



Food Safety in the 111th Congress: H.R. 2749 and S. 510

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Summary

American consumers spend more than \$1 trillion on food each year. The combined efforts of the food industry and government regulatory agencies often are credited with making the U.S. food supply among the safest in the world. Nonetheless, public health officials have estimated that each year in the United States, many millions of people become sick and thousands die from foodborne illnesses caused by any of a number of microbial pathogens and other contaminants. At issue is whether food safety agencies have the resources, authority, and structural organization to safeguard the public, and whether they use resources effectively. Also at issue is whether federal food safety laws, first enacted in the early 1900s, have kept pace with the significant changes in the food production, processing, and marketing sectors since then.

In the 111th Congress, comprehensive food safety legislation passed both the House (H.R. 2749) in July 2009 and the Senate (S. 510) in November 2010. Both the House and Senate bills mainly focus on the U.S. Food and Drug Administration's (FDA's) food regulation rather than that of the U.S. Department of Agriculture (USDA), which oversees most meat and poultry. The bills would generally expand or modify existing FDA authorities rather than create a new food safety structure or authorities.

Future congressional action, however, remains uncertain. Following passage of the Senate-passed bill, it was reported that the House might block the Senate bill using a procedure known as "blue-slipping," because the bill contains fees that might be subject to certain tax origination provisions.

Food safety legislation is a response to a number of perceived problems with the current food safety system. For example, a growing consensus is that the FDA's current programs are not proactively designed to emphasize prevention, evaluate hazards, and focus inspection resources on areas of greatest risk to public health. Given its widely acknowledged funding and staffing constraints, and no explicit requirement on the frequency of inspections, the agency infrequently visits food manufacturing and other facilities to check sanitary and other conditions. Both the House and Senate bills (in different ways) would require food processing, manufacturing, shipping, and other regulated facilities to conduct an analysis of the most likely safety hazards and to design and implement risk-based controls to prevent them. The bills envision establishment of science-based "performance standards" for the most significant food contaminants. To help determine such risks and hazards, the bills propose improvement of foodborne illness surveillance systems.

Both bills seek to increase frequency of inspections, tighten record-keeping requirements, extend more oversight to certain farms, and mandate product recalls if a firm fails to institute them voluntarily. Major portions of the bills are devoted to increasing the scrutiny of food imports, which account for a growing share of U.S. consumption; food import shipments would have to be accompanied by documentation that they can meet safety standards that are at least equivalent to U.S. standards. Such certifications might be provided by foreign governments or other so-called third parties accredited in advance. The House and Senate bills differ in how to accomplish these objectives. The bills have provisions for certifying or accrediting laboratories, including private laboratories, to conduct sampling and testing of food.

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Introduction

The combined efforts of the food industry and government regulatory agencies often are credited with making the U.S. food supply among the safest in the world. Nonetheless, public health officials have estimated that each year in the United States, many millions of people become sick and thousands die from foodborne illnesses caused by any of a number of microbial pathogens and other contaminants.¹ At issue is whether the current food safety system has the resources, authority, and structural organization to safeguard the health of American consumers, who spend more than \$1 trillion on food each year.² Also at issue is whether federal food safety laws, first enacted in the early 1900s, have kept pace with the significant changes that have occurred in the food production, processing, and marketing sectors since then.

In 2007 and again in 2009, the Government Accountability Office (GAO) placed food safety on its biennially published list of high risk areas, one of 30 needing concerted attention by Congress and the Administration.³ GAO has identified 15 federal agencies collectively administering at least 30 laws related to food safety. The majority of both total funding and total staffing, however, is with the Food Safety and Inspection Service (FSIS) at the U.S. Department of Agriculture (USDA), which regulates most meat and poultry, and the Food and Drug Administration (FDA) at the U.S. Department of Health and Human Services (HHS), which regulates virtually all other foods. FSIS's annual budget in FY2010 was approximately \$1.1 billion in appropriated funds plus an estimated \$131 million in industry-paid user fees. FDA's annual budget for its human foods program was \$784 million for FY2010, all of it appropriated.⁴

This CRS report discusses several recent food safety incidents and the systemic food safety problems that they illustrate. It also describes the existing food safety legal and regulatory landscape and presents an overview of efforts by the 111th Congress to revise federal food safety authorities and activities, principally at FDA. The two bills discussed are those that have passed in the House—H.R. 2749, the Food Safety Enhancement Act of 2009—and in the Senate—S. 510, the FDA Food Safety Modernization Act. This report also presents a number of selected food safety issues, describing how they are addressed in current law and regulation, and comparing their treatment in each of the bills. Finally, appendixes provide a crosswalk of all provisions in H.R. 2749 and S. 510, followed by a side-by-side comparison of all of these provisions with each other and with current law.

¹ According to the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 76 million people become sick, 325,000 are hospitalized, and 5,000 die from foodborne illnesses each year ("Foodborne Illness: Frequently Asked Questions," accessed at <http://www.cdc.gov/foodsafety/>). However, this estimate appears to be based primarily on 1997 and earlier data in a report by Paul S. Mead et al., "Food-related Illness and Death in the United States," *Emerging Infectious Diseases*, vol. 5, pp. 607-625, 1999.

² Nearly half of U.S. food spending is now in restaurants and other places outside the home. Roughly two-thirds of the \$1 trillion is for domestically produced farm foods; imports and seafood account for the balance. Data source: U.S. Department of Agriculture (USDA), Economic Research Service.

³ GAO, *High Risk Series: An Update* (GAO-09-271), January 2009.

⁴ Source: USDA and HHS budget materials for FY2011. The FDA figure does not include some food safety activities carried out by the Center for Veterinary Medicine and National Center for Toxicological Research. For more information on current food safety authorities and agencies, with sources, see CRS Report RS22600, *The Federal Food Safety System: A Primer*. Also see CRS Report R40721, *Agriculture and Related Agencies: FY2010 Appropriations*.

Food Safety Incidents⁵

Food safety-related incidents frequently heighten public and media scrutiny of the U.S. food safety system.⁶ Large recalls of FSIS-regulated meat and poultry products due to findings of *E. coli* O157:H7, *Listeria*, and other problems occur each year.⁷ In addition, in recent years, several large multi-state outbreaks have been linked to FDA-regulated foods. For example, in 2006 more than 200 confirmed illnesses and three deaths were linked to bagged fresh spinach grown in California and contaminated with *E. coli* O157:H7. In 2008, more than 1,400 persons were infected with the same unusual strain of bacteria, *Salmonella* Saintpaul. Officials first suspected fresh tomatoes, but later tests found the pathogen in serrano peppers and irrigation water from a farm in Mexico. These incidents raised public concerns about the safety of all fresh produce and stimulated a number of industry and government initiatives to limit future incidents.

