 18 COLO. J. INT'L ENVTL. L. & POL'Y 267, 335 (2007) (arguing that "[t]he lack of strong centralized environmental administration and a deep-seated political unwillingness to disrupt economic growth, combined with corruption and local protectionism, has precluded China from fully complying with its international treaty obligations and enforcing its domestic environmental laws.").

## 2. Rampant Corruption and Mr. Zheng's Execution

China has the most serious corruption problems among industrialized nations, despite government efforts to punish corrupt officials. Transparency International's 2008 survey indicated that China is very similar to other countries plagued with corruption scandals, such as Ghana, Romania, Mexico, and Peru.<sup>394</sup> Overall, China ranks 72 among 180 countries surveyed for general corruption perceptions,<sup>395</sup> despite its status as one of the most robust economies in the world.

In recent years, some corrupt officials and executives found safe havens in Canada and the United States because the two countries do not have extradition treaties with China.<sup>396</sup> The Ministry of Public Security estimated that in 2004 around 500 corrupt Chinese officials had fled overseas with approximately \$8 billion worth of state assets.<sup>397</sup> An infamous example is Mr. Lai Changxing, who circumvented Chinese customs and allegedly "smuggled goods worth as much as \$10 billion, under the protection of corrupt government officials."<sup>398</sup> Mr. Lai is now seeking asylum status in Canada on the ground that he would be executed if repatriated.<sup>399</sup> The relation between corrupt officials and China's food and drug industry is best illustrated by the case of Mr. Zheng Xiaoyu.<sup>400</sup> Mr. Zheng was the director of the State Food and Drug Administration (SFDA).<sup>401</sup> In 2007, the People's Court convicted Mr. Zheng on charges of bribery and

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394. See TRANSPARENCY INTERNATIONAL, 2008 CORRUPTION PERCEPTIONS INDEX, [http://www.transparency.org/news\\_room/in\\_focus/2008/cpi2008/cpi\\_2008\\_table](http://www.transparency.org/news_room/in_focus/2008/cpi2008/cpi_2008_table).

395. *Id.*

396. See Mathew Bloom, *A Comparative Analysis of the United States' Response to Extradition Requests from China*, 33 YALE J. INT'L L. 177, 180-81 (2008).

397. Chenglin Liu, *Informal Rules, Transaction Costs, and the Failure of the "Takings" Law in China*, 29 HASTINGS INT'L & COMP. L. REV. 1, 14 (2005).

398. The Associated Press, No. 1 Fugitive of China Fears Death if Repatriated, N.Y. TIMES, Aug. 10, 2009, <http://www.nytimes.com/2009/08/11/world/americas/11iht-canada.html> (last visited Mar. 31, 2010).

399. *See id.*

400. There are several law review articles citing Mr. Zheng's execution, but none of them provide a detailed analysis of why the death penalty does not deter corruption among Chinese officials. See Beverley Earle & Anita Cava, *Are Anti-Corruption Efforts Paying Off? International and National Measures in the Asia-Pacific Region and Their Impact on India and Multinational Corporations*, 31 HAWAII L. REV. 59, 59 (2008); Gregory H. Fuller, Comment, *Economic Warlords: How De Facto Federalism Inhibits China's Compliance with International Trade Law and Jeopardizes Global Environmental Initiatives*, 75 TENN. L. REV. 545, 546 (2008); Paulman, *supra* note 10, at 124; Julia A. Phillips, Comment, *Does "Made in China" Translate to "Watch Out" for Consumers?: The U.S. Congressional Response to Consumer Product Safety Concerns*, 27 PENN ST. INT'L L. REV. 217, 225 (2008); Laura C. Nastase, Note, *Made in China: How Chinese Counterfeits Are Creating a National Security Nightmare for the United States*, 19 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 143, 162 (2008); Russell Stetler, *Killing Fewer, and Killing Carefully: Death Penalty Defense In China on the Eve of the Beijing Olympics*, 32 CHAMPION, July 2008, at 22.

401. Zheng Xiaoyu de Dianxing Fubai: Yige Bumen Sunhai Yige Hangye [Mr. Zheng Xiaoyu: A typical Case of Corruption that Ruined the Whole Food and Drug Industry], Zhongguo Xinwen Zhoukan, Mar. 9, 2007, available at [http://cn.chinareviewnews.com/doc/1003/2/4/0/100324072\\_5.html?coluid=7&kindid=0&docid=100324072](http://cn.chinareviewnews.com/doc/1003/2/4/0/100324072_5.html?coluid=7&kindid=0&docid=100324072) [hereinafter *A Typical Case of Corruption*].

dereliction of duty; the combined sentences resulted in an order for his immediate execution.<sup>402</sup>

Even though the death sentence stemmed from Mr. Zheng's bribery conviction, his prosecution on dereliction charges revealed the entrenched administrative failures of China's food and drug safety system.<sup>403</sup>

Due to lack of oversight, the SFDA had no standard procedures for reviewing and approving new drug applications. Furthermore, the SFDA lacked a plan to handle the relentless number of new drug applications submitted by over 6,000 pharmaceutical companies across the nation.<sup>404</sup> Even after streamlining the verification process,<sup>405</sup> the flood of applications continued to overwhelm the SFDA. At its peak, one SFDA officer had to review over 30 applications per day.<sup>406</sup> During Mr. Zheng's eight-year tenure, the SFDA approved 150,000 new drugs.<sup>407</sup> In 2004 alone, the

402. See *Former Drug Head Sentenced to Death*, CHINA DAILY, May 29, 2007, available at [http://www.chinadaily.com.cn/china/2007-05/29/content\\_882475.htm](http://www.chinadaily.com.cn/china/2007-05/29/content_882475.htm).

