



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

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## Summary

Does the U.S. safety system, first created at a time when most Americans obtained their foods domestically, adequately protect public health? What, if any, changes should be made to enhance the safety of food imports (which now constitute about 15% of U.S. food consumed generally but are much higher for some products such as seafood)? Critics argue that major reforms are necessary because the present programs are both poorly designed and inadequately funded to meet today's challenges. An opposing argument is that imported foods already are subject to the same safety standards as—and pose no greater hazards than—domestically produced foods. The issue of import safety was the focus of numerous congressional hearings and bills in the 110<sup>th</sup> Congress, and remains high on the policy agenda of the 111<sup>th</sup> Congress.

Attention is now focused on two pending food safety bills, which seek to address the safety primarily of foods regulated by the U.S. Food and Drug Administration (FDA). The food inspection activities of the U.S. Department of Agriculture (USDA), which is responsible for meat and poultry safety, have not been targeted for changes by these bills. Both bills—H.R. 2749 by Representative Dingell, and S. 510 by Senator Durbin—seek tighter controls over imports, and both would require that imports be subject to certification systems whereby accredited third parties (such as foreign governments or others) might be tasked with assuring that imported food products meet U.S. food safety requirements. The bills variously would provide expedited entry for imports that meet additional standards; require preventive safety plans and more inspections, based on risk, of foreign as well as domestic facilities; and/or ban imports from foreign countries and facilities that refuse requests for U.S.-sponsored safety inspection, among other provisions.

The House cleared H.R. 2749 on July 30, 2009, after it had been amended and passed by the House Energy and Commerce Subcommittee on Health on June 10, 2009, and by the full committee on June 17, 2009. On the Senate side, the Committee on Health, Education, Labor, and Pensions reported an amended version of S. 510 on December 18, 2009.

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## **Introduction**

Officials continue to assert that the U.S. food supply, including the portion imported, is among the safest in the world. One challenge has been the steady increase in imports, a result of globalization and consumer desire for a wider variety of foods year-round. With this growth have come new concerns about whether current federal programs sufficiently ensure the safety of these imports.

Import alerts in 2007 and 2008 targeting adulterated pet food ingredients, farmed seafood, and dairy products and ingredients, all from China, are among the incidents that have heightened interest in the issue. However, concerns about unsafe imports from other countries also have garnered attention in recent years.

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

The issue was explored at numerous congressional hearings in 2007 and 2008, and Members of the 110<sup>th</sup> Congress introduced a variety of bills to modify or overhaul the current system, particularly the parts overseen by the U.S. Food and Drug Administration (FDA). (The U.S. Department of Agriculture oversees the safety of most meat and poultry; FDA all other foods). The House Energy and Commerce Committee and the Senate Health, Education, Labor, and Pensions (HELP) Committee have primary legislative jurisdiction over FDA, including its food safety activities.

In the 111<sup>th</sup> Congress, several new legislative proposals emerged. On July 30, 2009, the full House cleared an amended version of one of these proposals, H.R. 2749, by Representative Dingell. The principal Senate food safety bill, S. 510 by Senator Durbin, was amended and approved by the HELP Committee on November 18, and reported on December 18, 2009.<sup>1</sup>

## **Increase in Food and Agricultural Imports**

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, a growth of 35%. The increase by value was 94%, from \$43 billion in FY1997 to \$83.6 billion in FY2007. Among the product categories that more than doubled in volume during the period were live animals, wine/beer, fruit/vegetable juices, wheat, coffee, snack foods, and various seafood products. Agricultural and seafood imports increased again in FY2008, to 50.7 MMT valued at \$93 billion, before declining to 49.2 MMT and \$86.7 billion in FY2009.<sup>2</sup> The United States' NAFTA (North American Free Trade

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<sup>1</sup> See also CRS Report R40443, *Food Safety: Selected Issues and Bills in the 111<sup>th</sup> Congress*, by Geoffrey S. Becker.

<sup>2</sup> U.S. Department of Agriculture (USDA), Foreign Agricultural Service (FAS), U.S. Trade Internet System, BICO (continued...)

Agreement) partners, Canada and Mexico, have been the largest suppliers of food, agricultural, and seafood imports, with a combined one-third share of total imports. The percentage share of all other leading importers was in the single digits. (**Table 1** lists the top 25 country suppliers.)

Not all agricultural imports enter the human food supply; some products are used as ingredients in pet food and animal feed, in manufactured goods (e.g., rubber), and in the nursery plant trade. Nonetheless, many consumers are obtaining a growing portion of their diets from overseas. In 2005, nearly 15% of the overall volume of U.S. food consumption was imported, compared with 11%-12% in 1995. The proportions (volume) for some food product categories were much higher: in 2005 as much as 84% of all U.S. fish and shellfish was imported (55% in 1995); 43% of all noncitrus fresh fruits (34% in 1995); 37% of all processed fruits (20% in 1995); and 54% of all tree nuts (40% in 1995).<sup>3</sup>

## Federal Oversight Responsibilities

Two federal agencies—USDA’s Food Safety and Inspection Service (FSIS) and the U.S. Department of Health and Human Services’ Food and Drug Administration (FDA)—are responsible for the majority of the total funding and staffing of the government’s food regulatory system. For imports, FSIS relies on a very different regulatory system than FDA, including a differing approach to addressing equivalence, as described below. Also important are USDA’s Animal and Plant Health Inspection Service (APHIS), which is responsible for protecting plant and animal resources from domestic and foreign pests and diseases, and the Department of Homeland Security (DHS), which is responsible for coordinating agencies’ food security activities, including border inspections by DHS’s U.S. Customs and Border Protection (CBP).<sup>4</sup>

### FDA Role

The FDA’s food regulatory authority comes chiefly from the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 et seq.).<sup>5</sup> This authority makes the agency responsible for the safety of virtually all domestic and imported articles used for food and drink, except meat and poultry (see “FSIS Role,” below); these include animal as well as human foods. FDA-regulated foods may be deemed adulterated or misbranded for a variety of statutorily prescribed reasons. For example, a food may be deemed adulterated if it contains an added poisonous or deleterious substance or an unsafe food additive or if the food was prepared, packed, or held under insanitary conditions whereby it may have become contaminated or may have been

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

<sup>3</sup> USDA, Economic Research Service (ERS), unpublished data, obtained May 11, 2007. Other data including that provided by FDA indicate that the current percentage for seafood is somewhat lower than 84%.