Attention focused on the safety of food imports in 2007, when pet food ingredients imported from China, contaminated with the chemical melamine, sickened or killed an unknown number of dogs and cats and contaminated some livestock feeds. In 2008, melamine contamination of infant formula in China sickened thousands of children and raised concerns about the safety of infant formula in the United States. The melamine incidents highlighted the limited reach of FDA's oversight of imports, the difficulty in tracing the many pathways taken by a common food ingredient, and the frequent confluence of human and animal food ingredients.

In late 2008 and early 2009, a multi-state outbreak of *Salmonella* Typhimurium was linked to an institutional brand of peanut butter and other peanut-based ingredients from a single firm. The outbreak sickened more than 700 people in 46 states, and may have contributed to the deaths of nine people. A series of expanding recalls was announced by FDA in early 2009, involving thousands of peanut-containing products from more than 200 companies. Again, the incident highlighted the broad reach of a common contaminated ingredient, and the resultant challenges in rapidly tracing products and removing them from commerce.

In July 2010, health officials noticed a spike in cases of infection with *Salmonella* Enteritidis, a strain commonly associated with shell eggs, which are regulated by FDA.⁸ In August, FDA found the same pathogen on two egg farms in Iowa, leading to the nationwide recall by the companies of more than 500 million eggs.⁹ In July 2009, FDA had published a long-awaited egg safety regulation, which became effective in July 2010 as the outbreak was well underway.¹⁰ Although most observers believe that the rule, if enforced, will help to prevent shell egg contamination and outbreaks in the future, many remain concerned with the apparent lack of coordination between USDA's egg quality inspection activities and FDA's food safety activities.¹¹

⁵ Unless otherwise cited, material in this paragraph is adapted from CRS Report R40916, *Food Safety: Foodborne Illness and Selected Recalls of FDA-Regulated Foods*.

⁶ Three recent multi-state foodborne outbreaks and their implications for the nation's food safety system are discussed in more depth in CRS Report R40916, *Food Safety: Foodborne Illness and Selected Recalls of FDA-Regulated Foods*.

⁷ For information on meat and poultry recalls, see the FSIS website: http://www.fsis.usda.gov/fsis_recalls/index.asp.

⁸ USDA regulates processed egg products, and grades shell eggs for quality (such as grade and size), but does not oversee the safety of shell eggs.

⁹ FDA, "Salmonella Enteritidis Outbreak in Shell Eggs," <http://www.fda.gov/Food/NewsEvents/WhatsNewinFood/ucm222684.htm>.

¹⁰ FDA, "Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation; Final Rule," 74 *Federal Register* 33029, July 9, 2009. See also FDA, "Egg Safety Final Rule," <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/EggSafety/EggSafetyActionPlan/ucm170615.htm>.

¹¹ Alicia Mundy, Bill Tomson, "Egg Inspectors Failed to Raise Alarms," *The Wall Street Journal*, September 10, 2010.

Existing Food Safety Legal and Regulatory Landscape

Federal responsibility for food safety rests primarily with FDA and USDA.¹² FDA is responsible for ensuring that all domestic and imported food products—except for most meats and poultry—are safe, nutritious, wholesome, and accurately labeled. FDA also has oversight of all seafood, fish, and shellfish products. USDA’s FSIS regulates most meat and poultry and some egg products. State and local food safety authorities collaborate with federal agencies for inspection and other food safety functions, and they regulate retail food establishments.

The division of food safety responsibility between FDA and USDA is rooted in the early history of U.S. food regulation. Congress created separate statutory frameworks when it enacted, in 1906, both the Pure Food and Drugs Act and the Meat Inspection Act. The former addressed the widespread marketing of intentionally adulterated foods, and its implementation was assigned to USDA’s Bureau of Chemistry. The latter law addressed unsafe and unsanitary conditions in meat packing plants, and implementation was assigned to the USDA’s Bureau of Animal Industry. This bifurcated system has been perpetuated and split further into additional food safety activities under additional agencies (for example, the Environmental Protection Agency, the National Marine Fisheries Service, and others) by a succession of statutes and executive directives. The separation of the two major food safety agencies was further reinforced when, in 1940, the President moved responsibilities for safe foods and drugs, other than meat and poultry, from USDA to the progenitor of HHS, the Federal Security Agency. Meat inspection remained in USDA. There has been discussion over time regarding whether this dispersal of food safety responsibilities has been problematic, or whether a reorganization would divert time and attention from other fundamental problems in the system.¹³

Major food safety bills that have passed both in the House (H.R. 2749) and in the Senate (S. 510), which are the subject of this report, do not propose a major reorganization of food safety agencies. Rather, they focus on changes related to FDA, not USDA. The primary law authorizing FDA activities is the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. §§ 301 *et seq.*). Some key FFDCA provisions that are discussed throughout this report are presented in the text box on the next page.

Two of the basic statutory components from the FFDCA are “adulteration” and “misbranding.” 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. Persons who violate the FFDCA by, for example, introducing an adulterated or misbranded product into interstate commerce, commit what is referred to as a prohibited act under FFDCA § 301 (21 U.S.C. § 331). Persons who commit prohibited acts are subject to criminal and civil penalties.

¹² For further background information about the food safety system, see CRS Report RS22600, *The Federal Food Safety System: A Primer*. For further information about FDA’s regulatory authority, see CRS Report RS22946, *Food and Drug Administration (FDA): Overview and Issues*.

¹³ For a discussion of the history of federal food safety organization and of efforts to change it, see Merrill, Richard A. and Jeffrey K. Francer, “Organizing Federal Food Safety Regulation,” *Seton Hall Law Review*, vol. 31:61, 2000. See also GAO, *High Risk Series: An Update* (GAO-07-310), January 31, 2007; and *Ensuring Safe Food From Production to Consumption*, Committee to Ensure Safe Food from Production to Consumption, Institute of Medicine, National Research Council, National Academy Press, 1998.

Key Definitions and Authorities in the Federal Food, Drug, and Cosmetic Act (FFDCA)

Food: FFDCA § 201(f) [21 U.S.C. § 321(f)] defines food as “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.” Unless a provision in law regarding food limits its applicability to one or the other, it would apply equally to both human foods, and to animal foods and feeds.

Raw Agricultural Commodity: FFDCA § 201(r) [21 U.S.C. § 321(r)] defines the term *raw agricultural commodity* to mean “any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.” This may also refer to an unprocessed human food or animal feed crop, including fresh fruits and vegetables, grains, or other crops and products.

Adulteration: Under the FFDCA, introducing adulterated food into commerce, adulterating food that is in commerce, or the receipt and delivery of adulterated food in commerce, is prohibited (FFDCA § 402(a) [21 U.S.C. § 342(a)]).

A food shall be deemed to be adulterated—(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; [or](2)(A) if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of § 406; or (B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of § 408(a); or (C) if it is or if it bears or contains (i) any food additive that is unsafe within the meaning of § 409; or (ii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of § 512; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to § 409.

