

CRS Report for Congress

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

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Geoffrey S. Becker
Specialist in Agricultural Policy
Resources, Science, and Industry Division



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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 rapidly rising imports, a result of globalization and consumer desire for a wider variety of foods year-round. The issue of import safety has been the focus of numerous congressional hearings in the 110th Congress, where a variety of bills have been offered on the subject.

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. The Bush Administration had initially argued that smarter allocation of existing resources, and the food industry's own controls, can and should be capable of addressing any problems.

Still, a growing consensus among policymakers is that additional resources are needed. For example, 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. The Administration in June 2008 asked for a \$275 million increase for FDA in FY2009. Much of this would be to address the safety of food and other imports regulated by the agency. The Administration in November 2007 also issued new policy recommendations on food safety and on import safety.

Although these recommendations have received some attention in the 110th Congress, a more recent focus has been on draft bills circulated by the chairmen of the House Energy and Commerce Committee and the Senate Health, Education, Labor, and Pensions Committee. Although they differ in detail, both seek broad reforms in FDA's oversight of food and drug safety, including of imports. Recently introduced S. 3385 also seeks broad reforms, concentrating on food oversight. Numerous other food safety bills are pending that address one or more aspects of food import safety. Several are primarily import-oriented, such as H.R. 2997, S. 1776, H.R. 1148/S. 654, H.R. 2108/S. 1274, H.R. 3610, H.R. 3624, H.R. 3937, H.R. 3967, and S. 2418. Many, for example, propose that importing establishments, and/or the foreign countries in which they are located, first receive formal U.S. certification that their food safety systems provide at least the same level of safety assurances as the U.S. system. A number 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.

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

Introduction¹

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 rapid 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 targeting both adulterated pet food ingredients and farmed seafood from China are among the incidents that heightened interest in the issue in the 110th 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 has been explored at numerous congressional hearings in 2007 and 2008, and Members of Congress have introduced a variety of bills to modify or overhaul the current system. Some seek broad reforms in FDA's oversight of food and drug safety, including of imports. The House Energy and Commerce Committee and the Senate Health, Education, Labor, and Pensions Committee are likely starting points if and when these bills begin to advance.

The Bush Administration had released, on November 6, 2007, its own import safety plan and an accompanying food protection strategy. These documents make a number of recommendations, some of them entailing new legislative authority and additional funding, which the Administration requested in its FY2009 budget submission for FDA. FDA appropriations usually are considered each year as part of the Agriculture, Rural Development, FDA, and Related Agencies Appropriations Act (i.e., not by the authorizing committees).

¹ This report supersedes CRS Report RS22664 of the same title. Portions of the previous report were originally derived from information in out-of-print CRS Report 98-850, *The Safety of Imported Foods: The Federal Role and Issues Before Congress*.

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.²

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 FY2007 — with a combined one-third share of total imports. The percentage share of all other leading importers was in the single digits.

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).³

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).⁴

² U.S. Department of Agriculture (USDA), Foreign Agricultural Service (FAS), U.S. Trade Internet System, BICO (Bulk, Intermediate, and Consumer-Oriented) data.

³ 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%.

⁴ In total, as many as 15 federal agencies administer at least 30 laws related to food safety. See also CRS Report RS22600, *The Federal Food Safety System: A Primer*.

Table 1. Leading Suppliers of U.S. Agricultural and Seafood Imports, FY2007
(value in billion U.S. dollars)

Country	Agricultural	Seafood	Total	Share (%)
1. Canada	\$14.701	\$2.245	\$16.946	20.3
2. Mexico	9.916	0.503	10.419	12.5
3. China	2.800	2.049	4.849	5.8
4. Thailand	1.498	1.824	3.322	4.0
5. Italy	2.992	0.008	3.000	3.6
6. Chile	1.922	1.028	2.950	3.5
7. Indonesia	1.938	0.851	2.789	3.3
8. Australia	2.608	0.101	2.709	3.2
9. Brazil	2.525	0.126	2.367	2.8
10. Netherlands	2.288	0.037	2.325	2.8
11. Ireland	2.219	0.008	2.227	2.7
12. France	2.115	0.014	2.129	2.5
13. New Zealand	1.670	0.121	1.791	2.2
14. Colombia	1.519	0.033	1.552	1.9
15. India	1.094	0.275	1.369	1.6
16. Vietnam	0.623	0.712	1.335	1.6
17. Costa Rica	1.214	0.065	1.279	1.5
18. Ecuador	0.685	0.574	1.259	1.5
19. Argentina	1.104	0.104	1.207	1.4
20. Malaysia	1.025	0.170	1.195	1.4
21. Spain	1.147	0.040	1.187	1.4
22. Germany	1.158	0.005	1.163	1.4
23. Guatemala	1.028	0.015	1.043	1.2
24. Peru	0.661	0.073	0.734	1.0
25. Philippines	0.621	0.241	0.862	1.0
World Total	70.037	13.612	83.649	100.0

