



# U.S. Food and Agricultural Imports: Safeguards and Selected Issues

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## Summary

U.S. officials continue to assert that the U.S. food supply, including the portion provided through imports, is among the safest in the world. One challenge has been how to keep it safe in the face of steadily rising imports, a result of globalization and consumer desire for a wider variety of foods year-round. The issue of import safety was the focus of numerous congressional hearings and bills in the 110<sup>th</sup> Congress, and is expected to be on the policy agenda of the 111<sup>th</sup> Congress.

Does the U.S. safety system, first created at a time when most Americans obtained their foods domestically, adequately protect public health? What, if any, changes should be made to enhance the safety of food imports? Critics argue that major reforms are necessary because the present programs are both poorly designed and inadequately funded to meet today's challenges. An opposing argument is that imported foods already are subject to the same safety standards as—and pose no greater hazards than—domestically produced foods. An early argument of the Bush Administration was that smarter allocation of existing resources, and the food industry's own controls, could and should be capable of addressing any problems.

In early December 2007 a science advisory board of the U.S. Food and Drug Administration (FDA) Science Board concluded that the agency's overall appropriation, now at about \$1.5 billion, should be more than doubled in the next several years if it is to meet its current responsibilities, including but not limited to food safety. Congress did provide the FDA with some increased funding for FY2008 and part of FY2009.

The Bush Administration in November 2007 also had issued new policy recommendations on food safety and on import safety. Although these recommendations received some attention in the 110<sup>th</sup> Congress, by the second session many stakeholders were focusing on draft bills circulated by the chairmen of the House Energy and Commerce Committee and the Senate Health, Education, Labor, and Pensions Committee. The proposals differed in detail, but both sought broad reforms in FDA's oversight of food and drug safety, including of imports. The House draft has been formally introduced in the 111<sup>th</sup> Congress as the Food and Drug Administration Globalization Act of 2009 (H.R. 759).

Numerous other food safety bills in the 110<sup>th</sup> Congress addressed one or more aspects of food import safety, and elements of these bills also could be re-offered in the 111<sup>th</sup> Congress.

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## **Introduction**

Officials continue to assert that the U.S. food supply, including the portion imported, is among the safest in the world. One challenge has been the steady increase in imports, a result of globalization and consumer desire for a wider variety of foods year-round. With this growth have come new concerns about whether current federal programs sufficiently ensure the safety of these imports. Import alerts in 2007 and 2008 targeting adulterated pet food ingredients, farmed seafood, and dairy products and ingredients, all from China, are among the incidents that heightened interest in the issue in the 110<sup>th</sup> Congress.

Do U.S. safeguards, generally created at an earlier time when most Americans obtained their foods domestically, remain sufficient to protect public health? What, if any, changes should be made to enhance the safety of food imports? Critics argue that major reforms are necessary because the present programs are both poorly designed and inadequately funded to meet today's challenges. Those who oppose major changes assert that imported foods already are subject to the same safety standards as—and pose no greater hazards than—domestically produced foods. They also contend that smarter allocation of existing resources, and the food industry's own controls, can and should be capable of addressing any problems that arise.

The issue was explored at numerous congressional hearings in 2007 and 2008, and Members of Congress introduced a variety of bills to modify or overhaul the current system. Some sought broad reforms in the U.S. Food and Drug Administration's (FDA's) oversight of both food and drug safety, including of imports. (The U.S. Department of Agriculture oversees the safety of most meat and poultry; FDA all other foods). The House Energy and Commerce Committee and the Senate Health, Education, Labor, and Pensions Committee, the likely starting points for FDA food safety reform, did not mark up comprehensive legislation in the 110<sup>th</sup> Congress—but could consider major bills in the 111<sup>th</sup> Congress.

The Bush Administration had released, on November 6, 2007, its own import safety plan and an accompanying food protection strategy. These documents made a number of recommendations, some of them entailing new legislative authority and additional funding, which the Bush Administration requested in its FY2009 budget submission for FDA. (FDA appropriations usually are provided each year as part of the Agriculture, Rural Development, FDA, and Related Agencies Appropriations Act, not by the authorizing committees.) It was unclear in early 2009 whether the Obama Administration would incorporate any of the elements of the Bush plan into its own food safety strategy and funding recommendations.

## **Food and Agricultural Imports Increasing**

U.S. imports of agricultural and seafood products from all countries increased from 35.6 million metric tons (MMT) in FY1997 to 48.2 MMT in FY2007, or by 35%. The increase by value was 94%, from \$43 billion in FY1997 to \$83.6 billion in FY2007. 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. Agricultural and seafood imports increased again in FY2008, to 50.7 MMT valued at \$93 billion.<sup>1</sup>

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<sup>1</sup> U.S. Department of Agriculture (USDA), Foreign Agricultural Service (FAS), U.S. Trade Internet System, BICO (continued...)

**Table 1** shows that the United States' NAFTA (North American Free Trade Agreement) partners, Canada and Mexico, were by far the largest suppliers of food, agricultural, and seafood imports in FY2008—with a combined one-third share of total imports. The percentage share of all other leading importers was in the single digits.

**Table 1. Leading Suppliers of U.S. Agricultural and Seafood Imports, FY2008**  
(value in billion U.S. dollars)

<b>Country</b>	<b>Agricultural</b>	<b>Seafood</b>	<b>Total</b>	<b>Share (%)</b>
1. Canada	\$17.935	\$2.278	\$20.213	21.7
2. Mexico	10.761	0.482	11.243	12.1
3. China	3.427	2.027	5.455	5.9
4. Thailand	1.917	1.831	3.748	4.0
5. Indonesia	2.669	1.052	3.721	4.0
6. Italy	3.296	0.009	3.304	3.6
7. Chile	1.961	0.993	2.954	3.2
8. Brazil	2.598	0.103	2.701	2.9
9. Australia	2.404	0.072	2.477	2.7
10. Ireland	2.386	0.006	2.392	2.6
11. France	2.380	0.012	2.392	2.6
12. Netherlands	2.156	0.040	2.196	2.4
13. Malaysia	1.710	0.201	1.911	2.1
14. New Zealand	1.739	0.128	1.867	2.0
15. India	1.533	0.228	1.762	1.9
16. Colombia	1.716	0.041	1.757	1.9
17. Vietnam	0.691	0.765	1.456	1.6
18. Ecuador	0.722	0.615	1.338	1.4
19. Germany	1.279	0.005	1.284	1.4
20. Costa Rica	1.201	0.077	1.278	1.4
21. Guatemala	1.259	0.017	1.276	1.4
22. Argentina	1.177	0.084	1.261	1.4
23. Spain	1.189	0.039	1.228	1.3
24. Philippines	0.896	0.262	1.158	1.2
25. Peru	0.778	0.089	0.868	0.9
World Total	79.317	13.720	93.0379	100.0

**Source:** USDA, Foreign Agricultural Service (FAS), BICO Import Commodity Aggregations.

(...continued)

(Bulk, Intermediate, and Consumer-Oriented) data.

