Between Market and the State: Regulating Food Safety in the Wake of Pet Food and Frozen Dumplings Incidents

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Abstract

Food safety has become a widespread concern for consumers in China’s major trading partners. This article looks into the details of legal responses to food safety incidents in Japan, the United States and China. What the three countries have in common is what I label “inspection-based” approach to food safety. In Japan, after the frozen dumpling incident, people are proposing setting up a “comprehensive” regulatory agency. In the United States, the Bush Administration signed a bilateral agreement with China, making China’s product quality agency—AQSIQ—a certifying agent of the FDA. In China, the government launches national law enforcement campaigns on food safety. This article argues that the inspection-based approach would not achieve food safety. The article proposes an alternative, the so-called “liability-based” approach to food safety. The benefit of liability-based approach is that it brings consumer groups and market forces into the regulatory process.

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Early in September, 2008, a local newspaper in northwest China’s Lanzhou, capital city of Gansu province, reported that 14 babies were hospitalized for suffering from kidney stone problems. Health officials at Lanzhou suspected that a brand of baby milk powder was the reason but the paper did not reveal which brand it was. The brand was not named until it was revealed by an unknown journalist in his blog. The substandard milk powder was produced by Sanlu Group, based in Shi-jia-zhuang, capital city of Hebei province, a flagship dairy producer in China. The scandal soon spread beyond Gansu province, and then across the country to become one of the biggest food safety disasters in China’s history. More than 296,000 babies were sickened and at least 6 babies died as a consequence of consuming the problematic baby formula. Soon afterwards, warnings and concerns spread across the whole world. The Washington Post characterized it as a global backlash, from “Chocolate Pillows” sweets in Osaka, Japan, to a milkshake in Austria to White Rabbit Creamy Candies in West Hartford, Connecticut.

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For many, the Sanlu scandal is another reminder of food safety problems in the increasingly and helplessly globalized world, after a series of product safety incidents in the last couple of years: (1) in May and June 2007, diethylene glycol, a poisonous ingredient in some antifreeze, was found in 6,000 tubes of toothpaste in Panama; (2) pet food recalls from March to May of 2007 because wheat gluten from China contained industrial chemical melamine; (3) in June and August, 2007, lead-paint in toys. In food crises, often consumers at home in China are the first victims. A survey of consumers from 31 cities conducted by the Chinese State Food and Drug Administration (SFDA), published in February 2007, found that 35.2% of consumers had confidence in the quality of food. In 2005, the number was even 7 points lower! The 2005 number is largely consistent with a recent campus survey in Japan, where 79% of those surveyed said they did not believe food from China was safe.

But this does not mean that the foreign producer is the only culprit. Most recently, peanut butter contaminated by bacteria called salmonella by Peanut Corporation of America (PCA) claimed nine lives and 637 illnesses in 44 states and Canada, with an estimated 19,000 people sickened. The incident happened in the wake of repeated critiques on the United States Food and Drug Administration (FDA) for its lax oversight of food safety in the last several years. In mid February 2009, PCA filed for bankruptcy.

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3 The Problem with Made in China, ECONOMIST (Jan. 11 2007); Jyoti Thottam, The Growing Dangers of the China Trade, TIME (Jun. 28, 2007); China Food Fears Go from Pets to People, WASH. POST, Apr. 25, 2007, at A01.

4 Walt Bogdanich & Renwick McLean, Poisoned Toothpaste in Panama Is Believed to be from China, N.Y. TIMES, May 19, 2007.


recent experience in food poisoning in the “summers of living dangerously” in 2000 and 2001. The Snow Brand milk case of 2000 caused food poisoning eventually to 14,780 victims after having consumed milk from Snow Brand Foods Co., the largest food poisoning incident in terms of victim population. The scandal eventually led to the dissolution of the company in April 2002. In May 2003, the Osaka District Court found two of the executives of Snow Brand guilty of negligence and of violating the Food Sanitation Law for sending a false report.

So, what is the legal response to the food safety concerns? What measures are taken by the regulators? What do the measures taken by the regulators tell us about the regulatory styles and mentality? These are the questions raised and discussed in this Article in the context of the food safety incidents in three major economies—Japan, the United States and China. Part I tells the story of food poisoning case in Japan as a consequence of consumption of frozen dumplings made in China. The incident (and the controversy between the two countries) became a catalyst in the preexisting debate in Japan on food safety and aroused calls for establishing a comprehensive agency. Part II is centered on a bilateral agreement between the United States and China on food safety in 2007, in response to the pet food and other incidents. A careful analysis of the bilateral agreement suggests that the Bush Administration only tried to outsource regulatory obligations of the U.S. Food and Drug Administration (FDA) to its Chinese counterparts. Though it was claimed by the Bush Administration as an ambitious plan, its strength is largely dependent on collaboration from its Chinese counterparts. Part III discusses the rise and fall of China’s FDA—the experiment on setting up a regulatory agency with the U.S. FDA as the model. Despite its ambitious beginning around 2003 and 2004, by September 2008, soon after the breakout of the Sanlu scandal, all of the major regulatory agencies in China have failed to materialize that promise.

In the globalized world increasingly linked by food chains, this Article argues, what is being circulated is not only food, but also a common mentality in regulating food safety. One key thread that links Japan, the U.S. and China in the legal response to food safety crises is the notion of a powerful and

http://cspinet.org/new/pdf/senate_agriculture_testimony_-_feb_09.pdf (last visit on Mar. 9, 2009). Also, text accompanying notes 115 and 116, infra.


13 Snow Brand Foods’ Dissolution Approved, JAPAN TIMES, Apr. 27, 2002, Website: http://search.japantimes.co.jp/cgi-bin/nb20020427a1.html (last visit Nov. 30, 2008).

14 Snow Brand Employees Handed Suspended Terms for Poisoning, JAPAN TIMES, May 28, 2003, available at: http://search.japantimes.co.jp/cgi-bin/nn20030528a1.html (last visit Dec. 1, 2008). However, despite demands from victim families, the Osaka Prefectural Prosecutors insisted not to prosecute Tetsuro Ishikawa, President of the Snow Brand when the food poisoning occurred.
comprehensive regulator. In both Japan and China, policy makers often have in mind the United States FDA as an inspirational model. Part III tells the story of the failed experiment in establishing China’s FDA. In Japan, the LPD (Japan’s ruling Liberal Democratic Party) is proposing a FDA type regulatory agency. In China, consumer groups are regularly brushed aside, often constrained, sometimes even suppressed, by the regulators. Thus the mythical FDA, even if it is established in China and Japan, would still be a castle on sand. The Bush Administration’s agreement with China in 2007 represented an international version of castle on sand. The U.S. FDA, unlike what its Chinese and Japanese admirers tend to imagine, was paralyzed by its own lack of resources, fragmented authority, and the mounting challenge of food imports. Thus, legal responses to the food safety crises have been framed and limited by the mythology of an omnipotent regulatory agency.

This regulatory approach—though it varies in form and substance in Japan, the U.S. and China—can be characterized as the inspection-based approach. This Article argues for an alternative approach in which regulation is not measured by the “strength” or capacity of the regulator alone, but by its ability to bring consumer groups and market forces into the regulatory process. At the core of this approach is liability—liability of food producers, retailers and importers. I’ll label this alternative as liability-based approach. The main merit of the liability-based approach is that it has the potential of striking a better balance between the State and the market. This becomes also a practical issue because the United State Congress has started redesigning food safety law by publishing a draft of the FDA Globalization Act released in April 2008.15

I. Frozen Dumplings Incident and Legal Response in Japan

A. Frozen Dumplings from China: The Story

It started with a report on January 30, 2008 that ten persons from three families in Chiba and Hyogo suffered from food-poisoning after having consumed dumplings from China.16 Local police found methamidophos (an

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organic phosphorus insecticide) in the dumplings, and suspected that it was likely from outside as the packages were intact. The frozen dumplings were from Tianyang Food Processing of Hebei province in China.

This came as a shock in Japan. By February 7, confirmed victims of food poisoning as consequence of consumption of the frozen dumplings from China reached 10.\(^17\) The Ministry of Health kept a close eye on the number of victims and reports and updated reports online regularly. Though the number of confirmed victims remained unchanged up to its final report on March 31,\(^18\) the number of reports shot up quickly—showing a widespread panic among the general public. By March 31, confirmed cases remained 10, and 5919 were interviewed or consulted.\(^19\) Schools and restaurants in Japan removed Chinese-made food from their menus and TV stations warned viewers not to eat any food imported from China.\(^20\)

It was also a shock in China. The Ministry of Agriculture had just concluded a four-month nationwide campaign to crack down on substandard consumer products. The Agriculture Vice-Minister Gao Hongbin announced in a high-profile press conference that the mission was “complete” on January 8, 2008.\(^21\) This was in part to suggest that China was getting ready for the incoming 2008 Olympics Games.

AQSIQ (General Administration of Quality Supervision, Inspection and Quarantine)—China’s national regulatory agency in charge of product quality—immediately conducted tests on samples of the two batches of dumplings and but found no harmful chemicals.\(^22\) In the meantime, the company has been ordered to recall all its products from both domestic and foreign markets. Samples of the exported dumplings recalled from the Japanese market were brought back to China for inspection. Still, no harmful components were found. Investigators in China also questioned 30 Tianyang employees and probed the purchasing, manufacturing, storing and transporting processes. A team of five Chinese investigators reached Tokyo on Sunday, February 3, 2008 to join a bilateral investigation into the poisonings.\(^23\) But nothing was discovered. In the meantime, the Japanese government sent a team of officials to China to investigate the case on


\(^{19}\) MOH Japan, 2008c, id.


\(^{22}\) *Dumplings Contain No Traces of Pesticide*, CHINA DAILY, Feb. 1, 2008, at 1.

February 4. A joint investigation team of China and Japan conducted an on-the-spot inspection in the Tianyang Food Plant. Again, no abnormality was traced. By Tuesday, February 5, education boards of 606 public schools across Japan have been asked to refrain from serving food produced by Tianyang though no children had fallen ill.

Speculations on the media reports became sensational. The Japanese Health Minister Yoichi Masuzoe suggested the poisoning may have been deliberate. China was irritated by the speculations but was more on the defensive, focusing on the investigation. In its last effort, on February 12, AQSIQ made another inspection tour to the Tianyang Food Plant, checking the plant’s production chains, production records and videos. Nothing unusual was found. On February 13, AQSIQ told a news conference that earlier reports saying Chinese workers deliberately contaminated dumplings sickening 10 Japanese were “mere subjective guesswork”. On the same day, a senior AQSIQ official said the dumplings involved in the food poisoning incident were “an isolated case”, rather than the result of a general food safety problem. On February 15, the State Council Information Office and AQSIQ held a joint press conference in Beijing. On February 15, “We are considering this as an isolated case, not a food safety problem,” said Wei Chuanzhong, deputy director of AQSIQ.

Late in February, the Chinese side called for a “responsible” ending. Two weeks after, Yu Xinmin, deputy director of the criminal investigation bureau with the Ministry of Public Security (MPS), told a press conference organized by the State Council Information Office: “[o]ur investigation shows that the poisoning incident in Japan was a case of sabotage, and not a food safety problem,” He further added, “[a]nd it’s unlikely that the sabotage happened in China.” The People’s Daily, the most official newspaper, for the first time since breakout of the incident, covered the press conference in length, and complained about lack of cooperation from the Japanese side.


