

# CRS Report for Congress

## Food and Agricultural Imports from China

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# Food and Agricultural Imports from China

## Summary

China is now the third largest source of U.S. agricultural and seafood imports. A series of incidents have raised public concerns about the safety of these products. In September 2008, U.S. authorities said they broadened their testing of milk-derived products from China, following reports that melamine-contaminated baby formula has sickened tens of thousands of Chinese children. They also announced a recall of some coffee products that may contain melamine.

Early in 2007, evidence emerged that adulterated pet food ingredients from China had caused the deaths of a large number of dogs and cats. In late June 2007, the U.S. Food and Drug Administration (FDA) announced that it was detaining all imports of farm-raised seafood from China until shippers could confirm they are free of unapproved drug residues.

U.S. imports of Chinese agricultural and seafood products increased roughly fourfold, from 433,000 metric tons (MT) and \$1 billion in 1997 to 2.1 million MT and \$4.9 billion in 2007. However, the United States exported a much larger volume of these products to China in 2007: 14.7 million MT, valued at \$8.8 billion.

Two federal agencies — FDA and the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) — are primarily responsible for the government's food regulatory system, although a number of other federal, state, and local agencies also have important roles. For imports, FSIS (which regulates the safety of most meat and poultry) relies on a very different regulatory system than FDA (which regulates the safety of all other foods). Although all imported food products must meet the same safety standards as domestically produced foods, international trade rules permit a foreign country to apply its own, differing, regulatory authorities and institutional systems in meeting such standards, under an internationally recognized concept known as "equivalence."

China officials assert that they have been moving aggressively to improve their food safety system and to close unsafe plants. China in late 2007 concluded a memorandum of agreement with the United States aimed at improving the safety of traded food and feed products. Nonetheless, some Members of Congress continue to express sharp criticism of both China's food safety record and U.S. efforts to insure import safety. In the 110<sup>th</sup> Congress, committees on both sides of Capitol Hill held hearings on food safety concerns generally and on the China situation. Numerous bills were introduced focusing on imported food safety or containing such provisions, which would apply equally to Chinese imports. These bills include H.R. 2997, S. 1776, H.R. 1148/S. 654, H.R. 2108/S. 1274, H.R. 3100, H.R. 3610, H.R. 3624, H.R. 3937, H.R. 3967, and S. 2418.

A provision in the FDA Amendments Act of 2007 (P.L. 110-85), passed in September 2007, requires an annual report to Congress with detailed data on FDA-regulated food imports. Also in 2007, Congress cleared a consolidated appropriation act for FY2008 which includes a provision blocking an FSIS rule to allow certain poultry products to be imported from China.

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# Food and Agricultural Imports from China

## Introduction

Food and agricultural imports have increased significantly in recent years, causing some in Congress to question whether the U.S. food safety system can keep pace.<sup>1</sup> A series of recent incidents have raised safety concerns about many of these foods, medicines, and other products, particularly from China, the third-largest source of U.S. agricultural and seafood imports.

In September 2008, for example, U.S. authorities said they were more closely monitoring imports of dairy products and dairy-based ingredients from China, following reports that four infants died there and tens of thousands of other young children have been sickened by consumption of milk products, primarily infant formula, contaminated with the chemical melamine. A reported 13,000 infants were hospitalized. A number of countries have banned various dairy-related imports from China and/or pulled Chinese products from store shelves.

In early 2007, evidence had emerged that adulterated pet food ingredients from China had caused the deaths of many dogs and cats. A subsequent survey counted 347 cases (235 cats and 112 dogs) of pets dying from contaminated pet food.<sup>2</sup> Some ingredients also were fed to U.S. food animals, although federal officials claimed that humans were not at risk.

In late June 2007, the U.S. Food and Drug Administration (FDA) announced that it was detaining all imports of farm-raised seafood from China (specifically, shrimp, catfish, basa, dace, and eel) until the shippers of these products could confirm that they are free of unapproved drug residues. Chinese importers remained subject to these conditions in 2008.

While strongly defending its record, the Chinese government also has announced a variety of steps to improve the safety of its food and drug exports, including revisions in its regulations, new inspections, and the closure of problem plants. It also signed, in late 2007, a memorandum of agreement with the U.S. government pledging expanded cooperation to ensure the safety of many of its food and feed products. The FDA is moving to station some officials in China to provide closer oversight. At the same time, China has blocked the importation of some types of U.S. food products, ostensibly out of food safety concerns.

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<sup>1</sup> For an overview of food import safety issues, see CRS Report RL34198, *U.S. Food and Agricultural Imports: Safeguards and Selected Issues*, by Geoffrey S. Becker.

<sup>2</sup> Michigan State University, "MSU survey determines that more than 300 pets may have died from contaminated pet food; culprit may be lethal combination of contaminants," news release, November 29, 2007, at [<http://newsroom.msu.edu/site/indexer/3263/content.htm>].

These and other developments greatly heightened public and congressional scrutiny not only of China's own food safety regime, but also of the adequacy of U.S. import safeguards. During the 110<sup>th</sup> Congress, a number of congressional committees held hearings on, or launched investigations of, food imports from China and elsewhere. Committees reviewed U.S. laws and regulations designed to ensure import safety. Many bills were introduced to clarify and expand federal authorities affecting both imported and domestic foods, and/or to reorganize agency responsibilities.

This CRS report first provides information on the most recent Chinese-related food safety concern, the use of melamine in dairy ingredients. Following this section, the report provides data on U.S.-China trends in agricultural trade, examines U.S. programs to monitor the safety of imports, and reports on other recent Chinese food safety developments. It concludes with a brief discussion of the congressional role.

## **Milk Product Safety Concerns**

In a food safety crisis that was continuing to unfold in late September 2008, approximately 54,000 or more young children have been sickened in China, reportedly suffering from the consumption of milk powder contaminated with melamine.<sup>3</sup> A reported 13,000 of them were hospitalized, and four infants died. According to various press reports, as early as mid-July 2008, one provincial government had told Chinese health officials about an unusually high number of kidney stones in babies who had all consumed the same milk product. However, Chinese authorities did not hold a news conference to announce a nationwide recall of 700 tons of milk powder until September 11, 2008.

Melamine is an industrial chemical used in the manufacture of plastic, including kitchen products, countertops, and floor tiles. When ingested, it can crystallize and cause kidney stones and, ultimately, kidney damage and kidney failure. Pet foods made with melamine-tainted wheat gluten imported from China into the United States were linked to the hundreds of pet deaths in 2006 and 2007.

