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# **An Agricultural Law Research Article**

# Introduction to Food Law in the People's Republic of China

by

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# INTRODUCTION TO FOOD LAW IN THE PEOPLE'S REPUBLIC OF CHINA

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#### Introduction

The adequacy of the food regulation system in the People's Republic of China (PRC) has captured attention worldwide following numerous high profile cases of food safety problems in Chinese exports.<sup>2</sup> These food safety problems are especially vexing to U.S. policy makers given the dramatic growth in recent years of food product imports into the U.S. from China and the rising criticism of U.S. efforts, especially those by the Food and Drug Administration (FDA), to ensure the safety of food imports.<sup>3</sup> The primary criticism directed towards the FDA, who has jurisdiction over all food except for meat and poultry products,<sup>4</sup> is that the agency physically examines only just over one-

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<sup>&</sup>lt;sup>2</sup> See e.g., Nicholas Zamiska, *Invoice Links Two Chinese Firms To Bad Pet Food*, The Wall Street Journal Online, May 7, 2007; Jane Zhang & Ellen Byron, *FDA Blocks Imports of Chinese Toothpaste*, The Wall Street Journal Online, May 24, 2007; Jane Zhang & Neil King Jr., *FDA Blocks Chinese Seafood on Contamination Concerns*, The Wall Street Journal Online, June 29, 2007; Nicholas Zamiska & Jane Spencer, *China Faces a New Worry: Heavy Metals in the Food*, The Wall Street Journal Online, July 2, 2007. *See also* China-U.S. Trade Issues, CRS Report for Congress, Updated July 11, 2007, p. CRS-8 (outlining food safety problems between U.S. and China).

<sup>&</sup>lt;sup>3</sup> On October 5, 2007, the U.S. House of Representatives Committee on Energy and Commerce released a staff report entitled "Food From China: Can We Import Safely?" The report was compiled by Committee staff dispatched to China in August 2007 in a trip that involved interviews with Chinese and American officials and representatives from food companies and the media. The Committee has also held a series of hearings related to food and imports, with much of the attention focused on China. See The House Committee on Energy and Commerce News Release, Dingell, Stupak Release Report on Safety of Food Imported from China; Announce Series of Hearings, Oct. 5, 2007, available at http://energycommerce.house.gov/Press\_110/110nr101.shtml.

<sup>&</sup>lt;sup>4</sup> The safety of meat and poultry products for the most part is the responsibility of the U.S. Department of Agriculture's agency, the Food Safety Inspection Service (FSIS). Under the Federal Meat Inspection Act and the Poultry Products Inspection, the FSIS is responsible for determining the equivalence of other countries' meat and poultry safeguards. See 21 U.S.C. § 620(a); 21 U.S.C. 466(a). A foreign plant cannot ship meat and poultry products to the U.S. unless FSIS has certified that its country has a program that provides a level of protection that is at least equivalent to the U.S. system. China is not certified to ship FSIS-regulated meat and poultry products to the U.S. See FSIS Regulations and Policies, Import Information, available at http://www.fsis.usda.gov/Regulations/Eligible\_Foreign\_Establishments/index.asp. The FSIS also operates a reinspection program at U.S. border entry points. See Geoffrey S. Becker, Cong. Res. Serv., CRS Rep.

percent of food shipments.<sup>5</sup> If nothing else, the safety problems of food product from China underscore the dependency of the U.S. on the success of other national food regulatory systems, including China's, and the need to examine and evaluate these systems.

Notwithstanding the dearth of primary and interpretative sources in English, this article seeks to facilitate an understanding of the regulation of food safety in China. This article begins with a brief narrative of recent food safety issues in China and an overview of the legal system in China. The article then introduces food law in China, with a particular focus on the regulation of food safety. This analysis covers the administrative organization of government bodies that have authority over food safety and the substantive regulatory provisions that govern these government bodies and the safety of food product. Finally, this article briefly describes the most recent developments of food law in China. It is hoped that this introduction will lay a foundation for further evaluation of the evolving food regulatory system in China.

# I. Recent Food Safety Problems

In reaction to the high profile food safety challenges in China, both the Chinese and U.S. governments acted quickly and publicly, setting up panels to review current food safety issues and to recommend reforms. President Bush formed the Import Safety Working Group<sup>7</sup> and the Chinese government launched a five-year initiative on food safety.<sup>8</sup> Chinese politicians, in a rare show of public frustration, have pressed for reform.<sup>9</sup> The Chinese government has shut down food plants with safety issues,<sup>10</sup> published a list of safe food producers,<sup>11</sup> and rejected U.S. shipments of meat on grounds of contamination.<sup>12</sup> The Chinese government has also dealt harshly with those perceived to

RL34080, Food and Agricultural Imports from China 5 (2007).

<sup>&</sup>lt;sup>5</sup> See *id.* at 5-6. The FDA is authorized under the Federal Food, Drug, and Cosmetic Act to refuse entry to any food import if the product is adulterated, misbranded, or in violation of the law. 21 U.S.C. § 381(a).

<sup>&</sup>lt;sup>6</sup> Where available, the English version of China law is provided as a reference. If the English version is not available, the authentic China version is provided.