<sup>4</sup> In total, as many as 15 federal agencies administer at least 30 laws related to food safety. Also see CRS Report RS22600, *The Federal Food Safety System: A Primer*, by Geoffrey S. Becker.

<sup>5</sup> Portions of this section and the following section are based on Olsson, Frank and Weeda, P.C., and The Food Institute, *Importing Food into the United States: A Regulatory Guide*, 2007. Data sources for this section, unless noted: David Acheson, Assistant Commissioner for Food Protection, U.S. Food and Drug Administration, testimony before the House Agriculture Committee, May 9, 2007; and House Appropriations Committee hearings on Agriculture Appropriations for various years.

rendered injurious to health.<sup>6</sup> Of approximately 60,700 domestic food facilities (such as manufacturers, warehouses, and shippers), FDA designates between 6,000 and 8,000 as “high risk,” based on the types of foods they handle and/or past performance.<sup>7</sup> In general, FDA attempts to conduct annual inspections of these facilities; non-high risk establishments are inspected, on average, much less frequently.<sup>8</sup>

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

Section 801 of the FFDCFA empowers the FDA to refuse entry to any food import if it “appears,” based on a physical examination or otherwise, to be adulterated, misbranded, or in violation of the law.<sup>9</sup> In exercising its oversight, the agency relies on a system of prior notifications by importers and document reviews at points of entry (ports). Importers must have an entry bond and file a notification for every shipment. Import information is entered into FDA’s database, the Operational and Administrative System for Import Support (OASIS). This system is to help inspectors to determine a shipment’s relative risk and whether it needs closer scrutiny (i.e., a wharf or physical examination, and/or testing). FDA inspectors are to work closely with CBP officials on these tasks.<sup>10</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>11</sup> based on past history or other information indicating that it may be violative. Such detention compels the importer to demonstrate to FDA that the product is safe before it can enter U.S. commerce. Examples in 2007 were the detention of all Chinese plant protein products

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<sup>6</sup> 21 U.S.C. § 342(a)(2).

<sup>7</sup> The higher estimate of high-risk facilities is from *Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for 2008*, Part 5, hearings before a Subcommittee of the Committee on Appropriations, House of Representatives, 110<sup>th</sup> Cong., 1<sup>st</sup> sess. The lower estimate is from March 11, 2009, testimony before the House Energy and Commerce Subcommittee on Health by William Hubbard, former FDA Associate Commissioner for Policy and Planning, and Advisor, Alliance for a Stronger FDA.

<sup>8</sup> For example, *FDA Science and Mission at Risk*, a November 2007 report prepared by a subcommittee of the FDA Science Board (the Commissioner’s top advisory group) cited (on p. 21) an FDA estimate that “at most, it inspects food manufacturers once every 10 years.” The March 11, 2009, Hubbard testimony suggested that many such facilities “never see an FDA inspector.” Also, the *FDA Food Protection Plan* (November 2007) stated that there were over 136,000 registered domestic food facilities and approximately 189,000 foreign facilities that manufacture, process, pack, or hold food. These figures are inflated, because facilities engaged in more than one activity are counted multiple times. The *Food Protection Plan* is discussed later in this CRS report.

<sup>9</sup> 21 U.S.C. § 381(a).

<sup>10</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>11</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).

(including wheat gluten and rice gluten, destined for pet foods) after some were found to contain melamine, an unapproved substance; and of all farm-raised seafood from China (specifically, shrimp, catfish, basa, dace, and eel) until the shippers of these products could demonstrate that they are free of unapproved drug residues. In 2008, the FDA issued a detention import alert for all milk products, milk-derived ingredients, and food products containing milk from China until they can demonstrate that they do not contain melamine or cyanuric acid.

The volume of FDA-regulated imports has increased substantially in the past decade. The agency recorded more than 8.2 million imported food “lines” in FY2007 compared with fewer than 2.8 million entry lines in FY1997. Just over 1% of these lines were physically examined and/or tested.<sup>12</sup> In 2007 congressional hearings, witnesses testified that 450 inspectors must cover more than 300 ports of entry.<sup>13</sup>

FDA’s ability to operate within other countries appears to be limited. FDA can and does periodically visit foreign facilities to inspect their operations, but usually in response to a concern and only with the permission of the foreign government. Further, FDA asserts that it lacks the staff and funding to increase its presence overseas, regardless of whether it might have the legal authority to do so. FDA’s Center for Food Safety and Applied Nutrition (CFSAN) had a budget of \$457 million and staff of 2,700 (full-time equivalent or FTE) in FY2007, of which \$298 million and 1,900 FTEs were in the field.<sup>14</sup> For FY2008, the FDA foods budget was \$577 million, which included a mid-year supplemental appropriation of \$67 million. The Omnibus Appropriations Act, 2009 (P.L. 111-8), provided an increase in the agency’s foods budget to \$649 million. Congress again increased the FDA foods budget to approximately \$783 million in the FY2010 Agriculture and Related Agencies appropriations measure (P.L. 111-80).<sup>15</sup>