In the recent dairy product crisis, the focus initially was on milk powder manufactured by the Chinese company Sanlu, of which the New Zealand dairy giant Fonterra owns a 43% share. Sanlu reportedly obtains its milk from middlemen who collect it from local farmers. Investigators believe that these middlemen deliberately were adding melamine to boost product protein content readings of milk that had been watered down to increase its volume. Chinese officials said the practice could have been under way for years. Smaller traces of melamine also reportedly were found in the milk powder of 21 other Chinese companies.

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<sup>3</sup> Unless noted otherwise, this section was prepared from numerous press accounts published throughout September 2008, including by Reuters, *The Economist*, *The Times* of London, *Food Chemical News*, *The New Zealand Herald*, and the Associated Press.

## World Reaction

Concerns about these problems quickly spread to other countries throughout the world. Chinese dairy products were recalled or pulled from shelves throughout Asia and in some African countries. As of late September 2008, at least 12 countries had banned Chinese dairy imports. Health authorities in these and many other countries are testing various baked goods and candies most often sold at Asian specialty stores, if they contain dairy ingredients.

The New Zealand Food Safety Authority said it had found unacceptably high levels of melamine in Chinese-made White Rabbit Creamy Candies and warned people not to consume them.<sup>4</sup> The Canadian Food Inspection Agency issued a recall of, and warned consumers not to consume, the Mister Brown brand of instant coffee products (as did the United States; see below). Health authorities in a number of countries also were sampling and testing various dairy protein product imports from China, including casein, caseinates, milk powders, whey powder, and lactose powder.

Noting that other food products such as biscuits and chocolate, which could be made from contaminated milk powder, may have reached the European Union (EU), the European Commission asked the European Food Safety Agency (EFSA) to provide “urgent scientific advice” on the matter. EFSA issued a statement on September 25, 2008 saying, in part:

Estimated exposure does not raise concerns for the health of adults in Europe should they consume chocolates and biscuits containing contaminated milk powder. Children with a mean consumption of biscuits, milk toffee and chocolate made with such milk powder would also not exceed the TDI [tolerable daily intake, which is 0.5 mg/kg body weight]. However, in worst case scenarios with the highest level of contamination, children with high daily consumption of milk toffee, chocolate or biscuits containing high levels of milk powder would exceed the TDI. Children who consume both such biscuits and chocolate could potentially exceed the TDI by more than threefold. However, EFSA noted that it is presently unknown whether such high level exposure scenarios may occur in Europe.<sup>5</sup>

The EU also reportedly has banned imports of baby foods containing Chinese milk powder and required testing of all products containing more than 15% milk powder.

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<sup>4</sup> New Zealand Food Safety Agency, September 24, 2008, statement.

<sup>5</sup> “Statement of EFSA on risks for public health due to the presences of melamine in infant milk and other milk products in China,” accessed on September 25, 2008, at [[http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1211902098495.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902098495.htm)]. In the absence of actual data for milk powder, EFSA used the highest value of melamine (approximately 2,500 mg/kg) reported in Chinese infant formula as a basis for worst case scenarios.

## U.S. Implications

In a health information advisory issued on September 12, 2008, the U.S. FDA stated that there is no known threat of contamination in infant formulas “that have met the requirements to sell such products in the United States.” FDA said that it had been reassured by companies that manufacture infant formula for the U.S. market that they are not importing formula or sourcing milk-based materials from China. The FDA said it also was investigating Asian markets throughout the United States to see whether any were stocking Chinese-made infant formula.

Nonetheless, in a September 26, 2008, update, the FDA said that the King Car Food Industrial Co. was recalling six types of Mr. Brown instant coffee and one Mr. Brown Milk Tea due to possible contamination with melamine. FDA also warned consumers not to consume these products or White Rabbit Creamy Candy, adding that it was not aware of any U.S. health problems related to these products.

The United States does import from China some milk-based products, primarily as ingredients that are in turn used in the manufacture of other foods. In its September 23, 2008, update of its advisory, the FDA said it “has broadened its domestic and import sampling and testing of milk-derived ingredients and finished food products containing milk, such as candies, desserts, and beverages that could contain these ingredients from Chinese sources. Milk-derived ingredients include whole milk powder, non-fat milk powder, whey powder, lactose powder, and casein.”<sup>6</sup> **Table 1**, below, shows the volume of recent U.S. imports of Chinese dairy ingredients and products.

**Table 1. Imports of Chinese Dairy Ingredients and Products**  
(metric tons)

Item	2007 (January-December)	2008 (January-July)
Casein	1,945.6	847.5
Caseinates & derivatives	339.0	55.0
Other natural milk proteins	194.4	100.0
Yogurt	11.0	3.0
Butter	0.5	0.0
Cheese (proc.; not fresh)	14.3	0.0

**Source:** Data from USDA, Foreign Agricultural Service (FAS), U.S. Trade Imports - HS 6-Digit Codes.

As **Table 1** shows, casein is the largest type of dairy-related import from China. As context, China accounted for no more than 2% of all U.S. casein imports from January 2007 through July 2008. According to a U.S. government study, 68% of all

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<sup>6</sup>“FDA Updates Health Information Advisory on Melamine Contamination,” September 23, 2008, FDA statement. As of September 25, 2008, testing had not produced any positive results for melamine, according to FDA.

casein purchases in 2002 were used here for nondairy food products, primarily imitation cheese and coffee creamers. Fourteen percent were used in specialty nutrition products, 9% in other dairy foods, and 7% in processed cheese products. Caseinates are mainly (93%) used in specialty nutrition products such as ready-to-drink beverages, drink powders, power bars and other forms of sports and medical nutrition applications.<sup>7</sup>

## U.S.-China Trade Trends

U.S. imports of agricultural and seafood products from all countries increased from 35.9 million metric tons (MMT) in 1997 to 48.7 MMT in 2007, or by 36%. The increase by value was 95%, from \$43.8 billion in 1997 to \$85.4 billion in 2007. Among the product categories that more than doubled in volume during the period were live animals, wine/beer, fruit/vegetable juices, wheat, coffee, snack foods, and various seafood products.<sup>8</sup>

Not all agricultural imports are used for human food; some products are ingredients in pet food and animal feed, in manufactured goods (e.g., rubber), and in the nursery plant trade. Nonetheless, many consumers are obtaining a growing portion of their diets from overseas. In 2005, nearly 15% of the overall volume of U.S. food consumption was imported, compared with 11%-12% in 1995. The proportions (volume) for some food product categories were much higher: in 2005 as much as 84% of all U.S. fish and shellfish was imported (55% in 1995); 43% of all noncitrus fresh fruits (34% in 1995); 37% of all processed fruits (20% in 1995); and 54% of all tree nuts (40% in 1995).<sup>9</sup>

U.S. imports of Chinese agricultural and seafood products have increased far more rapidly, from 433,000 metric tons (MT) and \$1 billion in 1997 to 2.1 million MT and \$4.9 billion in 2007. China was the third leading foreign supplier of these products to the United States in 2007, after Canada and Mexico.