<sup>&</sup>lt;sup>7</sup> CNN.com, *Bush* sets up import safety panel, July 18, 2007, available at http://www.cnn.com/2007/US/07/18/safe.imports.ap/index.html.

<sup>&</sup>lt;sup>8</sup> China launches 5-year plan for food, drug safety, China Daily Online, June 6, 2007, available at http://www.chinadaily.com.cn/bizchina/2007-06/06/content\_888495.htm.

<sup>&</sup>lt;sup>9</sup> See China.org.cn, NPC Chews Over Food Hygiene, available at http://www.china.org.cn/english/28782.htm; Nicholas Zamiska, China Admits Safety Woes, THE WALL STREET JOURNAL Online, July 5, 2007.

<sup>&</sup>lt;sup>10</sup> Nicholas Zamiska, *China Shuts 180 Food Plants in Safety Push*, The Wall Street Journal Online, June 28, 2007.

<sup>&</sup>lt;sup>11</sup> Michael Connolly, *Success of Beijing's Fight to Curb Contamination Remains to Be Seen*, The Wall Street Journal Online, May 30, 2007.

<sup>&</sup>lt;sup>12</sup> CNN.com. China: 7 U.S. meat importers banned, available at http://edition.cnn.com/2007/WORLD/asiapcf/07/16/china.meat/index.html. China also seized 118 tons of Evian water from France on grounds that it had excessive amounts of bacterial. International Herald Tribune.com China seizes 118 tons of Evian water, available at http://www.iht.com/articles/2007/05/30/bloomberg/evian.1-64431.php.

have created problems in food regulation, executing the former director of China's State Food and Drug Administration after finding him guilty of accepting bribes.<sup>13</sup> Additional recent actions by the Chinese government that will be described later in this article demonstrate an emerging commitment to strengthen the safety of Chinese food product.

Efforts to strengthen the food safety regulatory system in China are of no small consequence to the interests of the U.S. From 1996 to 2006, U.S. imports of Chinese food, agriculture, and seafood products increased 346 percent, from nearly 0.411 million metric tons in 1996 to 1.833 million metric tons in 2006. The increase by value was 375 percent, from \$880 million in 1996 to \$4.2 billion in 2006. In 2006, China was the third leading foreign supplier of food, agriculture, and seafood products to the U.S., after only Canada and Mexico. In 1996 to \$4.2 billion in 2006.

When dealing with China's food safety issues, it is useful to view China's food problems with a balanced perspective. Due perhaps to the intense media focus on China's food import problems, there is a tendency to become China-centric when viewing the problems associated with the safety of imported food product into the U.S. Despite the recent public uproar, China ranks third, not first, in terms of number of shipments of food refused by the FDA.<sup>17</sup> Mexico ranks first and India ranks second.<sup>18</sup> This point has led Chinese officials to accuse the U.S. media of blowing isolated incidents out of proportion.<sup>19</sup>

China also has unique structural hurdles when it comes to food regulation. First and foremost is the massive size of China's population and the nature of its primary food producers.<sup>20</sup> China's agricultural system is composed mostly of small land-holding farmers and subsistence agriculture.<sup>21</sup> China has less arable land than other nations, and farmers intensively use fertilizer and pesticides to maintain high food production.<sup>22</sup> These small farms then funnel food product into a processing

<sup>&</sup>lt;sup>13</sup> Nicholas Zamiska & Jason Leow, *China Executes Former Safety Regulator*, THE WALL STREET JOURNAL Online, July 11, 2007.

<sup>&</sup>lt;sup>14</sup> Becker, *supra* note 4, at 2.

<sup>&</sup>lt;sup>15</sup> *Id*.

<sup>&</sup>lt;sup>16</sup> *Id*.

<sup>&</sup>lt;sup>17</sup> See Andrew Martin and Griff Palmer, *China Not Sole Source of Dubious Food*, THE NEW YORK TIMES, July 12, 2007, *available at* http://www.nytimes.com/2007/07/12/business/12imports.html.

<sup>&</sup>lt;sup>18</sup> *Id*.

<sup>&</sup>lt;sup>19</sup>See Zhu Zhe, *Food quality up to standard*, July 4, 2007, *available at* http://www.chinadaily.com.cn/bizchina/2007-07/04/content 909480.htm.

<sup>&</sup>lt;sup>20</sup> Fred Gale, *China at a Glance: A Statistical Overview of China's Food and Agriculture*, April 2002, *available at* http://www.ers.usda.gov/publications/aib775/aib775e.pdf.

<sup>&</sup>lt;sup>21</sup> *Id.* at 8.

<sup>&</sup>lt;sup>22</sup> *Id.* at 7-8.

industry that is also largely composed of small, family-based operations.<sup>23</sup> Thus, while China struggles for a national solution, much of its food operation is performed on a local level.<sup>24</sup>

It is also interesting to note that the first national food law in the U.S. was passed in 1906<sup>25</sup> in response to serious food safety problems in Chicago's stockyards that were graphically documented in Upton Sinclair's *The Jungle*.<sup>26</sup> The U.S. has had 101 years since the 1906 Act to adapt, change, and improve its food regulatory approach, and it still faces problems with the safety of its own domestic food supply.<sup>27</sup> Will China be extended the courtesy of a similar time period? Given the dynamic of the global food system in today's world, the answer is undoubtedly no. The question then becomes how does China accelerate the maturation pace of its food regulatory system? The answer(s) to this question starts with a fundamental understanding of China's food regulatory system, which is best understood in the context of China's overall legal system.

