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**FROM CHINA TO YOUR PLATE:  
AN ANALYSIS OF NEW REGULATORY EFFORTS  
AND STAKEHOLDER RESPONSIBILITY  
TO ENSURE FOOD SAFETY**

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“[F]rom the production line to the dining table . . .”<sup>1</sup>

## INTRODUCTION

The “flattening”<sup>2</sup> of the world economy has produced many consequences, not the least of which is the ability of consumers to obtain fresh foods from just about anywhere in the world. But, consumers not only want fresh foods from various countries, they want them at a reasonable, even cheap, cost.<sup>3</sup> In the twenty-first century, China has emerged as the primary source for U.S. suppliers looking for cheap foods and drugs.<sup>4</sup> Not surprisingly, China is the “largest exporter of seafood,” by volume, to the United States;<sup>5</sup> similarly, 50 percent of Heparin,<sup>6</sup> numerous antibiotics, and many other drugs are manufactured in China.<sup>7</sup> Unfortunately, China

1. USDA FOREIGN AGRIC. SERV., GAIN REP. NO. CH9019, FAIRS SUBJECT REPORT: FOOD SAFETY LAW OF THE PEOPLE’S REPUBLIC OF CHINA 2 (2009), available at <http://www.fas.usda.gov/gainfiles/200903/146327461.pdf>.

2. The term “flat” was first used relative to the world “economy” in Thomas L. Friedman’s book, *The World Is Flat: A Brief History of the Twenty-First Century*, which analyzes globalization in the early part of the twenty-first century. The title is a metaphor for viewing the world as a level playing field relative to commerce, where all competitors have an equal opportunity. See generally THOMAS L. FRIEDMAN, *THE WORLD IS FLAT: A BRIEF HISTORY OF THE TWENTY-FIRST CENTURY* (2005).

3. U.S. outsourcing has increased approximately 70 percent over the last decade, and, in the case of China, lower costs have induced U.S. companies to move their entire operations overseas, in particular due to China’s “lower labor and material costs.” 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, 233–34 (2008).

4. See *id.* at 234. As author Gardiner Harris noted in an article in *The New York Times Magazine*, “[c]onsumers like their commodities cheap, in the case of aspirin as with everything else. China now produces about two-thirds of all aspirin and is poised to become the world’s sole global supplier in the not-too-distant future.” Gardiner Harris, *The Safety Gap*, N.Y. TIMES MAG., Nov. 2, 2008, available at <http://www.nytimes.com/2008/11/02/magazine/02fda-t.html?r=3&pagewanted=print>.

5. Don Kraemer, Deputy Dir., Office of Food and Safety, Statement Before U.S. and China Economic and Security Review Commission (Apr. 25, 2008), available at <http://www.fda.gov/NewsEvents/Testimony/ucm115243.htm>.

6. *Heparin Chinese Supplier Was Never Checked by Chinese Drug Regulators*, MED. NEWS TODAY (Feb. 16, 2008), <http://www.medicalnewstoday.com/articles/97598.php>. As will be discussed in much greater detail later, Heparin is a blood-thinning drug administered to dialysis and surgery patients.

7. In the spring of 2008, Chinese Heparin manufacturers substituted a cheaper, ineffective ingredient in the doses they exported to the United States. The FDA discovered the fraud, but not until eighty-one people were stricken and tens of thousands were exposed to the tainted product. Harris, *supra* note 4; see also *E-Alert: FDA Opens Offices in China: More Inspections Likely*, COVINGTON & BURLING (Dec. 15, 2008) [hereinafter *FDA Opens Offices in*

has become as well known as a source of cheap food and drugs as for the headlines it grabs for tainted food and drug products.<sup>8</sup> Pet foods<sup>9</sup> and milk products tainted with Melamine, which is added to make the product satisfy the minimum requirements for protein, are two recent examples.<sup>10</sup> Other products recently in the news include: contaminated eggs, dumplings, pet food, toothpaste,<sup>11</sup> antibiotics, and an array of toys.<sup>12</sup>

Although the U.S. government has multiple agencies that oversee the safety of food and drugs,<sup>13</sup> and numerous inspectors tasked with examining specific aspects of U.S. food and drug production,<sup>14</sup> the inspection of foods sourced from other countries has become an increasing and worrisome challenge.<sup>15</sup> Not only is the U.S. government concerned with the quality of food and drug imports from abroad, but corporations that subcontract with suppliers from China for food and drug manufacturing also have concerns on a number of fronts. First, tainted foods harm their consumers. Second, once the public becomes aware of the source

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*China*], <http://www.cov.com/publications/?Practices=ed98f0ed-a934-4c19-9215-802e5997a587&search=1> (finding that 714 drug manufacturing establishments located in China supply finished drug products to United States, the highest number of manufacturers outside United States, and that from 2002 through 2007 the FDA inspected only eighty of these establishments).

8. See Harris, *supra* note 4.

9. Kate Paulman, Comment, *See Spot Eat, See Spot Die: The Pet Food Recall of 2007*, 15 ANIMAL L. 113, 120 (2009).

10. See GEOFFREY S. BECKER, CONG. RESEARCH SERV., RL 34198, U.S. FOOD AND AGRICULTURAL IMPORTS: SAFEGUARDS AND SELECTED ISSUES 3 (2009), available at <http://ncseonline.org/nle/crsreports/09Mar/RL34198.pdf>.

11. Meghan Josephine Carmody, Comment, *The Price of Cheap Goods: International Trade with China And The Need For Stringent Enforcement of Manufacturing Regulations*, 34 N.C. J. INT'L L. & COM. REG. 655, 656 (2008).

12. Gabriel Allen, Note, *Get the Lead Out: A New Approach for Regulating the U.S. Toy Market in a Globalized World*, 36 GA. J. INTL & COMP. L. 615, 616 (2008).

13. Overall, fifteen federal agencies oversee the administration of some thirty laws related to food safety. GEOFFREY S. BECKER, CONG. RESEARCH SERV., RS22600, THE FEDERAL FOOD SAFETY SYSTEM: A PRIMER, 2 (2006), available at <http://ncseonline.org/NLE/CRSreports/07March/RS22600.pdf>.

14. For example, the Meat Inspection Act of 1906, ch. 3913, 34 Stat. 674, 674, as amended by the Wholesome Meat Act 1967, 81 Stat. 584, 584, mandates that the USDA inspect all cattle, sheep, goats, and horses when slaughtered for human consumption. 21 U.S.C. § 603 (2006).

15. See GEOFFREY S. BECKER, CONG. RESEARCH SERV., RS22664, U.S. FOOD AND AGRICULTURAL IMPORTS: SAFEGUARDS AND SELECTED ISSUES 1 (2007), available at <http://www.au.af.mil/au/awc/awcgate/crs/rs22664.pdf> ("U.S. food and agricultural imports have increased significantly in recent years, leading to concerns about whether current federal programs and funding for them are sufficient to ensure their safety. The discovery of adulterated pet food ingredients from China has heightened interest in the issue in the 110th Congress.").

of consumer harm, the corporations will suffer consequential harm to their reputations. Finally, the risk of being sued for defects in these products under U.S. product liability laws is of significant concern.

A close analysis of these issues suggests that multiple players in global transactions over food and drugs must take measures to oversee the exportation and importation of safe food and drug products. The stakeholders involved in the transactions are numerous: the host country government, the home country government, the host country's suppliers, the home country's producers, consumer advocates, and finally, the global organizations whose standards have been universally adopted.<sup>16</sup> Therefore, the responsibility to oversee the safe transport of goods from one part of the globe to another falls on multiple parties. While regulations and inspections significantly help in protecting these goods, there has to be integrity in the marketplace for these safeguards to work effectively.

What kind of exposure do U.S. companies doing business in China potentially face as the result of tainted food and drugs? What legal protections are in place in China? How can the U.S. regulatory framework create a safety net for companies and consumers? What should companies do to ensure quality? This Article will analyze the above issues from the perspectives of the various stakeholders already identified. Part I of this Article describes two examples, milk and Heparin, illustrating the problems with food and drug safety. Part II analyzes China's developing regulations, focusing on the comprehensive new Food Safety Law, effective June 1, 2009. Part III details the U.S. regulatory framework and recent steps taken by the U.S. government to monitor food safety in China. Part IV contrasts the European Union approach to food safety regulation. Part V considers non-governmental organization and corporate responses. Part VI reviews ethical considerations. Lastly, Part VII makes specific recommendations for best practices and risk management. The goal of this Article is to analyze current host/home country prac-

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16. The Codex Alimentarius Commission (Codex Commission) is the de facto global legislative organization that creates guidelines on food hygiene and food safety. James Chyau, Note, *Casting A Global Safety Net: A Framework for the Safety in the Age of Globalization*, 64 *FOOD & DRUG L.J.* 313, 320 (2009) (proposing a new international agency with a global framework for food safety). The Hazard Analysis Critical Control Points (HACCP) are the universal food safety standards that the Codex Commission has adopted for standardized global application. For a full discussion of HACCP, see HACCP, <http://ag.arizona.edu/maricopa/fcs/haccp/index.htm>; see also *infra* Appendix.

tices, as well as those adopted by home country corporations to identify gaps and recommend regulations and policies that will enhance safety in the supply chain of food and drug imports from China to the United States.

## I. BACKGROUND: TWO ILLUSTRATIVE EXAMPLES

China's developing legal and regulatory framework governing food and drug safety is the direct result of problems with products sold in China and in the global marketplace.<sup>17</sup> Food imported from China has increased three-fold in the last decade, totaling more than \$5.2 billion in 2008.<sup>18</sup> Authorities in China investigated 76,500 cases of fake food in 2008.<sup>19</sup> Significantly, the major cause of China's food safety problem is "illicit substances."<sup>20</sup> This was particularly evident in the case of both the contamination of milk and Heparin in China.

### A. *The Sanlu Milk Contamination*

The Melamine-contaminated milk scandal involved Sanlu Group (Sanlu), one of China's four largest dairy companies.<sup>21</sup> Sanlu operated as a joint venture with Fonterra, a New Zealand conglomerate.<sup>22</sup> Recognized as a significant regional brand, Sanlu faced a significant challenge to its market share from competitor companies Mangniu and Yili.<sup>23</sup> Though Sanlu sold the tainted milk to the general public, it was not directly responsible for infusing the milk with Melamine. Rather, low-level suppliers apparently added the chemical to milk after buying the milk from local farmers.<sup>24</sup> "The adulterated milk was then resold to large companies like Sanlu."<sup>25</sup>

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17. See Dan Flynn, *China's Food Safety Expo on for November*, FOOD SAFETY NEWS (Sept. 27, 2009), <http://www.foodsafetynews.com/2009/09/-china-is-selling-three/>.

18. *Id.*

19. *Fake Food Cases in '08 at 76,500*, CHINA DAILY (Mar. 16, 2009) [hereinafter *Fake Food Cases*], [http://www2.chinadaily.com.cn/china/2009-03/16/content\\_7581236.htm](http://www2.chinadaily.com.cn/china/2009-03/16/content_7581236.htm).

20. *Id.*

21. NICK DEBNAM & THOMAS STANLEY, KPMG, *THE MILK AND DAIRY MARKET IN CHINA 4* (2008), available at <http://www.kpmg.com.au/Portals/0/The%20Milk%20and%20Dairy%20Market%20in%20China.pdf>. Melamine is an industrial chemical that can be found in cleaning supplies, plastics, and fertilizers. It is considered a contaminant in food, which can block filtering systems in the body and can lead to kidney stones, kidney disease, kidney failure, and death. BECKER, *supra* note 10, at 13.

22. See *Fake Food Cases*, *supra* note 19.

23. DEBNAM & STANLEY, *supra* note 21, at 4.

24. Edward Wong, *Company at Core of China's Milk Scandal is Declared Bankrupt*, N.Y. TIMES, Dec. 25, 2008, available at <http://www.nytimes.com/2008/12/25/world/asia/25milk.html>.

25. *Id.*

Twenty-two companies sold contaminated milk, which was “supplied by a chain of . . . producers and middlemen.”<sup>26</sup> Melamine was added to products to artificially inflate protein levels.<sup>27</sup> Hundreds of tons of “protein powder” laced with Melamine were added to milk powder. By using the less expensive Melamine to give the appearance of higher protein levels in milk, producers were able to increase their profits.

As a result of the contamination, six children were killed and nearly 300,000 others were sickened in China.<sup>28</sup> The reverberations of the tainted milk were felt around the world. In the United States, for example, Chinese products containing milk or milk powder, such as candy, snacks, bakery products, and pet food, were detained at U.S. borders until it could be proven that they were not contaminated.<sup>29</sup> Similarly, Cadbury recalled eleven confectionary products containing milk powder manufactured at its Beijing facility and M&Ms, Snickers bars, and Oreo biscuits made in China were also recalled.<sup>30</sup> The scare also prompted the European Union to ban all baby food containing even traces of Chinese milk, and to test other products containing Chinese milk.<sup>31</sup>

Ultimately, twenty-one people were convicted for intentionally tainting China’s dairy supply.<sup>32</sup> The former chairwoman of Sanlu pled guilty to selling adulterated baby formula and was sentenced to life in prison.<sup>33</sup> In addition, two milk producers were executed in November 2009.<sup>34</sup> The Hebei High People’s Court upheld the

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26. *Chinese Milk Scam Duo Face Death*, BBC NEWS (Jan. 22, 2009), <http://news.bbc.co.uk/2/hi/7843972.stm>.

27. Gardiner Harris & Andrew Martin, *F.D.A. Detains Chinese Imports for Testing*, N.Y. TIMES, Nov. 14, 2008, available at <http://www.nytimes.com/2008/11/14/business/worldbusiness/14fda.html?partner=rssnyt&emc=rss>.

28. David Barboza, *China Begins Trials for 9 in Tainted Milk Scandal*, N.Y. TIMES, Dec. 30, 2008, at A8, available at <http://www.nytimes.com/2008/12/30/world/asia/30china.html>.

29. Harris & Martin, *supra* note 27.

30. *Cadbury Recall All Chocolate Made in China over Fears It May Contain Contaminated Milk*, DAILY MAIL (Sept. 29, 2008), <http://www.dailymail.co.uk/news/worldnews/article-1063950/Cadbury-recall-chocolate-China-fears-contain-contaminated-milk.html>; see also Aaron O. Patrick et al., *Food Giants Scrutinize Chinese Suppliers*, WALL ST. J., Sept. 30, 2008, available at <http://online.wsj.com/article/SB122278326555990197.html>.

31. *EU Limits Imported Chinese Food*, BBC (Sept. 25, 2008), <http://news.bbc.co.uk/1/hi/world/europe/7635594.stm>.

32. *China Closes Dairy That Reused Tainted Condensed Milk*, TAIPEI TIMES (Jan. 8, 2010), <http://www.taipetimes.com/News/front/archives/2010/01/08/2003462970>.

33. *Id.*; *Chinese Milk Scam Duo Face Death*, *supra* note 26.

34. Sharon LaFraniere, *2 Executed in China for Selling Tainted Milk*, N.Y. TIMES, Nov. 25, 2009, available at [http://www.nytimes.com/2009/11/25/world/asia/25china.html?\\_r=1&emc=etal](http://www.nytimes.com/2009/11/25/world/asia/25china.html?_r=1&emc=etal).

convictions and sentences, and dismissed all appeals.<sup>35</sup> “The government . . . also fired local officials who may have covered up the adulteration of milk products.”<sup>36</sup> In October 2008, the Chinese Health Ministry announced new limits on Melamine in infant formulas, liquid milk, milk powder, and food products.<sup>37</sup>

### B. *The Heparin Contamination*

Similarly, contaminated Heparin was found in the drug supplies of ten countries around the world, including Australia, Canada, China, France, and the United States.<sup>38</sup> Dr. Janet Woodcock, Director of the U.S. Food and Drug Administration (FDA), testified before Congress that the FDA believes that the use of Heparin in contaminating milk was intentional.<sup>39</sup> The scandal began in January 2008, after the FDA learned about an increasing number of severe adverse reactions to Heparin, a widely used blood thinner.<sup>40</sup> Between January 1, 2007, and May 31, 2008, the FDA received reports of 246 deaths in patients receiving Heparin.<sup>41</sup> Researchers at the FDA identified “oversulfated chondroitin sulfate” as the contaminant.<sup>42</sup> Oversulfated chondroitin sulfate apparently mimics the characteristics of Heparin, but can cause deadly reactions.<sup>43</sup> The active ingredient in Heparin is manufactured using raw material from pig intestines, which is transformed into a dry substance.<sup>44</sup> Because the raw material is gathered from thousands of

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35. *Court Upholds Death Penalty in Milk Scandal*, CHINA DAILY (Mar. 26, 2009), [http://www.chinadaily.com.cn/china/2009-03/26/content\\_7620098.htm](http://www.chinadaily.com.cn/china/2009-03/26/content_7620098.htm).