Not all agricultural imports enter the human food supply; some products are used as 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>2</sup>

## Federal Oversight Responsibilities

Two federal agencies—USDA’s Food Safety and Inspection Service (FSIS) and the U.S. Department of Health and Human Services’ Food and Drug Administration (FDA)—are responsible for the majority of the total funding and staffing of the government’s food regulatory system. For imports, FSIS relies on a very different regulatory system than FDA, including a differing approach to addressing equivalence, as described below. Also important are USDA’s Animal and Plant Health Inspection Service (APHIS), which is responsible for protecting plant and animal resources from domestic and foreign pests and diseases, and the Department of Homeland Security (DHS), which is responsible for coordinating agencies’ food security activities, including border inspections by DHS’s U.S. Customs and Border Protection (CBP).<sup>3</sup>

### FDA Role

The FDA’s food regulatory authority comes chiefly from the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 et seq.).<sup>4</sup> This authority makes the agency responsible for the safety of virtually all domestic and imported articles used for food and drink, except meat and poultry (see “FSIS Role,” below); these include animal as well as human foods. FDA-regulated foods may be deemed adulterated or misbranded for a variety of statutorily prescribed reasons. For example, a food may be deemed adulterated if it contains an added poisonous or deleterious substance or an unsafe food additive or if the food was prepared, packed, or held under insanitary conditions whereby it may have become contaminated or may have been rendered injurious to health.<sup>5</sup> Of approximately 60,700 domestic food facilities (such as manufacturers, warehouses, and shippers), FDA designates about 8,000 as “high risk,” based on the types of foods they handle and/or past performance.<sup>6</sup> In general, FDA attempts to conduct annual inspections of these facilities; non-high risk establishments are inspected, on average, once

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<sup>2</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%.

<sup>3</sup> In total, as many as 15 federal agencies administer at least 30 laws related to food safety.

<sup>4</sup> Portions of this section and the following section are based on Olsson, Frank and Weeda, P.C., and The Food Institute, *Importing Food into the United States: A Regulatory Guide*, 2007. Data sources for this section, unless noted: David Acheson, Assistant Commissioner for Food Protection, U.S. Food and Drug Administration, testimony before the House Agriculture Committee, May 9, 2007; and House Appropriations Committee hearings on Agriculture Appropriations for various years.

<sup>5</sup> 21 U.S.C. § 342(a)(2).

<sup>6</sup> Source: *Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for 2008*, Part 5, hearings before a Subcommittee of the Committee on Appropriations, House of Representatives, 110<sup>th</sup> Cong., 1<sup>st</sup> sess.

every 5 years, according to FDA, although other estimates—including another of FDA's—indicate an inspection frequency of once every 10 years.<sup>7</sup>

All domestic and foreign food manufacturing facilities must adhere to FDA's regulations on Good Manufacturing Practices (21 C.F.R. part 110), which address safe handling and plant sanitation. Exempt are establishments such as farms engaged solely in harvesting, storing, or distributing raw agricultural commodities normally cleaned or otherwise treated before consumption.

Section 801 of the FFDCFA empowers the FDA to refuse entry to any food import if it “appears,” based on a physical examination or otherwise, to be adulterated, misbranded, or in violation of the law.<sup>8</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 is to help inspectors to determine a shipment's relative risk and whether it needs closer scrutiny (i.e., a wharf or physical examination, and/or testing). FDA inspectors are to work closely with CBP officials on these tasks.<sup>9</sup>

If closer examination is not deemed necessary, FDA allows the product to enter U.S. commerce. A shipment found to be noncompliant is subject to a number of corrective actions, such as relabeling or reconditioning to bring it into compliance, refused entry, or even seizure and destruction. Sometimes, the agency subjects an import to “detention without physical examination,”<sup>10</sup> based on past history or other information indicating that it may be violative. Such detention compels the importer to demonstrate to FDA that the product is safe before it can enter U.S. commerce. Examples in 2007 were the detention of all Chinese plant protein products (including wheat gluten and rice gluten, destined for pet foods) after some were found to contain melamine, an unapproved substance; and of all farm-raised seafood from China (specifically, shrimp, catfish, basa, dace, and eel) until the shippers of these products could demonstrate that they are free of unapproved drug residues. In 2008, the FDA issued a detention import alert for all milk products, milk-derived ingredients, and food products containing milk from China until they can demonstrate that they do not contain melamine or cyanuric acid.

The volume of FDA-regulated imports has increased substantially in the past decade. The agency recorded more than 8.2 million imported food “lines” in FY2007 compared with fewer than 2.8

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<sup>7</sup> For example, *FDA Science and Mission at Risk*, a November 2007 report prepared by a subcommittee of the FDA Science Board (the Commissioner's top advisory group) cited (on p. 21) an FDA estimate that “... at most, it inspects food manufacturers once every 10 years ...” Also, the *FDA Food Protection Plan* (November 2007) stated that there were over 136,000 registered domestic food facilities and approximately 189,000 foreign facilities that manufacture, process, pack, or hold food. These figures are inflated, because facilities engaged in more than one activity are counted multiple times. The *Food Protection Plan* is discussed later in this CRS report.

<sup>8</sup> 21 U.S.C. § 381(a).

<sup>9</sup> The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) greatly expands 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, among other provisions.

<sup>10</sup> FDA's authority to detain without physically inspecting an article derives from 21 U.S.C. § 381(a), which states that FDA must refuse admission of certain imports into the United States “[i]f it appears from the examination of such samples or otherwise” that such samples are adulterated, misbranded, or otherwise in violation of the law (emphasis added).

million entry lines in FY1997. Just over 1% of these lines were physically examined and/or tested.<sup>11</sup> In 2007 congressional hearings, witnesses testified that 450 inspectors must cover more than 300 ports of entry.<sup>12</sup>

FDA's ability to operate within other countries appears to be limited. 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. Further, FDA asserts that it lacks the staff and funding to increase its presence overseas, regardless of whether it might have the legal authority to do so. FDA's Center for Food Safety and Applied Nutrition (CFSAN) had a budget of \$457 million and staff of 2,700 (full-time equivalent or FTE) in FY2007, of which \$298 million and 1,900 FTEs were in the field.<sup>13</sup> For FY2008, the FDA foods budget was \$577 million, which included a mid-year supplemental appropriation of \$67 million.<sup>14</sup>

In a hearing before the House Agriculture Committee, FDA's chief food officer testified that the agency theoretically has the authority to require equivalency for imports but that FDA's situation is significantly more complex than USDA's (the latter regulates fewer types of food products; see below).<sup>15</sup>

CFSAN has stated on its website that it is "aggressively pursuing both informal and formal agreements with foreign government counterpart officials including Memoranda of Understanding for mutual recognition of equivalence of regulatory systems." Another FDA website lists nearly 100 "International Arrangements" with approximately 30 separate foreign entities, of which about a third appear to be directly food-related. Roughly a third of the food-related arrangements address aspects of shellfish or other seafood safety.<sup>16</sup> However, these are not the same as formal equivalency requirements (see "FSIS Role," below).

## FSIS Role

FSIS regulates the safety and labeling of most domestic and imported meat and poultry, under the Federal Meat Inspection Act (FMIA) as amended (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act (PPIA) as amended (21 U.S.C. 451 et seq.).<sup>17</sup> Inspectors are to be present at all times in slaughter plants and for at least part of each day in establishments that further process meat and poultry products. They are to examine all animals destined for human food both before

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<sup>11</sup> Source: FDA briefing for Senate staff, February 8, 2008. FDA FY2009 budget materials state that 94,743 import food field exams were conducted in FY2007. For definition of "line," see "FDA Import Refusals" later in this report.