### II. China's Legal System

Although the civilization of China has been in existence for 5,000 years, its current legal system is relatively young and developing.<sup>28</sup> On October 1, 1949, the People's Republic of China (PRC) was born.<sup>29</sup> Relying heavily on the communist Soviet Russian legal system, the Central Committee of the Communist Party abolished the old National Codes in China.<sup>30</sup> Later, during the Cultural Revolution in the mid-1960's, existing law in China was abrogated or suspended and law reform was abandoned.<sup>31</sup> When China's economy began to decline from the Cultural Revolution, it shifted from a pure socialist planned economy towards a mixture of a planned economy and what is now called a socialist market economy.<sup>32</sup> In 1979, the Chinese government began to reassemble the

<sup>&</sup>lt;sup>23</sup> See Jane Zhang, *China Strains to Police Quality*, The Wall Street Journal Online, October 5, 2007; United States House of Representatives, Committee on Energy and Commerce, Subcommittee on Oversight and Investigations Staff Trip Report, *Food from China: Can We Import Safety?* 2 (Oct. 4, 2007) (Draft Report).

<sup>&</sup>lt;sup>24</sup> Id.

<sup>&</sup>lt;sup>25</sup> See Pure Food and Drug Act, Pub. L. No. 59-384, 34 Stat. 768 (1906) (repealed 1938).;9018;9020;9021;9030;9018;9020;9021;9030

<sup>&</sup>lt;sup>26</sup> President Theodore Roosevelt was sickened after reading an advanced copy of *The Jungle* and called upon Congress to pass a law that lead to the establishment of food inspection standards. *See generally, The Long Struggle for the 1906 Law,* FDA Consumer (June 1981), *available at* http://www.cfsan.fda.gov/~lrd/history2.html.

<sup>&</sup>lt;sup>27</sup> See e.g., FDA News, *FDA Warning on Serious Foodborne E.coli 0157:H7 Outbreak: One Death and Multiple Hospitalizations in Several States*, FDA News (Sept. 14, 2006), *available at* http://www.fda.gov/bbs/topics/NEWS/2006/NEW01450.html; USDA Food Safety Inspection Service Recall Release, *New Jersey Firm Expands Recall On Ground Beef Products Due to Possible E.Coli 0157:H7 Contamination*, (Sept. 29, 2007).

<sup>&</sup>lt;sup>28</sup> See generally, Volker Behr, Development of a New Legal System in the People's Republic of China, 67 La. L. Rev. 1161 (Summer 2007).

<sup>&</sup>lt;sup>29</sup>See generally, JOHNATHAN D. SPENCE, THE SEARCH FOR MODERN CHINA (1990) at 514-540.

<sup>&</sup>lt;sup>30</sup> Behr. *supra* note 28, at 1163.

<sup>&</sup>lt;sup>31</sup> *Id.* at 1163-64.

<sup>&</sup>lt;sup>32</sup> *Id.* at 1164.

rudiments of a legal system, including the reopening of law schools, re-establishing the Ministry of Justice, and revamping the state court system.<sup>33</sup>

The 2001 accession of China to the World Trade Organization (WTO) and its increasing participation in the development of international conventions unifying the law have caused China to modify various aspects of its legal system.<sup>34</sup> These modifications are reflected in the gradual development of civil codes and legislation and in the 2004 version of the Chinese Constitution, where there is more of an opening to principles of market economies.<sup>35</sup> It is within this unique, developing legal system that China regulates the safety and quality of its food product.

#### III. Chinese Governmental Bodies Involved in Food Safety Regulation

### A. Survey of Administrative Bodies

China has several administrative organs with the authority to deal with the issues relating to food safety. First and foremost is the Ministry of Health (MOH) as the body granted general authority under the 1995 Food Hygiene Law.<sup>36</sup> Additional bodies include the Ministry of Agriculture (MOA), the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), the State Administration for Industry and Commence (SAIC), the State Environmental Protection Administration (SEPA), the Ministry of Commerce (MOC), formerly the Ministry of Foreign Trade and Economic Cooperation), and the State Grain Administration (SGA).<sup>37</sup>

AQSIQ functions as a law enforcement agency, overseeing food imports, exports and quarantines at the national and local levels.<sup>38</sup> In accordance with the PRC Standardization Law promulgated in 1989, AQSIQ works with the Standardization Administration of China to apply standardized measures across China via its thirty-five Entry-Exit Inspection and Quarantine Bureaus (CIQs) in China's thirty-one provinces.<sup>39</sup>

The State Food and Drug Administration (SFDA) was instituted in 2003, with the mandate, among other things, to provide "comprehensive supervision on the safety management of food." It was envisioned that the SFDA would be able to integrate the administration and supervision of food

<sup>&</sup>lt;sup>33</sup> SPENCE, supra note 29, at 705.