25 The London-based Time magazine commented that the incident could also poison the already strained ties between the two countries. Japan, China Head off a Dumpling War, TIME, (Feb. 7, 2008).


during the investigations.\textsuperscript{30} Chinese media was also critical of the Japanese media for sensational coverage of the incident.\textsuperscript{31}

In May 2008, investigation was interrupted by the large-scale earthquake in Sichuan province. The investigation made a sharp turn in August 2008. On August 6, the Chinese Ministry of Foreign Affairs admitted that in June, food poisoning also happened in China to people who had consumed the frozen dumplings from the Tianyang.\textsuperscript{32} On August 28, China admitted to the Japanese Foreign Ministry that it was likely that contamination had occurred inside China.\textsuperscript{33} The Japanese newspaper \textit{Asahi Shimbun} reported that after investigators interviewed 55 temporary workers in the Tianyang factory, it became clearer that more likely the chemicals were spread onto the dumplings deliberately inside the factory.\textsuperscript{34} The Japanese newspaper reasoned that the investigation ended earlier in Japan because the chemicals were highly concentrated thus the Japanese side concluded that it was unlikely that the frozen dumplings were contaminated in the transportation process. It commented that during the investigation, the lack of trust in Chinese foods among Japanese consumers was also a contributing factor in this incident. It called for improving exchange of information between sides.

**B. The Trouble with Private Ordering**

Importer of the dumplings, Japanese Consumers’ Cooperative Union (JCCU) [日本生活協同組合連合会], a national organization of consumer cooperatives in Japan formed in March 1951. Its mission includes both business and social functions. In business, it is an importer and exporter of foods. It also develops its own brand products. JCCU was a leader in promoting food safety since the 1960s. Many of its members joined the co-ops in order to gain access to safe and higher-quality foods.\textsuperscript{35} However, in early February 2008, when the frozen dumpling incident was still unfolding, there has been growing concerns among consumers questioning JCCU’s promises of good safety.\textsuperscript{36}


\textsuperscript{31} Ding Ying, \textit{The Dumpling Dilemma: A Food Safety Scare over Imported Frozen Jiaozi from China Causes Undue Media-infused Panic in Japan}, \textit{BELING REV.} (Mar. 6, 2008, No.10).


\textsuperscript{34} \textit{Temporary Workers Convened and Questioned, Dumplings Poison “Occurred in Factory [in China]”, Yumiuri Daily}, Aug. 31, 2008 (Yumiuri Shimbun 2008-08).

\textsuperscript{35} Patricia L. Maclachlan, id, at 181.

\textsuperscript{36} \textit{Before You Can Relax, JCCU Arrived: Food Poisoning in Chinese Dumplings Incident}, \textit{Senki News}, Feb. 6, 2008 (Senki News 2008).
From JCCU’s point of view, it was important to distinguish two categories of frozen dumplings involved in the incident: those dumplings made and packaged in China (marked as “made in China”); and those dumplings made in Japan with raw materials from China (without the mark “made in China”), but only those in the first category were found problematic. However, packages of both categories of dumplings are marked by JCCU's trademark, CO-OP in green color. Under Article 2(3) of the 1994 Product Liability Act, an importer of a product or “any person who presents its name, trade name, trademark or other mark on the product as its manufacturer” is considered as the “manufacturer” of the product thus will be held liable. In the past, the judiciary had no difficulty in finding the importer liable. In February 1999, the Sendai District Court applied PL Article 2(3) in a case where a restaurant filed lawsuit against a wholesaler and the importer who had supplied raw sea urchins (from China) when 23 of its customers suffered food poisoning. The Court had no difficulty in finding the importer liable.

In response, on February 13, 2008, JCCU launched a large-scale self-inspection that included: chemical residue in 265 products made in China, the origins of various raw materials, and an emergency inspection of 60 manufacturing sites inside China. On February 22, a special commission was formed by JCCU and held its first meeting. The commission was composed of people from research institutions, media, government, and consumer groups, and its mission was to evaluate the effectiveness of the responses of the JCCU and its branches, to propose new measures to improve food safety in the future. On May 8, JCCU published an announcement on


40 LUKE R. NOTTAGE, PRODUCT SAFETY AND LIABILITY LAW IN JAPAN: FROM MINAMATA TO MAD COWS 105-11 (2004).

41 LUKE R. NOTTAGE, id, at 109 (discussing the case).

42 LUKE R. NOTTAGE, supra note 40, at 162.


major newspapers across Japan, pledging to strengthen internal mechanisms on inspection to assure food safety. Under this plan, the JCCU will increase inspection facilities, the number of inspectors, more frequent inspections, etc. On May 15, 2008, leaders of the JCCU were penalized. On May 30, the Commission published its final report. The report followed the public announcement, focusing on internal reform: it called for better communication of information between co-operatives and between them and the JCCU, and for establishing a special food safety department within the JCCU; it played with terms like risk analysis.

C. Establishing a Comprehensive Regulatory Agency

Among consumer groups, shōdanren (National Federation of Consumer Associations) seized the frozen dumpling incident to actively push for its own reform agenda. On August 28, 2008, shōdanren publicized an opinion on the reform of FSC. In the wake of the frozen dumplings incident and the BSE, the opinion noted, FSC should be strengthened in its financial resources and structural functionality in order to be able to reduce risks and improve communication with consumers at large. Second, it is necessary to improve the collaboration between governments and local social groups in risk communication and management. In sum, Shōdanren was pushing for a new regulatory agency that can not only conduct risk analysis, but also be able to manage risks. In another publicized opinion targeting the Diet, it envisioned the new regulatory agency as the commodore on food safety.

Shōdanren efforts in seeking a political alliance with the LDP coincided with the frozen dumplings incident. After the 1994 electoral reform, LDP now needs a broader constituency in order to succeed in elections.


the LDP faced a defeat at the Upper House of the Diet. This led to efforts
to take on the issue of food safety in the mid of a series of incidents. In his
speech on October 1, Premier Fukuda talked about turning to politics with
citizens’ safety and confidence as a key.51 He stressed that in order to assure
food safety and confidence of citizens, government must adopt consumers’
point of view; supervision of imported food should be further strengthened,
proper labels should be required. On November 30, the LDP set up the
above-mentioned Consumer’s Issues Investigation Committee. Furthermore,
in his speech to the Diet on January 18, 2008, as part of his “consumer-
oriented society” plan, Fukuda proposed forming a new regulatory agency
to protect consumers’ interests. The new agency will consolidate the currently
dispersed functions in different departments of the government. It will
become a showcase for the general public to voice their opinions, to formulate
policy for the consumers and by the consumers.52 Shortly afterwards, on
January 22, 2008, Shōdanren expressed strong support for the LDP’s plan.53
On February 27, Shōdanren sent a support letter to LDP’s Consumer’s Issues
Investigation Committee.54 Referring to various consumer-related issues and
scandals, including the frozen dumplings incident, Seiko Noda [, Minister of
Consumer Affairs, was quoted as saying, “a major shift to truly consumer-
oriented policy is required.”55 In response to Fukuda’s sudden resignation on
September 1, Shōdanren issued a statement wishing that efforts on the new
agency would continue.56 A bill was submitted to the Diet on September 20.57
New Prime Minister Aso continued the efforts.58

Democratic Party of Japan (DPJ) also took up the Chinese dumpling
incident more closely, but with a proposal that was different from that of the
LDP’s. In February, DPJ made an announcement in response to the frozen

51第168回国会における福田内閣総理大臣所信表明演説 (Speech at the 168th Diet by Prime
Minister Fukuda), October 1, 2007, available at:

52第169回国会における福田内閣総理大臣施政方針演説 (Speech to the Diet), January 18,

53 自民党・消費者問題調査会「消費者行政のあり方」に関する意見(), Jan. 22, 2008, available
at: http://www.shodanren.gr.jp/database/179.htm (last visit on Nov. 30, 2008).

54 生活安心プロジェクトの充実のために、地方消費者行政の充実・強化を強く求めます
(Opinion), dated February 27, 2008, available at:

55 Kazuaki Nagata, Noda: The Time Is Ripe for Consumer Agency, JAPAN TIMES, Aug. 27,
2008, available at: http://search.japantimes.co.jp/cgi-bin/nn20080827a4.html (last visit
on Jan. 12, 2009).

56 新組織の早期創設への要望(), dated September 3, 2008, available at:

57消費者庁設置法案 (Establishing the Consumer Administration), dated September 20,
visit).

58麻生自民党の新たな経済対策「生活対策」(New Economic Policy: Life []), dated October
(last visit).
In August, DPJ started marketing the idea of a foot safety ombudsman. More importantly, it is not whether the unitary Consumer Agency can be established. Rather, the question is: even if it is established, would it function the way it is designed? Where does the strength of the new Agency come from?

II. Bilateral Approach?

A few months earlier, China just had engaged in a battle with the United States and European Union on food safety issues. Even before the dumpling incident, the two sides had been in contact on food safety. For example, on August 6, 2007, where the two sides discussed issues relevant to the incident: foodstuffs exported to Japan in violation of Chinese law; and assurance of conformity with Japanese food safety laws.

A. The Bilateral Proposal

Before the dumpling incident, there was an international framework that would have covered the legal issues: the World Health Organization's (WHO) International Health Regulations (2005), which have come into force in June 2007. Both China and Japan are parties to it. The IHR 2005 requires specific notification and response to incidents of international public health significance, and food safety incidents are covered by this umbrella. IHR 2005 mandates every member country to establish a National IHR Focal Point as the authority in charge of disseminating information about emergency with National IHR Focal Points of other countries or the WHO's Focal Point.

II. Bilateral Approach?
Network (INFOSAN) was established by the WHO to facilitate communication. From 2004 to 2008, China has established a wide range of contacts with the international community in relation to food safety. China held a Global Food Safety Forum in November 2004 in Beijing attended by 450 participants with more than 120 officials and experts from international organizations and foreign governments. Between Nov. 26 and 27, AQSIQ and Ministry of Health cosponsored with WHO the High—Level Food Safety Forum took place in Beijing. A “Beijing Declaration on Food Safety” was publicized, urging all countries to undertake a series of improvements to strengthen their national food safety systems.

Since both China and Japan identified the dumpling incident as a public health issue—rather than a trade issue—both should have followed the procedures prescribed by the IHR (2005). What happened during the dumpling incident shows little relevance or awareness of the IHR (2005) or INFOSAN on both sides. In the middle of February 2008, China had nothing to say about the existing INFOSAN mechanism when it called for establishing a cooperative mechanism with Japan.


68 During the epidemic of 2000–2003 severe acute respiratory syndrome (SARS), China had already worked with the WHO and had been widely criticized for its failure to provide the WHO information in a timely fashion, see, Alan Schnur, The Role of the World Health Organization in Combating SARS, Focusing on the Efforts in China, in SARS IN CHINA: PRELUDE TO PANDEMIC 31–52 (Arthur Kleinman & James L. Watson eds. 2005).


Wei, the deputy director of Bureau of Import and Export Food Safety of the AQSIQ wrote on the China Daily,\textsuperscript{72} to establish a regular cooperation mechanism between the China’s AQSIQ and Japan’s Ministry of Health: (1) inform in a timely manner food safety standards and testing requirements to each other, and provide personnel training and technical assistance; (2) send quality control officers to oversee relevant food-processing procedures in the other country; (3) rapidly inform the other country in case of any food safety emergencies, and take measures to prevent the situation from escalating; (4) release scientific and accurate information to the public and avoid causing panic.

