

The China Path to Global Food Safety



Global Food Safety Forum (GFSF)

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In memory of our friend and colleague,
Sang Liwei,
who dedicated his professional life to the
advancement of food safety.

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Executive Summary

1. Historical Setting for Food Safety

The safe handling, storage and consumption of foods have been concerns of mankind for thousands of years. The codification of food safety practices has evolved over time but these practices have their origins in ancient issues and customs, focusing mainly on the response to food safety problems. Today's laws are beginning to shift the focus to prevention through inspections and certification, while also improving response to and containment of problems when they do occur.

2. The Food Safety Mix or Mess

Several high profile food safety incidents and the increasing globalization of the food trade, as well, have created increased concern about the safety of the global food system. Recent outbreaks of foodborne illness in the US and the EU, and adulterated food scandals in China, resulting from the use of illegal food additives, have revealed gaps in the food safety system that need to be addressed at the country level and globally as a whole.

Governments and food industries in both developed and developing countries have been making efforts to improve their food safety systems in order to protect public health, consumer confidence, domestic economies, and international trade. In the US, the Food Safety Modernization Act (FSMA), signed into law in 2011, has been introduced in the wake of a spate of foodborne illness outbreaks. The Chinese government has focused its attention on the issue of food safety by severely punishing key participants in several of the scandals, creating a politically powerful Food Safety Commission, and enacting a sweeping new food safety law in 2009.

The main threats to the global food chain include pathogens, fraud, and weak regulatory environments.

- The global food supply chain has become increasingly interconnected, but the management of the food chain remains fractured.
- Food safety issues have brought direct and indirect public health threats.
- The costs of remedies are rising. In addition to losses due to decreased sales, recalls, and destroyed product, companies also face penalties from injured parties seeking compensation through the court system.
- Food safety incidents have dislocational effects on a multiplicity of trade and economic indicators.
- There is a lack of consumer and commercial incentives to underwrite national and international food safety systems.

3. Regimes: A Patchwork of Surveillance and Enforcement Mechanisms

3.1 Lack of harmonization of standards/certification. A continuous increase in consumer demand for safe food has led to the development of numerous food safety standards. Consequently, there is a need for harmonization of these standards. In an effort to harmonize the food safety standards, audits are now being used to measure companies' compliance with government regulatory and industry requirements. Nonetheless, the development of private standards by large international companies with specific audit requirements is generating further heterogeneity in the regulation of the international food trade.

3.2 Regional differences in enforcement, compliance, and illness surveillance. The formulation and implementation of food safety laws and regulations are often fragmented among different ministries and departments. In China, regulations designed to provide oversight of the food industry, to protect consumer rights, and to ensure fairness in the marketplace, are often interpreted differently by provincial and local governments or, in some cases, are simply ignored.

3.3 Overlap and lack of enforcement resources in place. Many developing countries and sometimes even developed countries lack the technical expertise, enforcement, and financial resources to implement food safety policies and often employ a multi-jurisdictional approach to food safety. As a result, a diverse set of government agencies ranging from agriculture to public health at the national, regional, and local levels is involved in the regulation of a country's food system. This agency overlap, in turn, causes the regulation of food to become more complex and confusing.

3.4 Insufficient collaboration platforms for public/ private sector. Food safety extends beyond any one company or country; it ultimately requires the private and public sectors to combine efforts, resources, and knowledge toward a shared vision of food safety with more unified actions. In the US, non-governmental organizations (NGOs) and food industry associations often advocate on behalf of consumers and some food sectors, and they provide a platform for communication between government and the private sector. Moreover, some international organizations offer platforms for multinational companies, exporters, and importers to lend their expertise in assisting government regulators and non-governmental organizations in developing systems and procedures in the food safety arena.

4. Food Protection and Food Fraud – Enabling a Shift to Prevention

The role of countries – whether the producer country or the consumer country -- in controlling and reducing Food Fraud is to engage international public and private partners to reduce the overall fraud opportunity. These countermeasures must consider the political and judicial capabilities of the governments, the needs and concerns of the citizens, and the social anthropology of the manufacturing and consumer marketplace. International standards and third-party organizations have an increasingly important role in controlling the trans-national public health threat of Food Fraud.

Food Fraud is a public health vulnerability that is growing, and the nature of global commerce will naturally continue to fuel the fraud opportunity. By focusing on the “bad guys” and reducing the fraud opportunity, on both an intra- and international level, we can reduce and control this public health threat.

Food adulteration is a food industry and government responsibility. Food safety, food fraud, and food defense can create food adulteration risks. Economically motivated adulteration is economically motivated, but the food public health risks are probably greater than those from the traditional food safety threats because the contaminants are unconventional and we are not specifically looking for them.

5. Food Safety Legislation, Regulation, and Practices in China

The Chinese government has focused its attention on the issue of food safety, severely punishing key participants in several of the scandals, creating a politically powerful Food Safety Commission, and enacting a sweeping new food safety law in 2009. The Chinese government has decided to launch national overhauls in 2011 in sectors including milk products, cooking oil, health foods, meat, and alcohol. The central government initiated a prolonged and stringent fight against the illegal use of additives in food, detailing measures to intensify supervision, upgrade safety limits, and increase penalties for violators.

Food safety is a massive social systematic project which is related to numerous factors including technical progress, economic development, social administration, and environmental quality, while public media are also a key component which requires constant improvement and perfection in the institutional mechanism. The construction of a long-term regulatory mechanism for food safety to form a coordinated, organized and orderly organic social supervisory system is a significant and pressing task that Chinese authorities, to their credit, recognize as a significant challenge.

6. Non-government Initiative

6.1 Building Brand for Food Quality and Safety: The China Example

Asian retailers' greatest sources of safety concerns have dealt with residual chemicals, contamination and spoilage, veterinary and plant diseases, and intentional poisoning. On the other hand, there is also an opportunity for companies to benefit from improved quality and product safety because consumers are willing to pay more for better, safer products.

6.2 Third Party Audit Certification

Requested by consumers and initiated by the food industry, certification and third party audits have been practiced for years in the western world, and these certification and third party audits have proved to be an effective means to help ensure food quality and safety. Faced with the problems brought by globalization,

some governments such as the U.S., plan to use third-party certification to manage food safety controls on imports into their countries.

6.3 Harmonization and International Food Safety Standards

Strict regulations and standards are critical to ensure food safety. The regulatory standards are to foster corporate responsibility to identify, protect, and control risks while coordinating with government counterparts at different levels. Compliance with strict standards will help improve consumers' confidence, build positive image for food product and companies, eliminate barriers for food trade, and reduce the negative effect on social stability for countries like China. On the other hand, standards-setting should rely on common science-based standards as a baseline, as should enforcement of standards implement common procedures.

Certification and harmonization in food safety standards will reduce transaction costs. Industry must take the initiative to improve food safety in its own operations and through a genuine partnership with key stakeholders, including governments. An industry collaboration network is needed to provide the platform for food industries in developed countries and the industries in less economically developed countries to exchange information with each other and cooperate on industry response.

6.4 Hands-on Strategies: Problem Solving

Legislation, laboratory capacity building, food inspection and certification, information-sharing, and consumer participation and empowerment have been identified as priority food safety areas for some Asian countries. Industry associations and nonprofit international organizations have become involved in helping improve the food safety capacity of these countries, with special emphasis on improving the operational level of food safety in emerging countries.

In order to address the food safety issues and trade concerns as a result of globalization, it is necessary to establish a long-term and lasting platform for food producers, processors, merchandisers/ shippers/ distributors and retailers. A dialogue is needed with government regulators, clients, consumers, and their counterparts in other countries. Global Food Safety Forum (GFSF) offers a platform for private-public sector collaboration; building members' brand for quality and food safety worldwide; integrating national and international regulatory regimes and standards; and offering food safety workshops to companies, government agencies, and consumers. This forum also serves as a multi-use platform for industries that could accommodate specialized interests in different links of the global food chain.

1. Historical Setting for Food Safety

Frank Rocco, Frank Rocco and Associates (Member of Food and Drug Law Institute)

The safe handling, storage and consumption of foods have been a concern of mankind for thousands of years. The codification of food safety practices has evolved over time but have their origins in ancient concerns and customs.

1.1 *The Books of Leviticus and Deuteronomy (2000 BCE)*

These ancient religious texts address a variety of food safety issues, including rules for the preparation of food for consumption by God himself¹.

1.1.1 Consumption

Birds may be consumed, but not birds of prey, nor fish-eating water birds. Bats are not birds – they are mammals – but they are lumped in with forbidden birds and may not be consumed.

An animal that lives in the water is considered ritually clean and may be consumed so long as it has both fins and scales, leaving lobster and shrimp on the forbidden list.

Animals can be consumed so long as they chew the cud² and have cloven hooves. Those animals are considered ritually clean. However, animals that only chew the cud *or* have cloven hooves are not clean and may not be consumed. Included on the forbidden list are hare, hyrax (a type of field mouse that may have been a delicacy 3,000 years ago), camels, and pigs.

Blood may not be consumed because it contains life. Certain types of fats – from cattle, sheep and goat – are also off-limits, as belonging exclusively to God.

The consumption of hindquarters is forbidden – owing to a story about Jacob having dislocated his thigh³. Filet mignon (a hindquarter cut) fails the kosher (fit or allowed to be eaten) test.

Dairy is permitted, so long as the milk comes from an animal whose meat is kosher. Cheese is more complicated because of the use of rennet, which can be

¹ According to Leviticus 1:3, "If the offering is a burnt offering from the herd, he is to offer a male without defect. He must present it at the entrance to the Tent of Meeting so that it will be acceptable to the Lord." Further down in Leviticus 1:9, the faithful are commanded that, "He is to wash the inner parts and the legs with water, and the priest is to burn all of it on the altar. It is a burnt offering, an offering made by fire, an aroma pleasing to the Lord." These sacrificial morsels were God's alone – to be shared with no others.

² Cud is plant material that ruminant animals regurgitate and chew again. This aids in digestion because the cow is able to chew plants, which are made mostly of cellulose, swallow them, and then basically "throw up" the material, and chew it some more. This helps break down the plant fibers. They'll then swallow the "cud" again and it will proceed to the later chambers of the stomach for further digestion.

³ The Book of Genesis, Chapter XXXII: 23-33. [New King James Version]

used only from the stomachs of kosher animals, slaughtered according to applicable rules.

1.1.2 Slaughter

Animals which die of natural causes or which are killed by other beasts may not be consumed. Springing from this prohibition is a requirement that the only animals that would be fit for consumption would be those slaughtered according to Jewish law, which requires that an animal be killed by a single cut across its throat at a precise depth relative to certain veins, nerves and organs.

Tools are likewise regulated and knives used in the ritual slaughter must be razor sharp and checked before each killing to guard against a jagged edge and therefore jagged cuts.

1.1.3 Cleanliness

The rules also prescribed the cleaning of clothes worn during the slaughter as well as bathing after ritual sacrifices.

1.2 The Assize of Bread and Ale (The 13th Century)

Fast-forwarding some 3,300 years, the Assize of Bread and Ale is a series of 13th century ordinances attributed to acts passed in England around 1266 - 1267 during the reign of Henry III.

The Assize was the first law in England to regulate the production and sale of food and was concerned primarily with price, weight and quality of breads and ales processed and sold in towns, villages and hamlets. The Assize resulted in the establishment of regulatory licensing systems, arbitrary recurring fees, and a system of fines and punishments.

The Assize was amended by the Bread Acts of 1822 and 1836, which stipulated that loaves should be sold by the pound, or multiples of pounds. It was repealed by the Statute Law Revision Act 1863.

1.3 Food Safety Regulation in the United States (1848 – 2009)

1.3.1 Welcome to the Jungle

Remedial regulations seem to be most often established in the aftermath of calamity. The 2008 melamine scandal in China is especially relevant, the sweeping overhauls established by The PRC Food Safety Law being enacted after that scandal took its disastrous toll.

It was no different – perhaps worse – in the United States during America's period of rapid industrialization. Among the shocking and atrocious scandals involving food safety were the swill milk scandals and snake oil salesmen.

1.3.2 The Swill Milk Scandals

In the middle 1800s in the United States, it was common practice for grain distillers to have dairy businesses on the side. The distillery businesses used huge amounts of corn, rye and other grains to make their distilled alcoholic

products. The grains were cooked to create mash, which was then distilled. The liquid product would be bottled and sold as whiskey and the cooked mash – known as swill – would typically be thrown away, until the distiller realized that it could be fed to their dairy cows.

The “swill herds” were treated barbarically. They were given no water because their owners thought that there was enough water in the swill. They were given no light or room to move and were fed nothing except swill. The animals, upon becoming too sick to stand, were hoisted up on slings in order for the milking to continue until they died.

When consumers began to notice that the swill-herd milk was of a mysterious blue color, the swill herd farmers began to add flour, starch, chalk, or plaster of Paris to thicken the mixture and give it a better hue. This adulteration increased the levels of harmful bacteria, turning an already sickening problem from bad to worse. In New York City, the mortality rate for infants and toddlers⁴ increased a shocking fivefold over a 13-year period from 1843 to 1856! Not until 1862, did the New York State government outlaw unsafe practices in the dairy industry. In 1864, the state outlawed the swill milk industry altogether. One author⁵ claims that it took 50 years for the New York State dairy industry to clean up its act. Compare that to the Chinese melamine scandals that, although residual problems remain, seem to have been addressed with force and speed once they were brought to light.

1.3.3 Snake Oil Salesmen

Children might have been the easiest but were not the only targets. Throughout the 1800s, various elements in American society developed an affinity for various tonics and elixirs⁶ that claimed to relieve all sorts of ailments. These products were often unreliable or, worse, toxic.

One product, “William Radam’s Microbe Killer” was labeled by its maker, “Cures all diseases”.⁷ Another, designed by Dr. Ebenezer Sibly, Reanimating Solar Tincture, made claim to restoring life in cases of sudden death.”⁸ These products

⁴ “Milk and kids’ are virtually synonymous in our culture with ‘good health.’ But that wasn’t always the case. Until the early 1900s, milk was often adulterated with foreign substances, taken from sick cows, or mis-handled during milking and storage. As a result, it was often host to tuberculosis, cholera, typhoid fever, and other life-threatening diseases. But few people knew that the milk made them sick. It wasn’t until the late 19th century, when scientists began to understand germ theory, that they realized diseases were being transferred through milk--and that they could do something to eliminate the hazard. Here’s a fascinating but little-known story from American history. Uncle John’s Giant 10th Anniversary Bathroom Reader. Discussed at <http://www.neatorama.com/tag/food-safety/>

⁵ See Zhen Ming, *New York had milk scandal too*, The New Paper (October 4, 2008)[available at <http://www.asiaone.com/Health/News/Story/A1Story20081003-91506.html>].

⁶ An elixir is a clear, sweet-flavored liquid (usually containing alcohol) used in compounding medicines to be taken orally in order to mask an unpleasant taste and intended to cure one’s ills. Elixirs are sometimes made from vodka or grappa. When used as a pharmaceutical preparation, an elixir contains at least one active ingredient dissolved in a solution that contains 15 to 50% by volume of ethyl alcohol and it is designed to be taken orally.

⁷ For more on Radam, see the Newsletter of The North Texas Skeptics, Volume 18 Number 1, available at www.ntskeptics.org

⁸ The full advertisement for the amazingly Re-animating Solar Tincture is available at <http://thequackdoctor.com/index.php/dr-siblys-re-animating-solar-tincture/>.

often included opiates, cocaine or alcohol, substances that might generally make one feel better for a while but which were unlikely to cure anything. For the even more unlucky, many of these potions contained toxic agents that caused paralysis.

It is noteworthy that the term “snake oil salesman” entered the American lexicon in the 1800s. This term was, of course, a pejorative used to describe salesmen who had sold these dubious, if not poisonous, potions to the public and has now come to be a reference to anyone making dubious claims about the quality of goods or services.⁹

1.3.4 Enough is Enough

Against an ocean of horror in the American foods and medicinal industry sprang The Pure Foods Movement of the 1870s.

The Movement was comprised of various women’s groups around the country, including the Ladies Health Association, which campaigned for and succeeded in cleaning up or closing down filthy slaughterhouses in New York City; and The Women’s Christian Temperance Union, which was created to protect communities from the consequences of alcohol abuse. In Louisiana, a Mrs. Richard Bloor sent descriptions of the conditions at packinghouses to Upton Sinclair to use in his expose of the meat industry. Some of these women’s clubs started the push for Prohibition, the period in American history during which the consumption of alcohol was banned by law. Members of the WCTU, the Ladies Health Association, and other women’s clubs laid the foundation for further pure food, drink, and drug campaigns in the early 1880s.

Momentum toward a national food and drug safety law consequently started in the 1890s. A meat inspection law passed Congress in 1890; but, it was enacted primarily as a result of pressure from the meatpacking lobby and the law was predictably worthless.

In 1892, the Paddock Bill, which would have prohibited some additives and required the accurate labeling of foods, cleared the Senate but failed in the House. As food safety incidents increased during the Great Depression, the interest of women’s clubs and other organizations increased as well.

General consumers were not the only ones suffering under the unsafe and dishonest practices of food producers.

Soldiers fighting in the Mexican War were treated with shoddy medicines, only to die horrible deaths. The Drug Importation Act of 1848 was enacted as an

⁹ Snake oil is, however, appreciated somewhat differently in Chinese culture; so, the term “snake oil salesman” might be lost in translation among the Chinese. Snake oil is part of traditional Chinese medicine and is actually a product of the Chinese Water Snake. It is used to treat joint pain and Chinese laborers on railroad gangs in North America gave snake oil to Europeans for that purpose. When rubbed on the skin at the painful site, snake oil was claimed to bring relief. Rival medicine salesmen, especially those selling patent medicines, had ridiculed these claims. See http://en.wikipedia.org/wiki/Snake_oil

untimely response to these deaths. The law was applicable only to imported articles because Congress had believed that the rising quality of foreign drugs would pressure domestic drug makers to improve their standards. Further military backlash was felt and brought up at Congressional hearings about rancid "embalmed beef" served to soldiers during the Spanish-American War of 1898.

Finally, in 1901, a melamine-like tragedy occurred in which thirteen children died in Missouri from a tainted diphtheria antitoxin that was collected from a horse¹⁰. Congress pounced and immediately enacted the Biologics Control Act, which became effective in 1902¹¹.

The tidal wave of government and public furor had, however, yet to reach its peak. In 1906, a 28-year old journalist from The Bronx named Upton Beall Sinclair Jr. authored *The Jungle*¹², an expose of the horrors that permeated the meat packing industry in Chicago. The tidal wave now came crashing down.

1.3.5 The Government Really Steps In

Within months of the release of *The Jungle*, Congress passed the *Pure Food and Drugs Act of 1906*¹³ and the *Federal Meat Inspection Act*¹⁴.

The Bureau of Chemistry pursued enforcement of the *Pure Food and Drugs Act* with zeal, but its authority was held in check by the United States Supreme Court and lower federal and state courts.

¹⁰ This horse, named Jim, was a former milk wagon horse whose job it was to produce serums containing antibodies to fight diphtheria toxins. Jim donated over 30 quarts of these antitoxins during his retirement from the milk routes. In autumn 1901, Jim showed signs that he had contracted tetanus and had to be put down. Shortly afterward, a girl died in St. Louis and her death was linked to contaminated diphtheria serum which was found to have contained tetanus. Simple quality control procedures could have detected the contaminants but they were not undertaken and 12 more children died from the vaccine. This incident, and a similar one involving contaminated smallpox vaccines, led to the passage of the *Biologics Control Act of 1902* which established the Center for Biologics Evaluation and Research.

¹² Based on undercover work in 1904, the novel was published in 1905 in a series of pieces in the socialist newspaper *Appeal to Reason*. Sinclair had spent seven weeks gathering information while working in the meatpacking plants in Chicago for the magazine's publishers. Sinclair self-funded the first edition after five rejections by publishers who found the stories too shocking for publication. It was finally published by Doubleday, Page & Company on February 28, 1906 and has been in print ever since. See http://en.wikipedia.org/wiki/The_Jungle.

¹³ In June 1906, President Theodore Roosevelt signed into law the *Food and Drug Act*, also known as the "Wiley Act" after its chief advocate. The Act prohibited, under penalty of seizure of goods, the interstate transport of food which had been "adulterated," with that term referring to the addition of fillers of reduced "quality or strength," coloring to conceal "damage or inferiority," formulation with additives "injurious to health," or the use of "filthy, decomposed, or putrid" substances. The Act also banned "misbranding" of food and drugs. The responsibility for examining food and drugs for such "adulteration" or "misbranding" was given to Wiley's USDA Bureau of Chemistry. *The Pure Food and Drugs Act* was not the first U.S. Federal law to deal with food safety. *The Drug Importation Act* was the first U.S Federal law to regulate the adulteration of products sold for human consumption. Regulation at the state level had come much earlier with the enactment in 1785 in Massachusetts of the first general food adulteration law in the America.

¹⁴ *The Federal Meat Inspection Act of 1906* (FMIA) worked to prevent adulterated or misbranded meat and meat products from being sold as food and to ensure that meat and meat products were slaughtered and processed under sanitary conditions. USDA inspection of poultry was added by the *Poultry Products Inspection Act of 1957* (PPIA). The FDA is responsible for all meats not listed in the FMIA or PPIA, including venison and buffalo, although USDA does offer a voluntary, fee-for-service inspection program for buffalo. See http://en.wikipedia.org/wiki/Federal_Meat_Inspection_Act

Food safety horror stories continued and included radioactive beverages, cosmetics which caused blindness and medicines for diabetes that were worthless. All these wrongs were unrightable by the Bureau of Chemistry, constrained as it was by the courts. The same grass roots and muckraking interests that had combined forces in the late 1800s and early 1900s geared up again for battle and lobbied to have enacted a tougher set of laws to promote food safety. For five years, Congress refused to act on tougher regulations until the "Elixir Sulfanilamide" tragedy¹⁵ claimed the lives of more than 100 persons in 1937.

