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If I Eat This Will it Kill Me? An Analysis of China's New Food Safety Law and Other Protections to Regulate Food Produced in China

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Reports about defective and dangerous food and drugs manufactured in China are a regular occurrence. The growing complexity these supply chains present legal liability and risks to the suppliers, manufacturers, retailers and, ultimately, to consumers. Part I of this paper 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 on 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 and Part VI reviews ethical considerations. Lastly, Part VII makes specific recommendations for best practices and risk management techniques.
“From the production line to the dining table . . .”

INTRODUCTION

The ‘flattening’ 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. For the 21st century, China has already emerged as that country from which U.S. suppliers can source not only cheap foods, but cheaper drugs. Not surprisingly, 80% of the fish U.S. consumers eat is imported from China. Heparin and numerous antibiotics among other drugs are manufactured in China. And, unfortunately, China has become as well known as a source of cheap food and drugs as


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 (2002) that analyzes globalization in the early part of the 21st 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.

3 U.S. outsourcing has increased approximately 75% 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).


6 In the spring of 2008, Chinese manufacturers substituted a cheaper fake ingredient for the proper one in manufacturing the drug heparin for export to the United States. Heparin is a drug administered to dialysis and surgery patients. The FDA discovered the fraud, but not until 81 people were stricken and tens of thousands were exposed to the tainted product. Id. at 2. See also, Covington & Burling, E-news Alert (“Covington & Burling”) at 2, http://www.cov.com (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 during period 2002-2007, FDA inspected only 80 of these establishments).
for the headlines it grabs for tainted food and drug products. A few recent examples include pet foods and milk products tainted with melamine, added to make the product satisfy the minimum requirements for protein. Other products recently in the news include: contaminated eggs, dumplings, pet food, toothpaste, antibiotics, and an array of toys.

Although the U.S. government has multiple agencies that oversee the safety of food and drugs, and numerous inspectors who are, for example, required to inspect each cow for slaughter within the confines of the U.S., the inspection of foods sourced from other countries has become an increasing and worrisome challenge. Not only is the U.S. government concerned with the quality of food and drug imports from abroad, but corporations who subcontract with suppliers from China for food and drug manufacturing also have concerns on a number of fronts. First, is the concern over importation of tainted foods and the ensuing harm to consumers; second, is the consequential harm to the U.S.

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7 *The Safety Gap*, supra note 4.
9 Becker, supra note 5, at 13.
13 GEOFFREY S. BECKER, CONGRESSIONAL RESEARCH SERV., CRS REPORT FOR CONGRESS RS22664, U.S. FOOD AND AGRICULTURAL IMPORTS: SAFEGUARDS AND SELECTED ISSUES, at Summary 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.…”).
company’s reputation; and third is the real risk of being sued for defects in these products under U.S. product liability laws.

A close analysis of the issues suggests that multiple players in the global transactions over food and drugs must take measures to oversee the exporting of safe food and drug products as well as their import. The stakeholders involved in the transactions are multitudinous: the host country government, the home country government, the host country suppliers, the home country producers, consumer advocates, and finally, the global organizations whose standards have been adopted universally.\textsuperscript{14} It is therefore a multi-responsibility to oversee the safe transport of goods from one part of the globe to another. And while regulations and inspections help in protecting these goods to a great extent, there has to fundamentally be integrity in the marketplace in order 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 various stakeholder perspectives identified. Part I of this paper 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, which became effective on June 1, 2009. Part III details the U.S.

\textsuperscript{14} The Codex Alimentarius Commission (“Codex Commission”) is by de facto the global legislative organization that creates guidelines on food hygiene and food safety. See generally James Chyau, \textit{Casting A Global Safety Net: A Framework for the Safety in the Age of Globalization}, 64 \textit{FOOD \\& DRUG L.J.} 313, 320 (2009) (proposing a new international agency with a global framework for food safety). The universal food safety standards that it has adopted for standardized global application is the Hazard Analysis Critical Control Points (“HACCP”) system. See, \url{http://ag.arizona.edu/maricopa/fcs/haccp/index.htm} for a full discussion of HACCP. See the diagram in Appendix.
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 selected corporate responses and Part VI reviews ethical considerations. Lastly, Part VII makes specific recommendations for best practices and risk management techniques to ensure that the food and drugs manufactured in China are safe. The goal of this article is to analyze current host/home country practices, as well as those adopted by home country corporations to identify gaps and recommend regulations and policies that will enhance the safety in the supply chain of food and drug imports 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.15 Food imported from China has increased three-fold in the last decade totaling more than $4.2 billion in 2008.16 Authorities in China investigated 76,500 cases of fake food in 2008.17 Significantly, the major cause of China’s food safety problem is “illicit substances.”18 This was particularly evident in the case of both the contamination of milk and heparin in China.

The case of melamine-contaminated milk involved Sanlu Group (“Sanlu”), one of China’s four largest dairy companies.19 Sanlu operated as a joint venture with Fonterra,

16 *Id.*
18 *Id.*
a New Zealand conglomerate. Recognized as a significant regional brand, Sanlu faced a significant challenge to their market share by competitor companies Mangniu and Yili. Low-level suppliers apparently added melamine to milk after buying the milk from local farmers. The adulterated milk was then resold to large companies, including Sanlu. Twenty-two companies sold contaminated milk, which was supplied by a chain of producers and middlemen. Melamine was added to products to artificially inflate protein levels. 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.

At last six children were killed as a result of the contamination and nearly 300,000 others were sickened in China. The reverberations of the tainted milk also were felt around the world. In the United States, for example, Chinese products containing milk or milk powders -- 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. Similarly, Cadbury recalled eleven confectionary products containing milk powder manufactured at its Beijing facility and M&Ms, Snickers bars and Oreo biscuits made in

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Melamine is an industrial chemical that can be found in cleaning supplies, plastics and fertilizer. It is considered to be a contaminant in food, which can block filtering systems in the body and can lead to kidney stones, kidney disease, kidney failure and death.

20 Id.
China were also recalled. The scare also prompted the European Union to ban all products containing even traces of Chinese milk.

Ultimately, 21 people were accused of intentionally tainting China’s dairy supply. Criminal charges against them include endangering public security by dangerous means, and manufacturing and selling toxic food. The former chairwoman of Sanlu pleaded guilty to selling adulterated baby formula and was sentenced to life in prison and two suppliers were condemned to death. The court in China upheld the convictions and sentences, dismissing appeals, and following through with the execution of two milk producers in November, 2009. The government also fired local officials who may have covered up the adulteration of milk products. Also, in October 2008, the Chinese Health Ministry announcement by of new limits on melamine in infant formulas, liquid milk, milk powder and food products.

Similarly, contaminated heparin was found in drug supplies in 10 countries around the world, including Australia, Canada, China, France, and the United States.

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28 “Chinese Milk,” supra note 22.


31 Barboza, China Begins supra note 24.

32 Edward Wong, China Announces Stricter Testing Because of Milk Scandal, N.Y. TIMES (Oct. 9, 2008), [link].

Dr. Janet Woodcock, director of the Food and Drug Administration (F.D.A.) center, testified before Congress that the F.D.A. believes that the contamination of heparin was intentional.\(^{34}\) The scandal began in January 2008, after the F.D.A. learned about an increasing number of severe adverse reactions to heparin, a widely used blood thinner.\(^{35}\) Between January 1, 2007 and May 31, 2008, the F.D.A. received reports of 246 deaths in patients receiving heparin.\(^{36}\) Researchers at the F.D.A. identified “oversulfated chondroitin sulfate” as the contaminant.\(^{37}\) Oversulfated chondroitin sulfate apparently mimics the characteristics of heparin, yet can cause deadly reactions.\(^{38}\) The active ingredient in heparin is manufactured using raw material from pig intestines which is transformed into a dry substance.\(^{39}\) Because the raw material is gathered from thousands of homes and tiny factories in China, the supply chain to chemical companies is very complex\(^{40}\) and difficult to monitor. There is also an issue of cost; the contaminant used is vastly cheaper – a Congressional investigator reported that oversulfated chondroitin sulfate costs $9 a pound, as compared to $900 pound for heparin.\(^{41}\)


\(^{35}\) Id.


\(^{37}\) 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.*


\(^{39}\) Id.