**Table 2**, below, shows the major types of food and agricultural imports from China in 2007. Seafood products, including shrimp, other shellfish (mollusks), and salmon, were the leading food-related (i.e., agricultural and seafood) imports. Fruits, fruit juices, vegetables, tree nuts, teas, and spices also were high on the list.

The broader categories in **Table 2** mask some specific products that the United States imports in large quantities from China. For example, a 2007 report by Food and Water Watch, a consumer advocacy organization, noted that China became the

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<sup>7</sup> U.S. International Trade Commission, *Conditions of Competition for Milk Protein Products in the U.S. Market* (Investigation No. 332 — 453), May 2004.

<sup>8</sup> U.S. Department of Agriculture (USDA), Foreign Agricultural Service (FAS), U.S. Trade Internet System, BICO (Bulk, Intermediate, and Consumer-Oriented) data.

<sup>9</sup> USDA, Economic Research Service (ERS), unpublished data, obtained May 11, 2007. Other data, including that provided by FDA, indicate that the current percentage for seafood is somewhat lower than 84%.



leading exporter of seafood to the United States in 2004. Aquaculture facilitated this export growth, particularly for shrimp and tilapia. Catfish, eel, and crab imports also rose significantly.<sup>10</sup>

**Table 2. Selected Agricultural and Seafood Imports from China, 2007**

<b>Import</b>	<b>Value (\$1,000)</b>	<b>(metric tons unless specified)</b>
Other fish & products (not listed below)	\$1,228,226	359,215
Fruit juices ( <i>kiloliters</i> )	433,387	1,610,250
Fruit, processed	286,207	323,767
Misc. horticultural products	283,667	118,194
Shrimp & prawns	236,354	48,610
Mollusks	207,262	55,184
Other crustaceans	186,580	23,217
Feed, ingredients & fodders	167,942	63,554
Vegetables, prepared or preserved	165,699	146,971
Misc. industrial use	154,106	11,876
Poultry, misc.	135,725	14,122
Sugar & related products	125,873	54,470
Salmon	111,322	27,119
Fresh vegetables, excluding potatoes	103,909	92,795
Vegetables, dried/dehydrated	103,862	70,711
Misc. meat products	97,322	18,230
Edible tree nuts	86,582	11,051
Grains and feed, misc.	84,239	50,104
Tea, excluding herbal	79,546	24,021
Vegetables, frozen	72,417	93,545
Misc. hair, industrial use	71,342	18,678
Other oilseed prods., nonagric.	68,091	25,965
Spices	64,470	45,092
Fruit, dried	56,519	13,079
Misc. sugar and tropical	49,711	16,236

**Source:** USDA, FAS, FAS Import Commodity Aggregations. Not all products listed.

The United States exports much more in food and agricultural products to China than China exports to the United States. In 2007, U.S. food, agricultural, and seafood exports to China totaled 14.7 MMT and were valued at \$8.8 billion. **Table 3**, below,

<sup>10</sup> *Import Alert: Government Fails Consumers, Falls Short on Seafood Inspections*, Food and Water Watch, May 2007.

shows some of the major types of these U.S. exports. Many of these exports (e.g., much of the seafood) may be sent to China as lower-value products, processed there, and returned to be consumed in the United States.

**Table 3. Selected Agricultural and Seafood Exports to China, 2007**

<b>Import</b>	<b>Value (\$1,000)</b>	<b>(metric tons unless specified)</b>
Soybeans, incl. oil & meal	\$4,117,405	11,771,605
Cotton	1,461,216	1,062,446
Hides and skins ( <i>number</i> )	826,942	1,276,317
Intermediate products, misc.	454,439	465,136
Poultry meat	347,528	324,711
Seafood, misc.	341,442	191,914
Salmon	158,000	56,864
Dairy products	153,597	90,759
Red meats	142,784	101,500
Consumer oriented, misc.	114,291	16,502
Fruits & vegetables, processed	101,589	102,522
Tobacco	65,955	9,521
Tree nuts	53,838	12,015
Feeds and fodders	51,875	80,477
Fresh fruit	38,793	39,170
Planting seeds	32,289	11,678
Other bulk commodities	27,600	6,149
Snack foods	22,929	9,677
Roe/urchin/fish eggs	16,072	4,869

**Source:** USDA, FAS, BICO data. Not all products listed.

## U.S. Import Safeguards

### Overview

Although all food products imported into the United States must meet the same safety standards as domestically produced foods, international trade rules permit a foreign country to apply its own differing, regulatory authorities and institutional systems in meeting such standards, under an internationally recognized concept known as “equivalence.”<sup>11</sup>

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<sup>11</sup> This concept is embodied in Article 4 of the Agreement on the Application of Sanitary (continued...)

Two federal agencies — the U.S. Department of Agriculture’s (USDA’s) Food Safety and Inspection Service (FSIS) and FDA, within the U.S. Department of Health and Human Services — are primarily responsible for the government’s food regulatory system, although a number of other federal, state, and local agencies also have important roles. For imports, FSIS relies on a very different regulatory system than FDA, including a different approach to addressing equivalence, as described in the following sections.

## FSIS

Under Section 20 of the Federal Meat Inspection Act (FMIA) as amended (21 U.S.C. 601 *et seq.*) and Section 466 of the Poultry Products Inspection Act (PPIA) as amended (21 U.S.C. 451 *et seq.*), FSIS is responsible for determining the equivalence of other countries’ meat and poultry safeguards.<sup>12</sup> A foreign plant cannot ship products to the United States 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.<sup>13</sup> In addition, FSIS operates a reinspection program at U.S. border entry points. Generally, agency inspectors review all import records, assisted by a computerized statistical sampling program, the Automated Import Inspection System (AIIS), that enables targeting of some shipments for actual inspection — examining their physical condition, labeling, and documentation. China is not yet certified to ship FSIS-regulated meat and poultry products (i.e., the major commercial species) to the United States.

Meat and poultry imports from other countries, however, have increased, from nearly 2.3 billion pounds presented for inspection in FY1996 to approximately 4 billion pounds annually now. FSIS has estimated that it physically examined approximately 20% of all such imports in FY1996 compared with approximately 10% in more recent years (after implementation of the AIIS in the early 2000s). About 4% of imports now undergo microbiological testing, according to USDA.

## FDA

Under Section 801 of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 *et seq.*), FDA can refuse entry to any food import if it “appears,” based on a physical examination or otherwise, to be adulterated,

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<sup>11</sup> (...continued)

and Phytosanitary Measures (the SPS Agreement), which entered into force January 1, 1995, for member nations of the World Trade Organization (WTO). For a more detailed explanation, see CRS Report RL33472, *Sanitary and Phytosanitary (SPS) Concerns in Agricultural Trade*, by Geoffrey S. Becker.