Sulfanilamide was used in tablet and powder form in the 1930s to treat streptococcal infections. In 1937, a salesman for the S.E. Massengill Co. reported a demand in the southern states for the drug in liquid form. The company's chemists found that sulfanilamide would dissolve in diethylene glycol and then went on to test the mixture for flavor, appearance, and fragrance – but not toxicity – and found it satisfactory.¹⁶

Toxic it was, indeed; diethylene glycol being a highly poisonous chemical used for antifreeze. The food and drugs laws in place prior to the enactment of the *Food, Drug, and Cosmetic Act* did not require that drug companies study the safety of new drugs. In fact, the laws in effect at that time did not prohibit the sale of dangerous, untested, or poisonous drugs.

In the case of the liquid Sulfanilamide, a few simple tests on animals would have shown its lethal toxicity. In fact, a simple review of then current literature would have shown that diethylene glycol was toxic and could cause kidney damage or failure. The owner of Massengill, Dr. Samuel Evans Massengill, said, "My chemists and I deeply regret the fatal results, but there was no error in the manufacture of the product. We have been supplying a legitimate professional demand and not once could have foreseen the unlooked-for results. I do not feel that there was any responsibility on our part."

Taking a somewhat different view of the matter, Massengill's chief chemist, Harold Watkins, committed suicide.

The FDA made 25 seizures of the elixir based on charges of misbranding, claiming that the term "elixir" falsely implied that the product was an alcoholic solution.

On June 24, 1938 President Franklin Delano Roosevelt signed into law the *Food, Drug, and Cosmetic Act* (FD&C Act). The FD&C Act significantly increased federal regulatory authority over drugs by mandating a pre-market review of the safety of all new drugs, as well as banning false therapeutic claims in drug labeling without requiring that the United States Food and Drug Administration (FDA) prove fraudulent intent. The law also authorized factory inspections and expanded enforcement powers, set new regulatory standards for foods, and

¹⁵ Using a drug formulated with a toxic, untested solvent. The only way that the FDA could even seize the product was due to a misbranding problem: an "Elixir" was defined as a medication dissolved in ethanol, not the diethylene glycol used in the Elixir Sulfanilamide.

¹⁶ See <http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/SulfanilamideDisaster/default.htm>

brought cosmetics and therapeutic devices under federal regulatory authority. This law, though extensively amended in subsequent years, remains the central foundation of FDA regulatory authority to the present day.¹⁷ The FD&C Act also paved the way for a series¹⁸ of laws aimed at controlling food and drug safety and protecting health and human welfare.

1.3.6 The Food & Drug Administration

The FDA is a successor agency¹⁹ to the Bureau of Chemistry, which was established pursuant to the Pure Food and Drugs Act of 1906. It was not until 1927 that the Bureau of Chemistry was reorganized into the Food, Drug, and Insecticide Administration (FDIA) and the Bureau of Chemistry and Soils. The FDIA was renamed the Food and Drug Administration in 1930.

The FDA is responsible for:

- “Protecting public health by assuring that foods are safe, wholesome, sanitary and properly labeled; human and veterinary drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective;
- Protecting the public from electronic product radiation;
- Assuring cosmetics and dietary supplements are safe and properly labeled;
- Regulating tobacco products;
- Advancing the public health by helping to speed product innovations;
- Helping the public get the accurate science-based information they need to use medicines, devices, and foods to improve their health.”²⁰

The FDA executes these responsibilities through various offices and centers, which include six product centers, one research center, and two offices:

¹⁷ See http://en.wikipedia.org/wiki/Food_and_Drug_Administration.

¹⁸ Those include: The Public Health Service Act of 1944, the 1951 Food, Drug, and Cosmetics Act Amendments PL 82–215, the 1962 Food, Drug, and Cosmetics Act Amendments PL 87–781, the 1966 Fair Packaging and Labeling Act PL 89–755, the 1976 Medical Device Regulation Act PL 94–295, the 1987 Prescription Drug Marketing Act, the 1988 Anti–drug Abuse Act PL 100–690, the 1990 Nutrition Labeling and Education Act PL 101–535, the 1992 Prescription Drug User Fee Act PL 102–57, the 1994 Dietary Supplement Health and Education Act, the 1997 Food and Drug Administration Modernization Act 105-115, the 2002 Bioterrorism Act 107-188, the 2002 Medical Device User Fee and Modernization Act (MDUFMA) PL 107-250, the 2003 Animal Drug User Fee Act PL 108-130, the 2007 Food and Drug Administration Amendments Act of 2007, the 2009 – Family Smoking Prevention and Tobacco Control Act, the 2011 FDA Food Safety Modernization Act.

¹⁹ The FDA is currently an agency of the United States Department of Health and Human Services, a U.S. federal executive department.

The United States federal executive departments (FEDs) are the administrative organs of the Office of the President of the United States. FEDs are analogous to ministries in parliamentary systems but, in the case of the United States, the heads of FEDs do not form a government as ministers might do in, say, in the nations of the British Commonwealth. The heads of the FEDs are known as secretaries and they form the so-called Cabinet, an executive organ that serves at the pleasure of the president. The FEDs are the oldest agents of the federal executive branch of the United States, with the Departments of State, War, and the Treasury all being established within a few weeks of each other in 1789. See http://en.wikipedia.org/wiki/United_States_federal_executive_departments.

²⁰ See <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194877.htm>.

- Center for Biologics Evaluation and Research, which regulates products such as vaccines, blood, and gene therapy
- Center for Devices and Radiological Health, which regulates medical devices ranging from thermometers to kidney dialysis machines, and electronic products that give off radiation, such as microwave ovens
- Center for Drug Evaluation and Research, which regulates over-the-counter and prescription medications
- Center for Food Safety and Applied Nutrition, which regulates most foods (except meat and poultry, which are regulated by the USDA), food additives, infant formulas, dietary supplements, and cosmetics
- Center for Tobacco Products, which regulates cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco
- Center for Veterinary Medicine, which regulates feed and drugs and devices used in pets, farm animals, and other animals
- National Center for Toxicological Research, which supports FDA's product centers by providing innovative scientific technology, training, and technical expertise
- Office of Regulatory Affairs, which conducts inspections and enforces FDA regulations
- Office of the Commissioner, which provides leadership and direction to FDA's product centers, research center, and Office of Regulatory Affairs.²¹

The Office of Regulatory Affairs is considered the "eyes and ears" of the agency, conducting the vast majority of the FDA's work in the field.

Consumer Safety Officers, more commonly called Investigators, are the individuals who inspect production and warehousing facilities, investigate complaints, illnesses, or outbreaks, and review documentation in the case of medical devices, drugs, biological products, and other items where it may be difficult to conduct a physical examination or take a physical sample of the product.

The Office of Regulatory Affairs is divided into five regions, which are further divided into 13 districts. Districts are based roughly on the geographic divisions of the federal court system. Each district comprises a main district office, and a number of Resident Posts, which are FDA offices located away from the district office to serve a particular geographic area. The Office of Regulatory Affairs also includes the FDA's network of laboratories, which analyze any physical samples taken. Though samples are usually food-related, some laboratories are equipped to analyze drugs, cosmetics, and radiation-emitting devices.²²

The Office of Criminal Investigations was established in 1991 to investigate

²¹ See <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194884.htm>

²² See http://en.wikipedia.org/wiki/Food_and_Drug_Administration

criminal cases. Unlike ORA Investigators, OCI Special Agents are armed, and are not focused on the technical aspects of the regulated industries. OCI agents pursue and develop cases where criminal actions have occurred, such as fraudulent claims, or knowingly and willfully shipping known adulterated goods in interstate commerce. In many cases, OCI will pursue cases where Title 18 violations have occurred (e.g. conspiracy, false statements, wire fraud, mail fraud), in addition to prohibited acts as defined in Chapter III of the FD&C Act.

OCI Special Agents often come from other criminal investigations backgrounds, and work closely with the Federal Bureau of Investigation, Assistant Attorney General, and even Interpol. OCI will receive cases from a variety of sources, including ORA, local agencies, and the FBI, and will work with ORA investigators to help develop the technical and science-based aspects of a case. OCI is a smaller branch, comprising about 200 agents nationwide.

The FDA frequently works in conjunction with other federal agencies including the Department of Agriculture, Drug Enforcement Administration, Customs and Border Protection, and Consumer Product Safety Commission.

The FDA's responsibilities extend to the 50 United States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, and other U.S. territories and possessions

The FDA regulates more than \$1 trillion worth of consumer goods, about 25% of consumer expenditures in the United States. This includes \$466 billion in food sales, \$275 billion in drugs, \$60 billion in cosmetics and \$18 billion in vitamin supplements. Much of the expenditures is for goods imported into the United States; the FDA is responsible for monitoring a third of all imports into the United States.

1.3.7 The Food Safety Modernization Act

We move forward nearly 75 years to 2011, the year in which President Barak Obama enacted the Food Safety Modernization Act (FSMA).²³

The FSMA was signed into law by President Obama on January 4, 2011. The new law shifts the FDA's focus more to prevention versus its traditional function of response.

The FSMA also grants to the FDA:

- new enforcement authorities designed to achieve higher rates of compliance with prevention- and risk-based food safety standards and to better respond to and contain problems when they do occur
- new tools to hold *imported foods* to the same standards as domestic foods and directs FDA to build an integrated national food safety system in partnership with state and local authorities

Concerns over imported food increased dramatically after incidents of

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See, generally, Dewaal, Caroline S, FSMA: Import Rules May Foster Global Food Safety, February 14, 2011 [available at <http://www.foodsafetynews.com/2011/02/fsma-import-rules-may-foster-global-food-safety/>].

contaminated heparin (a blood thinning drug), counterfeit glucose monitor strips and surgical mesh, melamine-tainted vegetable protein and dairy products, and salmonella in peppers. After melamine-tainted protein from China caused deaths and illnesses in dogs and cats all over the country, both the House and the Senate held hearings on the issues surrounding imports. The same year, contaminated drugs and toothpaste caused numerous deaths and illnesses, both in the United States and other countries, and there have been recurrent outbreaks linked to fruits and vegetables imported into the United States.

The FDA's efforts at monitoring imported foods were limited to border inspections that checked less than two percent of incoming foods. Although the United States Department of Agriculture (USDA) had the authority to strike food safety deals with foreign countries, the FDA did not. Congress considered these limitations on the FDA's authority as major shortcomings to the FDA's ability to protect the nation against unsafe foreign-origin foods coming into²⁴ the United States – a shortcoming that Congress seemed determined to resolve.

The FSMA now mandates the inspection of "not fewer than 600 foreign facilities," in the year following its passage²⁵. In addition, the FSMA requires the FDA to at least double foreign facility inspections each year for the next five years. Some commentators believe that this target is unachievable given current American budgetary constraints²⁶.

Increasing the Role of Foreign Governments

In addition to the requirement to undertake inspections of foreign food facilities, the FSMA requires the FDA to develop a plan that gives responsibility to the exporting country to ensure the safety of food²⁷ and, in this regard, the FDA is to seek bilateral and multilateral "arrangements and agreements".²⁸

Certification of Imports

The Act also contains authority for FDA to require certification for different foods or all food coming from certain countries as a condition of admission to the U.S. Certification can be done by either a foreign national government or an entity that is accredited as an approved quality assurance agent by the Secretary of the Department of Health and Human Services.

²⁴ Several new tools, like inspection and certification, originate in the country of origin. Others, like the Foreign Supplier Verification Program, will hold U.S. importers accountable.

²⁵ In 2009 (the last year with complete data), FDA conducted 210 foreign facility inspections, so while it is ambitious, the goal of 600 inspections by next January is not out of reach.

²⁶ See e.g., Dewaal, Caroline S, FSMA: Import Rules May Foster Global Food Safety, February 14, 2011 [available at <http://www.foodsafetynews.com/2011/02/fsma-import-rules-may-foster-global-food-safety/>]

²⁷ Under our laws, USDA is charged with the safety of all meat and poultry products sold in the U.S. When it comes to imported products, USDA doesn't inspect every foreign meat or poultry plant that imports to the U.S. Instead that agency relies on foreign governments to conduct inspections and certify that the products coming from approved plants meet our safety standards. USDA regularly audits the foreign inspection programs, and even visits some foreign plants, to provide oversight and assurance that the foreign programs are capable of enforcing our standards. In addition, USDA checks incoming meat and poultry at the border, including intensive checks on nine percent, as a verification of the foreign program's effectiveness. Foreign government export certification has long been in use in the meat sector for approving products from other countries.

²⁸ See section 405 of the FSMA.

2. The Food Safety Mix or Mess

Jianbo Lu and Richard Gilmore, Global Food Safety Forum (GFSF)

2.1 Current status

Food safety incidents, food trade, and some new and emerging trends in the consumer and food industry cause more concerns for food safety in the world. These emerging trends include changing consumption patterns such as increasing the proportion of calories from animal sources; globalized food production and supply chains challenging conventional and obsolete food safety regulations; the spread from animals to human beings of infectious diseases such as *Escherichia coli* O157:H7 and O104:H4 in fruit and vegetable production; avian influenza; and food irradiation. As the most spotlighted country regarding food safety in last few years, China is among the world's largest producers and exporters of processed foods and is the leading exporter of several products, including apple juice, canned peaches and pears, instant noodles, and dehydrated garlic. According to Global Trade Information Services (GTIS), bilateral agricultural trade in 2010 consisted of US \$17.8 billion in US exports to China and US \$3.2 billion in imports from China. The food industry is becoming globally inter-connected. Chinese processed food production has been growing at about 20 percent annually in recent years, largely in response to rising domestic disposable income, urbanization, and the trend toward higher quality and more convenience in food purchases.

2.1.1 Outbreaks in the U.S., EU, and China

Several outbreaks of foodborne illness in the US and the EU, and adulterated food scandals in China, resulting from illegal additives or fraud, have suggested that there are gaps in the food safety system that need to be addressed in each involved country and globally as a whole.

2.1.1.1 Cases in the United States

In the United States, in 2006, an outbreak of *E.coli* O157:H7 linked to California baby spinach and pet food contaminated by melamine sourced from China made the news, revealing new threats to the food supply. In April 2007, ConAgra peanut butter contaminated with *Salmonella Tennessee* sickened 425 people in 44 states. Later in 2008, the United States had its largest foodborne illness outbreak in 10 years that involved *S. Saintpaul* contamination of fresh jalapeno peppers (1,400 ill). This was followed in 2008 to 2009 by one of the largest food recalls in US history involving 2,100 food products contaminated by *S. Typhimurium* and linked to the Peanut Corp. In 2010, 1,813 people were sickened from *Salmonella enteritidis* linked to eggs, and more than 500,000,000 eggs were recalled. The US Center for Disease Control and Prevention recently released its latest and best estimate of the burden of foodborne illness in the

United States. Each year, 1 in 6 Americans can expect to experience foodborne illness. Of that number, more than 120,000 will be hospitalized, and, tragically, 3,000 will die.

2.1.1.2 Cases in Europe

In Europe, as of July 1, 2011, the recent outbreak of *E. coli* 0104:H4 first detected in Germany has so far killed 50 and sickened more than 4,000 people. The *E. coli* pathogen was initially identified on cucumbers imported from Spain. However, German health officials later announced that Spanish cucumbers were not the source of the outbreak on May 31. The German government identified the pathogen as hemolytic-uremic syndrome (HUS), a serious complication of a type of *E. coli* known as Shiga toxin-producing *E. coli* (STEC) at the beginning of June. The European Centre for Disease Prevention and Control said in a risk assessment that the HUS/STEC outbreak is the largest in the world of its kind.

On June 5, it was reported that sprouts grown in Germany were the likely source for this *E. coli* outbreak. There was a "direct link" between a company in the town of Uelzen and "these people getting sick." The firm has been shut down and its products have been recalled. However, it was not immediately clear how the *E. coli* strain may have gotten into the sprouts. Following weeks of uncertainty, Germany said on June 10 that bean sprouts were almost certainly the source of the deadly outbreak of *E. coli* 0104:H4.

On June 24 French authorities confirmed an *E. coli* outbreak in Bordeaux. By June 27, ten victims in France were suffering from bloody diarrhea, with five diagnosed with hemolytic uremic syndrome (HUS) – symptoms typically caused by Shiga toxin-producing *E.coli*. Initial tests have found the *E. coli* O104:H4 bacteria present in two of the cases, with French officials confirming it was the same strain as that responsible for the outbreak in Germany.

Epidemiological investigations found that a number of patients, who live in close proximity to each other, had attended an open day at a community centre in the Bègles on 8 June. Many were said to have eaten bean sprouts scattered on various dishes.

A report on June 29 by the European Food Safety Authority suggested the possibility that fenugreek seeds imported from Egypt in 2009 and 2010 are responsible for both outbreaks.

On June 30, the link between the outbreaks in Germany and France was further detailed by health authorities in the latest Eurosurveillance report from the European Centre for Disease Prevention and Control. It advanced suspicions that contaminated sprout seeds have remained in distribution for weeks after the German outbreak, and are still a public hazard two months after the first German illnesses.

Eurosurveillance reports that the seeds were purchased from a garden store, and had been supplied by a distributor in the United Kingdom. Earlier, French authorities said a British seed company, Thompson & Morgan, had packaged the fenugreek seeds and sold them in France.

Germany was spotlighted for its dioxin scare at the beginning of 2011. The health scare began when German officials announced on January 3 that eggs from German farms where hens ate dioxin-tainted feed had been contaminated. The origin of the feed contamination has been traced to a distributor of oils for animal feed production in the northern state of Schleswig-Holstein, where fatty acids meant for industrial use were distributed for animal feed. Operations at 4,700 German farms were shut down and thousands of hens were culled in eight German states to try to prevent food supplies being contaminated by the tainted feed.

The scare has led to temporary import bans on German meat and poultry products in South Korea and a drop in demand for eggs. The German Farmers' Association has said that total farming losses amounted to 40-60 million euros (\$51.64-77.45 million) per week. The crisis has led to German authorities toughening up regulatory oversight on dioxins, including the tabling of rules to ensure a separation in fats for industrial and feed end-users. The European Commission is thought to be considering the adoption of similar rules.

The US and EU cases highlight the growing volume and complexity of imported products, national security threats, corporations lacking accountability, and enforcement tools that do not reflect today's commercial practices. On the other hand, economic adulteration and intentional fraud should also be addressed, especially in some emerging countries such as China.

2.1.1.3 Cases in China

The last few years have seen a series of food safety incidents reported in the Chinese and international media, raising consumers' concerns both domestically and abroad. In 2008, melamine-tainted milk powder killed at least six infants and sickened 300,000 children across the country. As a result, consumer confidence in domestic dairy products has greatly decreased. Almost 70 percent of China's consumers feel insecure about food safety, according to a survey recently released by Tsinghua University's Media Survey Lab and Insight China Magazine. In 2011, the decision to renew production licenses was made in the face of continued concerns over the safety of Chinese dairy products. Only 643 out of the 1,176 dairies in the country were granted production licenses, forcing the rest into temporary closure.

China has been dealing with a slew of high-profile food safety scandals. In recent months alone, hundreds have been seriously sickened by clenbuteral-tainted pork; over a dozen noodle makers were ordered to stop production because they were using ink, industrial dyes, and paraffin wax as ingredients; and 16 tons of pork were pulled from the marketplace for containing sodium borate, a chemical that seemingly transforms cheap pork into darker, higher-value "beef." Chinese officials also arrested 12 people for involvement in a 40-ton bean sprout debacle, in which farmers were using sodium nitrite (a known carcinogen), urea, antibiotics, and a plant hormone called 6-benzaladenine to make the sprouts grow faster and look shinier.

Most of these Chinese incidents are non-pathogen but illegal additive related, and consumers are casualties of a kind of economic warfare in which profit motives are controlling.

2.1.2 Efforts to improve food safety

Globally, foodborne diseases and threats to food safety constitute a growing public health problem and WHO's mission is to assist Member States to strengthen their programs for improving the safety of food all the way from production to final consumption.

In May 2010 the World Health Assembly approved a new resolution on food safety: *Advancing food safety initiatives* (WHA63.3)²⁹. Governments and food industries in both developed and developing countries have been making efforts to improve their food safety systems in order to protect public health, consumer confidence, domestic economy, and international trade.

2.1.2.1 United States legislation and enforcement

In the US, the Food Safety Modernization Act (FSMA) has been introduced in the wake of a spate of foodborne illness outbreaks and was signed into law on January 4, which represents the most sweeping overhaul of the food safety system since the passage of the Food, Drug, and Cosmetic Act in 1938. Food safety plan and preventive control and science-based risk analysis are the guiding principles of FSMA. Secondly, FDA has an inspection mandate and legal powers to ensure companies are meeting their prevention duties and to stop potentially unsafe food from entering commerce, not just remove it after the fact. Thirdly, Congress has made efficient, risk-based use of resources and partnership among government food safety agencies the law of the land. Moreover, with the law's new importer accountability requirements there will be added assurances that food from abroad is as safe as domestic food.

2.1.2.2 European legislation

In all European Commission Member States and many third countries, the overarching principles concerning food safety and consumer protection are established in national legislation. However, at the EU level, food legislation has evolved without some of these basic principles having been established in an overarching legal instrument³⁰.