403. See David Barboza, *A Chinese Reformer Betrays His Cause, and Pays*, N.Y. TIMES, July 13, 2007, at A1. Mr. Zheng was a longtime drug maker who moved steadily up the bureaucratic ladder. When China decided to establish the SFDA in 1998, Mr. Zheng became its first director. See *id.* Mr. Zheng's appointment was the direct result of his two seminal proposals: (1) to consolidate drug registration and approval power under the SFDA; and (2) to mandate all drug makers across the country to adopt GMPs in line with internationally acknowledged standards for drug industries. See *id.* The two proposals offered promising solutions to the serious food and drug safety problems that China had experienced in the 1990s.

Prior to the establishment of the SFDA, only provincial governments had the power to approve new drugs. Thus, at that time, there existed no national standard for pharmaceutical products. Since the local governments had strong ties with pharmaceutical companies, drug approval processes were distorted by corruption. Fake and substandard drugs injured and killed a great number of patients each year. See *id.* In addition, some provincial governments used red tape to block drugs from being introduced in other provinces. To establish national standards for pharmaceutical products and curtail local protectionism, Mr. Zheng issued a departmental rule that revoked the provincial governments' power to approve new drugs. According to this rule, the SFDA became the sole authority for registration and approval of pharmaceutical products. See Ames Gross & Momoko Hirose, *Product Registration & Other Regulatory Issues in China*, SPECIALTY PHARMA (2007), available at [http://www.pacificbridgemedical.com/publications/china/2007\\_product\\_registration\\_and\\_other](http://www.pacificbridgemedical.com/publications/china/2007_product_registration_and_other).

The intent of the consolidation was to sever the ties between pharmaceutical makers and the local governments and consequently reduce corruption. See Hepeng Jia, *China Syndrome—A Regulatory Framework*, 25 NATURE BIOTECH, 835, 835–36. Apparently, pharmaceutical companies quickly adapted to the new changes and replaced their prior relationships with the provincial governments for one with the SFDA. See *id.*

404. See *A Typical Case of Corruption*, *supra* note 401.

405. See *id.* To reduce application backlogs, Mr. Zheng abandoned the original plan that required the SFDA to verify each application package. See *id.* Instead, Mr. Zheng authorized provincial food and drug departments to verify the application materials in their respective jurisdictions. See *id.* As a result, the SFDA missed the opportunity to identify phony applications and thus seriously compromised the very goal that the consolidation was designed to achieve. See *id.*

406. Dali L. Young, *Regulatory Learning and Its Discontents in China: Promise and Tragedy at the State Food and Drug Administration*, at 10, available at [http://www.daliyang.com/files/0\\_1\\_Yang\\_SFDA\\_regulatory\\_learning\\_and\\_its\\_discontents.pdf](http://www.daliyang.com/files/0_1_Yang_SFDA_regulatory_learning_and_its_discontents.pdf), *forthcoming in* PUSHING BACK GLOBALIZATION (John Gillespie and Randy Peerenboom eds., 2009).

407. Barboza, *supra* note 403.

SFDA approved 10,009 new drugs, while the U.S. FDA only approved 148 new drugs during the same year.<sup>408</sup> In other words, the SFDA approved a new drug every 12 minutes. At such a rapid pace, there was simply no way to ensure the authenticity of the applications.<sup>409</sup> It was no surprise when at least six fake drugs were subsequently identified among the SFDA approved drugs that seriously injured and killed patients.<sup>410</sup>

Mr. Zheng's tenure was also marked by his strenuous push for GMP standards to ensure drug safety and quality.<sup>411</sup> China's drug industry lagged behind those in developed countries. Many drug makers still kept antiquated equipment in operation. In some Chinese herb medicine factories, workers used their bare feet to blend drug ingredients.<sup>412</sup> As soon as Mr. Zheng became the head of the SFDA, he made implementation of GMP his top priority. The SFDA required all pharmaceutical producers to meet GMP standards by 2004.<sup>413</sup> As mandated, failure to meet the standards would result in losing a state production license.<sup>414</sup>

As with new drug approvals, the SFDA and drug industry were not fully prepared to handle the chaos caused by Mr. Zheng's changes. For the entire pharmaceutical industry, the adoption of GMP became a tremendous undertaking.<sup>415</sup> For small and mid-sized drug makers, GMP standards were all but an unrealistic goal. Facing the tough choice between losing accreditation and incurring additional costs to adopt GMP, pharmaceutical companies quickly attempted to avoid both possibilities by bribing Mr. Zheng and his family. Court documents show that Mr. Zheng took more than \$850,000 in bribes from pharmaceutical companies.<sup>416</sup> To solicit these bribes, Mr. Zheng directed his wife and son to form a consulting firm that provided guidance to pharmaceutical companies. For example, Double Doves Company (DDC) retained the consulting firm and paid his wife's salary and company stock even though she did not work for the company.<sup>417</sup> DDC also generously provided the down payment for a house in Shanghai for Zheng's son. In return, Mr. Zheng expedited the approval of DDC's application for production of sterilized syringes.<sup>418</sup>

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408. See *A Typical Case of Corruption*, *supra* note 401.