36. Barboza, *supra* note 28.

37. Edward Wong, *China Announces Stricter Testing Because of Milk Scandal*, N.Y. TIMES, Oct. 9, 2008, at A10.

38. Gardiner Harris, *U.S. Identifies Tainted Heparin in 11 Countries*, N.Y. TIMES, Apr. 22, 2008, available at <http://www.nytimes.com/2008/04/22/health/policy/22fda.html>.

39. Gardiner Harris, *Heparin Contamination May Have Been Deliberate, F.D.A. Says*, N.Y. TIMES, Apr. 30, 2008, available at <http://www.nytimes.com/2008/04/30/health/policy/30heparin.html>.

40. *Id.*

41. U.S. Food and Drug Admin., *Information on Adverse Event Reports and Heparin*, FDA.GOV, [http://www.fda.gov/cder/drug/infopage/heparin/adverse\\_events.htm](http://www.fda.gov/cder/drug/infopage/heparin/adverse_events.htm) (last visited Feb. 14, 2011).

42. Michael Smith, *How Tainted Heparin Slipped Through U.S. Safety Net*, MEDPAGE TODAY (Apr. 24, 2008), <http://www.medpagetoday.com/Nephrology/ESRD/9235>. Oversulfated chondroitin sulfate, which is derived from animal cartilage, is “structurally similar to Heparin” and not easily detected. Researchers used nuclear magnetic resonance techniques to determine the identity of the contaminant. *Id.*

43. *Id.*; David Barboza, *China Orders New Oversight of Heparin, With Tainted Batches Tied to U.S. Deaths*, N.Y. TIMES, March 22, 2008, available at <http://www.nytimes.com/2008/03/22/world/asia/22heparin.html>.

44. *Id.*

homes and tiny factories in China, the supply chain to chemical companies is very complex and difficult to monitor.<sup>45</sup> Cost is also an issue, as oversulfated chondroitin sulfate is vastly cheaper than Heparin.<sup>46</sup> A congressional investigator reported that oversulfated chondroitin sulfate costs \$9 a pound, while Heparin costs \$900 a pound.<sup>47</sup>

Changzhou SPL Company, Ltd. (Changzhou), a subsidiary of Scientific Protein Laboratories (SPL) operating in Jiangsu Province, China, was identified as the source of contaminated Heparin.<sup>48</sup> Changzhou sold the Heparin to SPL who, in turn, sold the Heparin to Baxter Healthcare Corporation (Baxter), the largest producer of Heparin.<sup>49</sup> Baxter purchased Heparin from Changzhou beginning in 2004, yet it did not inspect Changzhou's plant until September 2007.<sup>50</sup> Problems were also not uncovered by the FDA, which mistakenly failed to inspect the Changzhou plant.<sup>51</sup> In their defense, FDA officials claimed that an inspection would not have uncovered the contamination.<sup>52</sup> Millions of vials of Heparin are sold in the United States and approximately half of those doses are manufactured and sold by Baxter.<sup>53</sup> Baxter now faces at least forty product liability lawsuits in a well-organized effort in the United States.<sup>54</sup>

Although it is unclear what the motives are for the contamination, it is seemingly related to pressure felt by Chinese companies to cut costs by using inferior quality raw materials.<sup>55</sup> Whatever the reason, firms importing the products and selling them in the United States face significant legal liability<sup>56</sup> and must come up

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45. *See id.*

46. Harris, *supra* note 39.

47. *Id.*

48. *Id.*

49. *Id.*

50. *Id.*

51. *Id.*

52. *Id.*

53. *Resources Aid Attorneys Representing Clients Harmed by Heparin*, 44 TRIAL 11 (2008).

54. Christina Laga, *Lawsuits over Tainted Heparin Manufactured in China: Is the F.D.A. Becoming the Global Healthcare Authority?*, 14 PUB. INT. L. REP. 109, 110 (2008).

55. *See* Zhang Shouzhi, Gui Hongxia & Li Xiang, *New Toy and Food Recall Legislation: How China Is Addressing Global Product Safety Concerns*, CHINA L. REP., November 2007, at 4, 5, available at <http://meetings.abanet.org/webupload/commupload/IC860000/newsletterpubs/November07CLR.pdf>.

56. Nancy M. Erfle & Joshua S. DeCristo, *Chinese Products, American Lawsuits: Where Do We Go From Here?* CHINA L. REP., September 2007, at 14, 22. For a discussion about Chinese product liability law, see Elizabeth Ann Hunt, Note, *Made in China: Who Bears the Loss and Why?*, 27 PENN ST. INT'L L. REV. 915, 927-33 (2009).

with ways to ensure that the products they are selling are within acceptable standards.

## II. CHINA'S NEW FOOD SAFETY LAW AND REGULATIONS

Even before these two incidents, the Chinese government identified the need to address food and drug quality, as evidenced by the Five-Year Plan issued by the State Council in 2007.<sup>57</sup> Pursuant to this plan, the Chinese government will take steps to improve the monitoring and law enforcement systems related to food and drug production.<sup>58</sup> China also announced that it would invest more than \$1 billion to improve its infrastructure charged with monitoring and inspecting food and drugs.<sup>59</sup> Also in 2007, China published a "White Paper on Food Quality and Safety,"<sup>60</sup> describing the government's efforts to improve food safety.

The law addressing drug safety, the Drug Administration Law, went into effect on December 1, 2001,<sup>61</sup> and the Regulations for Implementation of Drug Safety Law went into effect the following September.<sup>62</sup> Although the Drug Administration Law contains broad provisions regulating the quality of drugs, their safety for human beings,<sup>63</sup> and legal liability for producing counterfeit or substandard drugs,<sup>64</sup> effective enforcement of these provisions is an ongoing issue.<sup>65</sup> This was particularly noticeable after the head of China's State Food and Drug Administration was convicted and

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57. *China Unveils Food, Drug Safety Plan from 2006 to 2010*, CHINA DAILY (May 12, 2007), [http://www.chinadaily.com.cn/bizchina/2007-05/12/content\\_871019.htm](http://www.chinadaily.com.cn/bizchina/2007-05/12/content_871019.htm).

58. *Id.*

59. *China Invests More Than \$1bn in Drug Safety*, CHEMISTRY WORLD (Aug. 10, 2007), <http://www.rsc.org/chemistryworld/News/2007/August/10080703.asp>.

60. STATE COUNCIL INFO. OFFICE, *THE QUALITY AND SAFETY OF FOOD IN CHINA* (2007) [hereinafter *FOOD QUALITY AND SAFETY*], available at <http://www.china-un.ch/eng/bjzl/t381573.htm>.

61. Drug Administration Law of the People's Republic of China (promulgated by the Standing Comm. Nat'l People's Cong., Feb. 28, 2001, effective Dec. 1, 2001), art. 106, available at <http://former.sfga.gov.cn/cmsweb/webportal/W45649037/A48335975.html>.

62. Regulations for Implementation of the Drug Administration Law of the People's Republic of China (promulgated by the St. Council, Aug. 4, 2008, effective Sept. 15, 2002), art. 86, available at <http://former.sfga.gov.cn/cmsweb/webportal/W45649038/A48335997.html>.

63. See Drug Administration Law of the People's Republic of China, art. 1.

64. See *id.* arts. 73–101.

65. See, e.g., *Chinese Court Gives Heaviest Sentence for Selling Fake Drug on the Internet*, PEOPLE'S DAILY ONLINE (Oct. 10, 2009), <http://english.peopledaily.com.cn/90001/90776/90883/6779617.html>; *Police Catch Suspected Distributor of Deadly Fake Diabetes Drug*, CHINA VIEW (Feb. 7, 2009), [http://news.xinhuanet.com/english/2009-02/07/content\\_10778108.htm](http://news.xinhuanet.com/english/2009-02/07/content_10778108.htm).

executed in 2007 for accepting bribes and dereliction of duty.<sup>66</sup> As of this date, drug safety standards have not yet been revised, but efforts are said to be underway to implement a new Pharmacopoeia in 2010, which would enhance quality control of drugs.<sup>67</sup>

The most progress has been made in the realm of food safety. After several drafts, China's National People's Congress Standing Committee passed the Food Safety Law (FSL), a comprehensive effort to oversee food safety, on February 28, 2009.<sup>68</sup> Shortly thereafter, on April 24, the State Council published the first draft of its implementation measures for the FSL.<sup>69</sup> The FSL became effective on June 1, 2009.<sup>70</sup> Then, following a period of public comment, the Final Food Safety Law Implementation Measures (the Rules) went into effect on July 20, 2009.<sup>71</sup> Major features of the FSL include requiring monitoring and supervision; increasing regulatory standards; establishing recall and notification systems; providing increased consumer rights; and creating liability for offenders.<sup>72</sup> Each of these features is discussed in detail below.

#### A. *Requiring Monitoring and Supervision*

As a threshold matter, it must be determined who will bear the responsibility for monitoring and supervising the ambitious FSL. One of the most difficult aspects of the FSL is sorting out the "chain of command" to determine who has responsibility for implementing and overseeing the implementation of the law. The Ministry of Health (MOH) plays a predominant role.<sup>73</sup> The Rules state that the MOH shall work in conjunction with the Administration

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66. *China Food Safety Head Executed*, BBC NEWS (July 10, 2007), <http://news.bbc.co.uk/2/hi/6286698.stm>.

67. *Compilation of Chinese Pharmacopoeia (2010 Edition) Gets Started*, ST. FOOD & DRUG ADMIN., <http://former.sfda.gov.cn/cmsweb/webportal/W43879541/A64025291.html> (last visited Feb. 14, 2011).

68. *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), pmbl. [hereinafter *Food Safety Law*], available at <http://www.fas.usda.gov/gainfiles/200903/146327461.pdf>.

69. USDA FOREIGN AGRIC. SERV., GAIN REP. NO. CH9040, *FOOD SAFETY LAW IMPLEMENTATION REGULATION 2 (2009)*, available at <http://www.fas.usda.gov/gainfiles/200905/146347786.pdf>.

70. *Food Safety Law*, *supra* note 68, pmbl.

71. *Final Food Safety Law Implementation Measures* (promulgated by the Standing Comm. Nat'l People's Cong., July 20, 2009), pmbl. [hereinafter *The Rules*].

72. *Food Safety Law*, *supra* note 68, arts. 4–5, 53, 55, 84–98.

73. See generally USDA FOREIGN AGRIC. SERV., GAIN REP. NO. CH9015, *PEOPLE'S REPUBLIC OF CHINA AGRICULTURAL SITUATION (2009)* ("While many of the ultimate responsibilities are not clear and fine tuning will continue, the big winner appears to be the Ministry of Health.").

for Quality, Supervision, Inspection and Quarantine (AQSIQ), State Administration for Industry and Commerce (SAIC), State Food and Drug Organization (SFDA), Ministry of Commerce and Trade (MOFCOM), and other authorities under the State Council, to prepare “the national food safety risk surveillance plan.”<sup>74</sup> This is a very ambitious and, seemingly, difficult-to-implement goal.<sup>75</sup> All of the various local and regional authorities are required to report to the MOH, which, in turn, must communicate information to departments under the State Council.<sup>76</sup>

The MOH’s role is further specified in the Rules. For example, the MOH is responsible for summary and analysis of data gathered in food safety risk surveillance,<sup>77</sup> and adjustment of the national food safety risk surveillance program.<sup>78</sup> The MOH is also charged with the important responsibility of organizing the National Food Safety Standard Review Committee,<sup>79</sup> which has the broad duty to review and approve national food safety standards.<sup>80</sup> The amount of discretion held by the MOH is unclear. The FLS merely states that the Standard Review Committee should be composed of experts in medicine, agriculture, food, and nutrition, as well as representatives from “relevant” departments under the State Council.<sup>81</sup> In December 2009, a forty-two-person panel was established, consisting of experts in hygiene, agriculture, food, and nutrition.<sup>82</sup>

The way in which the MOH should interact with other groups charged with responsibilities under the FSL is similarly unclear. The State Council is required to establish a Food Safety Committee and the Council’s Executive Department of Health (Executive Department) is responsible for the “overall food safety coordination, risk assessment of food safety, formulation of food safety standards, release of food safety information, development of accreditation criteria for food testing agencies and testing specifications, and the organization of investigation of and response to major food safety accidents.”<sup>83</sup> The FSL, though, provides no information regarding the membership of this Food Safety Com-

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74. The Rules, *supra* note 71, art. 5.

75. See Food Safety Law, *supra* note 68, arts. 76–83.

76. The Rules, *supra* note 71, art. 6.

77. *Id.* art. 11.

78. *Id.* art. 7.

79. *Id.* art. 17.

80. Food Safety Law, *supra* note 68, art. 23.

81. *Id.*

82. *China Sets Up Expert Panel to Assess Food Safety*, CHINA DAILY (Dec. 9, 2009), [http://www.chinadaily.com.cn/bizchina/2009-12/09/content\\_9147922.htm](http://www.chinadaily.com.cn/bizchina/2009-12/09/content_9147922.htm).

83. Food Safety Law, *supra* note 68, art. 4.

mittee or how it will coordinate with the MOH. It is also unclear whether this is a completely distinct committee from the one to be established by the MOH.<sup>84</sup> Moreover, the FSL calls for the establishment of a national surveillance system,<sup>85</sup> which appears to be under the Executive Department, but it is not clear if the MOH or the State Council has responsibility over this entity.

In other areas, the State Council appears to have supervisory authority, as opposed to the MOH. For example, the FLS calls for the establishment of a national assessment mechanism to assess "the risks on biological, chemical and physical hazards in food and food additives," and gives oversight responsibility to the Executive Department.<sup>86</sup> Similarly, the Executive Department must "consolidate the mandatory standards among existing quality and safety standards."<sup>87</sup> The State Council's Executive Department of Health and Agriculture has responsibility for pesticides, veterinary residue, and the slaughtering of livestock and poultry.<sup>88</sup> These responsibilities overlap with those of the MOH, and it is unclear exactly how the responsibilities should be divided.

Other complicating factors in the responsibility chain are the role of local authorities and the call for industry self-regulation. The FSL requires local people's governments at and above the county level to have a role in regulating food safety in their jurisdictions.<sup>89</sup> In the absence of a national standard, the local authorities may develop local food safety standards.<sup>90</sup> The risk is that these local standards may be used to protect local industries. At the other end of the spectrum, local authorities might rely on the absence of any national standards and not see the "need" to implement standards, which could decrease profits for local food producers and traders. In other words, authorities at the local level may not want to hold local companies to stringent standards, which could slow production, mandate increased inspections, or require costly cleanup for facilities. These are just a few examples of procedures that could cut into profits. The FSL also calls on food industry associations to "tighten the self-discipline of the industry"<sup>91</sup> and

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84. *Id.* (referring to food safety committees, but it is unclear if they are the same entity).

85. *Id.* art. 11.

86. *Id.* art. 13.

87. *Id.* art. 22.

88. *Id.* art. 21.

89. *Id.* art. 5.

90. *Id.* art. 24.

91. *Id.* art. 7.

“encourages” manufacturers to develop “standards more stringent than national or local food safety standards.”<sup>92</sup> Interestingly, any such standards are “applicable only to the enterprise” developing the standard and are to be reported to the provincial authorities.<sup>93</sup> These provisions raise a number of issues, including the following: the effect of the reporting requirement; the kind of liability that could result if a company’s own reported standards are not met; and whether one company’s standards should govern others in the same commercial enterprise. On its face, the FSL appears to set forth details about monitoring and supervision of food safety, but further inquiry leads to many unanswered questions about how the law will be implemented and how it will work in practice. This is particularly problematic because China has been criticized for having the “authority for food safety enforcement ‘dispersed’ among too many agencies and different levels of government.”<sup>94</sup> Ideally, the FSL would rectify that problem.