On the 28th of January 2002 the European Parliament and the Council adopted Regulation (EC)178/2002 laying down the General Principles and Requirements of Food Law. The aim of the General Food Law (GFL) Regulation is to provide a framework to ensure a coherent approach in the development of food legislation. At the same time, it provides the general framework for those areas not covered by specific harmonized rules and where the functioning of the internal market is ensured by mutual recognition.

²⁹ http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_R3-en.pdf

³⁰ http://ec.europa.eu/food/food/foodlaw/index_en.htm

The GFL lays down definitions, principles and obligations covering all stages of food/feed production and distribution. A core element of the GFL is to create the ability to trace foods and share information among members. For example, a centralized tracking system follows the movement of livestock from origin to slaughter.

European Food Safety Agency (EFSA), an independent entity, was created to provide scientific advice, risk assessment, and technical support for policy makers. It requires member states to maintain a separation between risk assessment and management. The European Commission, European Parliament, and European Council have responsibility for risk management decisions at the EU level. Within the EU, individual countries have passed laws to come into conformance with the GFL and to respond to the BSE crisis.

2.1.2.3 Food safety legislation improvement in some other OECD nations

Legislative and administrative reforms in some other OECD nations such as Australia, Canada, and New Zealand have been driven by a desire to enhance the efficiency of public administration by eliminating overlapping authorities. The reformed systems focus resources on high risk areas. Moreover, the efforts are to reduce inconsistencies in enforcement, and stimulate industry initiatives for risk minimization and collaboration.

2.1.2.4 China's legislation and enforcement

In recent years, shortcomings within China's food safety regime in monitoring and enforcing the quality of products such as milk, eggs, and pet food have severely undermined consumer confidence in the system. As a result, the Chinese government has focused its attention on the issue of food safety, severely punishing key participants in several of the scandals, creating a politically powerful Food Safety Commission, and enacting a sweeping new food safety law in 2009. Yet, much remains to be done.

China has taken important steps to make food safety a priority, with the nation's first food safety law taking effect in 2009. Last year, the Ministry of Health blacklisted 48 substances illegally added to food and 22 misused food additives.

The stakes are high in China's campaign to improve food safety. China is one of the world's largest producers and consumers of agricultural products. It exports approximately US \$3 billion in agricultural products to the US each year, ranking as one of the leading American food suppliers.

The Chinese government continues to accept primary responsibility for funding infrastructure. In October 2010, an agreement between China's Ministries of Commerce and Agriculture was signed; they will work together over the next five years to improve the distribution and marketing chain for agricultural goods. The ministries will fund the construction of large agricultural wholesale markets located between major production areas and transportation hubs, as well as promote business cooperation between large chain enterprises and agricultural regions. The two departments also agreed to improve efforts to standardize farm

produce distribution and monitor the quality of vegetables, fruits, and meat to help ensure food safety³¹.

The Chinese government has decided to launch national overhauls in 2011 in sectors including milk products, cooking oil, health foods, meat, and alcohol³². The Chinese food industry is on a fast track for development, but a large number of food producers and catering operators are running their businesses in a small-scale or scattered way. The central government initiated a prolonged and stringent fight against the illegal use of additives in food in April, detailing measures to intensify supervision, upgrade safety limits, and increase penalties for violators. China authorities have arrested more than 2,000 people and shut 5,000 businesses by August in a four-month campaign against recurring food safety problems³³.

Bribery is often involved in food safety scandals, partially contributes to lax food safety enforcement. In May 2011, China's Supreme Peoples court issued an order stating violations of food safety that cause fatalities should result in death sentences for those responsible. The court further stated that those involved in non-lethal food poisoning cases should pay larger fines and face longer prison terms, and that there should be harsher penalties for government food-safety officials who accept bribes or cover up violations.

Chinese prosecutors announced in the mid-May they are investigating 57 government officials for failing to enforce food safety standards. Eighteen officials are suspected of taking bribes, 39 are being investigated for dereliction of duty. Officials cited a huge economic cost to dereliction of duty in the realm of food safety regulation. A recent scandal with clenbuterol, a growth additive illegally used in pork production to promote leaner meat, cost hundreds of millions of dollars.

The regulatory infrastructure, industry technologies, and industry and consumer awareness of food safety concerns are at a relatively early stage of development in China., and China is not the only country that has low food safety development. Vietnam has less mature food safety awareness than China. There is, therefore, an urgent need to introduce and enforce uniform compliance procedures. Vietnam's new Law of Food Safety will be in effect in July 2011.

2.2 Statement of the problem

Food-borne diseases impose a heavy social and economic burden on communities, especially affecting their health care systems, and economic productivity. In the context of international food trade, the imposition of bans in consideration of food safety has resulted in economic losses for exporting countries. To improve market access and maintain their products' competitive edge, the

³¹ United States International Trade Commission: China's Agricultural Trade: Competitive Conditions and Effects on U.S. Exports. Investigation No. 332-518. USITC Publication 4219. March 2011.

³² http://usa.chinadaily.com.cn/business/2011-05/06/content_12460889.htm

³³ <http://online.wsj.com/article/SB10001424053111903885604576487780529072912.html>

exporting countries must aim for the long-term solution of building the trust and confidence of importing countries in the safety and quality of exported food or run the risk of having these goods rejected, thereby resulting in considerable financial loss, and damage to the commercial reputation of both parties³⁴.

The main problems of global food safety are threats to the global food chain from pathogens, fraud, weak regulatory standard, and defrauding the consumer.

2.2.1 The global food supply chain has become increasingly interconnected but the management of the food chain remains fractionated

Food trade is increasingly becoming a global issue with complex and interrelated supply chains, which raises the need to address the question of food safety. A Deloitte survey released in May found that 73 percent of Americans are now more concerned about food safety than they were five years ago – and imported food was among their top areas of concern³⁵.

Imports account for about 15 percent of the total US food supply, including 60 percent of fresh fruit and vegetables and 80 percent of seafood. According to the Government Accountability Office, there are about 189,000 registered foreign sites where food is made for sale in the United States, but the FDA only inspects a tiny fraction of them – just 153 in 2008.

The APEC subcommittee on Standards and Conformance's Food Safety Cooperation Forum and the World Bank have agreed to work together closely on training programs to improve food safety standards and practices in the Asian Pacific region, as well as to facilitate trade.

Sanitary and Phytosanitary Measures Agreement (SPS) has been employed by WTO to deal with trade disputes on food safety. However, some emerging countries' SPS measures have shortcomings as a result of the structure of their regulatory system, including a lack of expertise on the part of the bureaucracy issuing the standards, a shortage of resources, and an apparent lack of national treatment in their enforcement of their SPS standards³⁶. Some developed countries believe that SPS is in favor of lower level standards, thus, can not protect public health and consumers in their countries.

³⁴ Noraini Mohd Othman. Food Safety in Southeast Asia: Challenges Facing the Region. <http://www.searca.org/>.

³⁵ APEC and World Bank sign food safety agreement. May 19, 2011. <http://www.foodnavigator-usa.com/>.

³⁶ United States International Trade Commission: China's Agricultural Trade: Competitive Conditions and Effects on U.S. Exports. Investigation No. 332-518. USITC Publication 4219. March 2011.

2.2.2 Direct and indirect public health threats

Up to one-third of the populations of developed countries are affected by foodborne illness each year, and the problem is likely to be even more widespread in developing countries. The poor are the most susceptible to ill-health. Food and waterborne diarrhoeal diseases, for example, are leading causes of illness and death in less developed countries, killing an estimated 2.2 million people annually, most of whom are children. Diarrhoea is the most common symptom of foodborne illness, but other serious consequences include kidney and liver failure, brain and neural disorders, and death. The debilitating long-term complications of foodborne disease include reactive arthritis and paralysis. About 48 million Americans, one in six, get sick each year from tainted food, including 128,000 who have to be hospitalized and 3,000 who die, according to the U.S. Center for Disease Control and Prevention.

Cost addition to morbidity and mortality are high and has recently become U.S. \$152 billion annually in the U.S. with contaminated produce representing just over 25% of those cost³⁷.

2.2.3 Rising costs of remedies: in addition to losses due to decreased sales, recalls, and destroyed product, companies also face penalties from injured parties seeking compensation through the U.S. court system.

Shortly after being linked to the 2008-2009 of *Salmonella Typhimurium* outbreak, Peanut Corporation of America (PCA) filed for bankruptcy, along with its subsidiaries, Plainview Peanut Co. LLC and Tidewater Blanching Co. LLC. In October of 2009, a \$12 million fund to pay victims of the Peanut Corp. of America Salmonella outbreak was established by U.S. Bankruptcy Court Judge William E. Anderson.

On September 1, 2010, the United States District Judge in the Western District of Virginia approved settlement amounts "in their entirety" for the surviving victims and the families of those who died and ordered the bankruptcy trustee to make distributions³⁸.

2.2.4 Dislocational effects on a multiplicity of trade and economic indicators

In the wake of major foodborne illness outbreaks and product recalls, we see that food safety incidents are major disruptions to our economies and to international trade, and these crises can undermine consumer confidence for

³⁷ Richard A. Holley, Food Safety Challenges within North American Free Trade Agreement (NAFTA) Partners, Vol.10, 2011. Comprehensive Reviews in Food Science and Food Safety.

³⁸ <http://foodpoisoning.pritzkerlaw.com/archives/salmonella-judge-orders-distribution-of-12-million-peanut-corporation-of-america-bankruptcy-fund.html>

months and years to come. Consumers are not the only victims. Unscrupulous producers hurt reputable manufacturers. Take the impact of the melamine milk scandal on the China Dairy industry as an example. Imported dairy products nearly quintupled in volume in 2009, the year after the melamine scandal. Foreign brands now account for half of all infant milk powder sold in China.

There is an absence of uniform standards and compliance procedures for food safety in emerging countries like China which has redounding effects on US agricultural and food exports. Instead of serving to enhance these emerging countries' consumer attraction to higher quality and reliably safe feed and food products from the US, downturns or suspension of food and feed imports from the US are frequently correlated with internal fraud, pathogen contagions, and violations of food safety standards. Additionally, US exports to third market countries and regions containing emerging countries sourced ingredients have had to be suspended in the face of weak links in these Asian countries' food safety standards and enforcement standards, resulting in threats to US brand and market share.

Some multinational food and feed manufacturers using ingredients originating in some emerging countries have frequently seen their products fail to meet international standards, resulting in the loss of market share for their products in third market countries as well as within the US itself.

The world has endured a rash of food safety problems in recent years, resulting in serious loss of consumer confidence and erosion of business profits. These incidents have affected not only the food manufacturing sector and government regulatory systems in the countries with these incidents, but also the global food supply chain, with multiplier effects for other interrelated countries around the world.

Consumer confidence worldwide in food products has been seriously eroded in recent years. Since supply chains have gone global and become increasingly longer and more complex, traceability depends on uniform global standards, certification procedures, and shared risk management procedures.

Lacking a strong food safety system, Chinese consumers often look to prices as a proxy for food quality and safety, and 52 percent of consumers believe that low prices signify poor quality, compared to 16 percent of consumers in the United States³⁹.

2.2.5 Lack of consumer and commercial incentives to underwrite national and international food safety systems

Sharing information, education, and advice among stakeholders across the farm-to-table continuum is essential to enable food safety programs to reduce the

³⁹ United States International Trade Commission: China's Agricultural Trade: Competitive Conditions and Effects on U.S. Exports. Investigation No. 332-518. USITC Publication 4219. March 2011.

incidence of food-borne disease. However, in some countries, there is no powerful consumer lobby to agitate for reform, press lawsuits that punish wayward producers, or lobby the government to pay more attention to consumer safety. On the other hand, some food SMEs have no incentive to invest too much on food safety compliance, because they will not see direct benefit before incidents involve their business.

The problem of food safety is a global concern that is present in the United States, the European Union, China, and elsewhere in the world. Thus far, the global food safety problems have been discussed. There is now a need to discuss the inconsistencies surrounding food safety and why these inconsistencies exist.

3. Regimes: A patchwork of surveillance and enforcement mechanisms

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3.1 Lack of harmonization of standards/ certification

There has been a continuous increase in consumer demand for safe food. This has led to the development of numerous food safety standards. As a result, the growing number of national standards for food safety management has led to confusion, and there is a need for harmonization of these food safety standards. Many leaders throughout the food industry have increasingly recognized the cost and the inefficiencies created by the development of so many standards. Audits are now being used to measure companies' compliance with government regulatory and industry requirements. Neither ingredients suppliers nor retailers and foodservice companies are well served when duplicative standards and audits raise total supply chain costs without enhancing the overall safety of food. There is sound scientific potential for harmonizing standards to meet the needs of these many stakeholders. To eliminate the duplication and overlap among the many standards, government and private-sector stakeholders such as retailers, foodservice companies, processors, shippers, auditors, and standard owners, should work together to explore the potential value of harmonization and greater aligning food safety standards. Harmonization of standards/audits must be transparent with open communication of intent, progress, and conclusions.

Secondly, from the vantage point of trade, there is a debate between the tradeoff of food safety standards and the desire to increase the growth of agricultural exports. The way food safety is addressed in the world trade system is critical for developing countries that continue to rely on agricultural exports. In a fragmented system of conflicting national food safety standards and no globally accepted standards, export prospects for the least developed countries can be severely limited. This suggests that adopting a worldwide standard based on current international guidelines would increase food trade.

The Sanitary and Phytosanitary Agreement (SPS) and the Technical Barrier to Trade Agreement (TBT) both encourage the international harmonization of food standards that are regulated by each member country government. Collaboration between the World Trade Organization (WTO) and the Codex Alimentarius, a science-based organization, concerns the use of international food safety standards in the context of the SPS Agreement. The WTO's SPS Agreement states that "to harmonize sanitary and phytosanitary measures on as wide a basis as possible, members shall base their sanitary or phytosanitary measures on for the international standards, guidelines or recommendations." The agreement names that the joint forces of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) Codex Alimentarius as the relevant standard-setting organization for food safety. The FAO of the United

Nations and the WHO recognized the importance of developing international standards for the purposes of protecting public health and minimizing disruption in the international food trade.

The Codex Alimentarius, a science-based organization, has independent experts and specialists in a wide range of disciplines contributing to its work to ensure that its standards withstand the most rigorous scientific scrutiny. The work of the Codex Alimentarius Commission, together with that of FAO and WHO in their supportive roles, has provided a focal point for food-related scientific research and investigation, and the Commission itself has become an important international medium for the exchange of scientific information about the safety of food. The standards of Codex have also proved to be an important reference point and have been used by the WTO as a dispute settlement mechanism⁴⁰.

Equally as important, non-government organizations and some multinational companies have been making efforts on setting Hazard Analysis Critical Control Point (HACCP) based standards for certifying company's food management system against the requirements. This type of standards is intended to define the requirements for companies that desire to exceed the regulatory requirements for food safety. Each of them claims to be a truly international standard for any business in the entire food chain from "farm to fork" including interrelated organizations such as producers of equipment, packaging material, cleaning agents, additives, and ingredients. The standard combines generally recognized key elements to ensure food safety along the food chain including interactive communication; system management; control of food safety hazards through pre-requisite programs and HACCP plans; and continual improvement and updating of the management system. The development of private standards by large international companies with specific audit requirements is generating further heterogeneity in international food trade.

3.2 Regional differences in enforcement, compliance, and illness surveillance

In the three North America countries, the United States (U.S.), Canada, and Mexico, food safety responsibility falls in the hands of the government. In these countries, food safety is structured in a multijurisdictional manner; therefore, many agencies participate in the regulation of agriculture and public health at a national, regional, and local level. Heterogeneity, in terms of standards, safety programs, and inspection rigor, is consistent among the three tiers of government in these countries. There is a problem existing among small local business in that they cannot always afford to upgrade to the national standards. This, consequently, causes problems with their food's quality and safety. When standards for food marketed within regional (state/provincial) boundaries in a country are lower than national standards for importing the same product,

⁴⁰ <http://www.fao.org/docrep/008/y7867e/y7867e06.htm>

signatories of the SPS agreement are forced to allow imports from foreign countries produced/processed to the least stringent standards applicable for the product in question within that country⁴¹.

Within the European Commission, the illness surveillance system varies. In Denmark, for example, food regulatory agencies and public health agencies work together to create harmonizing safety regulations. The two agencies normally get together every week, but if there is an outbreak they meet more often because of the need to coordinate between the two agencies. In contrast, the United States' Center for Disease Control and Prevention (CDC) does not always work directly with the Food and Drug Administration (FDA) or the United States Department of Agriculture (USDA); consequently, this leads to inefficiencies that could be negated if the United States' agencies cooperated with each other more. Germany is similar to the U.S. in that they have states or, as stated in Germany, *lander*, so Germany also has problems with inefficiencies because of the many different players working at different levels.

The U.S. has been at the forefront for the last 10 or 15 years for its successful illness surveillance system. The U.S. has been able to find outbreaks faster than any other country. Pulsenet, created and used by the CDC, is extremely efficient at detecting foodborne illness outbreaks. The European Union (EU) also has a similar system called Eurosurveillance, but the United States' Pulsenet is much more efficient. The only problem that exists with the Pulsenet system is that it is not available in all the states, which slightly reduces the United States' ability to catch an outbreak. Nevertheless, the U.S. is the most efficient country at detecting outbreaks of foodborne illness. The EU is increasingly moving in that direction, but not all EU countries have such developed illness surveillance systems. It will take the countries that are lagging in the development of their illness surveillance systems time to develop and start their systems⁴².

The current policy environment in the Asia-Pacific region does not give significant impetus to food safety related issues. The formulation and implementation of food safety laws and regulations are often fragmented because the laws and regulations are divided among different ministries and departments⁴³.

In China, regulations to protect the food industry, to protect consumer rights, and to ensure fairness in the marketplace, are often interpreted differently by different provincial and local governments or, in some cases, are simply ignored. These circumstances make it difficult for foreign companies to produce, trade, and sell in China's agricultural sector. Local government autonomy also calls into question whether the programs are effective in achieving central governmental

⁴¹ Richard A. Holley, Food Safety Challenges within North American Free Trade Agreement (NAFTA) Partners, Vol.10, 2011. Comprehensive Reviews in Food Science and Food Safety.

⁴² <http://www.foodsafetynews.com/2011/06/qa-former-food-safety-lead-at-world-health-organization/>

⁴³ Food Safety in the Asia-Pacific Region: Current Status, Policy Perspectives, and a Way Forward. Institute for Global Environmental Strategies, Hayama, Japan. 2010.

objectives. The central government has been accused of having too little power to enforce its regulations; thus, this is often observed in the lack of enforcement of water, pollution, and food safety regulations⁴⁴.

The enforcement of China's food safety laws differs depending on the final destination of the product. Products destined for export markets typically undergo more thorough and stringent inspections to prevent market closures abroad. For example, local Chinese inspection and quarantine agents sample, inspect, and certify 15 percent of every export shipment of a certain garlic processor in Shandong, while processors in other provinces are rarely tested if they do not export⁴⁵.

According to the USTR, "China remains among the least transparent and predictable of the world's major markets for agricultural products, largely because of selective intervention in the market by China's regulatory authorities." As noted, China's national laws are enforced by many different ministries and agencies, and provincial and local jurisdictions may impose separate regulations, especially in the area of food safety. The necessity of dealing with multiple regulators increases the complexity of the system and increases the cost for traders of agricultural and food products.

The enforcement of regulations requiring zero tolerance for pathogens in meat products appears to be selective. The speed of China's Southeast Asian Nations Regional Forum (ARF) system is reported to vary with geopolitical relationships between China and its trading partners. The Quarantine Import Permit (QIP) system administered by the General Administration of Quality Supervision (AQSIQ) appears to be slow at times. Risk assessments that are reportedly based on scientific testing are instead said to be linked to market access for China's exports. Enforcement of regulations reportedly varies by location and according to personal relationships with regulators⁴⁶.

3.3 Overlap and lack of enforcement resources in place

Putting food safety on the political agenda is the first step in reducing foodborne illness; however, even with this step in place, many developing countries and sometimes even developed countries lack the technical expertise, enforcement, and financial resources to implement food safety policies.

⁴⁴ United States International Trade Commission: China's Agricultural Trade: Competitive Conditions and Effects on U.S. Exports. Investigation No. 332-518. USITC Publication 4219. March 2011.

⁴⁵ United States International Trade Commission: China's Agricultural Trade: Competitive Conditions and Effects on U.S. Exports. Investigation No. 332-518. USITC Publication 4219. March 2011.

⁴⁶ United States International Trade Commission: China's Agricultural Trade: Competitive Conditions and Effects on U.S. Exports. Investigation No. 332-518. USITC Publication 4219. March 2011.

In the North American countries, food safety responsibility within government is structured in a multijurisdictional manner. This causes many agencies within the agricultural and public health area and at the national, regional, and local level to participate in the regulation of food and produces overlap among the agencies, which makes the regulation of food more complex and confusing⁴⁷.

In China, the Food Safety Law seeks to create a safer food production system as well as boost confidence among Chinese consumers about the nation's food supply. However, the implementation of the new law has not yet produced these goals. Farmers and food companies are faced with the task of implementing regulations from overlapping government agencies, each requiring inspections. The Ministry of Health released a pamphlet in June of 2009 that instructed government agencies on how to apply the new Food Safety Law, and explained how to implement the new regulations. Regardless, too many government agencies play a role in the law's enforcement. The State Council coordinates national level enforcement; the Ministry of Agriculture supervises the production of agricultural products; the State Administration for Industry and Commerce supervises the transport and distribution of food products; and the Administration of Quality Supervision, Inspection, and Quarantine supervises imports and exports of food products and also regulates food production. Oversight remains shared among disparate bureaucracies: the Commerce Ministry supervises pork slaughterhouses, but beef and poultry slaughterhouses fall under the Agriculture Ministry. The overall point is that there are too many administrative and regulatory agencies regulating the food industry, and this leads to over complexity among the agencies and of the food system.