<sup>12</sup> See for example hearings held before subcommittees of the House Committee on Energy and Commerce, July 17, September 26, and October 11, 2007.

<sup>13</sup> Source: *FDA Science and Mission at Risk*, report of the Subcommittee on Science and Technology, Prepared for the FDA Science Board, November 2007.

<sup>14</sup> Source: CRS Report RL34638, *FDA FY2009 Appropriations*, by Susan Thaul et al.

<sup>15</sup> "Officials defend federal response to melamine contamination," *Food Chemical News*, May 14, 2007. GAO had suggested in 1998 that border inspections alone were ineffective, but that FDA lacks the authority to mandate equivalency (RCED-98-103, *Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable*).

<sup>16</sup> The arrangements were accessed December 2008 at <http://www.fda.gov/oia/default.htm>.

<sup>17</sup> FSIS inspects the major red meat and poultry species and their products; catfish was added to FSIS's responsibilities by the 2008 farm bill (P.L. 110-246; § 11016). FDA has jurisdiction over all meat and poultry not inspected by FSIS. The agencies share responsibility for egg safety, under the Egg Products Inspection Act, as amended (21 U.S.C. § 1031 et seq.). FSIS covers processed egg products; FDA covers most whole eggs.



and after slaughter, and to ensure that plants are operating in a sanitary manner, under an FSIS-approved safety plan.

Under Section 20 of the FMIA and Section 17 of the PPIA, FSIS also is responsible for determining the equivalence of other countries' meat and poultry safeguards. A foreign plant cannot ship products to the United States unless FSIS has determined that its country has a meat and/or poultry program that provides a level of protection that is at least equivalent to the U.S. system.<sup>18</sup> FSIS visits the exporting country to review its rules and regulations, meets with foreign officials, and accompanies them on visits to establishments. When a foreign program is approved, FSIS relies on that government to certify eligibility of, and to inspect, the establishments. FSIS periodically reviews foreign government documents and conducts on-site audits at least annually to verify continuing equivalence.

In addition, FSIS operates a reinspection program at 150 import houses located near approximately 35 border entry points. Agency inspectors review all import records, aided by a computerized sampling program, the Automated Import Information System (AIIS). This system generates inspectors' actual examination assignments based on what the agency believes to be the relative risks of particular product types and/or countries. It also can identify shipments that are to be denied reinspection because, for example, the foreign country or particular plant is not eligible to ship to the United States, or the product has not been certified to enter. Inspectors next are responsible for ensuring that all other imports are in acceptable condition, properly labeled, and accurately counted. This can include opening and physically examining boxes for physical defects, and collecting samples for laboratory testing for contaminants. FSIS can take a number of actions when violative products are found. Products that pass are released into interstate commerce; most are bulk products for further processing at U.S. plants, which are under continuous FSIS inspection.<sup>19</sup>

Meat and poultry imports have increased significantly, from nearly 2.3 billion pounds presented for inspection in FY1996 to nearly 3.9 billion pounds in FY2007. Approximately 2.5 billion pounds were presented during the first nine months of FY2008 (i.e., through June 30). FSIS estimated that it physically had 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 undergo microbiological testing, according to USDA.<sup>20</sup>

In FY2008, FSIS had a total budget of approximately \$1 billion (appropriated and user fees) and a staff of 9,400, of which 7,800 were in about 6,300 meat and poultry plants nationwide. The agency's international food safety budget that year was approximately \$20 million, more than half of which went for border reinspections. Other portions were devoted to evaluating foreign programs and to facilitating U.S. exports. The total international staff numbered an estimated 150, although a significant number were assigned to non-border duties.<sup>21</sup>

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<sup>18</sup> List of foreign establishments in the 34 eligible countries accessed November 2008 at [http://www.fsis.usda.gov/regulations\\_&\\_policies/Eligible\\_Foreign\\_Establishments/index.asp](http://www.fsis.usda.gov/regulations_&_policies/Eligible_Foreign_Establishments/index.asp).

<sup>19</sup> See CRS Report RL32922, *Meat and Poultry Inspection: Background and Selected Issues*, by Geoffrey S. Becker.

<sup>20</sup> The percentage tested is from comments by Dr. Richard Raymond, Undersecretary for Food Safety, November 7, 2007, before the House Agriculture Subcommittee on Livestock, Dairy, and Poultry.

<sup>21</sup> House Appropriations Committee hearings on agriculture appropriations for various years.

## APHIS Role

Most meat and poultry imports also must be accompanied by a veterinary permit, which APHIS administers under authority of the Animal Health Protection Act (AHPA; 7 U.S.C. 8301 *et seq.*). Under the Plant Protection Act (PPA; 7 U.S.C. 7701 *et seq.*), APHIS also requires phytosanitary certificates for many plants and plant product imports, and more detailed import permits for most foreign fruits and vegetables. Both laws are intended to ensure that imports are free of foreign diseases or pests that would threaten U.S. animal or plant resources. APHIS's border inspection function was transferred to DHS by the Homeland Security Act of 2002 (P.L. 107-296), but APHIS maintains most other AHPA and PPA responsibilities.

## International Trade Considerations

U.S. food safety programs operate within the basic constraints of internationally accepted trade rules. Any newly adopted measures, such as those discussed later in this report, would likely be closely scrutinized by U.S. trading partners for their adherence to such agreements. More specifically, the United States is a signatory to multilateral trade rules which allow governments to adopt, unilaterally, any measures to protect human, animal, or plant life or health. In doing so, however, they are not to be discriminatory or used as disguised protectionism.

This principle was clarified in 1994 when most major trading nations including the United States adopted, along with other so-called Uruguay Round Agreements, the "Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures." This document sets out the basic rules for ensuring that each country's food safety and animal and plant health laws and regulations are transparent, scientifically defensible, and fair. The United States also has signed, or is negotiating, numerous regional and bilateral free trade agreements (FTAs) that may contain SPS language. Such language in most of the FTAs generally references the signing parties' rights and obligations under the multilateral SPS agreement.

The United States also participates in the three major international scientific bodies designated by the WTO to deal with SPS matters. One, the Codex Alimentarius Commission, focuses on human food safety. The others are the Office of International Epizootics (OIE) for animal health and diseases, and the International Plant Protection Convention (IPPC) for plant health. These bodies meet regularly to discuss threats to human and agricultural health, evaluate SPS-related disputes, and develop scientifically based SPS standards. Such standards can provide guidance for countries designing their own national SPS measures, and help resolve trade disputes.

Although U.S. and World Trade Organization (WTO) officials frequently cite the benefits of SPS cooperation under trade agreements, some, among them food safety and environmental advocacy organizations, have been skeptical. They have argued that implementation of the agreements can result in "downward harmonization" rather than upgraded health and safety standards. Defenders counter that trade rules explicitly recognize the right of individual nations to enact stronger protections than international guidelines if they believe they are appropriate and are justified by scientific risk assessment.<sup>22</sup>

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<sup>22</sup> These arguments are covered at greater length in CRS Report RL33472, *Sanitary and Phytosanitary (SPS) Concerns in Agricultural Trade*, by Geoffrey S. Becker.

## FDA Import Refusals

Using its 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 does so only for the most recent 12 months, i.e., only one year’s worth of refusals. (Also listed in the refusal reports, but not examined here, are other FDA-regulated products: drugs, medical devices, and vitamins.) CRS examined the data for FY2007 and FY2008 (i.e., October through September of each year).