<sup>&</sup>lt;sup>34</sup> Behr, *supra* note 28 at 1173-74.

<sup>&</sup>lt;sup>35</sup> *Id.* at 1174-77.

<sup>&</sup>lt;sup>36</sup> See The Food Hygiene Law of the People's Republic of China, English Version (for reference only), available at www.cnca.gov.cn/rjwzcjgb/flfg/images/20061016/476.pdf.

<sup>&</sup>lt;sup>37</sup> See generally, Bian Yongmin, *The Challenges for Food Safety in China* (June 2004), available at http://www.cefc.com.hk/uk/pc/articles/art\_ligne.php?num\_art\_ligne=5301 (description of food safety administrative bodies).

<sup>&</sup>lt;sup>38</sup> See Chinese Premier on Quality, Supervision, Quarantine, People's Daily Online, July 16, 2001, available at http://english.people.com.cn/200107/16/eng20010716\_75046.html.

<sup>&</sup>lt;sup>39</sup> *Id*.

<sup>&</sup>lt;sup>40</sup> See State Food and Drug Administration, P.R. China, About SFDA, *available at* http://www.sda.gov.cn/cmsweb/webportal/W43879538/index.html?UID=DWV1\_WOUID\_URL\_43879538.

safety, coordinate, and organize investigations and impose penalties for serious violations of the law.<sup>41</sup>

The MOH and SFDA appear to fill an identical role with regards to promulgating food safety regulations. Included within the mandate of the MOH are the powers to "draft health laws . . . and to supervise their enforcement." Although the SFDA is supposed to act to "coordinate and conduct specific law-enforcement campaigns over safety of food," this role appears to be filled by AQSIQ as well. AQSIQ sees itself as "a ministerial administrative organ directly under the State Council," ather than reporting to the SFDA. The SFDA's distinction is that it has been given the responsibility of coordinating efforts of the many agencies involved, but this role is also filled by the Standardization Administration of China. In the latest push to update food safety standards, it was AQSIQ, acting in conjunction with the Standardization Administration of China that drafted the amendments. AQSIQ is also currently drafting regulations that will set up China's first food recall system. It is unclear whether, going forward, AQSIQ will continue to be the main policy body within China's system of food regulation, or whether it has assumed this role in the short term due to the corruption problems in the leadership of the SFDA.

# B. Assessment of Organization

The number of agencies involved in food safety, problems of overlap, and unclear lines of authority have provoked calls for reform, particularly in light of recent food safety issues. An article in the China Daily newspaper criticized the government's food safety regime, stating: "Who is in charge of solving these problems? The answer may surprise many because China has about 10 government departments overseeing food safety...." At a meeting of the SFDA, AQSIQ, SAIC, MOH, and MOA, Yan Jiangyin, deputy director at the SFDA's Department of Policies and Regulations, was asked to describe the hierarchy and organizational structure for food and drug regulation. She said the five agencies present "were directly responsible for the supervision of food and drug safety," but that other departments had "indirect responsibilities." She went on to use the example of tainted duck eggs, a

<sup>&</sup>lt;sup>41</sup> See id.

<sup>&</sup>lt;sup>42</sup> Gov.cn, Chinese Government's Official Web Portal, Ministry of Health, *available at* http://english.gov.cn/2005-10/09/content\_75326.htm.

<sup>&</sup>lt;sup>43</sup> State Food and Drug Administration, P.R. China, Main Responsibilities, *available at* http://www.sda.gov.cn/cmsweb/webportal/W45255826/index.html.

<sup>&</sup>lt;sup>44</sup> General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China, AQSIQ Function and Organizational Structure, *available at* http://www.aqsiq.gov.cn/zjwzywb/200611/t20061101\_22076.html#Law.

<sup>&</sup>lt;sup>45</sup> See Amendments to food safety standards completed, China Daily Online, July 4, 2007, available at http://www.chinadaily.com.cn/bizchina/2007-07/04/content 909750.htm.

<sup>&</sup>lt;sup>46</sup> Xie Chuanjiao and Hu Yinan, *Food recall system to be set up*, China Daily Online, *available at* http://www.chinadaily.com.cn/china/2007-05/29/content 882131.htm.

<sup>&</sup>lt;sup>47</sup> Liu Wei, Safe food for all should be the recipe, China Daily Online, March 15, 2007, available at http://www.chinadaily.com.cn/china/2007-03/15/content 828060.htm.