\(^{40}\) Id.

\(^{41}\) Harris, *Heparin Contamination*, supra note 34.
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. Changzhou sold the heparin to SPL who, in turn, sold the heparin to Baxter Healthcare Corp. (“Baxter”), the largest U.S. producer of heparin. Baxter purchased heparin from Changzhou beginning in 2004, yet it did not inspect the plant until September 2007. Problems were also not uncovered by the F.D.A., which mistakenly failed to inspect the Changzhou plant; officials, however, claimed that an inspection would not have uncovered the contamination. Millions of vials of heparin are sold in the United States and approximately half of those doses are manufactured and sold by Baxter. Baxter now faces at least 40 product liability lawsuits in a well-organized effort in the United States.

Although it is unclear what the motives are for the contamination, it appears to be related to pressure felt by Chinese companies to cut costs by using inferior quality raw materials. Whatever the reason, firms importing the products and selling them in the U.S. face significant legal liability and must come to terms with ways of ensuring that the products they are selling are within acceptable standards.

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42 Id.
43 Id.
44 Id.
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. Pursuant to this plan, steps will be taken to improve monitoring and law enforcement systems related to food and drug production. China also announced that it would invest more than $1 billion to improve its infrastructure charged with monitoring and inspecting food and drugs. Also in 2007, China published a White Paper on Food Quality and Safety, describing the government’s efforts to improve food safety.

The law addressing drug safety, the Drug Administration Law (“Drug Administration Law”), went into effect on December 1, 2001, and the Regulations for Implementation of Drug Safety Law went into effect the following September. Although the Drug Administration Law contains broad provisions regulating the quality of drugs and their safety for human beings, as well as legal liability for producing counterfeit or substandard drugs, effective enforcement is an ongoing issue. This was

50 Id.
56 Id. at Arts. 73-101.
particularly noticeable after the head of China’s State Food and Drug Administration was
convicted and executed in 2007 for accepting bribes and dereliction of duty.\textsuperscript{58} 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, to enhance quality control of drugs.\textsuperscript{59}

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) on February 28, 2009, a comprehensive effort to oversee food safety.\textsuperscript{60} Shortly thereafter, on April 24\textsuperscript{th}, the State Council published the first draft of implementation measures for the FSL.\textsuperscript{61} The FSL became effective on June 1, 2009.\textsuperscript{62} Then, following a period of public comment, the Final Food Safety Law Implementation Measures (“the Rules”) went into effect on July 20, 2009.\textsuperscript{63} Major features of the new law include requiring monitoring and supervision; increasing regulatory standards; establishing recall and notification systems; providing increased consumer rights; and creating liability for offenders. Each of these features is discussed in detail below.

\textbf{A. Requiring Monitoring and Supervision}


\textsuperscript{58} \textit{China Food Safety Head Executed}, BBC News (July 10, 2007), \url{http://news.bbc.co.uk/2/hi/6286698.stm}.


\textsuperscript{60} FSL, \textit{supra} note 1.

\textsuperscript{61} USDA FOREIGN AGRICULTURAL SERVICE, GAIN REP. NO. 9040, \textit{FOOD SAFETY LAW IMPLEMENTATION MEASURES} (May 4, 2009), \url{http://www.fas.usda.gov/gainfiles/200905/146347786.pdf}.

\textsuperscript{62} FSL, \textit{supra} note 1.

As a threshold question is 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. Overall, the Ministry of Health (“MOH”) plays a predominante role; the Rules state that it shall work in conjunction with the Administration 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. This is a very ambitious goal and, what seems on its face, to be unwieldy to implement. All of the various local and regional authorities are required to report to the MOH who, in turn, is responsible to communicate information to departments under the State Council.

The MOH’s role is further specified in the Rules. For example, the MOH is responsible to summarize and analyze data gathered in food safety risk surveillance, and to make adjustments to the national food safety risk surveillance program. The MOH is also charged with the important responsibility of organizing the National Food Safety Standard Review Committee, which has the broad responsibility of reviewing and approving national food safety standards. The amount of discretion the MOH has is

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64 See generally USDA FOREIGN AGRICULTURAL SERVICE, GAIN REP. NO. CH9018, CHINA’S NEW FOOD SAFETY LAW: EVOLUTION OVER REVOLUTION (2009), http://www.usdachina.org/info_details1.asp?id=2431 (“While many of the ultimate responsibilities are not clear and fine tuning will continue, the big winner appears to be the Ministry of Health”).
65 The Rules, supra note 63, at Art. 5; FSL, supra note 1, at Arts. 76-83.
66 The Rules, supra note 63, at Art. 6.
67 Id. at Art. 11.
68 Id. at Art. 7.
69 Id. at Art. 17.
70 FSL, supra note 1, at Art. 23.
unclear. The FLS merely states that the committee should be composed of experts in medicine, agriculture, food, and nutrition, as well as representatives from “relevant” departments under the State Council.\(^7^1\) In December, 2009, a 42-person panel was established, consisting of experts in hygiene, agriculture, food and nutrition.\(^7^2\)

The way in which the MOH should interface with other groups charged with responsibilities under the FSL is unclear. The State Council is required to establish a Food Safety Committee and the Executive Department of Health (“Executive Department”) under the State Council 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 is response to major food safety accidents,”\(^7^3\) but no details are supplied about the membership of this committee and how it will coordinate with the MOH. Moreover, it is unclear is this is a completely distinct committee from the one to be established by the MOH.\(^7^4\) Moreover, the FSL calls for the establishment of a national surveillance system,\(^7^5\) which appears to be under the Executive Department, but it is not clear if the MOH has responsibility over this entity or the State Council.

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

\(^7^1\) Id.
\(^7^3\) FSL, supra note 1, at Art. 4.
\(^7^4\) Id. at Arts. 4 and 23 (referring to food safety committees, but it is unclear if they are same entity).
\(^7^5\) Id. at Art. 11.
food additives,” and gives oversight responsibility to the Executive Department.76 Similarly, the Executive Department must “consolidate mandatory standards among existing quality and safety standards.” 77 The Executive Department of Health and Agriculture under the State Council has responsibility for pesticides, veterinary residue and slaughtering livestock and poultry.78 It is not clear what responsibility the MOH has, even though these responsibilities seem to be overlapping with its responsibilities.

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 jurisdiction.79 In the absence of a national standard, the local authorities may develop local food safety standards.80 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 might decrease profits for local food producers and traders. The FSL also calls on food industry associations to “tighten the self-discipline of the industry”81 and “encourages” manufacturers to develop “standards more stringent than national or local food safety standards.”82 Interestingly, any such standards are “only applicable to the enterprise” developing the standard and are to be reported to the provincial authorities.83 These provisions raise a number of questions, including: the effect of the reporting requirement; the kind of liability could result if a company’s own reported standards are not met;

76 Id. at Art. 13.
77 Id. at Art. 22.
78 Id. at Art. 12.
79 Id. at Art. 5.
80 Id. at Art. 24.
81 Id. at Art. 7.
82 Id. at Art. 25.
83 Id.
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 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.”

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.” The law is comprehensive in its scope, applying to food producers, who are involved with food production and processing, as well as food traders, who are involved with food distribution and catering service, operating in China. 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.” Under the FSL “food” then encompasses food additives, and food-related products, and 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.” This is important as food contamination can take place at many stages before it actually reaches consumers.

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

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85 FSL, supra note 1, at Art. 1.
86 *Id.* at Arts. 2 and 3.
87 *Id.* at Art. 99.
88 *Id.* at 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, cope 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.  

The some of the details of how each of these categories shall be regulated are included in the law. First, for example, there are specific provisions regarding the safe handling of food and storage of food, detailing safe storage of food and handling of food. 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. The FSL also requires food producers and traders to establish and implement an “employee health management system,” to ensure that any employee with an “infectious disease of the digestive tract” or “purulent or weeping skin diseases” is not in direct contact with food for consumers. 