For each import line, the system provides the name of the source company and the reason for refusal. A “line” is a portion of an import shipment that is listed separately on that import’s entry document. An item in a shipment must have a separate line if its tariff description differs from other items in that shipment. 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 correspond directly to the categories reported through the USDA trade databases (used for **Table 1**, above).

Efforts are under way to improve the collection and use of FDA import data. The agency reported in late 2008 that it was working on an advanced screening system it calls the Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting (PREDICT). Elsewhere, Section 1009 of the Food and Drug Administration Amendments Act of 2007 (P.L. 110-85) now requires an annual report to Congress on the number and amount of FDA-regulated food products imported by country and type of food, the number of inspectors and inspections performed, and aggregated data on inspection findings, including violations and enforcement actions.<sup>23</sup>

## FY2007 and FY2008 Refusals

Mindful of limitations of the OASIS data, CRS prepared a tabulation of the refusals, focusing on nearly 40 categories of FDA-regulated food and food-related products. For the entire FY2007, FDA logged a total of more than 8,400 refusals. This represents approximately one-tenth of one percent of the more than 8 million lines entered into OASIS during the same period. The countries involved in the most refusals were India and Mexico, each with approximately 1,150, China with more than 700, and the Dominican Republic with approximately 650. Indonesia and Vietnam each logged nearly 400. (See **Table 2**.)

In FY2008, total refusals increased to 9,600, out of a total of more than 8.1 million import entries. Mexico logged the most refused lines in FY2008 with 1,393, followed by India with 1,052, the United Kingdom with 1,034, and China with 697. Indonesia and Canada each had approximately 400 in FY2008. (See **Table 3**.)

It is important to note that a higher relative number of refusals does not necessarily indicate that one country’s products are less safe, or its food safety system less rigorous than that of another country. The country simply might be a more important source of U.S. agricultural and/or seafood imports. Mexico, for example, is the second most important exporter to the United States. On the

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<sup>23</sup> Other food safety provisions in the law affect imported as well as domestic foods. See CRS Report RS22779, *Food Safety: Provisions in the Food and Drug Administration Amendments Act of 2007*, by Donna V. Porter.

other hand, Canada, which exports more food and agricultural products to the United States than any other country, had fewer refusals than a number of countries with fewer imports in dollar value. India's import value ranked 16<sup>th</sup> in FY2007 and 15<sup>th</sup> in FY2008, but its shipments (as measured by lines) were more frequently refused U.S. entry than most other countries. And, as **Table 3** implies, the United Kingdom is not among the top 25 sources of U.S. food imports, but registered a high number of refusals in FY2008. The United Kingdom does export many types of confectionary items, among other products, to the United States.

**Table 2. FDA Refusals Among Leading Country Importers, FY2007**

(value of agricultural and seafood in billion U.S. dollars)

Country	U.S. Import Share (Value)	U.S. Import Share (%)	FDA Refusals (no. lines)	% Of All FDA Refusals
1. Canada	16.946	20.3	233	2.8
2. Mexico	10.419	12.5	1,144	13.5
3. China	4.849	5.8	731	8.6
4. Thailand	3.322	4.0	226	2.7
5. Italy	3.000	3.6	251	3.0
6. Chile	2.950	3.5	31	0.4
7. Indonesia	2.789	3.3	362	4.3
8. Australia	2.709	3.2	39	0.5
9. Brazil	2.367	2.8	132	1.6
10. Netherlands	2.325	2.8	70	0.8
11. Ireland	2.227	2.7	4	*
12. France	2.129	2.5	175	2.1
13. New Zealand	1.791	2.2	8	*
14. Colombia	1.552	1.9	52	0.6
15. India	1.369	1.6	1,156	13.7
16. Vietnam	1.335	1.6	385	4.6
17. Costa Rica	1.279	1.5	20	0.2
18. Ecuador	1.259	1.5	84	1.0
19. Argentina	1.207	1.4	79	0.9
20. Malaysia	1.195	1.4	33	0.4
21. Spain	1.187	1.4	46	0.5
22. Germany	1.163	1.4	18	0.2
23. Guatemala	1.043	1.2	87	1.0
24. Philippines	0.862	1.0	176	2.1
25. Peru	0.734	1.0	43	0.5
World Total	83.649	100.0	8,456	100.00

**Source:** Prepared by CRS based on FAS BICO Import Commodity Aggregations (first three columns) and FDA OASIS data (last two columns). A line is all or part of a shipment of no uniform size, so care should be used in attempting any comparisons between countries, or between a country's import value and its number of refused lines. Asterisk (\*) denotes less than one-tenth of one percent.

**Table 3. FDA Refusals Among Leading Country Importers, FY2008**

(value of agricultural and seafood in billion U.S. dollars)

Country	U.S. Import Share (Value)	U.S. Import Share (%)	FDA Refusals (no. lines)	% Of All FDA Refusals
1. Canada	\$20.213	21.7	392	4.1
2. Mexico	11.243	12.1	1,393	14.5
3. China	5.455	5.9	697	7.3
4. Thailand	3.748	4.0	254	2.6
5. Indonesia	3.721	4.0	410	4.3
6. Italy	3.304	3.6	277	2.9
7. Chile	2.954	3.2	35	0.4
8. Brazil	2.701	2.9	57	0.6
9. Australia	2.477	2.7	25	0.3
10. Ireland	2.392	2.6	1	*
11. France	2.392	2.6	145	1.5
12. Netherlands	2.196	2.4	23	0.2
13. Malaysia	1.911	2.1	69	0.7
14. New Zealand	1.867	2.0	10	0.1
15. India	1.762	1.9	1,052	11.0
16. Colombia	1.757	1.9	60	0.6
17. Vietnam	1.456	1.6	353	3.7
18. Ecuador	1.338	1.4	17	0.2
19. Germany	1.284	1.4	19	0.2
20. Costa Rica	1.278	1.4	15	0.2
21. Guatemala	1.276	1.4	156	1.6
22. Argentina	1.261	1.4	20	0.2
23. Spain	1.228	1.3	94	1.0
24. Philippines	1.158	1.2	252	2.6
25. Peru	0.868	0.9	89	0.9
World Total	93.0379	100.0	9,600	100.00

**Source:** Prepared by CRS based on FAS BICO Import Commodity Aggregations (first three columns) and FDA OASIS data (last two columns). A line is all or part of a shipment of no uniform size, so care should be used in attempting any comparisons between countries, or between a country's import value and its number of refused lines. Asterisk (\*) denotes less than one-tenth of one percent.

By industry, vegetables/vegetable products and seafood products appear to have been the most frequently refused products from all countries generally. Fruits/fruit products from all countries accounted for the next highest number of refusals, followed by candy products, and then spices/flavors/salts. Many refused fruit and vegetable products originated in the Dominican Republic, Mexico, or other Latin American and Caribbean nations; a frequently cited reason was pesticides. Bacterial contamination (e.g., Salmonella) or filthy condition was cited numerous times. Fish and shellfish were refused for a variety of reasons, often for bacteria, filthy condition,

and/or veterinary drug residues. These products most frequently appear to have originated in Asian countries, not only China but also Vietnam, India, Bangladesh, and others.