Misbranding: Under the FFDCA, introducing misbranded food into commerce, misbranding food that is in commerce, or the receipt and delivery of misbranded food in commerce is prohibited. (See “Prohibited Acts” below.) FFDCA § 403 [21 U.S.C. § 343] defines a number of conditions under which a food would be deemed to be misbranded, beginning with a broad provision in paragraph (a) saying that a food is deemed misbranded if its label “is false or misleading in any particular ...” Similar to the definition of adulteration, numerous specific types of misbranding are also defined. These include, among others, failure to disclose specific additives or allergens in the food, and failure to provide required nutritional information.

Person: FFDCA § 201(e) [21 U.S.C. § 321(e)] defines *person* to include an individual, partnership, corporation, and association. In this report, for simplicity, *facility* is often used to refer to actions that may or must be taken with respect to a facility, though it is, of course, a person, typically the owner, operator or agent in charge of the facility, who may or must act.

Facility: FFDCA § 415(b) [21 U.S.C. § 350d(b)] defines a food facility as “any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food. Such term does not include farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer; or fishing vessels (except such vessels engaged in processing as defined in [21 C.F.R. 123.3(k)].”

Retail Food Establishment: Defined in 21 C.F.R. 1.227(b)(11) as “an establishment that sells food products directly to consumers as its primary function.” Such establishments may include restaurants, grocery stores, convenience stores, vending machine locations, and establishments that manufacture/process, pack, or hold food as their primary function (if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers).

Prohibited Acts: Prohibited acts are listed in FFDCA § 301 [21 U.S.C. § 331]. Along with other specified prohibited acts in FFDCA § 301, paragraphs (a) through (c) provide that introducing adulterated or misbranded food into commerce; adulterating or misbranding food that is in commerce; or the receipt and delivery of adulterated or misbranded food in commerce is prohibited. Pursuant to FFDCA § 303 [21 U.S.C. § 333], in general, any person who violates a provision of FFDCA § 301 may be subject to civil or criminal penalties, including imprisonment, fines, or both. Criminal penalties provided for in the FFDCA are adjusted by 18 U.S.C. §§ 3559 and 3571. Certain exceptions may be made, including for the misbranding of foods.

Source: Prepared by CRS based on the FFDCA. A version of the FFDCA is available on FDA’s website at <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/default.htm>. It does not reflect two recent laws. P.L. 111-31, the Family Smoking Prevention and Tobacco Control Act, redesignated Chapter IX (miscellaneous provisions) as Chapter X, and inserted tobacco control provisions in Chapter IX. P.L. 111-148, the Patient Protection and Affordable Care Act, amended several FFDCA sections and added a new § 1011, establishing an FDA Office of Women’s Health.

Administration Views

The George W. Bush Administration issued several reports and studies calling for major changes in the food safety system. Two Bush Administration initiatives were unveiled in November 2007 and were critiqued and debated extensively during the 110th Congress. They were the FDA's *Food Protection Plan: An Integrated Strategy for Protecting the Nation's Food Supply*, and the Interagency Working Group on Import Safety's *Action Plan for Import Safety: A Roadmap for Continual Improvement*, part of which dealt extensively with food product imports.¹⁴ Both reports generally called for a more preventive risk-based approach to food safety oversight, including more attention to imported foods, among numerous other recommendations.

President Barack Obama, in a March 14, 2009, weekly radio address, called the food safety system a "hazard to public health."¹⁵ He announced a Food Safety Working Group (FSWG) of Cabinet secretaries and senior officials "to advise me on how we can upgrade our food safety laws for the 21st century; foster coordination throughout government; and ensure that we are not just designing laws that will keep the American people safe, but enforcing them."¹⁶ In July 2009, the FSWG announced a number of steps the Obama Administration was taking, under existing authorities, to improve government safeguards.¹⁷ The group released a one-year progress report in July 2010.¹⁸ Also, the Administration announced that it had "taken steps to reduce the prevalence of E. coli, implemented new standards to reduce exposure to Campylobacter, and issued a rule to control Salmonella contamination," and that "FDA has conducted a pilot study on a tracing system, and HHS, in collaboration with USDA, has rolled out an enhanced and updated www.foodsafety.gov site to provide consumers rapid access to information on food recalls."¹⁹

The Obama Administration has weighed in on the principal bills that have been considered by the House and Senate during the 111th Congress (and that are the subject of this report). The Administration declared its support for H.R. 2749, which had passed in the House.²⁰ Also, in a July 2010 statement, the Administration urged the Senate to complete its work on S. 510.²¹ In November 2010, the Administration expressed its continued support of the Senate's efforts on its bill.²² In addition, Administration officials have testified on aspects of the legislation. Testimony

¹⁴ FDA, "An Integrated Strategy for Protecting the Nation's Food Supply," November 2007, <http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/FoodProtectionPlan2007/ucm132565.htm>; and the Interagency Working Group on Import Safety, "Action Plan for Import Safety: A Roadmap for Continual Improvement," November 2007, <http://archive.hhs.gov/importersafety/report/actionplan.pdf>.

¹⁵ The White House, Remarks of President Barack Obama, "Reversing a Troubling Trend in Food Safety," weekly address, Washington, DC, March 14, 2009, <http://www.whitehouse.gov/briefing-room/weekly-address>.

¹⁶ The working group established a public website at <http://foodsafetyworkinggroup.gov/>, where the full text of these remarks may be viewed.

¹⁷ FSWG, "Food Safety Working Group: Key Findings," July 7, 2009, <http://www.foodsafetyworkinggroup.gov/>.

¹⁸ FSWG, "Food Safety Working Group: Progress at 1 Year," July 9, 2010, <http://www.foodsafetyworkinggroup.gov/>.

¹⁹ The White House, Statement by the President on Food Safety, July 7, 2010, <http://www.whitehouse.gov/the-press-office/statement-president-food-safety>.

²⁰ The White House, Statement by the President on House Passage of the Food Safety Enhancement Act of 2009, July 30, 2009, <http://www.whitehouse.gov/the-press-office/statement-president-house-passage-food-safety-enhancement-act-2009>.

²¹ The White House, Statement by the President on Food Safety, July 7, 2010, <http://www.whitehouse.gov/the-press-office/statement-president-food-safety>.

²² The White House, Statement of Administration Policy, "S. 510—The FDA Food Safety Modernization Act," November 16, 2010, http://www.whitehouse.gov/sites/default/files/omb/legislative/sap/111/saps510s_20101116.pdf.

regarding specific provisions of the House bill was given by FDA Commissioner Dr. Margaret Hamburg to the House Energy and Commerce Subcommittee on Health on June 3, 2009, and by FDA Senior Advisor Michael R. Taylor to the House Agriculture Committee on July 16, 2009.²³

In October 2009 testimony on the Senate bill, FDA Commissioner Hamburg called S. 510 a “major step in the right direction.” Provisions in the bill address a key policy concern by refocusing FDA’s food safety system on prevention, the Commissioner stated. She added that the bill also generally meets another key policy concern, the need for adequate FDA legal tools to implement the new requirements, although some additional provisions, such as effective enforcement mechanisms, should be added. Finally, the Commissioner stated, the legislation must provide or anticipate adequate resources, but it “does not provide a guaranteed consistent funding source to help FDA fulfill its new responsibilities.” The Commissioner recommended the inclusion of registration fees, flexibility to adjust facility inspection frequencies, and use of accredited third parties to ensure adequate resources.²⁴ (These issues are among those discussed later in this report.)