In a hearing before the House Agriculture Committee, FDA’s chief food officer at the time testified that the agency theoretically has the authority to require equivalency for imports but that FDA’s situation is significantly more complex than USDA’s (the latter regulates fewer types of food products; see below).<sup>16</sup>

CFSAN has stated on its website that it is “aggressively pursuing both informal and formal agreements with foreign government counterpart officials including Memoranda of Understanding for mutual recognition of equivalence of regulatory systems.” Another FDA website lists nearly 100 “International Arrangements” with approximately 30 separate foreign entities, of which about a third appear to be directly food-related. Roughly a third of the food-

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<sup>12</sup> Source: FDA briefing for Senate staff, February 8, 2008. FDA FY2009 budget materials state that 94,743 import food field exams were conducted in FY2007. For definition of “line,” see “FDA Import Refusals” later in this report.

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

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

<sup>15</sup> Sources: CRS Report RL34638, *FDA FY2009 Appropriations*, coordinated by Susan Thaul; and CRS Report R40443, *Food Safety: Selected Issues and Bills in the 111<sup>th</sup> Congress*. See also CRS Report R40721, *Agriculture and Related Agencies: FY2010 Appropriations*, and CRS Report R40000, *Agriculture and Related Agencies: FY2009 Appropriations*, both coordinated by Jim Monke.

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

related arrangements address aspects of shellfish or other seafood safety.<sup>17</sup> However, these are not the same as formal equivalency requirements (see “FSIS Role,” below).

## **FSIS Role**

FSIS regulates the safety and labeling of most domestic and imported meat and poultry, under the Federal Meat Inspection Act (FMIA) as amended (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act (PPIA) as amended (21 U.S.C. 451 et seq.).<sup>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 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 17 of the PPIA, FSIS also is responsible for determining the equivalence of other countries’ meat and poultry safeguards. A foreign plant cannot ship products to the United States unless FSIS has determined that its country has a meat and/or poultry program that provides a level of protection that is at least equivalent to the U.S. system.<sup>19</sup> FSIS visits the exporting country to review its rules and regulations, meets with foreign officials, and accompanies them on visits to establishments. When a foreign program is approved, FSIS relies on that government to certify eligibility of, and to inspect, the establishments. FSIS periodically reviews foreign government documents and conducts on-site audits at least annually to verify continuing equivalence.

In addition, FSIS operates a reinspection program at 150 import houses located near approximately 35 border entry points. Agency inspectors review all import records, aided by a computerized sampling program, the Automated Import Information System (AIIS). This system generates inspectors’ actual examination assignments based on what the agency believes to be the relative risks of particular product types and/or countries. It also can identify shipments that are to be denied reinspection because, for example, the foreign country or particular plant is not eligible to ship to the United States, or the product has not been certified to enter. Inspectors next are responsible for ensuring that all other imports are in acceptable condition, properly labeled, and accurately counted. This can include opening and physically examining boxes for physical defects, and collecting samples for laboratory testing for contaminants. FSIS can take a number of actions when violative products are found. Products that pass are released into interstate commerce; most are bulk products for further processing at U.S. plants, which are under continuous FSIS inspection.<sup>20</sup>

Meat and poultry imports increased significantly from nearly 2.3 billion pounds presented for inspection in FY1996 to nearly 3.9 billion pounds in FY2007. Imports were lower in FY2008 and FY2009, at approximately 3.3 billion pounds and 3.4 billion pounds, respectively. FSIS estimated

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<sup>17</sup> The arrangements were accessed December 2008 at <http://www.fda.gov/oia/default.htm>.

<sup>18</sup> FSIS inspects the major red meat and poultry species and their products; catfish was added to FSIS’s responsibilities by the 2008 farm bill (P.L. 110-246; § 11016). FDA has jurisdiction over all meat and poultry not inspected by FSIS. The agencies share responsibility for egg safety, under the Egg Products Inspection Act, as amended (21 U.S.C. § 1031 et seq.). FSIS covers processed egg products; FDA covers most whole eggs.

<sup>19</sup> List of foreign establishments in the 34 eligible countries accessed November 2008 at [http://www.fsis.usda.gov/regulations\\_&\\_policies/Eligible\\_Foreign\\_Establishments/index.asp](http://www.fsis.usda.gov/regulations_&_policies/Eligible_Foreign_Establishments/index.asp).

<sup>20</sup> See CRS Report RL32922, *Meat and Poultry Inspection: Background and Selected Issues*, by Geoffrey S. Becker.



that it physically had examined approximately 20% of all such imports in FY1996, compared with approximately 10% in more recent years (after implementation of the AHS in the early 2000s). About 4% of imports undergo microbiological testing, according to USDA.<sup>21</sup>

In FY2008, FSIS had a total budget of approximately \$1 billion (appropriated and user fees) and a staff of 9,400, of which 7,800 were in about 6,300 meat and poultry plants nationwide. The agency's international food safety budget that year was approximately \$20 million, more than half of which went for border reinspections. Other portions were devoted to evaluating foreign programs and to facilitating U.S. exports. The total international staff numbered an estimated 150, although a significant number were assigned to non-border duties.<sup>22</sup> FSIS's FY2009 budget was more than \$1.1 billion (appropriated and user fees); this figure is expected to be somewhat higher in FY2010, at nearly \$1.3 billion.