Probably, Chinese officials had their recent bilateral agreements with the European Union and the United States in mind when making the suggestions to Japan. In the summer of 2006 and 2007, Mattel lead high level talks between the United States and China;\textsuperscript{73} where the two sides concluded a bilateral agreement on toys in September 2007.\textsuperscript{74} In November, 2007, an Agreement on the Safety of Food and Feed (2007).\textsuperscript{75} With European Union: EU - China MOU on Product Safety in November 2005,\textsuperscript{76} which was put in very general and brief terms. A more formal agreement was reached in the January 2006 EU-China memorandum, which was extended and elaborated in more detail on Nov. 17, 2008 an EU-China MOU on Administrative Co-operation.\textsuperscript{77} Possibly, the fact that China was suggesting a bilateral approach indicates that China’s preference for horizontal governance—bilateralism in public health matters, like most other countries. So it is necessary to look into some of details of China’s existing bilateral agreements to understand what could the future arrangement with Japan, at least from China’s point of view.


\textsuperscript{73} U.S.-China Trade Talks Open with Food Safety an Issue, N.Y. TIMES, May 24, 2007.

\textsuperscript{74} China Signs Pact to Ban Lead Paint in Export Toys, N.Y. TIMES, Sep. 12, 2007, at C9.


There are three components in the bilateral agreements: infrastructure, information sharing, and regulatory cooperation. First, in terms of infrastructure, both the U.S.-China Agreement follows the idea of contact point in IHR (2005) by requiring the establishment of a contact point.\(^78\) Since these bilateral agreements are between AQSIQ and the United States Department of Health and Human Services (“HHS”), the contact points are internal offices within these agencies.

Second, both agreements are emphatic on regular information sharing. Information includes: (a) information on laws and regulations relating to food safety;\(^79\) (b) notification of the other party of any significant risk within two days of discovery of such risks;\(^80\) (c) information about compliance and enforcement programs;\(^81\) (d) incidental or intentional contamination of foods;\(^82\) (e) information regarding mandatory, pre-market review/approval processes for food ingredients;\(^83\) (f) information on possible adulteration of ingredients.\(^84\) Here, by sharing regulator legal information and law enforcement information, the U.S.-China Agreement goes further than the IHR (2005).

Third, regulatory cooperation: (a) enables on site inspection;\(^85\) (b) a registration program for all manufacturing establishments who export food products to the United States;\(^86\) (c) a certification for all manufacturing establishments who export food products to the United States.\(^87\) Essentially, the FDA seeks assistance from its Chinese counterparts in safeguarding the United States border. Under the registration and certification programs, FDA keeps the AQSIQ updated of all FDA import requirements. AQSIQ is to register only establishments that meet FDA requirements, and will monitor all the establishments to make sure they continue to meet those FDA requirements; and even is to keep all establishments informed of all applicable FDA requirements. Similarly, in the certification program, AQSIQ is to issue a certificate only if it determines a shipment meets FDA requirements; then AQSIQ transmits the certificate to the FDA through secure electronic system; AQSIQ is also to monitor the safety of products by a testing program determined by FDA.

\(^78\) Article VII(1), U.S.-China Agreement on Food Safety, supra note 75.

\(^79\) Article IV(2), U.S.-China Agreement on Food Safety, supra note 75.

\(^80\) Article IV(3), U.S.-China Agreement on Food Safety, supra note 75.

\(^81\) Article V(2)(c), U.S.-China Agreement on Food Safety, supra note 75.

\(^82\) Article V(2)(d), U.S.-China Agreement on Food Safety, supra note 75.

\(^83\) Article V(2)(f), U.S.-China Agreement on Food Safety, supra note 75.

\(^84\) Article V(2)(e), U.S.-China Agreement on Food Safety, supra note 75.

\(^85\) Article V(4), U.S.-China Agreement on Food Safety, supra note 75.

\(^86\) Section II(B), Annex to the U.S.-China Agreement on Food Safety, supra note 75.

\(^87\) Section II(C), Annex to the U.S.-China Agreement on Food Safety, supra note 75.
Significance of the registration and certification programs lies in the United States federal law: registration is required by the Federal Food, Drug and Cosmetic Act.\textsuperscript{88} “FDA will use registration and certification information provided to it by AQSIQ to inform FDA import entry decisions, which may include a reduction in the rate of examination of Designated Covered Products that are part of the registration and/or certification program.”\textsuperscript{89} This is perhaps the context in which law enforcement information, discussed above, is important and necessary. In his testimony before the U.S. House of Representatives, Stephen F. Sundlof, Director, Center for Food Safety and Applied Nutrition of the FDA highlighted the registration and certification program in the U.S.-China Agreement,\textsuperscript{90} as a part of a broader effort to move “the inspection of high-risk products of concern ‘upstream’ by entering into agreements with the exporting country’s regulatory authority” so that, legally, the foreign regulatory authority can certify each shipment for compliance with the FDA’s standards prior to shipment. Ambitious as it may sound, the program is truly part of the Bush Administration’s broader regulatory approach—to outsource the regulatory responsibility the FDA has in food safety.\textsuperscript{91}

C. Unanswered Questions

Like Japan, the United States is also importing a large amount of food. About 15 percent of the nation’s overall food supply is imported, according to the Government Accountability Office (GAO). Sixty percent of fresh fruits and vegetables are imported, and three-quarters of all seafood. In the wake of this globalization of food supply, FDA is in responsible for ensuring the safety of about 80% of the food supply, including $49 billion of imported food annually. However, as a key regulatory agency, FDA was understaffed and underfunded. The GAO revealed that from 2003 to 2006, FDA’s staff at the Center for Food Safety and Applied Nutrition (CFSAN) dropped by 14% at headquarters, while field-based staff responsible for inception and enforcement activities dropped by 11.5%.\textsuperscript{92} This leads to lower frequency of

\textsuperscript{88} Sec. 415 of the Federal Food, Drug and Cosmetic Act [21 USC 350d], on registration of food facilities, including foreign food facilities. The Bioterrorism Act of 2002 requires the submission, prior to arrival, of product-specific information, such as grower and product code, for FDA-regulated food consumed by humans and animals.

\textsuperscript{89} Section II.2, Annex to the U.S.-China Agreement on Food Safety, supra note 75.


\textsuperscript{92} UNITED STATES GOVERNMENT ACCOUNTABILITY OFFICE, FEDERAL OVERSIGHT OF FOOD SAFETY: FDA’S FOOD PROTECTION PLAN PROPOSES POSITIVE FIRST STEPS, BUT CAPACITY TO CARRY THEM OUT IS CRITICAL (GAO-08-435T), Statement of Lisa Shames, Director of Natural Resources and Environment before the Subcommittee on Oversight and
inspection. GAO’s analysis of FDA data suggests that the FDA’s inspection of foreign food firms—which number about 190,000—decreased from 211 in the fiscal year 2001 to fewer than 100 in the fiscal year 2007. According to FDA’s Science Board, the FDA’s inability to fulfill its mission can also be explained by numerous management problems, “such as a lack of coherent structure and vision, insufficient capacity in risk assessment,” in the wake of increasing food safety concerns.

Since 1998, FDA’s food safety policy and practice has been the main target of criticism from GAO and the National Academy of Sciences. Discontents also abound among officials or former officials in the FDA, consumer groups, as well as Congress. A series of high profile recalls in 2007—from pet foods to lead toys from China—mounted more pressures on the FDA. In response, President George W. Bush established an Interagency Working Group on Import Safety in July 2007, and the Group worked out a Strategic Framework in September. By taking some of the critiques, the Strategic Framework boasted of “a paradigm shift from an intervention, border-focused strategy to a life-cycle approach that stresses a risk-based approach to prevention with verification that identifies high-risk segments of the import life cycle and verifies the safety of products at those important phases.” By “verification,” the Strategic Framework seems to suggest a more aggressive approach in working with foreign countries on food safety, which would be a departure from the mutual recognition approach under the FDA Modernization Act of 1997. In the subsequently published Action Plan, Investigations, Committee on Energy and Commerce, House of Representatives, January 29, 2008 [hereinafter, GAO, FDA’S CAPACITY], at 6.

93 GAO, FDA’S CAPACITY, id, at 6. The Department of Agriculture began a new inspection system in 2002 and reduced the percentage of meat crossing the border that was inspected to 6% from 17%, see, Elizabeth Becker, Meat Inspections Declining; Impact of Policy Is Contested, N.Y. TIMES, Jul. 10, 2003.

94 GAO, FDA’S CAPACITY, supra note 92, at 12.

95 Two early critiques include: INSTITUTE OF MEDICINE, ENSURING SAFE FOOD FROM PRODUCTION TO CONSUMPTION (1998), and GAO, FOOD SAFETY AND SECURITY: FUNDAMENTAL CHANGES NEEDED TO ENSURE SAFE FOOD (GAO-02-47T) (2001). Food safety is not the only concern among consumers, and FDA is not the only target of criticism: Eric Lipton, Safety Agency Faces Scrutiny amid Changes, N.Y. TIMES, Sep. 2, 2007, at A01 (on the Consumer Product Safety Commission).


98 STRATEGIC FRAMEWORK, id, at 11.

verification is translated into certification programs under which a third party in the exporting country would conduct the verification work and certify that the export product has met all the criteria and standards that HHS/FDA requires. Here the third party becomes the core of “verification” in the Strategic Framework.

Who can be a third party certifier? Under the Action Plan, “FDA would accept certifications from either relevant government agencies or accredited third parties.” Though the Action Plan referred to FDA’s working on a plan to accredit private laboratories, but it is very vague and offers little indication of its development. The U.S.–China Agreement boasted of a political victory. This political symbolism continues with another high-profile move: in November 2008, the FDA opened three offices in China, with a staff of 13, who will inspect foods and certify third party inspectors. But the “victory” is a self-deceit. The expectation that somehow FDA can bring AQSIQ in for help in protecting consumers is wishful thinking. In the early 1970s, the United States Department of Agriculture had a hard time in bringing states in line with federal standards through a certification program under the Wholesome Meat Act of 1967. Questions are left unanswered. Dr. Steve Suppan of Institute for Agriculture and Trade Policy, raised concerns about AQSIQ’s potential conflicts of interests. This conflict of interest is yet


100 INTERAGENCY WORKING GROUP ON IMPORT SAFETY, ACTION PLAN FOR IMPORT SAFETY: A ROADMAP FOR CONTINUAL IMPROVEMENT (Nov. 6, 2007), available at http://www.importsafety.gov/report/actionplan.pdf (last visit Nov. 21, 2008) [hereinafter, ACTION PLAN].

101 ACTION PLAN, id, at 18.

102 ACTION PLAN, id, at 18.

103 ACTION PLAN, id, at 68-69.


105 As noted by the Chicago Tribune, “The agreement, announced by a U.S. official in Beijing, was hailed by Bush administration negotiators as a major step toward addressing the safety of imported goods. The White House can claim a political victory in the fight against tainted imports, and China can attempt a recovery from damaging publicity surrounding its products.” Stephen J Hedges & Evan Osnos, U.S., China Set Food-safety Pact Deal Gives American Inspectors Access to Chinese Factories, CHICAGO TRIBUNE, Dec. 12, 2007.


again demonstrated in the dumplings incident before the Japanese consumers. More recently, in November 2008, FDA, again, failed to act after discovering trace amounts of the industrial chemical melamine in baby formula sold in the United States.109

What is missing from the Action Plan, however, is liability of the importer. Commenting on the Action Plan, Michael Taylor noted that there was nothing in the Action Plan that would “call for any new accountability on the part of importers to ensure that problems have been prevented up the supply chain to the point of production in the exporting country.”110 A discussion draft of the FDA Globalization Act was released in April 2008.111 Title I, Food Safety section of the Bill largely follows the structure of the Action Plan. In Sec. 106, on certification, the Bill grants the authority that the FDA is asking for: the power to accredit a foreign government or a third party to certify food safety compliance.112 It also increased the civil penalty imposed by the FDA on individuals or firms in violation of the rules.113 Again, what’s missing is the liability of importers who are in the best position to ensure compliance with United States food safety rules. In his testimony before the House Committee, Taylor pointed out, again, that “however, to clarify and strengthen the duty and accountability of U.S.-based importers for ensuring the food they import meets U.S. food safety standards.”114

III. Legal Reform in China

A. Rise and Fall of China’s FDA

In March 2003, when the Primer Wen Jiabao and President Hu Jintao Administration came to power, they restructured the government, the SFDA was formed,115 on the basis of the State Drug Administration formed in 1998.