Second, the FSL also contains provisions addressing material that should not be included in food and regulating additives. The FSL expressly prohibits production and trading of food, which is made with “non-food raw material,” food with substances of possible hazard to human health that exceeds food safety standard limits (such as

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89 Id. at Art. 20.
90 Id. at Arts. 27, 40 and 41.
91 Id. at Art. 27(1)-(6).
92 Id. at Art. 34.
pathogenic microorganisms, pesticide residue, veterinary drug residue and heavy metals), and food that is “rotten or spoiled, has rancid fat contains mold or insect, is dirty or contaminated, contains foreign matters, has been adulterated, or displays abnormal sensory indication.” Although it is unclear how the system will work in practice, the FSL requires that the state adopt a licensing system for the production of food additives. 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. It is unclear what standards will be used to determine if these new foods and additives are “proven to be safe and reliable.” The FSL also makes specific reference to medicine, stating that it shall not be added to any food “unless that added substance is traditionally considered as both food and Chinese medicine.” This provision also raises many questions, including how “medicine” is defined and whether vitamins and minerals are considered to be “medicine.” The Executive Department is charged with the responsibility to develop and publish a catalogue of such substances, yet no timeframe is mandated for that endeavor to be completed.

The FSL also 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.” There is no definition for these terms. Neither is there any evaluative mechanism for testing compliance. The FSL also

93 Id. at Art. 28(1)-4.
94 Id. at Art. 43.
95 Id. at Art. 44.
96 Id. at Art. 45.
97 Id. at Art. 50.
98 Id.
99 Id. at Art. 29.
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.” On one hand, the FSL appears to mandate compliance by small food workshops, yet on the other, it seems to set aspirational goals for improved conditions. More detail and clear 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.” At the end of 2008, approximately 70 percent of China’s 500,000 food-processing firms were small-scale with less than 10 employees. Tighter standards for such processors seem essential to ensure compliance with the FSL.

The FSL requires all pre-packaged food to be labeled with basic information, including: name, date of production, table of ingredients, producer’s name and contact information, and shelf life. 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. The required records include production records, verification records and inspection records. Here, too, there are many questions unanswered, such as who will have access to the records; whether consumers will have access; if they will be subject to regular government review; and

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100 Id. at Art. 30.
102 FSL, *supra* note 1, at Art. 42.
103 Id. at Arts. 35-39.
how long shall the records 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. 104 The incident should then be reported immediately to the Executive Department. 105 After receiving a report of any possible food safety risk, the Executive Department must “immediately organize inspection and food safety risk assessment.” 106 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.” 107 The Rules also provide that the departments involved in the investigation “shall have the right to inquire about the incident from the relevant entities and individuals,” including obtaining documents and samples. 108 Importantly, the scope of the investigation encompasses making a determination if there was “any negligence or misconduct by regulatory agencies.” 109 The results of the food safety risk assessment are, in turn, to be used to be the “scientific basis for developing and modifying food safety standards” and regulating food safety. 110

104 The Rules, supra note 63, at Art. 43.
105 FSL, supra note 1, at Art. 12.
106 Id. at Art. 14.
107 The Rules, supra note 63, at Art. 44.
108 Id. at Art. 45.
109 FSL, supra note 1, at Art. 75.
110 Id. at Art. 16.
The FSL also provides that a food recall system shall be established in China.\textsuperscript{111} If a food producer discovers that the food produced in not in compliance with food safety standards, it is charged with the responsibility to: 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.\textsuperscript{112} Likewise, food traders have similar requirements to recall, notify and create records.\textsuperscript{113} What is not clear, however, is what is actually required of the food producers and traders in terms of recalling and notifying. For example, it is unclear what kind of notice is sufficient. There are many avenues to communicate, e.g. oral, newspapers, radio, television, Internet, mail, etc. The effectiveness of the actual form of the recall would depend on the market, location and scope of the distribution.

In addition to requirement for food producers and traders, the State Council is responsible to formulate emergency plans for national food safety incidents.\textsuperscript{114} Although the Food Safety Law 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. Governments at the county level or higher are required to formulate emergency plans to handle incidents in their jurisdiction; however, no timetable is set for the completion of the plans and submission to a higher level of government.\textsuperscript{115} 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 effective, the law needs some mechanism to require

\textsuperscript{111} Id. at Art. 53.
\textsuperscript{112} Id.
\textsuperscript{113} Id.
\textsuperscript{114} Id. at Arts. 70-75.
\textsuperscript{115} Id. at Art. 70.
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.”\textsuperscript{116}

\textbf{D. Providing Increased Consumer Rights}

Consumer rights figure predominately into the FSL, which encourages social and
community groups to conduct educational activities.\textsuperscript{117} 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.\textsuperscript{118}
Consumers and organizations also are expressly given the “right to report any act during
food production and trade” that violates the FSL.\textsuperscript{119} 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.”\textsuperscript{120}

By virtue of the fact that the media is required to publicize food safety laws,
regulations and standards, as well as provide “public oversight” on acts by producers and
traders violating the law,\textsuperscript{121} the Food Safety law seems to encourage greater transparency
and consumer awareness. The Executive Department is also responsible for “developing
and publicizing national food safety standards,”\textsuperscript{122} which is also designed to make more
information available to consumers. The standards are to be “accessible by the public for
free.”\textsuperscript{123} Lastly, another consumer-friendly aspect of the Food Safety Law is the
requirement that “food advertisements shall provide truthful information, shall not

\textsuperscript{116} Id.
\textsuperscript{117} Id. at Art. 8.
\textsuperscript{118} Id.
\textsuperscript{119} Id. at Art. 10.
\textsuperscript{120} Id.
\textsuperscript{121} Id. at Art. 8.
\textsuperscript{122} Id. at Art. 21.
\textsuperscript{123} Id. at Art. 26.
include any false or exaggerated information and shall not claim any disease prevention or treatment functions.”  

E. Creating Liability for Offenders

Lastly, Chapter 9 of the FSL sets forth the legal liabilities for food producers and traders who violate the law.  

The law provides for civil penalties, damages for consumers and criminal prosecution for offenders. 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 of RMB 2,000-50,000 will be imposed or, if the total value of the commodity exceeds RMB 10,000, a fine between five and 10 times the total value of the commodity can be imposed.  

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 the shelf life.  

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 in accordance with the Advertising Law of the People’s Republic.  

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.  

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124 Id. at Art. 54  
125 Id. at Arts. 84-98; see also The Rules, supra note 63, at Arts. 55-61.  
126 FSL, supra note 1, at Arts. 84 & 85. Conversion note: RMB 10,000 = approx. $460; RMB 50,000 = approx. $7,300; RMB 2,000 = approx. $292.  
127 Id. at Art. 85.  
128 Id. at Art. 94.  
130 FSL, supra note 1, at Art. 55.
of the law encompasses endorsements by celebrities.\textsuperscript{131} 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.”\textsuperscript{132} 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, dismissal from office, criminal prosecution, and prohibitions on working in food inspection for ten years.\textsuperscript{133}

The FSL also provides remedies for consumers. Individuals and entities violating the FSL, thereby causing personal or property damage, are liable to pay compensation.\textsuperscript{134} The law states that manufacturers producing non-conforming food and selling food “knowing its nonconformity with the food safety standards” can be held liable to customers.\textsuperscript{135} Under such circumstances, customers can demand damages from the manufacturer or seller in an amount of ten times the amount paid, in addition to compensation for loss.\textsuperscript{136} This provision makes some inroads for consumers who are injured, although the amount of damages may not be very substantial. In the case of the 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. Despite that fact, at least some progress is being made to provide consumers with remedies for their loss.

\textsuperscript{132} FSL, supra note 1, at Art. 71.
\textsuperscript{133} \textit{Id.} at Art. 93.
\textsuperscript{134} \textit{Id.} at Art. 96.
\textsuperscript{135} \textit{Id.}
\textsuperscript{136} \textit{Id.}
In addition to fines and damages, the FSL provides that “anyone” in violation of the law shall “be subject to criminal prosecution.” 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.