In the aftermath of consumer illnesses and several deaths in 2008, owing to the presence of melamine in dairy and other food products, awareness and spending on food safety compliance increased in China's agricultural production system. Despite these changes, in general, Chinese food processors reportedly spend less money on regulatory and food safety compliance than most firms in the United States. Any cost advantage this may confer on Chinese agricultural products, vis-à-vis imports, must be weighed against the negative perceptions that Chinese consumers may have about domestic food safety. Food safety compliance costs are therefore likely to increase in order to meet ongoing consumer demands for a safer domestic food supply.

3.3.1 Lack of developed industry structure

The Chinese processed food sector consists of about 40,000 firms. Operations vary dramatically in their use of labor and capital in production, depending on the nature of the end product. Manufacturers source raw agricultural products from the farming sector as inputs into processed food production. The small size of the

⁴⁷ Richard A. Holley, Food Safety Challenges within North American Free Trade Agreement (NAFTA) Partners, Vol.10, 2011. Comprehensive Reviews in Food Science and Food Safety.

average farm and the fragmented geographic location of the farm sector in China results in a variety of models for sourcing raw materials. Small farm sizes typically mean that processors are required to source their materials from a large number of farmers, each supplying a small volume of their input needs. However, higher quality and food safety precautions often require more mechanization and less labor to consistently meet stringent specifications⁴⁸.

China's food system currently is more vulnerable to illness outbreaks because the country's food industry is rapidly developing, and China has a large number of food producers and catering operators that are running their businesses in a small-scale or scattered way. This makes it more difficult for the governmental agencies to conduct and supervise food quality and safety. For example, the problems in China's dairy industry were a result of the rapid growth which was fueled by large investments from multinational dairy firms. Also, China's dairy industry developed a highly modern and concentrated processing sector that obtained its raw materials from millions of small, poor, and uneducated traditional farmers. In addition, the Chinese government supported and encouraged the growth of the dairy industry with little care for the inspection and safety of the industry.⁴⁹

In responding to this pattern, the Chinese government should make efforts to improve supervision and emergency handling capabilities; raise the credibility and personnel quality of the involved enterprises; and severely punish violators.

3.3.2 Lack of enforcement

The impact of food safety legislation may be jeopardized if countries have difficulties in enforcing the application of their legislation. The deficiency of law enforcement is mostly based on a lack of inter-institutional coordination or overlapping competencies, which again, is the result of insufficient legislation. A duplication of regulatory activities in some areas of food control and consequently all concerned ministries are rivals without good cooperation. It may also be caused by a problem of acceptance of new legislation by the private sector, if the infrastructure to implement the legislation does not exist.

Nearly half of responding countries in a survey⁵⁰ about national policy and activities related to food safety identified the cause of problems in their food safety system as food safety legislation that is insufficient, outdated or dispersed in the

⁴⁸ United States International Trade Commission: China's Agricultural Trade: Competitive Conditions and Effects on U.S. Exports. Investigation No. 332-518. USITC Publication 4219. March 2011.

⁴⁹ Melamine in milk products in China: Examining the factors that led to deliberate use of the contaminant, Food Policy, Volume 35, Issue 5, October 2010, Pages 463-470, Changbai Xiu, K.K. Klein.

⁵⁰ Survey of national policy and activities related to food safety in countries eligible for the Codex Trust Fund, World Health Organization and Food and Agriculture Organization of the United Nations, Geneva, 2006.

laws, or inadequate standardization. One problem is that the lack of a food policy in the countries is exacerbated by the absence or delay in the enactment of food safety law. Secondly, with the lack of a national policy on food safety activities, there are no guidelines on how to implement the food safety/control programs. This means that, even if food safety legislation exists, application of the programs is not ensured; consequently, this leads to it being difficult for countries to enforce, harmonize, integrate control systems, and other food safety procedures, such as emergency response, in their countries.

Obviously, competent food inspectors, who are adequately trained and equipped for food inspection, are vital in ensuring consistent, transparent, and effective food inspection. It is equally important that food inspectors are supported by well-planned, well-defined, and scientifically based inspection procedures that are preventive rather than reactive. An integrated surveillance system, like other components of a food safety program, should also be coordinated well with concerned parties.

Outdated regulations and models are another reason that countries have weak enforcement of food regulation laws. In most Southeast Asia countries, the current inspection approach emphasizes the visual inspection of food facilities, end-product testing, followed by sanctions on responsible parties when the test results contravene the provisions of the food law⁵¹.

Most of China's food processing industries are comprised of small processors. These small processors have little access to technology, and they do not have or are unaware of the food safety laws that have been created. Also, they have poor funds, rely on opportunism, and move around a lot. This creates a problem when regulators try to educate and enforce food safety standards.

Insufficient inspection is also a factor resulting in lack of enforcement. In China, provincial governments carry out enforcement. In many instances, local authorities require that annual quality supervision reports be completed by food processing facilities and sent to the authorities, but unannounced safety inspections, food testing, and site visits, to monitor quality standards, are rare⁵². China also does not have enough enforcement agents, with fewer than one food inspector for every 10,000 people. Instead of systematically identifying the safety risks and forcing producers to prove that they have eliminated them, Chinese inspectors follow a long-discredited strategy of randomly sampling and testing products.

⁵¹ Noraini Mohd Othman. Food Safety in Southeast Asia: Challenges Facing the Region. <http://www.searca.org/>.

⁵² United States International Trade Commission: China's Agricultural Trade: Competitive Conditions and Effects on U.S. Exports. Investigation No. 332-518. USITC Publication 4219. March 2011.

In addition, some food in China is simply unregulated. Pork accounts for two-thirds of the meat eaten by Chinese consumers, but only half of it goes through slaughterhouses that are subject to inspection. The rest comes from pigs slaughtered in backyards, villages, or markets, and is essentially untested.

3.3.3 Lack of coordination

The main problem that exists in regulating food in China is the way the national administration functions. The administration experiences difficulties as a result of the poor coordination, collaboration, and communication among the various responsible ministries, departments, and agencies. Hence, the agencies responsibilities occasionally overlap.

Furthermore, the lack of cohesion and communication between the laws passed at the national level and implementation at the local level leads to laws not being implemented correctly or efficiently. Also, the fear of increased unemployment in rural areas makes local authorities reluctant to close food facilities that are operating with food safety violations. Moreover, corruption leads to corrupt deals between food processors and government, especially local government.

3.3.4 Lack of infrastructure and personnel

Another major problem, according to a WHO survey⁵³, is that developing countries suggest that they lack appropriate infrastructure to ensure food safety. They mentioned the non-existence of an established, functional, and regular safety and quality control system and the need to improve the existing laboratories. This included insufficient facilities for accreditation and verification mechanisms and monitoring and risk analysis. Furthermore, a lack of trained personnel in the food industry was also cited as a reason that countries were unable to address the problems of food safety.

In China, since the implementation of the Food Safety Law in 2009, provincial agents from the Chinese Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ) and Chinese Inspection and Quarantine (CIQ) have reportedly increased inspections and compliance costs for food companies, and the government's funding of food safety initiatives is reportedly increasing in a number of ways. Although the financial impact of investments to build food testing laboratories and install equipment to meet stricter food safety controls varies, the estimates are that per-unit costs throughout China's food product system may increase by about 1 percent⁵⁴.

⁵³ Survey of national policy and activities related to food safety in countries eligible for the Codex Trust Fund, World Health Organization and Food and Agriculture Organization of the United Nations, Geneva, 2006

⁵⁴ United States International Trade Commission: China's Agricultural Trade: Competitive Conditions and Effects on U.S. Exports. Investigation No. 332-518. USITC Publication 4219. March 2011.

China's SPS measures have shortcomings as a result of the structure of its regulatory system, including a lack of expertise on the part of the bureaucracy issuing the standards, a shortage of resources, and an apparent lack of national treatment in China's enforcement of its SPS standards⁵⁵. Though the Chinese government employs some 150,000 food inspectors, experts say too many employees lack the technical and scientific skills needed to do their jobs well. In response to the poor publicity and because of a lack of qualified inspectors, the government closed a number of small milk collection points so it could improve inspection at higher-volume ones.

Moreover, in the case of the United States, the Food Safety Modernization Act (FSMA) pledges the Food and Drug Administration to science-based decision making. Science underlies everything the FDA does to serve the public health, so infrastructure is needed to effectively oversee the translation of breakthrough discoveries in science into innovative, safe, and effective products and life-saving therapies⁵⁶. The United States' Congress is currently trying to cut the FDA's budget, but the FDA is extremely important for securing the safety of food that enters and leaves the United States.

3.3.5 Lack of financial resources

A lack of financial resources such as a limited budget from the government often results in the lack of or weak national capacity. This is understandable in developing countries, but this is also the case in developed countries, unfortunately.

In the United States, the FSMA called for updated compliance and enforcement tools; new adequate funding to allow for inspections; examinations, sample collections, and analysis; and updated systems, including IT support⁵⁷. "FDA's job is much like national defense -- essential to our nation's well-being -- and providing protection that is too often taken for granted until a crisis occurs," said Richard Buckley, who also serves on the board of The Alliance for a Stronger FDA. "Now is not the time to cut the FDA, even with economic pressures to decrease the deficit. A strong FDA is welcomed by the industries it oversees and spurs innovation that drives our economy." However, lawmakers in the House of Representatives sparred over proposed cuts to the U.S. Food and Drug Administration in an appropriations markup. A proposal unveiled by House Republicans sought \$285 million in cuts to the FDA in Fiscal Year 2012, an 11.5

⁵⁵ United States International Trade Commission: China's Agricultural Trade: Competitive Conditions and Effects on U.S. Exports. Investigation No. 332-518. USITC Publication 4219. March 2011.

⁵⁶ Globalization forces FDA to prioritize global food safety. April 22, 2011. <http://www.foodnavigator-usa.com/>.

⁵⁷ Globalization forces FDA to prioritize global food safety. April 22, 2011. <http://www.foodnavigator-usa.com/>.

percent reduction from FY 2011, just as the agency is working to implement a sweeping new food safety law.

A recent report from the United States Government Accountability Office (GAO) on imported seafood safety oversight, which called FDA's system limited and called for more testing, was cited as the most recent example of why Congress should support strengthening FDA's oversight of food products and the implementation of FSMA. However, representatives of Congress emphasized the austere budget has been tight for all. Consumer and regulatory advocates blasted the proposal as a threat to public health.

Lack of financial resources to support fundamental research has an impact on food trade, and it is especially true for developing countries. A national health standard is illegal under the SPS Agreement if WTO decides that it is not "based on scientific principles and is maintained without sufficient scientific evidence." In making this judgment, WTO examines the extent to which the country has done a scientific assessment of the risk to "human, animal, or plant life or health."⁵⁸ Most of the developing countries have limited budget for scientific research on basic food microbiology, food-borne illness epidemiology, and risk analysis. This research is requested by the SPS. Otherwise, arbitrary regulations and standards might be set, which lead to disputes with the countries' food and agricultural products trade partners.

3.4 Insufficient collaboration platforms for public/ private sector

Food safety extends beyond any one company or country; it ultimately requires the private and public sectors to combine efforts, resources, and knowledge toward a shared vision of food safety with more unified actions. FSMA calls for the sharing of responsibilities between public and private sectors, with the primary responsibility for prevention resting on the shoulders of food producers and processors. Non-governmental organizations (NGOs) and food industry associations play an important role during the regulations, programs, and guidelines setting. These actors often advocate on behalf of consumers and some food sectors, and they provide a platform for the communication between government and the private sector. However, the FDA budget cutting implied that these collaboration platforms are not sufficient. Moreover, some international organizations can do more work to provide platforms for multinational companies, exporters, and importers to connect with more foreign countries, which they originally would not have been able to do. This platform will help these companies, importers, and exporters to understand how others around the world achieve collective outcomes from shared values.

Industries, scientists, and governments must work together to ensure that the food safety system is effective. Sharing information, education, and advice

⁵⁸ http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm

among stakeholders across the farm-to-table continuum is essential to enable food safety programs to reduce the incidence of foodborne disease. To achieve this strategy, an awareness campaign on food safety and education materials for consumers and the food industry is needed. This requires that the information, the communication channels, and the approaches have to be tailored to suit each different audience, especially the high-risk consumers. Additionally, officials involved in national food control programs need ongoing training to keep up with the international advances in science and technology, the general trends in the food trade, the legislation being created, and other developments such as emerging food safety problems⁵⁹.

The Chinese Food Safety Law from 2009 is an improvement from the previous ineffective food safety system, but the law does not help to improve the important problem of overlapping responsibilities for regulating food manufacturers. This is a major problem between the private and public sectors because the lack of clear communication and clear enforcement lead to the insufficiencies in China's food safety law, which leads to unsafe food production. Moreover, a successful food safety regulation structure must include the active collaboration of the government, consumers, food safety technology leaders, and the food industry. The United States' food safety system is highly dependent on voluntary industry participation, which is motivated by the need to ensure consumer confidence. Food is also kept safe by strong consumer safety laws, an independent legal system, free media, and civil society organizations. The strong independent associations will address their collective interests in ensuring food safety and help build a self-regulating private sector. Some governments restrict the news media coverage about food safety stories that might cause panic or would substantially decrease citizens' faith in the government system. Consequently, these food businesses have no incentive to fix their food safety problems. If these stories were allowed to be reported, it would cause the food businesses to be held accountable to their customers because these businesses would have to regain the trust of their people.

Chinese food safety regulators are reaching out to international partners to discuss issues of mutual interest. The fact that both the international partners and China need to strengthen their food inspection and regulatory systems emphasizes the ample opportunity for collaboration between the governments and private sector companies.

⁵⁹ Noraini Mohd Othman. Food Safety in Southeast Asia: Challenges Facing the Region. <http://www.searca.org/>.

4. Food Protection and Food Fraud – Enabling a Shift to Prevention

John Spink, PhD, Michigan State University

4.1 Introduction

When considering reducing and controlling global food safety threats from a supra-national perspective, the reactive intervention and response focus becomes impractical or potentially impossible. A challenge for the food response infrastructure of countries and companies in addressing growing issues such as Food Fraud and Food Defense is that the focus has been on food science, microbiology, and epidemiology based intervention and response. Advances have been made in food quality and safety through preventative programs such as Good Manufacturing Practices, quality standards such as ISO 9000 and programs such as Six Sigma, and by HACCP. To broaden the lens to cover all Food Protection, the concepts of Food Fraud and Food Defense require a fundamental shift in perspective. Food Fraud and Food Defense deal with intelligent adversaries, human who are actively seeking to avoid detection in our preventative programs and to inflict some kind of harm. These vulnerabilities occur even in the best and most secure supply chains and countries. The risk is not from a lack of capable guardians and hurdles but in the rapid growth of gaps and the evolutionary tactics by the adversaries. The risk is also from fraudsters using unconventional adulterants that are not expected to be in food, the fraudster's ability to stealthily slip product into the supply chain, and often the quality of the fakes that lead consumers or users to not perceive a problem. This chapter will review the concepts of Food Protection and then introduce the topic and countermeasures for the emerging discipline of Food Fraud, which includes economically motivated adulteration, intentional adulteration, intentional contamination, food counterfeiting, and smuggling.

The countermeasures are trying to create customer confidence through a safe and stable supply of food. Work has been conducted on making food safe (e.g. cooking, processing, and testing) but the real global goal is to make safe food (e.g. preventative programs and reducing vulnerability through programs such as HACCP and GMPs). The saying is “we’re not trying to make ‘food safe,’ we’re trying to make ‘safe food.’” This preventative approach is effective in both reducing costs of production and manufacturing and also in reducing costs from recalls and lost product.

There have been a number of private industry and non-governmental organization efforts that emphasize a growing focus on Food Fraud.

GMA Consumer Product Fraud Report. In January 2010, the Grocery Manufacturer's Association (GMA) published a report on Consumer Product Fraud which had an original intended focus on Economically Motivated Adulteration.(GMA, 2010) This was the result of the GMA Economic Adulteration working group that was focusing on a broad range of consumer product fraud but

did explicitly review details of food fraud incidents, industry countermeasures, and the beginning of a risk based approach.

USP/FCC Food Ingredient Intentional Adulteration Expert Panel. In 2010, the Food Chemicals Codex, through the U.S. Pharmacopeia parent organization, created the Food Ingredient Intentional Adulteration Expert Panel to specifically support industry through USP/FCC standards development.(USP, 2009) The goal was to create monographs (a specification defining the product including tests to verify quality acceptance criteria including authenticity) and reference standards (a reference material used to verify the product).(USP, 2011a, 2011b) The Expert Panel specifically focuses on Food Fraud and intentional adulteration with the primary goal to implement more effective intervention and response, or detection, standards. It is important to note that the selection of tests, and even the creation of a Food Fraud test, can lead to deterrence.

ISO Technical Committee 247 Fraud Countermeasures and Controls. In 2009, the International Standards Organization created Technical Committee 247 Fraud Countermeasures and Controls (ISO TC 247) to focus on counterfeiting but the group quickly expanded to all types of fraud, including Food Fraud. (ISO, 2010) The initial work on Authentication Tools focused on product counterfeiting by Project Committee 246 or PC 236; the broader TC has included clear Food Fraud related issues such as country-of-origin fraud. Active liaisons with other TCs deal with some aspect of fraud such as ISO 22000 Food Safety and ISO 28000 Supply Chain Security, as well as related concepts such as ISO 9000 Quality Management and ISO 31000 Risk Management. The exact application to Food Fraud is currently undefined but under review.

IFT Workshop on Intentional Food Adulteration. In 2010, the Institute of Food Technologists created a pre-annual-conference workshop on Intentional Food Adulteration to address industry need to understand and respond to intentional adulteration. This workshop continued in 2011. In addition to other seminars and symposiums, this is evidence of the interest in Food Fraud by the professional associations and industry members.

There have been a number of activities that demonstrate the growing need for a focus on more general Food Protection as well as specifically the discipline of Food Fraud.

FDA Economically Motivated Adulteration Open Meeting. In May 2009, FDA held an open meeting soliciting information on Economically Motivated Adulteration (EMA) across all FDA products including food, drugs, biologics, medical devices, and animal feed. (FDA, 2009; Spink, 2009; Spink & Harte, 2008). EMA is a subcategory of Food Fraud and was defined as, "...the fraudulent, intentional substitution or addition of a substance in a product for the purpose of increasing the apparent value of the product or reducing the cost of its production." (FDA, 2009) Also, "EMA includes dilution of products with increased quantities of an already-present substance to the extent that such dilution poses a known or possible health risk to consumers, as well as the addition or substitution of substances in order to mask dilution." This meeting was the direct

response to a number of high-profile, international food and drug fraud incidents. This was the meeting, though focused explicitly on EMA, which initiated the Food Fraud research and focus.

Food Safety Modernization Act (FSMA). In January 2011 the Food Safety Modernization Act (FSMA) has a focus on prevention and includes eleven mentions of “intentional adulteration” – which includes Food Fraud, smuggling, tampering and terrorism.(Elkin, 2011; Green, 2011)} The FSMA states that companies should “...ensure their plans account for all reasonably foreseeable hazards...” but the act does not really define “intentional contamination.”(Food Safety Modernization Act (FSMA), 2011) For this chapter, a key mandate is for FDA to produce a draft guidance document on Intentional contamination. In support of the Food Fraud focus and the shift to prevention, the important FSMA points are an emphasis on public health and protection, public-private partnerships, inter- and intra-country collaborations, prevention, and Food Fraud (“intentional contamination”).

FDA Pathway to Global Product Safety and Quality (PGPS). In July 2011, the US FDA released the draft guidance document entitled Pathway to Global Product Safety and Quality (PGPS) which specifically identifies “...fraud, and product adulteration.” (FDA, 2011c) This report states the need for all countries to work together and that “...the U.S. cannot work alone to ensure the safety of food imported from other countries.” The report also states “Just as public health leaders have long recognized that disease knows no borders, FDA in crafting its vision for the next decade knows that product safety and quality no longer begin or end at the border.” The first key building block is “Assembling global coalitions of regulators dedicated to building and strengthening a worldwide product safety net” to address Food Fraud given the “...ever more sophisticated threats of fraud, product adulteration, and even terrorism.” It is significant that the report states the even with unlimited resources, the agency would not be able to inspect all foreign food and drug manufacturing establishments. The report only briefly addresses that even if facilities are inspected, fraudsters will try to actively evade detection and circumvent agreed-to processes (or as they state “...intentional efforts by some importers to manipulate the system and avoid scrutiny”). The draft guidance document emphasizes the statements in the 2011 US Food Safety Modernization Act regarding explicit responsibility of the private industry importers to assure preventative controls, but the PGPS includes 15 mentions of leveraging “private-sector third parties” for certification. This is both a risk (increased scrutiny and liability) and an opportunity (collaborate, consolidate, and outsource) and does specifically lend credence to initiatives by the likes of ISO and GFSI.