A 2007 report by Food and Water Watch analyzed the FDA OASIS refusals of seafood in more detail, and for all calendar years from 2002 to 2006. Among its findings were that more than 70% of all imported seafood products were processed. More than 20% of all seafood refusals were due to Salmonella, of which 40% were shrimp. It also observed that more seafood is being refused for veterinary drug residues.<sup>24</sup>

Many refusals of all food types also appear to be due to concerns about mislabeling, failure to register, or failure to document that the product complied with safe manufacturing practices (e.g., using a system of hazard analysis and critical control points, or HACCP, for low acid canned foods or seafoods).

## Past Refusal Data

A more extensive study of the OASIS data was published in September 2008 by USDA's Economic Research Service (ERS).<sup>25</sup> ERS examined seven years of FDA refusals of food import shipments, by industry group and by type of violation, which totaled 70,369 violations. Because of differing time periods, and somewhat differing methods of counting and classifying OASIS-reported refusals, the CRS and ERS findings are not directly comparable, but do appear to reach parallel conclusions. Also, the ERS study did not classify refusals by country.

The ERS study found that more than half of all food safety or other violations of FDA law during the seven-year period were among three food categories: vegetables and vegetable products (20.6% of total violations), fishery and seafood products (20.1%), and fruits and fruit products (11.7%). The most common violations were unsafe pesticides for vegetables and vegetable products, filth (unsanitary) for both fishery and seafood products and fruits and fruit products, and unregistered processes for canned foods from all three categories.

Overall, misbranding or lack of appropriate labeling accounted for 33% of the 70,369 violations, and adulteration or safety and packaging integrity violations for 65%. "Adulteration violations pose a wide range of food safety risks, from less severe risks, such as an insect in cooked soup, to immediate risks to human health, like botulism in canned food. The data indicate that the most common adulteration violations were for the appearance of filth in a food product and failure to file information or register a specified process."<sup>26</sup>

Although the study revealed recurring problems in certain types of imported foods, it did "not indicate the actual level or distribution of food safety risk ... because FDA's process for selecting shipments for inspection or other administrative actions is not random," the authors wrote. "In

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<sup>24</sup> Food and Water Watch, *Import Alert: Government Fails Consumers, Falls Short on Seafood Inspections*, May 2007. Last accessed on the Internet on April 16, 2008, at <http://www.foodandwaterwatch.org/press/publications/reports/import-alert>.

<sup>25</sup> Buzby, Jean C., Laurian J. Unnevehr, and Donna Roberts, *Food Safety and Imports: An Analysis of FDA Food-Related Import Refusal Reports* (EIB-39), USDA, ERS, September 2008.

<sup>26</sup> *Food Safety and Imports: An Analysis of FDA Food-Related Import Refusal Reports*, pp. iii-iv. The report contains tables and accompanying discussion breaking out these violations in greater detail.

essence, import refusals highlight food safety problems that appear to recur in trade and where the FDA has focused its import alerts and monitoring efforts.”<sup>27</sup>

## FSIS Import Refusals

FSIS makes available through its website quarterly enforcement reports summarizing the actions it has taken to ensure that unsafe, unwholesome, and improperly labeled products do not reach consumers. **Table 4** shows the total volume of meat and poultry products presented for import reinspection and how much was refused entry into the country for several recent fiscal years—approximately one-third of one percent of total shipments.

**Table 4. Imported Meat and Poultry Products Presented for Inspection and Refused Entry, Selected Years**

(thousands of pounds)

Fiscal Year	Presented	Refused Entry	Pct. Refused
2005	4,303,345	14,081	0.33
2006	3,888,188	12,312	0.32
2007	3,897,098	9,207	0.24

**Source:** USDA/FSIS, various *Quarterly Enforcement Reports*, accessed December 2, 2008 at [http://www.fsis.usda.gov/Regulations\\_&\\_Policies/Quarterly\\_Enforcement\\_Reports/](http://www.fsis.usda.gov/Regulations_&_Policies/Quarterly_Enforcement_Reports/).

**Note:** The figures are based on an entirely different database and inspection regimen than the figures for FDA in **Table 2** and therefore are not comparable.

## China Concerns

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. The following are among the major food-related developments.

### Melamine in Pet Food Ingredients

In early 2007 pet food ingredients from China that contained the chemical melamine—apparently added to boost the ingredients’ protein readings—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. However, melamine again surfaced in a number of Chinese-sourced human foods in 2008 (see “Melamine in Human Foods,” below).

<sup>27</sup> *Food Safety and Imports: An Analysis of FDA Food-Related Import Refusal Reports*, p. iii.

## **Seafood Safety Concerns**

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. One month later, on June 28, 2007, FDA 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>28</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 (antibiotics) 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 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 observed: “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.”

## **Melamine in Human Foods**

On November 12, 2008, FDA issued a “Detention Without Physical Examination” alert for all milk products, milk-derived ingredients, and finished food products containing milk if they are from China.<sup>29</sup> In the alert, FDA stated that these products could be contaminated by melamine and/or melamine analogs. The substance 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.

The FDA explained that in September 2008, it had become aware of reports that more than 53,000 infants had been sickened, including 13,000 who were hospitalized and four who had died, due to consumption of infant formula containing melamine. Milk used in the formula has been implicated as the source of the melamine, added to watered-down bulk milk at collection points in China to inflate the protein content. However, the problem is not limited to infant formula products; Chinese government sources also indicated that contaminated milk

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<sup>28</sup> FDA Import Alert #16-13, accessed December 1, 2008 at [http://www.fda.gov/ora/fiars/ora\\_import\\_ia16131.html](http://www.fda.gov/ora/fiars/ora_import_ia16131.html). A November 21, 2008, attachment to the alert names 10 firms with various products which have since been exempted from the detention requirement.

<sup>29</sup> FDA Import Alert #99-30, accessed December 1, 2008, at [http://www.fda.gov/ora/fiars/ora\\_import\\_ia9930.html](http://www.fda.gov/ora/fiars/ora_import_ia9930.html).



components, especially milk powder, were used in a variety of finished foods dispersed throughout the Chinese food supply chain.<sup>30</sup>

By early 2009, Chinese authorities reportedly issued revised estimates indicating that seven infants had died and nearly 300,000 been sickened after consuming melamine-tainted milk products. It was reported that many hundreds of babies remained hospitalized with kidney or urinary-tract problems, a significant number of them in serious condition.<sup>31</sup>

More than a dozen countries throughout Asia and Europe, along with Australia and the United States, have detected contamination of milk-derived ingredients and products with melamine and a related contaminant. These have included candy and beverages, found here by the FDA; in other countries, melamine has been detected in Chinese-sourced fluid and powdered milk, yogurt, frozen desserts, biscuits, cakes and cookies, soft candy products, chocolates, and beverages. These are the types of products included in the FDA import alert. To be released from detention, any of these shipments must obtain independent (third-party) laboratory results that they do not contain melamine or cyanuric acid, or have documentation that they do not contain milk or milk-derived ingredients, according to the FDA notice. A firm importing such products can request exemption from these testing and documentation requirements—which can greatly slow if not completely stop its imports—by demonstrating that it has adequate safety controls in place and that it has five consecutive non-violative shipments.<sup>32</sup>

The import alert follows an earlier health information advisory issued on September 12, 2008, where the 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.<sup>33</sup>

Nonetheless, China has been exporting dairy proteins and other products to the United States for some time, but at somewhat low levels, according to USDA trade data. 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 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

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<sup>30</sup> Ibid.