111 Supra note 15.

112 Sec. 106(c) of the FDA Globalization Act 2008 (Draft), id.

113 Sec. 121 of the FDA Globalization Act 2008 (Draft), id.


115 王忠禹，《关于国务院机构改革方案的说明》《人民日报》（2003年03月07日第三版）
(a) Fuyang Milk Powder Scandal

On April 19, 2004, China Central Television (CCTV)—China’s State-owned national TV network—reported a strange disease in Fuyang city in Anhui province, southern China, where babies of six-month suffered severe malnutrition (the local people called it “big head disease”), which was caused by substandard baby formula milk powder.116 Prime Minister Wen Jiabao was reportedly shocked by the news.117 A high-level investigation team was immediately formed by the State Council—led by Zheng Xiaoyu, then Commissioner of the newly formed State Food and Drug Administration (SFDA)—and dispatched to Fuyang to investigate the situation. In mid May, the official investigation found that 12 babies died and 229 babies suffered malnutrition as a consequence of consuming the baby formula milk powder with little protein.118

The State Council’s investigation team comprised of officials and staff from the SFDA, AQSIQ, the Ministry of Health, Ministry of Public Security (the police), Ministry of Commerce, Ministry of Supervision (in charge of corruption), State Administration of Industry and Commerce (SAIC). From the composition of the team, it is clear that the task was not only to find out what had caused the problems, but also to deal with them, on the spot. The investigation team was accompanied by the media as well: CCTV, the Xinhua News Agency, and the People’s Daily. Thus, it’s not enough that the problems were dealt with; it must be seen. From April 22 to May 17, during its stay in Fuyang, the investigation team: (a) it called on parents to take their babies for examination, and 1,663 babies were physically examined; (b) it confiscated and destroyed those substandard products; it ordered those firms without health permits stop production; (c) detained criminal charges against owners of the manufacturing facilities; (d) brought criminal charges against local officials for dereliction of duty.


118阜阳劣质奶粉事件基本查清《人民日报》2004年05月17日 第二版 People's Daily, May 17, 2004, at 2. The report explained that the Fuyang local government had announced that 13 babies had died; but it was found out that three among the 13 died of other reasons, but two more babies were found dead of malnutrition caused by the milk powder. 国务院应急管理办公室, 《安徽阜阳劣质奶粉事件》(State Council Emergency Management Office, “The Substandard Milk Powder Incident in Fuyang, Anhui Province”), dated Aug. 9, 2005, available at: http://www.gov.cn/gygl/2005—08/09/content_21396.htm (last visit Dec. 23, 2008) [hereinafter, “Fuyang Incident Report”].
With the attention of the media, what happened in Fuyang on the ground was covered by television and newspapers, making Fuyang a national stage of food safety politics. At the outset, the media was a moral outcry in search of a target. On April 19, CCTV’s first report was fairly balanced in between the firm owners and the lack of efficacy of local bureaucrats. However, as the investigation progressed, focus was shifted to the liability of the local officials who have failed to fulfill their duties. On May 14, The *Outlook Orient Weekly*, a magazine owned by the Xinhua News Agency, published an article commenting on the Fuyang local bureaucracy as “substandard bureaucracy in the substandard milk powder incident.” The article told stories of how parents sought help from local bureaucrats in vain; how local officials had learned about the substandard milk powder but didn’t do anything because they were more interested in imposing a fine on the manufacturers so they could obtain personal gains. Expressing discontent with local bureaucracy was, of course, a way to channel the frustration of parents in Fuyang, as well as that of the general public. A national poll of public opinions by the Chinese Consumers Association during August and October 2003 found that foods, drugs, medical devices had already been on the top of consumers’ concerns. But to frame the issue this way was also to convert private grievances of parents to a public condemnation of moral failures of those individual bureaucrats. It was a convenient way to leverage support to the publicized crack down—thus to portray the officials from Beijing as the true help. In the process, all the talks about accountability were implicitly transformed as accountability to the center, thus to legitimize the political responses—the public trials of criminal suspects, etc.

The Fuyang incident was not a local one. Investigation found that most of the problem milk powder was not locally produced; rather, it was from over ten provinces across the country. CCTV’s report even tracked two manufacturers in Beijing, which led to a ten-day campaign targeting low-quality dairy products. The problem milk powder and the “big head disease” were soon discovered in many other cities. On April 28, the SFDA, joined by Ministry of Health, State Administration of Industry and Commerce, AQISQ, Ministry of Public Security decided to expand the investigation nationwide on all milk powder. This was followed by a still broader action.

119 王友明、叶俊学、潘书培，《劣质奶粉事件中的劣质行政》，《瞭望东方周刊》
The Outlook Orient Weekly’s report was followed by comments with similar tones in other official media such as the *People’s Daily*, and the *China News Weekly*—a journal owned by the China News Service, a semi-official news agency. 《劣质奶粉事件：劣质奶粉暴露出什么》，《人民日报》2004年05月17日第二版《劣质奶粉问责谁》，《中国新闻周刊》2004年05月17日


121Wang Ying, supra note 117.

on May 17, 2004, when the State Council launched a national campaign to crack down on illegal mills. The campaign targeted the vast rural areas, covering a wide range of food and food products: grains, meats, vegetables, fruits, dairy products, soy products, aquatic products, etc.

The State Council’s move, from local to national, from milk powder to food in general, had its own logic, of course. The drum-beat moves, one perhaps should be mindful of, were more than its theatrical rhythm, they also meant to show resolve and leadership, when the sentiments were high. Before the jump from local to national, one should perhaps pause and ask what lessons one has learned at the local. The scandal at Fuyang, was not a surprise for the local residents at all, neither to the local officials. Almost one year before, in May 2003, concerned parents had brought suspicious milk powder to the City Public Health Bureau’s Center of Disease Prevention and Control (CDPC); and the CDPC had known that the milk powder did not meet standards, and caused malnutrition. In June 2003, when more sick babies were brought to the City Hospital, the Hospital managed to contact the local television, which subsequently ran a special report on the issue in a popular program. In October, the City Bureau of Industry and Commerce—the agency in charge of fair trade—initiated some sporadic crackdowns on counterfeiting milk powder. Between December 2003 and January 2004, the Fuyang city authorities had been able to identify 189 manufacturers of the problem milk powder in a local law enforcement campaign. Thirty-three problem products were put on a “black list” publicized on local television and newspapers. However, none of the identified products was banned: the substandard milk powders were still openly on the market when CCTV’s reporters came to investigate the scandal.

Some questions must be asked. First, the official story presented the national campaigns as a response to the inaction by local officials. But the local officials had applied a campaign-style crackdown in Fuyang in their efforts to control the situation and which had been proved ineffective. Comparing the national campaigns and the local campaigns, the difference may be in scale, resources, publicity, but hardly in substance—measures taken, temporary nature. Thus, the official narrative portrayed the national campaign as something different, it denied the similarities. It also denied the fact that the national campaign was only to reinforce the existing game between the Center and the local. By making corruption the center of the concerns, it protects the structure. Neither the media nor the official report linked the coincidence with the SARS, where the cover-up happened in Beijing first!

Second, the investigation team showed a single-minded mentality of punishment: criminal trials of those owners of manufacturing facilities and local officials, the Party’s disciplinary process, as well as the publicity, it

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124戴敦峰，《一个父亲拷问执法部门：为何迟迟不清查劣质奶粉》，《南方周末》2004年04月29日
provided little incentives for the local officials who did their work and very little on how to reorganize local government and make it responsive.

Third, it was not interested in organizing the local parents and consumers at large. While the investigation in Fuyang was going on, the Chinese Consumers Association (CCA) advised parents to take legal action against the manufacturers for compensation. A few of those parents sought help from the local office of CCA in Fuyang. When approached by consumers, CCA’s most common practice was not to encourage litigation, but rather to mediate the dispute between the parent and the manufacturer. Parents were willing to take legal actions to seek compensation. The obstacle was neither their cultural averseness to litigation, nor their unwillingness to challenge authority and power. To file a lawsuit, parents must able to overcome tremendous difficulty, including geographical distance, long waiting period, and financial burden as a result of those conditions. CCA is not a grass root social organization, nor was it particularly popular in the rural areas—in fact, most parents in the rural areas never have heard of it. Even if the local office of CCA offered help to parent who filed lawsuits, its resources wouldn’t have enabled it to go very far. However, CCA’s voice never appeared on the media again. Thus, no mass litigation occurred in response to the scandal. Only one parent in Yingshang county filed a lawsuit and won the case at the Fuyang Intermediate People’s Court.

Rather, compensation was distributed through local government. The Fuyang city government even published a “Methods of Compensating Infants Who Have Suffered Malnutrition from Substandard Milk Powder in Fuyang City” on April 25, 2004. With terms of “consumer protection” replete in the text of the “Methods,” it assigned no role to the local CCA.

(b) China’s FDA Experiment

One lesson learned from the Fuyang incident was the lack of coordination among different branches of the government: the local bureaus in charge of public health, industry and commerce, quality inspection, and agriculture. Thus, in September, the State Council issued a Resolution on Further Strengthening Food Safety (“Resolution 2004”). Resolution 2004 allocated responsibility on food safety to these regulatory agencies according to the process of food production, from farm to the fork: the Ministry of Agriculture

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126《3·15 谁为农村消费者维权》, 《中国青年报》2005—3—16


128《阜阳市食用劣质奶粉受害婴儿救助办法》阜政发[2004]27号

supervises production of primary agricultural products; AQSIQ oversees the quality and hygiene of food in the processing stage; SAIC supervises food in circulation and distribution; and the Ministry of Health oversees restaurants and catering industry. The SFDA is given the power of overall food safety supervision, coordination between different agencies, and the authority to investigate serious incidents in food safety.

On the face, the SFDA is given a lot of power, making it look like the FDA, American style. For some years, Zheng Xiaoyu, Commissioner of the SFDA from its founding in 1998 until mid–2005, had long been an admirer of the United States FDA.\[^30\] In 2000, he had taken measures to restructure the SFDA so as to make it a stronger regulatory agency. Among these measures was to put local (county- and city-levels) bureaus under direct control of the provincial level bureaus,\[^31\] which are more closely overseen by the SFDA in Beijing, in order to overcome interferences from the latter. By 2002, Zheng had largely finished his ambitious plan,\[^32\] and was ready to take on new assignments. After the Fuyang incident, SFDA’s primary rival—the Ministry of Health—had been weakened politically. The Ministry of Health had just suffered a severe political problem during the SARS epidemic between February and May 2003. In April 2003, the Minister was removed from his post for his handling of the issues.