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

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.*).⁵ 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.⁶ 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.⁷ In general, FDA attempts to conduct annual inspections of these facilities; non-high risk establishments are inspected, on average, once every five years.⁸

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 FFDCA 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.⁹ 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

⁵ 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.

⁶ 21 U.S.C. § 342(a)(2).

⁷ 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, 110th Cong., 1st sess.

⁸ *Ibid.* However, *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.

⁹ 21 U.S.C. § 381(a).

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.¹⁰

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,"¹¹ 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.

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 million entry lines in FY1997. Just over 1% of these lines were physically examined and/or tested.¹² In 2007 congressional hearings, witnesses testified that 450 inspectors must cover more than 300 ports of entry.¹³

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

¹⁰ 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.

¹¹ 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).

¹² 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.

¹³ See for example hearings held before subcommittees of the House Committee on Energy and Commerce, July 17, September 26, and October 11, 2007.

and staff of 2,700 (full-time equivalent or FTE) in FY2007, of which \$298 million and 1,900 FTEs were in the field.¹⁴

In a hearing before the House Agriculture Committee, FDA's chief food officer, David Acheson, 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).¹⁵

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.¹⁶

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.).¹⁷ 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 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 466 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 program that provides a level of protection that is at least equivalent to the U.S. system.¹⁸ FSIS visits the exporting country to review its rules and regulations, meets with foreign officials, and accompanies them on visits

¹⁴ Source: *FDA Science and Mission at Risk*, report of the Subcommittee on Science and Technology, Prepared for the FDA Science Board, November 2007.

¹⁵ "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*).

¹⁶ The arrangements were last accessed June 2008 at [<http://www.fda.gov/oia/default.htm>].

¹⁷ FSIS inspects the major red meat and poultry species and their products, while 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.

¹⁸ List of foreign establishments in the 34 eligible countries last accessed June 2008 at [http://www.fsis.usda.gov/regulations_&_policies/Eligible_Foreign_Establishments/index.asp].

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.¹⁹

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. 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.²⁰

In FY2007, FSIS had a total budget of approximately \$1 billion (appropriated and user fees) and a staff of 9,400, of which 8,700 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 approximately 150, although a significant number were assigned to non-border duties.²¹

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.

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

²⁰ 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.

²¹ House Appropriations Committee hearings on agriculture appropriations for various years.

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 below, under "Issues in Congress," 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 reference 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 often 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.²²

²² These arguments are covered in more detail in CRS Report RL33472, *Sanitary and Phytosanitary (SPS) Concerns in Agricultural Trade*, by Geoffrey S. Becker.

FDA Import Refusals

Using the OASIS data (see page 5), 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 (October 2006 through September 2007).

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).

Mindful of these caveats, 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 8.2 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.

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 that of another country. The country simply might be a more important source of U.S. agricultural and/or seafood imports. On the other hand, Canada, which imports more to the United States than any other country, had far fewer refusals (233) than the above countries, which import less in dollar value. Although Mexico is the second most important exporter to the United States, India ranked 16th. **Table 2**, on the following page, compares selected countries’ percentage share of total recorded lines for FY2007 with its percentage share of total OASIS refusals.

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.

Table 2. Food Import Lines and Refusals, FY2007
(Selected Countries)