409. See Zheng Xiaoyu: Yao Zhi Hai [Mr. Zheng Xiaoyu: Disaster of Drugs] (CCTV Weekly television broadcast Jan. 29, 2007), transcript available at <http://news.cctv.com/china/20070129/108011.shtml>.

410. See Barboza, *supra* note 403.

411. See *id.*

412. See *id.*

413. *Id.*

414. *Id.*

415. See *id.*

416. *Id.*

417. See *id.*

418. See *People v. Zheng Xiaoyu*, available at [http://www.lawyee.net/Case/Case\\_Display.asp?RID=194443&KeyWord=\(SUP. PEOPLE'S CT. GAZ. July 7, 2007\)](http://www.lawyee.net/Case/Case_Display.asp?RID=194443&KeyWord=(SUP. PEOPLE'S CT. GAZ. July 7, 2007)). Kangyu Pharmaceutical acted less discretely, simply giving Zheng's son a check for 1 million Hong Kong Dollars (\$132,000). Shortly thereafter, Mr. Zheng directed SFDA staff to approve Kangyu's application for a new drug. Other drug companies followed suit, giving money or villas to Zheng's wife and son in exchange for SFDA's approval of an increasing number of drugs, medical equipment, and import quotas.



GMP certification is an important production enforcement tool in securing food safety. But Mr. Zheng's case demonstrates that ensuring GMP implementation in China's food and drug industries is virtually impossible. Sanlu and other milk processors that produced melamine tainted products were all GMP certified firms. Without rigorous follow-up testing and auditing by truly impartial and incorruptible agencies, GMP is nothing but a commercial tool to deceive consumers.

Ironically, China has the most serious penalties in the world for taking bribes, yet suffers some of the worst corruption problems among the world's leading economies.<sup>419</sup> The apparent reason is that the death penalty has not produced the kind of deterrence that the Chinese government desired because the government has not enforced its laws equally and consistently.<sup>420</sup> Both the judiciary and prosecutors lack independent authority and only act under the direction of the Party and government officials.<sup>421</sup> When high ranking officials are caught for taking bribes, they are often administratively disciplined rather than criminally prosecuted.<sup>422</sup> Occasionally, some officials are prosecuted and convicted, but are sent to special prisons with comfortable amenities.<sup>423</sup> This arbitrary and capricious manner of prosecution has created political rents for officials, such as Mr. Zheng, and thus incentivizes them to game the system. Mr. Zheng's luck simply ran out because of the frequent food and drug scandals in which people died after consuming tainted food and drug products approved by the SFDA under his watch.<sup>424</sup> The Chinese government did not treat Mr. Zheng's case as an ordinary criminal matter; rather, it used his execution as a statement to the world underscoring its seriousness about food safety.<sup>425</sup>

Despite Zheng's execution, corruption problems have continued to plague quality and safety systems. A New York Times article commented:

Industry analysts say Beijing will have to do a great deal more to solve the country's food and drug safety problems. "If the head of the drug agency is corrupt," said James J. Shen, a longtime industry analyst in Beijing and the publisher of *Pharma China*, "you can imagine how corrupt the whole system is."<sup>426</sup>

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419. See TRANSPARENCY INTERNATIONAL, *supra* note 394.

420. See Eric Pederson, *The Foreign Corrupt Practices Act and its Application to U.S. Business Operations in China*, 7 J. INT'L BUS. & L. 13, 27 (2008).

421. See Stephen L. McPherson, *Crossing the River by Feeling the Stones: The Path to Judicial Independence in China*, 26 PENN ST. INT'L L. REV. 787, 798 (2008).

422. See Mr. Wang Yong's Speech, *infra* note 427.

423. See Nanping Liu, *Trick or Treat: Legal Reasoning in the Shadow of Corruption in the People's Republic of China*, 34 N.C.J. INT'L L. & COM. REG. 179, 182-84 & nn. 12-17.

424. See Barboza, *supra* note 403.

425. See Joseph Kahn, *China Quick to Execute Drug Official*, N.Y. TIMES, July 11, 2007, available at <http://www.nytimes.com/2007/07/11/business/worldbusiness/11execute.html?ref=business>; Zhu Zhe, *Ex-Official Gets Death for Graft*, CHINA DAILY, May 30, 2007, available at [http://www.chinadaily.com.cn/china/2007-05/30/content\\_882994.htm](http://www.chinadaily.com.cn/china/2007-05/30/content_882994.htm).