## **APHIS Role**

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

## **International Trade Considerations**

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

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

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<sup>21</sup> The percentage tested is from comments by Dr. Richard Raymond, Undersecretary for Food Safety, November 7, 2007, before the House Agriculture Subcommittee on Livestock, Dairy, and Poultry.

<sup>22</sup> House Appropriations Committee hearings on agriculture appropriations for various years.

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

Although U.S. and World Trade Organization (WTO) officials frequently cite the benefits of SPS cooperation under trade agreements, some, among them food safety and environmental advocacy organizations, have been skeptical. They have argued that implementation of the agreements can result in “downward harmonization” rather than upgraded health and safety standards. Defenders counter that trade rules explicitly recognize the right of individual nations to enact stronger protections than international guidelines if they believe they are appropriate and are justified by scientific risk assessment.<sup>23</sup>

Some have raised concerns about whether the language in the pending food safety bills has been appropriately drafted to avoid potential challenges by U.S. trading partners. For example, language has been added to S. 510 (but not to H.R. 2749) that nothing in the bill is to be construed in a manner inconsistent with trade agreements. Nonetheless, the European Union reportedly has raised concerns about a provision in S. 510, which states that when FDA conducts a review of a foreign country’s food safety system, it must determine whether the country’s food “meets or exceeds” the safety of U.S. foods. This may violate the SPS agreement which calls for “equivalence.”<sup>24</sup>

## **FDA Import Refusals**

Using its OASIS data, the FDA compiles a monthly “Import Refusal Report” for food shipments that it rejects. Such products have to be either re-exported or destroyed by the importer. The agency posts these monthly refusal reports on its website, but does so only for the most recent 12 months, i.e., only one year’s worth of refusals. (Also listed in the refusal reports, but not examined here, are other FDA-regulated products: drugs, medical devices, and vitamins.) CRS examined the data for FY2007, FY2008, and FY2009 (i.e., October through September of each year).

For each import line, the system provides the name of the source company and the reason for refusal. A “line” is a portion of an import shipment that is listed separately on that import’s entry document. An item in a shipment must have a separate line if its tariff description differs from other items in that shipment. As noted earlier, the size of each shipment in the OASIS database varies. Therefore, it is not possible to calculate the volumes of products being rejected, either as an absolute quantity or as a proportion of total imports. Also, the types or categories of imports do not correspond directly to the categories reported through the USDA trade databases.

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<sup>23</sup> These arguments are covered at greater length in CRS Report RL33472, *Sanitary and Phytosanitary (SPS) Concerns in Agricultural Trade*, by Geoffrey S. Becker.

<sup>24</sup> Source: “Fears Over Trade Linger After Senate Committee Reports Food Safety Bill,” *Inside U.S. Trade*, November 25, 2009.

Efforts are under way to improve the collection and use of FDA import data. The agency reported in late 2008 that it was working on an advanced screening system it calls the Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting (PREDICT). FDA began to implement the new system in September 2009, starting in its Los Angeles district, with the intention of having it in place nationally sometime in 2010. In a February 2010 speech, FDA Commissioner Hamburg cited two primary benefits of the new system: automatically flagging potentially risky shipments, and giving lower risk scores to “more innocuous materials,” which FDA can then clear more rapidly. She stated that PREDICT:

considers everything from whether a product is intrinsically risky—raw seafood falls into this category—to information we’ve acquired from previous examinations of shippers or producers. We can even add information on things like floods, hot weather or market conditions that suggest whether a particular shipment is at risk of being spoiled or shoddy. These and other factors are added up to give a risk score—and the riskiest items are the ones are investigators will check first.<sup>25</sup>

Elsewhere, Section 1009 of the Food and Drug Administration Amendments Act of 2007 (P.L. 110-85) now requires an annual report to Congress on the number and amount of FDA-regulated food products imported by country and type of food, the number of inspectors and inspections performed, and aggregated data on inspection findings, including violations and enforcement actions.<sup>26</sup>

## **FY2007-FY2009 Refusals**

Mindful of limitations of the OASIS data, CRS prepared a tabulation of the refusals, focusing on nearly 40 categories of FDA-regulated food and food-related products. For the entire period from FY2007 through FY2009, FDA logged a total of more than 27,000 refusals. This represents a fraction of one percent of the many millions of lines entered into OASIS during the same period. The countries involved in the most refusals were Mexico, with nearly 3,700; India, with more than 3,000; and China, with more than 2,300. (See **Table 1.**)

It is important to note that a higher relative number of refusals does not necessarily indicate that one country’s products are less safe, or its food safety system less rigorous, than that of another country. The country simply might be a more important source of U.S. agricultural and/or seafood imports. Mexico, for example, is the second most important exporter to the United States. On the other hand, Canada, which exports more food and agricultural products to the United States than any other country, had fewer refusals than a number of countries with fewer imports in dollar value. India’s import value ranked 16<sup>th</sup> during the FY2007-FY2009 period, but its shipments (as measured by lines) were more frequently refused U.S. entry than those of most other countries.

By industry, vegetables/vegetable products and seafood products appear to have been the most frequently refused products from all countries generally. Fruits/fruit products from all countries accounted for the next highest number of refusals, followed by candy products, and then spices/flavors/salts. Many refused fruit and vegetable products originated in the Dominican

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<sup>25</sup> “FDA and the American Public: The Safety of Foods and Medical Products in the Global Age,” remarks of Dr. Margaret Hamburg, FDA Commissioner of Food and Drugs, at the Center for Strategic and International Studies, February 4, 2010. More information on PREDICT can be accessed at <http://www.fda.gov/ForIndustry/ImportProgram/ucm172743.htm>.