<sup>12</sup> FSIS coverage is of the major commercial red meat and poultry species and their products, while FDA has jurisdiction over any meat and poultry not inspected by FSIS.

<sup>13</sup> Eligible establishments from 33 countries (as of 2008) can be accessed at [[http://www.fsis.usda.gov/regulations\\_%26\\_policies/Eligible\\_Foreign\\_Establishments/index.asp](http://www.fsis.usda.gov/regulations_%26_policies/Eligible_Foreign_Establishments/index.asp)].

misbranded, or in violation of the law.<sup>14</sup> In exercising its oversight, the agency relies on a system of prior notifications by importers and document reviews at points of entry (ports). Importers must have an entry bond and file a notification for every shipment. Import information is entered into FDA's database, the Operational and Administrative System for Import Support (OASIS). This system helps inspectors determine a shipment's relative risk and whether it needs closer scrutiny (i.e., actual examination and/or testing). FDA inspectors work closely with Customs and Border Protection officials from the Department of Homeland Security on these tasks.<sup>15</sup>

The volume of FDA-regulated food imports has tripled in one decade. The agency received an estimated 8.2 million imported food lines (shipments) in FY2007, compared with fewer than 2.8 million shipments in FY1997. Approximately 1% of these shipments were physically examined in FY2007, compared with 1.7% in FY1996. A food line is a single shipment, regardless of size — whether a single carton or a large carlot — making it difficult if not impossible to determine the share of the total volume of imports that is actually being examined.

FDA's ability to operate within other countries appears to be more limited than that of FSIS. FDA can, and does, periodically visit foreign facilities to inspect their operations, but usually in response to a concern and only with the permission of the foreign government. Furthermore, agency officials acknowledged in 2007 that FDA has lacked the staff and funding to increase its presence overseas, regardless of whether it might have the legal authority to do so. FDA's budget for food activities (domestic and imported) was \$457.1 million in FY2007. FDA's food safety staff (FY2007) numbered approximately 1,900 in field offices throughout the United States, plus more than 800 in its headquarters offices near Washington, D.C.

FDA might theoretically have the authority to require equivalency standards for Chinese imports, but the agency's situation is significantly more complex than that of FSIS (which regulates fewer types of food products), according to David Acheson, the FDA's Assistant Commissioner for Food Protection.<sup>16</sup> The Government

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<sup>14</sup> 21 U.S.C. § 381(a); see also the online video CRS Multimedia MM70102, *Food Importation: Border Inspection, Detention, and Trade Issues*, by Vanessa K. Burrows and Jeanne J. Grimmett.

<sup>15</sup> The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) expanded the prior notification requirements for FDA-regulated imported foods. It also now requires any imported or domestic facility that manufactures, processes, packs, or holds food for U.S. consumption to register with the FDA; farms and retail establishments are among those exempted. Further, the act requires records sufficient to identify the immediate supplier as well as the subsequent recipient of the product.

<sup>16</sup> Comments at a May 9, 2007, hearing before the House Agriculture Committee. Source: "Officials defend federal response to melamine contamination," *Food Chemical News*, May 14, 2007. In a July 11, 2007 conference call, Dr. Acheson reportedly reiterated his concern about the complexity of trying to seek food safety equivalency agreements with the approximately 150 countries that ship products to the United States (*Food Chemical News*, July 13, 2007).

Accountability Office (GAO) in 1998, on the other hand, asserted that FDA lacks the statutory authority to mandate equivalency.<sup>17</sup>

## FDA Import Refusals

### Overview and Limitations of Analysis

Using the OASIS data, the FDA compiles a monthly “Import Refusal Report” for food shipments that it rejects. Such products have to be either re-exported or destroyed by the importer. The agency posts these monthly refusal reports on its website, but only for the most recent 12 months (i.e., only one year’s worth of refusals).<sup>18</sup> The refusals for each month can be searched by country or by product category, but not by both at the same time. Data for only 12 months, from May 2006 through April 2007, appeared on the website as of May 2007, when CRS last tabulated it, and the months were not aggregated by FDA into annual figures.<sup>19</sup>

For each line (recorded shipment), the system provides the name of the source company and the reason for refusal. As noted earlier, the size of each shipment in the OASIS database varies. Therefore, it is not possible to calculate the volumes of products being rejected, either as an absolute quantity or as a proportion of total imports. Also, the types or categories of imports do not necessarily correspond to the categories reported through the FAS trade databases (see **Tables 1** and **2**, above).

Mindful of these caveats, CRS prepared a tabulation of the refusals, focusing on nearly 40 categories of FDA-regulated food and food-related products.<sup>20</sup> For the one-year period examined (FY2007), FDA logged a total of nearly 8,500 refusals, representing approximately one-tenth of one percent of the 8.2 million lines entered into OASIS during the period. Of these, more than 700 separate shipments were from China. Two other countries had more shipments refused: Mexico and India, each with approximately 1,150.

It is important to note that a higher relative number does not necessarily indicate that one country’s products are less safe, or its food safety system less rigorous, than another country’s. The country simply might be a more important source of U.S. agricultural and/or seafood imports. On the other hand, Canada, which imports much more to the United States than any other country, had far fewer refusals than either China or Mexico, the second most important U.S. importer in dollar value. India had

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<sup>17</sup> GAO Report RCED-98-103, *Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable*. April 1998. GAO also had concluded that border inspections alone were ineffective.

<sup>18</sup> Website accessed September 25, 2008, at [[http://www.fda.gov/ora/oasis/ora\\_oasis\\_ref.html](http://www.fda.gov/ora/oasis/ora_oasis_ref.html)].

<sup>19</sup> CRS did not examine FSIS import refusals for this report. China currently is not certified by FSIS to export FSIS-regulated meat or poultry products to the United States.

<sup>20</sup> Also listed in the OASIS refusal reports, but not examined here, are other FDA-regulated products, e.g., human and animal drugs, medical devices, and vitamins.

the second highest number of refusals, even though it is not among the top 10 exporters of food, agricultural, and seafood products to the United States.<sup>21</sup>

## Types of Chinese Imports Refused

Of the more than 700 refused shipments from China, more than 300 were seafood products, and approximately one-third of these products were eel. The most frequently cited reason for rejecting the eel shipments was a concern about adulteration by unsafe levels of veterinary drug residues. Catfish products also were often refused, usually because of concerns about veterinary drug residues. A wide variety of other types of finfish, from tilapia fillets to cod and salmon products, was refused for numerous apparent concerns, including veterinary drug residues, filthy appearance, and *Salmonella* contamination. More than three dozen separate shrimp shipments were refused because of filthy appearance, the presence of nitrofurans (a banned antibiotic), or *Salmonella*. Other examples of refused seafoods were scallops, crawfish, and squid.