426. Barboza, *supra* note 403.

Unsurprisingly, Mr. Wang, director of AQSIQ, acknowledged that corruption still poses serious challenges in winning public trust. He revealed that from 2003 to 2008, 829 quality inspection officials were administratively disciplined, with 199 of them subject to criminal prosecution on corruption charges.<sup>427</sup> In 2009, AQSIQ administratively disciplined 105 officials, 40 of them subject to criminal prosecution on corruption charges.<sup>428</sup> In April 2010, Mr. Wei Liang and four other SFDA high officials were arrested on corruption charges.<sup>429</sup> Critics commented that Mr. Zheng's execution apparently failed to provide effective deterrence.<sup>430</sup>

### 3. *Fragmented Food Industry and Unethical Practices*

China's fragmented food industry also poses serious challenges to the implementation of the FSL. Despite the fact that China has become the largest exporter in the world, the Chinese food industry is still in a rudimentary stage.<sup>431</sup> The food industry is made up of over 170,000 food processing firms, 72% of which employ fewer than ten workers.<sup>432</sup> According to a recent SFDA survey of 450,000 food firms, 29% of them did not have any production standards.<sup>433</sup> Of the firms surveyed, 60% did not conduct quality checks of food products nor were they even capable of conducting self-inspections.<sup>434</sup> Furthermore, nearly 50% of the firms lacked sanitation certificates or production licenses.<sup>435</sup> In many cases small firms frequently changed locations to evade inspections.<sup>436</sup> As a result, it is almost impossible for the local government to keep track of these small firms, let alone maintain any meaningful supervision of the food production process.

427. Wang Yong, Dir., AQSIQ, Speech at the AQSIQ Annual Anti-Corruption Conference in Beijing: Zai Quanguo Zhijian Xitong Dangfeng Lianzheng Jianshen Gongzuo Huiyi Shang de Jianghua [Improving the Communist Party's Work Ethics and Building a Clean Government in the Quality Inspection System] (Feb. 18, 2009) (transcript on file with the author of this article).

428. Wang Yong, Dir., AQSIQ, Speech at the AQSIQ Annual Anti-Corruption Conference in Beijing: Zai Quanguo Zhijian Xitong Dangfeng Lianzheng Jianshen Gongzuo Huiyi Shang de Jianghua [Improving the Communist Party's Work Ethics and Building a Clean Government in the Quality Inspection System] (Jan. 28, 2010), transcript available at [http://www.ccic.com/web/static/articles/catalog\\_63100/2010-03-25/article\\_ff8080812760adee012793fa13520069/ff8080812760adee012793fa13520069.html](http://www.ccic.com/web/static/articles/catalog_63100/2010-03-25/article_ff8080812760adee012793fa13520069/ff8080812760adee012793fa13520069.html).

429. Hou Yijun, *Shexian Shouhui Bei Yiyao Qiye Jubao Goujia Yaojian Ju Wuren Bei Pibu* [Upon Pharmaceutical Companies Complaints, Five SFDA Officials were Arrested on Corruption Charges], BEIJING QINGNIAN BAO [BEIJING YOUTH DAILY], Apr. 19, 2010, <http://bjyouth.y.net.com/article.jsp?oid=64955945>.

430. Tong Tong, *Zheng Xiaoyu Men Qianpu Huoji de Qishi* [Lessons from the Repeat Corruption Cases in the SFDA], BEIJING 431 CHENBO [BEIJING MORNING NEWS], Apr. 19, 2010, [http://news.xinhuanet.com/legal/2010-04/19/c\\_1242243\\_2.htm](http://news.xinhuanet.com/legal/2010-04/19/c_1242243_2.htm).

431. Miao Junjie, Zhang Yanran, and Wang Yujuan, *Zhongguo Shipin Jianguan Qiangshi Chushou Zhongzhua Shipin Yuantao* [China's Food Safety Management Focuses on Food Supply], Liaowang, May 23, 2007, available at <http://health.sohu.com/20070522/n250158568.shtml>.

432. Ying, *supra* note 270.

433. See Miao, *supra* note 431.

434. See *id.*

435. See *id.*

436. *Id.*

Even worse, the small food processing firms obtain supplies from hundreds of millions of even smaller family-based farms, many of which are “no larger than a basketball court.”<sup>437</sup> China has 1.3 billion people, but it has only 122 million hectares of arable land, or 0.27 hectares per capita, which is 40% less than the world average, or 12.5% of the U.S. level.<sup>438</sup> Industrialization and urban expansion have not only caused significant shrinkage of China’s arable land but have also degraded land quality.<sup>439</sup> As a result, China has seen a rapid decline in agricultural production in recent years.<sup>440</sup> To ensure higher yields from limited farmland, farmers excessively use pesticides, fertilizers, and animal drugs including antibiotics and growth hormones.<sup>441</sup>

Unsanitary and unethical practices also pose challenges to FSL implementation. Many business owners in China are not convinced that sanitary requirements are worth implementing.<sup>442</sup> The President of Hami Food in Beijing revealed that “chilled and frozen products very often come in taxi cabs or in vans—not under properly controlled conditions.”<sup>443</sup> Just after the passage of the new FSL, a reporter from China Central Television (CCTV) made an investigative report that revealed the dreadful conditions under which food products were processed in small firms.<sup>444</sup> In a covert interview at a family-based sausage mill, a worker pointed to his legs and told the reporter that he had just come back from working in a manure pit without a shower. The reporter asked him if anyone would want to buy his sausages and the man replied, “Without knowing [what I did], people will enjoy my sausages.”<sup>445</sup>

In addition to unsanitary conditions, unscrupulous food producers have deliberately adulterated food with various industrial chemicals to increase profits. In 2005, food safety officials in Beijing ordered the removal of duck eggs from the shelves because farmers fed the ducks with Sudan Red I, a cancer-causing dye.<sup>446</sup> The purpose was to give the yolks a

437. SUBCOMM. ON OVERSIGHT AND INVESTIGATIONS, *supra* note 176, at 2.

438. Yingling Liu, *Shrinking Arable Lands Jeopardizing China’s Food Security*, WorldWatch Inst., Apr. 18, 2006, available at <http://www.worldwatch.org/node/3912>.