<sup>26</sup> Other food safety provisions in the law affect imported as well as domestic foods.

Republic, Mexico, or other Latin American and Caribbean nations; a frequently cited reason was pesticides. Bacterial contamination (e.g., Salmonella) or filthy condition was cited numerous times. Fish and shellfish were refused for a variety of reasons, often for bacteria, filthy condition, and/or veterinary drug residues. These products most frequently appear to have originated in Asian countries, not only China but also Vietnam, India, Bangladesh, and others.

**Table I. FDA Refusals Among Leading Country Importers, FY2007-2009**

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

<b>Country</b>	<b>U.S. Import Share (Value)</b>	<b>U.S. Import Share (%)</b>	<b>FDA Refusals (no. lines)</b>	<b>% Of All FDA Refusals</b>
1. Canada	54.541	20.7	928	3.4
2. Mexico	33.452	12.7	3,693	13.7
3. China	15.337	5.8	2,334	8.6
4. Thailand	10.649	4.0	709	2.6
5. Indonesia	9.463	3.6	1,071	4.0
6. Italy	9.151	3.5	766	2.8
7. Chile	8.872	3.4	123	0.5
8. Brazil	7.693	2.9	262	1.0
9. Australia	7.681	2.9	69	0.3
10. Ireland	6.815	2.6	10	*
11. Netherlands	6.470	2.5	132	0.5
12. France	6.377	2.4	422	1.6
13. New Zealand	5.542	2.1	22	0.1
14. Colombia	5.113	1.9	164	0.6
15. Malaysia	4.760	1.8	172	0.6
16. India	4.690	1.8	3,051	11.3
17. Vietnam	4.231	1.6	1,184	4.4
18. Ecuador	4.031	1.5	140	0.5
19. Guatemala	3.990	1.5	318	1.2
20. Costa Rica	3.753	1.4	44	0.2
21. Argentina	3.730	1.4	128	0.5
22. Germany	3.599	1.4	67	0.2
23. Spain	3.539	1.3	209	0.8
24. Philippines	2.996	1.1	650	2.4
25. Peru	2.498	0.9	220	0.8
World Total	263.427	100.0	27,011	100.00

**Source:** Prepared by CRS based on FAS BICO Import Commodity Aggregations (first three columns) and FDA OASIS data (last two columns).

**Notes:** A line is all or part of a shipment of no uniform size, so care should be used in attempting any comparisons between countries, or between a country's import value and its number of refused lines. Asterisk (\*) denotes less than one-tenth of one percent.

A 2007 report by Food and Water Watch analyzed the FDA OASIS refusals of seafood in more detail, and for all calendar years from 2002 to 2006. Among its findings were that more than 70% of all imported seafood products were processed. More than 20% of all seafood refusals were due to Salmonella, of which 40% were shrimp. It also observed that more seafood is being refused for veterinary drug residues.<sup>27</sup>

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

## **Past Refusal Data**

A more extensive analysis of the OASIS data was published in September 2008 by USDA's Economic Research Service (ERS).<sup>28</sup> ERS examined seven years of FDA refusals of food import shipments, by industry group and by type of violation, which totaled 70,369 violations. Because of differing time periods, and somewhat differing methods of counting and classifying OASIS-reported refusals, the CRS and ERS findings are not directly comparable, but do appear to reach parallel conclusions. Also, the ERS study did not classify refusals by country.

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

Overall, misbranding or lack of appropriate labeling accounted for 33% of the 70,369 violations, and adulteration or safety and packaging integrity violations for 65%. "Adulteration violations pose a wide range of food safety risks, from less severe risks, such as an insect in cooked soup, to immediate risks to human health, like botulism in canned food. The data indicate that the most common adulteration violations were for the appearance of filth in a food product and failure to file information or register a specified process."<sup>29</sup>

Although the study revealed recurring problems in certain types of imported foods, it did "not indicate the actual level or distribution of food safety risk ... because FDA's process for selecting shipments for inspection or other administrative actions is not random," the authors wrote. "In essence, import refusals highlight food safety problems that appear to recur in trade and where the FDA has focused its import alerts and monitoring efforts."<sup>30</sup>

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<sup>27</sup> Food and Water Watch, *Import Alert: Government Fails Consumers, Falls Short on Seafood Inspections*, May 2007. Last accessed on the Internet on April 16, 2008, at <http://www.foodandwaterwatch.org/press/publications/reports/import-alert>.

<sup>28</sup> Jean C. Buzby, Laurian J. Unnevehr, and Donna Roberts, *Food Safety and Imports: An Analysis of FDA Food-Related Import Refusal Reports* (EIB-39), USDA, ERS, September 2008.

<sup>29</sup> *Food Safety and Imports: An Analysis of FDA Food-Related Import Refusal Reports*, pp. iii-iv. The report contains tables and accompanying discussion breaking out these violations in greater detail.

<sup>30</sup> *Food Safety and Imports: An Analysis of FDA Food-Related Import Refusal Reports*, p. iii.

## 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 2** 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—ranging from 0.19% to 0.35% of total shipments.

**Table 2. Imported Meat and Poultry Products Presented for Inspection and Refused Entry, Selected Years**

(thousands of pounds)

Fiscal Year	Presented	Rejected/Refused Entry	Pct. Refused
2005	4,303,345	14,081	0.33
2006	3,888,188	12,312	0.32
2007	3,897,098	9,207	0.24
2008	3,273,517	11,624	0.35
2009	3,398,480	6,602	0.19

**Source:** USDA/FSIS, various *Quarterly Enforcement Reports*, accessed December 16, 2009, at [http://www.fsis.usda.gov/Regulations\\_&\\_Policies/Quarterly\\_Enforcement\\_Reports/](http://www.fsis.usda.gov/Regulations_&_Policies/Quarterly_Enforcement_Reports/).