<sup>31</sup> Various trade news reports, citing figures from a Chinese Ministry of Health statement.

<sup>32</sup> FDA announced in early 2009 that it planned to begin testing aquaculture imports from China for melamine. Studies have shown that fish can retain high levels of melamine if they received feed with the substance in it. Earlier, in December 2008, FSIS said that, as a precautionary measure, it had begun 12 weeks of sampling to test meat, poultry and dairy products for melamine.

<sup>33</sup> On November 26, 2008, the Associated Press (AP) reported that the FDA had found traces of melamine in samples of U.S. infant formula. Officials reportedly told the AP that the trace amounts had occurred during manufacturing, not intentionally, and posed no health concerns. “To date, FDA tests have found extremely low levels of melamine in one infant formula sample and extremely low levels of cyanuric acid in another,” the FDA subsequently announced on a web page, “Melamine Contamination in China,” accessed December 1, 2008. “The levels were so low (well below 1 ppm) that they do not pose a health risk to infants.” The FDA based this observation on an update of an earlier (October 2008) health risk assessment which had previously stated that it “cannot establish a level of melamine and its analogues in these products that does not raise public health concerns.” The FDA web page, accessed on December 1, 2008, also contains links to both health assessments. See <http://www.fda.gov/oc/opacom/hottopics/melamine.html>.

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>34</sup>

## Chinese Food Safety Challenges

China has faced a number of food safety challenges as it becomes a major food and agricultural exporter. USDA economists had written 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 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>35</sup>

Some analysts have contended 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:

- highly decentralized farm production, composed of 200 million households typically farming on plots of one to two noncontiguous acres;
- 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;
- 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 which handle 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

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<sup>34</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>35</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>.

- for many commodities and industries, outdated or nonexistent standards, or standards that are inconsistent with internationally accepted ones.<sup>36</sup>

A 2008 report published by the Woodrow Wilson International Center for Scholars summarized China's challenge:

China's capacity to effectively protect food quality is hampered by a weak legal, political, and regulatory infrastructure that has not forced food producers and processors to be accountable. Key weaknesses in China's food safety governance system include: strong local government protectionism of industries; a lack of product liability law; and weak monitoring capacity of food products, due both to vast numbers of small-scale food producers and processors and competition among regulating agencies. China also lacks an independent court system, which could better protect consumers and company whistleblowers. Consumer education is also lagging, in part due to few consumer watchdog organizations.<sup>37</sup>

The authors noted that contaminated Chinese food exports tend to be linked to unsafe use of chemicals, including high pesticide use, and illegal veterinary drugs in aquaculture.<sup>38</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 exports (including food and toys). However, the Ministry of Health and the SFDA have "minimal" roles in regulating exports.<sup>39</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>40</sup> According to another expert, China officially has 448,000 food enterprises, 78% of them "cottage industries" with 10 employees or fewer.<sup>41</sup>

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<sup>36</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.

<sup>37</sup> Ellis, Linden J., and Jennifer L. Turner, *Sowing the Seeds: Opportunities for U.S.-China Cooperation on Food Safety* (excerpt from Executive Summary), Woodrow Wilson International Center for Scholars, China Environment Forum, September 2008.

<sup>38</sup> *Ibid.*

<sup>39</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>40</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>41</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*.

## Efforts to Improve Chinese Compliance

The Chinese government says it has launched a series of major initiatives to bolster food safety programs (see below), notwithstanding its continuing assertions that its products are safe. Chinese officials also 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>42</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 States to check on whether Chinese exporters had been approved by the Chinese government.<sup>43</sup>

Bush Administration officials attempted to reassure Congress throughout 2007 and 2008 that they have been 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.

## Bilateral Memorandum of Agreement

The Chinese joined U.S. officials from the Department of Health and Human Services (HHS) in announcing, on December 11, 2007, a memorandum of agreement (MOA) to enhance the safety of food and feed imports from China (and, conversely, U.S. exports to 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>44</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>45</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

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<sup>42</sup> "U.S., Chinese leaders try to advance trade, food safety issues," *Agri-Pulse*, May 30, 2007.

<sup>43</sup> See for example: "Senior Chinese Official Hopes Chinese Actions Will Delay Legislation," *FDA Week*, September 14, 2007.

<sup>44</sup> Also announced on December 11, 2007, was a second bilateral agreement on drugs and medical devices.

<sup>45</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*, last accessed April 16, 2008, at <http://globalhealth.gov/news/agreements/ia121107b.html>.

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.

Progress in implementing the agreement appears to be slow. In a December 2008 progress report on its food safety strategy generally (see “Bush Administration Import and Food Safety Plans,” later in this report), FDA stated that it has met its first set of deadlines by providing registration materials to the Chinese government, identifying points of contact for the MOA, and drafting the first 12-month plan. It also described a March 2008 meeting with Chinese officials in Beijing, where there was “verbal agreement to limit the present efforts in fulfilling the MOA to aquaculture (five species plus tilapia) and ingredients (wheat gluten, corn gluten and rice protein).”<sup>46</sup>

Stakeholders earlier had 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 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>47</sup>

## Other Chinese Initiatives

China has cited numerous efforts underway to improve confidence in the safety of its food (and drug) exports, and reassure its own consumers. One prominent example is development of a new food safety law, a draft of which was presented to a committee of the National People’s Congress in December 2007. A revised draft circulating in 2008 proposes the creation of an agency under the Department of Health, use of an expert panel of scientists and stakeholders, and development of a national risk assessment system. Food additives would be more stringently regulated. Among other things, the draft would make local governments responsible for oversight of national standards, substantially increase penalties for violators, establish a “blacklist” for both exporters and domestic importers who distribute unqualified food products, and include recall provisions. The Chinese legislature reportedly began to review the draft law in October 2008.<sup>48</sup> Other widely reported announcements have included the following:

- Reform of the entire Chinese dairy industry was announced in late November 2008 following the melamine scandal. It is to include revised product quality and safety standards, new examination procedures to test for melamine and other

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<sup>46</sup> FDA, “Food Protection Plan: Once-year Progress Summary,” December 2008.

<sup>47</sup> See for example: “U.S.-China Food Safety Deal Could Give China Preferential Treatment,” *FDA Week*, December 21, 2007.

<sup>48</sup> Sources: various 2008 news reports; also, USDA, FAS, *Food Safety Top Priority*, GAIN report CH8016, March 14, 2008; USDA, FAS, *Agricultural Situation News Flash I.28*, GAIN report CH7065, August 10, 2007; and Xinhua Financial Network News, “China again vows to beef up product quality and safety standards, March 6, 2008. A translation of the April 20, 2008 version of the plan was accessed December 2, 2008 at [http://www.wilsoncenter.org/index.cfm?topic\\_id=1421&fuseaction=topics.item&news\\_id=407838](http://www.wilsoncenter.org/index.cfm?topic_id=1421&fuseaction=topics.item&news_id=407838).