Congressional Response

These and other developments have made food safety a top issue for many lawmakers. Some Members of Congress have called for major changes in the U.S. food safety system and/or funding increases that they assert are needed to meet current obligations to protect consumers from unsafe food. Perceived gaps in federal safeguards have been explored at more than two dozen congressional hearings since 2007.²⁵ The 110th Congress made several amendments to FDA’s food safety authorities,²⁶ and increased funding for the primary food safety agencies, but more comprehensive food safety legislation was not enacted.

In the House, U.S. food safety laws variously fall under the purview of the Energy and Commerce Committee, which claims jurisdiction over all FDA-regulated products, including foods, and the Agriculture Committee, which claims the lead on USDA’s meat and poultry inspection programs. Similarly, in the Senate, the Committee on Health, Education, Labor, and Pensions (HELP) has jurisdiction over FDA-regulated foods and other products, while the Agriculture Committee has jurisdiction over USDA inspection programs. In contrast with the split in jurisdictions among the authorizing committees, within each of the House and Senate Appropriations Committees, one subcommittee (Agriculture) is responsible for funding and oversight of both FDA and USDA.

²³ Dr. Hamburg’s comments were based on the introduced version of H.R. 2749; Mr. Taylor’s were based on the version reported by the full Energy and Commerce Committee (H.Rept. 111-234) in June 2009.

²⁴ Statement of FDA Commissioner Margaret Hamburg, U.S. Congress, Senate Committee on Health, Education, Labor, and Pensions, *Keeping America’s Families Safe: Reforming the Food Safety System*, 111th Cong., 1st sess., October 22, 2009, <http://help.senate.gov/hearings/index.cfm>.

²⁵ This includes hearings conducted by the House and Senate Agriculture Committees; House Committee on Energy and Commerce; Senate Committee on Health, Education, Labor, and Pensions (HELP); House Committee on Small Business; House Committee on Oversight and Government Reform; House Committee on Homeland Security; House Committee on Ways and Means; Senate Appropriations Committee; and Senate Committee on Commerce, Science, and Transportation.

²⁶ CRS Report RS22779, *Food Safety: Provisions in the Food and Drug Administration Amendments Act of 2007*.

Legislative Overview

In the 111th Congress, nearly a dozen food safety bills, several of them comprehensive, were introduced. The major vehicle in the House is H.R. 2749, introduced by Representative John Dingell. This bill was amended and approved by the Subcommittee on Health of the House Energy and Commerce Committee on June 10, 2009; and by the full committee on June 17, 2009 (H.Rept. 111-234, July 29, 2009). After failing to reach the needed two-thirds majority under suspension of the rules on July 29, 2009, the bill passed the House under regular order, with a recorded vote of 283 to 142, on July 30, 2009.²⁷

In the Senate, S. 510 was introduced by Senator Richard Durbin. The HELP Committee amended and reported the bill (without a written report) on December 18, 2009. During the spring and summer of 2010, Senators discussed potential amendments to S. 510, aimed at addressing issues of continued interest. In August 2010, several members of the HELP Committee, including Chairman Senator Tom Harkin and Ranking Member Senator Mike Enzi, along with Senator Durbin, released a “manager’s package,” an amendment to S. 510 in the nature of a substitute.²⁸ Following the release of the proposed manager’s amendment, Senate floor action was widely anticipated. However, further action on the measure stalled. Among other things, Senator Tom Coburn objected to the projected cost of the measure.²⁹ Also, amendments to the Senate manager’s proposal were being considered, including a proposal by Senators Jon Tester and Kay Hagan to exempt certain small facilities from the proposed requirements under some circumstances. These and other proposed amendments are discussed in this report.

In November 2010, the Senate resumed consideration of its bill. A second substitute amendment to S. 510 (S.Amdt. 4715) was offered³⁰ and included modified provisions proposed by Senators Tester and Hagan, among other changes. This substitute amendment to S. 510 passed the Senate on November 30, 2010, with a recorded vote of 73-25. Among other prepared amendments, two amendments offered by Senator Coburn—one banning earmarks for three years and another substituting S. 510 with a separate food safety proposal—did not pass the Senate.

Following passage of the Senate bill, however, it was reported that the House may block the Senate bill using a procedure known as “blue-slipping,” because the bill contains fees that might be subject to certain tax origination provisions.³¹ In addition, Representative Dingell has expressed reservations about the Senate-passed bill’s lack of industry fees and about added provisions under the Tester-Hagan amendment.³²

²⁷ Two other comprehensive House bills were introduced by Representative Rosa DeLauro (H.R. 875) and by Representative Jim Costa (H.R. 1332).

²⁸ U.S. Senate Committee on Health, Education, Labor, and Pensions, “Senate Leaders Release Manager’s Package of the FDA Food Safety Modernization Act,” press release, August 12, 2010, <http://help.senate.gov/newsroom/press/>.

²⁹ Senator Tom Coburn, Unanimous Consent Request, S. 510, *Congressional Record*, daily edition, vol. 156 (September 23, 2010), pp. S7394-S7397.

³⁰ Senator Tom Harkin, “Proposed Amendment, S. 510,” *Congressional Record*, November 18, 2010, pp. S8069-S8093.

³¹ John Stanton, “House May Block Food Safety Bill Over Senate Error,” *Roll Call*, November 30, 2010. For more information on blue-slipping, see CRS Report RS21236, *Blue-Slipping: The Origination Clause in the House of Representatives*, and CRS Report RL31399, *The Origination Clause of the U.S. Constitution: Interpretation and Enforcement*.

³² Ellyn Ferguson, “Senate’s Food-Safety Bill Might Need Some Work, Dingell Says,” *CQ Today Online News*, November 30, 2010.

Overview of Major Provisions

Both the House- and Senate-passed bills focus primarily on FDA-regulated foods, and would achieve their proposed reforms through the agency's existing structure and authorities, in particular the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. §§ 301 *et seq.*).

Although differing somewhat in approach, both bills seek to address many of the same perceived problems with the current food safety system. For example, a growing consensus among industry and consumer groups is that the FDA's current programs are not proactively designed to emphasize prevention, evaluate hazards, and focus inspection resources on areas of greatest risk to public health.³³ Rather, FDA generally has been reactive, usually stepping in when adulterated or misbranded products are found in commerce or an illness outbreak leads them to a problem. Given FDA's funding and staffing constraints, and no explicit requirement for the frequency of inspections, the agency infrequently visits food manufacturing and other facilities to check sanitary and other conditions.³⁴

Both the House and Senate bills would require (although in different ways) food processing, manufacturing, shipping, and other regulated facilities to conduct an analysis of the most likely food safety hazards and to design and implement risk-based controls to prevent them. These proposals are similar conceptually to the so-called hazard analysis and critical control point, or HACCP, plans required of meat and poultry establishments. The bills envision the establishment of science-based "performance standards" for the most significant food contaminants. To aid in determining such risks and hazards, both bills propose the improvement of foodborne illness surveillance systems aimed at better data reporting, analysis, and usefulness, with the CDC playing a lead role.