	Total Lines	Total Refusals
World	8,244,748	8,456
Country	Pct. of Total	Pct. of Total Refusals
Canada	31.2%	2.8%
Mexico	24.8%	13.5%
Japan	4.1%	3.2%
France	3.8%	2.1%
Italy	3.8%	3.0%
China	3.3%	8.6%
Thailand	1.8%	2.7%
India	1.6%	13.7%
United Kingdom	1.5%	1.9%
Germany	1.4%	0.2%
Chile	1.3%	0.4%
Korea (South)	1.3%	1.7%
Spain	1.1%	0.5%
Netherlands	1.0%	0.8%
Australia	1.0%	0.5%
Philippines	0.9%	2.1%
Taiwan	0.9%	1.5%
Ecuador	0.8%	1.0%
Guatemala	0.7%	1.0%
Costa Rica	0.6%	0.2%
Colombia	0.6%	0.6%
Peru	0.6%	0.5%
Dominican Republic	0.6%	7.7%
Indonesia	0.6%	4.3%
Vietnam	0.5%	4.6%
Poland	0.5%	0.5%
Brazil	0.5%	1.6%
Argentina	0.5%	0.9%
Israel	0.5%	0.2%
Belgium	0.5%	0.0%
Switzerland	0.4%	0.2%
Honduras	0.4%	0.7%
Ireland	0.4%	0.0%
New Zealand	0.4%	0.1%
Sweden	0.3%	0.0%
Greece	0.3%	0.3%
Turkey	0.3%	1.1%
Russia	0.2%	0.3%
Portugal	0.2%	0.1%
Hong Kong	0.2%	0.5%
Malaysia	0.2%	0.4%
Panama	0.2%	0.0%
Nicaragua	0.2%	0.2%

Source: Prepared by CRS based on FDA OASIS data. A line is all or part of a shipment of no uniform size, so country rankings do not reflect relative volume.

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.²³ 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).

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 3** 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 3. 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*, last accessed April 16, 2008 at [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.

²³ 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/>].

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. For example, 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.

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.²⁴ 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 be carcinogenic to laboratory animals; and fluoroquinolones, which when used in food animals may increase antibiotic resistance in humans, the agency said.²⁵

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.”

Types of Chinese Imports Refused

Of the 720 refused food shipment lines from China in FY2007, nearly half were seafood products, including eel, catfish, other finfish, shrimp, and crabmeat, among others. The most frequently cited reason for rejecting many such seafood shipments was a concern about adulteration by unsafe levels of veterinary drug residues. Other

²⁴ FDA Import Alert #16-13, last accessed April 16, 2008 at [http://www.fda.gov/ora/fiars/ora_import_ia16131.html]

²⁵ 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.

reasons included filthy appearance, the presence of nitrofurans (a banned antibiotic), or *Salmonella*.

FDA also refused more than 200 shipment lines 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, wheat gluten, teas, and various nuts and spices.

Chinese Food Safety Challenges

China has faced a number of food safety challenges as it becomes a major food and 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 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.²⁶

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;

²⁶ 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>].

- 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
- for many commodities and industries, outdated or nonexistent standards, or standards that are inconsistent with internationally accepted ones.²⁷

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.²⁸

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.²⁹ According to another expert, China officially has 448,000 food enterprises, 78% of them “cottage industries” with 10 employees or fewer.³⁰

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

²⁷ Calvin. Also, Fengxia Dong and Helen H. Jensen, “Challenges for China’s Agricultural Exports: Compliance with Sanitary and Phytosanitary Measures,” *Choices*, 1st quarter 2007.

²⁸ 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.”

²⁹ 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.

³⁰ 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*.

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.³¹ 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.³²

Administration officials attempted to reassure Congress throughout 2007 and early 2008 that they have been working diligently on plans to improve oversight of all food imports generally and of Chinese imports particularly. By 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.³³ 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."³⁴

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

³¹ "U.S., Chinese leaders try to advance trade, food safety issues," *Agri-Pulse*, May 30, 2007.

³² See for example: "Senior Chinese Official Hopes Chinese Actions Will Delay Legislation," *FDA Week*, September 14, 2007.

³³ Also announced on December 11, 2007, was a second bilateral agreement on drugs and medical devices.

³⁴ *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>].

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.³⁵

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 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.³⁶

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 draft is to be made public by June 2008, and it will among other things 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, among other things.³⁷ Other widely reported announcements have included the following:

- The death sentence handed down to the former head of the 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;³⁸
- 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,

³⁵ Despite these deadlines, HHS has announced few additional details.

³⁶ See for example: "U.S.-China Food Safety Deal Could Give China Preferential Treatment," *FDA Week*, December 21, 2007.

³⁷ Sources include 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.

³⁸ See for example: "China Executes Former Head of Food Safety Agency," *Wall Street Journal*, July 10, 2007.

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;³⁹
- 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.⁴⁰

Administration Proposals

Import and Food Safety Plans

The Administration released, on November 6, 2007, two separate but related reports on how it wants to improve food import safety. 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.⁴¹ 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 broader report.⁴²

Both plans are 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 appear 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 in the food system.