- contaminants, a dairy product tracking system, and more regulation at raw milk collection stations.<sup>49</sup>
- Planned spending of \$73 million to enhance food safety surveillance was announced.<sup>50</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 attaché 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>51</sup>
  - On August 20, 2007, the Chinese government announced that it had created a 19-member cabinet-level panel to oversee product quality and food safety and would start a four-month nationwide campaign to improve the quality of goods and food.
  - Government officials and private company employees alike have been arrested on criminal charges and in some cases been given stiff sentences. For example, a death sentence was handed down to the former head of the national government's food and drug safety agency, who was convicted of taking bribes for approving potentially dangerous drugs. He reportedly was executed on July 10, 2007.<sup>52</sup>

## Bush Administration Import and Food Safety Plans

The Bush Administration had released, on November 6, 2007, two separate but related reports on how it wanted to improve food import safety. The broader of the two covered 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>53</sup> The other report is FDA's *Food Protection Plan*, which focused on food, whether imported or domestically produced, and which contained recommendations for food imports that generally parallel those in the broader report.<sup>54</sup>

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<sup>49</sup> AP, "China to overhaul battered dairy industry," November 20, 2008.

<sup>50</sup> *China Daily*, "CHINA: \$73 million to beef up food safety surveillance," November 19, 2008.

<sup>51</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.

<sup>52</sup> See for example: "China Executes Former Head of Food Safety Agency," *Wall Street Journal*, July 10, 2007. See also CRS Report RS22713, *Health and Safety Concerns Over U.S. Imports of Chinese Products: An Overview*, by Wayne M. Morrison.

<sup>53</sup> Accessed April 16, 2008, at <http://www.importsafety.gov/report/actionplan.pdf>.

<sup>54</sup> Accessed April 16, 2008, at <http://www.fda.gov/oc/initiatives/advance/food/plan.html>.

Both plans were oriented toward assessing and prioritizing risks regardless of where they occur (starting with a product's origin), and preventing rather than waiting for problems to occur. Both plans appeared to rely heavily on cooperation with others, including private industry stakeholders and foreign governments, to assure safety, but they also would require some new regulations and, in a number of areas, new legislative authorities, which would affect importers as well as others

It was unclear in January 2009 what elements of the plans the Obama-led FDA might continue to pursue and/or build upon. Critics, among them the Government Accountability Office (GAO), consumer organizations, and the chair of the House Appropriations Subcommittee on Agriculture, have complained that the Bush Administration failed to provide enough details on the various initiatives, including their costs and how they intended to implement them. Some criticized both the food safety and import plans as largely a collection of objectives, lacking resources and/or enforcement controls to be effective, or otherwise inadequate.

The FDA released, in early December 2008, a one-year progress report on its plan, taking note of a number of accomplishments, including the establishment of the first overseas offices—three in China in November 2008.<sup>55</sup> The FDA also said it was opening additional permanent offices in other foreign countries throughout the world, as part of an effort to build and maintain relationships with regulators and companies in those countries, and to discourage their export of substandard foods and drugs in the first place.<sup>56</sup>

Consumer advocacy organizations expressed skepticism about FDA's progress and again challenged the basic plan itself, which, they asserted, does not fundamentally change a flawed U.S. food safety system. Specifically, they questioned the potential impacts of opening offices in China and other countries. Suggesting that the offices "might be window dressing," one consumer advocate expressed uncertainty about whether China will cooperate with U.S. officials there. A food safety expert indicated that to be more effective, those officials should be skilled at, and tasked with, conducting inspections, for example.<sup>57</sup>

## **Selected Legislative Issues and Options**

Pending at the close of the 110<sup>th</sup> Congress were at least a dozen major food safety bills which contained provisions addressing some aspect of food import safety. Several of the pending bills focused almost exclusively on the import issue. Also being circulated widely in spring and summer of 2008 were separate draft bills by Chairman Kennedy of the Senate Health, Education, Labor, and Pensions Committee and Chairman Dingell of the House Energy and Commerce Committee; these were broad FDA food and drug safety proposals with significant import-related provisions. Another broad bill focusing on food safety, with a separate import title, was S. 3385, introduced July 31, 2008, by Senator Durbin. In the 111<sup>th</sup> Congress, the language from these or similar bills could become the chief vehicles for the next round of food safety legislation.

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<sup>55</sup> FDA, "Food Protection Plan: Once-year Progress Summary," December 2008. At the same time the offices were formally opened, China announced that it intended to establish its own food safety offices in the United States, to be staffed by AQSIQ and State Food and Drug Administration officials.

<sup>56</sup> Various sources including "FDA Plans to Put 8 People in China; Next Up: India, South America, Middle East," *Inside Health Policy*, March 17, 2008; *World Trade Daily*, April 14, 2008; and "State Department Allows FDA to Place Eight Staffers in China," *Congress Daily P.M.*, March 13, 2008.

<sup>57</sup> Sources: Various news sources, including *Food Chemical News*, *InsideHealthPolicy.com*, and *Congress Daily*.

Among other relevant panels likely to be involved in the food safety debate are the House and Senate Agriculture Committees, where USDA-related food safety bills are referred, and the Appropriations Committees, which recommend the annual funding for such initiatives.

In the 111<sup>th</sup> Congress, the first of the major bills to be offered formally, in January 2009, is the Food and Drug Administration Globalization Act of 2009 (H.R. 759), a version of the so-called Dingell draft from the last Congress. H.R. 759 is a wide-ranging measure aimed at improving oversight of all FDA-regulated products—whether domestic or imported—including foods. Among its many provisions are those that would set new registration requirements for all commercial importers (and for domestic facilities), including fees to help offset inspection costs; require mandatory food safety plans and traceback capabilities, including electronic record-keeping, for all foods; and require that all imports be certified for safety by FDA-accredited third parties.

The following selected issues and options are expected to continue as topics of debate in the coming year.

## **Import Certification**

One oft-proposed legislative option that would affect importers directly is specific authorization for FDA to require import certificates for shippers and/or shipments of products, prior to their arrival in the United States. FDA's current statute does not expressly offer this authority. The Bush Administration's plan, for example, called for electronic certificates for products deemed to be of high risk, i.e., those products "that have been shown to pose a threat to public health for U.S. consumers and thus would be unlike other imports where there is no such showing of risk." For such products, FDA would have to negotiate and implement government-to-government agreements whereby an importer would obtain certificates from either the appropriate foreign agency or an accredited third party. This new certification system, which appeared to be based at least in part on the concept of the FSIS foreign equivalency determinations, presumably would have to be consistent with international trade obligations.

In the 111<sup>th</sup> Congress, H.R. 759 would require every import shipment to be accompanied by a safety certification, issued by an accredited third party, that the products meet all FDA requirements. FDA would be responsible for accrediting third parties, which could be a foreign government, state or regional food authority, grower or processor cooperative, or any other entity the HHS Secretary deems appropriate. FDA would have to follow certain review steps spelled out in the bill before granting such accreditation.

In the 110<sup>th</sup> Congress, the Kennedy draft bill would have authorized (but not required) the HHS Secretary to require an electronic certification by the "competent regulatory authority" of the exporting country that a food shipment entering the United States meets FDA food safety standards. HHS would have been required to notify the Secretary of Homeland Security of any such requirement, who in turn must deny the importation of an item that lacks certification. The Durbin bill (S. 3385) contained authority for the Secretary to require certifications, from qualified entities, for foods deemed to be of high risk from countries with which FDA has an agreement for such a program. Foods that require such a certificate but lack it would have been denied import entry under S. 3385. A number of other food safety bills also proposed 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



have been denied or revoked if foreign safeguards are found to be insufficient, unsafe imports are discovered, or foodborne illnesses are linked to such products.