### B. *Increasing Regulatory Standards*

The primary purpose of the FLS is to “assure food safety and safeguard people’s health and life.”<sup>95</sup> The law is comprehensive in its scope, applying to food producers, who are involved in food production and processing, as well as food traders, who are involved in food distribution and catering service, operating in China.<sup>96</sup> The FSL also construes “food” broadly, defining it as “any substance that has been processed or not processed that is suitable for eating and/or drinking, including substances used as food and medicine, excluding substances solely used as medicine.”<sup>97</sup> Under the FSL “food,” then, encompasses food additives and food-related products. The FSL also specifically states that it extends to “packing materials, vessels, detergents and disinfectants for food, as well as utensils and equipment used in food production and trading.”<sup>98</sup> This is important, as food contamination can take place at many stages before it reaches consumers.

The new mandatory food safety standards cast a very broad net, covering:

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92. *Id.* art. 25.

93. *Id.*

94. Gordon Fairclough, *U.N. Criticizes China on Food Safety*, WALL ST. J., Oct. 23, 2008, at A12.

95. Food Safety Law, *supra* note 68, art. 1.

96. *Id.* arts. 2–3.

97. *Id.* art. 90.

98. *Id.* art. 2.

- 1) The limits of pathogenic microorganisms, pesticide residues, veterinary drug residues, heavy metals, contaminants, and other substances hazardous to human health in food and food-related products;
- 2) Varieties, scope of application, and dose of food additives;
- 3) Requirements for nutritional ingredients in staple and supplementary food dedicated to babies and other specific populations;
- 4) Requirements for labeling, identification and instructions relevant to food safety and nutrition;
- 5) Hygienic requirements for food production and trading processes;
- 6) Quality requirements related to food safety;
- 7) Methods and procedures for food testing; and
- 8) Other particulars necessary for developing food safety standards.<sup>99</sup>

Some of the details of how each of these categories will be regulated are included in the law. First, there are specific provisions regarding the safe handling and storage of food.<sup>100</sup> Even these provisions, however, contain subjective guidelines, which are not fully explained. Phrases such as "appropriate places," "appropriate production," "technical staff," "reasonable equipment," "wash and sterilize," and "safe and harmless containers" are subject to differing interpretations.<sup>101</sup> The FSL also requires food producers and traders to "establish and implement an employee health management system," to ensure that any employees with an "infectious disease of digestive tract . . . or . . . purulent or weeping skin diseases" does not directly contact any food.<sup>102</sup>

Second, the FSL contains provisions regulating additives and addressing material that should not be included in food. The FSL expressly prohibits production and trading of food made with "non-food raw material," food with substances of possible hazard to human health that exceeds food safety standard limits (such as pathogenic microorganisms, pesticide residue, veterinary drug residue and heavy metals), and food that is "rotten or spoiled, has rancid fat, contains mold or insects, is dirty or contaminated, contains foreign matters, has been adulterated, or displays abnormal sensory indication."<sup>103</sup> Although it is unclear how the system will work in practice, the FSL requires that the state adopt a licensing system

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99. *Id.* art. 20.

100. *Id.* arts. 27, 40-41.

101. *See id.* art. 27(1)-(6).

102. *Id.* art. 34.

103. *Id.* art. 28(1)-(4).

for the production of food additives.<sup>104</sup> Additionally, if anyone seeks to produce “novel foods, new food additive varieties, or new food-related products” materials need to be submitted to the Executive Department to determine if the applications comply with food safety requirements and should be granted a license.<sup>105</sup> It is unclear what standards will be used to determine if these new foods and additives are “proven to be safe and reliable.”<sup>106</sup> The FSL also makes specific reference to medicine, stating that it shall not be added to any food “unless the added substance is traditionally considered as both food and Chinese medicine.”<sup>107</sup> This provision also raises many questions, including how “medicine” is defined and whether vitamins and minerals are considered “medicine.” The Executive Department is responsible for the development of a catalog of such substances,<sup>108</sup> yet no timeframe is mandated for that endeavor to be completed.

Third, the FSL attempts to increase regulatory standards for small food workshops and food vendors, specifically stating that they shall comply with the law and have conditions that are “clean, nontoxic and harmless.”<sup>109</sup> The law, though, contains no definition for these terms. Neither is there any evaluative mechanism for testing compliance. The FSL also required governments at the county level or above to “encourage small food workshops to improve the production conditions and encourage food vendors to trade in fixed locations, such as centralized markets and shops.”<sup>110</sup> On one hand, the FSL appears to mandate compliance by small food workshops, yet, on the other, it seems to merely set aspirational goals for improved conditions. Clearer and more detailed mandatory requirements for small food workshops are important to ensure food safety in China. It was the contaminated milk scandal that prompted Chinese officials to announce that they would target food products made by small factories, which may be under supervised and lack “a self-discipline system.”<sup>111</sup> At the end of 2008, approximately “70 percent of China’s 500,000 food process-

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104. *Id.* art. 43.

105. *Id.* art. 44.

106. *Id.* art. 45.

107. *Id.* art. 50.

108. *Id.*

109. *Id.* art. 29.

110. *Id.* art. 30.

111. Mike Stones, *Chinese Target Small Producers' Food Safety Standards*, FOOD PRODUCTION DAILY (Dec. 8, 2008), <http://www.foodproductiondaily.com/Quality-Safety/Chinese-target-small-producers-food-safety-standards>.

ing firms [were] small-scale with fewer than ten employees.”<sup>112</sup> Tighter standards for such processors seem essential to ensure compliance with the FSL.

Fourth, the FSL requires all pre-packaged food to be labeled with basic information, including: “name,” “date of production,” “table of ingredients,” “producer name . . . and contact information,” and “shelf life.”<sup>113</sup> If labeling is done properly, this information can help consumers and officials track the origins of unsafe products.

Lastly, the FSL contains record-keeping requirements for food producers and food traders.<sup>114</sup> The required records include production records, verification records, and inspection records. Here, too, there are many unanswered questions, such as who will have access to the records; whether consumers will have access; if records will be subject to regular government review; and for how long the records will be retained. Although the FSL appears comprehensive on its face, it leaves open many questions as to how the law will be implemented.

### C. *Establishing Notification and Recall Systems*

Notification and recall systems are key features of the FSL. When a food safety incident occurs, the “concerned entity” has the duty to take immediate “control measures”—such as sealing the food, materials, tools, and equipment that may be involved in the incident—and to report the incident to the county-level health authorities within two hours.<sup>115</sup> The incident should then be reported immediately to the Executive Department.<sup>116</sup> After receiving a report of any possible food safety risk, the Executive Department must “immediately organize inspection and food safety risk assessment.”<sup>117</sup>

The ensuing investigation should be conducted in a “realistic and scientific manner to timely and correctly find out the nature and reasons and determine the responsibilities and propose corrective measures.”<sup>118</sup> The Rules also provide that the departments involved in the investigation “shall have the right to inquire about

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112. *Id.*

113. Food Safety Law, *supra* note 68, art. 42.

114. *Id.* arts. 37, 39.

115. The Rules, *supra* note 71, art. 43.

116. Food Safety Law, *supra* note 68, art. 12.

117. *Id.* art. 14.

118. The Rules, *supra* note 71, art. 44.

the incident from the relevant entities and individuals,” including obtaining documents and samples.<sup>119</sup> Importantly, the scope of the investigation requires a determination of whether there was “any negligence or misconduct by regulatory agencies.”<sup>120</sup> The results of the food safety risk assessment are, in turn, to be used as a “scientific basis for developing and modifying food safety standards as well as regulating food safety.”<sup>121</sup>

The FSL also provides that a food recall system must be established in China.<sup>122</sup> If a food producer discovers that its product is not in compliance with food safety standards, it must: 1) “immediately stop production of the food,” 2) “recall the food product released to the market,” 3) “notify relevant producers, traders and consumers,” and 4) “create a record on recalls and notifications.”<sup>123</sup> Likewise, food traders have similar requirements to recall, notify, and create records.<sup>124</sup> What is not clear, however, is what recall and notification procedures are actually required of food producers and traders. For example, it is unclear what kind of notice is sufficient. Currently, producers and traders may use any of a number of avenues, such as newspapers, radio, television, Internet, or mail to provide notice of a recall. The effectiveness of the actual form of the recall would depend on the market, location, and scope of the distribution.

In addition to requirements for food producers and traders, the State Council must formulate emergency plans for national food safety incidents.<sup>125</sup> Although the FSL refers to “national food safety incidents” and “major food safety accidents,” these phrases are not defined, so it is difficult to know how widespread an incident must be to trigger these provisions.<sup>126</sup> Governments at the county level or higher are required to formulate emergency plans to handle incidents in their jurisdictions; however, no timetable is set for the completion of the plans and submission to a higher level of government.<sup>127</sup> For the FSL to be effective, such emergency plans need to be in place. Additionally, to the extent that the emergency plans are not detailed or comprehensive enough to be

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119. *Id.* art. 45.

120. Food Safety Law, *supra* note 68, art. 75.

121. *Id.* art. 16.

122. *Id.* art. 53.

123. *Id.*

124. *Id.*

125. *Id.* art. 70.

126. *See id.* arts. 70–71.

127. *See id.* art. 70.

effective, the law needs some mechanism to require revision. As it stands now, the plans merely need to be submitted to a higher level of government to become part of the "official record."<sup>128</sup>

#### D. *Providing Increased Consumer Rights*

Consumer rights figure predominately into the FSL, which "encourages social and community groups to conduct educational activities."<sup>129</sup> The Chinese government appears to call on consumers to become better educated about food safety standards and healthy diets in order to raise their awareness and provide for a modicum of self-protection.<sup>130</sup> Consumers and organizations also are expressly given the "right to report any act during food production and trade" that violates the FSL.<sup>131</sup> The law also gives consumers and organizations the "right to inquire food safety information from relevant agencies and provide comments and suggestions about food safety regulation."<sup>132</sup>

By virtue of the media being required to "publicize food safety laws, regulations and standards," as well as to provide "public oversight" on acts by producers and traders violating the law,<sup>133</sup> the FSL seems to encourage greater transparency and consumer awareness. The Executive Department is also responsible for "developing and publicizing national food safety standards,"<sup>134</sup> which is designed to make more information available to consumers.<sup>135</sup> The standards are to be "accessible by the public for free."<sup>136</sup> Lastly, the FSL requires that "food advertisements shall provide truthful information, shall not include any false or exaggerated information and shall not claim any disease prevention or treatment functions."<sup>137</sup> This part of the law appears to protect consumer rights through its ban on all puffing.

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128. *Id.*

129. *Id.* art. 8.

130. *See id.* arts. 8–10.

131. *Id.* art. 10.

132. *Id.*

133. *Id.* art. 8.

134. *Id.* art. 21.

135. *See id.* art. 26.

136. *Id.*

137. *Id.* art. 54.

E. *Creating Liability for Offenders*

Chapter 9 of the FSL sets forth the legal liabilities for food producers and traders who violate the law.<sup>138</sup> The law provides for civil penalties, damages for consumers and criminal prosecution for offenders.<sup>139</sup> Food traders and producers who violate the FSL are subject to fines as follows: if the total value of the food or food additive is less than RMB 10,000, a fine between RMB 2,000 and RMB 50,000 will be imposed or, if the total value of the commodity exceeds RMB 10,000, a fine between five and ten times the total value of the commodity can be imposed.<sup>140</sup> Additionally, revocation of business licenses can be ordered for “serious cases,” including adding non-food raw materials to food, producing or trading food dedicated to babies, which fails to comply with food safety standards, and trading in food exceeding its shelf life.<sup>141</sup>

Not only food producers and traders can be held liable under the FSL; the law provides that if food advertisements contain “false publicity to cheat consumers,” violators shall be punished<sup>142</sup> in accordance with the Advertising Law of the People’s Republic.<sup>143</sup> The FSL goes a step further, explicitly stating that civil societies, organizations, and individuals “who recommend a food to consumers in untruthful advertisements” bear joint responsibility with the food producer or trader.<sup>144</sup> This aspect of the law encompasses endorsements by celebrities.<sup>145</sup> The FSL also contains a general provision that any individual or organization “shall not conceal, lie, delay, or intentionally destroy the evidence of any food safety accident.”<sup>146</sup> If a food inspection agency or individual “issues false inspection reports” in violation of the FSL, a range of penalties may be applied, including revocation of certification qualifications,

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138. *See id.* arts. 84–98; The Rules, *supra* note 71, arts. 55–61.

139. Food Safety Law, *supra* note 68, arts. 84–98.

140. *Id.* arts. 84–85. Conversion note: RMB 10,000 = approximately \$1,460; RMB 50,000 = approximately \$7,300; RMB 2,000 = approximately \$292. *See Currency Converter*, OANDA.COM, <http://www.oanda.com/currency/converter> (last visited Feb. 14, 2011).

141. Food Safety Law, *supra* note 68, art. 85.

142. *Id.* art. 94.

143. *See generally* Advertising Law of the People’s Republic of China (promulgated by the Standing Comm. Nat’l People’s Cong., Oct. 27, 1994, effective Feb. 1, 1995), *available at* <http://www.chinagate.cn/english/434.htm>.

144. Food Safety Law, *supra* note 68, art. 55.

145. Lin Shujuan, *Celebrity Row is ‘Aiding Food Safety,’* CHINA DAILY (Mar. 13, 2009), [http://www.chinadaily.com.cn/china/2009npc/2009-03/13/content\\_7575030.htm](http://www.chinadaily.com.cn/china/2009npc/2009-03/13/content_7575030.htm).

146. Food Safety Law, *supra* note 68, art. 71.

dismissal from office, criminal prosecution, and a prohibition on working in food inspection for ten years.<sup>147</sup>

While the FSL clearly punishes those who violate the law, it also provides remedies for consumers. Individuals and entities that cause personal or property damage through violations of the FSL are liable to pay compensation.<sup>148</sup> Furthermore, the law states that manufacturers that produce non-conforming food and sell it “knowing its nonconformity with the food safety standards” can be held liable by customers.<sup>149</sup> Under such circumstances, customers can demand damages from the manufacturer or seller in an amount ten times the amount paid, in addition to compensation for loss.<sup>150</sup> This provision makes some inroads for injured consumers, although the amount of damages may not be very substantial. In the case of tainted milk, for example, ten times the cost of the milk powder would still be a nominal amount. The amount of damages for other injuries to an individual’s health and property likewise may be small when compared to liability for selling a defective product in the United States.<sup>151</sup> Despite that fact, at least some progress is being made to provide consumers with remedies for their losses.

In addition to fines and damages, the FSL provides that “anyone” in violation of the law shall “be subject to criminal prosecution.”<sup>152</sup> A literal reading of this provision means that food producers, traders, and other individuals—including corporate executives and government officials involved in manufacturing, approving, or selling defective products—can be held criminally liable. All of these penalties suggest that China is taking the issue of food safety seriously. From a corporate and consumer point of view, however, even though China has new measures, effective enforcement may still be a problem.<sup>153</sup>

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147. *Id.* art. 93.

148. *Id.* art. 96.

149. *Id.*

150. *Id.*

151. See Meg Kinnard, *Maker of Tainted Dog Food Settles*, WASH. POST, Jan. 5, 2008, available at <http://www.washingtonpost.com/wp-dyn/content/article/2008/01/04/AR2008010403398.html> (the pet food manufacturer paid \$3.1 million to settle product liability actions for selling tainted dog food).

152. Food Safety Law, *supra* note 68, art. 97.

153. Hao Huang, Note, *Maximizing Chinese Imports' Compliance with United States Safety and Quality Standards: Carrot and Stick From Whom?*, 18 S. CAL. INTERDISC. L.J. 131, 135–36 (2008).