<sup>&</sup>lt;sup>48</sup> Edward Lanfranco, *Analysis: China's Product Safety Means Bad PR for the PRC*, UPI Asia Online, July 11, 2007, *available at* 

http://www.upiasiaonline.com/politics/2007/07/12/analysis chinas product safety means bad pr for the prc/

case that went public in November 2006, in which a carcinogenic dye called Sudan Red was found to be widely used to change the pigment of egg yolks.<sup>49</sup> She described the regulatory landscape:

Experts from the Ministry of Health evaluate the presence of toxins and determine the extent of risk to humans. The Ministry of Agriculture takes action on matters directly related to animals or plants. The SAIC handles items pertaining to "circulation," meaning distribution nodes like markets and food service industries. The AQSIQ is involved with food production and processing facilities and is responsible for product recalls and imposition of punitive measures against companies.<sup>50</sup>

In addition, notwithstanding the multiple national agencies with food safety oversight authority, the enforcement of standards largely remains up to the local authorities.<sup>51</sup> Local regulation is reportedly spotty, and there are apparently some anecdotal reports of corruption at the local level.<sup>52</sup>

# **IV. Chinese Food Regulatory Provisions**

## A. PRC Food Hygiene Law

The PRC Food Hygiene Law ("Food Hygiene Law") by the Standing Committee of the National People's Congress went into effect on October 25, 1995. <sup>53</sup> This law forms the basis of the legal framework for food safety, food production, and the regulation of China's food industry. The Food Hygiene Law specifies the hygiene standards for foodstuffs, food additives, food containers, and the requirements for food packaging labels. <sup>54</sup> It also establishes hygiene standards with respect to storage and production facilities and equipment used for food production and transportation. <sup>55</sup>

The system of supervision and regulation under the Food Hygiene Law is administered by the MOH, which is authorized to formulate, approve, or promulgate state hygiene standards and rules for inspection. The Food Hygiene Law requires that before commencing operations, food production enterprises must obtain a hygiene license first from the local public health administration and then from the local administration of industry and commerce. These licenses are specific to the production facility at the specified location, meaning that production facilities cannot be moved without acquiring state permission, as American ice cream producer Häagen-Dazs discovered the hard way

<sup>&</sup>lt;sup>49</sup> China.org.cn, *Fresh Duck Eggs Found to Contain Sudan Red in Fujian*, November 20, 2006, *available at* http://www.china.org.cn/english/health/189567.htm.

<sup>&</sup>lt;sup>50</sup> See Lanfranco, supra note 48.

<sup>&</sup>lt;sup>51</sup> See Subcommittee Staff Trip Report, supra note 23 at 3.

<sup>&</sup>lt;sup>52</sup> *Id.* 

<sup>&</sup>lt;sup>53</sup> See The Food Hygiene Law, *supra* note 36.

<sup>54</sup> See id..

<sup>55</sup> See id.

<sup>56</sup> See id.

<sup>&</sup>lt;sup>57</sup> See *id.* at art. 27.

when its food hygiene permit was determined to be invalid when it changed the manufacturing location. Pursuant to the Measures for the Administration of Food Hygiene Licenses that took effect in 2006, a food hygiene license is valid for four years, and any food producer that has a license revoked is forbidden to apply for a license within three years. In addition to the revocation of a license, disciplinary measures for violations of the Food Hygiene Law include confiscation of its illegal gains, imposition of fines, stop production orders, and required recalls for sold food. If a violation constitutes a crime or a party interferes with the work of health authorities, the enterprise may be prosecuted.

#### B. PRC Law on the Quality and Safety of Agricultural Products

The Law of the PRC on Agricultural Product Quality Safety ("PRC Quality and Safety Law") went into effect on November 1, 2006, and regulates the quality and safety of agricultural products. <sup>62</sup> It aims to maintain public health and to promote China's agricultural industry and economic development in rural areas. <sup>63</sup> Under the PRC Quality and Safety Law, agricultural products include plants, animals, micro-organisms, and other related products. <sup>64</sup> The PRC Quality and Safety Law regulates the use of fertilizer, pesticides, veterinary medicine, feed and feed additives, and requires production records to be maintained for agricultural products for a period of two years. <sup>65</sup> The PRC Quality and Safety Law imposes harsh penalties for violations and includes a private right of action for domestic consumers against producers and sellers. <sup>66</sup>

The PRC Quality and Safety Law also has certain labeling requirements. Article 28 imposes stringent packaging and labeling requirements on agricultural products, requiring that labels contain the name of the product, place of production, producer, date of production, expiry date, product quality grade, and any additives employed.<sup>67</sup> Article 30 requires that any genetically modified

<sup>&</sup>lt;sup>58</sup> Trust in Ice Cream Maker Melts Away, People's Daily Online, June 20, 2005, available at http://english.peopledaily.com.cn/200506/20/eng20050620\_191203.html ("...law enforcers found the firm's hygiene permit was invalid because the manufacturing location had changed.").

<sup>&</sup>lt;sup>59</sup> TDCTrade.com, *Administrative Measures for Food Hygiene Licensing to be Implemented*, Issue 2, Feb. 1, 2006, *available at* http://gbcode.tdctrade.com/gb/www.tdctrade.com/alert/cba-e0602c-1.htm.

<sup>&</sup>lt;sup>60</sup> Fines vary based on whether or not the food has entered the market and resulted in illness or food poisoning. Fines range from RMB 1,000 to RMB 50,000. See Food Hygiene Law, supra note 34, at arts. 51-53.

<sup>&</sup>lt;sup>61</sup> See id.

<sup>&</sup>lt;sup>62</sup> See Order of the People's Republic of China No. 49, English version (for reference only) available at http://fdi.gov.cn/pub/FDI\_EN/Laws/GeneralLawsandRegulations/AdministrativeRegulations/P0200606203216767 16045.pdf.