The FDA report observes that the type of imported foods has been changing, from largely unprocessed bulk ingredients for subsequent processing by domestic establishments, to more ready-to-eat products, fresh produce, and seafood. "This is

³⁹ For details of the change see USDA, FAS, *China to attach inspection and quarantine labels for food exports*, GAIN report CH7059, July 23, 2007.

⁴⁰ See also CRS Report RS22713, *Health and Safety Concerns Over U.S. Imports of Chinese Products: An Overview*, by Wayne M. Morrison.

⁴¹ Accessed April 16, 2008, at [<http://www.importsafety.gov/report/actionplan.pdf>].

⁴² Accessed April 16, 2008, at [<http://www.fda.gov/oc/initiatives/advance/food/plan.html>].

not to suggest that food imported into the United States, as a whole, poses a greater food safety risk than domestically produced food. But increases in the volume and complexity of imported foods have taxed the limits of FDA's approach to handling imports," the report states, adding that the agency often has "very limited information regarding conditions under which most food is produced in foreign countries." Some countries have well-developed food safety systems, while others may not, it concludes.

The Administration's anticipated initiatives under both the import and food safety plans are spelled out under three broad categories of activities: (1) prevention of foodborne contamination through increased corporate responsibility and assessment of relative risks; (2) intervention at critical points in the food supply chain and focusing surveillance and sampling at those points; and (3) improving responses to contaminated products and illness outbreaks when they do occur.

Many of the changes within these categories are to be implemented through administrative action, or cooperative activities with foreign countries and industry stakeholders — like the Chinese bilateral agreement described above. Most changes cite FDA as the lead agency; few would appear to involve FSIS-regulated products. Many of them are expected to necessitate more funding, which neither report quantified. Officials stated that they would seek additional funds to help pay for these initiatives as part of their FY2009 budget request.

The Administration import action plan also notes that the Department of Commerce's National Oceanic and Atmospheric Administration (NOAA), which operates a voluntary seafood quality and safety inspection program, had inspected and certified seven seafood processing plants in China as of October 24, 2007, and intended to inspect at least 12 additional plants. NOAA stated that it is stationing a full-time seafood inspector in Hong Kong and plans to do so in other countries that export large volumes of seafood to the United States.⁴³

FY2009 Appropriations

The Administration's initial funding request, sent to Congress in February 2008, recommended a total increase over FY2008 of \$32.7 million for FDA's foods program, to bring FY2009 spending to \$537.8 million. Of the total, \$179.6 million (a \$10 million increase) would be for headquarters activities and \$358.1 million would be for field activities (a \$22.6 million increase). Another \$9.5 million increase would be allocated to FDA's animal drugs and feeds program, the National Center for Toxicological Research, and headquarters Office of Compliance activities, bringing the proposed increase (FY2009 over FY2008) to \$42.2 million, and 94 new staff.⁴⁴

⁴³ See also CRS Report RS22797, *Seafood Safety: Background and Issues*, by Geoffrey S. Becker and Harold F. Upton.

⁴⁴ Source: FDA, "Protecting America's Food Supply: An Investment in the FDA Protection Plan," material to accompany the agency's FY2008 budget request.

On June 9, 2008, the Administration amended its FDA appropriations request to ask for an additional \$275 million for FDA to support implementation of its food protection and import safety plan recommendations, of which more than \$120 million is for food safety. Among the activities to be supported with the additional funds are increased technical assistance on food standards to countries that export to the United States; more risk-based inspections of foreign food and medical product facilities; development and validation of rapid testing technologies to detect and mitigate potential contamination problems; and improvements among food testing laboratories.

Congressional action is pending on the FY2009 appropriation for FDA (see “Funding and Fees” under “Legislative Proposals,” below.)

Overseas Offices

The FDA also intends to begin opening permanent offices in foreign countries, 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. The U.S. Department of State reportedly has signed off on a plan for the agency to place eight staff members in three offices in China, including Beijing, Shanghai, and Guangzhou. The plan was still awaiting Chinese approval in summer 2008. Future offices are planned in India and other foreign countries as well.⁴⁵

Legislative Proposals

At least a dozen major food safety bills were pending which contain provisions addressing some aspect of food import safety. One (H.R. 3580) has been enacted as P.L. 110-85; see below. Several of the pending bills focus 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, is S. 3385, introduced July 31, 2008, by Senator Durbin.