## III. U.S. LEGAL AND REGULATORY FRAMEWORK

A first step to enhance the safety of food and feed imports and exports between the United States and China was taken in 2007, when the Department of Health and Human Services entered into two Memoranda of Agreement with the Chinese government.<sup>154</sup> In 2008, the United States imported \$5.2 billion worth of foods from China, “making China [its] third largest source of food imports.”<sup>155</sup> Surprisingly, and despite these numbers, China provides less than 1 percent of the U.S. food supply.<sup>156</sup> Still, China is a major supplier of certain types of U.S. food imports, such as apple juice (60 percent), garlic (50 percent), shrimp (10 percent), and catfish (2 percent).<sup>157</sup> The year 2007 saw the first U.S. refusal of entry<sup>158</sup> to Chinese goods and preceded negative publicity over a number of incidents, including the refusal of wheat gluten and vegetable protein due to the discovery of Melamine therein<sup>159</sup> and refusal of several kinds of fish due to their high levels of toxic veterinary drug residues.<sup>160</sup> Further negative publicity surrounded the discovery of Melamine contamination in dog and cat food imported from China, which caused the sickening and death of thousands of U.S. household pets.<sup>161</sup> Even more publicity surrounded human food contamination and adulteration in Chinese food imports in 2008 and 2009, when it was discovered that numerous milk products and

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154. Two Memoranda of Understanding were signed in December 2007 between the Chinese and U.S. governments: one specifically on the safety of food and livestock feed exports to the United States (and correlative imports to China), and one on the safety of pharmaceuticals and medical devices. Mike Leavitt, Sec’y of Health and Human Servs., Statement on Signing Memoranda of Agreement Between the United States and The People’s Republic of China to Improve the Safety of Food, Feed, Drugs, and Medical Devices (Dec. 11, 2007), available at <http://www.hhs.gov/news/press/2007pres/12/pr20071211a.html>.

155. FRED GALE & JEAN C. BUZBY, IMPORTS FROM CHINA AND FOOD SAFETY ISSUES, ECONOMIC INFORMATION BULLETIN NO. 52, at iii (2009), available at <http://www.ers.usda.gov/Publications/EIB52/EIB52.pdf>.

156. *Id.*

157. *Id.* These figures represent percentages of the total supply of the items supplied to consumers in the United States for the year 2007.

158. Pursuant the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, the FDA has the right to refuse entry of any food import if it “appears,” based on a physical examination or otherwise, to be adulterated, misbranded, or in violation of the law. 21 U.S.C. § 381(a).

159. Chyau, *supra* note 16, at 313.

160. See BECKER, *supra* note 10, at 11.

161. *Id.* at 12; see also Chyau, *supra* note 16, at 313. See generally Aleda V. Roth et al., *Unraveling the Food Supply Chain: Strategic Insights from China and the 2007 Recalls*, 44 J. OF SUPPLY CHAIN MGMT. 22 (2008).

milk had been adulterated yet again with Melamine.<sup>162</sup> Consumption of the adulterated products in China caused the deaths of six infants, and approximately 300,000 children fell ill with kidney problems after drinking infant formula tainted with Melamine.<sup>163</sup> At the time, China was exporting dairy proteins and other products used in infant formula to the United States.<sup>164</sup>

At the same time, the FDA became aware of a spike in Heparin-related deaths linked to imports of the drug from Chinese manufacturers.<sup>165</sup> Heparin was linked to 171 U.S. deaths during the period from November 2007 to May 2008.<sup>166</sup> The United States government began to realize the magnitude of the consequences of unregulated trade with China. It therefore set about to create either an effective system to monitor the processing of food substances manufactured there or a framework to screen products at ports of entry. With these goals in mind, the U.S. government worked to tighten controls and inspections both at United States ports of entry and Chinese ports of egress.

While effective U.S. and Chinese regulations on the processing of food products for import are critical, in the United States, consumers typically have *ex post facto* recourse through civil lawsuits to obtain redress from the manufacturer, wholesaler, or retailer for a defective product, including food.<sup>167</sup> When, as in these cases, the ultimate party responsible is a supplier overseas, however, the con-

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162. See *FDA Import Alert #99-30*, U.S. FOOD AND DRUG ADMIN. (May 3, 2009), [http://www.accessdata.fda.gov/cms\\_ia/importalert\\_401.html](http://www.accessdata.fda.gov/cms_ia/importalert_401.html) (last visited Feb. 14, 2011).

163. Tan Ee Lyn, *China Eyes Milk Test After Melamine Deaths Scandal*, REUTERS (Jun. 15, 2010), <http://www.reuters.com/article/idUSTRE65E11G20100615>.

164. See *Interim Safety and Risk Assessment of Melamine and Its Analogues in Food for Humans; Availability*, 73 C.F.R. § 67186 (2008). The Associated Press did report the discovery of traces of Melamine in U.S. infant formula in November 2008; however, the levels were extremely low as reported by the FDA and did not pose a significant risk to infants. See *Update: Interim Safety and Risk Assessment of Melamine*, U.S. FOOD AND DRUG ADMIN. (Nov. 28, 2008), <http://www.fda.gov/Food/FoodSafety/FoodContaminantsAdulteration/ChemicalContaminants/Melamine/ucm164520.htm>.

165. See Press Release, Baxter International, Inc., *Baxter to Proceed with Recall of Remaining Heparin Sodium Vial Products* (Feb. 28, 2008), available at <http://www.fda.gov/Safety/Recalls/ArchiveRecalls/2008/ucm112384.htm>.

166. *Information on Adverse Event Reports and Heparin*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm112669.htm> (last updated June 18, 2009).

167. See, e.g., *Averitt v. Southland Motor Inn*, 720 F.2d 1178 (10th Cir. 1983) (holding defendant liable when plaintiff became ill after eating contaminated food from defendant hotel resulting from unsanitary condition); see also RESTATEMENT (SECOND) OF TORTS § 402A (1965); Mary T. Yelenick & Nicole C. Maddox, *Product Liability Litigation Against The Food Industry*, INT'L L. OFF. (Sept. 22, 2005), <http://www.internationallawoffice.com/Newsletters/Detail.aspx?r=11485>.

sumer's ability to recover against such a party is virtually zero.<sup>168</sup> Nevertheless, "[i]n the wake of [the] Heparin recall[s], more than 40 products liability lawsuits have been filed in both federal and state courts on behalf of patients" who were allegedly injured by or died from tainted Heparin imported from China.<sup>169</sup> Many of these lawsuits, however, name the U.S. pharmaceutical manufacturer, Baxter Corporation, as the defendant, not the Chinese supplier.<sup>170</sup> Although, under U.S. product liability law, the supplier could easily be joined in the lawsuit as the party liable, challenging issues arise because the supplier is overseas and outside the jurisdiction of the U.S. courts.<sup>171</sup> This raises the traditional legal issues of *in personam* jurisdiction over the defendant and *forum non conveniens*, as well as uncertainty as to the application of U.S. product liability law to foreign defendants. Further complicating the matter is that the product was not defective in the traditional definition of product liability laws (no "design defect, manufacturing defect or failure to warn"), but was a "*deliberate and sophisticated tampering*" that was not capable of being caught by Baxter's internal monitoring measures.<sup>172</sup>

The difficulties in bringing civil lawsuits against the Chinese supplier and in applying punitive damages against such defendants to deter tampering in the future make it all the more important that the U.S. government, that of China, and the other stakeholders involved collectively do all that they can to minimize the import of tainted foods and pharmaceuticals into the United States. Below is a discussion of current U.S. laws covering the importation of foods and drugs, and an examination of the bilateral U.S.-China Agreement on Food Safety (Bilateral Agreement).<sup>173</sup>

#### A. *The U.S.-Chinese Bilateral Agreement*

A first step to enhance the safety of food and feed imports and exports between the United States and China was taken in 2007,

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168. See Daniel J. Herling, *The New China Syndrome: How to Litigate Tainted Chinese Imports Case*, LAW.COM (Nov. 8, 2007), <http://www.law.com/jsp/article.jsp?id=1194429836233> (complete free registration).

169. Laga, *supra* note 54, at 109.

170. *Id.*

171. *See id.*

172. *Id.* at 111 (emphasis added).

173. *See generally* 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 (Dec. 11, 2007) [hereinafter Agreement], available at <http://globalhealth.gov/news/agreements/ia121107b.html>.

when the U.S. Department of Health and Human Services entered into a Memorandum of Agreement with the Chinese government.<sup>174</sup> Concerns over the safety of Chinese foods had been mounting since the recall of more than 150 brands of pet foods that were contaminated with ingredients incorporated from China, which “sickened or killed [ ] 39,000” U.S. pets in the spring of 2007.<sup>175</sup> In June of the same year, the FDA began detaining farm-raised seafood imported from China over concern about unsafe drug levels in the fish.<sup>176</sup> In September of that year, a survey of 1000 U.S. consumers by Reuters/Zogby revealed that 25 percent of them had ceased purchasing food imported from China, due to concerns over its safety.<sup>177</sup> The next month, Congress held hearings on the findings of a congressional mission to China that examined food safety issues.<sup>178</sup> And, finally, November 2007 saw the publication of reports from President Bush’s Interagency Working Group on the issues of import safety and the role of the FDA.<sup>179</sup> Clearly safety of food imports from China had become a national priority.

The issue of food safety was no less important to the Chinese government: By 2007, food exports to the United States from China had increased by 133 percent over the 2003 figures and represented \$3.3 billion by 2007.<sup>180</sup> It is hard to imagine that China was not concerned that its trade with the United States would be damaged if the Chinese government did not take immediate steps

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174. See generally *id.* While two agreements were entered into, this Article will focus only on the one that addresses food and food additives.

175. PUB. CITIZEN, TRADE DEFICIT IN FOOD SAFETY 3 (2007), available at <http://www.citizen.org/documents/FoodSafetyReportFINAL.pdf>.

176. U.S. FOOD AND DRUG ADMIN., HOW FDA REGULATES SEAFOOD: FDA DETAINS IMPORTS OF FARM-RAISED CHINESE SEAFOOD 1 (2007), available at <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm094558.htm>.

177. See Daphne Kasriel, *Global Consumers are Edgy About the Made in China Brand*, EUROMONITOR INT’L (Oct. 10, 2007), [http://www.euromonitor.com/Global\\_consumers\\_are\\_edgy\\_about\\_the\\_Made\\_in\\_China\\_brand](http://www.euromonitor.com/Global_consumers_are_edgy_about_the_Made_in_China_brand).

178. See *Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation’s Food Supply? Hearings Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy and Commerce*, 110th Cong. 1–3 (2007) (statement of Hon. Bart Stupak, Chairman).

179. INTERAGENCY WORKING GRP. ON IMPORT SAFETY, DEP’T. HEALTH & HUMAN SERVS., ACTION PLAN FOR IMPORT SAFETY: A ROAD MAP FOR CONTINUAL IMPROVEMENT 42–43 (2007), available at <http://archive.hhs.gov/importafety/report/actionplan.pdf>; see U.S. FOOD AND DRUG ADMIN., FOOD PROTECTION PLAN: AN INTEGRATED STRATEGY FOR PROTECTING THE NATION’S FOOD SUPPLY 3–4 (2007) [hereinafter FOOD SAFETY PLAN], available at <http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/FoodProtectionPlan2007/ucm132565.htm>.

180. WAYNE M. MORRISON, CONG. RESEARCH SERV., RL 33536, CHINA-U.S. TRADE ISSUES 7–8 (2008), available at <http://fpc.state.gov/documents/organization/102624.pdf>.

to address the concerns raised by the pet food scandal and the other food contamination issues mentioned above. An immediate step, announced by the Chinese in July of 2007, was shutting down 152,000 unlicensed food producers and retailers and revising a large number of food safety standards.<sup>181</sup> These preliminary measures were followed in August of 2007 by the publication of a “White Paper on Food Quality and Safety,”<sup>182</sup> describing the nature of its domestic and export food safety programs. The concerns of both countries culminated in the execution of the Bilateral Agreement to help ensure the safety of the supply chain from China to the United States.<sup>183</sup>

The Bilateral Agreement states that the two countries intend to “establish a bilateral cooperative mechanism regulating food and safety. Such a mechanism may include current and future registration and certification systems. The mechanism aims to provide the parties with information to use in judging whether an imported product meets the requirements of the importing country.”<sup>184</sup> The Bilateral Agreement requires that Chinese exporters to the United States register with Chinese regulatory authorities, including the General Administration of Quality, Supervision, Inspection and Quarantine (AQSIQ)<sup>185</sup> and the State Food and Drug Administration (SFDA).<sup>186</sup> The former has general responsibility for product quality and safety, including food safety<sup>187</sup> while the State Food and Drug Administration (SFDA) is responsible for human pharmaceuticals and medical devices.<sup>188</sup> Pursuant to this agreement, the Chinese government agrees to require certain Chinese exporters to submit to annual inspections by such organizations to assure that their goods meet U.S. food safety standards.<sup>189</sup> The agreement further requires AQSIQ to provide the FDA with the names of all exporters who fail inspection, the reasons why, and the names of those companies who have lost their registration sta-

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181. George Reynolds, *China Expects to Close Half of Smaller Processors*, AP-FOOD-TECHNOLOGY.COM (July 12, 2007), <http://www.ap-foodtechnology.com/Processing/China-expects-to-close-half-of-smaller-processors>.

182. FOOD QUALITY AND SAFETY, *supra* note 60.

183. See GALE & BUZBY, *supra* note 155, at 24.

184. Agreement, *supra* note 173, art. 1.

185. See *id.* annex § II; see also GEN. ADMIN. OF QUALITY SUPERVISION, INSPECTION AND QUARANTINE OF P.R.C., <http://english.aqsic.gov.cn> (last visited Feb. 14, 2011).

186. Agreement, *supra* note 173, annex § II.A.1.

187. See *generally id.*

188. See ST. FOOD AND DRUG ADMIN., P.R. CHINA, <http://eng.sfda.gov.cn/eng> (last visited Feb. 14, 2011).

189. See Agreement, *supra* note 173, annex § II.B.4.

tus.<sup>190</sup> In addition, AQSIQ must develop a tracking system to follow certain products from the point of production to the point of exportation, and must create a statistically-valid testing program for such exports.<sup>191</sup>

One of the major features is that both parties under the agreement are required to notify one another within forty-eight hours in the case of a new public health risk that is related to food or to feed.<sup>192</sup> AQSIQ further agrees to facilitate FDA access to, and inspection of, Chinese processing and cultivation sites.<sup>193</sup> Pursuant to the first phase in the implementation of the Bilateral Agreement, the parties specify that export certificates issued by AQSIQ are required for all exporters of products with current high refusal rates, which the agreement specifies as: low acid caned products or acidified foods; pet foods and pet treats of plant origin or animal origin; ingredients of food and feed, such as wheat gluten and rice protein; and all aquaculture farming products except for mollusk shellfish.<sup>194</sup> The Annex also provides that other items may be added to this list during later phases.<sup>195</sup> The Bilateral Agreement is to be reviewed every twelve months, at which time a new work plan for the coming year will be established.<sup>196</sup> Parties on both sides are to meet once a year to discuss implementation of the agreement and review its progress.<sup>197</sup>

As an outgrowth of this agreement, in late 2008, the FDA opened three offices in China: one in Beijing, one in Guangzhou, and a third in Shanghai.<sup>198</sup> These are the first FDA offices to open outside the United States.<sup>199</sup> The Beijing office acts as “a liaison between the FDA and [the] Chinese regulatory agencies,” while the two other offices “conduct inspections and train Chinese inspectors.”<sup>200</sup> Further, these offices will advise Chinese government agencies and Chinese companies on U.S. quality stan-

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190. *Id.* annex § II.B.8.

191. *Id.* annex §§ II.B.10, II.C.6.

192. *Id.* art. IV. “Each party shall immediately notify the other Party of significant risks to public health related to product safety, manufacturing conditions, recalls, and other instances that involve imminent or significant danger to health, or the gross deception of consumers with regard to Covered Products.” *Id.*

193. *Id.* annex § II.D.3–4.

194. *Id.* annex § I.B.1.

195. *Id.* annex § I.B.2.

196. *Id.* art. VIII.

197. *Id.*

198. *FDA Opens Offices in China*, *supra* note 7.