Both bills seek to increase the frequency of plant inspections, taking into account the risks posed by specific foods or processes. To aid in such inspections, and to improve the ability to rapidly trace food products through the production and marketing chain in the event of a foodborne illness outbreak, suspected contamination, or other problems, the bills generally seek to strengthen record-keeping requirements and food traceability systems. Industry participants would be required to maintain records for certain time periods and in formats to be prescribed by FDA. The importance of adequate records has been demonstrated in recent food safety incidents, particularly in the case of outbreaks eventually linked to fresh produce. Food establishments, which are already subject to a one-time registration requirement under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188; 21 U.S.C. § 350d), would have to re-register more frequently under the bills, which ask for additional registration information. Also, the House-passed bill would require a \$500-per-facility annual registration fee.

The bills also appear to agree on the need to give FDA the authority to mandate product recalls if a firm with suspect products fails to do so voluntarily. Currently FDA lacks such authority for food, except for infant formula. However, the measures differ somewhat on how such authority might be applied, and on related requirements for notification when adulterated or misbranded food threatens public health.

³³ See, for example, Jerry Hagstrom, "Array of Groups Push Senate Action on Food Safety Bill," *CongressDailyAM*, September 21, 2010.

³⁴ See, for example, FDA, "Strategic Priorities 2011–2015: Responding to the Public Health Challenges of the 21st Century," draft, September 29, 2010, pp. 14-15, <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm227527.htm>.

Both bills contain extensive provisions for heightened scrutiny of imports, which have comprised an increasing share of U.S. food consumption. Food import shipments might newly have to be accompanied by documentation that they are from facilities and establishments certified as meeting safety standards at least equivalent to U.S. standards. Such certifications might be provided by foreign governments or other so-called third parties accredited in advance by an accrediting body recognized by FDA; again, the House and Senate bills differ in detail on how to accomplish these objectives. They also address the need for certifying or accrediting laboratories, including private laboratories, to conduct sampling and testing of food.

Provisions in the bills seek, in differing ways, to extend safeguards to the farm level, generally calling for new, science-based regulations for safe production mainly of fruits, vegetables, and related products, and expanding enforcement and record-keeping authorities.

A key difference between the two bills is how the proposed program changes would be funded. Specifically, the House-passed bill would institute a new \$500 annual facility registration fee that would help offset the cost of various FDA activities in the bill; a similar annual facility fee is not included in the Senate-passed bill, and other fees included in the Senate bill are not expected to raise as much revenue. The Congressional Budget Office (CBO) estimates that implementing H.R. 2749 (as reported by the Energy and Commerce Committee) would increase net federal spending subject to appropriation by about \$2.0 billion over a five-year period (FY2010-FY2014); federal revenues from civil penalties for food-related violations under the FFDCFA would increase by \$10 million over the same period.³⁵ CBO estimates that spending under S. 510 (reflecting the August 2010 Senate amendment) would increase net federal spending subject to appropriation by about \$1.4 billion over a five-year period (FY2011-FY2015); collections from possible revenue and direct spending increases from new criminal penalties would be “insignificant, yielding a negligible net impact in each year.”³⁶ Despite higher offsetting fee revenues proposed in the House bill, CBO scored higher net federal costs for the House bill than for the Senate bill due to higher costs in the House bill for FDA activities (principally related to facility inspections) that would not be supported by fees.

Another key difference between the two bills is the Senate bill’s addition of provisions that would exempt certain food processing operations from the proposed HACCP requirements and also would exempt certain farms from the new produce standards. Under the Senate-passed bill, farms and food facilities that would qualify for an exemption are those businesses with an “average annual monetary value” of all food sold during the previous three-year period of less than \$500,000, provided that the food is sold directly to “qualified end users” such as consumers, restaurants, or retail food establishments located in the same state where the facility sold the food or within 275 miles of the facility, among other requirements. In addition, although both the House and Senate bills clarify the types of businesses that should be considered to be “retail food establishments” and therefore generally not subject to the facility registration requirements, the Senate bill specifies that roadside stands, farmers’ markets, and foods sold through a community-supported agriculture (CSA) program would also not be subject to the requirements. Additional information on these provisions is provided later in this report.

³⁵ CBO, Cost Estimate, “H.R. 2749, Food Safety Enhancement Act of 2009 as ordered reported by the House Committee on Energy and Commerce on June 17, 2009,” July 24, 2009.

³⁶ CBO, Cost Estimate, “S. 510, Food Safety Modernization Act, as reported by the Senate Committee on Health, Education, Labor, and Pensions on December 18, 2009, incorporating a manager’s amendment released on August 12, 2010,” August 12, 2010.

Neither the House-passed nor the Senate-passed bill encompasses a major reorganization of food safety agencies. Both measures have provisions (§ 4 and § 403, respectively) to ensure that the jurisdiction between FDA and USDA would not be altered.³⁷

Table 1 provides a crosswalk of topics covered in this report and corresponding section numbers from the two major proposals. This table does not contain all of the topics or sections in the two proposals, only those included in the body of this report.

Table 1. Crosswalk of Food Safety Provisions
(House-passed H.R. 2749 and Senate-passed S. 510, by topic)

Topic	H.R. 2794 (House-passed)	S. 510 (Senate-passed)
Registration	101	102
Record-Keeping	106	101
Hazard Analysis and Risk-Based Preventive Controls	102	103, 114
Performance Standards	103	104
On-Farm Safety Standards; Safety of Produce	104	105
Mitigating Effects on Small Business and Farming Operations	101, 102, 104, 106, 107, 112	101, 102, 103, 105, 201, 204
Targeting of Inspections	105, 207	201, 306
Use of Third Parties for Imports and for Laboratory Accreditation	109, 110	202, 303
Mandatory Recall Authority	102, 105, 108, 111, 204	206
Notification of Contaminated Products and Product Tracing	107, 112	204, 211
Foodborne Illness Surveillance and Outbreak Response	121	205
Criminal Penalties	134	None
Food Imports	109, 113, 136, 204, 205, 206	301, 302, 303
Bisphenol A (BPA)	215	None
Paying for Food Safety with User Fees	101, 108, 203, 204	107, 401

Source: Prepared by CRS based on the text of the House-passed and Senate-passed bills (H.R. 2749 and S. 510).

Note: Terms in the “Topic” column are hyperlinked to corresponding sections in this report.