III. U.S. LEGAL AND REGULATORY FRAMEWORK

A first step to enhance the safety of food and feed imports from China (and conversely, from the United States to China) was taken in 2007, when the Department of Health and Human Services entered into two Memoranda of Agreement with the Chinese government. In 2008, the U.S. imported $5.2 billion worth of foods from China thereby making China the third largest source of U.S. food imports. Surprisingly, and despite these numbers, China provides less than 1% of the U.S. food supply. However, China is a major supplier for certain types of food imports such as apple juice (60%),

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137 Id. at Art. 97.
139 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.
141 Id.
garlic (50%), shrimp (10%) and catfish (2%). The year 2007 saw the first large spike in refusal of entry to Chinese goods and preceded negative publicity over a number of incidents including the refusal of wheat gluten and rice protein due to the discovery of melamine therein; and refusal of several kinds of fish due to their high levels of toxic veterinary drug residues. Further negative publicity surrounded the discovery of the contamination of dog and cat food with melamine from Chinese imports and the subsequent sickening and death of thousands of American household pets. Even more publicity surrounded human food contamination and adulteration in Chinese food imports in 2008-2009, when it was discovered that numerous milk products and milk had been adulterated yet again with melamine. Consumption of the adulterated products in China itself caused the death of seven infants, and approximately 300,000 children fell ill with kidney problems after imbibing infant formula tainted with melamine. This additive is an industrial chemical added to milk to raise its apparent protein content thereby allowing farmers and middlemen the opportunity to fraudulently dilute the milk

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142 Id. These figures represent percentages of the total supply of the items supplied to consumers in the U.S. for the year 2007.
143 Pursuant to Section 801 of the Federal Food, Drug and Cosmetic Act (FFDCA), as amended (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).
145 See, Becker supra note 5, at 11.
146 Id. at 12; See also, Chyau, supra note 144; Aleda Roth, et al., Unraveling The Food Supply Chain: Strategic Insights From China and the 2007 Recalls, 44 J. OF SUP. CH. MGMT. 22 (2008).
148 Friedman, supra note 2, at 12-13.
product with water. At the time, China was exporting dairy proteins and other products used in infant formula to the United States.\(^{149}\)

At the same time, the FDA had become aware of a spike in heparin related deaths that was linked to imports of the drug from Chinese manufacturers.\(^{150}\) This blood thinner, used by millions of patients undergoing dialysis and surgery to prevent clots, was possibly linked to 161 deaths of Americans during the period November, 2007 to May, 2008.\(^{151}\) The U.S. federal government was now beginning to realize the magnitude of the consequences of trading with China without having the ability to effectively monitor the processing of food substances manufactured there for import to the U.S. market, nor the ability to successfully screen products at the port of entry. It was with these examples in mind that the government set about to tighten both controls and inspection at the port of entry, and the ability to inspect these imports prior to their leaving China.

While effective U.S. and Chinese regulations relative to the processing of food products for import are critical, in the U.S., 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.\(^{152}\) However, when the ultimate party

\(^{149}\) The Associated Press (AP) 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 FDA, *Update: Interim Safety and Risk Assessment of Melamine* (2008) http://www.fda.gov/Food/FoodSafety/FoodContaminantsAdulteration/ChemicalContaminants/Melamine/ucm164520.htm (accessed January 20, 2010).


\(^{152}\) *RESTATEMENT (SECOND) OF TORTS*, section 402A (1965) provides in pertinent part:

1. One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to
responsible, as in these cases, is a supplier overseas, the consumer’s ability to recover against such a party is virtually nil. Nevertheless, in the wake of the Heparin recalls, more than 40 product liability lawsuits have been filed in both federal and state courts on behalf of patients who were allegedly injured by or died from the tainted Heparin imported from China. All these lawsuits however name the U.S. pharmaceutical company manufacturer, Baxter Corporation, as the defendant, not the Chinese supplier. Although, under U.S. product liability law, the supplier could easily be joined in the lawsuit as indeed the party liable, challenging issues arise due to the fact that the supplier in this case is overseas and outside the jurisdiction of the U.S. courts. That fact raises the traditional legal issues of *in personam* jurisdiction over the defendant, *forum non conveniens*, and uncertainty as to the application of U.S. product liability law over foreign defendants. Compounding the difficulties of the plaintiffs’ case is also the issue 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. The difficulties in bringing civil lawsuits against the Chinese

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liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
(a) the seller is engaged in the business of selling such a product, and
(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although
(a) the seller has exercised all possible care in the preparation and sale of his product, and b) the user or consumer has not bought the product from or entered into any contractual relationship with the seller.

155 Id. at 111.
supplier and in applying punitive damages against such defendants to deter tampering in 
the future makes it all the more important that the U.S. government, that of China, and 
the other stakeholders involved collectively do all that they can do 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”). 156 

A. The U.S.-Chinese Bilateral Agreement 

A first step to enhance the safety of food and feed imports from China (and conversely, 
from the United States to China) was taken in 2007, when the Department of Health and 
Human Services entered into a Memorandum of Agreement with the Chinese 
government. 157 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. 158 In June, of the same year, the FDA commenced detaining farm-raised seafood 
imported from China over concern of unsafe drug levels in the fish. In September of that 
year, a survey of 1000 U.S. consumers by Reuters/Zogby 159 revealed that 25% of them 
had ceased to purchase food imported from China due to concerns over its safety. The 
next month, Congress held hearings on the findings of a congressional mission to China 

156 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 (2007) 
157 Id. While two agreements were entered into, this article will focus on the one that addresses 
food and food additives. 
159 Report of the Reuters/Zogby 2007 Survey can be found at: 
http://www.euromonitor.com/Global_consumers_are_edgy_about_the_Made_in_China_brand.
to examine food safety issues. And finally, November of that year saw the publication of reports from President Bush’s Interagency Working Group on the issues of import safety and the role of the FDA. Clearly food safety of imports to China had become a national priority.

And the issue of food safety was no less an important concern 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. 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 to address the concerns raised by the pet food scandal and other food contamination issues mentioned above. An immediate step announced by the Chinese in July of 2007 was to shut 152,000 unlicensed food producers and retailers and to revise a large number of food safety standards. Such measures were followed in August of 2007 by the publication of a “White Paper on Food Quality and Safety” describing the nature of its domestic and export food safety programs. The culmination of concerns of both countries was the execution of the

162 WAYNE MORRISON, CONGRESSIONAL RESEARCH SERV., CRS REP. FOR CONG. NO. (INSERT), CHINA-U.S. TRADE ISSUE, at 7-8 (March 7, 2008), available at [website].
bilateral agreement to help ensure the safety of the supply china form China to the United States.\textsuperscript{165}

The bi-lateral agreement states that the two countries intend to “establish a bilateral cooperative mechanism that “may include current and future registration and certification systems. The mechanism aims to provide the parties with information to use judging whether an imported product meets the requirements of the importing country.”\textsuperscript{166} The bi-lateral 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”) and The State Food and Drug Administration (“SFDA”). The former has general responsibility for product quality and safety, including food; the latter for human pharmaceuticals and medical devices. Pursuant to this agreement, the Chinese Government agrees to require Chinese exporters to submit to annual inspections by such organizations to assure that their goods meet U.S. food safety standards.\textsuperscript{167} The agreement further requires that the AQSIQ give the names of all exporters who fail inspection, the reasons why, and the names of those companies who have lost their registration status.\textsuperscript{168} The agreement further requires the AQSIQ to develop a tracing system that tracks products from the point of production to the point of exportation, and to create a statistically valid testing program for such exports.\textsuperscript{169}

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

\textsuperscript{165} Imports From China, supra, note 140.
\textsuperscript{166} Id. at 1.
\textsuperscript{167} Id. at 3.
\textsuperscript{168} Id.
\textsuperscript{169} Id.
related to food or to feed.\textsuperscript{170} AQSIQ further agrees to facilitate access by the FDA to, and
inspection of, Chinese processing and cultivation sites.\textsuperscript{171} Pursuant to the first phase in
the implementation of the bilateral agreement, the parties specify that export certificates
issued by AQSIQ are to be required for all exporters of products with current high refusal
rates which are specified in the agreement as being: low acid caned products or acidified
foods; pet foods/pet treats of plant origin or animal origin; ingredients of food and fee
such as wheat gluten and rice protein; and all aquaculture farming products except for
mollusk shellfish.\textsuperscript{172} The Annex to the agreement provides that other items of food may
be added to this list during later phases.\textsuperscript{173} The bi-lateral agreement is to be reviewed
every twelve months at which time a new Work Plan for the coming year will be
established, and parties on both sides are to meet once a year to discuss implementation
of and review progress under the agreement.\textsuperscript{174}

As an outgrowth of this agreement, the FDA opened, in late 2008, three offices in
China: one in Beijing, one in Guangzhou, and a third in Shanghai.\textsuperscript{175} These are the first
FDA offices to open outside the United States. The Beijing office will act as a liaison
between the FDA and the Chinese regulatory agencies while the offices in the other two

\textsuperscript{170} \textit{Id.} at 3: “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.”