However, the American style FDA label cannot be more misleading.\[^33\] Fragmentation continued. First of all, SFDA had no licensing power and authority. Before 1998, the Food and Drug Bureau was a part of the Ministry of Health. With the bureaucratic structure in mind, the 1995 Food Hygiene Act granted the most important licensing power to the Ministry.\[^34\] But the Food Hygiene Act was never changed to reflect the structural change in the executive branch. The State Council signaled to revise the Act in its

\[^30\] Dali Yang, Regulatory Learning and Its Discontents in China: Promise and Tragedy at the State Food and Drug Administration, in PUSHING BACK GLOBALIZATION (John Gillespie & Randall Peerenboom, eds. 2009) (forthcoming), available at:
http://www.daliyang.com/files/Yang_SFDA_paper.pdf (last visit on Dec. 24, 2008) [hereinafter, Dali Yang, Promise and Tragedy at the SFDA].

\[^31\] 国家药品监督管理局, 《药品监督管理体制改革方案》, SFDA, Drug Administration Reform Plan, dated May 11, 2000, approved by the State Council.

\[^32\] 《中国药品监管体制改革初步到位》, Aug. 12, 2002, at Xinhua News Agency at:
http://news.xinhuanet.com/zhengfu/2002-08/12/content_521115.htm (last visit Dec. 27, 2008).

\[^33\] Despite the Chinese leadership has sought to emulate the FDA in establishing the SFDA, the SFDA’s resemblance to the U.S. FDA is skin-deep at best. The SFDA is far from being an agency with enough authority to exercise unified and comprehensive supervision over food safety.” Waikeung Tam & Dali Yang, Food Safety and the Development of Regulatory Institutions in China, 29 ASIAN PERSPECTIVE 5 (2005, No.4), at 14.

\[^34\] Article 27 of 中华人民共和国食品卫生法 Food Hygiene Act of the People’s Republic of China, adopted by the Eighth NPC Standing Committee on October 30, 1995, taking effect on the date of promulgation. English translation available at: http://www.chinadflaw.com/laws/detail_156.html (last visit on Nov. 29, 2008). Under Article 27, health bureaus of provincial level have the authority to issue hygiene license, which is required for every firm in the food production or distribution business.
Resolution 2004, and in the meantime its Legislative Bureau had started working on, initially, revisions of the Food Hygiene Act. Up to March 2006, the State Council was still planning to revise the Food Hygiene Act. But soon the SFDA was facing a similar problem like that of the MOH. In May 2006, allegations of corruption forced Zheng to retire from his post; and in December 2007, it became clear that Zheng had very serious problems. Zheng’s problems must have been one reason behind the State Council’s ambiguous position on the licensing power of the SFDA.

Second, the State Council’s decision to rely on local governments in the Bill was not a surprise. In May, 2004, the State Council instructed the local governments—county and provincial levels—to enforce the campaign. In the 2005 campaign, the State Council’s program was that the “local governments are ultimately responsible for food and drug safety.” Therefore, the Food Safety Bill was just a confirmation that the State Council expects the local government to shoulder the responsibility of food safety. This is rather in line with the general arrangement between the central and the local governments in other areas, such as the Environmental Protection Act of 1989; education, and work safety. The central government is outsourcing its social responsibilities to local governments, often without corresponding allocation of financial resources or legal authorities. This is, shocking as it is, similar to the way the United States FDA outsourced its own law enforcement responsibility to AQSIQ through the 2007 Agreement.

Third, other competitors in the central bureaucracy continue to bid for power. One such competitor who was successful was the Ministry of Agriculture. Since it was believed that most of the problems originated from rural areas, lawmakers identified a legislative gap because a food producer in the rural area was neither covered by the Food Hygiene Act nor by the Product Quality Act. The Agriculture Ministry thus pushed the idea of

III(4) of the , supra note 134.

135 Resolution 2004, supra note 134.


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139 《立法，为了让百姓吃地放心——全国人大常委会法工委有关负责人解读新通过的农产品质量安全法》, Responsible Official of the NPC Standing Committee’s Legal Commission on the New Agricultural Product Quality and Safety Act, Apr. 29, 2006, available at:
having a special legislation to fix this gap. On April 29, 2006, the Agricultural Product Quality and Safety Act (APQSA), passed by the NPC Standing Committee.\(^\text{141}\) However, Article 3 of the APQSA grants agricultural bureaus the power to be in charge. Another achievement of the APQSA was traceability code—an identification that is unique to the product—which would help to track every stage of a product’s production and distribution cycle. Traceability code system, or sometimes called electronic supervision, was first advocated by the Ministry of Agriculture in 2004 when it started pilot projects in eight cities.\(^\text{142}\) Article 28 of APQSA requires producers of agricultural products to have labels or identifiers that contain information of name of the product, where it was produced, name of producer, production date, warranty period, quality, etc. By December 2007, the Ministry was able to claim substantial progress.\(^\text{143}\)

Perhaps a more formidable competitor is the AQSIQ, which has an edge in terms of technical expertise and testing capabilities. The AQSIQ was formed in 2001, and also adopted an ambitious plan to consolidate its power. The State Council has invested heavily in building up facilities in national labs and testing centers. Its licensing power includes: (a) the Product Quality Act only grants AQSIQ the inspection power, but it gradually converts that into licensing power by certification programs. In 2002, two years before the Fuyang incident, AQSIQ had started a program called “Food Quality and Safety Market Entry Control”, which required all food producers to have “Food Production Permission” [食品生产许可证](a QS mark standing for quality safety) before they can put their products on the market.\(^\text{144}\) It started as pilot programs, limited to rice, flour, vegetable oil, etc. at the very beginning, and gradually expanded to cover a wider range of foodstuff and

http://www.gov.cn/zwhd/2006—04/29/content_271179.htm (last visit on Dec. 28, 2008). According to the official, Food Hygiene Act does not cover crops or farm animals; and the Product Quality Act only covers processed or manufactured products, thus does not cover unprocessed agricultural primary produce.

\(^{141}\)中华人民共和国农产品质量安全法 Agricultural Product Quality and Safety Act, passed by the Standing Committee of the Tenth National People’s Congress on April 29, 2006, taking effect on Nov. 11, 2006. The Act was drafted by the Ministry of Agriculture and submitted to the NPC Standing Committee for the first time on October 25, 2005.


\(^{143}\) In December 2007, the Ministry of Agriculture sponsored a national conference on traceability system on agricultural products that has been tried in different locales in China. 中国农产品质量安全追溯制度建设取得重要进展 2007年 12 月 09 日 (“Substantial Progress Has been Made in Traceability on Agricultural Products”), dated Dec. 9, 2007.

products. From September 2005, the AQSIQ specifically targeted the small-sized food processors and producers in rural areas, forcing them to obtain the QS marks. AQSIQ’s main policy tool in the food safety campaigns was to force those food producers and processors to obtain FPPs and shut down those who haven’t obtained theirs. It also measured its success and failure by the number of QS marks. During the 2007 campaign, more than 98,000 food producers or processors were certified by the QS mark, and the AQSIQ declared “mission accomplished.”

(b) AQSIQ also promulgated first recall rules on July 24, 2007 for both food products and children’s toys, where it established both voluntary and mandatory recall systems. Five months after, the SFDA followed suit by issuing a similar rule for drugs. The recall system had been explicitly contemplated since the Resolution 2004, and was frequently promised in State Council’s subsequent policy statements. A few years earlier, AQSIQ has had some experience with recall in the auto industry. A Recall system was finally introduced by AQSIQ in China not by reason of judicial pressure; it was more out of political pressure from the graved consumers who have been wakened by capitalist market flooded by all sorts of substandard products. By issuing the recall rules, AQSIQ not merely meant to gain political capital in the food safety campaigns. It also gained in power by granting itself the exclusive authority to issue mandatory recall orders when necessary. It says nothing about the role of other regulatory agencies, such as Ministry of Agriculture, or the SFDA when AQSIQ orders a mandatory recall, just like the

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145 《食品生产加工企业质量安全监督管理实施细则（试行）》国家质量监督检验检疫总局令第 79 号 (AQSIQ, Implementing Rules for Quality and Safety Supervision for Food Producers and Processors”), dated Sep. 1, 2005, AQSIQ Decree No.79.


147 《国家质检总局：食品安全专项整治目标实现》，《人民日报海外版》(AQSIQ: The Goals of Food Safety Special Campaigns Have been Achieved, People’s Daily (Overseas Edition), Jan. 21, 2008.

148 国家质量监督检验检疫总局，《食品召回管理规定》2007 年 7 月 24 日通过 (Food Products Recall Regulations), Jul. 24, 2007, issued by AQSIQ.


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151 The best study of recall system and the its relations with rulemaking in the regulatory structure is perhaps JERRY L. MASHAW & DAVID L. HARFST, THE STRUGGLE FOR AUTO SAFETY (1990), where the authors argue that [].

152 Article 25 of the Food Products Recall Regulations, supra note 148, authorizes the AQSIQ the authority to order a mandatory recall when AQSIQ decides certain conditions have met.
SFDA is silent in any role AQSIQ can play in the Drugs Recall Regulations.\textsuperscript{153} Thus it is clear that the licensing based approach fragments the regulatory structure, even in the middle of food safety campaigns that were supposed to be unitary and comprehensive.

(c) AQSIQ was in charge of import and export, which gives it power when it comes to trade. From 2002 on, AQSIQ required all food exporters to establish a quality and safety management system to be certified by and register themselves with the Certification and Accreditation Administration (CNCA).\textsuperscript{154} CNCA used to be part of AQSIQ but now has become a non-governmental institution in the certification business. In its domestic domain, AQSIQ actively promotes international standards or practices such as HACCP or Hazard Analysis and Critical Control Point. In foreign relations, AQSIQ plays the leading role in negotiations with the Americans and the Europeans, thus often appears to be a defender of “made-in China.”

In a sense, the AQSIQ was functioning more like the United States FDA in the 2000s than the SFDA. Its similarity is not only in form, but also in substance. Like the FDA in the United States during the Bush Administration, however, the AQSIQ in China also played a big role in deregulation—one persistent theme of its policies is the market approach to food safety. It encouraged firms to follow higher standards by granting them a special status—exemption from inspection since November 2001.\textsuperscript{155} Exemption was decided upon application and submission of documents showing its product quality control system, good quality record, market occupation and if it passed three inspections.\textsuperscript{156} Once approved, the status would enable the firm to be exempted from any inspection by all levels of authorities for three consecutive years. The firm was also able to affix an Exemption Mark on its product and use it as a marketing tool. The Exemption Mark became an icon of the AQSIQ as it was expanded to every industry including food. In October 2006, in the middle of a series of food poisoning cases in domestic markets, AQSIQ nevertheless pushed for exemption from inspection for export-

\textsuperscript{153} Article 25 the Drugs Recall Regulations, \textit{supra} note 149, authorizes SFDA the authority to order a mandatory recall when SFDA decides certain conditions have met. Interestingly, the wording of Article 25 is very similar to that of Article 25 of the Food Products Recall Regulations.

\textsuperscript{154} 出口食品生产企业卫生注册登记管理规定 AQSIQ, Rules on Hygiene Registration for Export-oriented Food Producers, Mar. 27, 2002, taking effect on May 20, 2002.

\textsuperscript{155} 国家质检总局，《产品免于质量监督检查管理办法》(AQSIQ, “Administrative Rules on Exemption from Inspection”), dated Nov. 21, 2001 [hereinafter, the 2001 Exemption Rules].