If and when the committee chairmen’s bills are formally introduced, they appeared likely to become the chief vehicles for the next round of food safety legislation. However, by late summer 2008 there was wide speculation that significant action might not occur until after a new Congress convenes in 2009.

Among other relevant panels 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.

⁴⁵ 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.

Selected Issues and Options

Import Certification. One widely proposed legislative option which would directly affect importers 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 Administration's plan, for example, calls 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 appears 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.

The Kennedy draft bill would authorize (but not require) 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 be required to notify the Secretary of Homeland Security of any such requirement, who in turn is to deny the importation of an item that lacks certification. The Dingell draft would require the HHS Secretary to establish a program for accreditation of foreign governments, state or regional food authorities, foreign or domestic cooperatives, or other appropriate third parties to certify food facilities. Under the certification program, which could be limited to specific food types, HHS (i.e., FDA) would first have to evaluate the foreign government's food safety system, among other Dingell provisions. The Durbin bill (S. 3385) contains 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 be denied import entry under S. 3385.

A number of other pending food safety bills also 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.

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 Administration have 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 authorize 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. FDA wants mandatory recall authority in cases where firms (whether foreign or domestic) are unwilling to do so voluntarily or expeditiously. The agency notes 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 is 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.⁴⁶ The day after the 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.⁴⁷ Others, however, are seeking it for USDA-regulated foods, and several pending bills reflect this proposed change.⁴⁸ The Dingell and Kennedy drafts 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 differ among the bills.

Third-Party Inspections and Testing. Some bills seek 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 Administration's, seek authority for FDA accreditation of qualified third parties to conduct some types of inspections and testing. Both the Dingell and Kennedy drafts also would involve third-party certification for certain types of inspection and/or testing, as would S. 3385. Conceptually under a third-party approach, FDA might officially certify qualified private companies, professional organizations, or other government agencies (whether foreign, state, or local), which importers could in turn use (and presumably pay a service fee) to certify the safety of their products using prescribed tests, inspection regimes, or other FDA-issued criteria. 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.⁴⁹ Many consumer advocates are skeptical of more third-party responsibility, arguing that it can weaken government oversight of public health.

⁴⁶ “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&>].

⁴⁷ Dr. Richard Raymond, Undersecretary for Food Safety, November 7, 2007, testimony before the House Agriculture Subcommittee on Livestock, Dairy, and Poultry.

⁴⁸ 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 Brougher and Geoffrey S. Becker.

⁴⁹ See for example: “Lab Chief Tells Lawmakers Importers Can Hide Food Contamination Data From FDA,” *Inside Health Policy*, February 26, 2008.

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. This should start with an increase of \$375 million in FY2009, the board recommended.⁵⁰

FDA and FSIS receive most of their funding through the annual Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act. The appropriations committees have begun their deliberations on the FY2009 measure, and several lawmakers believe that appropriations should match or even exceed the Administration’s proposed increase for the agency. 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.

Nonetheless, a number of pending food safety bills discussed in this report include 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, the Dingell draft would require importers of food, drugs, and other FDA-regulated products to register and pay an annual fee of \$10,000. The Kennedy draft also would provide for various registration and certification fees.

Other Proposed Legislative Changes. Among other proposed statutory changes that would affect importers and domestic firms alike are: 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

⁵⁰ *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, Donna V. Porter, Susan Thaul, and Erin D. Williams.

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 originate.⁵¹

Provisions of Selected Bills

Food and Drug Administration Amendments Act of 2007 (P.L. 110-85). Section 1009 in the Food Safety title (X) of this law 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. Other food safety provisions in the law affect imported as well as domestic foods.⁵²

Food, Conservation, and Energy Act of 2008 (P.L. 110-246). Several sections of the 2008 omnibus farm law will bring changes to food safety policy, primarily within USDA, and these would impact on imported as well as domestic foods. One prominent change is to subject catfish products to mandatory inspections similar to those for red meat and poultry; the provision would appear to require foreign catfish processing to be operated under equivalent safety systems.⁵³

Food and Drug Administration Globalization Act (Dingell Draft). Chairman Dingell of the House Committee on Energy and Commerce began circulating this bill in draft form in April 2008; as of mid-August 2008 it had not been formally introduced.⁵⁴ It contains some elements of his earlier import measure, H.R. 3610 (see below). The newer Dingell draft is a broad food, drug, device and cosmetic safety bill with numerous changes to the FFDCA that would affect both domestic and imported products, such as authority for FDA to require new process controls, and performance standards, for facilities, more frequent inspections of facilities, annual registration requirements and fees for food facilities, new sampling and testing requirements for food shipments, reinspection fees when a facility's violation requires additional inspection, and mandatory recall authority.