FDA also refused more than 200 shipments of various fruits and vegetables from China, including processed products. Approximately one-fourth of these shipments were of mushrooms, often in dried form; these were most frequently rejected for filthy appearance. Other reasons for refusing fruit and vegetable product shipments ranged from concerns about the presence of violative levels of pesticides or other unacceptable ingredients, including unsafe color additives, to the lack of proper documentation and/or labeling.

Seafood products and fruit and vegetable products together constituted the majority of refused shipments from China. Examples of other types of food products that were refused, although in fewer numbers, were certain candies, bean curd and bean paste, teas, and various nuts and spices.

Chinese officials have strongly defended their safety record. One official asserted at a May 31, 2007, news conference that U.S. inspectors had approved “99 percent” of all Chinese food and medical shipments over the last three years and that recent reports of rejected Chinese shipments had been sensationalized. He further argued that most of those that had been rejected were unauthorized shipments that had skirted Chinese controls.<sup>22</sup> Other Chinese officials declared in 2007 that U.S. importing companies need to look beyond their emphasis on low prices and communicate more clearly what their standards are.<sup>23</sup> In September 2007, a Chinese official asserted that problems with Chinese exports have been due either to improper information on U.S. standards from U.S. importers, or to the failure of the United

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<sup>21</sup> Nonetheless, India’s exports to the United States were valued at a still substantial level of more than \$1.4 billion in FY2007.

<sup>22</sup> Li Yuanping, director general of the Chinese Import and Export Food Safety Bureau, as quoted in various news reports including “China Says Food Export Inspections Are Effective,” *Washington Post*, June 1, 2007. Also see “China Confronts Crisis Over Food Safety,” *Wall Street Journal*, May 30, 2007.

<sup>23</sup> “U.S., Chinese leaders try to advance trade, food safety issues,” *Agri-Pulse*, May 30, 2007.

States to check on whether Chinese exporters had been approved by that government.<sup>24</sup>

FDA officials had told CRS that in FY2006, the overall refusal rate for shipments from China (food and all other types of FDA-regulated shipments) was 0.15%. They cautioned that the 99.85% of shipments were not necessarily in compliance, because the agency only has the resources to examine 1% of all line entries (shipments) into the country.<sup>25</sup>

William Hubbard, a former FDA deputy commissioner, told National Public Radio (NPR) in 2007 that total “individual shipments of food and ingredient exports from China to the United States have gone from 82,000 in 2002 to 199,000 in 2006. And I’m told by FDA officials that they’re rapidly reaching up to 300,000 this year.”<sup>26</sup>

## Chinese Food Safety Challenges

As noted, the FDA OASIS database does not provide answers as to whether Chinese imports are any less safe than those from other countries. Nonetheless, the country has come under intense criticism in the wake of several widely publicized incidents involving adulterated food, agricultural, and medical exports. In early 2007 pet food ingredients from China that contained the chemical melamine — apparently added to boost the ingredients’ protein levels — sickened or killed many dogs and cats in North America. The ingredients subsequently were found in some hog, chicken, and fish feed. A risk assessment indicated the problem posed virtually no risk to humans, USDA and FDA officials asserted. Another incident attracted attention in early May 2007, when the Mississippi Commissioner of Agriculture ordered a number of stores there to stop selling catfish from China after samples tested positive for antibiotics banned in the United States.

Such concerns are not new. An FDA import inspector was quoted in 1991: “Some countries we almost never have problems with.... But others, such as India, Thailand, China, Korea, and many countries in Africa, require constant vigilance.”<sup>27</sup>

A number of analysts has examined the food safety challenges China faces as it becomes a major agricultural exporter. USDA economists wrote in 2006:

China emerged in the 1990s as a low-cost exporter of food products such as vegetables, apples, seafood, and poultry. But in recent years, China’s exports

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<sup>24</sup> See for example: “Senior Chinese Official Hopes Chinese Actions Will Delay Legislation,” *FDA Week*, September 14, 2007.

<sup>25</sup> FDA e-mail communication to CRS, June 6, 2007.

<sup>26</sup> “Q&A: Why China Tops the FDA Import Refusal List,” accessed May 25, 2007, at [<http://www.npr.org/templates/story/story.php?storyID=10410111>].

<sup>27</sup> Sharon Snider, “From Psyllium Seeds to Stoneware: FDA Insures the Quality of Imports,” *FDA Consumer Magazine*, March 1991.

slowed when shipments of vegetables, poultry and shrimp were rejected for failing to meet stringent standards in Japan, Europe, and other countries, revealing a gap between Chinese and international food safety standards.<sup>28</sup>

Some analysts contend that China's problems in complying with other — usually more developed — countries' safety requirements are typical of those faced by most developing countries. They point to a number of specific obstacles the Chinese have encountered in upgrading their safeguards, including:

- the difficulty of standardizing and monitoring production practices at the farm production level, to which many safety problems can be traced due to widespread noncompliance with existing regulations such as environmental rules, and which is composed of 200 million households typically farming on plots of one to two noncontiguous acres;
- heavy use of fertilizers and pesticides to counteract intensively cultivated soils and large pest pressures;
- wide use of antibiotics to control diseases in intensive livestock, poultry, and aquaculture systems;
- industrialization, lax environmental controls, and untreated human and animal waste in fields and waters, which raise concerns about toxic, metal, and microbial contaminants in food;
- a fragmented marketing system dominated by millions of small firms handling small volumes, often on a cash basis with no documentation or ability to trace products;
- a fragmented regulatory and oversight structure involving 10 national government ministries and little coordination with lower levels of government, which often have their own, differing standards for food products; and
- for many commodities and industries, outdated or nonexistent standards, or standards that are inconsistent with internationally accepted ones.<sup>29</sup>

Responsibility for domestic food safety is shared among a number of Chinese agencies at the national, provincial, and local levels, including the national Ministry of Agriculture, which supervises the quality of primary agricultural products; and the Ministry of Health and the State Food and Drug Administration (SFDA), both with responsibilities in regulating processed foods. Quality assurance for both imports and exports is under the purview of the General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ), which also has oversight over all

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<sup>28</sup> Linda Calvin et al., "Food Safety Improvements Underway in China," *Amber Waves*, November 2006, USDA, ERS. The Codex Alimentarius Commission is the major international body for encouraging international trade in food while promoting the health and economic interest of consumers. Codex is a subsidiary of the Food and Agriculture Organization and the World Health Organization. One of its key functions is to develop standards, codes of practice, and guidelines for the safety of foods, in accordance with the SPS Agreement. The Codex website is at [<http://www.codexalimentarius.net>].

