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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 rapidly rising imports, a result of globalization and consumer desire for a wider variety of nutritious and inexpensive foods year-round. In part to address this challenge, the Administration unveiled in late 2007 a wide-ranging import safety "action plan" and a separate "Food Protection Plan," both of which propose new legislative authorities affecting food imports.

The issue of import safety, including the Administration's efforts to improve it, was the focus of numerous congressional hearings during the first session of the 110th Congress, where a variety of bills were offered on the subject. Some of these bills could receive closer consideration in 2008.

Do U.S. safeguards, generally created at a 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.

Section 1009 in the Food Safety title (X) of the Food and Drug Administration Amendments Act of 2007 (H.R. 3580; P.L. 110-85), passed in September 2007, requires an annual report to Congress providing more detailed statistics on FDA-regulated food imports. Numerous other food safety bills are pending that address some aspect of food import safety. Several focus on the import issue, including 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 of the bills propose that importing establishments, and/or the foreign countries in which they are located, first receive formal certification from U.S. authorities that their food safety systems demonstrably provide at least the same level of safety assurances as the U.S. system.

Under some of these bills, certification could be denied or revoked if foreign safeguards are found to be insufficient, unsafe imports are discovered, or foodborne illnesses are linked to such products. A number of the bills also propose the collection of user fees from importers to cover the costs of inspecting foreign products at the borders. Some bills seek to require more physical inspections and testing by FDA at the border or within other countries, to authorize more research into inspection and testing technologies, or to restrict imports to specific ports.

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Introduction[1]

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 the rapid increase in imports, a result of globalization and consumer desire for a wider variety of nutritious and inexpensive foods year-round.[2] 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 have heightened interest in the issue in the 110th Congress.

Do U.S. safeguards, which generally were created at a 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 a number of congressional hearings in 2007, and several Members of Congress have introduced bills to change the current system. Meanwhile, the Administration 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.

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

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[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*.

[2] David Acheson, Assistant Commissioner for Food Protection, U.S. Food and Drug Administration, testimony before the House Agriculture Committee, May 9, 2007.

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.[3]

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).[4] **Table 1**, below, shows that the United States' NAFTA (North American Free Trade Agreement) partners, Canada and Mexico, were the largest suppliers of food, agricultural, and seafood imports in FY2007.

Table 1. Leading Suppliers of U.S. Agricultural and Seafood Imports, FY2007

(value in billion U.S. dollars)

Country	Agricultural	Seafood	Total
Canada	$14.701	$2.245	$16.946
Mexico	9.916	0.503	10.419
China	2.800	2.049	4.849
Thailand	1.498	1.824	3.322
Italy	2.992	0.008	3.000
Chile	1.922	1.028	2.950
Indonesia	1.938	0.851	2.789
Australia	2.608	0.101	2.709
Brazil	2.525	0.126	2.367
Netherlands	2.288	0.037	2.325
World Total	70.037	13.612	83.649

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

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

[4] 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%.

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).[5]

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*.).[6] 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, 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.[7] Of a total 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.[8] In general, FDA attempts to conduct annual inspections of these facilities; non-high risk establishments are inspected, on average, once every five years.[9]

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[5] 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*.

[6] 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: Acheson, May 9, 2007, testimony, and House Appropriations Committee hearings on Agriculture Appropriations for various years.

[7] 21 U.S.C. § 342(a)(2).

[8] 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.

[9] 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

(continued...)

All domestic and foreign food manufacturing facilities must adhere to FDA's 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.[10] 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.[11]

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,"[12] 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.

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[9] (...continued)
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.

[10] 21 U.S.C. § 381(a); see also [http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9auto.html].

[11] 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.

[12] 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).

The volume of FDA-regulated imports has roughly tripled in the past decade. The agency recorded more than 9.1 million imported food entries (i.e., shipments of various sizes) in FY2007 compared with fewer than 2.8 million entries in FY1997. Less than 1% of these shipments are now being physically examined.[13] In 2007 congressional hearings, witnesses testified that 450 inspectors must cover more than 300 ports of entry.[14]

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.[15] 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.[16]

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). An equivalence-type approach is one possible option for the future, he added.[17]

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.[18]

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[13] Staff Statement, July 17, 2007, hearing before the Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, *Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply — Part 2*.

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

[15] An FDA website had noted that "[f]ull equity in foreign inspections is far beyond the resources of FDA." Accessed May 15, 2007, at [http://www.cfsan.fda.gov/~comm/intl-toc.html].