<sup>&</sup>lt;sup>63</sup> See id. at art. 1.

<sup>&</sup>lt;sup>64</sup> See id. at art. 2.

<sup>65</sup> See id., at art. 24.

<sup>&</sup>lt;sup>66</sup> See id. at arts. 43-54.

<sup>&</sup>lt;sup>67</sup> *Id.* at art. 28.

organisms shall be indicated.<sup>68</sup> Article 32 allows producers to apply to local authorities for permission to use pollution-free and high quality product labels.<sup>69</sup>

#### C. PRC Standardization Law

The PRC Standardization Law came into effect on April 1, 1989.<sup>70</sup> It sets out the legal framework for the development of standard directives and their applications by all industries and sectors nationwide. Pursuant to the Standardization Law, AQSIQ created the Standardization Administration of China to disseminate mandatory nationwide food hygiene standards and codes, in conjunction with the MOH.<sup>71</sup> Where products do not conform to the mandatory standards, manufacturers may be required to stop production and such products may be confiscated, destroyed, or sent for mandatory technical testing. Relevant manufacturers and responsible persons will be fined.<sup>72</sup> Distributors may be required to stop sales of such products, recall the products, destroy the products or send the products for mandatory technical testing.<sup>73</sup> Any profits will be forfeited, and the distributors and relevant responsible persons will be fined.<sup>74</sup> These fine amounts may range from 20% to 50% of the total value of the goods imposed on the enterprise, and a fine of 5,000 RMB or less on the persons held responsible.<sup>75</sup>

# D. Measures on the Administration of Genetically Modified Food

Measures on the Administration of Genetically Modified Food took effect on July 1, 2002. <sup>76</sup> Prior to 2002, GM foods were imported into China as normal food. Pursuant to the Measures, the production or import of genetically modified food is subject to the examination and approval of the MOH. <sup>77</sup> Any genetically modified food without such approval is prohibited from being produced or imported. Manufacturers must ensure the safety for consumption and nutritional quality of genetically modified food. <sup>78</sup>

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<sup>68</sup> Id. at art. 30.
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<sup>&</sup>lt;sup>69</sup> *Id.* at art. 32.

<sup>&</sup>lt;sup>70</sup> See www.StandardsPortal.org, People's Republic of China, English Version, available at http://www.standardsportal.org/prc\_en/ov\_laws\_rules.aspx.

<sup>71</sup> See id. at art. 33

<sup>&</sup>lt;sup>72</sup> *Id.* 

<sup>&</sup>lt;sup>73</sup> *Id*.

<sup>&</sup>lt;sup>74</sup> *Id.* 

<sup>&</sup>lt;sup>75</sup> *Id.* 

<sup>&</sup>lt;sup>76</sup> See Regulations on Safety of Agricultural Genetically Modified Organisms, English version (for reference), available at http://english.biosafety.gov.cn/image20010518/5420.pdf.

<sup>&</sup>lt;sup>77</sup> See *id.* at art. 4.

<sup>&</sup>lt;sup>78</sup> See *id.* at arts. 19-25.

#### E. PRC Foreign Trade Law

The PRC Foreign Trade Law was adopted in 1995 and further amended in 2004.<sup>79</sup> The PRC Foreign Trade Law permits products to be imported and exported freely, although the government may impose quotas or permit requirements on certain imported or exported products and tariff rate quotas on certain imported products.<sup>80</sup> The PRC Ministry of Commerce promulgated the Measures for the Administration of Licenses for the Export of Goods in 2005.<sup>81</sup> Article 3 states "[t]he Ministry of Commerce shall, together with the General Administration of the Customs, formulate, regulate, and promulgate the annual Catalogue for Goods Subject to the Administration of Export Licenses."<sup>82</sup> Pursuant to the 2007 Catalogue, the government may impose quotas and permit restrictions on the export of corn, rice and wheat.<sup>83</sup> Different restrictions, including many on livestock, apply only to Hong Kong and Macau but not mainland China.<sup>84</sup>

## F. Regulations on the Administration of Grain Distribution

On May 26, 2004, the State Council promulgated the Regulations on the Administration of Grain Distribution to regulate the purchase, storage, transportation, processing, import and export of wheat, corn, food grains, and other food products. Enterprises are prohibited from engaging in grain purchases without holding a grain purchase permit or having registered with the relevant local industrial and commercial administration. Violators are to be subject to administrative penalties. If failure to comply with the law constitutes a crime, the violating company may also be prosecuted. From the comply with the law constitutes a crime, the violating company may also be prosecuted.

<sup>&</sup>lt;sup>79</sup> See PRC Foreign Trade Law, Chinese version (authentic), *available at* http://www.npc.gov.cn/zgrdw/common/zw.jsp?id=335694&lmfl=%B7%A8%C2%C9%CE%C4%BC%FE&label=W XZLK&pdmc=010602.

<sup>80</sup> See id.

<sup>&</sup>lt;sup>81</sup> See Order of the Ministry of Commerce of the People's Republic of China No. 28, English version (for reference), *available at* http://fdi.gov.cn/pub/FDI\_EN/Laws/GeneralLawsandRegulations/MinisterialRulings/t20060620\_51135.jsp

<sup>82</sup> See id. at art. 3.