199. *Id.*

200. *Id.*

dards.<sup>201</sup> The long-term goal of these FDA offices is “to train credible, independent, third party institutions to inspect factories that produce pharmaceuticals, medical devices and food for export to the United States.”<sup>202</sup>

The FDA reported that it met its first set of deadlines under the agreement, providing the requisite materials to the Chinese government and has drafted its twelve-month plan.<sup>203</sup> The FDA further wrote that it had met with Chinese officials in March of 2008, as required by the agreement, and there was “verbal agreement to limit the present efforts in fulfilling the MOA [Bilateral Agreement] to aquaculture (five species plus tilapia) and ingredients (wheat gluten, corn gluten ad rice protein).”<sup>204</sup>

A number of stakeholders have expressed doubt as to whether the Chinese will meet their obligations under the Bilateral Agreement because the Chinese government has not been able or willing to enforce the strict food laws that it currently has in place.<sup>205</sup> The Consumers Union in the United States expressed two concerns in particular: first, that the agreement neglected to include certain food items that have questionable safety records, such as apple juice<sup>206</sup>; and, second, that the Bilateral Agreement did not give FDA inspectors *immediate* access to Chinese plants in the face of a crisis.<sup>207</sup> Further, there has been speculation that the agreement grants preferential status to Chinese importers over others.<sup>208</sup> Others question whether the FDA will have adequate resources to oversee and enforce the agreement, and even whether the FDA has the legal authority to share the information concerning U.S. food companies required by the Bilateral Agreement, or to demand certificates from foreign importers.<sup>209</sup>

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201. *Id.*

202. *Id.*

203. *Food Protection Plan: One-Year Progress Summary*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/food/foodsafety/foodsafetyprograms/foodprotectionplan2007/ucm131730.htm> (last updated June 18, 2009).

204. *Id.*

205. *See U.S.-China Food Safety Deal Could Give China Preferential Treatment*, FDA WEEK, Dec. 21, 2007 [hereinafter *Preferential Treatment*].

206. *Id.* More than 60 percent of apple juice in the United States comes from Chinese exports. *See GALE & BUZBY, supra* note 155, at iii.

207. *See Preferential Treatment, supra* note 205.

208. *Id.*

209. *Id.*

## B. *The Food and Drug Administration*

The FDA is a federal agency within the Department of Health and Human Services<sup>210</sup> responsible for protecting the health of the U.S. public “by assuring the safety, efficacy and security” of most human foods.<sup>211</sup> Not only does the agency regulate foods that U.S. citizens consume, but it also regulates drugs and medical devices, among other substances.<sup>212</sup> Its authority derives primarily from the Federal Food, Drug, and Cosmetic Act (FFDCA).<sup>213</sup> The FFDCA makes the FDA responsible for the safety of virtually all foreign as well as domestic components used in food (with the exception of meat, poultry and eggs<sup>214</sup>), drink, and drugs, as well as imported and domestic finished food, drink, and drug products.

The FDA’s food safety responsibilities include the following: risk assessment from farm to table for FDA-inspected products; inspection of all foods with the exception of meat, poultry, and eggs; and implementation and oversight of the U.S. nutrition-labeling law as it applies to FDA-inspected products.<sup>215</sup> Finally, the FDA is responsible for the administration of the FFDCA, which prohibits the “introduction or delivery for introduction” of adulterated and misbranded food.<sup>216</sup> The Federal Food and Drugs Act of 1906, along with the Federal Meat Inspection Act of 1906,<sup>217</sup> were the first laws

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210. *Centers and Offices*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/opacom/7org.html> (last visited Feb. 14, 2011).

211. *What We Do*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/default.htm> (last visited Feb. 14, 2011).

212. *Id.*

213. 21 U.S.C. § 393.

214. *Importing Meat, Poultry & Egg Products to the United States*, FSIS.USDA.GOV, [http://www.fsis.usda.gov/factsheets/importing\\_meat\\_poultry\\_egg\\_products/index.asp](http://www.fsis.usda.gov/factsheets/importing_meat_poultry_egg_products/index.asp) (last visited Feb. 14, 2011).

215. 21 U.S.C. §§ 341–50(f).

216. 21 U.S.C. § 331.

217. Federal Food and Drugs Act of 1906 (The Wiley Act), Pub. L. No. 59-384, 34 Stat. 768 (repealed 1938); Federal Meat Inspection Act of 1906, Pub. L. No. 59-382, 34 Stat. 674 (amended 1976). The Federal Meat Inspection Act was superseded by the Wholesome Meat Act, which required that all meat products sold in the United States be produced under sanitary conditions, remain unadulterated, and be properly labeled. 21 U.S.C. § 608; *see also* Chyau, *supra* note 16, at 316; Note, *Reforming the Food Safety System: What if Consolidation Isn't Enough?*, 120 HARV. L. REV. 1345, 1348 (2007). Today, the Federal Meat Inspection Act is enforced by the Food Safety Inspection Service under the auspices of the U.S. Department of Agriculture (USDA). Shawn Stevens, *USDA to Mandate Country of Origin Labeling*, DEFENDINGFOODSAFETY.COM (Feb. 24, 2009), <http://www.defendingfoodsafety.com/tags/food-laws>.

enacted by the U.S. government to establish a nationwide food-safety system.<sup>218</sup>

Traditionally, the FDA worked to ensure that food generated within the United States met certain safety standards.<sup>219</sup> Increasingly, however, the FDA has a more challenging responsibility of ensuring that imported foods, including those from China, meet U.S. standards, which are “among the highest in the world.”<sup>220</sup> Because of these high standards, the FDA’s ability to inspect the rapidly-growing number of food products coming from foreign countries is taxed heavily.<sup>221</sup> While the FDA enforces its watchdog responsibility through these inspections, it is actually able to conduct very few.<sup>222</sup>

Further, the agency’s ability to act once contaminated foods are found is seriously limited: Federal law does not even provide it with the power to recall poisoned or contaminated products.<sup>223</sup> Instead, it must rely on companies’ compliance with FDA requests that tainted foods be removed from the market.

Pursuant to the FFDCA, the FDA has the right to refuse entry to any food import that “appears” to be adulterated, mislabeled, or in violation of a federal statute, based upon a physical examination.<sup>224</sup> The agency’s response depends on the prior notification by importers and on document examination at ports of entry.<sup>225</sup> If there is information suggesting that a product is in violation of the FFDCA, the FDA may detain an import without physical examination.<sup>226</sup> In 2007, the FDA used such power to detain the import of certain Chinese plant protein products that were intended to be added to pet foods because they contained the illegal additive Mel-

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218. On an historical note, the latter law was enacted in response to Sinclair Lewis’ book, *The Jungle*, published in 1906, which described appalling conditions in the meat markets of the United States. Stevens, *supra* note 217.

219. Michael R. Taylor, *Preparing America’s Safety System for the Twenty-First Century – Who is Responsible For What when It Comes To Meeting the Food Safety Challenges Of The Consumer-Driven Global Economy*, 52 FOOD & DRUG L.J. 13, 15–16 (1997).

220. *See id.* at 26–27; Chyau, *supra* note 16, at 315.

221. *See* Taylor, *supra* note 219, at 26–27.

222. *See* Chyau, *supra* note 16, at 317.

223. *See* Food and Drug Administration requested recall, 21 C.F.R. § 7.45 (2010). *See generally* Levick & Grabowski, *Contaminant At The Gate: Crisis Communications in the Age of China Recalls*, 7-3 MEALEY’S PROD. LIAB. & RISK 26 (2007).

224. 21 U.S.C. § 381(a).

225. BECKER, *supra* note 10, at 4.

226. 21 U.S.C. § 381(a). The FDA has the authority to detain a product without physical inspection and to refuse admission of the product if “it appears from examination *or otherwise*” that the product is adulterated, misbranded or in statutory violation. *Id.* (emphasis added).

amine.<sup>227</sup> Also detained from entry from China that year were all shipments of farm-raised seafood, until shippers were able to demonstrate that the seafood contained no unapproved drug residues.<sup>228</sup> Further, in 2008, the FDA issued a detention alert covering all milk-based products entering from China until it could be proven that they contained no Melamine.<sup>229</sup>

All foreign food and drug imports are required to meet the same safety standards as domestically produced products,<sup>230</sup> however, rules of international trade permit foreign countries to apply their own, differing standards under an internationally recognized concept known as “equivalence.”<sup>231</sup> The ability of the FDA to inspect facilities of importers overseas for contamination has traditionally been very limited, thereby making the inspections at ports of entry critical.<sup>232</sup> However, the volume of FDA-regulated imports has increased significantly over the past decade and there simply are not enough inspectors to do the job effectively.<sup>233</sup> While the FDA recorded approximately 2.8 million food-line imports in 1997, that number increased dramatically to 8.2 million in 2007.<sup>234</sup> Only approximately 1 percent of these food lines were either physically examined or tested.<sup>235</sup>

The FDA has inspected foreign manufacturing operations, but has done so only sporadically, with the permission of the foreign country, and only subsequent to the discovery of a contamination problem.<sup>236</sup> With the volume of FDA-regulated imports increasing steadily, and public concerns mounting after the Heparin and Melamine scandals out of China, the FDA took things into its own

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227. BECKER, *supra* note 10, at 4.

228. *Id.*

229. *Id.*

230. 21 U.S.C. 381(a).

231. The concept of “equivalence” may be found under Article 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures, effective January 1, 1995, for those member nations of the World Trade Organization (WTO). Multilateral Agreement on Trade in Goods, Apr. 15, 1994, 1867 U.N.T.S. 493, 495. For a more complete explanation, see GEOFFREY BECKER, CONG. RESEARCH SERV., RL33472, SANITARY AND PHYTOSANITARY (SPS) CONCERNS IN AGRICULTURAL TRADE 11–12 (2006), available at <http://ncseonline.org/NLE/CRSreports/06Jul/RL33472.pdf>.

232. See Chyau, *supra* note 16, at 315.

233. See *id.*

234. See FOOD SAFETY PLAN, *supra* note 179, at 5.

235. See GEOFFREY S. BECKER, CONG. RESEARCH SERV., RL 34080, FOOD AND AGRICULTURAL IMPORTS FROM CHINA 5 (2007), available at <http://www.dtic.mil/cgibin/GetTRDoc?AD=ADA471242&Location=U2&doc=GetTRDoc.pdf>.

236. See *Revamping Federal Oversight of Food Safety*, GOV. ACCOUNTABILITY OFF., [http://www.gao.gov/highrisk/risks/safety-security/food\\_safety.php](http://www.gao.gov/highrisk/risks/safety-security/food_safety.php) (last visited Feb. 14, 2011).

hands and created a “Beyond our Borders” initiative in 2008.<sup>237</sup> One of the primary mandates was to open the three offices in China, with future plans to open offices in India, Central America, and the Middle East.<sup>238</sup> The offices in China are now up and running with the permission of the Chinese government. These offices are intended to improve inspections of food and drug products at their points of origin, giving the FDA an earlier and clearer opportunity to prevent tainted food and drugs from entering the United States, where the ability to inspect is limited.<sup>239</sup> A further and broader goal of the China offices is to create a new strategy embracing an increased cooperation between the U.S. and Chinese governments to establish more uniform industry-wide standards.<sup>240</sup> Congress, aware of the inability of the FDA to cope with the problems it was facing in connection with the importation of food and drugs, drafted a number of bills to address gaps identified in current legislation and import problems that have arisen over the last several years.

### C. Proposed U.S. Legislation

Currently pending before Congress is bill H.R. 875, the Food Safety Modernization Act (FSMA), introduced by Representative Rosa Delauro.<sup>241</sup> Of the three bills being considered in Congress, the FSMA calls for the most significant changes, as it creates a new administrative agency entitled “Food Safety Administration.”<sup>242</sup> This agency would oversee food safety, but not have jurisdiction over the drug approval program, which is currently paired with food safety under the FDA.<sup>243</sup> The FSMA would require that imported foods meet the same high safety standards of domestic food and would not allow the continuation of the “equivalence” substitutes.<sup>244</sup> The FSMA would also create a program to certify imported food that would ensure that foreign companies only

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237. Astrid Fiano, *FDA Initiates Overseas Inspection and Collaboration Program in China*, DOTMED NEWS (Apr. 30, 2008), <http://www.dotmed.com/news/story/5886>.

238. *Id.*; see also *FDA Expects to Open China Offices in '08*, WALL ST. J., June 18, 2008, at A12 [hereinafter *China Offices*], available at <http://online.wsj.com/articles/SB121375629176383195.html?apl=y&cr=649610>.

239. See BECKER, *supra* note 231, at 6.

240. *China Offices*, *supra* note 238.

241. See generally Food Safety Modernization Act of 2009, H.R. 875, 111th Cong. (2009).

242. *Id.* § 101.

243. See *id.*

244. See Martha Goodsell, *Food Safety Bills of 2009*, HUBBARD TOWN PATRIOT (March 20, 2009), <http://hubbardtownpatriot.com/content/view/132/2>.

imported foods that meet U.S. standards.<sup>245</sup> The main goals of the FSMA are to: protect the public health by preventing food-borne illness, ensure the safety of food, improve research on contaminants leading to food-borne illness, and improve security of food from intentional contamination.<sup>246</sup> The FSMA would require that food companies register annually<sup>247</sup> and implement prophylactic measures on their production lines to ensure the safety of their foods.<sup>248</sup> In addition, companies would have to meet standards identified for the control of hazardous contaminants.<sup>249</sup> Most importantly, the bill strengthens the enforcement arm of the new agency by providing it with the power to: order recalls; require that all products be traceable; detain and destroy unsafe foods when inspectors find it; seek longer criminal sentences when consumers are hurt or killed; assess new civil fines on food companies that violate the law; and detect unlawful conduct by protecting whistleblowers from retaliation.<sup>250</sup> The FSMA has been referred to the following committees where it is currently being reviewed: the House Subcommittee on Energy and Commerce, the House Subcommittee on Agriculture, and the House Subcommittee on Livestock, Dairy and Poultry.<sup>251</sup> There are no indications that this bill has been discussed in committee at this time.<sup>252</sup>

Also in 2009, Representative John Dingell introduced a competing bill, H.R. 2749, addressing similar issues: The “Food Safety Enhancement Act of 2009,” (FSEA), the main purpose of which is to “amend the Federal Food, Drug, and Cosmetic Act to improve the safety of food, drugs, devices, and cosmetics in the global market.”<sup>253</sup> This bill has progressed further in the 111th Congress than any of the others, as it was passed by the House of Representatives.<sup>254</sup> It is now being reviewed by the Senate Committee on Health, Education, Labor and Pensions and has already been read

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245. See *H.R. 875: Food Safety Modernization Act of 2009*, GOVTRACK.US [hereinafter *FSMA Tracking*], <http://www.govtrack.us/congress/bill.xpd?bill=h111-875> (last visited Feb. 14, 2011).

246. H.R. 875 § 2.

247. *Id.* § 202.

248. *Id.* § 203.

249. *Id.* § 204.

250. See *id.* §§ 401–09 for coverage of these provisions.

251. See *H.R. 875: Food Safety Modernization Act of 2009, Committee Assignments*, GOVTRACK.US, <http://www.govtrack.us/congress/bill.xpd?bill=h111-875&tab=committees> (last visited Feb. 14, 2011).

252. See *FSMA Tracking*, *supra* note 245, to track information on this bill.

253. Food Safety Enhancement Act of 2009, H.R. 2749, 111th Cong., pmb1. (2009).

254. *H.R. 2749: Food Safety Enhancement Act of 2009*, GOVTRACK.US, <http://www.govtrack.us/congress/bill.xpd?bill=h111-2749> (last visited Feb. 14, 2011).

twice on the floor of the Senate.<sup>255</sup> The FSEA does not go so far as to restructure the Department of Health and Human Services as the FSMA does, but it contains important provisions for strengthening the regulation of drugs, devices, and cosmetics, and for enhancing the regulation of food, particularly food imported from other nations.<sup>256</sup>

Following in brief is a summary of the bill.<sup>257</sup> The FSEA, amending the Federal Food, Drug, and Cosmetic Act requires that each food facility (1) conduct a hazard analysis; (2) implement preventive controls; and (3) implement a food safety plan. It further requires that the Secretary of Health and Human Services (1) issue science-based performance standards to minimize the hazards from food borne contaminants; (2) establish science-based standards for raw agricultural commodities; (3) inspect facilities at a frequency determined pursuant to a risk-based schedule; (4) establish a food tracing system; (5) assess fees relating to food facility re-inspection and food recall; and (6) establish a program for accreditation of laboratories that perform analytical testing of food for import or export. The bill further authorizes the secretary to: (1) order an immediate cessation of distribution, or a recall, of food; (2) establish an importer verification program; and (3) quarantine food in any geographic area within the United States. It specifically defines the term “color additive” to include carbon monoxide that may affect the color of fresh meat, poultry products, or seafood. It further requires country of origin labeling on food and annual registration of importers. It provides for unique identifiers for food facilities and food importers; deems a food to be adulterated if an inspection is delayed or refused; requires the secretary to establish a corps of inspectors dedicated to inspections of foreign food facilities; and sets forth provisions governing the reorganization of the FDA’s field laboratories and district offices. It further gives the Commissioner of Food and Drugs subpoena authority with respect to a food proceeding. It requires the FDA to create a risk-based inspection system that would ensure the inspection of all domestic and foreign food facilities channeling food into the U.S. once every four years.<sup>258</sup> Pursuant to the bill, all imported food would have to be certified as meeting FDA guide-

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255. *Id.*

256. *See* H.R. 2749 §§ 201–16.