439. *See id.*

440. *See id.*

441. *See* Liu, *supra* note 268, at 415.

442. *See* Aleda V. Roth et al., *Unraveling the Food Supply Chain: Strategic Insights from China and the 2007 Recalls*, 44 J. SUPPLY CHAIN MGMT 22, 30 (2008).

443. *Id.*

444. Cai Jing, Kaowen Shipin Zhiliang Haiyou Sha Neng Chi [Food Quality: What is Left to Each?], (China Central Television (CCTV) broadcast Mar. 11, 2009), available at <http://www.39kf.com/focus/spaq/01/2009-03-11-573535.shtml>. The full transcript of the interview is still on a few websites as of the time of this writing. The author has a printed copy of this interview on file.

445. *Id.* In another interview, a worker at a dry tofu plant added industrial dye to make the finished products appealing to consumers. When asked if she would eat the dyed tofu, the worker replied, “it is poisonous, I would never eat it.” *Id.*

446. *Beijing Yi Chakou 37361 bottles of Heinz Tiaoweipin [Beijing Has Detained 37361 Bottles of Heinz Seasoning]*, XINHUA NEWS, Mar. 17, 2005, available at [http://news.xinhuanet.com/newscenter/2005-03/17/content\\_2710373.htm](http://news.xinhuanet.com/newscenter/2005-03/17/content_2710373.htm).

deep red color<sup>447</sup> and deceive consumers who often believe that intensely red yolks were more nutritious than plain ones.<sup>448</sup> Several Kentucky Fried Chicken (KFC) stores in China abruptly stopped selling hot wings for a week because the hot sauces the stores purchased from a Chinese vendor were tainted with Sudan Red I.<sup>449</sup> Sudan Red I has been widely found in foodstuffs across the country.<sup>450</sup>

In 2007, AQSIQ published a long list of poisonous industrial chemicals that food processors had deliberately added to foods for better taste or as preservatives. The following list offers a few examples:<sup>451</sup>

- a) *Melamine* added to milk to boost protein counts;
- b) *Hydrochloric acid* and human hair, which are rich in *amino acid*, added to soy sauce;
- c) *Tannic acid* used with alcohol and water to make red wine;
- d) *Dichlorvos* (a pesticide) added to sausage for better taste;
- e) *Formaldehyde* added to hot pot soups for better taste;
- f) *Sulphur* added to dry fruits as a preservative;
- g) *Paraffin wax* as a preservative used in rice;
- h) *Copper sulfate* used as a preservative in dry mushrooms; and
- i) *Clenbuterol* added to pig feeds, a chemical that can turn fat into red meat in a few weeks.

After the promulgation of the new FSL, the CCTV reports showed that vendors continued to market illegal chemicals designed to boost protein counts in food inspection.<sup>452</sup>

#### 4. Environmental Degradation and the Case of Aquacultured Seafood

Another obstacle for the implementation of the new FSL is environmental degradation. A World Health Organization (WHO) expert advised the Chinese government that implementing “from farm to table” checks is the ultimate solution to food safety.<sup>453</sup> However, China’s serious environ-

447. Li Huiying, *Fuzhou Chahuo Han Sudanhong de “Hongxin” Jidan, Egg [Eggs Tainted with Sudan Red Found in Fuzhou]*, XINHUA NEWS, Nov. 19, 2006, available at [http://news.xinhuanet.com/fortune/2006-11/19/content\\_5350233.htm](http://news.xinhuanet.com/fortune/2006-11/19/content_5350233.htm).

448. See Wu Beibei, *Jidan Yingyang Jiazhi yu Danke Yanse Wuguan [Nutrition of an Egg Has Nothing to Do with Shell Color]*, XINHUA NEWS, Jan. 20, 2010, [http://www.sn.xinhuanet.com/2010-01/20/content\\_18816571.htm](http://www.sn.xinhuanet.com/2010-01/20/content_18816571.htm).

449. Ke Huiming, *Yin Han Sudan Hong Kendeji Zhihai, Baisheng Yuan Chengdan Falv Zeren [Kentucky Fried Chicken is Liable for its Products Tainted Sudan Red]*, SINA NEWS, Mar. 17, 2005, available at <http://finance.sina.com.cn/xiaofei/consume/20050317/16061438808.shtml>.

450. Lei Min & Liu Juhua, *Woguo 30 Jia Qiye 88 Zhong Shipin Bei Chachu You Sudan Hong [Eighty-Eight Food Products Produced by 30 Firms Are Tainted with Sudan Red]*, Xinhua News, Apr. 6, 2005, available at <http://finance.sina.com.cn/xiaofei/puguangtai/20050406/00041490488.shtml>.