<sup>&</sup>lt;sup>83</sup> See Announcement No. 85 of Ministry of Commerce and General Administration of the Customs Promulgating Catalogue of Commodities Subject to Export Licenses in 2006, English translation (for reference), available at <a href="http://www.lawyee.com/Act/Act\_Other\_Trans\_Collate.asp?ChannelID=1010201&RID=12190">http://www.lawyee.com/Act/Act\_Other\_Trans\_Collate.asp?ChannelID=1010201&RID=12190</a>.

<sup>&</sup>lt;sup>84</sup> *Id.* 

<sup>&</sup>lt;sup>85</sup> See Regulations on the Administration of Grain Distribution, Chinese version (authentic) available at: http://www.gov.cn/zwhd/2006-05/25/content 290657.htm.

<sup>86</sup> See id.

<sup>87</sup> See id.

#### G. Exported Food

On April 19, 2002, AQSIQ promulgated the Provisions on the Administration of the Hygiene Registration of Export Food Production Enterprises, pursuant to which all enterprises engaged in the production, processing, or storage of food for export must obtain hygiene registration certificates that are valid for a term of three years. 88

## H. Imported Food

Imported food, as well as additives, containers, packing materials, instruments, and equipment used for food production, must conform to state hygiene standards and hygiene management measures and must be inspected by the hygiene supervision and inspection authorities at the entry ports prior to customs clearance.<sup>89</sup> The importing units are required to provide inspection reports and relevant information on the pesticides, additives, and fumigants used in the exporting countries.<sup>90</sup>

Where there are no state hygiene standards on the imported food, the importing units must provide a hygiene appraisal issued by the health departments or authorities of the exporting countries. The imported food must then be examined and inspected by the hygiene supervision and inspection authorities at the entry ports and reported to the MOH for approval. In 2003, AQSIQ and the Certification and Accreditation Administration of the People's Republic of China (CNCA) jointly implemented a new system of compulsory certification—the Compulsory Product Certification System (CPCS). This new regime includes Regulations for Compulsory Product Certification, Regulations for Compulsory Product Certification Mark, and the First Catalogue of Products Subject to Compulsory Certification. Under this system, any enterprise that wishes to import commodities listed in the First Catalogue of Products Subject to Compulsory Certification must obtain a China Compulsory Certification certificate and purchase corresponding "CCC" marks for the imported commodities from the CNCA before goods can be marketed, imported, or used for any commercial purposes. Both the importer and exporter must apply in tandem to the China Quality Certification Center.

<sup>&</sup>lt;sup>88</sup> See Administration of the Hygiene Registration of Export Food Production Enterprises, Chinese version (authentic) available at: www.fdi.gov.cn/pub/FDI/zcfg/jck/ck/P020060619703599539879.pdf.

<sup>89</sup> Food Hygiene Law, supra note 36 at art. 30.

<sup>90</sup> Id.

<sup>&</sup>lt;sup>91</sup> *Id.* 

<sup>&</sup>lt;sup>92</sup> *Id.* 

<sup>&</sup>lt;sup>93</sup> See Certification and Accreditation, Administration of the People's Republic of China, Chinese version (authentic), available at http://www.cnca.gov.cn/cnca/default.shtml.

<sup>94</sup> See id.

<sup>&</sup>lt;sup>95</sup> See China's Compulsory Product Certification System, *available at* http://www.cccmark.com/ (application forms online).

<sup>&</sup>lt;sup>96</sup> See China Quality Certification Centre, available at http://www.cqc.com.cn (application forms online).

#### V. Recent Regulatory Developments

#### A. New Committee

On August 17, 2007, the State Council, the highest government body in China, announced that it had formed a cabinet-level committee to improve the quality and safety of its food products, both for consumption in China and for export. The State Council revealed few details about the committee, except that Vice Prime Minister Wu Yi had been appointed to chair it. The committee will help steer the government's new four-month nationwide campaign to improve the quality and safety of food. The campaign will target farm produce, processed food, the catering sector, pork, and imported and exported food products. The committee improves the quality and safety of food.

# B. White Paper

106 See id.

The announcement of the new cabinet-level committee came on the same day that the government issued a white paper, the first of its kind on China's food safety. The white paper is a thirty-nine page document that sets forth a series of achievements and planned measures to improve food quality. The white paper provides a numerical accounting of food safety standards: over 1,800 national standards, 2,500 industrial standards, 7,000 local standards, and 140,000 enterprise standards. It notes the repeal of more than 530 national and industrial standards and notes that China has sped up the revision of over 2,460 national and industrial standards, issued over 200 new national standards, and worked out plans to enact 280 national standards. The white paper points to achievements by referring to the proportion of Chinese food products that passed quality inspections, having risen from 77.9 percent in 2006 to the current figure of 85.1 percent. The white paper states that the Standardization Administration administers the country's food standardization work, while relevant departments under the State Council are in charge of specific food standardization work in respective sectors.