FDA Food Anti-Smuggling Strategy. In July 2011, the FDA announced a food anti-smuggling strategy in coordination with the Department of Homeland Security (DHS) (DHS includes Customs and Border Protection [CBP] as well as the investigative arm Immigration and Customs Enforcement [ICE]), which is a component of Food Fraud.(FDA, 2011b) This strategy is a direct response to “Section 309 Smuggled Food (a) In General” that states this strategy must be in

place within 180 days of passing the bill.(Food Safety Modernization Act (FSMA), 2011) The FMSA and strategy prioritize actions such as a press-release if the smuggled food is identified, would be dangerous to public health, and believed to be in commerce. Section 309(e) defines smuggled food as any food that a person introduces into the United States through fraudulent means or with the intent to defraud or mislead. Specific additional new countermeasures and resources were not identified. The significance of the implementation of this strategy is that the agencies are reacting to the requirements of the FSMA – over time the actual investigations and actions can be judged.

FDA New Dietary ingredient Notification and Related Issues. In July 2011, the FDA issued a new draft guidance document on New Dietary Ingredient (NDI) Notification and Related Issues which increases the FDA ability to identify Food Fraud.(FDA, 2011a) This is another response to the FSMA.(FDA, 2011a) Specifically, this emphasizes pre-market approval for NDI's, and product that is not registered will be considered adulterated. This will enable the FDA to more efficiently monitor and inspect all food and dietary supplement products since can more clearly indentify and enforce technical variables and not only rely on extensive, complex tests and analysis. This does directly address Food Fraud by increasing the capabilities of the guardians and implementing another hurdle for the fraudsters to overcome.

USDA/FSIS Marking, Labeling, and Packaging to Reduce Counterfeiting. In June 2011, the US Department of Agriculture's (USDA) Food Safety Inspection Service (FSIS) issued a request for comments on a revision to regulatory requirements for marking, labeling, and packaging within their regulatory responsibility for meat, poultry, and egg products. (FSIS/USDA, 2011) The regulation specifically identifies the goal to reduce "counterfeiting" of these marks – Food Counterfeiting is a type of Food Fraud. This revision to the regulation mandates that to control the printing of USDA certifications, they are requiring registration of the companies that make the marking equipment. Those entities using the equipment must also register their equipment. This will control who is registered to apply the USDA certificate to packages and will increase the efficiency of the USDA inspectors by enabling them to identify and enforce technical variables not only rely on extensive, complex tests and analysis. It will now be illegal to manufacture or possess unregistered USDA certificate marking equipment. This is similar to the intellectual property rights laws that make it illegal to possess equipment or labels for manufacturing counterfeit products. This revision is another example that addresses Food Fraud by making it illegal to manufacture or possess equipment that could produce a counterfeit (unauthorized) USDA mark.

There has been a government, non-governmental, and private effort to shift efforts to prevention of Food Protection issues such as Food Safety and Food Fraud. Recently, Food Fraud incidents have raised the profile of this public health vulnerability in the eyes of consumers, companies, and countries alike. Laws are beginning to mandate prevention and regulations are beginning to show results of this intent. Ultimately, legal liability (lawsuits) or government actions (laws and regulations) will dictate the development of the definitions of

the terms, formalize risk assessments, and develop harmonized and standardized solutions.

4.2 Food Protection

The Food Protection concept includes prevention, intervention and response and covers Food Quality, Food Safety, Food Fraud, and Food Defense. The FDA created the Food Protection Plan which stated, “The plan focuses FDA’s efforts to prevent problems before they start. It employs risk-based interventions to ensure preventive approaches are effective. This was one of the first major US food agency statements that prioritized prevention. It provides for a rapid response when contaminated food or feed are detected, or when there is harm to humans or animals.” (FDA, 2007)

The logical process is to try to prevent an incident in the first place, but that can only be achieved after a contaminant and process is known.(Spink & Moyer, 2011b) A new incident may enter the process in the intervention stage (i.e. what is it) and then shift to the response stage (i.e. public-private partnership engagement to figure how to identify the contaminant and most efficiently remove it from the supply chain). Once the contaminant is identified and the delivery mechanism is identified, then the supply chain partners can formulate a preventative strategy.

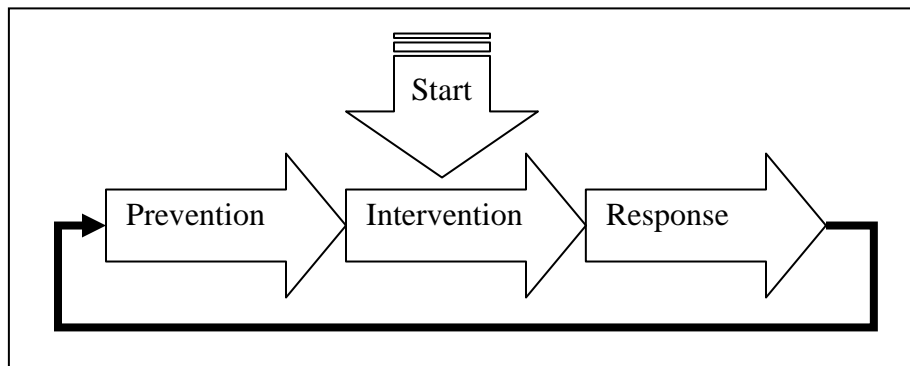


Figure 1. Food Protection Plan Progression (Spink & Moyer, 2011b)

The Food Risk Matrix was developed to define the components of Food Protection including Food Quality, Food Safety, Food Fraud, and Food Defense.(Spink & Moyer, 2011b) The matrix discusses the motivation of the fraudster but not the effect. Any product that is adulterated is dangerous, and the typical agency intervention and response are activated regardless of the cause. The only difference in the response is whether the incident is from traditional food contaminants (e.g. Salmonella or pesticide residue) or more dangerous our unknown Food Defense sources (e.g. poisons or pathogens such as cyanide or anthrax).

Food Quality	Food Fraud (1)	Motivation Gain : Economic
Food Safety	Food Defense	Harm: Public Health, Economic, or Terror
Unintentional Intentional Action		

(1) Includes the subcategory of economically motivated adulteration and food counterfeiting

Figure 2. The Food Protection Risk Matrix (Spink & Moyer, 2011b)

Food Quality.

“Food Quality focuses on the unintentional spoilage or deterioration of food that only results in economic loss, such as an unsalable or down-graded product. This could be due to specific product characteristics deviating from industry reference standards, including expected physical or chemical attributes. Similarly, food fraud can result in economic losses in the form of unsalable product, lower margins, lost tax revenues, or brand equity damages from recalls or consumer concerns. If a food quality incident leads to a product that is harmful, then, although the *cause* is unintentional, the *effect* makes it a food safety incident.” (Spink & Moyer, 2011a)

Food Safety.

“Food Safety focuses on the unintentional contamination of food by known ingredients, organisms, mishandling, or processing. Food fraud differs since it is an intentional act perpetrated for economic gain. Food fraud also differs from food safety since the types of adulterants are unconventional and may only become known once encountered. Food fraud and food safety are very similar in that both can lead to public health risks.” (Spink & Moyer, 2011a)

Food Fraud.

“Food fraud is a collective term used to encompass the deliberate and intentional substitution, addition, tampering, or misrepresentation of food, food ingredients, or food packaging; or false or misleading statements made about a product, for economic gain. Food fraud is a broader term than either the economically motivated adulteration (EMA) defined by the

Food and Drug Administration (FDA) or the more specific general concept of food counterfeiting. Food fraud may not include “adulteration” or “misbranding,” as defined in the Food, Drug, and Cosmetic Act (FD&C Act), when it involves acts such as tax-avoidance and smuggling. The economic motivation behind food fraud is distinctly different from those for food safety, food defense, and food quality. The *cause* of an event might be food fraud, but if a public health threat becomes involved, the *effect* is an adulterated product and a food safety incident. All of this is under the umbrella of food protection, which encompasses food fraud, food quality, food safety, and food defense.”(Spink & Moyer, 2011a)

Food Defense.

“Food Defense is a collective term that encompasses preventing and recovering from an intentional and deliberate contamination or tampering of food, motivated by either economic gain or public health harm. Food fraud differs in that the motivation is *only* for the perpetrator’s economic gain.”(Spink & Moyer, 2011a)

Food Protection is the overall concept of reducing and controlling the public health and economic threats for all food products. Understanding the cause or motivation of each of the factors provides a framework for selecting efficient and effective detection and deterrence countermeasures.

4.3 The Special Issue of Food Fraud

General criminal and economic fraud is clearly present and understood and is part of overall economic business fraud risks.(PriceWaterhouseCooper, 2007) Food Fraud poses a unique challenge to Food Protection since the human adversaries are intelligent, resilient, clandestine and are stealthy at avoiding detection. In fact, they actively seek to understand the detection countermeasures to adapt their schemes to capitalize on gaps. We must assume an extreme case, in which the counterfeiters are criminals not concerned with breaking laws, sociopaths not concerned with cheating others, and/or not educated about the inherent public health or safety dangers.(Spink, 2011c) The fraudsters and fraudster networks are often complex, extremely technically advanced, and able to product very high quality product. These networks are often affiliated with trans-national organized crime groups, extremely well-funded, and unlike unsophisticated criminals they are often hard to catch since they are often disciplined. The modern criminal networks for perpetrating a specific type of fraud, disband after the illicit activity, return to their legitimate cover operations, and then reform to perpetrate a future fraud. These are not vertically oriented, hierarchical structures in which one broken link causes the entire network to crash. There are a near infinite number of fraudsters and a near infinite number of types of fraud, so we cannot incarcerate our way to safety. The cause or motivation for Food Fraud in the global supply chain is the opportunity to profit by circumventing some systems or cheating the victims in some way. The

opportunities for the fraudsters are motivated by financial opportunities created by a product and/or brand name that are in demand combined with a guardian and hurdle gap – an Achilles heel that can be exploited for financial gain.

To understand the risk in more detail, there are three types of Food Fraud public health risks: direct, indirect, and technical. (Spink & Moyer, 2011b) Direct Food Fraud Risks are when the public is in immediate or imminent danger, such as ingesting an acutely toxic or lethal contaminant. Indirect Food Fraud Risks are when the public is at risk through long-term exposure or the lack of benefit (such as vitamins or nutrients). Technical Food Fraud Risks are non-material in nature, such as documentation fraud or smuggling of genuine products.

Table Food Fraud Components (Spink, 2011b)

- Action: Intentional adulteration
- Motivation: Economic Gain
- Effect:
 - Economic ***Threat***
 - Public Health ***Vulnerability or Threat***
- Examples
 - Peanut Corporation of America selling known contaminated product
 - Diluted or extra virgin olive oil
 - Melamine in pet food and infant formula

To further understand the underlying motivation of the fraudster, it is important to deconstruct and understand the underlying fraud opportunity. It is efficient to examine this by engaging the Crime Triangle and the related concept of The Chemistry of The Crime. (Clarke, 1997; Felson, 1998). The Crime Triangle is based on three elements of the crime opportunity which are the victim including consumers, retailers, brand owners, or governments who do not receive tariffs or taxes; the fraudster or the criminal; and the guardian and/or hurdle gaps. Adapting the elements to refer to fraudsters rather than criminals is important since the action is often not a crime or even a civil violation – actually, in some countries, the action may not even be considered fraud. Also, while there are many capable guardians and hurdles, the very nature of the emerging and evolving fraud continually creates new gaps – in fact, the very best practices and process refinements address some gaps that could inherently create new gaps. As the elements grow – or as the legs of the triangle grow – the area of the triangle grows and the fraud opportunity grows. It is also important that the risk be referenced as the “fraud opportunity” and not the “crime opportunity” since, as mentioned, the action is often not crime but also, could be vulnerability and not necessarily an actual incident. The goal is to understand how and why there is a fraud opportunity so countermeasures can be selected that precisely address specific types of fraud and fraudsters.

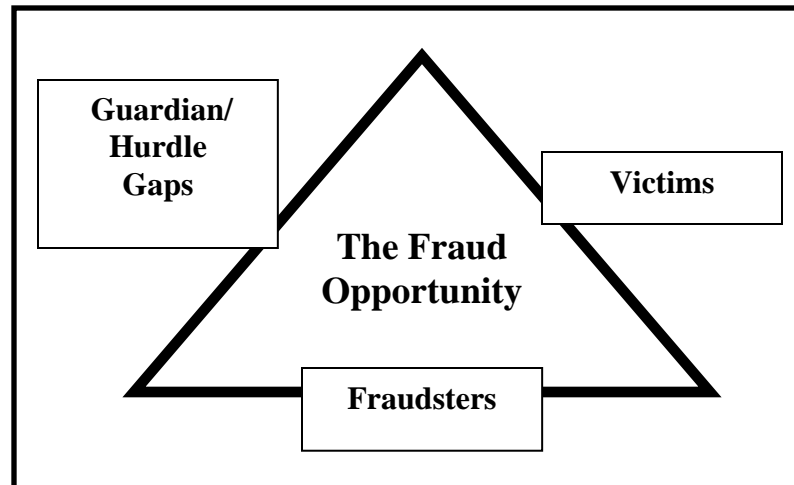


Figure 3. The Crime Triangle [(Spink, 2007) Adapted from (Felson, 1998)]

Food Fraud is a unique Food Protection issue that requires a unique food industry approach engaging behavioral sciences such as criminology and social anthropology.

4.4 The Role of the Countries

The efficient and swift movement of material goods and food across borders and around the world is the very foundation of the world economy, whether for developed- or developing-countries. Government enforcement systems are based on physical borders which are often only minor hindrances for the trans-national organized crime organizations. In many cases, the borders and national laws are used to reduce suspicion (or increase the complexity of investigations) to shield multiple components of the fraudulent activity from detection by conducting different parts of the operations in different jurisdictions.

Some key concepts about the illicit trade are noted in *Illicit: The Dark Trade* by Moises Naim. He states that in general illicit trade:

- Is driven by high profits, not low morals;
- Is a political phenomenon—illicit traders cannot prosper without help from governments or accomplices in key public offices;
- Is more about transactions than products—we are so accustomed to parsing the illicit trades into separate product lines;

- Cannot exist without licit trade—all illicit businesses are deeply intertwined with licit ones—traffickers have strong incentives to combine their illicit operations with legitimate business ventures;
- Involves everyone—someone is buying; and
- Governments can't [enforce and prevent this] alone.(Naim, 2005, p. 239)

He also stated that illicit trade is so complex and profitable that it is, "...a new form of politics in the twenty-first century."(Naim, 2005, p. 9) The role of enforcement and prosecution is also often limited: for example, the US Central Intelligence Agency stated the existence of "stateless zones" in 50 countries—regions where there was little central government control. (Central Intelligence Agency CIA, 2004) The nature of the fraud and fraudsters is such that, other than when there is state-sponsored overt counterfeiting, this is so complex and technical that the fraud is often very difficult to control in developing-countries or rapidly expanding economies.

There are "good guys" in the same country as "bad guys." Deterring the fraud activity is not about focusing on intellectual property rights and not really about food products, but focusing on the "bad guys." The goal is to reduce the prevalence of Food Fraud in the first place not to see how many "bad guys" we can catch.(Spink, 2011d) The goal is to focus on many ways that all parties can focus on reducing the fraud opportunity. To explain the use of the term "bad guys," in many successful bi-lateral and multi-lateral international engagements, it has been a best practice to begin addressing issues that are clearly agreed to be fraud (e.g. diethylene glycol in cough syrup, medicines with no active ingredients, food with toxic levels of pesticide residue) and start by focusing on clear criminals (thus, emphasis on the term "bad guys"). Once entities can begin to effectively work together, the focus can shift to other areas where there may be less agreement.

One way to grow inter- and intra-country trust is to create public-private partnerships. This is where industry and agencies – including agencies from multiple countries – meet to address common problems. This is common in the U.S. and often yields successful results of open communication, clearer understanding of the problem, and collaboration on identifying efficient solutions. Of course there are often major breakdowns in the initiatives, but if the problem is clearly identified, if the problem is important to all parties, and if the parties are genuinely interested in solving the underlying problem, then these partnerships can be very effective and efficient for all. The goal is to open communication to create laws and regulation that meet the needs of the public (including the public organization of the government) but also do not stifle commerce.

Laws and regulations are necessary for commerce to function efficiently. To maximize efficiency, compliance with the regulations facilitates smooth transactions, which reduce costs due to uncertainty or risk. "Trust in compliance also avoids cost that might otherwise be borne by the parties to the transaction."(deKieffer, 2010, p. 16) Key to this is the expectation of

compliance, that the rules will be followed, and that the rule-breakers can be stopped. [...] The enforcement and prosecution of laws in *all* countries are important but are being strained as globalization leads to more production being consolidated while distribution is expanding farther around the world.(Kochhar, 2004, 2008; Laudicina, 2005) In reality, it may be more dangerous to buy a product from a sloppy local manufacturer than from a trusted supplier half-a-world away. [...] Laws and regulations naturally lag in a rapidly changing marketplace.(Spink, 2011a)

An example of an effective public-private partnership is the US State of Michigan's Agriculture and Food Protection Strategy Steering Committee. This group was formed through the support of a Department of Homeland Security (DHS) grant to support State Food Defense efforts after the terrorist attacks on "9/11". The committee was created to address the clear and present danger to all stakeholders. The committee had a very clear objective, to address the agriculture and food terrorism threat and to implement efficient and effective laws and regulations that would protect all. While there are many task forces and groups that are effective on a national scale, a best practice for this steering committee is that all the members were geographically located close together and could commute to and from the meetings in the same day. Another best practice was the active role of a research university, Michigan State University, which hosted the meetings and included many scholars in the sessions. The role of the University both helped direct new research projects and, more importantly, brought an early science- and evidence-based perspective to the proceedings. Other important participants are consumer advocates. These groups engage throughout the process and not only represent the voice of the consumer but provide science- and evidence-based insight on the common concerns and fears. The insight provided is very important in the shaping of laws and regulations, and probably more importantly, effectively communicating to the consumers. Over a ten year period, the committee members have formed strong relationships – true trust – that have led the State of Michigan to implement some of the most efficient and effective Food Defense and Food Safety laws. The group is beginning to address Food Fraud and intentional adulteration.

4.5 Conclusions

The role of countries in controlling and reducing Food Fraud – whether producer or consumer – is to engage international public and private partners to reduce the overall fraud opportunity. These countermeasures must consider the political and judicial capabilities of the governments, the needs and concerns of the citizens, and the social anthropology of the manufacturing and consumer marketplace. International standards and third-party organizations have an increasingly important role in controlling the trans-national public health threat of Food Fraud.

Some overall concepts are important to understand and address:

- It is impossible to inspect all imported or domestic products. After a crisis, there is often consumer or industry outrage at the mere presence of the

fraudulent or dangerous products, and there are often calls for increased inspection. While increased inspection may be warranted, inspecting all products is not practical. Actually, considering fraudsters, inspecting all products is also not possible – the risk will be reduced initially but if the fraud opportunity persists, the fraudsters will continue to find ways to avoid detection.

- It is impossible to inspect all international food manufacturing facilities. After a crisis involving imported products, there is often a call for inspection increases of all international food manufacturing facilities. Again considering fraudsters, even when US domestic facilities are repeatedly and competently inspected and certified, fraudsters find ways to circumvent the systems.(Spink, 2011a) The types of fraud can range from very simple and easy to extremely complex and technical.
- Focus on reducing the fraud opportunity. The efficient solution is to shift some focus to reducing the public health risk in the first place. This has been successful in Food Safety for programs such as HACCP and quality programs such as Six Sigma. Detection in the form of intervention and response is still vital. If efficient prevention is allowed to occur there must be a realization we are reducing vulnerability, and thus, a reduction in enforcement and prosecution volume is not a sign of failure.
- The Food Fraud strategy:
 - Intelligence gathering. Continue to research the problem and solutions, as well as the nature of emerging fraud and fraudsters. The analysis of the “intel” should be both quantitative (what risks do the data define) and qualitative (where is there a new vulnerability so where might there be fraud), as well as rely on expert opinion such as suspicious activity reports. In addition, broad, random marketplace monitoring (such as an early warning system) may catch the next widespread, systemic adulteration before there is a mass public health event.
 - Create a public forum. There should be expanded formal engagements on the topic to create the opportunity for engagement and information sharing.
 - Create awareness and harmonization. The awareness can be distributed by domestic or international conferences, workshops, publications, and curriculum such as in graduate programs. Harmonization should occur both domestically and internationally by standards, certificates, and multi-lateral agreements. This will provide sharing of best practices and create world-wide systems and processes that form a more seamless net that reduces the fraud opportunity. Some key points are developing leadership and collaboration initiatives, furthering Food Safety/ Food Fraud/ Food Defense university curriculum to expand the insight for current leaders and to prepare future leaders, encourage the evolutionary

role of science and academia to address these problems and from new perspectives, expand the perspective to include all Food Protection and even broader supply chain management, seek public-private partnerships that engage consumer advocates, all with the goal to enhance transparency and communication.

Food Fraud is a public health vulnerability that is growing and the nature of global commerce will naturally continue to fuel the fraud opportunity. The countermeasures to combat this risk are non-traditional to the food industry but well founded in the behavioral sciences and social science disciplines of criminology and social anthropology. By focusing on the “bad guys” and reducing the fraud opportunity – on both an intra- and inter-national level – we can reduce and control this public health threat.

Regardless of the cause of the food risk, food **adulteration** is a food industry and government responsibility. Food safety, food fraud, and food defense can create food **adulteration** risks. Economically motivated **adulteration** is economically motivated, but the food public health risks are probably more risky than the traditional food safety threats because the contaminants are unconventional we are not specifically looking for them. (Spink, 2011b)

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5. Food Safety Legislation, Regulation, and Practices in China

Liwei Sang, Global Food Safety Forum (GFSF)

This chapter is published posthumously out of admiration for our colleague, Liwei Sang. The contents are strictly his own personal views, drawn from a long career in the field of food safety.