451. Cai, *supra* note 444.

452. *Id.*

453. Chua Chin Hon, *Call for “Farm to Table” Checks: Expensive Tests on End-Products Less Effective: WHO*, STRAITS TIMES (Singapore), Oct. 23, 2008, available at [http://www.straitstimes.com/Breaking%2BNews/Asia/Story/STIStory\\_293882.html](http://www.straitstimes.com/Breaking%2BNews/Asia/Story/STIStory_293882.html).

mental problems make ensuring the safety of the food supply from polluted farms extremely difficult, if not entirely impossible.

China's explosive economic growth has taken a heavy toll on its environment, largely because of a "pollute first, control later" development model.<sup>454</sup> In 2007, China became the world's biggest emitter of carbon dioxide, overtaking the United States.<sup>455</sup> Amid the zealous pursuit for a high GDP, local leaders have rarely considered environmental damage as a cost. In some regions, local governments have stretched the development model to the extreme by claiming that people would "rather be choked [by pollution] to death than be starved to death."<sup>456</sup> Because of China's excessive dependence on coal for energy, large numbers of so-called "cancer villages" have emerged, in which many villagers are struck with similar types of cancers.<sup>457</sup> Studies have shown that outdoor pollution has contributed to between 300,000 and 400,000 premature deaths every year in China.<sup>458</sup> It is estimated that air pollution alone has cost \$25 billion in health and loss of productivity costs.<sup>459</sup> In August 2009, more than 600 children near a metal smelter house in Shaanxi Province were found to have high levels of heavy metals in their blood.<sup>460</sup> The pollution was so severe that over one hundred children required hospitalization.<sup>461</sup> The incident prompted an angry protest calling for compensation from the smelter.<sup>462</sup>

Industrial revolution has also had catastrophic effects on China's water systems. According to a joint study by the United Nations Development and Environment Program (UNDP) and the Chinese government, "only five percent of household sewage and seventeen percent of industrial waste are properly treated prior to discharge."<sup>463</sup> Approximately 3.7 billion tons of industrial waste and sewage are discharged daily into rivers,

454. Alex Wang, *The Role of Law in Environmental Protection in China: Recent Developments*, 8 VT. J. ENVTL. L. 195, 198 (2007); see also Yuhong Zhao, *Trade and Environment: Challenges After China's WTO Accession*, 32 COLUM. J. ENVTL. L. 41, 48-49 (2007) (providing Table 2, which shows the correlation between trade growth and environmental pollution).

455. See Elisabeth Rosenthal, *China Increases Lead as Biggest Carbon Dioxide Emitter*, N.Y. TIMES, June 14, 2008, available at <http://www.nytimes.com/2008/06/14/world/asia/14china.html>.

456. Li Jia, Liu Junlu & Han Qing, Wuran Xiyi: Wuran Qiye Weihe Bu Choujia [Polluting Factories Are Moving to the Western Region of China: Why Are They Well Received?], XINHUA NEWS, Sept. 30, 2006, available at [http://news.xinhuanet.com/politics/2006-09/30/content\\_5158939.htm](http://news.xinhuanet.com/politics/2006-09/30/content_5158939.htm).

457. Yu Cheng, Yianhai Duoge Shengfen Zhuxian Ai Zheng Cun ["Cancer Villages" Emerged Along Coastal Regions], Nanfang Dushi Bao, Nov. 5, 2007, available at <http://news.163.com/07/1105/16/3S14DUL600011SM9.html>.

458. Nicholas D. Kristof, Op-Ed., *Where Breathing is Deadly*, N.Y. TIMES, May 25, 2008, available at <http://www.nytimes.com/2008/05/25/opinion/25kristof.html>.

459. Sitaraman, *supra* note 393, at 277.

460. Protesters Storm Plant After Children Are Poisoned, Aug. 17, 2009, available at <http://www.france24.com/en/20090817-protesters-storm-plant-after-children-are-poisoned-china-lead-school-dongling-shaanxi>.

461. *Id.*

462. *Id.*

463. Sitaraman, *supra* note 393, at 280.

lakes and coastal waters.<sup>464</sup> The Chinese Environmental Science Academy reported that 80% of the 200 lakes surveyed are no longer suitable for drinking because of industrial pollution.<sup>465</sup> In 2006, the State Environmental Protection Agency (SEPA) revealed an even bleaker outlook of the water systems: seven of the nine lakes under its surveillance were even dangerous “to human skin on contact.”<sup>466</sup>

Alarming, China is the largest exporter of aquacultured seafood in the value of \$8.7 billion,<sup>467</sup> which accounts for 70% of the world’s total production.<sup>468</sup> China is the third largest exporter of seafood into the United States.<sup>469</sup> “Approximately 80% of the seafood consumed in the U.S. is imported from approximately 62 countries.”<sup>470</sup> Seafood from China makes up about 21% of the total imported seafood into the United States.<sup>471</sup> According to Food & Water Watch, the conditions that aquacultured seafood is grown under in China are deplorable: [P]roducers tightly cram thousands of finfish and shellfish into their facilities to maximize production. This generates large amounts of waste, contaminates the water, and spreads disease, which can kill off entire crops of fish if left untreated. Even if a disease does not kill off all the fish in an aquaculture facility, remaining bacteria, such as *Vibrio*, *Listeria*, or *Salmonella*, can sicken people who eat the fish.<sup>472</sup>