\textsuperscript{171} \textit{Id.}

\textsuperscript{172} \textit{Id.} at 7.

\textsuperscript{173} \textit{Id.}

\textsuperscript{174} \textit{Id.} at 11.

\textsuperscript{175} Covington and Burling, Food & Drug E-Alert, \textit{FDA Opens Offices in China: More Inspections
Likley} (Dec. 15, 2009), http://www.cov.com/files/Publication/48698171-ab95-475a-a851-
09434d0cd1b5/Presentation/PublicationAttachment/1d5f8968-83a5-4047-a5cb-
0b4d747522fe/FDA%20Opens%20Offices%20in%20China%20-
%20More%20Inspections%20Likely.pdf.
cities will conduct inspections and train Chinese inspectors. Further, these offices will advise Chinese government agencies and Chinese companies on U.S. quality standards. 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.”

As far as the effectiveness of the agreement, 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 12-month plan. 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 to aquaculture (five species plus tilapia) and ingredients (wheat gluten, corn gluten ad rice protein.)

A number of stakeholders have expressed doubt as to whether the Chinese will meet their obligations under the MOU due to the fact that the Chinese government has not be able or willing to enforce the strict food laws that it has currently in place. The Consumers Union expressed two concerns in particular: that the agreement neglected to include certain food items that have questionable safety records, such as apple juice; and that the MOU did not give FDA inspectors immediate access to Chinese plants in the face of a crisis. Further, there has been speculation that the agreement may grant

\[176\] Id.  
\[177\] Id.  
\[179\] More than 60% of U.S. apple juice comes from Chinese exports. See, Imports From China, supra note 140.
preferential status to Chinese importers over others. Concerns expressed by others question whether the FDA will have adequate resources for oversight and enforcement of the agreement, and even whether the FDA has the legal authority to share the information specified in the MOU concerning U.S. food companies, or further, has the authority to demand certificates from foreign importers.

B. The Food and Drug Administration

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

The responsibilities of the FDA relative to food safety include: responsibility for risk assessment from farm to table for FDA inspected products; for the inspection of all foods with the exception of meat, poultry and eggs; implementation and oversight of the

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180 See, e.g., U.S.-China Food Safety Deal Could Give China Preferential Treatment, FDA WEEK (December 21, 2007).
181 Id.
184 Id.
186 Id.
U.S. nutrition labeling law as it applies to FDA inspected products. Further, the Center for Disease control (CDC) is under the auspices of the FDA and is responsible for responses to food-born illness outbreaks. And finally, the FDA is responsible for the administration of the Pure Food Drug Act of 1906 that requires that the FDA find and remove adulterated and misbranded food from the marketplace. This Act, along with the Federal Meat Inspection Act of 1907 (formerly the Wholesome Meat Act which required that all meat products sold in the U.S. be produced under sanitary conditions, not adulterated and properly labeled), were the very first laws enacted by the federal government to establish a nationwide food safety system.

Traditionally, the FDA worked to ensure that food generated within the United States met certain safety standards. Increasingly however, the FDA has a more challenging responsibility of ensuring that imported foods, including those from China, meet U.S. standards. Although U.S. standards are among the highest in the world, the FDA’s abilities are taxed heavily when it comes to the issue of inspecting the rapidly growing number of food products coming from foreign countries, and in particular, from China.

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187 Id.
191 Interestingly, on an historical note, it has been noted that the latter law was enacted in response to Sinclair Lewis’ book, The Jungle (1906), which described appalling conditions in the meat markets of the United States.
193 Id.; See also, Chyau, supra note 189 at 315.
China. The means by which the FDA can enforce its watchdog responsibility is through inspections of which it has the capacity to do very few.\footnote{Chyau, supra note 189 at 317.} 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.\footnote{21 C.F.R. § 7.45 (2006); See also, Levick & Grabowski, Contaminant At The Gate: Crisis Communications in the Age of China Recalls, 7-3 MALEY’S PROD. LIAB. & RISK at 3 (2007).} Instead, it must rely on companies’ compliance with FDA requests that tainted foods be removed from the market.

Pursuant to section 801 of 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.\footnote{21 U.S.C. § 381(a) (2008).} The agency’s response depends on the system of prior notification by importers and on document examination at ports of entry.\footnote{Becker, supra note 5, at 4.} On occasion, the FDA detains an import without physical examination if there is information available suggesting that the product is in violation of the FFDCA.\footnote{21 U.S.C. § 381(a) (2008). 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. \textit{Id.} (emphasis added.)} 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 melamine.\footnote{Becker, supra note 5.} Also detained from entry from China that year were all shipments of farm-raised seafood until the shippers were able to demonstrate that the seafood contained no unapproved drug residues.\footnote{\textit{Id.}} 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.\textsuperscript{201}

All foreign food and drug imports are required to meet the same safety standards
as domestically produced products, however, rules of international trade permit foreign
countries to apply their own, differing standards under an internationally recognized
concept known as “equivalence.”\textsuperscript{202} The ability of the FDA to inspect facilities of
importers overseas for contamination has traditionally been very limited, thereby making
the inspections at the port of entry critical. 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. While the FDA recorded approximately 2.8 million
food line imports in 1997, that number increased dramatically to 8.2 million in 2007.\textsuperscript{203}
Only approximately 1\% of these food lines were either physically examined or tested.\textsuperscript{204}

The FDA has visited foreign manufacturing operations for the purposes of
inspection, but has only done so sporadically with the permission of the foreign country
and only subsequent to the discovery of a contamination problem.\textsuperscript{205} With the volume of
FDA-regulated imports increasing steadily, and public concerns mounting after the
heparin drug concerns, the melamine and milk related scandals out of China, the FDA in
2008 took things into its own hands and created a “Beyond our Borders” initiative. One of
the primary mandates was to open three offices in China with future plans to open offices

\textsuperscript{201} Id.
\textsuperscript{202} 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”). For a more complete explanation, see,
GEOFFREY BECKER. CONGRESSIONAL RESEARCH SERVICE, CRS REPORT FOR CONGRESS NO.
RL33472, SANITARY AND PHYTOSANITARY (SPS) CONCERNS IN AGRICULTURAL TRADE, at 11
\textsuperscript{203} Id. at 6.
\textsuperscript{204} Id. at 6.
\textsuperscript{205} Id. at 5.
in India, Central America and the Middle East.\textsuperscript{206} 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 point of origin, giving the FDA an earlier and clearer opportunity to prevent tainted food and drugs from entering the U.S. where the ability to inspect is limited.\textsuperscript{207} A further and broader goal of the China offices is to create a new strategy embracing a new cooperation between the U.S. and Chinese governments to establish more uniform industry-wide standards.\textsuperscript{208} Congress, aware of the inability of the FDA to cope with the problems it was facing from the importation of food and drugs, drafted a number of bills to address the gaps identified in current legislation and the import problems that have arisen over the last several years.

\textbf{C. Proposed U.S. Legislation}

Currently pending before Congress is bill H.R. 875, the Food Safety Modernization Act, introduced by Representative Rosa Delauro. It was originally introduced in 2007, in the 109\textsuperscript{th} Congress. It calls for the most significant changes of the four bills under consideration, calling for the creation of a new administrative agency entitled \textquotedblleft Food Safety Administration.\textquotedblright\  This agency would cover food safety, but not have jurisdiction over the drug approval program, which is currently paired with food safety under the FDA. It would require that imported foods meet the same high safety standards of domestic food and not allow the continuation of the \textquoteleft equivalence\textquoteright substitutes. It would create a program to certify imported food that would ensure that

\begin{itemize}
\item \textsuperscript{206} \textit{FDA Initiates Overseas Inspection and collaboration Program in China}, MED. INDUS. BUS.WKLY. (May 29, 2008) available at \url{http://www.dotmed.com/news/story/5886}.
\item \textsuperscript{207} Becker, \textit{supra} note 202 at 6.
\item \textsuperscript{208} \textit{FDA Expects to Open China Offices in '08}, WALL ST. J. at A12 (June 18, 2008), available at \url{http://online.wsj.com/articles/SB121375629176383195.html?ap=1\&r=649610}.
\end{itemize}
foreign companies only imported foods that met U.S. laws. Its goals 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, among other purposes. It would require that food companies register annually and to implement prophylactic measures on their production lines to ensure the safety of their foods and to meet standards identified for the control of hazardous contaminants. 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 people are hurt or killed; assess new civil fines on food companies that violate the law, and detect unlawful conduct by protecting whistleblowers from retaliation. The bill has been referred to the following committees where it is currently being reviewed: the House Energy and Commerce committee, the House Agriculture committee, and subcommittee on livestock, dairy and poultry. There are no indications that this bill has been discussed in committee at this time.