257. *See FSMA Tracking, supra* note 245, for the full text of the bill and its progress through Congress.

258. H.R. 2749 § 105.

lines for safety. Those manufacturers that met the FDA guidelines would be allowed an expedited entry program. Further, ambitious provisions of this bill would: allow the FDA to order recalls; require that all food products be traceable through electronic records; detain unsafe food where inspectors detect it; impose new civil fines on food companies that break the law; and encourage whistleblowers to disclose unlawful conduct by providing them with protection.<sup>259</sup> Allowing the FDA to make recalls is an important extension of their current power and could lead to more immediate protection for consumers from tainted food products.<sup>260</sup>

Another related bill that has been introduced in the 111th Congress is H.R. 1332 (the Safe FEAST Act).<sup>261</sup> It would require food companies to register with the federal government every two years. Additionally, food companies would be required to conduct hazard analyses and implement measures on their production lines to ensure their products were safe and that they met the standards adopted for hazards set by the FDA. If a food processor was identified as "high risk," the FDA would be required to do an inspection every year; all other food processors would be inspected at least once every four years.<sup>262</sup> The burden under the Safe FEAST Act would be on the food importers to ensure that their foreign suppliers complied with U.S. food safety laws.<sup>263</sup> Further, the bill would give the FDA the option to require that high risk foods be certified as complying with U.S. food safety requirements.<sup>264</sup> The FDA would accredit third-party certifiers to audit foreign food companies for compliance.<sup>265</sup> The FDA would also set standards for the safe production and importation of fresh fruits and produce.<sup>266</sup> As with the bills mentioned above, the Safe FEAST Act would strengthen the FDA's ability to order recalls, to detain unsafe foods when found by inspectors, and to set traceability requirements.

A comparative analysis of the three bills suggests that all three share, for the most part,<sup>267</sup> six critical provisions in overhauling the

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259. *Id.* §§ 107, 111, 134, 212.

260. See *id.* § 111 for specifics on recalls of food.

261. Safe Food Enforcement, Assessment, Standards, and Targeting Act of 2009, H.R. 1332, 111th Cong. (2009).

262. *Id.* § 107.

263. *Id.* § 301.

264. *Id.* § 303.

265. *Id.* § 308.

266. *Id.* § 106.

267. H.R. 1332 does not focus on research and education, H.R. 1332 does not address whistleblower protection or penalties under enforcement authority, and S510 does not address whistleblower protection. *Food Safety Legislation, Legislation—111th Congress, CTR. FOR*

food safety legislation currently existing in the United States: process controls and performance standards; inspections and import controls; research and education; on-farm inspections; recall of contaminated or suspected foods; and enforcement authority, including: trace suspected foods to their origins, detention of tainted foods immediately upon inspection, stricter penalties, and whistleblower protection.<sup>268</sup> Of these, all but two issues, research and education and on-farm inspection, directly affect trade with foreign nations, and, in particular, with China. The four key provisions affecting trade with foreign nations are discussed below.

### 1. Process Controls and Performance Standards

While current food safety laws under the FDA provide for inspections, they do not go far enough in creating a system that acts to prevent food safety issues from arising in the first place. Clearly, to be effective, mandatory process controls along with specific performance standards must be a core focus of any new law. While the FDA and USDA currently perform in-plant and border inspections, these are far too infrequent to truly prevent the cross-border entry of contaminated foods.

While no current bill specifies the exact standards that should be adopted to check for food contamination, the Center for Science in the Public Interest (CSPI) has done so.<sup>269</sup> CSPI recognizes what this Article recommends: that food processors themselves should promote programs of quality assurance and preventive process control by adopting general standards developed by the individual industries. Standards, such as the “Hazard Analysis and Critical Control Points” (HACCP),<sup>270</sup> have already been developed and adopted globally by several industries and could serve as general industry standards. As CSPI states:

HAACP systems are already mandated in some segments of the food supply, including seafood, juice, and all types of meat and poultry products – both raw and processed. A modern food safety system mandated by Congress should require FDA to

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SCIENCE IN THE PUB. INT. [hereinafter *Legislation*], <http://www.cspinet.org/foodsafety/legislation.html> (last visited Feb. 16, 2011).

268. See CAROLINE SMITH DEWAAL & DAVID W. PLUNKETT, BUILDING A MODERN FOOD SAFETY SYSTEM FOR FDA REGULATED FOODS 5 (2009), available at <http://www.cspinet.org/new/pdf/fswhitepaper.pdf>.

269. *Id.* at 5–6.

270. *Hazard Analysis and Critical Control Points*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/default.htm> (last visited Feb. 16, 2011).

implement HACCP or HACCP-like systems for all food processors and tie agency inspections to an audit of these systems.<sup>271</sup>

While each of the bills discussed refers to process controls and performance standards<sup>272</sup> to some degree, none requires the precision suggested by CSPI. Using HACCP and performance-standard approaches would, according to CSPI, place the emphasis of food safety on prevention rather than on mere response to problems.<sup>273</sup> Further, the CSPI suggests that such an approach would create a "more efficient and effective government" monitoring "through analysis of record as well as visual and laboratory inspection."<sup>274</sup>

## 2. Inspections and Food Import Controls

Currently, the FDA "lacks a minimum inspection mandate for the food companies it regulates."<sup>275</sup> Further, the FDA is not sufficiently staffed to inspect in-country food plants more than once every ten years, on average.<sup>276</sup> Prior to the new agreement with China that became effective June 2009,<sup>277</sup> there was no real opportunity to monitor food plants overseas. Consequences of these gaps in legislation have led to a number of serious food safety outbreaks, including: the September 2008 recall of salmonella contaminated peanut products from the Peanut corporation of America that sickened 691 people and caused nine deaths, the aforementioned Melamine-adulterated Chinese dairy recall in September 2008, and the aforementioned February and March 2007 Melamine-contaminated Chinese pet food recall.<sup>278</sup> These are only a few examples of thirteen incidents of national outbreaks due to food borne illnesses in the United States.<sup>279</sup> These examples emphasize the importance of revising the FDA's inspection and import control policies.

Each of the four bills proposed by Congress address the issues of inspections and food import controls. The FSMA contains heavier protections for consumers than does the Safe FEAST Act.<sup>280</sup> The importance of these policies is highlighted by the fact that "[l]ess

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271. DEWAAL & PLUNKETT, *supra* note 268, at 6.

272. H.R. 875 § 204; H.R. 2749 § 103; H.R. 1332 § 105.

273. *Building a Modern Food Safety System at FDA*, CTR. FOR SCIENCE IN THE PUB. INT., <http://www.cspinet.org/foodsafety/captions.html> (last visited Feb. 16, 2011).

274. DEWAAL & PLUNKETT, *supra* note 268, at 6.

275. *Id.*

276. *Id.*

277. *See supra* notes 184–209 and accompanying text.

278. DEWAAL & PLUNKETT, *supra* note 268, at 2.

279. *Id.*

280. *Id.* at 14.

than one percent of the food imported into the [United States] is inspected.”<sup>281</sup> As Representative John Dingell so aptly put it, “[w]ithout regular inspection and analysis there is little incentive for food producers and importers to ensure that our food supply is free from harmful and sometimes fatal contaminants.”<sup>282</sup> Recommendations in the bills include inspection programs that examine whether food operations have installed mandated process controls and performance standards; and required product sampling at both foreign- and U.S.-based food suppliers.<sup>283</sup> Further, recommendations in these bills grant the FDA the ability to go to the farm itself to inspect for any contamination before an outbreak occurs.<sup>284</sup> These inspections would be carried out on a “risk-based schedule.”<sup>285</sup>

In addition to enhancing the inspection process, the four bills all provide strong mandates on food imports. Specifically addressing inspection and monitoring of food imports is a critical step for the FDA, whose former regulations reflected the idea that the United States was its own primary source of food. Recent figures suggest that the average American eats “263 pounds of imported food” per year, representing 13 percent of the average diet,<sup>286</sup> yet the FDA lacks the basic ability to inspect and oversee these foods or their foreign sources, or require them to implement safety plans that identify and protect against food hazards. Dingell’s bill, for example, would give the FDA the authority to specify minimum food safety plan requirements that foreign importing companies must adhere to, and to audit food safety plans.<sup>287</sup> The bill would also give the FDA the power to require that foreign governments certify foods exported to the United States as meeting all U.S. food safety requirements.<sup>288</sup> The other three bills contain similar provisions.<sup>289</sup> Two other important provisions in the Dingell bill require country-of-origin labeling on all processed food labels, and require

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281. *Id.* at 7.

282. *Id.* (quoting Press Release, H.R. Comm. on Energy and Commerce, Dingell Introduces H.R. 3610, the “Food and Drug Import Safety Act of 2007”).

283. DEWAAL & PLUNKETT, *supra* note 268, at 12–13.

284. *See id.*

285. *See, e.g., Summary of the Food and Drug Administration Globalization Act of 2009, RESTAURANT.ORG*, [http://www.restaurant.org/pdfs/government/friday\\_special/fdaga\\_summary.pdf](http://www.restaurant.org/pdfs/government/friday_special/fdaga_summary.pdf) (last visited Feb. 16, 2011).

286. DEWAAL & PLUNKETT, *supra* note 268, at 8.

287. *See* H.R. 2749 § 102.

288. *See id.* § 113.

289. *See* DEWAAL & PLUNKETT, *supra* note 268, at 14.

food manufacturers to identify the country of origin for all ingredients on their websites.<sup>290</sup>

### 3. FDA Power to Recall Unsafe Foods

Another critical issue that the three bills address is that of enhancing the FDA's ability to detain unsafe foods at their place of origin and prevent them from entering the U.S. food chain, whether from foreign countries, or from within the United States.<sup>291</sup> Dingell's bill provides the FDA with authority to quarantine unsafe foods by prohibiting their movement from a specific geographic area.<sup>292</sup> Further, all four bills grant the FDA the right to recall foods that are suspected of being contaminated, thereby removing them from markets immediately.<sup>293</sup> The FDA currently lacks this power, which tremendously limits its ability to immediately contain unsafe foods. The language of the FSEA reads in relevant part as follows:

c) Order to Cease Distribution- If the Secretary has reason to believe that the use or consumption of, or exposure to, an article of food may cause serious adverse health consequences or death to humans or animals, the Secretary shall have the authority to issue an order requiring any person who distributes such article to immediately cease distribution of such article.<sup>294</sup>

### 4. Enforcement Authority

It is important for the FDA to have expanded enforcement powers, even beyond the newly suggested recall power. All but two of the bills<sup>295</sup> have enforcement tools covering not only recall ability, but the ability to trace back,<sup>296</sup> to detain suspect food for a reasona-

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290. See *supra* notes 253–60 and accompanying text.

291. BECKER, *supra* note 235, at 13–15.

292. See *supra* notes 253–60 and accompanying text.

293. See DEWAAL & PLUNKETT, *supra* note 268, at 14.

294. H.R. 2749 § 111.

295. Neither H.R. 1332 nor S. 510 address protection of whistleblowers, and H.R. 1332 does not identify penalties. *Legislation, supra* note 267.

296. Language relative to "traceability" being considered by the Senate is as follows:

'(c) Tracing System for Food-

'(1) IN GENERAL- The Secretary shall by regulation establish a tracing system for food that is located in the United States or is for import into the United States.

'(2) INFORMATION GATHERING-

'(A) TRACING TECHNOLOGIES- Before issuing a proposed regulation under this subsection, the Secretary shall—

'(i) identify technologies and methodologies for tracing the distribution history of a food that are, or may be, used by members of different sectors of the food industry, including technologies and methodologies to enable each person who produces, manufactures, processes, pack, transports, or holds a food to—

ble time,<sup>297</sup> to impose civil<sup>298</sup> and criminal penalties,<sup>299</sup> and to provide whistleblower protections.<sup>300</sup> For example, the FSEA provides

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- '(I) maintain the full pedigree of the origin and previous distribution history of the food;
  - '(II) link that history with the subsequent distribution of the food;
  - '(III) establish and maintain a system for tracing the food that is interoperable with the systems established and maintained by other such persons; and
  - '(IV) use a unique identifier for each facility owned or operated by such person for such purpose, as specified under section 1011; and
  - '(ii) to the extent practicable, assess—
  - '(I) the costs and benefits associated with the adoption and use of such technologies;
  - '(II) the feasibility of such technologies for different sectors of the food industry; and
  - '(III) whether such technologies are compatible with the requirements of this subsection.

H.R. 2749 § 107.

297. *See id.* §§ 131–32.

298. *Id.* § 135. The following language appears in the bill:

(a) IN GENERAL- Paragraph (2) of section 303(f) (21 U.S.C. 331 et seq.) is amended to read as follows:

'(2) (A) Any person who violates a provision of section 301 relating to food shall be subject to a civil penalty for each such violation of not more than—

'(i) \$20,000 in the case of an individual, not to exceed \$50,000 in a single proceeding; and

'(ii) \$250,000 in the case of any other person, not to exceed \$1,000,000 in a single proceeding.

'(B) Any person who knowingly violates a provision of section 301 relating to food shall be subject to a civil penalty for each such violation of not more than—

'(i) \$50,000 in the case of an individual, not to exceed \$100,000 in a single proceeding; and

'(ii) \$500,000 in the case of any other person, not to exceed \$7,500,000 in a single proceeding.

'(C) Each violation described in subparagraph (A) or (B) and each day during which the violation continues shall be considered to be a separate offense'.

*Id.* § 135(a).

299. *See, e.g., id.* § 134:

(3) Notwithstanding paragraph (1) [of this section], any person who knowingly violates paragraph (a), (b), (c), (k), or (v) of section 301 with respect to any food that is misbranded or adulterated shall be imprisoned for not more than 10 years or fined in accordance with title 18, United States Code, or both.

300. *See, e.g., id.* § 212(a)–(b)(1):

'(a) IN GENERAL- No person who submits or is required under this Act or the Public Health Service Act to submit any information related to a food, or any officer, employee, contractor, subcontractor, or agent of such person may discharge, demote, suspend, threaten, harass, or in any other manner discriminate against an employee in the terms and conditions of employment because of any lawful act done by the employee, including within the ordinary course of the job duties of such employee—

'(1) to provide information, cause information to be provided, or otherwise assist in any investigation regarding any conduct which the employee reasonably believes constitutes a violation of this Act, or any other provision of Federal law relating to the safety of a food, if the information or assistance is provided to, or an investigation stemming from the provided information is conducted by—

'(A) a Federal regulatory or law enforcement agency;

'(B) any Member of Congress or any committee of Congress; or

for a voluntary recall and, if the food producer refuses, then the FDA may mandate a recall.<sup>301</sup>

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'(C) a person with supervisory authority over the employee (or such other person working for the employer who has the authority to investigate, discover, or terminate the misconduct);

'(2) to file, cause to be filed, testify, participate in, or otherwise assist in a proceeding filed, or about to be filed (with any knowledge of the employer), in any court or administrative forum relating to any such alleged violation; or

'(3) to refuse to commit or assist in any such violation.

'(b) Enforcement Action-

'(1) IN GENERAL- An employee who alleges discharge or other discrimination in violation of subsection (a) may seek relief in accordance with the provisions of subsection (c) by—

'(A) filing a complaint with the Secretary of Labor; or

'(B) if the Secretary of Labor has not issued a final decision within 210 days of the filing of the complaint and there is no showing that such delay is due to the bad faith of the claimant, or within 90 days after receiving a final decision or order from the Secretary, bringing an action at law or equity for de novo review in the appropriate district court of the United States, which court shall have jurisdiction over such action without regard to the amount in controversy, and which action shall, at the request of either party to such action, be tried by the court with a jury.

301. The specific language of the recall provision now under review in the Senate states in part:

'(b) VOLUNTARY RECALL- The Secretary may request that any person who distributes an article of food that the Secretary has reason to believe is adulterated, misbranded, or otherwise in violation of this Act voluntarily—

'(1) recall such article; and

'(2) provide for notice, including to individuals as appropriate, to persons who may be affected by the recall.

