

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

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## Summary

U.S. food and agricultural imports have increased significantly in recent years, leading to concerns about whether current federal programs and funding for them are sufficient to ensure their safety. The discovery of adulterated pet food ingredients from China has heightened interest in the issue in the 110<sup>th</sup> Congress, where bills include H.R. 357, H.R. 1148, H.R. 1600, H.R. 2108, S. 404, S. 654, S. 887, S. 1082, and S. 1274.<sup>1</sup>

# Food and Agricultural Imports Increasing

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.<sup>2</sup> Total imports of agricultural and seafood products increased from 31.7 million metric tons (MMT) and \$39 billion in FY1996 to 46.1 MMT and \$76.9 billion in FY2006. Among the product categories that at least doubled in volume in that time were live animals, red meats, fresh fruits, wheat, coffee, tropical oils, snack foods, and various seafood products.<sup>3</sup>

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, consumers are obtaining a growing portion of their diets from overseas. In 2005, nearly 15% of the overall U.S. food supply was imported, compared with 11%-12% in 1995. The proportions for some food product categories are

<sup>&</sup>lt;sup>1</sup> Portions of this report are derived from information in out-of-print CRS Report 98-850, *The Safety of Imported Foods: The Federal Role and Issues Before Congress*, by Donna U. Vogt.

<sup>&</sup>lt;sup>2</sup> David Acheson, Assistant Commissioner for Food Protection, U.S. Food and Drug Administration, testimony before the House Agriculture Committee, May 9, 2007.

<sup>&</sup>lt;sup>3</sup> U.S. Department of Agriculture (USDA), Foreign Agricultural Service (FAS), U.S. Trade Internet System, BICO (Bulk, Intermediate, and Consumer-Oriented) data.

much higher: more than 84% in 2005 of all fish and shellfish (55% in 1995); 43% of all noncitrus fresh fruits (34% in 1995); 37% of all processed fruits (20% in 1995), and 54% of all tree nuts (40% in 1995).<sup>4</sup>

## **Federal Oversight Responsibilities**

Although all food products imported into the United States must meet the same safety standards as domestically produced foods, international trade rules permit a foreign country to apply its own, differing regulatory authorities and institutional systems in meeting such standards, under an internationally recognized concept known as "equivalence."<sup>5</sup> Two federal agencies — USDA's Food Safety and Inspection Service (FSIS) and the U.S. Department of Health and Human Services' Food and Drug Administration (FDA) — are responsible for the majority of the total funding and staffing of the government's food regulatory system. For imports, FSIS relies on a very different regulatory system than FDA, including a differing approach to addressing equivalence, as described below.

Also important are USDA's Animal and Plant Health Inspection Service (APHIS), which is responsible for protecting plant and animal resources from domestic and foreign pests and diseases, and the Department of Homeland Security (DHS), which is responsible for coordinating agencies' food security activities, including border inspections by DHS's U.S. Customs and Border Protection (CBP).<sup>6</sup>

**FDA Role.**<sup>7</sup> 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.*). 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 Inspection," 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.<sup>8</sup> 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

<sup>&</sup>lt;sup>4</sup> USDA, Economic Research Service (ERS), unpublished data, obtained May 11, 2007.

<sup>&</sup>lt;sup>5</sup> This concept is embodied in Article 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement), which entered into force January 1, 1995, for member nations of the World Trade Organization (WTO). For a more detailed explanation, see CRS Report RL33472, *Sanitary and Phytosanitary (SPS) Concerns in Agricultural Trade*, and the WTO SPS website at [http://www.wto.org/english/tratop\_e/sps\_e.htm].

<sup>&</sup>lt;sup>6</sup> In total, 15 federal agencies administer at least 30 laws related to food safety. See also CRS Report RS22600, *The Federal Food Safety System: A Primer*.

<sup>&</sup>lt;sup>7</sup> Portions of this section and the following section are based on Olsson, Frank and Weeda, P.C., and The Food Institute, *Importing Food into the United States: A Regulatory Guide*, 2007.