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

⁵¹ This report does not cover COOL proposals. See CRS Report 97-508, *Country-of-Origin Labeling for Foods*, by Geoffrey S. Becker, for more information.

⁵² See CRS Report RS22779, *Food Safety: Provisions in the Food and Drug Administration Amendments Act of 2007*, by Donna V. Porter.

⁵³ See CRS Report RS22886, *Food Safety Provisions of the 2008 Farm Bill*, by Geoffrey S. Becker.

⁵⁴ A discussion draft dated April 16, 2008 is posted on the Energy and Commerce Committee website at [<http://energycommerce.house.gov/FDAGlobalAct-08/index.shtml>].

a total of 13 FDA field laboratories but well over 300 ports of entry.⁵⁵ However, an exception to the port limitation would be made for imports derived from facilities participating in a new voluntary “food facility certification program.” More specifically, FDA could accredit a foreign government as a certifying agent for such facilities, but only after conducting a review of the adequacy of that government’s food safety programs, systems, and standards.

Untitled Kennedy Draft. Chairman Kennedy of the Senate Committee on Health, Education, Labor, and Pensions began circulating draft FDA legislation in May 2008. Like the Dingell draft, it contains amendments intended to reform the agency’s oversight of both domestic and imported food, drugs, and other FDA-regulated products. Under the food safety title, all facilities would have to develop and implement risk-based preventive controls to reduce or eliminate hazards, and would have to meet new FDA-developed performance standards. The title also contains provisions to modify food facility registrations, including authority for FDA to suspend registration under certain conditions. Facilities could apply and pay for a voluntary certification program entailing additional compliance requirements in exchange for expedited entry at the border, among other incentives. Some inspections of these facilities could be conducted by designated third parties, under the Kennedy draft. Other provisions affecting imports and domestic products alike include mandatory recall authority, broader authority for FDA to require and inspect records, and new registration and certification fees to help pay for the bill’s costs.

Among the import-focused provisions in the food safety title of the Kennedy draft are a requirement that an importer have a program to verify that its suppliers meet FDA standards; FDA ability to require the competent authority of a foreign country to certify that FDA safety standards are met before food shipments from that country can import into the United States; and new requirements regarding efforts to import foods that were refused admission here or in other countries.

Assured Food Safety Act of 2007 (H.R. 2997). Introduced in July 2007 by Representative Kaptur, H.R. 2997 would require USDA and FDA jointly to establish a program requiring all imported food items to be accompanied by a certificate of safety issued by the government of the exporting country. (The bill does not reference existing food safety authorities.) Items could be excepted if they were from a country that has not been the source of a contaminated food item involved in a health or safety recall in the preceding five years.

If a certified item is found to be unsafe, imports would be prohibited until U.S. officials receive an opportunity to inspect the production facility to assess whether corrections have been made, and determine that the country has taken adequate corrective actions. Another provision would require USDA and FDA to prepare a report on, and implement, the minimum amount of inspection necessary to assure the safety of imports.

⁵⁵ In 2007 controversy arose over an FDA tentative decision to close a number of the 13 field testing laboratories. The new Dingell draft (and H.R. 3610) would prohibit HHS from closing any of these laboratories, as well as any of the 20 FDA district offices.

A key provision in the bill would require the collection of user fees to defray the increased costs of such inspections, including the costs of hiring additional inspectors. The fees would be assessed beginning in FY2008 on each line item of food imported, up to \$20 per line (USDA and FDA would define the meaning of this). The bill also provides for fee adjustments, including for inflation.

Imported Food Safety Act of 2007 (S. 1776). Also introduced in July 2007, S. 1776 by Senator Durbin is similar in intent to H.R. 2997. However, it amends the FFDCFA and applies only to FDA-regulated food imports with regard to certifications and user fees. The bill would require HHS to establish a certification system within two years of enactment, which would apply to a foreign government or foreign food establishment seeking to import food to the United States. Before granting a certificate to a foreign government, HHS would have to review, audit, and certify that its food safety program is at least equivalent to the U.S. program. Before granting a certificate to a foreign establishment, HHS would have to certify, based on an onsite inspection, that the establishment has equivalent food safety programs and procedures.⁵⁶

Certifications would be valid for no more than five years; HHS would be required to audit foreign governments and establishments at least every five years to determine their continued compliance. S. 1776 would authorize HHS to withdraw certification of a food if it is linked to an outbreak of a human illness, if the foreign program is no longer equivalent to the U.S. program, or if U.S. officials are not permitted to conduct an audit or investigation.