\textsuperscript{156} Article 8 of the Administrative Rules on Exemption from Inspection, \textit{id}, required the applicant to show: (1) that the applicant had good standing as a legal personality, and that it has established product quality control system; (2) that the applicant is a major player in the industry with significant market occupation; (3) that the applicant’s products have satisfied national or industrial standards; (4) that the applicant has successfully passed three inspections; and (5) that the applicant’s products are in compliance with other legal requirements and national industrial policies.
oriented food and agricultural products.\textsuperscript{157} Similarly, the rules on exemption gave AQSIQ the exclusive authority to decide which firm was eligible for the status. No other regulatory agencies had a say in the decision-making process. Participation of the general public or consumer groups was minimal: they had no role in the decision-making process, the only thing they were “empowered” to do was to report to the AQSIQ local branches of any problem in the quality of the product they’ve bought.\textsuperscript{158}

Thus, if AQSIQ was a competitor to SFDA, the competition was more entrenched in the terms of licensing power. But licensing power tends to fragmentize rather than unify regulatory structure. Therefore, the Chinese efforts on food safety are plagued by an inescapable dilemma: national campaigns are often launched in response to a social crisis, and yet major players taking part in the national campaigns would take the opportunity to grab more power for themselves, only causing further fragmentation in the process. In the official lexicon, regulatory agencies in China like using the term “strengthen” in their policy statements without any sense of irony: “strengthening” is often weakening, only in a different form.

So what was the job of the SFDA after Resolution 2004? It largely served as an instrument in the national law-enforcement campaigns. From 2004 to 2007, The State Council organized “special rectification” \textsuperscript{159} campaigns every year, and the SFDA led and coordinated other ministries in these campaigns. This is in part because emergencies have become increasingly regular: seafood \textsuperscript{160} and snail dish \textsuperscript{160} in August 2006 Beijing caused 132 people sickened; In October and November, 2006, red-yolk salted duck eggs \textsuperscript{161} in three provinces were found to contain excessive amounts of the industrial chemical, with experts blaming chicken feed as the source of the contamination. Pork \textsuperscript{161} (September 2006). No to mention many incidents in the pharmaceutical industry, a spate of major drug safety disasters as a consequence to Zheng’s mismanagement of the licensing and approval procedures. Given the fact that the SFDA had

\textsuperscript{157} 国家质检总局《出口食品、农产品免验管理规定〈试行〉》(AQSIQ, “Administrative Rules on Exemption from Inspection for Export-oriented Food Products and Agricultural Products (for Trial Use),” AQSIQ Doc. No.150, dated Oct. 9, 2006 [hereinafter, the 2006 Exemption Rules].

\textsuperscript{158} Article 18 of the 2001 Exemption Rules, supra note 155. The 2006 Exemption Rules, id, was totally silent on the role of the general public.

\textsuperscript{159} 从田间到餐桌《人民日报》Food Safety Regulation: From Farm to the Dinner Table, PEOPLE’S DAILY, Aug. 7, 2007, at 2.


\textsuperscript{161} 《“合格”猪肉为何“放倒”3 0 0多人？》, 《人民日报》Why Pork Certified Safe Sickened More than 300 People? PEOPLE’S DAILY, Sep. 18, 2006, at 2.

\textsuperscript{162} Dali Yang, Promise and Tragedy at the SFDA (2009), supra note 130, at [13].
limited staff and had been handicapped in terms of legal authority, its
coordination power was limited.\textsuperscript{163}

Second, the SFDA took the lead in working on the “Eleventh Five-Year-
Plan on Food and Drug Safety,”\textsuperscript{164} published the State Council on April 17,
2007. The 11th FYP set goals, principles and strategies for the period 2006-
2010. SFDA’s contribution was mostly conceptual: it introduces important
ideas such as risk-assessment, traceability; and emergency preparedness and
response, collection of information on food safety, infrastructure, testing
facilities and centers, emergency response system, and the legal system. In
the two years working on the 11th FYP took, the SFDA worked closely with
other ministries and agencies related to food safety in redesigning the system,
which included studying food safety rules of the Codex and of other countries.
The collaboration with other departments of the executive branch provided
the SFDA a lot new ideas, but they hardly made the SFDA a powerful law
enforcement agency on food safety. The most innovative measure within the
SFDA was to create a position called “Special Supervision Officer” [监察专员],
so as to strengthen its position in the coordinating process.

The pet food incident in the United States broke out shortly after the 11th
FYP was published. It was followed by high-profile recalls of the lead toys in
the United States in June. Pressure was mounting on China’s leadership. In
Beijing, on April 23, the Party’s Politburo invited two specialists to give a
three-hour lecture on food safety.\textsuperscript{165} In addition to the Party leaders, sitting
in the audience were ministers in charge of major ministries and governors of
provinces. International pressure, ironically, facilitated the end of China’s

\textsuperscript{163} It does not seem that the State Council had learned any lesson from the SARS, when the
Ministry of Health—as a politically weak ministry—could not function well. When
commenting on the Ministry of Health during the SARS in 2003, Tony Saich has noted, “[a]
major problem is that the MOH is an institutionally weak player; for example, the
Guangdong and Beijing party secretaries outrank the minister. This makes not only policy
coordination but also policy implementation difficult.” Tony Saich, \textit{Is SARS China’s
Chernobyl or Much Ado about Nothing?} in \textit{SARS in China: Prelude to Pandemic} 71-104

\textsuperscript{164} 《国家食品药品安全“十一五”规划》(State Council General Office, “Eleventh Five-
Year-Plan on Food and Drug Safety,” Apr. 17, 2007), available at:
http://www.gov.cn/zwgk/2007-06/05/content_637391.htm (last visit on Dec. 28, 2008).
For more than two years, the SFDA worked with Ministries of Science and Technology,
Finance, Agriculture, Commerce, Health, State Administration of Industry and Commerce,
AQSIQ, and State Environmental Protection Agency on the FYP, Chinese government高度重视食品药品
安全工作并编制规划 (Chinese Government Attach Great Importance to Food and Drug
Safety and Has Made a Plan), Press Conference at the State Council’s Information Office,
visit on Dec. 28, 2008).

\textsuperscript{165} 《农大教授罗云波：农业标准化保障食品安全》，《21 世纪经济报道》2007 年 4 月 30
日 (\textit{Agriculture University Professor Luo Yunbo: Agriculture Standardization Good for
Food Safety}, \textit{21ST CENTURY BUSINESS HERALD}, Apr. 30, 2007. The two specialists were: Luo
Yunbo, a professor from China Agriculture University, and Ye Zhihua, from Chinese
Academy of Agriculture.
FDA experiment. In May 2007, Zheng was sentenced to capital penalty.\textsuperscript{166} The \textit{People's Daily} published an Op-Ed using Zheng's death penalty to prove that the Party has always been careful with people's livelihood, "especially on safety of foods and drugs."\textsuperscript{167}

The State Council restructured the local food and drug bureaus in November 2008, making them part of the local branches of the Ministry of Public Health. The end of the SFDA as the regulatory agency, a return to the situation of 2000.\textsuperscript{168}

(c) The End of FDA Experiment

On July 26, 2007, the State Council issued a special regulation on food safety.\textsuperscript{169} Premier Wen Jiabao made food safety a top priority.\textsuperscript{170} On August 13, 2007, the State Council established the Leading Group on Product Quality and Food Safety, bringing together all relevant regulatory agencies under the leadership of Vice Premier Wu Yi. On August 17, the State Council's Information Office published the China's first White Paper entitled \textit{The Quality and Safety of Food in China}.\textsuperscript{171} While the white paper is defensive in many aspects, it does recognize the problems, those have been recognized in the Fuyang incident. The White Paper offers no alternative as a program.

On August 24, Wu declared a "special war" to crack down on poor-quality products and unlicensed manufacturers. "This is a special war to protect the safety and interests of the general public, as well as a war to safeguard the 'Made in China' label and the country's image," Vice Premier Wu Yi, was quoted as saying at a news conference.\textsuperscript{172} A four-month campaign on

\textsuperscript{166} \textit{Ex-Chief of China Food and Drug Unit Sentenced to Death for Graft}, \textbf{N.Y. Times}, May 30, 2007.

\textsuperscript{167} 本报特约评论员, \textit{《人民利益高于一切》}, \textbf{《人民日报》} (2007-05-31 第 02 版)


agricultural products was launched. Early in January 2008, victory was declared.\footnote{Food Safety Mission “Complete,” CHINA DAILY, Jan. 09, 2008, at 3.}

On October 31, 2007, however, the State Council approved a Food Safety Bill prepared by its Legislative Bureau. On December 17, it was submitted to the NPC Standing Committee at the end of December for its first deliberation.\footnote{Food Safety Law Put on Review Agenda, CHINA DAILY, Dec. 18, 2007, at 3. 《食品安全法（草案）》加大惩罚力度《财经》Food Safety Bill: Increasing Penalty, CAIJING, Dec. 28, 2007. 《全国人大常委会组成人员热议食品安全法草案: 让食品实现“从农田到餐桌”的安全》, 《人民日报》( 2007-12-29 第 06 版 )NPC Standing Committee Members Debate on the Food Safety Bill: Food Safety from Farm to Dinner Table, PEOPLE’S DAILY, Dec. 29, 2007, at 6.} The text of this Bill was not published. From the media’s accounts, the Bill did not attempt to reshape the regulatory structure so as to create a powerful and unitary FDA. Rather, it remained very ambivalent. On the one hand, it largely confirmed the existing system by assigning supervisory responsibilities to the regulatory agencies; on the other, it stated explicitly that the local government above county level be responsible for food safety within its own jurisdiction. Many of the members of the legislature were critical of this ambivalence. Together with other problems, the legislature sent the Bill back to the State Council to continue their work on it.

The Bill was discussed in March 2008 at the NPC plenary session for the second deliberation. But it did not pass. In April, the NPC Standing Committee published the Bill to the general public for comments.\footnote{It was publicized on the People’s Daily in the mid of the incident, seeking comments from the general public,《中华人民共和国食品安全法（草案）》, 《人民日报》2008-04-21 第 10 版 (Food Safety Bill of the People’s Republic of China, PEOPLE’S DAILY, Apr. 21, 2008, at 10.} In its April version, the State Council clarified the regulatory issue by retaining “local government is fully responsible for food safety in its own jurisdiction” only in Article 4; but it was totally silent regarding the power of the regulatory agencies such as the SFDA, AQSIQ, and others.\footnote{Article 4 of the Food Safety Bill, id.} At this stage, if the State Council was no longer expecting AQSIQ to play a leading role, then two subsequent things would confirm the State Council’s decision.

AQSIQ lost its support from the food industry. The second Food Safety Bill contained a clause requiring all food companies to install traceability code.\footnote{Food Safety System Put in Draft Law, CHINA DAILY, Apr. 9, 2008, at 3.} As discussed earlier, the Ministry of Agriculture advocated traceability since 2004. But it did not insist on a particular technology for the job. However, AQSIQ became interested in the idea in 2005 and tried to expand it to much broader areas in a more forceful way. At the end of November 2007, AQSIQ, joined by the Ministry of Commerce, State Administration of Industry and Commerce, launched an ambitious program called the “Product Identification Authentication and Tracking System

\footnote{Food Safety System Put in Draft Law, CHINA DAILY, Apr. 9, 2008, at 3.}
PIATS covered a wide range of products, including food, cosmetics, appliances, etc. that required product permit or subject to mandatory certification. When join PIATS, producers of these products must purchase a traceability barcode provided exclusively by PIATS, operated by China Credit Information Technology Co. Ltd., a company listed in Hong Kong Stock Exchange. AQSIQ was a main shareholder (30%) until April 2008. Food companies were strongly opposed to this Network, arguing the system would not be of much use but would increase production costs. In March 2008, 19 firms, including Nestle, Mars, Coca-Cola and PepsiCo, submitted a joint petition to the Legislative Affairs Commission of the NPC Standing Committee and State Council’s Legislative Affairs Office. Firms specializing in product-authentication and tracking systems were also agonized by AQSIQ’s policy. In August, when China’s new Antimonopoly Act took effect, eight firms filed the first anti-monopoly lawsuit against the AQSIQ. In response, the published Food Safety Bill deleted the clause on traceability code.