<sup>&</sup>lt;sup>8</sup> 21 U.S.C. § 342(a)(2).

attempts to conduct annual inspections of these facilities; non-high risk establishments are inspected, on average, once every 3.7 years.<sup>9</sup>

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.<sup>10</sup> In exercising its oversight, the agency relies on a system of prior notifications by importers and document reviews at points of entry (ports). Importers must have an entry bond and file a notification for every shipment. Import information is entered into FDA's database, the Operational and Administrative System for Import Support (OASIS). This system helps inspectors 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 work closely with CBP officials on these tasks.<sup>11</sup>

If closer examination is not deemed necessary, FDA allows the product to enter U.S. commerce. A shipment found to be noncompliant is subject to a number of corrective actions, such as relabeling or reconditioning to bring it into compliance, refused entry, or even seizure and destruction. Sometimes, the agency subjects an import to "detention without physical examination,"<sup>12</sup> based on past history or other information indicating that it may be violative. Such detention, which forces the importer to demonstrate to FDA that the product is safe before it can enter U.S. commerce, has been used to detain all Chinese plant protein products (including wheat gluten and rice gluten, destined for pet foods) after some were found in early 2007 to contain melamine, an unapproved substance.

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 less than 2.8 million entries in FY1996. Just over 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.<sup>13</sup> 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.

<sup>&</sup>lt;sup>9</sup> Data sources for this section, unless noted: Acheson, May 9, 2007 testimony, and House Appropriations Committee hearings on Agriculture Appropriations for various years.

<sup>&</sup>lt;sup>10</sup>21 U.S.C. § 381(a); see also [http://www.fda.gov/ora/compliance\_ref/rpm\_new2/ch9auto.html].

<sup>&</sup>lt;sup>11</sup> The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) greatly expands the prior notification requirements for FDA-regulated imported foods. It also now requires any imported or domestic facility that manufactures, processes, packs, or holds food for U.S. consumption to register with the FDA; farms and retail establishments are among those exempted. Further, the act requires records sufficient to identify the immediate supplier as well as the subsequent recipient of the product, among other provisions.

<sup>&</sup>lt;sup>12</sup> FDA's authority to detain without physically inspecting an article derives from 21 U.S.C. § 381(a), which states that FDA must refuse admission of certain imports into the United States "[i]f it appears from the examination of such samples *or otherwise*" that such samples are adulterated, misbranded, or otherwise in violation of the law (emphasis added).

<sup>&</sup>lt;sup>13</sup> 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.

Furthermore, the 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.<sup>14</sup> The FDA's Center for Food Safety and Applied Nutrition (CFSAN) had a total budget of \$450 million and staff of 2,843 (full-time equivalent or FTE) in FY2006, of which \$285 million and 1,962 FTEs were in the field.<sup>15</sup>

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 standards for Chinese 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.<sup>16</sup> At May 15 and May 17, 2007, media briefings on adulteration of plant proteins from China, Dr. Acheson stated that he was currently reviewing all aspects of the U.S. food safety system including imports. FDA officials declined to provide specifics on any ongoing efforts to secure some form of cooperative safety agreement with China but did point out that, after shipments of Mexican cantaloupes were halted after testing positive for salmonella several years ago, the U.S. and Mexican governments had developed an agreement to improve agricultural practices there.

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.<sup>17</sup>

**FSIS Role.** FSIS regulates the safety and labeling of most domestic and imported meat and poultry, under the Federal Meat Inspection Act (FMIA) as amended (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act (PPIA) as amended (21 U.S.C. 451 et seq.).<sup>18</sup> Inspectors are to be present at all times in slaughter plants and for at least part of each day in establishments that further process meat and poultry products. They are

<sup>17</sup> Both websites accessed May 15, 2007, at [http://www.cfsan.fda.gov/~comm/intl-toc.html].

<sup>&</sup>lt;sup>14</sup> 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].

<sup>&</sup>lt;sup>15</sup> House Appropriations Committee Hearings, Agriculture Appropriations for FY2007. A further breakdown of field staff involved with imported foods was not immediately available, although CRS reported it to be 595 FTEs out of a total of 1,452 field staff in FY1996 (out-of-print CRS Report 98-850, *The Safety of Imported Foods: The Federal Role and Issues Before Congress*, by Donna U. Vogt).

<sup>&</sup>lt;sup>16</sup> "Officials defend federal response to melamine contamination," *Food Chemical News*, May 14, 2007. GAO in 1998 had concluded that border inspections alone were ineffective but that FDA lacks the statutory authority to mandate equivalency (GAO Report RCED-98-103, *Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable*, April 1998).

<sup>&</sup>lt;sup>18</sup> FSIS inspects the major commercial red meat and poultry species and their products, while FDA has jurisdiction over any meat and poultry not inspected by FSIS. The two 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.