Also in 2009, Representative John Dingell in the House introduced a competing bill, HR bill 2749, addressing similar issues: The “Food Safety Enhancement Act of 2009 whose purpose is to amend the Federal Food, Drug, and Cosmetic Act to improve the safety of food, drugs, devices, and cosmetics in the global market, among other goals. This bill has progressed further in the 111th Congress than any of the others, having


Id.


See [http://www.opencongress.org/bill/111-h759/actions_votes](http://www.opencongress.org/bill/111-h759/actions_votes) for a discussion of this bill which was referred to the House committee on Energy and Commerce on January 1, 2009.
passed the House. It is now being reviewed by Senate committee on Health, Education, Labor and Pensions. It has already been read twice on the floor of the Senate.

Representative Dingell’s bill does not go so far as to restructure the Department of Health and Human Services as does Representative DeLoares’ bill mentioned above. HR 2749 contains important provisions for strengthening the regulation of drugs, devices and cosmetics and for enhancing the regulation of food, in particular, imported foods.214

Following in brief is the summary of the bill as set forth by the Congressional Research Service.215 The Food Safety Enhancement Act of 2009, 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 reinspection 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

214 Id.
215 See http://www.govtrack.us/congress/bill.xpd?bill=h111-2749&tab=summary, for the full text of the bill and its progress through Congress.
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 Food and Drug Administration’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 which would ensure the inspection of all domestic and foreign food facilities channeling food into the U.S. once every four years. Pursuant to the bill, all imported food would have to be certified as meeting FDA guidelines 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 protection. Allowing the FDA to make recalls is an important extension over their current power and could lead to more immediate protection for consumers from tainted food products.

Two more related bills have been introduced in the 111th Congress, one other in the House HR 1332, and one in the Senate, S. 510. House Bill, HR 1332 (the Safe FEAST Act’), sponsored by Representative Jim Costa and S. 510 (FDA Food Safety Modernization Act), sponsored by Senator Richard Durbin, are virtually the same bill.

216 Id.
217 Id.
218 See http://www.govtrack.us/congress/bill.xpd?bill=h111-1332 for the full text of this bill, and information relative to its status. At this moment, it is under subcommittee review.
219 See http://www.govtrack.us/congress/bill.xpd?bill=s111-510 for the full text of this bill which has been referred to committee for review.
Both bills require that food companies themselves introduce food safety plans. Both require food companies to register with the Federal government every two years. Similarly in both bills, food companies would further be required to conduct hazard analysis 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,” then the FDA would be required to do an inspection every year; all other food processors would be inspected at least once every four years under both bills. The burden under both would be on the food importers themselves to ensure that their foreign suppliers complied with U.S. food safety laws. Further, the bills would give the FDA the option to require that high risk foods be certified as complying with U.S. food safety requirements. The FDA would accredit third party certifiers to audit foreign food companies for compliance. The FDA would further set standards for the safe production and importation of fresh fruits and produce. As with the previous bills that have been examined, these bills 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 four bills suggests that these four bills share, for the most part,\(^\text{220}\) six critical provisions in overhauling 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: traceback to origin of suspected

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\(^{220}\) Neither HR 1332 nor S510 focus on research and education; HR 1332 does not address whistleblower protection or penalties under enforcement authority, and S510 does not address whistleblower protection. See Center for Science in the Public Interest, Food Safety Legislation: Legislation in the 111th Congress (2009), http://www.cspinet.org/foodsafety/legislation.html.
foods; detention of tainted foods immediately upon inspection, stricter penalties, and whistleblower protection. Of these, all but two issues (research and education and on-farm inspection) directly affect trade with foreign nations, and in particular, with China. These four key provisions 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 which acts to prevent food safety issues from arising in the first place. Clearly, to be effective, government mandatory process controls along with specific performance standards must be a core focus of any new law created. While the FDA and USDA currently perform in-plant and border inspections, these are few and 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. CSPI has recognized what this article is recommending: that the stakeholder food processors themselves promote programs of quality assurance and preventive process control by adopting general standards developed by the individual industries. Such standards as the “Hazard Analysis and Critical Control Points” (HACCP) have already been developed and adopted globally by several industries and could serve such a purpose. 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

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221 CAROLINE SMITH DEWAAL & DAVID W. PLUNKETT, BUILDING A MODERN FOOD SAFETY SYSTEM (May 2009).

require FDA to implement HAACP or HACCP-like systems for all food processors and tie agency inspections to an audit of these systems.\textsuperscript{223} While each of the bills discussed refers to process controls and performance standards\textsuperscript{224} to some degree, none requires the precision suggested by CSPI. Using HAACP and performance – standard approaches would, according to CSPI, place emphasis of food safety on prevention rather than mere response to problems.\textsuperscript{225} Further, the CSPI suggests that such an approach would create a more efficient and effective government monitoring through the analysis of records and the inspection via laboratory and visual means.\textsuperscript{226}

2. Inspections and Food Import Controls

Currently, the FDA lacks minimum inspection mandates for the food companies that it regulates.\textsuperscript{227} Further, the FDA is not sufficiently funded that it can inspect in country food plants on average more than once every ten years.\textsuperscript{228} Prior to the new agreement with China that became effective June, 2009,\textsuperscript{229} there was no real opportunity to monitor food plants overseas. Consequences of these gaps has led recently 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 caused 9 deaths; the September 2008, recall of dairy products imported form China due to intentional melamine adulteration that sickened 300,000 infants in China and caused 7 deaths, and the recall in February and March of 2007, of over 100 brands of pet food,

\begin{footnotes}
\textsuperscript{223} Center for Science in the Public Interest (CSPI), http://www.cspinet.org/.
\textsuperscript{224} See, supra notes 209-226.
\textsuperscript{225} FDA Mission Statement, http://www.fda.gov/AboutFDA/WhatWeDo/default.htm (last visited Jan. 4, 2010).
\textsuperscript{226} Id.
\textsuperscript{227} Id. at 6
\textsuperscript{228} Id.
\textsuperscript{229} See discussion, supra, notes 157-181.
\end{footnotes}
again due to melamine contaminated ingredients imported from China. These are only a few examples of thirteen incidents of national outbreaks due to food-borne illnesses in the United States. 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. HR 875 and HR 759 both contain heavier protections for consumers than do HR 1332 and S 510. The importance of these policies is highlighted by the fact that less than one percent of the foods imported into the United States is inspected. As Rep. John Dingell so aptly put it, “without 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.” Recommendations in the bills include inspection programs which examine whether food operations have themselves installed mandated process controls and performance standards; required product sampling at both foreign and U.S. based food suppliers. 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. These inspections would be carried out on a “risk-identified” basis.

As well as enhancing the inspection process, the four bills all address strong mandates on food imports in particular. Specifically addressing inspection and monitoring of food imports is a critical step for the FDA whose former regulations focused on the idea that the United States was our primary source of food. Recent

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230 CSPI, supra note 223 at 2.
231 Id.
232 Id. at 14.
233 Id. at 7
figures suggest that the average American eats 263 pounds of imported food (representing 13% of our diet), 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. The bill also proposes that the FDA have the power to require that foreign governments certify foods exported to the United States as meeting all U.S. food safety requirements. The other three bills contain similar provisions. A further important provision in the Dingell bill relative to imports is that of requiring country of origin labeling on all processed food labels as well as requiring food manufacturers to identify country of origin for all ingredients on their website.