Like H.R. 2997, S. 1776 would set a user fee of up to \$20 per line item with adjustments for inflation, among other similarities. Unlike H.R. 2997, the Senate bill provides more detail on how the fees will be used. S. 1776 directs that not less than 50% be used for border inspections and not more than 50% be used for a newly authorized research program under the bill. Such research would focus on improved testing and sampling techniques to check for adulteration of imported foods.

Safe Food Act of 2007 (H.R. 1148/S. 654). The primary thrust of these companion bills, H.R. 1148 and S. 654, introduced by Representative DeLauro and Senator Durbin in February 2007, is to consolidate federal food safety responsibilities under a new, independent Food Safety Administration (FSA). Section 208 of the bills would require foreign governments or foreign establishments that want to export food to the United States to be certified by the new FSA. Such certification would be granted to a foreign government and/or establishment if it could demonstrate that its food safety programs are at least equivalent to the U.S. program; certification of a foreign establishment would have to be based on an onsite inspection. Certifications would be valid for no more than five years. Certification of a food establishment could be revoked any time if it is linked to a foodborne illness, if the country's or establishment's safeguards are found to be no longer equivalent, or if U.S. officials are refused permission to conduct an audit or investigation.

⁵⁶ An establishment generally is defined here as any place that processes, holds, or transports food or food ingredients, with the explicit exception of farms, and of restaurants and other retailers.

FSA also is to “routinely inspect” food and food animals via a physical examination before they enter the United States to ensure they are safe and properly labeled. Section 402 of the bills provides for holding a food at ports of entry for up to 24 hours if there is reason to believe it is unsafe or misbranded.⁵⁷

Human and Pet Food Safety Act of 2007 (H.R. 2108/S. 1274). Section 419 of these companion bills, introduced in May 2007 by Representative DeLauro and Senator Durbin respectively, contain certification and auditing requirements similar to those in S. 1776, including the five-year limit on approvals and a requirement to routinely inspect imports (see above). Another provision in H.R. 2108/S. 1274 would require importers to give HHS representatives access to inspection-related records.

Import Safety Act of 2007 (H.R. 3100). H.R. 3100 was introduced in July 2007 by Representative Kirk. The measure would amend the FFDCA to significantly increase civil penalties for violations of the act and also would increase the authorization of appropriations for FDA inspection of imported processed foods (and toothpaste) by \$20 million annually through FY2012.

Food and Drug Import Safety Act of 2007 (H.R. 3610). Chairman Dingell’s earlier bill was introduced in September 2007 as H.R. 3610. It would require the collection of user fees on imported foods, beginning in FY2008. As in other proposed bills, the fees would be based on the number of entry lines of food, but HHS-FDA could set them as high as \$50 per line, with provisions for inflation adjustments. At least 90% of the fee revenue would have to be used to carry out import inspection activities, with priority on inspections at ports of entry and on detection of intentionally adulterated food. The funds also could be used to pay for FDA inspections overseas. Not more than 10% of the revenue could be used for the bill’s newly authorized research into testing techniques for use in import inspections.⁵⁸

H.R. 3610 reiterates that all imported foods must meet the same standards as U.S.-produced foods; entry would be denied to foods even if they appear not to meet them. No foods would be permitted entry unless they are from a foreign facility holding a certificate issued by HHS, or are from a foreign country that has been certified by HHS as having food safety standards at least as protective as those in the United States. Another proposed amendment would require HHS-FDA to restrict imports of all foods to ports of entry located in a metropolitan area that has an FDA laboratory capable of testing such foods, although waivers could be granted allowing other ports to be used if the food in question poses no increased likelihood of adverse health consequences. Among other provisions, The Dingell bill also require the department to establish a voluntary “Safe and Secure Food Importation Program” under which food importing companies could receive expedited movement of their

⁵⁷ The Senate-passed version of the omnibus farm bill (H.R. 2419), which in April 2008 was before a House-Senate conference, includes a provision requiring a bipartisan congressional commission to study and recommend changes in the U.S. food safety system, including import oversight. It is based on a bill (S. 2245) introduced by Senator Durbin.

⁵⁸ H.R. 3610 also would implement a similar fee system for imported drugs.

products in exchange for abiding by HHS-developed food safety and security guidelines.