**Note:** The figures are based on an entirely different database and inspection regimen than the figures for FDA in **Table 1** and therefore are not comparable.

## Bush Administration Import and Food Safety Plans

The Bush Administration had released, on November 6, 2007, two separate but related reports on how it wanted to improve food import safety. The broader of the two covered the safety of most imports for consumers, including but not limited to food. This *Action Plan for Import Safety* was prepared for the President by the Interagency Working Group on Import Safety.<sup>31</sup> The other report was FDA's *Food Protection Plan*, which focused on food, whether imported or domestically produced, and which contained recommendations for food imports that generally parallel those in the broader report.<sup>32</sup>

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

Critics, among them the Government Accountability Office (GAO), consumer organizations, and the chair of the House Appropriations Subcommittee on Agriculture, complained that the Bush Administration had failed to provide enough details on the various initiatives, including their

<sup>31</sup> Accessed April 16, 2008, at <http://www.importsafety.gov/report/actionplan.pdf>.

<sup>32</sup> Accessed April 16, 2008, at <http://www.fda.gov/oc/initiatives/advance/food/plan.html>.

costs and how they intended to implement them. Some criticized both the food safety and import plans as largely a collection of objectives, lacking resources and/or enforcement controls to be effective, or otherwise inadequate. Nonetheless, the FDA released, in early December 2008, a one-year progress report on its plan, taking note of a number of accomplishments. Consumer advocacy organizations expressed skepticism about FDA's progress and again challenged the basic plan itself, which, they asserted, does not fundamentally change a flawed U.S. food safety system. Specifically, they questioned the potential impacts of opening offices in China and other countries. Suggesting that the offices "might be window dressing," one consumer advocate expressed uncertainty about whether China will cooperate with U.S. officials there.<sup>33</sup> A food safety expert indicated that to be more effective, those officials should be skilled at, and tasked with, conducting inspections, for example.<sup>34</sup>

## Obama Administration Views

President Obama, in his March 14, 2009, weekly radio address, called the food safety system a "hazard to public health." He announced a Food Safety Working Group of Cabinet secretaries and senior officials "to advise me on how we can upgrade our food safety laws for the 21<sup>st</sup> century; foster coordination throughout government; and ensure that we are not just designing laws that will keep the American people safe, but enforcing them." He asked for the group's recommendations "as soon as possible."<sup>35</sup>

On July 7, 2009, the working group announced a number of steps the Administration was taking under existing authorities to improve oversight and reiterated that it would continue to work with Congress on needed legislative changes. Obama Administration officials also have expressed support generally for the House-passed bill (H.R. 2749) and for key features of the pending Senate bill (S. 510).<sup>36</sup>

In early December 2009, the Administration announced the creation of a new Import Safety Commercial Targeting and Analysis Center (CTAC) in the Department of Homeland Security's U.S. Customs and Border Protection. The center is to "specifically target shipments of imported cargo, including food, for possible safety violations," with federal agencies including the FDA, FSIS, the Environmental Protection Agency, and the Consumer Product Safety Commission providing "on-site expertise" at the center.<sup>37</sup> The center is intended to improve interagency communication and coordination of import (including food) safety. At issue at the start of 2010 is

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<sup>33</sup> FDA, "Food Protection Plan: Once-year Progress Summary," December 2008. At the same time the offices were formally opened, China announced that it intended to establish its own food safety offices in the United States, to be staffed by AQSIQ and State Food and Drug Administration officials.

<sup>34</sup> Sources: Various news sources, including *Food Chemical News*, *InsideHealthPolicy.com*, and *Congress Daily*.

<sup>35</sup> The working group held a workshop for invited stakeholders on May 13, 2009, in Washington, D.C., and also established a public website at <http://foodsafetyworkinggroup.gov/>, where the President's remarks and updates on the group's activities can be viewed.

<sup>36</sup> See, for example, the June 3, 2009, testimony of Margaret Hamburg, FDA Commissioner, before the House Energy and Commerce Subcommittee on Health; the July 16, 2009, testimony of Mike Taylor, her senior advisor on food safety, before the House Agriculture Committee; and the Statement of Administration Policy on H.R. 2749, at [http://www.whitehouse.gov/omb/111/legislative\\_sap\\_date/](http://www.whitehouse.gov/omb/111/legislative_sap_date/). Also see Dr. Hamburg's October 22, 2009, testimony on S. 510 before the Senate HELP Committee, at [http://help.senate.gov/Hearings/2009\\_10\\_22/2009\\_10\\_22.html](http://help.senate.gov/Hearings/2009_10_22/2009_10_22.html).

<sup>37</sup> "USDA and HHS Continue Food Safety Working Group Efforts; Customs and Border Protection Opens Import Food Safety Center," FDA news release, December 9, 2009, accessed March 17, 2010, at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm193668.htm>.

how the CTAC's activities will be implemented and incorporated into the existing import safety system, and whether it will improve food import safety oversight.