The white paper sets out a strategy for dealing with small-scale food workshops. According to the white paper, of the 448,000 enterprises engaged in foodstuff production and processing in China,

<sup>David Barboza, China Seeks to Regain Confidence on Food Safety, THE NEW YORK TIMES ONLINE, August 18, 2007, available at http://www.nytimes.com/2007/08/18/business/worldbusiness/18safety.html.
Id.
Id.
See China Daily.com, Full Text: White Paper on Food Quality and Safety, August 18, 2007, available at http://www.chinadaily.com.cn/bizchina/2007-08/18/content\_6032837.htm.
See id.
See id.
See id.
See id.
See id.</sup> 

353,000 of them are small businesses or workshops with less than ten employees. Although these small workshops comprise almost 80 percent of China's food producers according to the white paper, they produce less than 10 percent of the goods on the market. The paper states that China will make small-scale producers unite into larger ones to create efficiencies in the handling of safety and quality and reports that by the end of June 2007, the government had weeded out 5,631 unqualified small producers, forced 8,814 producers to stop production, and asked 5,385 companies to improve their production.

## C. Memorandum of Understanding

The U.S. Department of Health and Human Services has entered into negotiations with China for a memorandum of understanding (MOU) aimed at improving China's food and drug safety by the end of the year. A MOU is a legal document that describes a bilateral agreement between parties. A Memorandum of Cooperation is in place between the USDA and AQSIQ, but it does not have the weight of a legally binding agreement. There is precedence for a standards-setting MOU between the two countries, as there is a current MOU in place concerning standards for ceramic ware imported into the U.S. from China. It will be interesting to see if the food and drug MOU that is being negotiated between the two countries in its final form could be used as a model with other trade partners to ensure the safety of food product imported into the U.S.

#### D. New Food Safety Law

On October 31, 2007, the State Council approved in principle a draft food safety law. The draft law is based on the existing Food Hygiene Law. The draft law reportedly outlines a program for food safety supervision and evaluation mechanism to serve as the basis for food safety standards and

<sup>&</sup>lt;sup>107</sup> *Id*.

<sup>108</sup> See id.

<sup>&</sup>lt;sup>109</sup> See id.

<sup>&</sup>lt;sup>110</sup> China, U.S. to Consult on Food Safety, China Daily, Online, July 18, 2007, available at http://www.chinadaily.com.cn/china/2007-07/18/content\_5438688.htm; Jason Leow and Nbsp, U.S. Aims to Reach Agreements With China on Food, Drug Safety, The Wall Street Journal Online, July 31, 2007; Jason Leow, U.S. Aims to Reach Agreements With China on Food, Drug Safety, The Wall Street Journal Online (July 31, 2007).

<sup>&</sup>lt;sup>111</sup> Letter, from U.S. Senator Dick Durbin (D-IL) and Congresswoman Rosa DeLauro (D-CT) to the secretaries of the Department of Health and Human Services and the Department of Agriculture and to the Commissioner of the Food and Drug Administration, June 18, 2007, available at <a href="http://www.house.gov/delauro/press/2007/June/Fish\_Ban\_06\_28\_07.html">http://www.house.gov/delauro/press/2007/June/Fish\_Ban\_06\_28\_07.html</a>.

<sup>&</sup>lt;sup>112</sup> *Id.* 

<sup>&</sup>lt;sup>113</sup> See id; see also Memorandum of Understanding Between the Food and Drug Administration, Department of Health and Human Services, of the United States of America and the Certification and Accreditation Administration of the People's Republic of China Covering Ceramicware Intended for Use In the Preparation, Serving or Storage of Food or Drink and Offered for Export to the United States of America, 71 Fed Reg. 15188 (Mar. 27, 2006).

<sup>&</sup>lt;sup>114</sup> See Gov.cn, Chinese Government's Official Web Portal, *Cabinet approves draft food safety law*, Oct. 31, 2007, *available at* http://english.gov.cn/2007-10/31/content\_792114.htm.

control measures.<sup>115</sup> The draft law also requires that food products exported from China to other countries satisfy the compulsory requirements set by importers and pass local entry inspection.<sup>116</sup> No time line is provided for the enactment of the new law, but it will be submitted to the National People's Congress for debate and adoption.<sup>117</sup>

#### VI. Conclusion

Given the increasing amount of food product being imported into the U.S., the safety of food in the U.S. depends to a large extent on the ability of other national systems, including China's, to regulate the safety of the production and manufacturing of food products. China's evolving legal system may make it challenging for China's food regulatory system to mature into an effective and responsive system. On the other hand, China's unique political and legal environment may enable it to respond more quickly and effectively than some have anticipated. Recent reform efforts by China evidence a commitment by China to step up to the plate and engage in meaningful reform, and reports seem to indicate that the government is taking forceful steps to improve food safety. Time will tell whether these reforms and efforts in China's emerging food regulatory system will alleviate concerns and meet expectations.

<sup>&</sup>lt;sup>115</sup> See id.

<sup>&</sup>lt;sup>116</sup> See id.

<sup>117</sup> See id.

<sup>&</sup>lt;sup>118</sup> See *id.* (accounting of enforcement activity against the production and sales of substandard food and farm produce during the product safety inspection campaign launched in August 2007).