Food safety regulation is a holistic undertaking that requires government leadership as the guardian of its citizenry in tandem with companies held to a standard of corporate responsibility, non-governmental organizations, and health and consumer associations. Absent government leadership for the introduction and enforcement of equitable and uniform regulations, any stakeholder collaboration will be jeopardized over time.

5.1 Food Safety Situation in China

5.1.1 Prevailing Problems in Food Safety in China

5.1.1.1 Gaps in Legal Oversight

Article 28 of *Food Safety Law* defines 11 categories of food banned from production or trading but no distinction applies under this law between fraud and errors or system failures in management systems. The former seemingly would require criminal enforcement whereas the latter may more appropriately be enforced under civil law standards.

5.1.1.2 The Power of Price

With insufficient disposable income for high priced, quality-safe foods, the Chinese consumer invariably opts for lower priced, non-verifiable food items. GFSF has conducted a survey with the question “if there were only two kinds of milk on the shelf of supermarkets, one is 20 RMB per pack and the other is 2 RMB per pack, which one would you buy?” Nearly 90% of people surveyed chose the lower priced milk, notwithstanding the food security and quality risks. Although evolving, the Chinese consumer still places the highest priority on the price of food products.

5.1.1.3 Food Safety Standards in Urgent Need of Reinforcement

China Food Safety Law was inaugurated on February 28, 2009, followed by the promulgation of *Enforcement Regulation of Food Safety Law* not long afterwards; however, relevant supporting laws and regulations as well as agency regulations are not yet completed. The new Food Safety Law supercedes the *Food Hygiene Law* and thus, its rules and regulations. The net result is wide gaps and contradictions in written regulations and grandfathered standards, many of which are now antiquated. According to officials of the Ministry of Health, China faces a

daunting task in reviewing and reconciling over 1,600 national food safety standards currently in effect and numerous local and industrial standards.

The food industry is changing rapidly in China and around the world. The praiseworthy introduction of the new *Food Safety Law* cannot yet fully account for new food technologies and prevailing practices. *The Food Safety Law*, for example, stipulates that food safety standards are national standards; however, until now, only 176 food safety standards have been released by the Ministry of Health, accounting for less than 5% of the more than 10,000 standards including food hygiene standards, food quality standards and chemical residue limits previously released.

5.1.1.4 Regulatory Effectiveness

China's food safety laws, regulations, and enforcement procedures suffer from the weaknesses of a system in "catch-up" mode. Notwithstanding the tremendous strides to date, the most notable gaps are in: a/ the science of food safety; 2/ food hygiene operating systems in food manufacturing; 3/ traceability and verification equipment systems; 4/ overlapping agency authority; and 5/ weak food safety practitioner qualifications and training.

The regulatory system suffers from a top down approach. Unlike western economies, the private sector is not yet sufficiently organized to provide inputs respecting food safety measures or offer a channel for either self enforcement or collaboration.

5.1.2 Mapping the Food Safety Regulatory System in China

According to the *Food Safety Law*, the food safety regulation system to be instituted in China is as follows:

1. As a high-level consultation and coordination institution, the Food Safety Committee of the State Council will coordinate and instruct the regulatory work of food safety.

2. Health authorities pertaining to the State Council shall perform the task of comprehensive coordination of food safety and are responsible for food safety risk assessment, food safety standard formulation, food safety information release, formulation of certification qualifications of food testing institutions and of inspection code, as well as organizing the persecution of major food safety incidents.

3. Quality supervision, industrial and commercial administration and national food and medicine supervision and administration authorities pertaining to the State Council are respectively responsible for the supervision and administration of food production, food distribution and catering services.

4. Local people's governments above the county level shall assume responsibility and leadership for, organize, and coordinate the food safety supervision and administration within their respective administrative regions. They will establish and improve the working mechanisms of whole-process food

safety supervision; exercise unified leadership and command emergency response work in food safety incidents; perfect and implement the accountability system of food safety supervision and administration while conducting appraisal and assessment of food safety supervision and administration authorities.

5. Health administration, agricultural administration, industrial and commercial administration, and food and medicine supervision and administration authorities above county level shall strengthen communication and intensify collaboration in exercising their authority and assuming their responsibilities in compliance with the law according to their division of labor.

The above elaborates the division of labor among various functional departments of the Chinese government and local governments in food safety regulation. Besides these regulations, the supervisory role of relevant industry associations is also provided in *Food Safety Law*, which encourages consumers to improve their awareness and capability of self-protection and strengthens the role of media in public supervision.

5.1.3 Regulation of Food Import and Export in China

5.1.3.1 Supervision of Imported Food

Exploration and practice over the years have enabled China to set up a complete framework for a food quality and safety supervisory system and guarantee measures to ensure the safety of imported food.

Scientific risk management system. According to the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and common international practice, the Chinese government adopts an inspection and quarantine entry system based on risk management for high-risk imported food, such as meat and vegetables, which includes making a risk analysis on the high-risk food that the exporting country applies to export to China; signing an inspection and quarantine agreement with the exporting country on food involving acceptable risks; carrying out hygiene registration for foreign food enterprises; and quarantining, examining and approving imported food of animal and plant origin. If epidemic animal or plant diseases or severe food safety problems occur in the exporting country, China shall take timely risk management measures, including suspending food imports from that country.

Strict inspection and quarantine system. When imported food arrives at the port of entry, the entry-exit inspection and quarantine authorities carry out inspection and quarantine in accordance with law, and approve the foodstuffs to be imported only if they meet the required standards; and the customs house clears the imported food upon the strength of the Customs Clearance List of Inward/Outward Goods as issued by the entry-exit inspection and quarantine authorities. Only then can the food be sold in the Chinese market. If safety or hygiene problems are found in the food when inspected and quarantined, corresponding measures are immediately taken.

Complete quality and safety supervisory system. While carrying out inspection and quarantine in accordance with law, the entry-exit inspection and quarantine authorities pay special attention to higher-risk food and problematic foodstuffs as found in the inspection and quarantine at the ports of entry. The authorities promptly issue early warnings of risks when finding imported food with serious problems or the same type of imported food with repeated problems, and take such measures as increasing the proportion of sample survey, adding more items for inspection, and suspending import.

5.1.3.2 Supervision of Imported Food

Following the principle of "prevention first, supervision at the source, and control throughout the process," the Chinese government has set up and improved an export-food safety management framework composed of "one pattern and ten systems."

"One pattern" refers to the managerial pattern for the production of export food -- "enterprise + base + standardization." China has basically put this pattern in place for major export food items, especially high-risk foodstuffs such as meat, aquatic products and vegetables.

The "ten systems" are: three for supervision at the source -- the archiving management system for the inspection and quarantine of planting and breeding bases, the epidemic disease monitoring system, and the supervisory system for pesticide and veterinary medicine residue; three for factory supervision -- the hygiene registration system, the classified management system for enterprises, and the resident quarantine official system for large enterprises producing high-risk food for export; three for product supervision -- the legal inspection and quarantine system for export food, the system of quality tracing and substandard products recalling, and the early risk warning and quick response system; and one for credit building -- a red list and a blacklist for food export enterprises.

Strengthening supervision of planting and breeding at the source. To effectively control the risks of animal epidemics, plant diseases and pesticide and veterinary medicine residue, and guarantee food quality and safety and traceability at the source, the entry-exit inspection and quarantine authorities adopt the archiving management system for the inspection and quarantine of export food material bases with such risks. Only the raw materials of planting and breeding bases with archiving approval can be used in processed export food, and all the raw material bases with archiving approval are publicized on the website of the General Administration of Quality Supervision, Inspection and Quarantine. So far, 6,031 breeding farms and 380,000 hectares of planting bases have obtained such approval. For these bases, the relevant agencies strengthen supervision, prevention and control of epidemic diseases, exercise tight management of agricultural input materials, and enforce a strict supervision system over pesticide and veterinary medicine residue, so that these problems are brought under effective control.

Strengthening supervision of food producing enterprises. China has adopted a hygiene registration system for all enterprises producing export food, and an

enterprise has to be granted such registration before engaging in the production of export food. So far, 12,714 enterprises have been registered, among which 3,698 have passed the HACCP certification of the entry-exit inspection and quarantine authorities. The local entry-exit inspection and quarantine authorities carry out routine supervision and administration of the registered food producing and processing enterprises in a unified way to ensure that the raw materials come from archived planting and breeding bases, and that the production and processing meet the required standards. As regards large enterprises producing or processing high-risk export food such as meat, the entry-exit inspection and quarantine authorities send resident officials to supervise them when needed. The packaging of export food should be labeled with traceable signs according to requirements, so as to ensure the traceability of the products and recall of substandard products.

Strengthening inspection and quarantine before the food is exported. As prescribed by Chinese laws, all food should meet the standards set by the inspection and quarantine authorities before being exported, and the customs houses at the ports of exit should clear the export food upon the strength of the Customs Clearance List of Outward Goods issued by the entry-exit inspection and quarantine authorities. If it is demanded by the importing country, the relevant entry-exit inspection and quarantine authorities should issue a hygiene certificate to prove that the food meets the required standards, and enter on the certificate the name, address, hygiene registration number of the producing enterprise, date of production, date of export, loading port, and destination port. When the goods arrive at the port of exit, the inspection and quarantine authorities at the port should examine the goods again, making sure they are intact and conform to the information on the certificate. All these measures guarantee the traceability of the food.

Strengthening the construction of the export enterprise credit system. An export enterprise quality undertaking system and a red list and blacklist system for export enterprises are implemented in a comprehensive way, and efforts are being made to increase the awareness of the persons primarily responsible for product quality and help enterprises to form a mechanism of self-management, self-discipline and consciousness of operation in good faith. Included on the List of Sound Enterprises are those with a complete and effective control system, good faith, effective control over safety risks, and a good reputation in the importing countries. Such enterprises are granted favorable policy treatment. Enterprises with serious quality problems as reported by the importing countries or regions, or which have avoided inspection and quarantine or cheated the inspection and quarantine authorities are punished in accordance with the law and included in the List of Unlawful Enterprises and publicized on the Internet so as to enhance the self-disciplinary awareness of enterprises producing export food.

5.1.4 Relevant Standards of Food Safety in China

Existing food standards are categorized into four major categories: national standards, industry standards, local standards, and enterprise standards, each under the administration of different authorities. Industry standards of fruits and vegetables alone are subject to six administrative authorities including agriculture, forestry, commercial inspection, commerce, light industry and supply and marketing.

A total of 484 maximum chemical residue limits are set in China, a negligible 2.2% of the 22,289 limits set in the European Union.

This is only the tip of iceberg of food safety standards in China. With recent disputes over differences in testing standards of heavy metals including arsenic, lead and cadmium in well-known European brands of baby formulas such as Nestle, etc., public concern that food safety standards in China are lower than international standards has heated up again. Compared to their foreign counterparts, food safety standards in China are insufficient in both quantity and quality, resulting in numerous international trade disputes.

At present, international standards and analysis methods for food are mainly released by International Organization for Standardization (ISO), Codex Alimentarius Commission (CAC), World Health Organization (WHO), etc. Up to 2009, CAC has stipulated over 8,000 international food standards, 3,274 maximum limits of chemical residue and safety assessment of 1,005 food additives.

In the national hygienic standard for fresh and frozen poultry implemented from 2006, only terramycin content is consistent with CAC standards. There exists a considerable gap between national standards in China and international, especially European Union, standards; for example, the maximum residue limit of diethylstilbestrol (an environmental hormone) is 0.001 mg/kg as stipulated by the European Union and 0.25 mg/kg according to national standards in China, featuring a 250-fold difference.

Another prominent problem is the overlapping between national standards and industrial standards for the same types of food. For example, the maximum limit of aureomycin residue is 1mg/kg according to GB16869 national standard and 0.1mg/kg as stipulated by the General Administration of Quality Supervision, Inspection and Quarantine. Yet according to other standards, the maximum limit of aureomycin is 0.1 mg/kg in meat, 0.3 mg/kg in liver and 0.6 mg/kg in kidney.

The last three decades have seen only three massive rounds of promulgation and revision of food standards in China. As is disclosed, one fourth of the prevailing standards are more than ten years old, and some have remained unrevised for over twenty years.

In China, governmental departments involved in standard formulation include the Ministry of Agriculture, the Ministry of Health, the General Administration of Quality Supervision, Inspection and Quarantine, etc., and standardization commissions involved include China National Institute of Standardization, National Technical Committee on Feed Industry of Standardization

Administration of China, National Technical Committee on Animal Quarantine of Standardization Administration of China, etc. Coordination among various departments is necessary from the planning to the promulgation of standards, which results in the prolonged cycle of standard formulation.

Up to the end of 2006, revision plans for national food standards were formulated by nine governmental departments including the Ministry of Agriculture, increasing the application of international standards from 23% to 55%.

5.1.5 Food Safety Testing Technologies in China

In China, testing technologies for organochlorine pesticides and organophosphorus pesticides include mainly packing gas chromatography separation technology, nitrogen-phosphorous detector, electron capture, etc, which, despite their sensitivity, are comparatively weak in specificity and selectivity. At present, capillary column is universally used as an internationally acknowledged method for chemical pesticide testing due to its high sensitivity, selectivity and specificity. Liquid chromatography—ultraviolet detector—is widely used for the testing of carbamate pesticides in China, yet its sensitivity, selectivity and specificity are comparatively low, while high-efficiency liquid chromatography-mass spectrometry or high-efficiency mass spectrometry/ mass spectrometry are universally applied internationally. The application of mass spectrometry technology would tremendously enhance the sensitivity, selectivity, specificity, confirmation capacity and the scope of coverage of this method. However, standards are still absent in the above two tests.

Food safety testing is the eyes of food safety, and its technological level has a direct bearing on the situation of food safety administration. Taking chemical pesticide residue as an example, we still have much space for improvement compared to developed countries. Among the 197 maximum limits of 79 kinds of chemical pesticides formulated in China, corresponding testing methods are defined for only 33 of them but not for the other 46 kinds, hence giving rise to considerable problems in implementation. Currently, numerous testing methods for multiple chemical residues are internationally applied, such as DFG method and S19 method in Germany, FDA multiple residue testing method of the United States, multiple residue testing method of the Ministry of Health of Holland, multiple residue testing method of Canada, all of which are more complete than the methods used in China.

5.1.6 Professionals of Food Safety in China

According to Article 32 of *Food Safety Law*, “An enterprise engaging in the production or business operation of food shall establish and improve its food safety management system, strengthen the training of its employees in respect to food safety knowledge, be provided with full-time or part-time food safety managers, do a good job in inspecting the food which it produces or operates, and carry out food production and business operation activities according to law.”

Yet no profession corresponds to the “full-time or part-time food safety managers” hereby referred to. There can be no normalization without professionalization, and the enhancement of food safety management would be impossible.

Professionals with technical expertise are especially lacking in food safety regulatory institutions. Currently there are over 70 vocational colleges in China where education in food testing or similar fields is available, most of which started their enrolment and major construction after 2000; hence their foundations are still weak, especially in that no effective major construction system is yet formed in cultivating students’ practical capability. Prevailing problems in these vocational colleges include weak competency of faculty, insufficient numbers of teachers with certification in both teaching and professional proficiency in specific fields, inconsistency between curriculum arrangement / content and requirements for vocational skills, low proportion of practical courses, failure of on-campus and off-campus training bases to meet students’ needs of competency cultivation, absence of a well-structured mechanism combining work with studies in off-campus training bases, inadequate service provided by these majors for industry and their limited influence.

5.2 Background Observation of Focal Issues

5.2.1 Food Safety Standards

5.2.1.1 Food Safety Standard System in China

Before the implementation of *Food Safety Law*, the food safety standard system in China was a combination of compulsory and recommendatory standards and coordination among national standards, industry standards, local standards, and enterprise standards, which had the following problems: (1) low overall level of standards; (2) discordance, overlapping and even contradiction among certain standards; (3) absence of important standards; (4) poor implementation of certain standards, even compulsory standards.

Therefore, a scientific, uniform and authoritative food safety standard system must be established as soon as possible to reverse the current situation of multiple authority and overlapping or contradictory food safety standards in China resulting in disorder in food production and circulation. According to *Food Safety Law*, food safety standards are compulsory standards and no other food-related compulsory standard shall be formulated besides food safety standards. National food safety standards must be conscientiously observed wherever they exist and local standards may be formulated where national standards do not exist. Therefore, the food safety standard system in China is transformed from the former four-layer system into a tri-layer one consisting of national standards, local standards and enterprise standards of food safety.

5.2.1.2 Formulation of Food Safety Standards

It is clearly stipulated in the law that food safety standards are organized, formulated and released by the Ministry of Health and that codes of food safety are provided by the Standardization Administration of the People's Republic of China. Limits and testing methods and procedures of chemical pesticide and veterinary medicine residues in food are formulated by the health and agricultural administrative departments of the State Council. Inspection procedures of butchered animals and poultry are formulated by competent authorities of the State Council in coordination with health administrative departments of the State Council.

National food safety standards are subject to approval upon review by the Review Committee for National Food Safety Standards composed by experts in medical sciences, agriculture, food, nutrition, etc., as well as representatives of competent authorities of the State Council. Therefore it can be seen from this article that various regulatory departments participate in the formulation of food safety standards via the platform of Review Committee for National Food Safety Standards in China. Meanwhile, it is also stipulated that the formulation of national food safety standards should be based on the results of food safety risk assessment with full consideration of quality safety risk assessment results of edible agricultural produce, while referring to relevant international standards and results of international food safety risk assessment and consulting the opinions of food producers and traders as well as consumers.

5.2.2 Food Additives

In China, a substance must be scrupulously assessed before it is applied as a food additive. The safety assessment mainly includes three aspects: toxicology test, toxicological categorization of food additive, and the determination of maximum usage.

The principle of technical necessity: the use of an additive should be contributive to ensure food quality or be beneficial rather than hazardous for human health so that the food is safer and more nutritious with the use of food additives.

The principle of compliance with standards: food additives are categorized into two types according to their chemical compositions: one is general food nutrient additives, whose metabolism and way of digestion and absorption in the human body are similar to normal nutrients in food, hence basically non-hazardous for human health; the other is non-nutrient food additives, whose metabolites are non-hazardous to human health until a certain quantity is reached. Therefore, reasonable use of food additives in compliance with national standards will neither cause any harm nor produce carcinogenic effects. Up to now, none of the food safety incidents in China is caused by correct use of food additives.

Non-edible substances exclude food ingredients, non-traditional food resources approved for food or pharmaceutical use, or synthetic foods subject to general food administration. For example, non-edible substances whose use is detected

and prosecuted in recent years include Sudan, melamine, formaldehyde, malachite green, and clenbuterol (lean meat powder).

5.2.3 Amendment VIII to the Criminal Law of the People's Republic of China

Amendment VIII to the Criminal Law of the People's Republic of China was passed by the National People's Congress on February 25, 2011, with conditions for punishment modified for food safety related crimes, demonstrating strengthened protection of food safety, an issue of significant bearing on people's livelihood, by the criminal law.

Two criminal charges related to food safety are stipulated in the *Criminal Law*, i.e., the crime of producing or selling food not up to food safety standards in Article 143 and the crime of producing and selling toxic or harmful food in Article 134.

There exist five differences between the stipulations of *Amendment VIII to the Criminal Law of the People's Republic of China* and *the Criminal Law of the People's Republic of China*:

1. The stipulation of fine alone is abolished; while a fine is given to the criminal unit, the responsible person shall be sentenced to incarceration.

2. The Amendment requires the imposition of severe punishment. Since *Amendment VIII to the Criminal Law of the People's Republic of China* entered into effect, criminals of producing and selling toxic or harmful food shall be sentenced to fixed-term imprisonment of at least six months. The death penalty is not cancelled for producing and selling toxic or harmful food in *Amendment VIII to the Criminal Law of the People's Republic of China*.

3. The range of result of damage is expanded. Since the implementation of *Amendment VIII to the Criminal Law of the People's Republic of China*, criminals of producing and selling toxic or harmful food may be sentenced to fixed-term imprisonment of not less than five years even if no serious harm to human health is caused.

4. The maximum limit of fine is cancelled. Fines can be imposed on criminals of producing and selling toxic or harmful food until they go bankrupt.

5. The crime of dereliction of duty in food safety regulation is listed in a separate item in *Amendment VIII to the Criminal Law of the People's Republic of China*, "A State functionary with food safety supervision and management duties shall be sentenced to fixed-term imprisonment of not more than five years or criminal detention if he/she abuses powers or neglects duties, thus causing a major food safety accident or resulting in other serious consequences. If especially serious consequences are caused, he/she shall be sentenced to fixed-term imprisonment of not less than five years but not more than ten years," while emphasizing that "Any person who commits the foregoing crime and engages in malpractice for personal gains shall be subject to a heavier

punishment."

5.3 Tracking Report of Typical Cases

5.3.1 Toxic Yardlong Beans in Hainan

From January 25 to February 5, 2010, agricultural authorities in Wuhan detected an excessive amount of isocarbofos residue, a prohibited chemical pesticide, in yardlong beans from two regions in Hainan, and announced a 3-month ban of yardlong beans from Hainan in the Wuhan market starting February 6, and the ban would be lifted only for those having been approved upon testing. On February 24, Guangzhou Agricultural Standard and Supervisory Center tested 5 samples of yardlong beans from Hainan at Guangzhou Jiangnan Fruit and Vegetable Wholesale Market, and the results showed that banned chemical pesticides were discovered in two samples. Excessive chemical pesticide residues are detected in yardlong beans from Hainan in a total of 11 cities in China, including Wuhan, Shanghai, Hefei.