To maintain productivity in severely polluted waters, aquaculture farmers routinely use excessive amounts of antibiotics, fungicides, and pesticides, none of which would be approved by either the Chinese or U.S. government.<sup>473</sup> The U.S. FDA has concluded that the unapproved chemicals used by the Chinese aquaculture farms, such as malachite green, nitrofurans, fluoroquinolones, and gentian are carcinogenic.<sup>474</sup> An FDA report stated, “The presence of antibiotic residues may contribute to an increase of antimicrobial resistance in human pathogens.”<sup>475</sup> In addition to animal drugs and pesticides, farmers feed fish and shrimp substances such as melamine, vitamin C, contraceptive drugs, fertilizers, and olaquinox

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464. Food & Water Watch, *supra* note 7, at 5.

465. Li Jing, *Fu Yingyang Hua Weixie Woguo Hubo Shengtai Anquan [Eutrophication Threatens Ecological Condition of Lakes in China]*, CHINA DAILY, March, 31, 2009, available at [http://www.chinadaily.com.cn/zgzx/2009-03/31/content\\_7635373.htm](http://www.chinadaily.com.cn/zgzx/2009-03/31/content_7635373.htm).

466. Sun Xiaohua, *Ban Slapped on Polluting Cities, Zones*, CHINA DAILY, July 4, 2007, available at [http://www.chinadaily.com.cn/china/2007-07/04/content\\_909239.htm](http://www.chinadaily.com.cn/china/2007-07/04/content_909239.htm).

467. David Barboza, *China Says Its Seafood Is Now Safer and Better*, N.Y. TIMES, Jan. 18, 2008, at C3.

468. FDA IMPORT ALERTS, *supra* note 2.

469. *Id.*

470. *Id.*

471. Food & Water Watch, *supra* note 7, at 2.

472. *Id.* at 5.

473. Wu Milu & Tan Na, *Jiekai Yuye Yangzhi Heimu: Du Shiliao Chuifei Yuxia [Piercing the Black Veil of Aquaculture Farming: Using Toxic Feeds to Increase Fish and Shrimps Production]*, Beijing Keji Bao [Beijing Sci. & Tech. Daily], Apr. 7, 2009, available at [http://www.sxgov.cn/souqi/souqi\\_content/2009-04/16/content\\_69982.htm](http://www.sxgov.cn/souqi/souqi_content/2009-04/16/content_69982.htm).

474. FDA IMPORT ALERTS, *supra* note 2.

475. *Id.*

order to increase production while saving feed costs.<sup>476</sup> In April 2009, the local government was alerted to the use of olaquinox in the feed only after farmers reported large numbers of dead fish.<sup>477</sup>

## VI. Comparative Perspectives: Hong Kong and Japan

Hong Kong imports 95% of its food supply, the bulk coming from China.<sup>478</sup> While food scandals break out frequently in China, Hong Kong has kept a nearly impeccable food safety record. The measures that the Hong Kong government take to protect the public from deleterious imported food may provide some lessons to the United States.<sup>479</sup> First, Hong Kong allocates considerable resources to screening Chinese imports. The government not only conducts visual inspections but also conducts tests on samples of imports checking for microbiological or chemical contaminations at the Hong Kong government's laboratories.<sup>480</sup> For example, vegetables are tested for pesticide residues.<sup>481</sup> Second, Hong Kong only imports eggs, chickens and vegetables from farms and processing plants that have registered with the Hong Kong government.<sup>482</sup> Moreover, Hong Kong sends inspectors to audit the registered farms and plants to ensure compliance.<sup>483</sup> Third, Hong Kong designates ports for import entry according to product type; for example there is a fish port and a vegetable port. Through specialization, the government can efficiently allocate resources to maximize the effect of border inspections.<sup>484</sup>

Japan imports more foods from China than the United States.<sup>485</sup> Japan samples and tests about 15% of food imports from China,<sup>486</sup> while the FDA only tests 1% of imported foods. Like Hong Kong, Japan only imports food from a small number of process plants and farms in China. For example, only 36 processing plants are qualified to ship processed chickens to Japan.<sup>487</sup> Moreover, the Japanese government sends food safety officials to inspect those processing plants and farms annually.<sup>488</sup>

In addition to the rigorous physical inspections at their ports of entry, Hong Kong and Japan have taken a systematic approach to selecting and auditing processing plants and farms. In contrast, the "FDA often has very limited information regarding conditions under which most food is pro-

476. Wu & Tan, *supra* note 473.

477. *Id.*

478. See SUBCOMM. ON OVERSIGHT AND INVESTIGATIONS, *supra* note 176, at 8.

479. See *id.*

480. *Id.*

481. See *id.*

482. See *id.*

483. *Id.*

484. *Id.*

485. Martin Fackler, *Safe Food for Japan*, N.Y. Times, Oct. 11, 2007, at C1, available at <http://www.nytimes.com/2007/10/11/business/worldbusiness/11safety.html>.