## **Selected Legislative Issues and Options**

Pending at the close of the 110<sup>th</sup> Congress were at least a dozen major food safety bills that contained provisions addressing some aspect of food import safety. Several of the pending bills focused almost exclusively on the import issue. In the 111<sup>th</sup> Congress, a number of comprehensive food safety bills have been introduced, including H.R. 2749, S. 510, H.R. 875, and H.R. 1332. All contain major provisions aimed at increasing oversight of imported foods, in addition to domestically produced foods. In marking up an FDA food safety bill in June, the House Energy and Commerce Committee used as its starting point H.R. 2749, a redrafted version of a measure offered earlier in 2009 by Representative Dingell (the earlier bill was H.R. 759). More specifically:

- H.R. 2749 would achieve its proposed food safety changes through the FDA's existing structure and authorities, and activities. The bill would set registration fees for both domestic and foreign facilities and for commercial importers to help offset inspection costs; it would also authorize the HHS Secretary to require designated imports to be certified for safety by FDA-accredited third parties, and provide for a system of expedited imports for those who meet additional, presumably higher, standards, among other provisions. H.R. 2749 was amended and approved on June 10, 2009, by the House Energy and Commerce Subcommittee on Health, and on June 17, 2009, by the full committee. It was passed, with several additional modifications, by the full House on July 30, 2009.
- S. 510 by Senator Durbin also focuses on FDA-regulated foods. The bill would require importers to have an effective foreign supplier verification program in place, authorize the HHS Secretary to require certifications of specified food imports from countries where HHS-FDA has certification agreements, and explicitly authorize FDA to conduct foreign equivalency determinations. As noted, the Senate HELP Committee modified and approved S. 510 on November 18, 2009. Floor action was pending in late 2009. (H.R. 1332 by Representative Costa was a similar but not identical legislative approach.)
- H.R. 875 by Representative DeLauro would have provided a blueprint for a new, independent Food Safety Administration (FSA), separated from the current FDA but still within HHS, which would operate a comprehensive new food safety program (but would not include the meat and poultry inspection programs operated by FSIS). With regard to imports, the DeLauro bill would have required the FSA Administrator to establish a system for certifying food imports, either by an accredited foreign government, or, for foods from some types of establishments, by an accredited certifying agent that meets specified standards. Beginning not later than five years after enactment, imports from establishments that are not certified could not enter except through U.S. ports of entry in areas with an accredited food testing laboratory. The DeLauro bill also would have required the Administrator to "routinely" inspect food before or upon entry into the United States to ensure ongoing compliance with the law. Most observers believe the DeLauro bill is unlikely to receive closer consideration in this Congress due to the movement of the Dingell bill.



Besides the above wide-ranging bills, several other pending measures of more limited scope have provisions potentially impacting food imports. These include S. 429 by Senator Casey, which seeks to address problems, particularly with smuggled food imports, through increased personnel hiring and training, new reporting and data-sharing requirements, new civil penalties for illegally imported meat and poultry products, and certification standards for laboratories that test imports; and S. 92 by Senator Vitter, which targets unsafe seafood imports.

The following selected issues and options have been topics of debate. Where pertinent, provisions in the major bills, H.R. 2749 and S. 510, are noted.

## **Import Certification**

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

In the 111<sup>th</sup> Congress, the House-passed H.R. 2749 directs the HHS Secretary to require, as a condition of granting admission for an imported food article, that a "qualified certifying entity provide a certification that the article complies with specified requirements" of the FFDCA. This requirement would take effect on or after three years from date of enactment. However, the Secretary could only require such certification in the following situations:

- for food imported from a particular country, territory, or region, based on scientific, risk-based evidence, a finding that the government controls there are inadequate to ensure safety such certification would assist in determining the admissibility of the food;
- for a food type for which there is scientific evidence that it could pose a particular risk presenting a threat of serious adverse health consequences or death, if such certification would assist in determining whether to refuse the article admission; or
- for an article imported from a particular country or territory, if the Secretary has an agreement with that government providing for such certification.

Under H.R. 2749, such certification would have to be granted by qualified certifying entities, would have to include any compliance information specified by the Secretary, and would have to be submitted electronically. The information could be provided in any form specified by the Secretary, including a listing of certified facilities or other entities. A qualified certifying entity would have to notify the Secretary whenever it cancels or suspends the certification of a facility or other listed entity. Imports required to have but lacking certification are to be denied entry.

S. 510 would authorize the HHS Secretary to require written and electronic certifications, from qualified third parties but specifically for designated foods (based on health considerations such as the risk or origin of a product), from countries with which FDA has an agreement for such a program. Foods that require certification but lack it would be denied import entry under the bill's provisions. S. 510 would first require HHS to designate accrediting bodies (or to designate itself if no such body gains recognition), which in turn would accredit the third parties that are responsible for conducting certification activities. H.R. 2749 appears to be somewhat less detailed with regard to the elements of a certification program than S. 510; for example, it does not appear to authorize explicitly the use of accrediting bodies, but may not prohibit them either.

Both S. 510 and H.R. 2749 provide, in differing ways, explicit authorization for the Secretary to review foreign food safety programs to determine their equivalency to U.S. standards. S. 510 contains another requirement that each importer "perform risk-based foreign supplier verification activities" to verify that imports meet U.S. requirements. Failure to do so would be a prohibited act under the FFDCFA. H.R. 2749 requires importers to comply with "good importer practices," i.e., measures they must take to ensure there is adequate information about an imported food and the compliance with safety requirements by those handling it.

## **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 some believe it lacks for overseas establishments. The Bush Administration plan proposed that to "provide parity" between domestic and imported foods, authority should be enacted enabling FDA to block imports of foods by foreign firms that impede entry to their facilities that produce, process, or hold such foods. All of the major pending bills include this provision.

H.R. 2749 would require risk-based inspection of foreign (and domestic) facilities at least once every five years, with higher-risk facilities visited more frequently—the highest-risk ones every 6 to 12 months. However, the HHS Secretary could adjust the inspection schedule, and could authorize foreign country representatives to inspect the foreign facilities. Another provision in the bill would require the establishment of a dedicated FDA foreign inspectorate.