The yardlong beans with an excessive amount of chemical pesticide residue, as well as their source, were discovered as early as January and early February, and the letter of joint investigation was sent by Wuhan Agriculture Bureau to the Agriculture Department of Hainan Province on February 6; however, no information was released to the public until late February after the Chinese New Year, with attendant risks for Chinese and foreign consumers of the yardlong beans.

5.3.2 Incident of Hogwash Oil

Scientifically known as waste edible oil, hogwash oil refers to animal fat and vegetable oil from the production and business operation of catering services, restaurants and food processing enterprises which are unsuitable for human consumption. Undesirable odors and colors of hogwash oil are removable by processing. Hogwash oil contains strong chemical carcinogen and is thus seriously harmful to human health.

Public reports indicate that the use of this waste oil was due to flawed supervision of procurement operations, especially among catering service providers. Also, the absence of self-enforcement and a culture of corporate irresponsibility partially explains the wanton use of the cheaper product, despite the threat to human health.

The incident also points to the lack of uniform and comprehensive standards. More importantly, the ingredient went undetected due to rudimentary testing technologies at the plant level in China.

5.3.3 Clenbuterol (Lean Meat Powder) Incident

Adding clenbuterol into animal feed helps to produce larger quantities of lean meat while reducing the use of feed and shortening the time of meat production, hence cutting costs. The use of clenbuterol, particularly in small scale swine production facilities, has been widely reported as a dramatic illustration of the failings of the regulatory system and fraudulent commercial practices that prevail among companies outside the reach of government regulators.

5.3.4 Dyed Steamed Buns in Shanghai

Dying of steamed buns was a widespread practice to extend product shelf-life in Shanghai supermarkets. Detection evidently slipped between the cracks because of the patchwork of the municipal, provincial and national regulatory systems. Agency duplication assuredly exists in European and American regulatory systems but findings suggest that China still lacks the supervisory overlay to coordinate regulatory actions.

At the operational level, the supermarkets often have not introduced the bar code system which allows for immediate tracing once food safety incidents occur.

5.4 Proposal and Solutions

Food safety is a massive social systematic project which is related to numerous factors including technical progress, economic development, social administration, environmental quality, while public media are also a key component which requires constant improvement and perfection in the institutional mechanism. The construction of a long-term regulatory mechanism for food safety to form a coordinated, organized and orderly organic social supervisory system is a significant and pressing task that Chinese authorities, to their credit, recognize as a significant challenge.

5.4.1 Scientific Integration of Existing Regulatory Resources for Full-Process Seamless Regulation in Its Real Sense

Food safety is placed at a highlighted position on the national level, yet food safety incidents continue emerging due to the absence of regulation resulting from years of multi-department regulation without clear accountability when incidents do occur. For strengthened regulation, there must be one department assuming major responsibility and engaged in full-process regulation. Equipment, systems and environment must be scrutinized based on food safety standards at the application for foodstuff factory construction, with higher threshold for access of food enterprises. Legal representatives must be subject to ethics inspections and public notice before official appointment, automatically excluding those with flawed morals or criminal records. Sampling tests should be conducted regularly in the production process and temporary production suspension for rectification is obligatory once safety hazards are detected. The food industry features a long industrial chain, numerous links and components and decentralized regulation; therefore, joint regulatory efforts shall be waged to enhance the efficiency of regulation. The Food Safety Committee of the State Council should be authorized to coordinate all sectional regulation processes of various

departments in order to eliminate loopholes and exercise full-process monitoring in a real sense. Only by this means can the accountability system be scrupulously implemented and local protectionism avoided. Individuals of local governments and various regulatory departments charged with negligence, abuse of power and malpractice for personal gains should be severely punished.

5.4.2 Transformation in Government Performance Evaluation System from GDP-Oriented to Combination of Happiness Index of Residents

Food safety should be integrated into government performance evaluation with the implementation of the district chief's (county mayor) accountability system for food safety. Functional adjustment of municipal-county dual-level food safety regulation should be coordinated and promoted, with all links in close coordination, for effective full-chain regulation. In prefectures below the provincial level, the chief executive officer accountability system and one-ballot-veto system should be implemented, with "Three Integrations" and "Five In-Place" achieved. That is, there should be integration of food safety into the government work plan, into the government objective evaluation, and into the budget, ensuring that the necessary institutions, personnel, assignment of responsibilities, system policies, and funding are all in place.

5.4.3 Acceleration of Formulation of Supporting Laws and Regulations on Food Safety and Food Safety Standards

With the promulgation of the *Food Safety Law* and its *Executive Regulations*, existing laws, regulations and rules on food safety regulation will be rearranged and improved at a quicker pace. Repetitive or conflicting provisions on the same issues will be cleared out on the basis of the entire process from field to fork, and the food safety legal framework including food safety technical norms and standard requirements will be constructed in a timely manner so as to gradually form a food safety legal system with Chinese characteristics and geared toward international standards. Meanwhile, a professional department with expertise will be established for food safety standard design, with increased input to accelerate the formulation of national standards of food safety.

5.4.4 Ensuring Personnel, Equipment and Fund of Grassroot Regulatory Departments, Hence Detaching Fines from Department Interests, Prohibiting Return of Fines Which Is a Form of Handling Revenues and Expenditures without Entering into Account

It is clearly stipulated in *Food Safety Law of the People's Republic of China* that a local people's government at or above the county level shall undertake the overall responsibility for the food safety supervision and administration within its own administrative region. The establishment of a work responsibility system and guaranteed fund allocation are the key points in inspection and accountability. Meanwhile, local governments on various levels should establish and improve the awarded reporting system for food security with specifically appropriated funds for award and improved working mechanisms. Fallacious or misleading

news reports need to be cracked down on, and those who fabricate such fallacious or misleading news that it causes social panic, will be severely prosecuted.

5.4.5 Transformation from Passive Administration to Regulation on Initiative to Enhance the Effectiveness of Regulation

A high-quality food safety system geared up to international standards will be established with strict control of food business operation approval and food quality market access; a food safety emergency response mechanism will be created with a rapid-response emergency law enforcement corps and higher comprehensive competence of law enforcers ready for emergency response. A scrupulous system of food source inspection and supervision will be instituted and a food traceability system should be built for China's mainland as soon as possible. For highly controversial issues such as the safety of genetically-modified food, the State should organize professional institutions for food safety risk assessment, animal tests and even human experiments, hence determining its safety rather than staying silent.

5.4.6 Acceleration of Establishment and Perfection of Third-Party Accreditation and Testing Systems

At present, all food safety inspection institutions existing in China pertain to the government, some constrained by outdated equipments and undersupply of talents as a result of limitations in the government's input of human resources, materials and funds, hence unable to providing full-range service to the society. According to media coverage, in line with work arrangements of national food safety rectification, relevant authorities and departments are accelerating their efforts towards inspection and testing resource and information sharing while dynamically facilitating the construction of third-party technical institutions. Third-party testing is known as fair and just inspection, and refers to commodity inspection activities conducted by a third party, independent of the trading interests (e.g., a professional supervisory and inspection institution) as a just and authoritative non-interested party in accordance with relevant laws, standards or contracts.

5.4.7 Construction of an Accomplished Industry Self-Discipline System and Performance of Social Management Functions of Public Interest Organizations

Food regulation is a world challenge, with self-regulation of enterprises becoming an important means of standardizing corporate behaviors and competitors in the same industry as the most self-conscious regulators of each other. This shows the necessity of introducing the model of third-party regulation with full public participation in supervision as regulation of both market and government may be dysfunctional. The vast majority of trade associations in China is transitioned from the system of planned economy and is attached to relevant departments; constrained by underperformance and poor service quality, these trade associations are unlikely to win support from enterprises.

Therefore, China should learn from the practices of developed countries and strengthen the industry self-discipline system and enhance self-regulation and self-discipline within industries. Food enterprises should appoint well-acknowledged food production safety control experts as corporate inspectors, and trade associations can institute strict expulsion policies for any members responsible for creating severe enough quality problems.

5.4.8 Highlighting the Legal Liability of the Primary Liable Person

It is beyond doubt that producers and business operators are the primary liable persons in ensuring food safety. In the legislation of food safety, many members of the Standing Committee of the National People's Congress have explicitly pointed out that food safety is directly related to people's health and survival, and that food producers and business operators should not only engage in production and business activities in abiding by the law but should also assume social responsibility.

The current Food Safety Law highlights the social responsibility of food producing and trading enterprises with the clear stipulation that food producers and business operators shall follow relevant laws, regulations and food safety standards when engaging in food production and business operation activities, be responsible to the society and the general public, ensure food safety, accept social supervision and assume social responsibilities.

6. Non-government Initiative

Jianbo Lu and Richard Gilmore, Global Food Safety Forum (GFSF)

Recently, there has been more concern for food safety in the world as a result of food safety incidents, food trade, and new and emerging trends in the consumer and food industry. The increased access to the global marketplace will continue to increase the scale of harm to consumers from economic or other intentional adulteration, fraud, and counterfeiting.

The food manufacturers and producers face intense pressure to lower costs and increase worker productivity. Products entering one country come from new and diverse markets, and these globally sourced products are eventually processed into finished goods through long, multi-step processes. As a result of the extensive distances that food products travel, businesses and regulators face a difficult challenge of maintaining transparency in the start-to-finish processes of food production. It has also become increasingly difficult to prevent and detect international imports that have been tampered with to try to avoid scrutiny. The highly-public incident involving melamine-tainted baby formula has helped to underscore how serious food safety is. It also serves as a reminder that there are manufacturers around the world for whom the temptation of economic gain is greater than the concern for human and animal health; for example, Asian retailers already rate intentional poisoning as one of their top concerns⁶⁰.

Solutions can be found through a dynamic mix of policies and actions which include harmonization of food safety standards; policy coordination with relevant stakeholders through a lifecycle approach; producer and consumer capacity building in safe food practices; and better storage infrastructure⁶¹. Industry initiative plays an important role in food safety in terms of training and capability building as well as in harmonizing highly technical safety standards in order to address food safety problems that arise as a result of the lack of incentives for various size companies to comply with food safety regulations, the lack of awareness of food safety regulations and global standards, and the lack of appreciation of the commercial implications if food safety standards are not higher.

China is among the countries with the biggest impact on the global food chain because of its global market share and higher occurrence of food safety incidents over the years. When China joined the World Trade Organization (WTO) in late 2001, its share of world exports stood at 4.3%. By 2010, that share had soared to 10.6%, and the country had become the world's biggest exporter⁶². From 2005 to 2009, China's food exports rose by 9.4% and its imports by 20.4% over the same

⁶⁰ Pathway to Global Product Safety and Quality, FDA, 2011.

<http://www.fda.gov/downloads/AboutFDA/CentersOffices/OC/GlobalProductPathway/UCM259845.pdf>

⁶¹ Food Safety in the Asia-Pacific Region: Current Status, Policy Perspectives, and a Way Forward. Institute for Global Environmental Strategies, Hayama, Japan. 2010.

⁶² <http://www.economist.com/node/18925947>

period⁶³. In some cases, Chinese foods or ingredients have entered the global food supply wrapped in the familiar labels of international food companies. In 2008, the chemical melamine contaminated Chinese dairy products, sickening 300,000 children and infants in China, six of whom died. Melamine was then found in the food supplies of multinational agribusinesses, including Mars, Unilever, Heinz, Cadbury and Pizza Hut. China's largest role in the American diet may come through the myriad ingredients it exports for processed foods that reach U.S. consumers every day. China had supplied up to 90% of U.S. imports of citric acid, a flavor enhancer and preservative that is used in soft drinks, cheese, and baked goods, although these imports dropped off in 2009. China is also a leading supplier to the United States of other ingredients like xylitol, used as a sweetener in candy, and sorbic acid, a preservative. China also supplies around 85% of U.S. imports of artificial vanilla, as well as many vitamins that are frequently added to food products, like folic acid and thiamine⁶⁴.

6.1 Building Brand for Food Quality and Safety: The China Example

A recent survey of retailers in Asia revealed that Asian retailers' greatest sources of safety concerns dealt with residual chemicals, contamination and spoilage, veterinary and plant diseases, and intentional poisoning.⁶⁵ On the other hand, there is also an opportunity for companies to benefit from improved quality and product safety because consumers are willing to pay more for better, safer products.

6.1.1 Branding

Food industries that have food production in developed countries attempt to ensure the safety of their food in an effort to protect the citizens of their country and their brand name. The government and the private sector in developed countries have made painstaking efforts to ensure that the brands of their countries are recognized as quality products that are safe to eat. With the globalization of the food market, a weak institutional capacity in one country can influence the health and safety of food globally. When a food scandal is uncovered in a country, it threatens the legitimacy of that country's exports as well as the country's brand names. Conversely, the lack of reliable quality ingredients within these ingredient sourcing countries casts a pall on all end-users of the ingredients, jeopardizing the final products' export competitiveness in third country markets. China has become an agricultural powerhouse and leading food exporter. Though supermarket labels may not always indicate it, a growing portion of the American diet is now made in China. In 2009, 70% of the

⁶³ http://www.wto.org/english/res_e/statis_e/its2010_e/section2_e/its10_highlights2_e.pdf

⁶⁴ <http://documents.foodandwaterwatch.org/DecadeofDangerousImports-media-release.pdf>

⁶⁵ Pathway to Global Product Safety and Quality, FDA, 2011.

<http://www.fda.gov/downloads/AboutFDA/CentersOffices/OC/GlobalProductPathway/UCM259845.pdf>

apple juice, 43% of the processed mushrooms, 22% of the frozen spinach, and 78% of the tilapia Americans ate came from China⁶⁶.

On the other hand, as per capita income continues to grow in developing countries, consumers are increasingly looking to buy products that are differentiated by a strong brand name reputation. Chinese consumers typically view imports, both processed and fresh, as higher in quality and safer to eat than domestically produced food. As consumer awareness of food safety has increased and import volumes of higher-quality products have risen, Chinese agricultural producers and food processors have been forced to improve their product quality to compete with imports. Internationally recognizable food brands, often produced locally in China, are some of the most recognized brands to Chinese consumers⁶⁷. As a result of melamine scare in 2008, Chinese mainland parents, wary of locally produced milk powder, stock up on imported baby formula. China's milk powder imports are significantly increasing, as shown in Fig. 1.

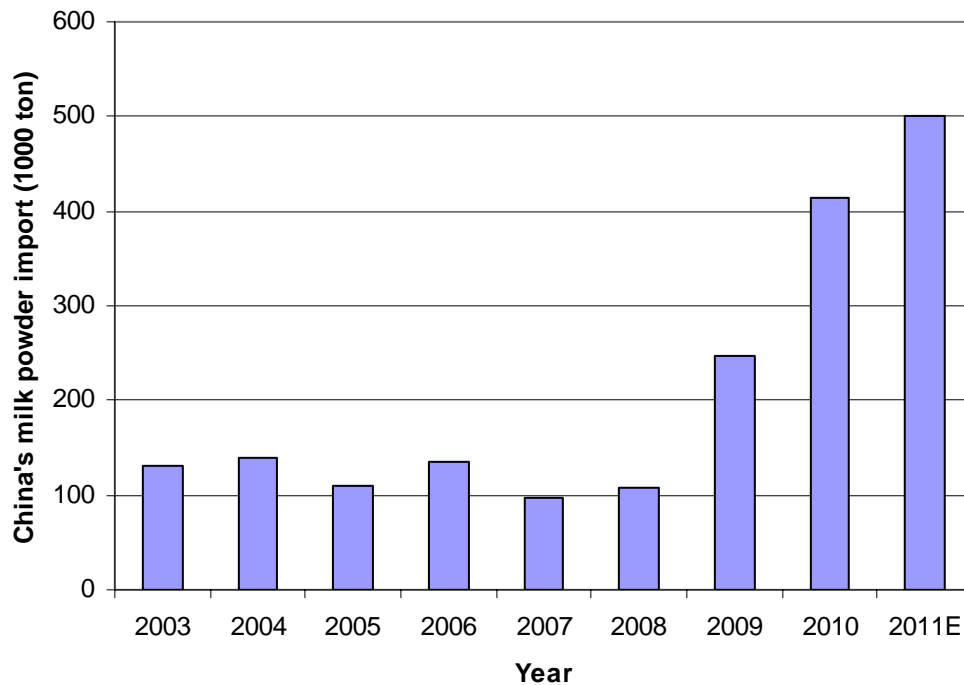


Figure 1. China's milk powder import (2003-2011)⁶⁸

A study which analyzes how consumers in Beijing determined milk safety when they purchased liquid milk, indicates that milk brand and purchase venue were ranked as the first two important safety indicators in fluid milk purchases; this

⁶⁶ <http://documents.foodandwaterwatch.org/DecadeofDangerousImports-media-release.pdf>

⁶⁷ United States International Trade Commission: China's Agricultural Trade: Competitive Conditions and Effects on U.S. Exports. Investigation No. 332-518. USITC Publication 4219. March 2011.

⁶⁸ <http://www.foodqs.cn/news/ztzs01/2010310104821337.htm>

suggests that China's milk safety regulators should put more resources toward supervising the safety of milk produced from branded firms and milk sold in ostensibly trustworthy stores and not allow exemptions to inspections⁶⁹.

6.1.2 Raise consumer awareness and stimulate demand for safe products

In China, brand is often a good indicator of product safety and quality. A study conducted in 2005 found that when consumers were asked about their preferences for milk company brands, respondents overwhelmingly chose the two largest dairies in China⁷⁰.

By educating customers about product quality issues and the safeguards that are in place, companies can help to create and maintain demand for improved performance. One way to educate customers is to publicize the types of policies and protocols that are being used to protect consumers. With the food safety scandals that have shaken Chinese consumer confidence in the last few years, there is also an opportunity for companies to benefit from improved quality and product safety because consumers are willing to pay more for better, safer products. In addition to the national government's push for stricter food safety systems, companies can respond through innovative development and implementation of their own initiatives.⁷¹

6.2 Third Party Audit Certification

Requested by consumers and initiated by the food industry, certification and third party audits have been practiced for years in the western world, and these certification and third party audits have proved to be an effective means to help ensure food quality and safety. Faced with the problems brought by globalization, some governments such as the U.S., plan to use third-party certification to manage food safety controls on imports into their countries.

6.2.1 Consumers request

Severe food safety scandals were observed recently in China. These events not only caused direct economic problems and loss of life, but also created distrust in the Chinese food system domestically as well as internationally. Results of a study about Chinese consumer preferences for select food safety attributes suggest that Chinese consumers rank government certification programs the highest, followed by third-party certification, a traceability system, and a product-specific information label. The results of this study call for the direct involvement of the Chinese government in the food safety system. A stricter monitoring

⁶⁹ Caiping Zhang, Junfei Bai, Bryan T. Lohmar, Jikun Huang. How do consumers determine the safety of milk in Beijing, China? *China Economic Review*, Volume 21, Supplement 1, September 2010, Pages S45-S54.

⁷⁰ David L. Ortega et al., *Got (Safe) Milk? Chinese Consumers' Valuation for Select Food Safety Attributes*, 2011.

<http://ageconsearch.umn.edu/bitstream/98723/2/Ortega%20et%20al%20SAEA%202011.pdf>

⁷¹ How the private sector is boosting standards. *China Brief of the American Chamber of Commerce in China*. 2011, Vol. 19.

system will not only improve consumer well-being in the short run, but also restore consumers' trust⁷².

Chinese food processors initially sought Hazard Analysis Critical Control Point (HACCP) certification to access export markets, but now HACCP is rapidly being adopted for domestic products. HACCP's logo has begun to appear on labels in China. Surveys of Beijing consumers found that less than one in five respondents were aware of HACCP, and most who had heard of HACCP had learned about it within the previous year. After receiving information about HACCP, nearly all respondents were willing to pay a modest price premium for HACCP-certified products. Products with HACCP labels in Beijing supermarkets sold at a price premium of about 5% over products without such labels. The results indicate that demand for food safety is emerging as a demand by Chinese consumers⁷³. There is room to improve consumer awareness and to convey consumers' concerns to regulatory agencies and the food industry.

6.2.2 Industry initiative

Retailers, manufacturers, foodservice operators, caterers, industry associations, technical experts and governments all have one thing in common when it comes to food safety: they recognize that consumers' confidence dropped to an all time low after a number of public food scares sent shock waves through these industries just over ten years ago. This widespread concern for safety prompted action. Retailers and branded manufacturers began to audit their suppliers so that they could feel confident in their suppliers' abilities to meet their food safety system demands⁷⁴.

With certified food-safety standards, plant operators must be prepared to satisfy auditors that protocols exist and are being followed. Failure of the plant operators to prove that they are functioning within the set procedures could result in a loss of certification for a plant, negative publicity, and a loss of market share.

As food manufacturers involved in the global standards initiative push their raw-material and ingredient suppliers to attain certification, proponents hope a critical mass in the international supply chain will embrace the sanctioned audits⁷⁵. However, the awareness and adoption incentive of standards vary over the world. Unfortunately, those who lack awareness of these standards and certification systems, and of incentives, are often the sources of food safety problems. To bring the standards initiators, certifiers, and food industries to the most needed countries will benefit all of them.

6.2.3 An alternative tool for government

⁷² David L. Ortega, H. Holly Wang, Laping Wu, Nicole J. Olynk. Modeling heterogeneity in consumer preferences for select food safety attributes in China. *Food Policy*, Volume 36, Issue 2, April 2011, Pages 318-324.