For a comprehensive listing of all sections and topics addressed in the two bills, see the two appendix tables at the end of this report. The first table, **Appendix A**, provides a snapshot of each section and topic covered by the proposals. It is arranged numerically by section of H.R. 2749, and then by those remaining sections of S. 510 that have no corollary in the House bill.

³⁷ Past debates have examined proposals to combine all federal food safety agencies and authorities under a single, possibly Cabinet-level, agency. For example, a bill introduced by Representative DeLauro bill (H.R. 875) proposed to transfer FDA’s food safety activities to a new food safety agency within HHS, creating a Food Safety Administration with an Administrator appointed to a five-year term by the President and confirmed by the Senate.

The second table, **Appendix B**, contains a side-by-side comparison of current law with provisions in the two proposals. **Appendix B** is arranged in the same order as **Appendix A**, so the latter can be used as a table of contents for the former. Topics in **Appendix B** are hyperlinked to corresponding sections of this report where they exist, so that readers can easily move from the side-by-side to related policy context and analysis.

Selected Issues

The following sections provide a discussion of the key provisions in H.R. 2749 and S. 510, as passed by their respective chambers. Unless otherwise noted, references to “the Secretary” mean the HHS Secretary.

Registration

Keeping Track of Food Facilities

The FFDCA already requires domestic and foreign food facilities to register with FDA, pursuant to provisions in P.L. 107-188, the Bioterrorism Act (FFDCA § 415; 21 U.S.C. § 350d). Excepted are farms, restaurants, retailers, and certain types of nonprofit food establishments and fishing vessels. Renewal is not required on any periodic basis, but registrants must notify the HHS Secretary in a timely manner of relevant changes in their status. The FFDCA (§ 801(l); 21 U.S.C. § 381(l)) provides that imported food may not be delivered to the importer, owner, or consignee of the article unless the foreign facility is registered. FDA does not have explicit authority to require a registration fee from domestic or foreign facilities.

Some assert that registration requirements should be strengthened so that authorities will be notified when a firm moves, undertakes a new food business, or changes product lines. Otherwise, FDA’s records of facilities that are manufacturing and marketing food are continually out of date, it is argued. Others have argued that additional registration requirements would be needlessly intrusive and costly for industry.

Legislative Proposals

The House-passed bill (§ 101) would require annual registration, and would deem foods from unregistered facilities to be misbranded, which therefore would prohibit such food from being introduced into, or delivered or received in, commerce. The bill would amend FFDCA § 415 to clarify (but not change) the types of facilities that would remain exempt from the registration requirement, explicitly defining “retail food establishment” and “farm.” It also would spell out additional types of information to be required of registrants. The bill also would provide procedures for the suspension of registration for “a violation of [the FFDCA] that could result in serious adverse health consequences or death to humans or animals,” and procedures for vacating such a suspension. Registration fees would be imposed (discussed later in this report).

The Senate-passed bill (§ 102) would require domestic and foreign facilities to register every two years, and to provide some additional types of contact information, with an abbreviated renewal process available to facilities with no change in status. The bill would provide procedures for the suspension of registration if the HHS Secretary “determines that food manufactured, processed, packed, received, or held by a facility registered under this section has a reasonable probability of

causing serious adverse health consequences or death to humans or animals.” It also would provide procedures, somewhat different from those in the House-passed bill, for vacating such a suspension. Facilities with suspended registrations would be barred from importing or introducing food into commerce. Importing or introducing such food into commerce would be prohibited, and subject to possible civil and criminal penalties and other enforcement actions. The bill would not change the current exemptions from the registration requirement for farms, restaurants, retailers, and certain types of nonprofit food establishments and fishing vessels. It also would not impose registration fees.

Both the House and Senate provisions clarify the types of facilities that would be included as a “retail food establishment”³⁸ and therefore generally would not be subject to the requirements. The Senate-passed bill would require the HHS Secretary to amend the definition of “retail food establishment” to include food sold directly to consumers by a roadside stand or farmers’ market, food sold through a community supported agriculture (CSA) program, or sale and distribution of food at any other such direct sales platform as determined by the Secretary (§ 102(c)). The House-passed bill specifies that a “retail food establishment” would include an establishment that, as its primary function, “sells food products (including those food products that it manufactures, processes, packs, or holds) directly to consumers (including by Internet or mail order),” and also would include grocery stores, convenience stores, vending machine locations, and stores that sell bagged feed, pet food, and feed ingredients or additives over the counter directly to consumers and final purchasers for their own personal animals.

Record-Keeping

Should Documentation Requirements and Access to Records Be Strengthened?

Pursuant to provisions in P.L. 107-188, the Bioterrorism Act (FFDCA § 414; 21 U.S.C. § 350c), the FFDCA authorizes the HHS Secretary to impose record-keeping requirements on domestic and foreign food facilities (except farms and restaurants), and to inspect and copy such records “[i]f the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.” The Secretary must take appropriate measures to ensure that unauthorized disclosure of any trade secret or confidential information is prevented. Through rulemaking, the Secretary has required facilities to maintain records that allow for the identification of the immediate previous sources and immediate subsequent recipients of food.³⁹

Advocates of food safety reform often argue that record-keeping requirements must be strengthened to help regulators determine whether firms are complying with the law, and to facilitate outbreak investigations and product recalls. Among their concerns is that records do not have to be maintained in electronic format, which, these advocates assert, delays outbreak response. Related concerns include the types and level of detail of records to be kept, how long they should be retained, and access to and use of these records by authorities. For example, is the current “trigger” for accessing records (quoted above) too stringent to assure food safety, too permissive to protect industry interests, or appropriately balanced between the two? Concerns

³⁸ 21 C.F.R. 1.227(b)(11).

³⁹ FDA, “Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002,” 69 *Federal Register* 71561, December 9, 2004. Facilities are required to retain records for specified periods of time, up to a maximum of two years, depending on the type of food.

about increased record-keeping requirements and access authority often involve concerns about the intrusiveness of government, as well as about privacy and the protection of sensitive commercial information (trade secrets), for example.

Legislative Proposals

The House-passed bill (§ 106) would expand the Secretary’s authority to inspect and copy relevant records of a food facility in order to determine whether a food is adulterated or misbranded, by removing the requirement that the Secretary have “a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.” Removing this requirement would authorize access to records during routine inspections. The bill also would remove the requirement to provide written notice before having such access, and would authorize the Secretary to require that records be kept for up to three years and be maintained in a standardized electronic format. Farms would generally remain exempt from the requirement to provide access to records unless the Secretary determined, with respect to specified commodities, that such commodities posed a risk to public or animal health, or were the subject of an active investigation of a foodborne illness outbreak. Restaurants would be required to provide access to records, but would only have to keep records regarding their suppliers and any subsequent distribution other than to consumers.