## Access to Foreign Facilities

FDA generally has access to domestic food facilities because it can obtain a warrant or initiate criminal proceedings if it is denied entry—authorities it lacks for overseas establishments. Some including the Bush Administration proposed that to “provide parity” between domestic and imported foods, authority should be enacted enabling FDA to block imports of foods by foreign firms that impede entry to their facilities that produce, process, or hold such foods. S. 3385, for example, would have authorized the Secretary to enter into agreements with other governments that would enable such inspections; imports from facilities that impede such inspections would be refused entry.

## Mandatory Recall Authority and Access to Records

The Bush FDA requested mandatory recall authority in cases where firms (whether foreign or domestic) are unwilling to do so voluntarily or expeditiously. The agency noted that it already has the authority to seize adulterated or misbranded food, but that may not be practical once a product is in wide distribution. The agency also was seeking authority to give it more access to records in cases of food emergencies. Significantly, a major food industry group, the Grocery Manufacturers Association (GMA), endorsed the proposal for mandatory recall authority.<sup>58</sup> The day after the Bush Administration proposed it for FDA, a USDA official asserted that the Department does not need similar mandatory recall authority for the meat and poultry products it regulates. Responding to questions on whether he would request such authority, he stated that USDA already has sufficient enforcement tools and that the voluntary approach now in place works well.<sup>59</sup> Others, however, continue to seek it for USDA-regulated foods, and several bills in the 110<sup>th</sup> Congress reflected this proposed change.<sup>60</sup> H.R. 759 in the 111<sup>th</sup> Congress, and the Kennedy draft in the 110<sup>th</sup> Congress, both contain authority for FDA to require a recall if a person or firm fails to do so voluntarily, although the details of this authority differed among the bills. H.R. 759 (unlike its predecessor from the 110<sup>th</sup> Congress, the so-called Dingell draft) contains new record-keeping requirements to enable tracking of products. Moreover, the new version of the bill appears not to exempt farmers and restaurants.

## Third-Party Inspections and Testing

Some bills have sought to require more physical inspections and testing at the border or within other countries, and to authorize more research into inspection and testing technologies. Some want FDA or another public health agency to undertake more of these activities. However, some proposals, including the Bush Administration’s, sought authority for FDA accreditation of

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<sup>58</sup> “GMA Applauds Bush Administration’s Focus on Prevention in Effort to Improve Safety of Imported Food,” November 6, 2007, press release, at <http://www.gmaonline.org/news/docs/NewsRelease.cfm?DocID=1806&>.

<sup>59</sup> Dr. Richard Raymond, Undersecretary for Food Safety, November 7, 2007, testimony before the House Agriculture Subcommittee on Livestock, Dairy, and Poultry.

<sup>60</sup> See also CRS Report RL34167, *The FDA’s Authority to Recall Products*, by Vanessa K. Burrows, and CRS Report RL34313, *The USDA’s Authority to Recall Meat and Poultry Products*, by Cynthia Brouger and Geoffrey S. Becker.

qualified third parties to conduct some types of inspections and testing. Both the new Dingell bill (H.R. 759, as noted above) and the earlier Kennedy draft also involved third-party certification for certain types of inspection and/or testing, as did S. 3385 from the 110<sup>th</sup> Congress. According to proponents, so-called third-party accreditation could help to address FDA staffing and funding limitations. Certifying third parties also could deter errant importers from testing their own products—or from “shopping for” private laboratories—to obtain more acceptable results, these proponents argue.<sup>61</sup> Many consumer advocates are skeptical of more third-party responsibility, arguing that it can weaken government oversight of public health.<sup>62</sup>

## Funding and Fees

Most policymakers concede that regardless of the policy approach adopted, additional resources are needed to adequately address import safety problems. According to a report released in early December 2007 by the FDA Science Board, the FDA Commissioner’s expert advisory panel, a critical lack of resources has seriously weakened the FDA’s scientific basis generally and its mission to protect the food supply particularly. The panel noted that the FDA was unable to “sufficiently monitor either the tremendous volume of products manufactured domestically or the exponential growth of imported products. During the past 35 years, the decrease in FDA funding for inspection of our food supply has forced FDA to impose a 78 percent reduction in food inspections, at a time when the food industry has been rapidly expanding and food importation has exponentially increased.” As noted, the Science Board recommended that the overall FDA appropriation (not just for food) be more than doubled over the next several years from its FY2008 level of approximately \$1.5 billion, exclusive of user fees.<sup>63</sup>

FDA and FSIS receive most of their funding through the annual Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act. However, requests for higher appropriations must compete with other priorities throughout the federal discretionary budget. An alternative, to fill perceived shortfalls through new user fees on the food industry, always meets with resistance, both from the companies that would have to absorb such costs and from consumer advocates, who have long argued that industry funds might “taint” programs that are first and foremost public health programs.<sup>64</sup>

Nonetheless, a number of food safety bills have included proposed user or other types of fees to pay for such new activities as certification of food imports, re-inspection of products initially kept out of commerce, and the auditing of private food testing laboratories. For example, H.R. 759 in the 111<sup>th</sup> Congress would require importers of food, drugs, and other FDA-regulated products to

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<sup>61</sup> See for example: “Lab Chief Tells Lawmakers Importers Can Hide Food Contamination Data From FDA,” *Inside Health Policy*, February 26, 2008.

<sup>62</sup> A more extensive discussion can be found in CRS Report R40109, *FDA Authority to Oversee Private Laboratories that Analyze Imported FDA-Regulated Food*, by Vanessa K. Burrows.

<sup>63</sup> *FDA Science and Mission at Risk*, Report of the Subcommittee on Science and Technology, prepared for the FDA Science Board, November 2007. See also CRS Report RL34334, *The Food and Drug Administration: Budget and Statutory History, FY1980-FY2007*, by Judith A. Johnson et al.

<sup>64</sup> FDA received additional funding, including for its food safety activities generally, as part of the FY2008 supplemental appropriation (P.L. 110-252); this increased level was continued by the Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009 (P.L. 110-329). For more information see CRS Report RL34638, *FDA FY2009 Appropriations*, by Susan Thaul et al.

register and pay an annual fee of \$10,000. In the last Congress, the Kennedy draft also would have provided for various registration and certification fees.

## **Other Proposed Legislative Changes**

Among other proposed statutory changes that would affect importers and domestic firms alike have been authority for regulations that would require food chain entities to implement measures solely intended to prevent intentional food adulteration by terrorists or criminals; more explicit authority to require additional preventive (HACCP-like) controls for high-risk foods (authority some believe FDA already has); restriction of food and drug imports to specific ports with FDA labs for testing; authority to require facilities to renew their currently required FDA registrations every two years, to establish food categories within this system, and to deny re-registration to those who violate food safety rules; and more extensive mandatory country-of-origin labeling (COOL), so that consumers can determine where food products and their ingredients originate. The Dingell bill (H.R. 759), for example, requires all foods to be labeled with their country of origin, and all processed foods also to have a manufacturer website identifying where the ingredients originated<sup>65</sup>

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<sup>65</sup> This report does not extensively cover COOL. See CRS Report RS22955, *Country-of-Origin Labeling for Foods*, by Geoffrey S. Becker.