Another disaster for AQSIQ was the Sanlu milk powder scandal that broke out on September 8. The Sanlu Group, as a leading dairy producer in China, had enjoyed exemption status for several years before the scandal. AQSIQ quickly issued a decision to cancel the exemption for all producers on September 17. On the same day, CNCA quickly withdrew three certificates that had been issued to Sanlu: the certification license, its lab’s certification license, and its Export-oriented Hygiene Registration. The Sanlu scandal

178质检总局、商务部、工商总局，《关于贯彻《国务院关于加强食品等产品安全监督管理的特别规定》实施产品质量电子监管的通知》国质检质联〔2007〕582号（AQSIQ, Ministry of Commerce, State Administration of Industry and Commerce, “Circular on Introducing Electronic Supervision on Products in Order to Implement the State Council’s Special Regulations on Strengthening Supervision on Safety of Food and Other Products”), Nov. 29, 2007, AQSIQ Doc. No.582.


suggests that none of the institutions that advocated and promoted by AQSIQ had worked to prevent the disaster—it has been a castle on sand. It was not just a coincidence. A mother in Hunan Province had written a detailed letter to AQSIQ pleading for help on June 30, but it decided not to act. On September 22, 2008, Li Changjiang, head of the AQSIQ since April 2001, resigned from his post when the Sanlu scandal became clear and was still unfolding. It was reported that the State Council, before Li’s resignation, decided that AQSIQ had to bear its own “supervision responsibility for the milk food contamination.” The fall of Li Changjiang, like the fall of Zheng Xiaoyu, Commissioner of SFDA, or Zhang Wenkang, the Minister of Health, was another blow to the State Council’s confidence in the regulatory agency in Beijing.

The third deliberation of the Food Safety Bill was October 23 to 28, 2008. A United Nations study entitled “Advancing Food Safety in China,” was released in October 2008, right before the Chinese legislature’s session. The UN study, apparently uninformed of what has been going on within the Chinese bureaucratic politics, still tried to preach the notion of a unitary food safety agency by recommending that a “[l]egislation to establish an authority with the overall statutory responsibility for the enforcement of all food safety legislation in China is desirable.” Having experienced the fall of three ministers, it is hard to imagine the State Council would, in the near future, entrust any of the three agencies—AQSIQ, the SFDA, or MOH—to be “China’s FDA” without a fundamental restructure of the bureaucracy. Rather, through Article 4 of the Food Safety Bill, the State Council, it seems, has no other choice but to put the bet on the local governments. However, how trustworthy are the local governments? While the Sanlu story was unfolding, the Southern Metro Daily revealed that officials involved in the Fuyang scandal four years ago have been quietly reinstalled.

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183 Jim Yardley & David Barboza, Despite Warnings, China Failed to Stop Milk, N.Y. TIMES, Sep. 27, 2008, at A01.
186 UNITED NATIONS IN CHINA, ADVANCING FOOD SAFETY IN CHINA (Mar. 2008), available at: http://www.un.org.cn/public/resource/2aebcd033e334d961febf1588b70f2ab.pdf (last visit Nov. 22, 2008) [hereinafter, the UN Study]. It is noted that the report came in the wake of a dairy products scandal, and one day before the Standing Committee of the NPC is to review a draft law on food safety. China Needs Better Food Safety Laws: UN Report, CHINA DAILY, Oct. 23, 2008, at 3.
187 It is noted that the report came in the wake of a dairy products scandal, and one day before the Standing Committee of the NPC is to review a draft law on food safety. China Needs Better Food Safety Laws: UN Report, CHINA DAILY, Oct. 23, 2008, at 3.
188 UN Study, supra note 186, at 11.
B. Role of the Consumer Groups

The 2008 Food Safety Bill also has a punitive damage clause. Article 90 provides that manufacturers and operators are liable for damages caused by violation of laws and regulations on food safety. It goes further by specifying that consumers can demand punitive damages ten times of the price from retailers. During deliberation at the NPC, the punitive damage was a widely talked about topic.\textsuperscript{190}

The China Consumers’ Association (CCA), represents consumers in China. CCA was approved by the State Council and founded by on Dec. 26, 1984, CCA[]. From the very beginning, CCA was not a typical non-governmental organization (NGO) despite what its name suggests.\textsuperscript{191} Rather, it is a so-called GONGO—the government-organized NGO, CCA is a NGO operating in close connection with the State apparatus. Why should the government be interested in forming a consumers’ group? The official story is this:\textsuperscript{192} in the spring of 1981, the Chinese government received an invitation from the United Nations Asian Pacific Social and Economic Council regarding a conference in Bangkok, Thailand in June. Officials in Beijing were surprised because there was no consumer group at the time. So a small delegation consisted of officials from the State Administration for Industry and Commerce (SAIC)—the regulatory agency in charge of commerce at the time—was sent attend the conference. When returned home, the delegation proposed in its report to the central leadership to form a national consumers association. Vice Premier Gu Mu—with the support from several other Vice Premiers—quickly approved the proposal and instructed relevant departments to start working on it. During internal deliberation, it was understood that the association would be sponsored by the SAIC, and under the supervision of three regulatory agencies: SAIC, the State Standards Administration and the State Commodity Inspection Administration. The first president of the CCA was Li Yanshou, who was Vice Minister at the SAIC.

CCA’s basic strategy was to push forward legislations. The first movement was in the early 1980s: local legislations on consumer protection have become widely available. Before national law on consumer protection was made in 1993, there had been local rules on consumer protection in 27

\textsuperscript{190} 《“法律的威严就在于此”：代表讨论食品安全法草案 惩罚性赔偿响应者多》，《法制日报》2008年3月13日第7版


\textsuperscript{192} The “official” story is most recently told in a reflection on the 30 years history of consumers’ rights movements in China: 《中国消费者权益保护运动 30 年回眸》，《法制日报》2008年9月21日第6版；《保护消费者合法权益是全社会的共同责任：中国消费者协会常务副会长兼秘书长母建华答记者问》，《工商行政管理》2007, No.8, at 43-44.
provinces and 8 major cities. The Regulations on Protecting Consumers’ Rights in Shanghai was first adopted in December 1988. Code of Civil Procedure (for Trial Use) 1982; Food Hygiene Act (for Trial Use) 1982; General Principles of Civil Law of 1986 (GPCL). The basic principles of liability were established in legislation during this period of time. For example, Article 39 of the 1982 Food Hygiene Act (for Trial Use) granted victims of food poisoning as a consequence of a manufacturer’s violation of mandatory rules the cause of action for damages. As a more general legal issue, Article 122 of GPCL provides: “When the quality of products is not up to standard and causes damages to the property of another person or injuries to the person, the manufacturer of the product and the seller shall be liable according to law.”

Scholars started discussing legal protection of consumers. For example, Shi Jichun and Guo Shiping, the former a law professor at Renmin University in Beijing and the latter economics professor at Wuhan University in Wuhan city, Hubei province, had started exploring the basic principles of consumer protection law in 1987 in academic journals. In their efforts to reconcile consumer protection with the predominant political ideology, they argued forcefully that consumers’ interests were consistent with the fundamental principles of socialism. Furthermore, they argued that consumers’ interests should be protected by law; when their legal rights are infringed upon, restitution and compensation should be the legal remedy. In making these arguments, Shi and Guo were inspired by the consumers’ movements in the West, especially the United States.

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194 上海市保护消费者合法权益条例,
196 中华人民共和国食品卫生法（试行）Food Hygiene Act (for Trial Use), adopted by the Fifth NPC Standing Committee on November 19, 1982, taking effect on July 1, 1983.
The second round of legislations was in the early 1990s: Code of Civil Procedure 1991; Consumer Rights and Interests Protection Act of 1993 (CRIPC); Product Quality Act of 1993. CCA not only promoted these ideas, it took part in drafting the CRIPC. From the mid 1990s, there was a growing interest in seeking remedy through litigation, both inside the CCA and outside. Reports on how CCA helped a consumer fight her case in court began to appear regularly. One innovation was class action. Two categories of class action were introduced in the 1991 Code of Civil Procedure: first, when the number of litigants is large, they could elect one or more representatives. Second, when the number of litigants was uncertain, the court would issue a public notice informing potential litigants to register with the court within a specified period of time. They then would elect one or more of their representatives. The change of Code of Civil Procedure coincided with deterioration of social conditions subsequent to the 1989 Tiananmen massacre, thus large scale social protests were becoming a serious political concern. In such circumstances, class action by consumers in the

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203 C. David Lee, *supra* note [], at 417;

204 For example, 罗伟、陈凤翔, 《胜诉, 在消费者协会支持下》, 《北京工商》1996/05 Luo Wei & Chen Fengxiang, *Winning Your Case, with the Help of the Consumer Association, BEIJING INDUSTRY AND COMMERCE* (1996, No.5) (the authors were members of the Beijing Dongcheng District Consumer Association).


206 These social protests and conflicts included a broad range of issues, from political dissidents, to labor, environment, one-child policy, religion, and ethnic relations. They were well captured in the book, *CHINESE SOCIETY: CHANGE, CONFLICT, AND RESISTANCE* (Elizabeth J. Perry & Mark Selden eds. 2000).
courtroom was not only given a green light, but also considered necessary and a good choice.

Another legal change was punitive damage. Article 49 of CRIPC entitles a consumer punitive damage two times of the price of the good or service she has purchased when the retailer or manufacturer committed fraud. From 1995, there emerged a group of individuals who decided to take advantage of this punitive damage clause and among them was Wang Hai. Wang would go to a department store to buy goods that he suspected as fake or substandard, have it inspected by an AQSIQ test center, bring the official test result to the retailer and demand double compensation under Article 49. When the retail refused, he would file a lawsuit in the court. Wang soon gained a lot of publicity in the media, where he was hailed as a hero, an icon of *dajia* professional—people who make a living by pursuing retailers or producers of counterfeit products for their liabilities under Article 49. The judiciary’s reaction, however, was split. Some judges supported Wang’s action; some other judges, however, insisted that when a consumer knowingly purchased a fake product, then he was not a “consumer” who made the purchase for his consumption. By late 2000, Wang faced more defeats in the courtrooms. In March 2004, about a month before the Fuyang milk powder scandal broke out, Shanghai courts announced that Article 49 did not apply to those consumers who knowingly buy fake products as there was no fraud involved. Judges in Beijing largely shared the view.

In this debate, CCA supported Wang Hai and a broader interpretation of Article 49. In 1999, CCA decided to set up its Department of Legal Affairs, part of the plan was to support consumers taking legal action to protect their

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207 Benjamin L. Liebman, *id*, 1528-29 (discussing cases consumer suits against department stores).

208 For example, an article written by the research office of the Weifang City Intermediate People’s Court, Shandong province discussed how the Weifang court handled class action cases in such social context in that part of the country: 山东潍坊市中级人民法院研究室, 《审理集团诉讼案件中的几个问题》, 《人民司法》1994/05 Several Issues in Class Action Litigation, *PEOPLE’S JUSTICE* (1994, No.5).