The Senate-passed bill (§ 101) would expand the Secretary’s authority to inspect and copy relevant records of a food facility in two ways, but would not appear to authorize access during routine inspections, as would the House-passed bill. The bill would require that access be provided to the HHS Secretary if he or she “has a reasonable belief that an article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, is adulterated and presents a threat of serious adverse health consequences or death to humans or animals,” or if the Secretary “believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals.” The Secretary would have greater flexibility under the second provision, no longer having to have a reasonable belief that food is adulterated in order to access records. The Secretary also would be allowed access to records regarding foods likely to be affected in a similar manner, but would need to believe there is at least a risk of harm. Unlike the House bill, farms and restaurants would (as under current law) be fully exempt from this provision. For other facilities, written notification would still be required to gain access.

(See the subsequent section on “Notification of Contaminated Products and Product Tracing.”)

Hazard Analysis and Risk-Based Preventive Controls

Reactive vs. Preventive Intervention

A broad consensus of policymakers agrees that FDA’s system of food safety safeguards should be more proactive in addressing the nation’s complex food supply.⁴⁰ By and large, the agency’s statute and regulations spell out the reasons a food article is to be considered adulterated or

⁴⁰ Emily Ethridge, “Food Safety Bill Advances,” *CQ Markup and Vote Coverage*, Senate Health, Education, Labor and Pensions Committee Markup of S. 510, November 18, 2009.

misbranded and therefore unfit for consumption. In effect, industry players are expected to abide by the rules; generally it is only when a problem is detected—often after an illness outbreak is reported or testing finds a contaminant in a product—that officials step in to correct it, or order the industry to do so.

A recurring theme now in discussions of food safety modernization is prevention. Virtually all stakeholders, including regulators, the regulated industries, consumer advocates, and food safety scientists agree that the foundations of any new program should be an understanding of what, and how, hazards can enter the food supply, followed by implementation of measures to prevent these hazards.⁴¹ A popular version of this approach is the so-called HACCP system, which many private companies already use, and which was incorporated in the 1990s by FSIS as a regulatory requirement for all meat and poultry slaughtering and processing establishments.⁴² Variations of the HACCP system also are required by FDA in the processing of seafood, juices, and low-acid canned foods, but not other product categories.

Committees of the National Academy of Sciences' National Research Council (NAS-NRC) have, in a number of reports, recommended the HACCP approach for food safety. For example, its Committee on the Review of the Use of Scientific Criteria and Performance Standards for Safe Food stated at the outset of a 2003 report:

The balance of progress in reduction of certain human foodborne illnesses following implementation of [HACCP] in various areas of the food industry is decidedly favorable.... The committee believes that the emphasis of food safety regulatory agencies must continue to be on prevention, reduction, or elimination of foodborne hazards along the food continuum.⁴³

The National Advisory Committee on Microbiological Criteria for Foods, established to offer ongoing advice to the FDA and USDA, agreed with the NAS-NRC recommendations, which have dated at least to the early 1990s. The advisory committee also noted that HACCP principles should be standardized to provide uniformity in training and applicability, but also must be developed by each food establishment so they can be tailored to individual products, processing, and distribution conditions.⁴⁴

Legislative Proposals

The House and Senate bills (§ 102 and § 103, respectively) contain somewhat similar provisions requiring each owner, operator, or agent of a facility to evaluate the hazards that could affect food manufactured, processed, packed, transported, or held there; identify and implement preventive

⁴¹ Testimony of Margaret A. Hamburg, FDA Commissioner, before the U.S. Senate Committee on Health, Education, Labor, and Pensions, October 22, 2009; Committee on the Review of the Use of Scientific Criteria and Performance Standards for Safe Food, National Research Council, *Scientific Criteria to Ensure Safe Food*, National Academies Press, 2003; Center for Science in the Public Interest (CSPI), "Building a Modern Food Safety System for FDA Regulated Foods," May 2009; Consumers Union, August 1, 2008, letter to the U.S. House of Representatives.

⁴² Savage, Robert A. and Daniel Lafontaine, "HACCP Principles: Benchmark for Food Safety," *Food Quality* magazine, February/March 2010, <http://www.foodquality.com/>. Also see CRS Report RL32922, *Meat and Poultry Inspection: Background and Selected Issues*.

⁴³ Committee on the Review of the Use of Scientific Criteria and Performance Standards for Safe Food, National Research Council. *Scientific Criteria to Ensure Safe Food*, National Academies Press, 2003.

⁴⁴ National Advisory Committee on Microbiological Criteria for Foods, *Hazard Analysis and Critical Control Point Principles and Application Guidelines*, adopted August 14, 1997.

controls to significantly minimize, prevent, or eliminate such hazards; and monitor and maintain records on these controls once they are in place. The bills further specify types of hazards that should be evaluated, and they require facilities to conduct a re-analysis at specified intervals, and to maintain at least two years of records to document and verify their control measures, among other details (which differ somewhat between the bills, with the House version appearing to be somewhat more prescriptive). Written HACCP-type and/or broader written food safety plans containing HACCP requirements are also elements of the bills. Under the House-passed bill, higher-risk facilities must submit test results when finished products are found to contain contaminants “posing a risk of severe adverse health consequences or death” (although there are some limitations on the extent of the Secretary’s authority). The Senate-passed bill contains requirements regarding available FDA guidance documents for seafood (see § 114 and § 103) that are not in the House-passed bill.

In addition, the Senate bill would exempt some facilities from the requirements under certain conditions, as discussed in more detail in the section titled “Mitigating Effects on Small Business and Farming Operations.”

Performance Standards

Can Safety Be Better Measured?

Performance standards typically are specific, quantitative measurements of a property of, or a substance in, food that are selected to serve as benchmarks for whether the food is safe in a broader sense. For example, a microbial performance standard could be used to determine whether a product is contaminated with microbes in general, and whether a problem with the product’s processing should be investigated and corrected. The NAS-NRC standards committee reported that a common theme of regulatory performance standards is “to provide clear articulation of what is and is not acceptable in the process or system being regulated.”⁴⁵ The committee added that regulators like the FDA, USDA, and the Environmental Protection Agency (EPA) have employed specific standards for diverse reasons and conditions and based on numerous scientific, legal and practical constraints, including:

tolerances (which set legal limits) on the presence of chemicals in food, prohibitions on specific microbial pathogens in specific foods, standards for process control, and standards defining the acceptable outcome of a food process for reducing pathogenic contamination. All of these are performance standards in the sense that they define what must be achieved in controlling risk factors for food safety.⁴⁶

The FFDCA does authorize FDA to promulgate standards for certain hazards, such as tolerances for pesticide or drug residues in foods, but does not grant explicit authority to develop standards solely as a means to verify that processing is done in a manner that ensures safe food.⁴⁷

⁴⁵ Committee on the Review of the Use of Scientific Criteria and Performance Standards for Safe Food, National Research Council, *Scientific Criteria to Ensure Safe Food*, National Academies Press, 2003, p. 16.

⁴⁶ *Ibid.*, p. 17.