<sup>29</sup> Calvin. Also, Fengxia Dong and Helen H. Jensen, "Challenges for China's Agricultural Exports: Compliance with Sanitary and Phytosanitary Measures," *Choices*, 1<sup>st</sup> quarter 2007.



exports (including food and toys). However, the Ministry of Health and the SFDA have had “minimal” roles in regulating exports.<sup>30</sup>

At one 2007 hearing, an FDA official observed that China has some 400,000 food or feed manufacturers. From 12,000 to 15,000 are registered with AQSIQ and are therefore eligible to export products, yet an estimated one-third of China’s food exports come from non-registered establishments.<sup>31</sup> According to another expert, China officially has 448,000 food enterprises, 78% of them “cottage industries” with 10 employees or fewer.<sup>32</sup>

## U.S. Efforts to Improve Import Compliance

Administration officials have attempted to reassure Congress that they are working diligently on plans to improve oversight of all food imports generally and of Chinese imports particularly. In late 2007, they had unveiled several documents focused on these objectives.

**Food Safety and Import Plans.** On November 6, 2007, the Administration released two separate but related reports. The broader of the two covers the safety of most imports for consumers, including but not limited to food. This *Action Plan for Import Safety* was prepared for the President by the Interagency Working Group on Import Safety.<sup>33</sup> The other report is FDA’s *Food Protection Plan*, which focuses on food, whether imported or domestically produced, and which contains recommendations for food imports that generally parallel those in the import report.<sup>34</sup>

Both plans are oriented toward assessing and prioritizing risks regardless of where they occur (starting with a product’s origin), and preventing problems rather than waiting for them to occur. Both plans appear to rely heavily on cooperation with others, including private industry stakeholders and foreign governments, to assure safety, but they also propose some new regulations and new legislative authorities affecting importers and others in the food system. Officials stated that they were

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<sup>30</sup> House Energy and Commerce Committee, Subcommittee on Oversight and Investigations staff trip report, “Food from China: Can We Import Safely?” Released October 5, 2007. The trip report observed, among other things, that the Chinese food supply chain apparently does not meet international safety standards, and that the Chinese government “appears determined to avoid embarrassing food safety outbreaks in export markets.”

<sup>31</sup> David Acheson, FDA Assistant Commissioner for Food Protection, in response to questions at a September 26, 2007 hearing before the House Committee on Energy and Commerce, Subcommittee on Health.

<sup>32</sup> Source: Drew Thompson, Director of China Studies and Starr Senior Fellow, The Nixon Center, “U.S.-China Food Safety and Trade,” September 9, 2007, presentation at a Woodrow Wilson Center conference, *Regulating Food Safety in China*.

<sup>33</sup> Available at [<http://www.importsafety.gov/report/actionplan.pdf>].

<sup>34</sup> Available at [<http://www.fda.gov/oc/initiatives/advance/food/plan.html>]. Both plans are described in more detail in CRS Report RL34198, *U.S. Food and Agricultural Imports: Safeguards and Selected Issues*.

seeking additional funds to help pay for these initiatives as part of the FY2009 budget request.

**Bilateral Memorandum of Agreement.** On December 11, 2007, the Administration announced that it had signed a memorandum of agreement (MOA) with the Chinese government intended to enhance the safety of food and feed imports from China. The MOA was the culmination of four sets of meetings with the Chinese, plus part of a side meeting of President Bush and Chinese leader Hu Jintao at the September 2007 Asia-Pacific Economic Cooperation (APEC) ministerial in Sydney, Australia.<sup>35</sup> The food and feed MOA states the two countries' intention "to establish a bilateral cooperative mechanism" that "may include current and future registration and certification systems. The mechanism aims to provide the Parties with information to use in judging whether an imported product meets the requirements of the importing country."<sup>36</sup>

Under the agreement, China is to require exporters to the United States to register with the Chinese AQSIQ, and to agree to annual inspections to assure that their goods meet U.S. standards. AQSIQ is to notify FDA of those that fail inspection and why, and of all companies that have lost their registration status. The Chinese agency also is to develop both a system for tracing products from source of production to point of exportation, and a statistically valid testing program. Also under the agreement, the two countries are to notify one another within 48 hours of any new public health risks related to food or feed, and AQSIQ is to facilitate FDA access to, and inspection of, Chinese processing and cultivation sites.

Starting with the first phase of implementation, AQSIQ-issued export certificates are to be required of exporters of commodities that have high import refusal rates, specifically low-acid canned products or acidified foods, pet foods, ingredients of food and feed like wheat gluten and rice protein, and all farmed seafood except molluscan shellfish. Other commodities could be added during later phases, according to the MOA annex. The agreement commits the two sides to forming a working group to develop further implementation details of the plan, with a final plan due within 120 days, among other specified deadlines.

Stakeholders raised a number of concerns about the agreement. The Consumers Union asserted that the agreement neglected other Chinese products with questionable safety records, such as apple juice, and failed to give U.S. inspectors immediate access to Chinese plants. Several others expressed doubts about China's willingness or capacity to meet its obligations, noting that the government already has strict food standards but has not widely enforced them. Among other questions are whether the agreement might effectively give unfair preferential treatment for Chinese over other foreign imports; whether FDA will have adequate resources for

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<sup>35</sup> Also announced on December 11, 2007, was a second bilateral agreement on drugs and medical devices.

<sup>36</sup> *Agreement between the Department of Health and Human Services of the United States of America and the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China on the Safety of Food and Feed*, accessed on December 31, 2007, at [<http://globalhealth.gov/news/agreements/ia121107b.html>].

oversight and enforcement; and whether the agency has the appropriate legal authority to share information about U.S. food companies or to demand certificates from foreign importers.<sup>37</sup>

On June 18, 2008, the United States and China issued a “Joint Progress Statement” on implementation of the agreement, noting that the two parties had established mechanisms for cooperation and communication on food safety events; developed “concrete steps” toward a system where AQSIQ will electronically certify to FDA that specific China-exported products to the United States meet FDA safety and quality standards; and agreed to train Chinese officials on U.S. regulatory requirements, focusing on inspections and laboratory testing standards.<sup>38</sup>

**Other Bilateral Efforts.** FDA’s Center for Food Safety and Nutrition (CFSAN) website indicates that it has been aggressively pursuing both formal and informal agreements with foreign government counterparts to achieve mutual recognition of equivalence of regulatory systems. Another FDA website lists more than 90 “International Arrangements” with approximately 30 separate foreign entities, of which 36 appear to be directly food-related. Roughly a third of these address aspects of shellfish or other seafood safety.<sup>39</sup> FDA’s agreements with China apparently do not include any for food, but are in place for lead in tableware.