3. FDA Power to Recall Unsafe Foods

Another critical issue which the four 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 within the Untied States. Dingell’s bill further provides the FDA with authority to quarantine unsafe foods by prohibiting their movement from a specific geographic area. Further, all four bills grant the FDA the right to recall foods that are suspected of being contaminated, thereby getting them out of markets immediately. The FDA is currently without this power which limits

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236 CSPI, supra note 223 at 8.
238 CSPI, supra at 14.
239 See discussion, supra notes 213-217.
240 Becker supra note 202 at 14
241 See discussion, supra notes 213-217.
tremendously their ability to immediately contain unsafe foods. The language of HR Bill 2749 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. 242

4. Enforcement Authority

It is important that the FDA have expanded enforcement powers even beyond the newly suggested recall power. All but two of the bills 243 have enforcement tools covering not only recall ability, but the ability to trace back, 244 to detain suspect food for a reasonable

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244 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--

‘(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
time, to impose civil and criminal penalties and whistleblower protections. For example, HR 2749 provides for a voluntary recall and, if the food producer refuses, then the FDA may mandate a recall.

SEC. 135. CIVIL PENALTIES FOR VIOLATIONS RELATING TO FOOD.

(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.’.
§ 333. Penalties

(a) Violation of section 331 of this title; second violation; intent to defraud or mislead

(1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.

(2) Notwithstanding the provisions of paragraph (1) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

SEC. 1012 PROTECTIONS FOR EMPLOYEES WHO REFUSE TO VIOLATE, OR WHO DISCLOSE VIOLATIONS OF, THIS ACT.

(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

(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.

The specific language of the recall provision of the draft Bill HR 2749 section 420 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;
And finally, in connection with importation of foods from China and elsewhere, note should be taken of three more provisions of HR 2749 in particular: the creation of "foreign inspectors," the requirement of country of origin labeling, and the extraterritorial jurisdiction provision.

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

‘(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.

See, e.g. H.R. Bill 2749 at section 208:
Enhancing the FDA’s authority to inspect foods on a more regular basis, to require that foreign countries or their agents certify that imports meet U.S. food safety regulations, and to provide 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 our government to protect Americans from contaminated foods. Further, the hiring of inspectors dedicated to inspecting foreign imports, requiring the labeling of foods denoting their country of origin, 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 ensure the safety of our food supply chain. These measures, if passed, and coupled with the U.S-China Agreement on Food Safety, and the measures that China is taking to monitor their own exporters of food to the United States 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 1850’s, a number of European countries had independently adopted legislation concerning the “purity” of food. Many of the laws enacted at this time evolved due to the intentional adulteration

“(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.”

251 See, e.g., HR Bill 2749 at section 202.

252 Section 213 of HR Bill 2749 reads as follows:

SEC. 312. EXTRATERRITORIAL JURISDICTION.

‘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.

253 See supra notes 49 to 138 and accompanying text for a discussion of the new China regulations enacted and made effective July 1, 2009.

254 Linden J. Ellis and Jennifer L. Turner, Sowing the Seeds: Opportunities for U.S.-China Cooperation On Food Safety at 59, Woodrow Wilson International Center for Scholars, China
or misbranding of foods. The European Union, which now has 28 member states, is the current governing European body which sets guidelines for its member states on food safety production standards. Food Safety laws in the EU were reviewed in 2002 subsequent to the crisis produced by Britain’s outbreak of ‘mad cow disease’ and a White Paper on Food Safety was published which set out a host of recommendations for new pro-active food legislation. A key element to the new approach to food regulation was the development of a “framework regulation,” EC/178/2002 of the European Parliament and of the Council of 28 January, 2002, 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. 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 and feed chain, with traceability as a critical element to its approach. A second important element was the establishment of an independent body that serves as an advisory board on scientific issues to the legislators. The final piece of the new legislation provided for the development of specific food and feed safety legislation which was a major overhaul of the former legislation and created a framework for harmonized food controls. Another important concept in the EU’s overhaul of food law was the “precautionary principle,” drafted in February, 2000. It is basically a call to protect the environment when considering food

255 See e.g., the British Sale of Food and Drugs Act of 1875: http://tcbh.oxfordjournals.org/cgi/content/abstract/9/3/350.
258 Id.
safety. However, in practice, its scope proved 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 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.259

Article 7 of EC Regulation 178/2002 however adds a precautionary note to the
application of the precautionary principle by stating that measures taken in the event of a
case potentially determined to expose humans to possible negative health affects will not
be more trade restrictive than necessary to meet the minimal desired level of health
protection.260 And the steps that are taken should be reviewed “within a reasonable period
of time.”261 Application of the Precautionary Principle clearly raises issues of a
pretextual nature - restrictive competitive market access - and is a sensitive subject
among developing countries who fear its application will serve to disguise protectionism
and favor domestic markets.262 Although the EU has long been advocating the use of 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

261 Id.
262 International Centre for Trade and Sustainable Development, New EU Food Safety Law
perceived as unscientific and arbitrary. This is not to say that the United States does not support a precautionary approach as part of a scientifically sound decision process.\footnote{HR bill 2749 \textit{supra} note 213.}

A brief summary of the White Paper, and a comparative analysis to HR bill 2749\footnote{White Paper, \textit{supra} note 256 at Preamble.} follows. The objective of the White Paper is specifically spelled out as “to outline a comprehensive range of actions needed to complement and modernize 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.”\footnote{HR Bill 2749, \textit{supra} note 213.} In contrast, the preamble to HR Bill 2749 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.”\footnote{White Paper, \textit{supra} note 256 at 1.}

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 harmonisation of national control systems; dialogue with consumers and other stakeholders.\footnote{White Paper, \textit{supra} note 256 at 1.}

The 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;
- 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);

\footnote{“Summary of EU Legislation,” \url{http://europa.eu/legislation_summaries/other/132041_en.html}.}
• scientific advice to the highest standards of independence, excellence and transparency;
• application of the precautionary principle in risk management.\textsuperscript{268}

Besides the creation of a new European Food Authority mentioned above, and the development of new food safety laws, The White Paper emphasizes the importance of providing consumers with up to date information. U.S. bill, HR 2749 neither sets forth the goals of the legislation, nor addresses the need to inform and receive input from consumers.

In keeping with the White Paper’s goal of addressing the issues from farm to table, the Paper identifies each of the 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, BSE 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.\textsuperscript{269} HR bill 2749 does not take such an holistic approach to food protection, but zeroes in more particularly on details such as requirements for registration of food facilities;\textsuperscript{270} performance standards;\textsuperscript{271} risk-based inspection schedules;\textsuperscript{272} and access to

\textsuperscript{268} \textit{Id.}

\textsuperscript{269} \textit{Id.} at 2. 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 [1] (‘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.

\textsuperscript{270} See, e.g., HR Bill 2749, \textit{supra} note 213 at sections 101 and 103.

\textsuperscript{271} \textit{Id.} at § 103.

\textsuperscript{272} \textit{Id.} at § 105
records of those in the food supply chain among other administrative issues. Nowhere in the White Paper is there mention of penalties, while HR bill 2749 identifies both criminal and civil penalties and exerts its jurisdiction outside its territories to enforce the Act; facility registration and fees; inspection and re-inspection. The emphasis in the White Paper envisioned 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. 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 Community level; development of Community control guidelines; and an enhanced administrative cooperation in the design and operation of control systems. These elements mandate a policy of traceability of feed, food and their ingredients. Traceability is also a critical element in the proposed bill HR 2749. The White Paper anticipates the creation of a new monitoring and surveillance system. Unique to the EU is the Rapid Alert System which is currently in place to provide consumers with emergency information about dangerous products. The White Paper recommends that this system be enlarged 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

273 Id. at § 103.
274 Id. at § 134, 135.
275 Id. at § 213.
276 White paper, supra note 256, at 3.
277 Id.
278 HR Bill 2749, supra note 132, at section 107.
information systems must be made. This system should also be extended to third countries for incoming and outgoing information.279

Both HR 2749280 and the White Paper281 address the issues of research and its importance in preventing food crises. HR Bill 2749 continues the tradition of leaving responsibility for watch dogging food importers, exporters, etc., to the FDA. The system in the EU however is not so unified and therefore more difficult to regulate. The White Paper recommends a community framework of national control systems with community control guidelines with community cooperation among the members of the EU to promote and enforce mutual assistance.282. As with HR 2749, the White Paper calls for imported food stuffs to meet the health requirements of those set by the EU; however, unlike HR 2749, the White Paper acknowledges its obligation to abide by international standards and the WTO requirements:

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.283

Both HR Bill 2749 and the White Paper are ambitious efforts to stem the problems of food contamination in the global supply chain. While the EU’s White Paper and regulations have been in effect since 2002, the U.S. is only now seeing a bill actually reach the Senate after many previous starts of such legislation in both houses in the past. The measures identified in either the U.S. proposed legislation, the Bilateral Agreement

279 White Paper, supra note 132, at 11
280 HR Bill 2749, supra note 213 at section 123.
281 White Paper, supra note 256, at 11.
282 Id. at 30.
283 Id. at 34.
with China, or the White Paper that should have the most impact on food contamination such as has been seen in the U.S., Britain, and exports coming form China 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 U.S. to seize and to recall contaminated foods.