⁷³ Zhigang Wang, Yanna Mao, Fred Gale. Chinese consumer demand for food safety attributes in milk products. *Food Policy*, Volume 33, Issue 1, February 2008, Pages 27-36.

⁷⁴ <http://www.sgs.com/comparing-gfsi-recognized-standards-information-request>

⁷⁵ <http://www.foodprocessing.com/whitepapers/2010/014.html>

Food product imports, representing the largest share by volume of import lines, have grown by an average of nearly 10% each year for the past seven years. This growth has led to an increase in the volume of food import lines from 5.6 million in 2002 to 10.7 million by 2009. Currently, between 10 and 15% of all food consumed each year by U.S. households is imported from abroad. In some food categories, more food is imported than produced domestically. For example, 60% of fruits and vegetables and 80% of seafood are produced outside the U.S. Between 70 and 85% of the import refusals of produce and seafood were for potentially dangerous violations including the presence of pathogens, chemical contamination, and “other sanitary violations.”⁷⁶

As demanded by the Food Safety Modernization Act (FSMA), importers will have explicit responsibility to verify that their foreign supplies have adequate preventive controls in place and that the food they ship to the U.S. is otherwise safe. The Food and Drug Administration (FDA), responsible for implementing the FSMA, also has the power to establish a third-party program for certifying that foreign food facilities comply with U.S. food safety standards; to require certification as a condition of entry for certain high risk foods; and to reject entry of food if the foreign facility or country refuses an inspection by FDA or its designee⁷⁷. While the FDA is having “*robust dialogue*” with the certificated bodies about the use of third-party certification schemes to manage food safety controls on imports into the US, it is not yet clear whether the FDA will still require its own inspections and laboratory analysis of foodstuffs from suppliers’ plants⁷⁸.

The FDA will maintain broad-based oversight of the entire range of products within its purview by developing compliance and inspection programs that contemplate enlisting public and private third parties to conduct audits and other oversight activities on behalf of the FDA. The FDA intends to establish a review and audit infrastructure to verify the integrity of the information that it receives from public and private third parties and to ensure that the agency can rapidly take follow-up enforcement measures or actions where needed. In addition, industries’ own safety monitoring efforts will also be a critical support for more comprehensive oversight⁷⁹.

6.3 Harmonization and International Food Safety Standards

6.3.1 Apply strict standards of product safety

Strict regulations and standards are critical to ensure food safety. The regulatory standards are to foster corporate responsibility to identify, protect, and control

⁷⁶ Pathway to Global Product Safety and Quality, FDA, 2011.

<http://www.fda.gov/downloads/AboutFDA/CentersOffices/OC/GlobalProductPathway/UCM259845.pdf>

⁷⁷ Pathway to Global Product Safety and Quality, FDA, 2011.

<http://www.fda.gov/downloads/AboutFDA/CentersOffices/OC/GlobalProductPathway/UCM259845.pdf>

⁷⁸ http://www.foodnavigator-usa.com/Financial-Industry/Closer-scrutiny-of-US-food-imports-promised/?c=mgVER3HH5%2FBpxjaHzqIb42dQqpnEI05&utm_source=newsletter_daily&utm_medium=email&utm_campaign=Newsletter%2BDaily

⁷⁹ Pathway to Global Product Safety and Quality, FDA, 2011.

<http://www.fda.gov/downloads/AboutFDA/CentersOffices/OC/GlobalProductPathway/UCM259845.pdf>

risks while coordinating with government counterparts at different levels⁸⁰. Compliance with the strict standards will help improve consumers' confidence, build positive image for food product and companies, eliminate barriers for food trade, and reduce the negative effect on social stability for countries like China. On the other hand, standards-setting should rely on common science-based standards as a baseline.

Modern retailers, middle class consumers, and export markets are increasingly demanding higher quality and safer food, and the result is that food processors are increasingly demanding high-quality products and assurances of food safety from their suppliers⁸¹. Some companies and collaborative groups apply strict standards and detailed guidance that suppliers must agree to follow. Wal-Mart Stores has told its beef suppliers that it expects them to find ways to achieve a 100,000-fold reduction of enteric pathogens found on beef in their slaughterhouses by June 2012, and a 100-fold reduction of pathogens in their processing plants, according to sources with knowledge of the situation. The new standards seem to be part of an emerging trend. Retailers and wholesalers large enough to effectively demand these types of changes are taking new steps to try to reduce the incidence of *E. coli* 0157:H7 in ground beef. Demanding that all their suppliers establish new science-based, documented interventions, starting at slaughter sites, they are requiring specific reductions of harmful bacteria over a specific period of time⁸². In addition to establishing standards and requirements for suppliers' practices, companies can provide guidance on how to implement those standards more effectively. Unilever has taken an innovative approach to helping suppliers reduce the use of low-quality and illegal pesticides in China⁸³.

In China, the foreign direct investment in the Chinese food processing sector has improved Chinese food safety standards because investors typically install stringent screening and testing methods that often exceed Chinese standards. For example, international dehydrated garlic producers have increased levels of product sorting, high-tech screening, metallic testing, and employee sanitation in their Chinese plants. International companies that source inputs for their products also require their suppliers to comply with strict food safety precautions; for example, frozen French fry producers that supply McDonald's must implement McDonald's food safety measures⁸⁴.

⁸⁰ http://www.foodnavigator-usa.com/Financial-Industry/Globalization-forces-FDA-to-prioritize-global-foodsafety/?c=mgVER3HH5%2FAmAonNZcFwUTtWTYld2teL&utm_source=newsletter_daily&utm_medium=email&utm_campaign=Newsletter%2BDaily

⁸¹ United States International Trade Commission: China's Agricultural Trade: Competitive Conditions and Effects on U.S. Exports. Investigation No. 332-518. USITC Publication 4219. March 2011.

⁸² http://subscribers.supermarketnews.com/Food_Safety_Recalls/wal-mart-sets-strict-0517/index.html

⁸³ How the private sector is boosting standards. China Brief of the American Chamber of Commerce in China. 2011, Vol. 19.

⁸⁴ United States International Trade Commission: China's Agricultural Trade: Competitive Conditions and Effects on U.S. Exports. Investigation No. 332-518. USITC Publication 4219. March 2011.

In May of 2010, the World Bank's Board of Executive Directors approved a loan of \$100 million to China to support the government's efforts to enhance food safety and meet increasing demand for higher quality and safer food by the Chinese population. The investment has been appropriated to implement The Jilin Agricultural Product Quality and Safety Project which will assist in the development of new standards for good agricultural practices. These new standards include both legal minimum standards and detailed recommendations for farmers⁸⁵.

6.3.2 Harmonization of standards

6.3.2.1 Regulatory standards

Continued safe globalization of food trade will require establishing quality and safety standards that are science-based and uniformly acceptable.

National regulatory standards must be formulated and reviewed based on risk assessment, and thus incorporate available scientific evidence. Whenever possible, these standards must be harmonized with international standards; i.e., the Codex standards. These regulatory standards must also be able to keep up with advances in new technology, emerging hazards, and changing consumer demands, among others. In addition, differences in public perception and scientific assessment of food risk remain a challenge. As such, it is imperative to involve all relevant stakeholders -- the government, industry, consumers, academia, and professional bodies -- in the standard-setting process⁸⁶. Many national governments, particularly in developed countries, established elaborate rate and complex food-quality and safety-monitoring systems for imported food products.

The food trade, both domestic and international, must meet certain consumer demands and address consumer concerns. Of primary importance to the consumer is the assurance that the food supply is safe, wholesome, and nutritious. Differences in legal requirements for food exist from country to country depending on a whole range of different attitudes, opinions, and interests related to food imported into a country. These differences have caused considerable confusion and uncertainty for food traders at the international level and in many cases, represent technical barriers to trade⁸⁷.

In the case of trade, the Sanitary and Phytosanitary Measures Agreement (SPS) requires that WTO members shall, when preparing and enforcing food safety measures, take into account the special needs of developing countries. The SPS Agreement requires that developing countries be provided with technical assistance to help them comply with health and safety standards. But, developed countries have not lived up to their obligations in this area. Absent adequate technical assistance, governments representing developing countries are

⁸⁵ <http://www.worldbank.org/en/news/2010/05/13/world-bank-help-improve-food-safety-china>.

⁸⁶ Noraini Mohd Othman. Food Safety in Southeast Asia: Challenges Facing the Region.

<http://www.searca.org/>.

⁸⁷ <http://www.netlibrary.com.ezproxy.lib.uwf.edu/Reader/>

sometimes forced to argue at Codex for downward harmonization on the grounds that they cannot meet high, international standards. This situation is not acceptable for either developing or developed countries. Developed countries must provide developing nations with technical assistance that will allow them to meet world class standards to both benefit their own citizens and compete effectively in international markets⁸⁸. Industry organizations from developed countries can provide their expertise to developing countries by conducting education programs such as workshops, seminars, and on-site training funded by public-private partnership programs or government contracts from developed countries.

6.3.2.2 Industry efforts at standard harmonization

Suppliers often find themselves being repeatedly audited by individual customers, creating a massive duplication of audit procedures. While consumers need to be reassured that the food they are purchasing and eating is guaranteed as safe for consumption, the unnecessarily repetitive audits need to be reduced. It is also important that, as food supply chains stretch across the globe, industry solutions cover the end-to-end supply chain and are able to influence the industry on an international scale. In the past, interested parties have joined forces to support the creation of benchmarking and approval schemes that could lay the foundations for an industry-wide expectation in terms of food safety management system deliverables. This has now become the benchmark against which all food safety standards can be tested, verifying that the standard once gained by an organization proves they are producing or handling food at the level of safety specified.

As a result of the continued duplication of audits, some organizations set out to develop a uniform structure, the standard for benchmarking, not the standard for auditing, for food safety standards by detailing food safety criteria that should be incorporated. By putting common procedures in place for accreditation and certification bodies, they hope to verify the implementation of standards⁸⁹. They have been making efforts to have governments worldwide establish confidence in and use the standards when assessing the suitability of products for sale globally⁹⁰.

The certification, harmonization in food safety standards, will reduce transaction costs. Food safety at all stages of the food chain requires every stakeholder to assume the relevant responsibility, even though small and medium enterprises, representing a majority of the industries in less economically developed countries, are often unable to fulfill the requirements of international standards. Industry must take the initiative to improve food safety in its own operations and through a genuine partnership with key stakeholders, including governments⁹¹. An industry

⁸⁸ Bruce Silverglade. The WTO Agreement on Sanitary and Phytosanitary Measures: Weakening Food Safety Regulations to Facilitate Trade? Vol. 55, No 4 Food and Drug Law Journal, p. 517.

⁸⁹ Comparing Global Food Safety Initiative (GFSI) Recognised Standards. 2011. SGS. <http://www.sgs.com/comparing-gfsi-recognized-standards-information-request>.

⁹⁰ <http://www.foodprocessing.com/whitepapers/2010/014.html>

⁹¹ APEC and World Bank sign food safety agreement. May 19, 2011. <http://www.foodnavigator-usa.com/>.

collaboration network is needed to provide the platform for food industries in developed countries and the industries in less economically developed countries to exchange information with each other and cooperate on industry response.

6.4 Hands-on Strategies: Problem Solving

Legislation, laboratory, food inspection and certification, information-sharing, and consumer participation and empowerment have been identified as priority food safety areas for some Asian countries⁹². Industry associations and nonprofit international organizations have become involved in helping improve the food safety capacity of these countries, with special emphasis on improving the operational level of food safety in emerging countries.

6.4.1 Problems encountered by China in upgrading safeguards and food industry standards

China is one of the biggest exporters of agricultural produce and food ingredients. Bilateral agricultural trade in 2010 consisted of \$17.8 billion in U.S. exports to China and \$3.2 billion in imports from China. However, the farm scale is smaller in China relative to farms in the western world, and Chinese farmers typically farm on plots of one to two noncontiguous acres, which results in difficulties of standardizing and monitoring production practices at the farm production level. First, it is hard to trace safety problems to a specific farm. Secondly, the small scale farming leads to a fragmented marketing system dominated by millions of small farms handling small volumes, often on a cash basis with no documentation or ability to trace products. For example, a study⁹³ indicated that the problems in China's dairy industry were a result of rapid growth fueled by large investments from multinational dairy firms; development of a highly modern and concentrated processing sector that obtained its raw materials from millions of small, poor and uneducated traditional farmers; and government support and encouragement for growth but with little emphasis on inspection and safety issues.

In the primary production, some food safety problems are from heavy use of fertilizers and pesticides to counteract intensively cultivated soils and large pest pressures; wide use of antibiotics to control diseases in intensive livestock, poultry, and aquaculture systems; industrialization; and untreated human and animal waste in fields and waters which raise concerns about toxic, metal, and microbial contaminants in food. It is also important to address the fragmented regulatory and oversight structure comprised of 10 national government ministries which has little coordination with lower levels of government. These lower levels of government often have their own differing standards for food products, and as in the case of many commodities and industries, they have

⁹² Noraini Mohd Othman. Food Safety in Southeast Asia: Challenges Facing the Region. <http://www.searca.org/>.

⁹³ Changbai Xiu, K.K. Klein. Melamine in milk products in China: Examining the factors that led to deliberate use of the contaminant. Food Policy, Volume 35, Issue 5, October 2010, Pages 463-470.

outdated or nonexistent standards or standards that are inconsistent with internationally accepted ones⁹⁴.

Public concern about food safety is placing increasing pressure on government agencies to be more prescriptive and proactive in their regulation of the food industry. However, given the scarcity of public sector resources, concerns about the impact of regulation on competitiveness and the scale of the task at hand, there is growing interest in co-regulation with the public and the private sectors; each will work hand-in-hand to deliver safer food at lower (regulatory) cost. Coordination of public and private food safety management efforts at different stages in the regulatory process can potentially result in improvements in the level of food safety at a lower cost and the more effective allocation of scarce regulatory resources⁹⁵. Equally important is to extend this public-private coordination to the implementation of this regulation at operational level.

Food safety issues cannot be corrected by one nation alone, so the involved nations should share information, data, and workload. For example, the U.S. FDA is planning to team up with regulatory counterparts worldwide to develop international information systems and networks to share data and regulatory resources. And, stakeholders such as industry and some organizations can play an important role in this regard. Chinese regulators have sought industry assistance in their efforts to provide technical assistance at the operational level. Multinational companies with international sourcing and global marketing capabilities have launched a variety of technical assistance programs. Cargill, for example, has signed a joint training program with AQISQ. It has also implemented Hazard Analysis and Critical Control Points (HACCP) in all its 34 plants in China to promote food safety⁹⁶. Nestlé has established several technical assistance initiatives for milk and coffee farmers in China. Nestlé buys fresh milk from thousands of farmers across China, offering them assistance to increase the quality, quantity and efficiency of their production. In Yunnan province, Nestlé has been encouraging and supporting coffee cultivation for almost twenty years, and nearly 4,100 farmers have received direct training on planting, quality control and processing techniques⁹⁷.

Asia-Pacific Economic Cooperation (APEC) established Food Safety Cooperation Forum (FSCF) in 2007, with an aim to facilitate trade and protect public health by building the capacity of stakeholders in the supply chain in the use of international standards. Grocery Manufacturers Association (GMA) is already working in conjunction with suppliers in the 21 countries covered by the APEC group to improve food safety standards.

However, a forum which can integrate all of the abovementioned single company's or association's efforts and affix them to long lasting initiatives will help deal with food safety issues in less developed countries. This platform is to

⁹⁴ <http://www.fas.org/sgp/crs/row/RL34080.pdf>

⁹⁵ <http://www.sciencedirect.com.ezproxy.lib.uwf.edu/science/article/pii/S030691920600090X#secx2>

⁹⁶ <http://www.cargill.com.cn/china/en/home/corporate-responsibility/projects/index.jsp>

⁹⁷ <http://infoseekchina.wordpress.com/category/china-dairy/>

exchange and present information on food safety issues, new risk minimization strategies, and industry collaborative initiatives as well as to provide a rapid advisory response system to assist those countries' government ministries in addressing threatening food safety events, and to help food industries in those countries advance food safety through workshops, public sector liaison, consumer education, trade missions, and technical advances.

6.4.2 Global Food Safety Forum

In order to address the food safety issue and trade concerns as a result of globalization, it is necessary to establish a long-term and lasting platform for food producers, processors, merchandisers/ shippers/distributors and retailers. A dialogue is needed with government regulators, clients, consumers, and their counterparts in other countries.

The Food Safety Roundtable, held in Beijing in April of 2009, brought together senior international food industry executives to discuss collaboration to help address such questions as: 1) How can companies build and maintain public confidence and brand loyalty in the event of a food safety crisis? 2) How can companies preserve profits in the face of changing oversight and regulation policies? and 3) How can companies build effective communication with regulatory agencies? Some participating industry leaders proposed to fix this roundtable as a sustainable forum.

The anticipated results for that forum in the short term are: 1) information sharing with emerging countries' regulators and experts to increase their awareness of international standards, regulations, guidelines, and experiences; 2) industry initiatives to harmonize local, private sector, and international standards; 3) workshops and social consumer network communication and promotion; and 4) greater industry coordination in the global food chain through delegation meetings and visits to developed countries and the ingredient sourcing emerging countries, respectively.

At the industry level, this platform fills the niche to facilitate coordination as well as risk minimization and rapid response systems. The effort is designed to provide a "hands-on" approach to advancing food safety norms and practices in Asia while using China as the first step in developing the "brand" and the architecture for an industry platform in Asia. In addition to China, the model and experience will be expanded to other Asian countries. Trade and current account balances all point to a continuation of the trend towards higher per capita income and a growing middle class with consumer preferences for high quality food products.

Global Food Safety Forum (GFSF) offers a platform for private-public sector collaboration; building members' brand for quality and food safety worldwide; integrating national and international regulatory regimes and standards; and offering food safety workshops to companies, government agencies, and consumers. This forum also serves as a multi-use platform for industries that could accommodate specialized interests in different links of the global food chain. GFSF, accordingly, has created partnerships with other organizations

such as National Center for Food Protection and Defense (NCFDP), Global Initiative for Food Systems Leadership (GIFSL), Food Marketing Institute- Safe Quality Food Institute (FMI-SQFI), etc. These collaborations are all designed to capture the synergies of these respective organizations and serve as a model for industry leadership in Asia.

GFSF accomplished some USDA EMP program funded events with the support of our distinguished members such as Pfizer Animal Health, Novus International, Thermo Fisher Scientific, Safe Quality Food Institute (SQFI), AAK, Minnesota Department of Agriculture, Sino:Genesis PTE. LTD.

China Food Safety Workshops: The workshops covered China's role in the global food chain; the U.S. example; China New Food Safety Law; regulations, standards, and compliance procedures in China; FMSA compliance provisions; and the U.S., third party audit and certification, technology advances, and risk management. The workshops improved Chinese participants' awareness of internationally recognized food safety management systems and exposed participants to new operating procedures, global standards, and compliance with the US Food Safety Modernization Act. This has helped increase the potential to eliminate some market constraints and barriers, and it has helped Chinese participants adopt internationally recognized regulations and standards.

After the successful Food Safety workshop on Meat in Shanghai, November 8-9, 2010, GFSF held workshops in Hangzhou and Hefei, China, on June 10 and 12, 2011, that were both over-subscribed (more than 110 participants for each). The Hangzhou workshop consisted of four hours of presentations and discussions which addressed risk management and new provisions to importers of FSMA; a 4-hour site visit to Wahaha and Youcan. Presenters were mainly from GFSF members. At the Hefei workshop, GFSF worked with Dairy Association of China (DAC) to address the increasing global concerns about dairy food safety that resulted from the 2008 melamine tainted milk scandal and leather protein milk in China.

GFSF Technical Ambassador Corps: The GFSF Ambassador Corps provides a reliable industry resource and a platform to introduce standards and procedures commensurate with US market requirements. A consumer education campaign will be addressed in participating countries through social networks to improve the food safety awareness of consumers. A team of food safety expert ambassadors from GFSF members visited two Chinese food processors in Hangzhou, Zhejiang province on June 10, 2011. The food expert ambassadors visited a beverage plant, an R&D center, a testing center, and the Engineering Department and Facility of Wahaha Food Group and Youcan Food Ltd. The Ambassador Corps discussed food safety issues at the operational level, such as certification, food safety management, and the ingredient supply system with R&D and the Quality Assurance team members of the two companies.

GFSF – Government Dialogue: GFSF organizes dialogue events to strengthen the government-industry coalition and institutionalize government-industry cooperation. A GFSF delegation comprised of industry representatives and food

safety experts met with officials from the local Chinese food safety regulatory agencies in Hangzhou on June 10, representatives from the Chinese Ministry of Agriculture and DAC in Hefei on June 12, and representatives of the Food Industry Association and the Certification and Accreditation Administration in Beijing on June 13-14. Both exchanged information on food safety issues, new risk minimization strategies, and industry collaborative initiatives.

Food Safety White Paper - US and China: The GFSF is writing a comprehensive paper detailing problems and solutions regarding food safety matters affecting trade between the United States and China as a result of food and agricultural products. GFSF released the White Paper Executive Summary at its workshops in Hangzhou on June 10 and in Hefei on June 12. What it points out is that, despite advances in regulations, there remains a patchwork of standards, enforcement systems, industry self-regulation strategies, and compliance systems. The report will be released in its entirety in July 2011, and it will include contributing chapters from our new associates at Michigan State University and Food and Drug Law Institute.