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

[17] "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*, April 1998).

[18] The arrangement can be viewed at [http://www.fda.gov/oia/default.htm].

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.).[19] 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.[20] 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.[21]

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[19] 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.

[20] A list of foreign establishments in the 33 eligible foreign countries can be accessed at [http://www.fsis.usda.gov/regulations_%26_policies/Eligible_Foreign_Establishments/index.asp].

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

Meat and poultry imports have increased significantly, from nearly 2.3 billion pounds presented for inspection in FY1996 to approximately 4 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.[22]

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.[23]

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 (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).

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

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[22] 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.

[23] House Appropriations Committee hearings on agriculture appropriations for various years.

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 actively 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 common, scientifically based SPS standards. Such standards can provide guidance for countries formulating 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.[24]

FDA Import Refusals

Overview and Limitations of Analysis

Using the OASIS data (see page 4), the FDA compiles a monthly "Import Refusal Report" for food shipments that it rejects. Such products have to be either re-exported or destroyed by the importer. The agency posts these monthly refusal reports on its website, but only for the most recent 12 months (i.e., only one year's worth of refusals).[25] The refusals for each month can be searched by country or by product category, but not by both at the same time. CRS examined the data for the one-year period from May 2006 through April 2007, and the months were not aggregated into annual figures.

For each line (shipment), the system provides the name of the source company and the reason for refusal. As noted earlier, the size of each shipment in the OASIS database varies. Therefore, it is not possible to calculate the volumes of products being rejected, either as an absolute quantity or as a proportion of total imports.

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

[25] FDA website, accessed May 31, 2007, at [http://www.fda.gov/ora/oasis/ora_oasis_ref.html].

Also, the types or categories of imports do not necessarily correspond to the categories reported through the USDA trade databases (see **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.[26] For the one-year period available at the time of this CRS tabulation (May 2006-April 2007), FDA logged a total of approximately 8,200 refusals. Of these, the leaders were Mexico with nearly 1,300, India with more than 1,100, and China with more than 700 (see **Table 2**).[27]

Table 2. Number of Food Import Refusals by Country, May 2006-April 2007

Argentina	59	Guatemala	97	Peru	39
Australia	34	Honduras	113	Philippines	153
Bangladesh	54	Hong Kong	52	Poland	76
Brazil	123	India **(2)**	1,109	Russia	26
Canada	193	Indonesia **(5)**	334	South Africa	42
Chile	35	Iran	26	Spain	75
China **(3)**	720	Italy **(8)**	228	Sri Lanka	72
Colombia	45	Jamaica	36	Syria	70
Costa Rica	35	Japan **(7)**	295	Taiwan	165
Dominican Republic **(4)**	593	Korea (South)	111	Thailand **(9)**	218
Ecuador	56	Lebanon	26	Turkey	81
Egypt	47	Malaysia	35	Ukraine	25
El Salvador	25	Mexico **(1)**	1,271	United Kingdom **(10)**	206
France	178	Netherlands	54	Vietnam **(6)**	335
Ghana	49	Pakistan	140		

Source: FDA Import Refusal Reports for OASIS. See text for caveats on use of data. Countries with fewer than 25 refusals are omitted here.
Note: Numbers in parentheses indicate top ten countries by rank of number of import refusals.

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 than either

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[26] Also listed in the OASIS refusal reports, but not examined here, are other FDA-regulated products, e.g., human and animal drugs, medical devices, and vitamins.

[27] *The New York Times* reportedly compiled a more recent 12-month tabulation (July 2006 to June 2007), which indicated that refusals were higher during the period: 1,763 for India, 1,480 for Mexico and 1,368 for China. See "China Not Sole Source of Dubious Food," *New York Times*, July 12, 2007.

Mexico or China, the second and third most important U.S. importers in dollar value. India had the second highest number of refusals, even though it is not among the top 10 foreign sources of food, agricultural, and seafood products for the United States.[28]

Because of technical problems with OASIS at the time **Table 2** was prepared, FDA officials said they could not immediately respond in detail to CRS questions about the database that might have shed additional light on the significance, if any, of the numbers in the table. For example, the information published on the FDA website does not include the overall number of shipments. Thus, CRS could not calculate for this report the percentage of overall shipments that had been refused for a given month, country, or product. However, FDA did receive a total of nearly 15 million import shipments of all types of FDA-regulated products, including but not limited to foods, during FY2006, or an average of approximately 1.25 million shipments per month.[29]

Reviewing refusals by industry, vegetables/vegetable products and seafood products appear to have been the most frequently refused products (at approximately 1,700 shipments from all countries for each of these two product types). Fruits/fruit products from all countries accounted for nearly 900 refusals. Candy products accounted for nearly 600, and spices/flavors/salts for more than 500. Many fruit and vegetable product refusals originated in the Dominican Republic, Mexico, and several other Latin American and Caribbean nations; a frequently cited reason was pesticide contamination. Bacterial contamination (e.g., Salmonella) or filthy condition was cited numerous times.