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 certified that its country has a program that provides a level of protection that is at least equivalent to the U.S. system.<sup>19</sup> FSIS experts visit the exporting country to review its rules and regulations, meet with foreign officials, and accompany them on visits to slaughtering and processing plants. When a foreign program is approved, FSIS relies on that government to certify eligibility of, and to inspect, the plants. FSIS periodically reviews foreign government documents and conducts on-site audits at least annually to verify continuing equivalence.

In addition, FSIS operates an extensive reinspection program at U.S. border entry points. Generally, agency inspectors review all import records, assisted by a computerized statistical sampling program. Called the Automated Import Information System (AIIS), this system generates inspectors' actual examination assignments based on potential risk of particular product types and/or countries. The inspectors then examine lots from targeted shipments for physical condition, labeling, documentation, and so forth. FSIS also 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 also operate under continuous FSIS inspection.

Meat and poultry imports have increased significantly, from nearly 2.3 billion pounds presented for inspection in FY1996 to 4.3 billion pounds in FY2005. FSIS estimated that it physically examined approximately 20% of all such imports in FY1996 and 9.7% in FY2005 (after implementation of the AIIS in the early 2000s).

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; a significant number of these were assigned to non-border duties.<sup>20</sup>

**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).

<sup>&</sup>lt;sup>19</sup> 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].

<sup>&</sup>lt;sup>20</sup> House Appropriations Committee hearings on agriculture appropriations for various years.

#### **Issues in Congress**

Food safety-related incidents frequently heighten public and media scrutiny of the U.S. food safety system in general. In spring 2007, import safeguards drew attention after adulterated pet food ingredients imported from China sickened or killed an unknown number of dogs and cats and subsequently were found in some hog, chicken, and fish feed. Others point out that domestically sourced 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. Several Members of Congress have called for changes, in some cases sweeping ones, in the overall system and/or funding increases to meet existing obligations. Perceived gaps in federal safeguards were explored at a number of congressional hearings in early 2007.

One immediate concern has been the adequacy of China's own safeguards and what, if anything, the United States should do to encourage improvements. China's emergence as a world agricultural exporter reportedly has been hampered by difficulties in satisfying importing countries' SPS standards. The Chinese have been working to improve what critics say is a patchwork of inconsistent, unclear, duplicative, and/or outdated rules, which lacks a sound food safety law to provide necessary guidance and enforcement.<sup>21</sup> China's shortcomings were cited by Senator Durbin and Representative DeLauro in a May 10, 2007, letter to the U.S. Trade Representative (USTR) requesting a review of SPS measures in U.S. trade agreements and of legal options the United States has with respect to imported food products that pose a public health threat.

On May 2, 2007, Senator Durbin won unanimous approval of an amendment to the Senate-passed FDA Revitalization Act (S. 1082) that would require domestic and foreign facilities to notify FDA of food safety problems; FDA to establish a central registry for collecting information on adulterated foods, and for notifying the public about adulterated human or animal foods; and FDA to implement uniform national standards and labeling for pet foods. The amendment includes elements of his proposed Human and Pet Food Safety Act of 2007 (S. 1274), introduced as H.R. 2108 by Representative De Lauro. The two lawmakers also have introduced more comprehensive bills (H.R. 1148; S. 654) to combine current federal food safety oversight under a new Food Safety Administration.

Recent developments with food imports also have spurred calls for speedier implementation of mandatory country of origin labeling (COOL) for fresh meats, produce and peanuts, now scheduled to take effect on September 30, 2008. H.R. 357 and S. 404 would mandate COOL by September 30, 2007. (For arguments for and against COOL, see CRS Report 97-508, *Country-of-Origin Labeling for Foods*, by Geoffrey S. Becker.)

Some agricultural interests also have charged that the transfer of APHIS border inspection responsibilities to DHS in 2003 has reduced the attention paid to foreign agricultural pests and diseases.<sup>22</sup> S. 887 would shift these inspectors back to USDA-APHIS; a similar provision is in H.R. 1600, Section 403. Opponents counter that the transfer improved vigilance for both agricultural and security purposes.

<sup>&</sup>lt;sup>21</sup> Fengxia Dong and Helen H. Jensen, "Challenges for China's Agricultural Exports: Compliance with Sanitary and Phytosanitary Measures," *Choices*, 1<sup>st</sup> quarter 2007.

<sup>&</sup>lt;sup>22</sup> See CRS Report RL32521, Agroterrorism: Threats and Preparedness, by Jim Monke.