Consumer Food Safety Act of 2007 (H.R. 3624). H.R. 3624 was introduced in September 2007 by Representative Pallone. It would require the establishment, within two years, of a comprehensive import food safety system involving routine HHS inspections of foreign processing facilities and of imports at ports of entry. It authorizes (but does not appear to require) HHS to enter into an agreement with any foreign country desiring to export food to the United States, provided that HHS determines that the foreign food safety system provides at least the same level of protection. Any such agreement would have to: provide for a foreign system which ensures safe food that is not adulterated or misbranded under the FFDCFA; enable HHS to undertake activities to verify that the foreign system has at least the same level of safety; and provide for reciprocity in the treatment of U.S. imports. HHS would have to certify the specific types of food products covered by the foreign safety system, and to review each foreign certification at least once every three years.

Fresh Produce Safety Act (S. 2077). Introduced by Senator Harkin in September 2007, S. 2077 includes in Title III a requirement that HHS, in consultation with USDA, establish by regulation equivalency procedures to ensure that foreign countries exporting produce to the United States meet the criteria set forth for U.S. produce growers.

Food Import Safety Act of 2007 (H.R. 3937). Introduced in October 2007 by Representative DeLauro, H.R. 3937 would require an import certification program for all food imports. Such imports would have to come from a foreign country or establishment that HHS has determined is enforcing safety standards at least as protective as those of the United States, and certifications would be valid for not more than five years. The bill also would authorize HHS to prohibit, by regulation, the importation of specific foods or types of foods from a particular country, if there were a pattern of violations from there. The bill also contains mandatory recall and notification provisions for both imported and domestic foods.

Imported Food Safety Improvement Act of 2007 (H.R. 3967). Introduced in October 2007 by Representative Burgess, H.R. 3967 would authorize HHS to deny entry for any food or type of food from a growing area, country, producer, manufacturer, or shipper if HHS determines that it has been associated with repeated illness outbreaks, or is likely to cause disease, death, or other adverse health consequences. The bill's language further provides authority for emergency determinations to block a food import for up to 30 days.

EAT SAFE Act of 2007 (S. 2418). The EAT SAFE Act (an acronym for Ending Agricultural Threats: Safeguarding America's Food Supply for Everyone) was introduced in December 2007 by Senator Casey. It 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 certification and audit process developed by FDA. Laboratories would have to submit to the agency the results of all tests it conducted.

The bill also would authorize annual funding to hire and train personnel to monitor food safety at the border, including the detection of smuggled food and agricultural products, and to establish a competitive grant program for food safety education. Other provisions would impose new civil penalties for importers and laboratories that violate the law.

Keeping America's Food Safe Act of 2008 (H.R. 5827). Introduced in April 2008 by Representative Roskam, this bill would, among other things, require the HHS Secretary to establish, within two years, a food safety certification program for foreign facilities or countries wanting to export to the United States. The foreign facility or country would have to demonstrate that its standards are at least equivalent to those of the United States. No foods could be imported without such certification.

Safe Food Enforcement, Assessment, Standards, and Targeting (FEAST) Act of 2008 (H.R. 5904). Introduced in April 2008 by Representative Costa, this measure reportedly has the support of some industry groups, including the Grocery Manufacturers of America. Like a number of other bills, it would require foreign and domestic facilities to identify and implement risk-based preventive controls to guard against food safety hazards. It would direct FDA to allocate its inspection resources based on relative risk, authorize mandatory recall authority, and provide for a third-party certification program to evaluate producers' processors' food safety management practices, among other general food safety provisions. The bill's import-specific language includes the establishment of a mandatory program whereby importers must verify that each of their food suppliers has an effective safety assurance program, which could be verified through the use of a recognized third-party certification system; provision for the certification, by the competent authority of an exporting country, of designated foods destined for importation into the United States, and for denial of import entry to any foods needing such certification; a voluntary qualified importer program that could enable some imports to enter the country on an expedited basis; and recognition of qualified (i.e., third-party) laboratories to test imported foods.

FDA Food Safety Modernization Act (S. 3385). Introduced July 31, 2008, by Senator Durbin, S. 3385 contains numerous provisions on oversight of FDA-regulated foods, addressing such issues as registration and inspection of facilities and their records, mandatory recall authority, required use by facilities of risk-based hazard analyses and preventive control plans, and development of performance standards for adulterants in foods, for example. Title III of the 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.