'(c) ORDER TO CEASE DISTRIBUTION- If the Secretary has reason to believe that the use or consumption of, or exposure to, an article of food may cause serious adverse health consequences or death to humans or animals, the Secretary shall have the authority to issue an order requiring any person who distributes such article to immediately cease distribution of such article.

'(d) ACTION FOLLOWING ORDER- Any person who is subject to an order under subsection (c) shall immediately cease distribution of such article and provide notification as required by such order, and may appeal within 24 hours of issuance such order to the Secretary. Such appeal may include a request for an informal hearing and a description of any efforts to recall such article undertaken voluntarily by the person, including after a request under subsection (b). Except as provided in subsection (f), an informal hearing shall be held as soon as practicable, but not later than 5 calendar days, or less as determined by the Secretary, after such an appeal is filed, unless the parties jointly agree to an extension. After affording an opportunity for an informal hearing, the Secretary shall determine whether the order should be amended to require a recall of such article. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

'(e) ORDER TO RECALL-

'(1) AMENDMENT- Except as provided under subsection (f), if after providing an opportunity for an informal hearing under subsection (d), the Secretary determines that the order should be amended to include a recall of the article with respect to which the order was issued, the Secretary shall amend the order to require a recall.

'(2) CONTENTS- An amended order under paragraph (1) shall—

'(A) specify a timetable in which the recall will occur;

'(B) require periodic reports to the Secretary describing the progress of the recall; and

Finally, in connection with importation of foods from China and elsewhere, note should be taken of three more provisions of the FSEA: the creation of foreign inspectors,<sup>302</sup> the requirement of country of origin labeling,<sup>303</sup> and the extraterritorial jurisdiction provision.<sup>304</sup>

Enhancing the FDA's authority to inspect foods on a more regular basis, requiring that foreign countries or their agents certify that imports meet U.S. food safety regulations, and providing the FDA with the power to block unsafe foods from entering the U.S. food supply chain, are all important steps which need to be taken by the U.S. government to protect its citizens from contaminated foods. Further, hiring inspectors dedicated to inspecting foreign

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'(C) provide for notice, including to individuals as appropriate, to persons who may be affected by the recall.

In providing for such notice, the Secretary may allow for the assistance of health professionals, State or local officials, or other individuals designated by the Secretary.

'(3) NONDELEGATION- An amended order under this subsection shall be ordered by the Secretary or an official designated by the Secretary. An official may not be so designated unless the official is the director of the district under this Act in which the article involved is located, or is an official senior to such director.

'(f) EMERGENCY RECALL ORDER-

'(1) IN GENERAL- If the Secretary has credible evidence or information that an article of food subject to an order under subsection (c) presents an imminent threat of serious adverse health consequences or death to humans or animals, the Secretary may issue an order requiring any person who distributes such article—

'(A) to immediately recall such article; and

'(B) to provide for notice, including to individuals as appropriate, to persons who may be affected by the recall.

'(2) ACTION FOLLOWING ORDER- Any person who is subject to an emergency recall order under this subsection shall immediately recall such article and provide notification as required by such order, and may appeal within 24 hours after issuance such order to the Secretary. An informal hearing shall be held within as soon as practicable but not later than 5 calendar days, or less as determined by the Secretary, after such an appeal is filed, unless the parties jointly agree to an extension. After affording an opportunity for an informal hearing, the Secretary shall determine whether the order should be amended pursuant to subsection (e)(1). If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

*Id.* § 420(b)-(f); *see also id.* § 111.

302. *Id.* § 208. The bill states:

'(k) DEDICATED FOREIGN INSPECTORATE- The Secretary shall establish and maintain a corps of inspectors dedicated to inspections of foreign food facilities. This corps shall be staffed and funded by the Secretary at a level sufficient to enable it to assist the Secretary in achieving the frequency of inspections for food facilities as described in this Act.'

*Id.*

303. *Id.* § 202.

304. Section 213 of H.R. 2749 reads as follows:

'There is extraterritorial Federal jurisdiction over any violation of this Act relating to any article of food if such article was intended for import into the United States or if any act in furtherance of the violation was committed in the United States.

*Id.* § 213.

imports, requiring country-of-origin labeling of foods, and creating a jurisdictional basis for extending the FDA's power to investigate and pursue violators outside the United States, all show a government commitment to ensuring the safety of its food supply chain. These measures, if passed, and coupled with the U.S-China Agreement on Food Safety, and the measures China is taking to monitor its own exporters of food to the United States,<sup>305</sup> represent critical steps in ensuring the safety of the food supply chain for U.S. consumers.

#### IV. EUROPEAN UNION LEGAL AND REGULATORY FRAMEWORK

Food regulation in Europe has a long history. As early as the 1850s, a number of European countries independently adopted legislation concerning the "purity" of food.<sup>306</sup> Many of the laws enacted at this time evolved due to the intentional adulteration or misbranding of foods.<sup>307</sup> The European Union (EU), which now has twenty-eight member states, is the current governing European body that sets food safety production guidelines for its member states.<sup>308</sup> Food safety laws in the EU were reviewed in 2002, following the outbreak of "mad cow disease" in Great Britain. This study resulted in the "White Paper on Food Safety" (EU White Paper), which set out a host of recommendations for new proactive food legislation.<sup>309</sup>

A key element to the new approach to food regulation was the development of a "framework regulation,"<sup>310</sup> which identifies the general principles and requirements of current EU food law, established the European Safety Food Authority, and laid down procedures in matters of food safety.<sup>311</sup> Critical to the EU's new approach was the adoption of a "farm-to-fork" approach to food safety and inspection. This approach covers all sectors of the food

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305. See *supra* notes 57–153 and accompanying text for a discussion of the new China regulations enacted and made effective July 1, 2009.

306. LINDEN J. ELLIS & JENNIFER L. TURNER, WOODROW WILSON INT'L CTR. FOR SCHOLARS China Endowment Forum, *Sowing the Seeds: Opportunities for U.S.-China Cooperation On Food Safety* 59 (2008), available at [http://www.wilsoncenter.org/topics/pubs/CEF\\_food\\_safety\\_text.pdf](http://www.wilsoncenter.org/topics/pubs/CEF_food_safety_text.pdf).

307. See generally Jim Phillips & Michael French, *Adulteration and Food Law, 1899-1939*, TWENTIETH CENTURY BRIT. HIST., 1998.

308. See generally Council Regulation 178/2002, 2002 O.J. (L 31) 1 (EC).

309. See *Commission White Paper on Food Safety*, at 3, COM (1999) 719 final (Jan. 12, 2000) [hereinafter *White Paper*], available at [http://ec.europa.eu/dgs/health\\_consumer/library/pub/pub06\\_en.pdf](http://ec.europa.eu/dgs/health_consumer/library/pub/pub06_en.pdf).

310. See Council Regulation 178/2002, *supra* note 308, art. 1.

311. *Id.*

and feed chain, with traceability as a critical element.<sup>312</sup> A second important element was the establishment of an independent body that serves as an advisory board on scientific issues to the legislators.<sup>313</sup> The final piece of the new legislation provided for the development of specific food and feed safety legislation, which overhauled the former legislation and created a framework for harmonized food controls.<sup>314</sup>

Another important concept in the EU's overhaul of food law was the "Precautionary Principle," drafted in February 2000.<sup>315</sup> Theoretically, the Precautionary Principle is simply a call to protect the environment when considering food safety.<sup>316</sup> In practice, however, its scope has proven to be much wider. The commission described its application and intent in a Commission Communication:

The precautionary principle is not defined in the Treaty, which prescribes it only once - to protect the environment. But in practice, its scope is much wider and, specifically where preliminary objective scientific evaluation, indicates that there are reasonable grounds for concern that the potentially dangerous effects on the *environment, human, animal or plant health* may be inconsistent with the high level of protection chosen for the Community.

The Commission considers that the Community, like other WTO members, has the right to establish the level of protection - particularly of the environment, human, animal and plant health, - that it deems appropriate. Applying the precautionary principle is a key tenet of its policy, and the choices it makes to this end will continue to affect the views it defends internationally, on how this principle should be applied.<sup>317</sup>

Article 7 of EC Regulation 178/2002, however, adds a precautionary note to the application of the Precautionary Principle, stating that measures taken in response to a case presenting potential negative health effects will not be more trade restrictive than necessary to meet the minimal desired level of health protection.<sup>318</sup> And the steps taken should be reviewed "within a reasonable period of time."<sup>319</sup> Application of the Precautionary Principle clearly raises

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312. *See id.* art. 3.

313. *Id.*

314. *Id.*

315. *Communication from the Commission on the Precautionary Principle*, COM (2000) 1 (Feb. 2, 2000), available at [http://ec.europa.eu/dgs/health\\_consumer/library/pub/pub07\\_en.pdf](http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf).

316. *Id.* at 3.

317. *Id.*

318. Council Regulation 178/2002, *supra* note 308, art. 7.

319. *Id.*

issues of restricting competitive market access, and is a sensitive subject among developing countries who fear its application will serve to disguise protectionism and favor domestic markets.<sup>320</sup> Although the EU has long advocated using the principle in various groups, such as the WTO, the United States is less sanguine about its application. The United States generally opposes *explicit* use of the principle because it is perceived as “unscientific and arbitrary.”<sup>321</sup> This is not to say that the United States does not support a precautionary approach as part of a scientifically sound decision process.<sup>322</sup>

#### A. *Comparing the U.S. and E.U. Approaches to Food Safety*

The objective of the EU White Paper is specifically spelled out as to “outline[ ] a comprehensive range of actions needed to complement and modernise existing EU food legislation, to make it more coherent, understandable and flexible, to promote better enforcement of that legislation, and to provide greater transparency to consumers;” in addition, “to guarantee a high level of food safety.”<sup>323</sup> In contrast, the preamble to the FSEA simply states that the purpose of the Act is “To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of food in the global market, and for other purposes.”<sup>324</sup> As mentioned above, the goals of the White Paper were: “the establishment of an independent European Food Authority” with responsibility for “independent scientific advice on all aspects relating to food safety, operation of rapid alert systems” and communication of risks; an improved legislative framework covering all aspects of food products “from farm to table;” greater harmonization of national control systems; and dialogue with consumers and other stakeholders.<sup>325</sup>

The EU White Paper goes on to identify the general principles on which European food safety policy should be based:

- a “comprehensive, integrated approach” throughout the food chain;

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320. Int'l Ctr. for Trade and Sustainable Dev., *New EU Food Safety Law Elaborates Precautionary Principle*, BRIDGES TRADE BIORES, Mar. 7, 2002, available at <http://icstd.net/i/news/biores/8714>.

321. *Id.*

322. *Id.*

323. *White Paper*, *supra* note 309, at 3, 7.

324. H.R. 2749, pmbl.

325. *White Paper*, *supra* note 309, at 3.

- a clear definition of the roles of all stakeholders in the food chain (feed manufacturers, farmers and food operators, the Member States, the Commission, consumers);
- “traceability of feed and food and their ingredients;”
- a “coherent, effective and dynamic food policy;”
- risk analysis (comprising risk assessment, management and communication);
- scientific advice to the highest standards of “independence, excellence and transparency;”
- application of the precautionary principle in risk management.<sup>326</sup>

In addition to the creation of a new European Food Authority mentioned above, and the development of new food safety laws, the EU White Paper emphasizes the importance of providing consumers with up to date information.<sup>327</sup> The FSEA, conversely, neither sets forth the goals of the legislation nor addresses the need to inform and receive input from consumers.

In keeping with its goal of addressing the issues from farm to table, the EU White Paper identifies each of the wide range of areas in which the law is to be changed: from animal feed to its labeling; from animal health and welfare to new methods of tackling zoonoses, mad cow disease and other animal illnesses; from refining current legal requirements to ensure consistency and clarity throughout the food production; to limits and controls on contaminants and on veterinary residues on human food; and to safeguard measures in emergencies.<sup>328</sup> The FSEA does not take such an holistic approach to food protection, but, instead, zeroes in on details, such as requirements for registration of food facili-

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326. *Id.* at 8–9.

327. *Id.* at 4.

328. *See generally id.* The *White Paper* specifies that:

The guiding principle throughout this White Paper is that food safety policy must be based on a comprehensive, integrated approach. This means throughout the food chain ('farm to table'); across all food sectors; between the Member States; at the EU external frontier and within the EU; in international and EU decision-making fora, and at all stages of the policy-making cycle. The pillars of food safety contained in this White Paper (scientific advice, data collection and analysis, regulatory and control aspects as well as consumer information) must form a seamless whole to achieve this integrated approach.

*Id.* at 8.

ties<sup>329</sup>; performance standards<sup>330</sup>; risk-based inspection schedules<sup>331</sup>; and access to records of those in the food supply chain.<sup>332</sup>

Nowhere in the EU White Paper is there mention of penalties, while the FSEA identifies both criminal and civil penalties and exerts its jurisdiction outside its territories to enforce the Act, and also addresses facility registration and fees, inspection, and re-inspection. The EU White Paper envisions a new set of controls and acknowledges that, while primary responsibility for compliance with legislative mandates rests with economic “operators,” it is up to the national authorities to ensure that food safety standards are met by these operators.<sup>333</sup>

The controls anticipated by the EU Commission envision a “community framework of national control systems” comprising three core elements: definition of “operational criteria set up at the community level;” “development of community control guidelines;” and an “enhance[ment] [of] administrative cooperation in the [design] and operation of control systems.”<sup>334</sup> These elements mandate a policy of “*traceability* of feed, food, and their ingredients.”<sup>335</sup> Traceability is also a critical element in the proposed FSEA.<sup>336</sup> The EU White Paper anticipates the creation of a new “monitoring and surveillance system.”<sup>337</sup> Unique to the EU is the Rapid Alert System that exists to provide consumers with emergency information about dangerous products.<sup>338</sup> The EU White Paper recommends enlarging this system to include all food and feeds, and advises a comprehensive approach that extends to warnings to foreign countries:

It should extend obligations of economic operators to notify food safety emergencies and ensure appropriate information of consumers and trade organisations. Furthermore, an appropriate link with other rapid information systems must be made. This system should also be extended to third countries for incoming and outgoing information.<sup>339</sup>

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329. H.R. 2749 § 101.

330. *Id.* § 103.

331. *Id.* § 105.

332. *Id.* § 106.

333. *See White Paper, supra* note 309, at 29.

334. *Id.* at 30.

335. *Id.* at 8 (emphasis in original).

336. *See* H.R. 2749 § 107.

337. *White Paper, supra* note 309, at 10.

338. *See id.* at 11.

339. *Id.*

Both the FSEA<sup>340</sup> and the EU White Paper<sup>341</sup> address the issues of research and its importance in preventing food crises. The FSEA continues the tradition of leaving watch dog responsibility for food importation, exportation, and the like, to the FDA. The system in the EU, however, is not so unified and, therefore, is more difficult to regulate. The EU White Paper recommends a “community framework” of national control systems with community control guidelines and community cooperation among the members of the EU to promote and enforce mutual assistance.<sup>342</sup> As with the FSEA, the EU White Paper calls for imported food stuffs to meet the health requirements set by the EU; however, unlike the FSEA, the EU White Paper acknowledges the obligation to abide by international standards and the WTO requirements, stating as follows:

In order to ensure that these requirements are met, our WTO obligations require either that we base those measures on international standards or in so far as they are not based on international standards, that the measures are scientifically warranted. In cases where scientific evidence is insufficient, provisional measures may be adopted on the basis of available pertinent information.<sup>343</sup>

The measures identified in the U.S. proposed legislation, the Bilateral Agreement, and the EU White Paper that should have the most impact on food contamination include: registration of providers, whether foreign or local; establishment of performance standards; risk-based inspection schedules; traceability of foods; surveillance; country of origin labeling; exportation certificates programs; heightened foreign inspections; and the authority in the United States to seize and to recall contaminated foods.

## V. NON-GOVERNMENTAL AND CORPORATE RESPONSES

In addition to the new Food Safety Laws in China and responses in the United States and the European Union, food safety has also been addressed by non-governmental organizations. One of the most comprehensive responses was from the United Nations, which urged China to revise its food safety law based on best inter-

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340. H.R. 2749 § 123.