S. 510 specifically requires the HHS Secretary to direct resources to inspections of foreign (as well as domestic) facilities, particularly high-risk ones. The bills also authorize the Secretary to enter into arrangements with foreign governments to facilitate these inspections.

## **Mandatory Recall Authority and Access to Records**

The Bush FDA had requested mandatory recall authority in cases where firms (whether foreign or domestic) are unwilling to do so voluntarily or expeditiously. The agency noted that it already has the authority to seize adulterated or misbranded food, but that may not be practical once a product is in wide distribution. The agency also was seeking authority to give it more access to records in cases of food emergencies. Significantly, a major food industry group, the Grocery Manufacturers Association (GMA), endorsed the proposal for mandatory recall authority.<sup>38</sup> The day after the

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<sup>38</sup> "GMA Applauds Bush Administration's Focus on Prevention in Effort to Improve Safety of Imported Food," November 6, 2007, press release, at <http://www.gmaonline.org/news/docs/NewsRelease.cfm?DocID=1806&>.

Bush Administration proposed it for FDA, a USDA official asserted that the Department does not need similar mandatory recall authority for the meat and poultry products it regulates. Responding to questions on whether he would request such authority, he stated that USDA already has sufficient enforcement tools and that the voluntary approach now in place works well.<sup>39</sup> Others, however, continue to seek it for USDA-regulated foods.

Both major food safety bills contain authority for FDA to require a recall if a person or firm fails to do so voluntarily, although the details of this authority differ somewhat among the bills. The bills also contain new requirements for notifying authorities of potentially unsafe foods, as well as new record-keeping provisions to enable tracking of products. Moreover, several bills including H.R. 2749 would no longer fully exempt farmers and restaurants from some current record-keeping requirements.

## **Funding and Fees**

Most policymakers concede that regardless of the policy approach adopted, additional resources are needed to adequately address import safety problems. According to a report released in early December 2007 by the FDA Science Board, the FDA Commissioner's expert advisory panel, a critical lack of resources has seriously weakened the FDA's scientific basis generally and its mission to protect the food supply particularly. The panel noted that the FDA was unable to "sufficiently monitor either the tremendous volume of products manufactured domestically or the exponential growth of imported products. During the past 35 years, the decrease in FDA funding for inspection of our food supply has forced FDA to impose a 78 percent reduction in food inspections, at a time when the food industry has been rapidly expanding and food importation has exponentially increased." As noted, the Science Board recommended that the overall FDA appropriation (not just for food) be more than doubled over the next several years from its FY2008 level of approximately \$1.5 billion, exclusive of user fees.<sup>40</sup>

FDA and FSIS receive most of their funding through the annual Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act. However, requests for higher appropriations must compete with other priorities throughout the federal discretionary budget. An alternative, to fill perceived shortfalls through new fees on the food industry, often meets with resistance, both from the companies that would have to absorb such costs and from consumer advocates, who have long argued that industry funds might "taint" programs that are first and foremost public health programs.<sup>41</sup>

In fact, congressional appropriators have increased funding for FDA food safety activities for FY2008, FY2009, and FY2010. Nonetheless, H.R. 2749 includes fees to cover the cost of such activities as re-inspection of products initially kept out of commerce, and the auditing of private

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<sup>39</sup> Dr. Richard Raymond, Undersecretary for Food Safety, November 7, 2007, testimony before the House Agriculture Subcommittee on Livestock, Dairy, and Poultry.

<sup>40</sup> *FDA Science and Mission at Risk*, Report of the Subcommittee on Science and Technology, prepared for the FDA Science Board, November 2007. See also CRS Report RL34334, *The Food and Drug Administration: Budget and Statutory History, FY1980-FY2007*, coordinated by Judith A. Johnson.

<sup>41</sup> FDA received additional public funding, including for its food safety activities generally, as part of the FY2008 supplemental appropriation (P.L. 110-252); this increased level was continued by the Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009 (P.L. 110-329). For more information see CRS Report RL34638, *FDA FY2009 Appropriations*, coordinated by Susan Thaul.

food testing laboratories. Also, H.R. 2749 would require all registered facilities (foreign and domestic) and commercial importers to pay an annual \$500 registration fee. S. 510 also contains some authorities to charge fees, but not the registration fee in H.R. 2749. It does authorize new budget authority for food safety related activities at \$825 million in FY2010 and such sums as necessary for FY2011 through FY2014, as well as specified increases in field staffing. Meanwhile, the Obama Administration has expressed concern about whether enough money will be available—regardless of source—to meet the new inspection and other mandates in the bills.

## **Other Proposed Legislative Changes**

Among other proposed statutory changes that would affect importers and domestic firms alike have been authority for regulations that would require food chain entities to implement measures solely intended to prevent intentional food adulteration by terrorists or criminals; more explicit authority to require additional preventive (HACCP-like) controls for high-risk foods (authority some believe FDA already has); and more extensive mandatory country-of-origin labeling (COOL), so that consumers can determine where food products and their ingredients originate. H.R. 2749 but not S. 510, for example, would require all processed and nonprocessed foods to be labeled with their country of origin. The House bill would, however, provide that imports subject to and meeting other COOL requirements under Customs or USDA authorities are deemed to be in compliance.<sup>42</sup> Other provisions in one or more bills would seek to help build foreign governments' capacity to improve their oversight of entities that produce and export food to the United States.

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<sup>42</sup> This report does not extensively cover COOL. See CRS Report RS22955, *Country-of-Origin Labeling for Foods*, by Remy Jurenas.