In August, 2004, CCA even was joined by the China Bar Association in organizing the CCA Lawyers Group. However, CCA’s support to consumers’ litigation efforts was more symbolic. The ambiguity of CCA’s identity could have worked the other way: CCA was not only an organization sponsored by SAIC, a lot of its staff came directly from SAIC, in some local branches. Thus CCA should have been in a perfect position to lobby SAIC and other regulatory agencies on policy matters. This was also the hope during the 2004 controversy over the meaning of Article 49. A senior leader of CCA suggested in an interview that the SAIC could lend its support to the CCA and consumers in general.214

However, the SAIC issued a new rule on March 12, 2004, shortly after the decision in Shanghai.215 The new rule, surprisingly perhaps, did not address the question of Article 49 at all. Rather, it tried to find a role for itself. For example, the new rule required that when a business operator found the product it sold is defected, and may cause personal injury or property damage, then it must stop marketing the product, and report to the SAIC. Failing to do so, the business operator would be ordered to rectify by the SAIC.216 When consumers demanded compensation, the business operator should not delay nor deny its liabilities; if it did, then SAIC would impose a fine on the business operator.217 Clearly, SAIC was not interested in encouraging self-initiated actions taken by the consumers themselves. SAIC wanted to bring CCA and the consumers into its own power structure, forcing them to be the informants who would bring in the necessary information but stay away from the “law enforcement” process. Private grievance, once entered into public domain, must be brought under public control. Thus, dajia professionals complained that one of the difficulties they faced, in addition to, for example, threats made by counterfeiters, was ridicule from the law enforcement officers, typically from the SAIC’s local bureaus, for standing in the way of their law enforcement.218

Therefore, it was not at all surprising that before the Fuyang milk powder scandal broke out, the local branches of CCA had only a limited role. What they did was to mediate the dispute between the parent and the retailer or

213 《开创保护消费者运动的新纪元—访中国消费者协会会长曹天战》，《消费经济》1999年第 2 期 A New Era in Consumer Movement: An Interview with President of CCA, Mr. Cao Tianchan, CONSUMPTION ECONOMICS 3 (1999, No.2).

214 Teng Jiacai, Vice Secretary-General of CCA, indicated in an interview with Law and News magazine, an outlet of the Legal Daily, that SAIC was working on a new regulation on consumers’ rights, and he hoped that SAIC could clarify some of the issues. 《职业打假人渐行渐远》，《法制与新闻》2004 年 05 月 11 日 Dajia Professionals Are Disappearing, LAW AND NEWS (Beijing), May 11, 2004.


216 Article 2, SAIC Rule 2004, id.

217 Article 6, SAIC Rule 2004, id.

218 For example, Dong Bai, supra note 210.
producer. They had no independent legal standing to take legal action against any of the retailers or producers. Neither did they have the resources to help those parents wanted to bring counterfeiters into the court. After the scandal broke out, even on symbolic level, as noted earlier, CCA itself was largely silenced after giving advice to parents to file lawsuits. During subsequent food safety campaigns, CCA’s role remained marginal. The obscure identity of CCA often works against its aspirations. Its proximity to power is more an irony.

National laws on food safety, often drafted by the regulatory agencies who are more interested in grabbing licensing powers and keeping those powers for themselves, hardly have any reference to CCA. In the wake of the Sanlu scandal, AQSIQ prepared a draft regulation on products recall for the State Council to consider. Following its earlier rules on recalls, AQSIQ’s draft put itself in the position of the sole authority in charge of recalls, saying nothing about the role of other regulatory agencies, or CCA, or individual consumers. Thus at a hearing in September 2008, consumer representatives challenged it and demanded that consumers should be given the right or power to petition the authorities to initiate investigation on defected products.219

Similarly, victims of Sanlu milk powder also had a clash with the Ministry of Health. When the scandal broke out, many parents went to the court to seek compensation.220 On October 13, parents of the first casualty baby took legal action in Gansu province at Lanzhou Intermediate People’s Court, seeking a million yuan for damages. Soon, a public interest lawyer group was formed and their goal was to seek compensation through litigation in the courtroom.221 On November 24, three volunteer lawyers went to Sanlu’s headquarters to serve a formal demand for compensation on behalf of 54 victims. Considering the large number of victims, one group of lawyers wrote late in October to the State Council, AQSIQ and MOH proposing that the government develop a uniform plan to manage the cases. What the lawyers didn’t know was that the government had been working on a plan—the Legislative Bureau of the State Council, AQSIQ, MOH and SAIC were engaged in intensive negotiations behind the scene with Sanlu and other firms involved in the scandal on a compensation scheme. By the end of October, a deal had been reached,222 but MOH did not reveal it until

219. AQSIQ held on a hearing on September 24, 2008 on its draft regulation. 《缺陷产品该如何召回》，《人民日报》(2008年9月25日09版)


221. 《司法途径索赔困难重重 律师团矛头指向三鹿》，《21世纪经济报道》2008年12月2日

222. 《善后未了局》，《财经》杂志总第228期 2009年1月5日 Not the End Yet, CALJING (No.228), Jan. 5, 2009, available at:
December 10, thus the victims’ lawyers were never able to take part in the negotiations. And given the “uniform plan” of the government, courts across the country are unlikely to take individual cases on Sanlu.

IV. An Alternative

Despite their differences in culture, legal tradition, political orientation, among others, China, Japan and the United States actually share a basic approach in their legal response to food safety crises—to “strengthen” the regulatory power of the agency. In Japan, the ruling party’s hope in food safety is bet on a new and comprehensive regulatory agency; in the United States, to “strengthen” means to bring in a partner to work “together”; in China, to “strengthen” means relentless food safety campaigns to crack down illegal producers and vendors. As a consequence of this basic approach, questions about food safety are more often framed as and thus limited to an issue of how much more resources, power, and authority that the regulator should have. Surely the approach is favored for different reasons in different countries. But the result of this approach is, individually or jointly, castles are built without a solid foundation. What is missing is a mechanism that can mobilize social resources and market forces to become part of the regulatory framework.

This Article proposes an alternative, the liability-based approach. At the core of this approach is liability of importers and retailers in their relations with consumers. Compared with consumers, importers have more information and means of control of the quality of food they import from abroad. Thus, importers’ accountability becomes the key. In this aspect, European Union’s Product Liability Directive, 85/347/EEC, sets a good example. Recently, there is also a growing interest in stricter importer liability in the United States. Caroline Smith DeWaal and David Plunkett of the Center for Science in the Public Interest, a non-profit organization based in Washington, D.C., argued that the United States’ current food safety regime is too much dependent on port of entry inspection. Michael Taylor argued for more accountability of importers: “even more fundamentally


important” to clarify and strengthen the duty and accountability of U.S.-based importers.\textsuperscript{228} In the words of Kenneth A. Bamberger and Andrew T. Guzman, the “de facto regulators” of international trade.\textsuperscript{229} Bamberger and Guzman proposed that, “in certain circumstances the United States should impose strict regulatory obligations on importers and sellers without regard to what they know, should have known, or even could have known about the process of production and service provision.”\textsuperscript{230}

The subsequent question is: what are the tools available for the importers to discipline their suppliers from abroad? In European Union, importers use private certification programs to assure compliance with EU food safety standards.\textsuperscript{231} Both the draft FDA Globalization Act and the Bush Administration’s Action Plan anticipate, rightly, a broader function of certification programs in the United States. But they both contemplate voluntary certification programs at this stage and the certifying agents include foreign governments, cooperatives and other third-party agents. A key issue would be whether to take certification as an extension of inspection or to take it as a main disciplinary instrument in bringing in compliance. The liability-based approach would take the latter position. In this alternative framework, certification by an independent certifying agent with expertise in the relevant areas becomes a crucial service for the global trade in food.

Compared with inspection, certification as a service will gradually bring in investment into the area, thus end the constant struggle for more funding and resources in the federal or state levels. The Peanut Corporation of America (PCA) case reveals problems with current certification programs in the U.S. domestic market. Before the breakout, PCA had its own private inspectors as well as inspectors from the State of Georgia. Shortly before the breakout, private inspectors graded PCA’s overall food safety level as “superior.”\textsuperscript{232} The State of Georgia, which was under contract with the FDA to monitor food plants, had only 60 agents to monitor 16,000 food-handling businesses.\textsuperscript{233} There was also a question of information sharing. PCA had found salmonella 12 times since 2007, but the information was not disclosed until federal investigators invoked a bioterrorism law.\textsuperscript{234} State and federal


\textsuperscript{230} Kenneth A. Bamberger & Andrew T. Guzman, \textit{id}, at 1431.

\textsuperscript{231} Caroline Smith DeWaal and David Plunkett proposed that certification is an important alternative to inspection; but the FDA does not necessarily adopt exactly the EU private certification. Rather, they favor the voluntary certification program provided in the FDA Globalization Act. David Plunkett & Caroline Smith DeWaal, \textit{supra} note 227, at 662-63.

\textsuperscript{232} Michael Moss & Andrew Martin, \textit{Food Problems Elude Private Inspectors}, N.Y. TIMES, Mar. 6, 2009, at A01.

\textsuperscript{233} Michael Moss, \textit{Peanut Case Shows Holes in Safety Net}, \textit{supra} note 9.

\textsuperscript{234} Michael Moss, \textit{Peanut Case Shows Holes in Safety Net}, \textit{supra} note 9.
inspectors do not require the peanut industry to inform the public—or even the government—of salmonella contamination in its plants.\textsuperscript{235}

On international level, there is also need to change. I have analyzed in Part II(B) of this Article a certification program created by the U.S.-China Food Safety Agreement (2007). I have argued that this is problematic certification program because AQSIQ—the certifying agent—has conflicts of interests as a regulatory agency and policymaker in China. As described in Part III, AQSIQ’s own certification arm—the Certification and Accreditation (CNCA)—was becoming independent from the government since early 2000s. Thus FDA’s deal with AQSIQ was a misguided move from the very beginning. It was also clear that as a regulatory agency, AQSIQ had its own agenda—promoting national industry flagship firms such as the Sanlu Group—and its own approach—such as the exemption from inspection. These elements posed enormous principal-agent questions than a more typical third-party certifying agent would have in its relations with FDA. Thus, as a service, certification’s first requirement is its independence from exporting country’s government.

The second problem of making AQSIQ the certifying agent is that the arrangement weakens FDA’s ability to supervise and discipline a certifying agent through accreditation. AQSIQ’s status as a regulatory agency, a policy maker, a monopolistic power on many issues relating to food safety in China, all put AQSIQ more in a position as a negotiator, rather than an agent of FDA. Furthermore, AQSIQ’s monopolistic position also creates problems on the price of its services, which will eventually born by the consumers in the United States market. Certification is a service to exporters in China, thus should not be monopolized by one certifying agent. For a big market like China’s, there should a number of certifying institutions in the business in competition with each other. Thus, as a service, certifying agents must be brought under the control of the FDA through its accreditation process. Third, making AQSIQ a certifying agent also reflects a technocratic vision of the food safety issues, while ignoring the participation of consumer groups. Food safety is not only about lab testing, it is also about empowering consumers, including letting consumers access to information produced in the certification process. In this aspect, certification is also a public service to society.

V. Conclusion

In the wake of frozen dumplings and pet food incidents, social discourse on food safety in the United States, like that in Japan and China, is understandably focused on the capacity, resources, and regulatory authority of the FDA. No doubt these are important elements. But a Herculean regulatory agency can be easily a moving target, eventually leading to the endless debate about more capacity, resources and authority. The danger, however, is that food safety is much narrowed by the inspection-based

\textsuperscript{235}Michael Moss, \textit{Peanut Case Shows Holes in Safety Net}, supra note 9.
approach. The liability-based approach proposed here, is to bring consumer groups and market forces into the regulatory process.