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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.

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 in this report.

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 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. Nearly a dozen other food safety bills pending as of October 2007 contain provisions addressing some aspect of food import safety. Several focus almost exclusively on the issue. Many of these bills (including H.R. 2997, S. 1776, H.R. 1148/S. 654, H.R. 2108/S. 1274, H.R. 3610, and H.R. 3624) propose that importing establishments, and/or the foreign countries in which they are located, first receive formal certification from U.S. authorities that their food safety systems demonstrably provide at least the same level of safety assurances as the U.S. system. Under some of these bills, certification could be denied or revoked if foreign safeguards are found to be insufficient, unsafe imports are discovered, or foodborne illnesses are linked to such products. A number of the bills also propose the collection of user fees from importers to cover the costs of inspecting foreign products at the borders.

Some bills seek to require more physical inspections and testing by FDA at the border or within other countries, to authorize more research into inspection and testing technologies, or to restrict imports to specific ports. H.R. 3100 is another measure with import safety provisions. (This report supersedes CRS Report RS22664.)

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

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.

Food and Agricultural Imports Increasing

U.S. imports of agricultural and seafood products from all countries increased from 32.9 million metric tons (MMT) in calendar year 1996 to 46.7 MMT in 2006, or by 42%. The increase by value was 98%, from $40.1 billion in 1996 to $78.5 billion in 2006. Among the product categories that at least doubled in volume during

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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.

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 are 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 2006.

Table 1. Leading Suppliers of U.S. Agricultural and Seafood Imports, CY2006

(value in billion U.S. dollars)

Country	Agricultural	Seafood	Total
Canada	$13.433	$2.184	$15.617
Mexico	9.390	0.454	9.844
China	2.262	1.922	4.184
Thailand	1.812	1.334	3.146
Italy	2.802	.009	2.811
Indonesia	2.023	0.778	2.801
Chile	1.774	.952	2.726
Australia	2.487	.091	2.578
Brazil	2.237	.130	2.367
Ireland	2.354	.008	2.362
World Total	65.333	13.143	78.475

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 58,000 food establishments (such as manufacturers, warehouses, and shippers), FDA designates about 7,000 as "high risk," based on the types of foods they handle and/or past performance. In general, FDA attempts to conduct annual inspections of these facilities; non-high risk establishments are inspected, on average, once every 3.7 years.[8]

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

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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] 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.

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 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 more than tripled in the past decade. The agency received more than 10 million imported food entries in FY2006 compared with fewer than 2.8 million entries in FY1996. Approximately 1% of these shipments were physically examined in FY2006, compared with 1.7% in FY1996.

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.[12] FDA's Center for Food Safety and Applied Nutrition (CFSAN) had a budget of $450 million

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[9] 21 U.S.C. § 381(a); see also [http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9auto.html].

[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] An FDA website notes 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].

and staff of 2,843 (full-time equivalent or FTE) in FY2006, of which $285 million and 1,962 FTEs were in the field.[13]

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.[14] At various hearings and media briefings, FDA officials have stated that the agency is reviewing all aspects of the U.S. food safety system including imports, and intends to complete a food protection strategy by mid-November 2007. This time frame also is when the President's cabinet-level working group is to release its "action plan" aimed at enhancing import safety for all imported foods, drugs and other consumer products. The working group unveiled in September 2007 a "strategic plan" which broadly recommends that safety oversight be shifted from border interdiction to risk-based prevention activities throughout the "import life cycle" of products.[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 more than 90 "International Arrangements" with approximately 30 separate foreign entities, of which 36 appear to be directly food-related. Roughly a third of these address aspects of shellfish or other seafood safety.[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

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[13] Although a further breakdown of field staff involved with imported foods was not immediately available, witnesses have testified that 450 inspectors cover between 300 and 400 ports of entry. The hearings were held before subcommittees of the House Committee on Energy and Commerce, July 17 and September 26, 2007. (Other congressional panels, including the House Appropriations subcommittee on agriculture, also have held food import hearings in 2007.)

[14] "Officials defend federal response to melamine contamination," *Food Chemical News*, May 14, 2007. GAO, however, 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).

[15] Interagency Working Group on Import Safety, *Protecting American Consumers Every Step of the Way: A strategic framework for continued improvement in import safety*, September 10, 2007, accessed at [http://www.importsafety.gov/report/report.pdf]. Also see the September 26, 2007, testimony of Randall Lutter, FDA Deputy Commissioner for Policy before the House Energy and Commerce Subcommittee on Health.

[16] Both websites accessed at [http://www.cfsan.fda.gov/~comm/intl-toc.html].

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 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 3.9 billion pounds in FY2006. 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).

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[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] A list of the 38 current agreements can be accessed on the FSIS website at [http://www.fsis.usda.gov/regulations_%26_policies/Eligible_Foreign_Establishments/index.asp].

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

In FY2006, FSIS had a total budget of approximately $950 million (appropriated and user fees) and a staff of 9,400, of which 8,000 were in about 6,300 meat and poultry plants nationwide. The agency's international food safety budget that year was $19.355 million, of which $11.75 million went for border reinspections. Other portions were devoted to evaluating foreign programs and to facilitating U.S. exports. The total international staff numbered 165, although a significant number were assigned to non-border duties.[20]

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 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

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

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.[21]

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).[22] 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. 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.[23] 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**).[24]

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

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

[23] 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.

[24] *The New York Times* reportedly compiled a more recent 12-month tabulation (July 2006 (continued...)

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 much more to the United States than any other country, had far fewer refusals than either 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.[25]

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

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[24] (...continued)
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.

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

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.[26]

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.[27]

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).[28]

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.

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

[27] 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].

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

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.

Issues 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.[29]

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.[30]

Scope of Legislation

As of October 1, 2007, nearly 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

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[29] 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.

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

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 mandatory country of origin labeling (COOL), so that consumers can determine where food products originate.[31]

Food and Drug Administration Amendments Act of 2007 (H.R. 3580; 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.[32]

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.

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[31] 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.

[32] 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.

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 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.[33]

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, 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).

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[33] 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.

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.

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.

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)

This bill 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.[34]

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. 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.

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

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.