The Chinese have approved necessary visas to enable FDA to establish permanent offices in the country, FDA Associate Commissioner for Foods Acheson told a House hearing in September 2008. The agency intends to place about eight or nine staffers plus five Chinese nationals in three locations in China, with the first likely to open in October 2008, he added. Their presence will allow for closer oversight and coordination on food and drug safety matters.<sup>40</sup>

**Detention of Chinese Seafood.** In one significant move last year, FDA on June 28, 2007, issued an import alert ordering the “Detention Without Physical Examination” of all of the following aquacultured products from China: catfish, basa (related to catfish), shrimp, dace (related to carp), and eel.<sup>41</sup> FDA said it issued the notice after targeted sampling during October 2006 through May 2007 “repeatedly found that farm-raised seafood imported from China were contaminated with antimicrobial agents that are not approved for this use in the United States.” The agents are nitrofurans, malachite green, and gentian violet, which have been found to

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<sup>37</sup> See for example “U.S.-China Food Safety Deal Could Give China Preferential Treatment,” *FDA Week*, December 21, 2007.

<sup>38</sup> HHS, “United States and China Outline Progress on Agreement on Food and Feed Safety,” June 18, 2008, press release, accessed on the Internet September 25, 2008, at [<http://www.hhs.gov/news/press/2008pres/06/20080618a.html>].

<sup>39</sup> Both websites accessed May 15, 2007, at [<http://www.cfsan.fda.gov/~comm/intl-toc.html>].

<sup>40</sup> See for example, “Acheson: China Has Granted Visas for FDA Outpost,” *FDA Week*, September 19, 2008.

<sup>41</sup> FDA Import Alert #16-13, which may be viewed at [[http://www.fda.gov/ora/fiars/ora\\_import\\_ia16131.html](http://www.fda.gov/ora/fiars/ora_import_ia16131.html)].

be carcinogenic to laboratory animals; and fluoroquinolones, which when used in food animals may increase antibiotic resistance in humans, the agency said.

Under such an import alert, FDA detains all covered products until the importing firm demonstrates, through testing by an independent laboratory, that a representative sample of their product is free of these contaminants. Although the FDA has long issued these types of alerts for various imports, they generally are more limited in scope — for example, to a particular firm or product.

The import alert reiterated that approximately 80% of U.S. seafood consumption is from imports and that over 40% of these imports come from aquaculture operations. Shrimp and catfish are two of the top 10 most frequently consumed seafood products. China is the largest aquaculture producer in the world, with 70% of total production, and the third largest exporter to the United States. The alert observes: “As the aquaculture industry continues to grow and compete with wild-caught seafood products, concerns regarding the use of unapproved animal drugs and unsafe chemicals and the misuse of animal drugs in aquaculture operations have increased substantially.”

## **Chinese Efforts to Address Food Safety**

Chinese government officials appear to have launched a series of major initiatives to bolster their food safety programs, notwithstanding their assertions, throughout 2007 and 2008, that their products are safe. To deal with the most recent crisis regarding tainted dairy products, the Chinese agriculture ministry announced on September 23, 2008, that it would require all milk dealers to register and would conduct regular inspections of milk to ensure there is no more tampering. Earlier, the Chinese said they had fired their top inspection official.

In 2007, officials announced their intention to update a 1995 consumer food law, and in 2006 the Chinese legislature adopted a national framework for building an agricultural product safety system. The Chinese have said they do require registration of all land and processing facilities used for exported products, and exporters must have facilities that can test for pesticide residues. The government also says it does sample and test products for export to help ensure they meet foreign buyers' standards.<sup>42</sup>

China also has been encouraging investment, including foreign direct investment, in production and processing to improve technology, marketing and management skills, and transportation and infrastructure. Six types of processed foods — canned food, aquatic products, meat and meat products, frozen vegetables, fruit/vegetable juice, and some frozen convenience foods — reportedly are to be manufactured under HACCP (hazard analysis and critical control point) standards.<sup>43</sup>

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<sup>42</sup> Calvin.

<sup>43</sup> Dong.

HACCP is a system of assessing risks, determining the points at which they might occur during production, and instituting measures to prevent them.<sup>44</sup>

At a May 31, 2007, news conference, a Chinese official also pointed to the death sentence handed down to the former head of the government's food and drug safety agency, as an example of its determination to improve product oversight. The agency head had been convicted of taking bribes for approving potentially dangerous drugs. He reportedly was executed on July 10, 2007.<sup>45</sup>

In late June 2007, one Chinese government agency reportedly announced the closure of 180 food manufacturers that it said had been using industrial materials such as dyes, mineral oils, hydrochloric acid, paraffin, and formaldehyde in a variety of food products, including flour, candies, seafood, pickles, and biscuits. Another agency reportedly claimed to have closed 152,000 unlicensed food manufacturers and retailers in 2006 for making counterfeit or low-quality products.

According to U.S. agricultural attache reports, China's AQSIQ announced that it would begin affixing inspection and quarantine labels to all food product packages for export after inspection, effective September 1, 2007.<sup>46</sup> USDA and other China experts observe that China has made its oversight of food exports the highest priority. They note that China has restricted eligibility to a relatively small proportion of its estimated 448,000 food processors.

Other announcements have included a Chinese State Council regulation intended to intensify controls over food product producers and distributors, where more records would be made public, new higher fines would be levied on food exporters who violate regulations, and a "blacklist" would be established for both exporters and domestic importers who distribute unqualified food products. The regulation reportedly notes that local governments are mainly responsible for food safety oversight.<sup>47</sup>

Other reported actions include the designation of the equivalent of \$1.6 billion to improve food and drug supervision by the SFDA, and new rules to tighten oversight of food and drug processors including their acquisition of raw materials.<sup>48</sup> Meanwhile, another agency, the Standardization Administration of China, announced at a July 2007 press conference that it planned to revise by 2010 as many as 4,000 food safety standards, notably for food additives, dairy, meat, eggs, and fisheries.

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<sup>44</sup> FDA information on HACCP is at [<http://www.cfsan.fda.gov/~lrd/haccp.html>].

<sup>45</sup> "China Executes Former Head of Food Safety Agency," *Wall Street Journal*, July 10, 2007.

<sup>46</sup> For details of the change see USDA, FAS, *China to attach inspection and quarantine labels for food exports*, Gain report CH7059, July 23, 2007, accessed on the Internet at [<http://www.fas.usda.gov/gainfiles/200707/146291796.pdf>].

<sup>47</sup> This announcement and other recent China food safety news is covered in: USDA, FAS, *Agricultural Situation News Flash I.28*, GAIN report CH7065, August 10, 2007, accessed on the Internet at [<http://www.fas.usda.gov/gainfiles/200708/146292018.pdf>].