Fish and shellfish were refused for a variety of reasons, often bacterial contamination, 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.[30]

Many refusals of foods of all 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).[31]

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[28] Nonetheless, India's exports to the United States were valued at a significant $1.4 billion in calendar 2006.

[29] FDA e-mail communication to CRS, June 6, 2007.

[30] Food and Water Watch, *Import Alert: Government Fails Consumers, Falls Short on Seafood Inspections*, May 2007. Accessed on the Internet on June 5, 2007, at [http://www.foodandwaterwatch.org/press/publications/reports/import-alert].

[31] The FDA website defines each of these terms, which are among approximately 180 possible specific reasons for refusal.

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 (9 months)	2,949,449	7,596	0.26

Source: USDA/FSIS, various *Quarterly Enforcement Reports*, accessed 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.

The Administration's 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.[32] 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.[33]

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 propose some new regulations and new legislative authorities affecting importers and 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

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[32] Available at [http://www.importsafety.gov/report/actionplan.pdf].

[33] Available 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 handing 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. Most cite FDA as the lead agency; few would appear to involve FSIS-regulated products. Many of them are expected to necessitate more spending, which neither report quantified. Officials stated that they would seek additional funds to help pay for these initiatives as part of the upcoming FY2009 budget request.

Proposed Legislative Changes

Import Certification. A number of the recommendations would entail legislative changes to FDA's authority. One proposed legislative change directly affecting importers would be new authorization for FDA to require electronic import certificates for shipments of 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, and likely would be one of the initiatives requiring additional resources.

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. To "provide parity" between domestic and imported foods, the agency said it will seek authority to block entry of foods imported by foreign firms that impede entry to their facilities that process, pack, or hold such foods.

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.[34] 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.[35] 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.[36]

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);
- authority to require facilities to renew their currently required FDA registrations every two years, and to establish food categories within this system;
- authority for FDA accreditation of qualified third parties to conduct some types of inspections; and
- new user fees to be imposed on facilities that have to be reinspected because they have failed to meet FDA safety requirements.

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. Other food-related actions underway include ongoing negotiations with China to forge binding safety agreements on food and animal feed, and the development of a proposed rule by mid-2008 to require that imported food that is refused entry be marked accordingly.

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[34] For more information on FDA recall authority see CRS Report RL34167, *The FDA's Authority to Recall Products*, by Vanessa K. Burrows.

[35] "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&].

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

Selected Bills in Congress

U.S. food import safeguards drew renewed attention in 2007 when adulterated pet food ingredients imported from China sickened or killed an unknown number of dogs and cats and subsequently were found in some food animal feed, and after FDA flagged all farmed seafood from China over concerns about unapproved drug residues. One concern has been the adequacy of China's own safeguards and how the United States might encourage improvements. China's emergence as a world agricultural exporter reportedly has been hampered by difficulties in satisfying importing countries' SPS standards.[37]

Others argue that China should not be singled out as the only source of concern. They assert that food imports from other countries also have potentially serious safety risks (see "FDA Import Refusals," above). Furthermore, they contend, domestic foods also can pose safety problems, as evidenced by recent outbreaks of illness linked to consumption of raw produce and by continuing recalls of meat and poultry products due to bacterial contamination. Nonetheless, many of the food safety bills offered in the 110th Congress have focused on proposals to increase scrutiny of imported foods; several of these bills could be considered during the second session.[38]

Scope of Legislation

During the first session, at least a dozen food safety bills were pending which contain provisions addressing some aspect of food import safety. One (H.R. 3580) has passed Congress; see below. Several of the pending bills focus almost exclusively on the import issue. Many of these bills propose that importing establishments, and/or the foreign countries in which they are located, first receive formal certification from U.S. authorities that their food safety systems demonstrably provide at least the same level of safety assurances as the U.S. system. Under some of these bills, certification could be denied or revoked if foreign safeguards are found to be insufficient, unsafe imports are discovered, or foodborne illnesses are linked to such products.