486. See SUBCOMM. ON OVERSIGHT AND INVESTIGATIONS, *supra* note 176 at 9.

487. *Id.*

488. *Id.*

duced in foreign countries.”<sup>489</sup> Experts predict that the United States will not adopt either the Hong Kong or Japanese model because the costs for additional inspections and audits would be prohibitively expensive for U.S. groceries.<sup>490</sup> Besides, American consumers would most likely be unwilling to pay for additional regulatory costs.<sup>491</sup> For this precise reason, the Grocery Manufacturers Association (GMA) has avidly lobbied the government to avoid any increase in import inspections.<sup>492</sup>

### Conclusion: Some Thoughts on Regulatory Costs, Adverse Selection and Food Safety

There are three approaches for securing food safety in the U.S.: (1) increase inspections at the borders by utilizing traditional outcome-based enforcement tools; (2) certify and inspect foreign food facilities, utilizing production-based enforcement tools on exports to the U.S.; and (3) reduce imports by increasing domestic production. The use of outcome- and enforcement-based tools has proven effective in the domestic context, but applying similar methods to imported food will invariably increase costs for importers and retailers. The FDA is unwilling to incur such costs on imported foods because doing so would hinder international trade.<sup>493</sup> Part of the FDA’s reluctance to impede trade is due to the successful lobbying efforts of the Grocery Manufacturers Association (GMA).<sup>494</sup> The GMA is adamantly against both named enforcement choices because the subsequent rise in regulatory costs will reduce profits. The result is that the Agreement with China on food safety wholeheartedly embraces the GMA’s wishes to outsource regulatory power to China. As analyzed in Part IV, however, the Chinese government is not capable of handling this task because of inherent flaws in its food safety regulatory framework. In addition, environmental degradation now threatens China’s raw food supply.

Therefore, the most sensible approach to ensuring food safety in the United States is to increase domestic production. This approach, however, is difficult to implement, because it largely hinges on consumer demand. Without knowing the conditions under which imported foods are grown and processed, consumers naturally opt for the cheapest products.<sup>495</sup>

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489. FDA FOOD PROTECTION PLAN, *supra* note 1, at 8; see SUPPAN, *supra* note 247247, at 11.

490. See SUPPAN, *supra* note 247, at 7 (finding that the FDA cannot “afford the cost of rising to Japanese and Hong Kong’s inspection and testing rates.”).

491. See *id.* at 7-8 (noting that unlike American consumers, Japanese consumers are “willing to pay a premium for safety.”).

492. *Id.* at 6; see also GROCERY MFRS. ASS’N, *supra* note 262, at 6.

493. See SUPPAN, *supra* note 247, at 9.

494. See *id.* at 6; see generally Vincent R. Johnson, *Regulating Lobbyists: Law, Ethics, and Public Policy*, 16 CORNELL J.L. & PUB. POL’Y 1 (2006) (extensively analyzing the effect that lobbyists’ conduct has on law and policy).

495. See, e.g., George A. Akerlof, *The Market for “Lemons”: Quality Uncertainty and the Market Mechanism*, 84 Q.J. ECON., 488, 488 (1970) (finding that when product quality is unknown to consumers then producers are incentivized to produce inferior goods to maximize profit).



When domestic food manufacturers are subject to more frequent inspections and other regulatory costs, they find it impossible to compete with imported foods subject to little or no regulatory oversight. For example, Louisiana shrimpers sustained substantial financial losses when importers placed mislabeled low quality Chinese shrimp in the U.S. market.<sup>496</sup> As consumers are incapable of telling differences from appearance, their uninformed demand for inferior imported foods drives high quality domestic foods out of the market. According to George Akerlof, a Nobel Prize winning economist, this phenomenon is called “adverse selection.”<sup>497</sup>

When market failure occurs because of “adverse selection,” governmental intervention is imperative to protect consumer welfare.<sup>498</sup> With regard to food safety, governmental intervention means effective use of both outcome- and production-based enforcement tools. Unwisely, the FDA’s action plan runs contrary to established wisdom by moving away from traditional enforcement tools and outsourcing regulatory power to China. While recent food scares caused by domestically produced foods frustrated U.S. consumers, they have yet to fully realize that U.S. food safety problems pale in comparison to those in China.

Consequently, there is no shortcut to food safety. Utilizing traditional outcome- and production-based enforcement tools for imported foods is the only way to ensure food safety. Regulatory costs are inevitable. In this regard, Japan and Hong Kong have set a good example for the United States by not only frequently inspecting imports, but also certifying Chinese food facilities. When the FDA implements direct supervision over imported foods, the rising regulatory costs will force importers to be vigilant about selecting supply sources and increased food safety will result. Greater regulatory expenditures will also put domestic foods on an equal footing with imported foods in terms of market competition. The simple truth is that with lax governmental regulation, producers under-invest in food safety. Consequently, regulatory power over food safety cannot be delegated.

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496. See Jeremy Alford, *Shrimper Group Boiling Mad Over Foreign Fraud*, DAILY COMET, Apr. 4, 2009.

497. See Akerlof, *supra* note 495, at 488-500.

498. See *id.*