<sup>48</sup> *Ibid.*

Whether these commitments applied to other Chinese bodies such as AQSIQ was uncertain.<sup>49</sup>

The same AQSIQ regulation (see above) also was to impose new requirements on importers into China. U.S. exporters already were encountering sanitary barriers to trade first imposed in July 2007 by Chinese officials. At that time, they announced that meat and poultry imports shipped by some U.S. companies were being suspended. These included chicken products that, China asserted, contained *Salmonella* bacteria (although U.S. interests have long noted that proper cooking destroys the bacteria), and pork products that contained an unapproved feed additive (which appears to be legal in the United States).<sup>50</sup> Shortly after that, poultry exports from seven U.S. states were banned from China due to the presence of Low Pathogenic Avian Influenza (LPAI), a move that the United States asserted was not based on sound science.<sup>51</sup> In early October 2007 China reportedly rejected 47 tons of U.S. frozen sardines that were said to be contaminated with *Listeria*.

Some U.S. interests contended that these actions were in retaliation for U.S. complaints about the safety of Chinese goods. Others maintain that the Chinese are seeking to demonstrate to their own consumers that they are protecting them from unsafe products, including imported goods. For example, they also have blocked poultry imports from Brazil based on sanitary concerns.

## Congressional Consideration

Members of Congress have expressed sharp criticism both of China's food safety record and of U.S. efforts to insure the safety of that country's imports. Among panels that have examined the issue in the 110<sup>th</sup> Congress are the House Agriculture Committee; the House Energy and Commerce Committee's Subcommittee on Oversight and Investigations, and its Subcommittee on Health; the House Ways and Means Subcommittees on Oversight and on Trade; the Agriculture Subcommittee of the House Appropriations Committee; the Senate Commerce Committee; and the Senate Health, Education, Labor, and Pensions Committee.

A number of bills with food import safety provisions were introduced in 2007, and several passed. For example, Section 1009 in the Food Safety title (X) of the Food and Drug Administration Amendments Act of 2007 (H.R. 3580; P.L. 110-85), passed in September 2007, requires an annual report to Congress on the number and amount of FDA-regulated food products imported by country and type of food, the

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<sup>49</sup> USDA, FAS, *Food and Agricultural Import Regulations and Standards, Country Report — Mandatory Update*, GAIN report CH7066, August 16, 2007, accessed on the Internet at [<http://www.fas.usda.gov/gainfiles/200708/146292078.pdf>]. This report is intended to catalogue the key standards affecting imports for the Chinese market, according to FAS.

<sup>50</sup> Various news reports, including *Food Chemical News*, July 2, 2007; *The Wall Street Journal*, July 16, 2007; and Reuters, July 15, 2007.

<sup>51</sup> USDA, FAS, *Poultry and Products Annual Report*, GAIN report CH7077, September 26, 2007, accessed at [<http://www.fas.usda.gov/gainfiles/200709/146292545.pdf>].

number of inspectors and inspections performed, and aggregated data on inspection findings, including violations and enforcement actions. Elsewhere, Division A of the Consolidated Appropriations Act, 2008 (H.R. 2764), provides funding for the balance of the fiscal year for both FDA and FSIS. A provision of this act prohibits FSIS from implementing an FSIS rule that would allow certain poultry products to be imported from China. This proposal to permit some types of processed poultry had been published in the November 23, 2005, *Federal Register*.

Approximately a dozen other food safety bills containing one or more provisions that address food import safety were pending in 2008. Several focus almost exclusively on the issue. Many (including H.R. 2997, S. 1776, H.R. 1148/S. 654, H.R. 2108/S. 1274, H.R. 3610, and H.R. 3624) propose that importing establishments, and/or the foreign countries in which they are located, first receive formal certification from U.S. authorities that their food safety systems demonstrably provide at least the same level of safety assurances as the U.S. system. Under some of these bills, certification could be denied or revoked if foreign safeguards are found to be insufficient, unsafe imports are discovered, or foodborne illnesses are linked to such products. A number of the bills also propose the collection of user fees from importers to cover the costs of inspecting foreign products at the borders.

Some bills seek to require more physical inspections and testing by FDA at the border or within other countries, to authorize more research into inspection and testing technologies, or to restrict imports to specific ports. H.R. 3100 is another measure with import safety provisions. S. 2418 would require USDA to provide public notification whenever smuggled food products are identified in commerce, and to provide public notification on all recalled food products, using methods prescribed in the bill. The bill would require private laboratories that conduct tests on FDA-regulated imports to be certified by the agency, under a fee-funded process for certification and audits to be developed by FDA. Laboratories would have to submit to the agency the results of all tests they conducted. (These bills are described in more detail in CRS Report RL34198, by Geoffrey S. Becker.)

In 2008, attention focused on two comprehensive safety bills, one by Senator Durbin (S. 3385) and another a draft proposal being circulated by Representative Dingell. Title III of the Durbin bill is specific to imported foods, with provisions such as a requirement that each importer establish a food safety supplier verification program; authorization to permit importers to qualify for expedited review and entry if they exceed minimum safety standards; and explicit authority for HHS (FDA) to require export certificates for foods determined to be of higher risk, with certificates to be issued in the foreign countries of origin by qualified “certifying entities.”

Title III also would direct FDA to establish a system to accredit qualified third parties that could certify that food facilities are in compliance with U.S. standards. Such parties could include foreign governments, states, and foreign or domestic cooperatives. Other notable provisions in the Durbin bill’s import title would authorize HHS to enter into agreements with foreign governments that would enable FDA to inspect foreign facilities and to deny entry of food imports from those facilities that impede such inspections; give FDA additional authority to review foreign food safety systems; and require FDA to develop a comprehensive plan to improve the regulatory capacities of foreign governments.

Import-specific provisions in the Dingell draft include a requirement for all importers of food, drugs, devices and cosmetics to register with the FDA and to pay an annual fee of \$10,000; the establishment of a corps of inspectors dedicated solely to import inspections; more stringent country-of-origin labeling requirements; and limiting, within five years, all imports (of FDA-regulated foods and other products) to ports of entry that are located near a federal food testing laboratory. There are now a total of 13 FDA field laboratories but well over 300 ports of entry.

Recent developments with food imports also spurred calls for implementation of mandatory country-of-origin labeling (COOL) for fresh meats, produce and peanuts, taking effect as of September 30, 2008. The omnibus 2008 farm bill (P.L. 110-246) maintained this date, but it added more covered commodities including chicken and modified some labeling and record-keeping requirements. (For further information on COOL, see CRS Report RS22955, *Country-of-Origin Labeling for Foods*, by Geoffrey S. Becker.)