A number of the bills also propose the collection of user fees from importers to cover the costs of inspecting foreign products at the borders. These and other 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. Still other bills call for more extensive

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[37] Fengxia Dong and Helen H. Jensen, "Challenges for China's Agricultural Exports: Compliance with Sanitary and Phytosanitary Measures," *Choices*, 1st quarter 2007. See also CRS Report RL34080, *Food and Agricultural Imports from China*, by Geoffrey S. Becker.

[38] For a broader overview of food safety legislation see CRS Report RL34152, *Food Safety: Selected Issues and Bills in the 110th Congress*, by Geoffrey S. Becker.

mandatory country of origin labeling (COOL), so that consumers can determine where food products originate.[39]

Food and Drug Administration Amendments Act of 2007 (P.L. 110-85)

Section 1009 in the Food Safety title (X) of this new 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. A similar food safety title (Title VI) was in the Senate-passed version (S. 1082), the Food and Drug Administration Revitalization Act. The House FDA bill (H.R. 2900) lacked the food safety title. H.R. 3580 was the measure which emerged from House-Senate negotiations and replaced the earlier versions. It was cleared by both the House and Senate and signed into law (P.L. 110-85) on September 27, 2007.[40]

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.

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

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[39] This report does not cover COOL proposals, although recent developments with food imports also have spurred calls for implementation of the (COOL) law for fresh meats, produce and peanuts, now scheduled to take effect on September 30, 2008, or for extension of such requirements to more types of currently uncovered products. See CRS Report 97-508, *Country-of-Origin Labeling for Foods*, by Geoffrey S. Becker.

[40] See also CRS Report RL34102, *FDA Legislation in the 110th Congress: A Side-by-Side Comparison of S. 1082 and H.R. 2900*, by Erin D. Williams, Susan Thaul, Sarah A. Lister, Donna V. Porter, and C. Stephen Redhead. Also see CRS Report RL34089, *FDA Legislation in the 110th Congress: A Guide to S. 1082 and H.R. 2900*, by Erin D. Williams, Susan Thaul, and Donna V. Porter.

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 FFDCA 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.[41]

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.

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[41] Establishments generally are defined here as any place that processes, holds, or transports food or food ingredients, with the explicit exceptions 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.[42]

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)

Representative Dingell, Chairman of the House Energy and Commerce Committee, in August 2007 began circulating a "discussion draft" of his legislation to reform and fund food import inspections, among other provisions, most of which would be amendments to the FFDCA. The draft 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.[43]

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

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[42] The Senate-passed version of the omnibus farm bill (H.R. 2419), which at the start of 2008 was awaiting 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 earlier by Senator Durbin.

[43] H.R. 3610 also would implement a similar fee system for imported drugs.

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. Failure to do so could result in revocation of the certificate. HHS would be charged with enforcing the provision through random inspections, sampling and testing.

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. At a July 17, 2007 hearing before the House Energy and Commerce Subcommittee on Oversight and Investigations, the panel's investigators testified that FDA border inspectors currently had to cover 326 ports of entry, greatly straining the existing workforce. Another topic of the hearing was FDA's tentative decision to close a number of its 13 field testing laboratories, which many subcommittee members strongly criticized. H.R. 3610 would prohibit HHS from closing any of these laboratories, as well as any of the 20 FDA district offices.

The Dingell bill also would require labeling of all foods to identify the country of origin, with implementation details left to HHS; and require the department to establish a voluntary "Safe and Secure Food Importation Program" under which food importing companies could receive expedited movement of their 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 FFDCA; 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)

H.R. 3967, introduced in October 2007 by Representative Burgess, 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.

Appendix: Selected Bill Provisions at a Glance

(Bills differ in detail; see text for further explanation of each.)

Certification of imports	H.R. 2997 S. 1776 H.R. 1148/S. 654 H.R. 2108/S. 1274 H.R. 3610 H.R. 3624 S. 2077 H.R. 3937
More or "routine" inspections	H.R. 1148/S. 654 H.R. 2108/S. 1274 H.R. 3624
New import user fees	H.R. 2997 S. 1776 H.R. 3610 S. 2418 (lab certification)
New funding authorization	H.R. 3100 S. 2418
Limit on eligible entry ports	H.R. 3610
Expedited entry for some importers	H.R. 3610
More access to records	H.R. 2108 S. 1274
Targeted bans on problem imports	H.R. 3937 H.R. 3967
New import data reporting	H.R. 3580/P.L. 100-85