V. NON-GOVERNMENTAL AND CORPORATE RESPONSES

In addition to the new Food Safety Law laws in China, 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 and to draw on best international practices. The UN Report, 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 and ongoing and arduous one.” 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;

285 Id. at 6.
• 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.  

Many of these recommendations are incorporated in China’s new FSL. In contrast, the World Trade Organization (“WTO”) is explicit that it does not dictate food safety standards. Instead, Article 20 of the General Agreement on Tariffs and Trade (“GATT”) allows countries to establish their own standards. 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. For example, after learning reports 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. Although the WTO does not set standards, it acts to guard against protectionist measures under the guise of food safety.

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286 Id. at 7-8. Codex Alimentarius Commission is a joint organization of the Food and Agriculture Organization and the World Health Organization designed to develop international food standards. See, Codex Alimentarius Commission (2009), http://www.codexalimentarius.net/web/index_en.jsp. 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 9, 2009), http://www.reuters.com/article/healthNews/idUSTRE5654W120090706.

287 See Part II, supra, detailing features of the new law.


289 The General Agreement on Tariffs and Trade, Art. XX, available at http://www.wto.org/english/docs_e/legal_e/gatt47_02_e.htm#articleXX (last visited Jan. 10, 2010).

290 WTO, Standards and Safety, supra note 288.
One of the roles of the American Chamber of Commerce (“AmCham”) in Beijing is to act as an advocate in China for U.S. business and consumers. Recognizing that the new FSL has been implemented in China, AmCham notes that the real keys are “enforcement, commitment, and implementation.” 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. 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, encompassing factories, and standards for any raw materials that are used in manufacture. Effective January 2009, Wal-Mart began requiring all suppliers to sign new agreements requiring them to certify that they are in compliance with the law. 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 from Kraft Foods and Mars who suspended all sales of Chinese-made Oreo cookies, M&M’s and Snickers bars in Indonesia following

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292 Id.
295 Id.
reports of possible contamination and British candy maker Cadbury’s recall of all of its Chinese-made chocolate. 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 who provide inspection and compliance services, such as Intertek, who certify 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.”

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

VI. Ethical Considerations

As is evident by the forging analysis, sourcing from China is a huge issue for the United States, and our dependence on it is only going to grow larger as China emerges in the global economy as a deep supplier of goods and foods. While both China and the United

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296 Patrick, supra note 26.
300 Id.
States are making tremendous efforts through their legislative arms to protect the food supply chain, more is needed to be done outside the regulatory arena. 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 – and failure to understand the Chinese culture - that has led to the number of problems experienced in outsourcing from China. A brief discussion of the cultural and ethics perspective in China is critical to closing the gap in the safety of the food supply chain.

A survey conducted in the late 1990s disclosed that 39% of Chinese business men surveyed were dissatisfied with the ethical climate in their own businesses. 87% approved of the idea of corporate codes of ethics or a set of ethical norms for business. Researchers have suggested that much of this dissatisfaction derives form the social, political and economic upheaval that China has experienced over the last several decades. As one author has noted, the current business climate in China is similar to the “opening of the Wild West in America – a vast area of opportunity with many uncharted and risky paths, governed by a legal system that is still a work in process.” 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 from Chinese suppliers. Further, Chinese culture based on Confucius teaching favors familial relationships over those with

302 Id.
304 Id. at 26.
strangers. Confucianism is defined by hierarchical relationships among five groups: ruler/subject; father/son; husband/wife; brother/brother; and friend/friend.\textsuperscript{305} The Confucian orientation implies a degree of mistrust and suspicion of those outside the familial circle.\textsuperscript{306} Further, the concept of friend/friend is based on a long-term relationship, not the typical impersonal relationship identified in today’s business of foreign supplier to middleman to retailer. 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 typically uses an intermediary instead of transacting directly with the Chinese supplier. This impersonal relationship with a Chinese supplier does not tend to encourage the mutual bonds of trust and obligation suggested by a relationship of guanxi.\textsuperscript{307} And indeed, a recent survey of Chinese businessmen reveals that they neither appreciate nor understand the value of responsible corporate behavior.\textsuperscript{308} Furthermore, during the social revolution, the Chinese people had a history of poverty and a disciplined life dedicated to the state which stripped them from any and all luxuries. While China is hugely transformed today, the Chinese are very careful about spending money. In today’s frenzied global market where China has become synonymous with “cheap resources,” there is still much concern in China itself for 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,

\textsuperscript{305} Day, \textit{supra} note 287, at 9.
\textsuperscript{306} \textit{Id.}
\textsuperscript{307} Roth, \textit{supra} note 289, at 29.
\textsuperscript{308} Economy, E.C. \textit{The Great Leap Backward?}, 86 FOREIGN AFFAIRS, 39 (2007).
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.\textsuperscript{309}

Compounding the problem is the Chinese cultural aversion to reporting misconduct and thus, even those Chinese who are concerned by unethical behavior of co-employees are reluctant to “rat” on them. This is understandable given the behavior encouraged during China’s period of the “Cultural Revolution” from 1966-1976. During this period, even children were encouraged to “report” on parents, siblings, teachers and friends who did not follow Maoist thinking.\textsuperscript{310} Those ratted on were often sent to prison or were executed. Consequently, the Chinese are reluctant to report on anyone. Further, during this period, there was no privacy in China and concern that reporting misfeasance today would be revealed publicly continues to discourage whistleblowers. These factors then compound the problem U.S. merchants have in sourcing safe foods and drugs from China. Clearly, whistleblower provisions found in most corporate codes are not understood by Chinese workers and imposition of them 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.

\textbf{VII. RECOMMENDATIONS}

Our analysis has identified the steps that the 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.

\textsuperscript{309} Roth, supra note 289, at 29.
\textsuperscript{310} Day, supra note 284, at 11.
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, we perceive that the government action in the U.S. and China is not sufficient for companies to delegate responsibility to them.

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.\(^{311}\) Although the government steps are all important, issues of enforcement, particularly in China, necessitate corporate policing of the supply chain. As was seen in the heparin example, Baxter’s failures to inspect its manufacturing facility lead to disastrous consequences. It was not able to rely on the FDA, which inadvertently failed to inspect. Companies must inspect and test food to ensure that it is safe for consumption.

Next, companies should adopt their own standards for dealing with all vendors. These standards can be based on worldwide industry standards, such as HACCP, ISO, etc. that establish protection for foods in the food 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 immediately identify and rectify and deficiencies. The agreements should contain penalties for any vendor who fails to comply to deter conduct that could result in liability.

\(^{311}\) FSL, supra note 1 at Arts. 2 & 23.
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 could help vendors look more to long-term dealings. Without establishing relationships of trust globally, we cannot expect to have open and honest relationships with the Chinese. Corporate partners must work hard to establish this relationship and to bridge the cultural differences that have made these relationships challenging in the past.

It is clear that all the stakeholders identified (see the diagram in the appendix) a vested interest in the food supply chain and must work collectively to ensure the safety of food and drugs sourced from China. All these parties must work collectively 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 sellers of contaminated products, the heaviest burden of responsibility “tolls” for those companies. 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 and trust toward the common goal of food safety.