341. See *White Paper*, *supra* note 309, at 11.

342. See *id.* at 30.

343. *Id.* at 34.

national practices.<sup>344</sup> The United Nations Report (UN Report) on this issue acknowledges that there are approximately “450,000 different enterprises engaged in food production and processing in China” and the “sheer scale of China’s food industry makes the task of aligning all Chinese food products with international standards an ongoing and arduous one.”<sup>345</sup> The UN Report made a number of recommendations that China might consider including:

- “A legal framework developed in a coordinated manner that is consistent nationwide;”
- “A food safety system that is risk-based and in harmony with international standards, i.e. Codex Alimentarius;”
- “A unified, authoritative and efficient food safety testing and inspecting system;”
- “A uniform and standardized food certification and qualification system;”
- “An effective food safety emergency response system;”
- “An improved food traceability system;”
- “An enhanced information service system that has links with the media to ensure the media and consumers can have confidence in the safety of the food in China;”
- “A well-designed national food contaminants monitoring system;”
- “A strengthened programme of international communication and cooperation;” and
- “Greater emphasis on public-private partnership.”<sup>346</sup>

Many of these recommendations are incorporated in China’s new FSL.<sup>347</sup> In contrast, the World Trade Organization (WTO) is explicit that it does not dictate food safety standards.<sup>348</sup> Instead, Article 20 of the General Agreement on Tariffs and Trade (GATT)

344. UNITED NATIONS IN CHINA, OCCASIONAL PAPER: ADVANCING FOOD SAFETY IN CHINA 6 (2008), available at <http://www.un.org.cn/public/resource/2aebcd033e334d961fefb1588b70f2ab.pdf>.

345. *Id.*

346. *Id.* at 7–8. The Codex Alimentarius Commission is a joint organization of the Food and Agriculture Organization and the World Health Organization, designed to develop international food standards. CODEX ALIMENTARIUS, [http://www.codexalimentarius.net/web/index\\_en.jsp](http://www.codexalimentarius.net/web/index_en.jsp) (last visited Feb. 16, 2011). For example, the Codex Alimentarius Commission set new standards for baby food in October 2009 and plans to establish maximum levels for Melamine in food. Svetlana Kovalyova, *Food Safety Body Sets French Fries, Baby Food Rules*, REUTERS (July 6, 2009), <http://www.reuters.com/article/healthNews/idUSTRE5654W120090706>.

347. See generally Food Safety Law, *supra* note 68.

348. *Understanding the WTO: The Agreements – Standards and Safety*, WTO.ORG [hereinafter *WTO Agreements*], [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/agrm4\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm4_e.htm) (last visited Feb. 16, 2011).

allows countries to establish their own standards.<sup>349</sup> Although the WTO becomes involved when such measures are challenged as protectionist, it also references the FAO/WHO Codex Alimentarius as a guide for its members.<sup>350</sup> For example, after learning of several countries introducing import bans on Chinese milk products, the WTO urged countries to base measures only on science, risk assessment, and information from the World Health Organization (WHO).<sup>351</sup> Although the WTO does not set standards, it acts to guard against protectionist measures under the guise of food safety.

One of the roles of the American Chamber of Commerce (AmCham) in Beijing is to advocate for U.S. business and consumers in China.<sup>352</sup> Recognizing that the new FSL has been implemented in China, a recent presentation at AmCham noted that the real keys are “enforcement, commitment, and implementation.”<sup>353</sup> Merely having the Food Safety law on the books is not sufficient to ensure food safety. There must be meaningful follow-through by Chinese authorities. It is unclear, however, the extent to which AmCham will seek to ensure that China follows through with the FSL. Additionally, U.S. consumer groups, such as Food and Water Watch, are dedicated to food safety, acting as consumer advocates and lobbying for safe products.<sup>354</sup> Although these groups can offer valuable reporting, lobbying, and consumer education about the status of food safety in China, they have no real power to ensure enforcement.

Perhaps the most effective work is being done by corporations themselves, who face direct legal exposure if they sell contaminated food to U.S. consumers. Wal-Mart, for example, has new quality standards for all suppliers, including factories, and standards for any raw materials that are used in manufacture.<sup>355</sup> As of January 2009, Wal-Mart began requiring all suppliers to sign new

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349. General Agreement on Tariffs and Trade, art. XX, Oct. 30, 1947, 61 Stat. A-60, 55 U.N.T.S. 194.

350. *WTO Agreements*, *supra* note 348.

351. *See id.*

352. *Welcome to AmCham-China*, AMCHAMCHINA.ORG, <http://amchamchina.org/article/10> (last visited Feb. 16, 2011).

353. *Food Safety Solutions for China in 2010*, AMCHAMCHINA.ORG (Dec. 11, 2009), <http://www.amchamchina.org/article/index/5387>.

354. *About Food & Water Watch*, FOODANDWATERWATCH.ORG, <http://www.foodandwaterwatch.org/about> (last visited Feb. 16, 2011).

355. *See* Andria Cheng, *Wal-Mart Sets New Rules for Suppliers, Starting in China*, MARKET WATCH, Oct. 22, 2008, available at <http://walmartstores.com/FactsNews/NewsRoom/8709.aspx>.

agreements certifying their compliance with the law.<sup>356</sup> Accordingly, all Wal-Mart suppliers should now be fully compliant with China's new FSL. Thus, even if there is not effective enforcement by Chinese officials, suppliers are contractually bound to be in compliance. This proactive measure is intended to head-off recalls of potentially contaminated food, which have affected many companies, such as Kraft Foods and Mars, who suspended all sales of Chinese-made Oreo cookies, M&Ms, and Snickers bars in Indonesia following reports of possible contamination.<sup>357</sup> Likewise, British candymaker, Cadbury recalled all of its Chinese-made chocolate after a similar contamination.<sup>358</sup>

Another important aspect of avoiding recalls is testing and inspection of products before they enter the market. Companies can undertake their own testing, but many may want to outsource this task. This will create an increased need for companies that provide inspection and compliance services, such as Intertek,<sup>359</sup> which certifies the safety of a wide range of products, including food and pharmaceutical products. Similarly, just days after the new FSL went into effect in China, Neogen Corporation announced a multi-million pound partnership agreement with the Chinese government to research food safety issues, specifically to develop "screening test kits for quality and safety of agricultural commodities."<sup>360</sup>

Overall, the outlook for ensuring food safety in China is daunting. A report from global management consulting firm A.T. Kearney states that that "China's fragmented and inadequate standards and supply chain make it difficult to get safe food to consumers."<sup>361</sup> In 2007, they estimated that it would require a \$100 billion to correct.<sup>362</sup> One can only speculate if that number is now higher in the wake of the recent recalls.

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356. *Id.*

357. Lisa Wade McCormick, *Melamine Scandal Continues to Expand*, CONSUMERAFFAIRS.COM (Oct. 8, 2008), [http://www.consumeraffairs.com/news04/2008/10/chinese\\_formula11.html](http://www.consumeraffairs.com/news04/2008/10/chinese_formula11.html).

358. See Patrick et al., *supra* note 30.

359. INTERTEK, <http://www.intertek.com> (last visited Feb. 16, 2011).

360. Rory Harrington, *Neogen Signs Multi-Million Food Safety Deal with China*, FOODPRODUCTIONDAILY.COM (June 3, 2009), <http://www.foodproductiondaily.com/Quality-Safety/Neogen-signs-multi-million-food-safety-deal-with-China>.

361. *Fixing China's Food Safety Issues will Require a \$100 Billion Investment*, ATKEARNEY.COM (June 26, 2007), <http://www.atkearney.com/index.php/News-media/fixing-chinas-food-safety-issues-will-require-a-100-billion-investment.html>.

362. *Id.*

## VI. ETHICAL CONSIDERATIONS

As is evident by the foregoing analysis, food importation from China is a huge issue for the United States, and the country's dependence on it is only going to grow as China emerges as an even more prominent supplier of goods and foods in the global economy. While both China and the United States are making tremendous legislative efforts to protect the food supply chain, additional steps outside the regulatory arena are needed. And indeed, looking back at the stakeholders identified in the introduction, we have discussed the responsibilities of each of the stakeholders identified relative to keeping the food supply chain safe. What is left is a discussion of the element critical to all business transactions: trust. It is this failure of trust, accompanied by a failure to understand the Chinese culture, that have led to the number of problems experienced in outsourcing from China. A brief discussion of the cultural and ethical perspective in China is critical to closing the safety gap in the food supply chain.

A survey conducted in the late 1990s disclosed that 39 percent of Chinese businessmen were dissatisfied with the "ethical climate" in their own businesses.<sup>363</sup> Moreover, 87 percent approved of the idea of corporate codes of ethics or a set of ethical norms for business.<sup>364</sup> Researchers have suggested that much of this dissatisfaction derives from the "social, political, and economic" upheaval China has experienced over the last several decades.<sup>365</sup> As one author has noted, the current business climate in China is similar to the "opening of the American Wild West . . . —a vast area of opportunity with many uncharted and risky paths, governed by a legal system that is still a work in process."<sup>366</sup> With a lax legal system, cheap labor, and high demand for its burgeoning food production capabilities, it is no wonder that the accompanying pressure to produce goods quickly and ever more cheaply has caused ethical lapses by Chinese suppliers.<sup>367</sup>

Further, Chinese culture, which is primarily based on Confucius' teaching, favors familial relationships over those with strangers. Confucianism is defined by "hierarchical relationships among five groups: ruler/subject; father/son; husband/wife; brother/brother;

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363. Kris Day & Lori Tansey, *Business Ethics in China*, 11 *ΕΤΗΙΚΟΣ* 8, 8 (1998).

364. *Id.*

365. *Id.*

366. Roth, *supra* note 161, at 28.

367. *Id.* at 26.

and friend/friend.”<sup>368</sup> The Confucian orientation implies a degree of mistrust and suspicion of those outside the familial circle.<sup>369</sup> Further, the concept of friend/friend is based on a long-term relationship, not the typical impersonal relationship identified in today’s foreign supplier to middleman to retailer chain. Hence, the critical obligation of moral behavior implied by one of China’s most important social norms, “guanxi,” is absent in transactions in which a U.S. buyer uses an intermediary instead of transacting directly with the Chinese supplier. This impersonal relationship with a Chinese supplier does not encourage the mutual bonds of trust and obligation suggested by a relationship of guanxi.<sup>370</sup> Indeed, a recent survey of Chinese businessmen reveals that they neither appreciate nor understand the value of responsible corporate behavior.<sup>371</sup>

Furthermore, during the social revolution, the Chinese people had a history of poverty and a disciplined life dedicated to the state that stripped them of any and all luxuries.<sup>372</sup> While China is greatly transformed today, the Chinese are very careful about spending money.<sup>373</sup> In today’s frenzied global market, where China has become synonymous with “cheap resources,” there is still much concern in China about spending money on expensive ingredients where cheaper ones can be had. As one food supply chain article has pointed out:

they [the Chinese] are relatively new to the idea of paying for attributes that do not have immediate and concretely perceivable impact- including process integrity concepts like traceability and transparency. This thinking appears among Chinese consumers, who put pricing pressure on Chinese manufacturers, as well as in the supply managers who make procurement and supply chain decisions for these companies. Likewise, the export market incessantly pressures Chinese companies for low prices, even while surging demand has an inflationary impact on the costs of inputs . . . All this leads to an obsession with keeping costs low and helps to explain Chinese companies’ swapping out of approved ingredients for cheaper substitutes or skimping on proper handling.<sup>374</sup>

Compounding the problem is the Chinese cultural aversion to reporting misconduct and, thus, even those Chinese who are con-

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368. Day & Tansey, *supra* note 363, at 9.

369. *Id.*

370. Roth, *supra* note 161, at 33–34.

371. Elizabeth C. Economy, *The Great Leap Backward?*, 86 FOREIGN AFF. 38, 53 (2007).

372. Roth, *supra* note 161, at 29–30.

373. *Id.* at 28.

374. *Id.* at 29.

cerned by unethical behavior of coworkers are reluctant to “rat” on them.<sup>375</sup> This is understandable given the behavior encouraged during China’s period of the “Cultural Revolution” from 1966 to 1976. During this period, even children were encouraged to “report” on parents, siblings, teachers, and friends who did not follow Maoist thinking.<sup>376</sup> Those reported on were often sent to prison or executed.<sup>377</sup> Consequently, the Chinese are reluctant to report on anyone.

During the Cultural Revolution, there was no privacy in China, and concern that reporting malfeasance today would be revealed publicly continues to discourage whistleblowers.<sup>378</sup> These factors compound the problem of U.S. merchants in sourcing safe foods and drugs from China. Whistleblower provisions found in most corporate codes are not understood by Chinese workers and their imposition would only widen the gap between Chinese suppliers and U.S. merchants, created by the absence of a long-term relationship with true “*guanxi*.”

These factors present challenges for companies who are trying to foster ethical behavior.

## VII. RECOMMENDATIONS

This Article has identified the steps that host and home governments are taking to safeguard the food supply chain as U.S. companies continue to source foods and other products from China. Critical in the efforts of both governments are: monitoring and supervision; heightening regulatory standards; establishing notification and recall systems; providing increased consumer rights (in the case of China); increasing sanctions for offenders; enhancing process controls and performance standards (U.S. bills); increasing inspection and food import controls (U.S. bills); and enhancing the recall power of the FDA. While these are vital and effective steps to increase the safety of foods in the supply chain, the government action in the United States and China is an insufficient step to cure the problems. Responsibility for addressing the problems also lies with exporting suppliers from China as well as importing companies in the United States. Again, the responsibility lies with

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375. *Id.* at 31.

376. Day & Tansey, *supra* note 363, at 11.

377. See Didi Kristen Tatlow, *A Grim Chapter in History Kept Closed*, N.Y. TIMES, July 22, 2010, available at [http://www.nytimes.com/2010/07/23/world/asia/23iht-letter.html?\\_r=1](http://www.nytimes.com/2010/07/23/world/asia/23iht-letter.html?_r=1).

378. *See id.*

a variety of stakeholders who must work collectively to address the problem of safe foods.

First and foremost, companies importing food from China into the United States must undertake their own due diligence at all junctures to ensure that their products are safe for consumers. It is significant that China's FSL calls on food industry associations to tighten self-regulation.<sup>379</sup> Although the Chinese government's steps are important, issues of enforcement, particularly in China, necessitate corporate policing of the supply chain. As was seen in the Heparin example, Baxter's failure to inspect its manufacturing facility led to disastrous consequences; Baxter was not able to rely on the FDA, which inadvertently failed to inspect the contaminated food products. Companies must inspect and test food to ensure that it is safe for consumption.

Next, companies should adopt their own standards for dealing with vendors. These standards may be based on worldwide industry standards, such as HACCP or ISO, which establish protection for foods in the supply chain. Companies would be well served to require all vendors to enter into contractual agreements to comply with these standards, as well as all applicable laws. Monitoring vendors is crucial to the immediate identification and rectification of deficiencies. To deter conduct that could result in liability, the agreements should contain penalties for any vendor who fails to comply.

Additionally, to the extent that companies can eliminate middlemen when dealing with Chinese suppliers, they will be able to create direct-link relationships generating trust and respect, with the goal of preventing suppliers from cutting costly corners. Developing *guanxi*, or valuable relationships, may help vendors look more to long-term dealings. Without establishing relationships of trust globally, U.S. companies cannot expect to have open and honest relationships with Chinese suppliers. Corporate partners must work hard to establish such a relationship and to bridge the cultural differences that have made these relationships challenging in the past.

It is clear that all the stakeholders identified have a vested interest in the food supply chain and must work collectively to ensure the safety of food and drugs sourced from China.<sup>380</sup> These parties

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379. See Food Safety Law, *supra* note 68, arts. 2-3.

380. See *infra* app. A.

must also work jointly to build a level of trust and respect that will overarch all efforts to enhance the safety of the food supply chain.

#### CONCLUSION

All of the various stakeholders in the global food chain must work together for an effective, safe system: host and home country governments, suppliers and producers, consumers and their advocates, and global organizations. To the extent that there is legal liability in the United States for the sale of contaminated products, the heaviest burden of responsibility “tolls” for those companies selling tainted food and drugs. As such, they must take affirmative steps to establish and enforce standards, including routine testing and inspection of products. Merely policing, however, is not enough. Ultimately, U.S. companies doing business in China must work to establish long-term relationships with the common goal of food safety.

APPENDIX A