⁴⁷ FSIS in 1996 had established two performance standards to verify the microbial safety of meat and poultry products as part of its HACCP regulation. FSIS’s efforts to take enforcement action for violations of its standard upper limit for *Salmonella* contamination were constrained by a successful legal challenge, but it still interprets noncompliant *Salmonella* test results as a HACCP violation rather than a specific violation of the standard. For more information see (continued...)

Legislative Proposals

The House and Senate bills both include language on performance standards (§ 103 and § 104, respectively). Although differing in detail, both bills would amend the FFDCa to require the HHS Secretary to, at least every two years, review and evaluate epidemiological data, health data, or other information to identify the most significant hazards and to issue guidance or regulations on science-based performance standards to significantly minimize, prevent, or eliminate such hazards. Such standards must be specific to products or product classes, not individual facilities. The Senate provisions would place conditions on the issuance of standards, requiring them to be “[b]ased on such review and evaluation, and when appropriate to reduce the risk of serious illness or death to humans or animals or to prevent the adulteration of food” under the FFDCa. The Senate bill further requires that this review and evaluation of “health data and other relevant information” be conducted in coordination with USDA. The House-passed bill says such issuance shall be “as soon as practicable” and “as appropriate, to minimize to an acceptable level, prevent, or eliminate the occurrence of such hazards.”

On-Farm Safety Standards; Safety of Produce

Should Agricultural Producers Get More Scrutiny?

Food safety experts agree that an effective, comprehensive food safety system should include consideration of potential hazards at the farm level. Viewpoints diverge on whether this should be mandatory or voluntary. Should farmers and ranchers be subject to mandatory safety standards, enforced through certification of their practices, periodic inspections, and penalties for noncompliance? Or, should public policy continue to encourage voluntary strategies for producing safe foods on farms and ranches, through education, cooperation, and market-based incentives? Historically, the federal and state governments have largely relied on the latter approach. In addition, numerous existing laws and regulations already impose restrictions, both direct and indirect, on producers of food commodities; these restrictions involve compliance costs and are intended to meet certain food safety objectives. They include requirements on the use of animal drugs, feed additives, and pesticides.

FDA’s “current good manufacturing practice” (CGMP) requirements (at 21 C.F.R. Part 110) apply to manufacturing, packing, or holding human food, but establishments engaged solely in harvesting, storing, or distributing raw agricultural commodities generally are excluded.⁴⁸ Farms are among those exempted from a requirement that food facilities be registered with FDA, pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.⁴⁹ Further, the FFDCa specifically exempts farms (and restaurants) from requirements to maintain records for up to two years for purposes of identifying “immediate previous sources and the immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals,” and to permit

(...continued)

CRS Report RL32922, *Meat and Poultry Inspection: Background and Selected Issues*.

⁴⁸ 21 C.F.R. 110.19(b). The FFDCa at 21 U.S.C. § 321(r) defines a “raw agricultural commodity” as “any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.”

⁴⁹ P.L. 107-188; 21 U.S.C. 350(d).

officials access to these records if a food is suspected of being adulterated and presenting a serious health threat.⁵⁰

FDA's general approach has been not to impose mandatory on-farm safety standards or inspections of agricultural facilities.⁵¹ Rather, the agency tends to rely on farmers' adoption of so-called good agricultural practices to reduce hazards prior to harvest. Such practices are issued as FDA guidance, not regulations.⁵² In July 2009, the Obama Administration released new draft guidances on three specific types of produce: tomatoes, melons, and leafy greens.⁵³ However, FDA's final rule (effective July 2010) requiring shell egg producers to implement on-farm safety measures to prevent contamination of eggs by *Salmonella* Enteritidis (SE) is one example of FDA regulatory activity on-farm.⁵⁴

Legislative Proposals

Several provisions in the House- and Senate-passed bills could potentially affect agricultural producers, including smaller farms and food processors, as well as organic, direct-to-market, and sustainable farming operations. The provisions that could have the most direct effect on on-farm activity, especially produce growers, would be the establishment of new standards for produce safety (§ 104 and § 105, respectively).

The House-passed bill would require the Secretary, in consultation with the Secretary of Agriculture, to publish a notice of proposed rulemaking, and within three years after such date, final rules, establishing scientific and risk-based standards for the safe growing, harvesting, processing, packing, sorting, transporting, and holding of those types of raw agricultural commodities that are a fruit, vegetable, nut, or fungus, and for which the Secretary has determined such standards are reasonably necessary to minimize the risk of serious adverse health consequences or death to humans or animals. The House-passed bill states that these regulations could set forth procedures and practices that the Secretary determines to be reasonable to prevent

⁵⁰ 21 U.S.C. 350c and 21 U.S.C. § 374. Dr. Andrew C. von Eschenbach, FDA Commissioner, observed that produce farms generally do pack and hold food for introduction into interstate commerce, so it can and does inspect them periodically, usually in areas associated with illness outbreaks or to conduct surveillance sampling. Source: U.S. Congress, House Committee on Appropriations, Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, *Appropriations for 2008*, 110th Cong., 1st sess., February 28, 2007 (Washington: GPO, 2007), pp. Part 5, p. 479.

⁵¹ The FDA advisory panel acknowledged that “[t]he Agency conducts no inspections of retail food establishments or of food-producing farms.” *FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology*, November 2007, p. 21.

⁵² Most FDA guidance documents include the following: “FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.” Sources: FDA, *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens*, Draft Guidance, July 2009; and FDA, *Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables*, February 2008.

⁵³ FDA, *Guide to Minimize Microbial Food Safety Hazards of Tomatoes*, *Guide to Minimize Microbial Food Safety Hazards of Melons*, and *Guide to Minimize Microbial Food Safety Hazards of Leafy Greens*. Available at FDA’s website: <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/default.htm>. 74 Federal Register 38437-38440, August 3, 2009. See also FDA, “FDA Issues Draft Guidances for Tomatoes, Leafy Greens and Melons,” July 31, 2009.

⁵⁴ FDA, “Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation; Final Rule,” 74 Federal Register 33029, July 9, 2009. See also FDA, “Egg Safety Final Rule,” <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/EggSafety/EggSafetyActionPlan/ucm170615.htm>.

known or reasonably foreseeable biological, chemical, and physical hazards, including natural ones, that may be intentionally or unintentionally introduced. These regulations could include minimum safety standards, and address manure use, water quality, employee hygiene, sanitation and animal control, and temperature controls, as the Secretary determines to be reasonably necessary. They may provide for coordination of education and enforcement activities and must provide a reasonable time for compliance, taking into account the needs of small businesses for additional time, among other permitted activities. The Secretary would be required to take into consideration (consistent with public health) “the impact on small-scale and diversified farms, and on wildlife habitat, conservation practices, watershed-protection efforts, and organic production methods” (§ 104(b)(7)).

The Senate-passed bill also focuses on fresh produce, by requiring within one year proposed regulations for the safe production, harvesting, handling and packing of those fruits and vegetables (that are raw agricultural commodities) for which the HHS Secretary has determined that such standards minimize the risk of serious adverse health consequences or death. Required contents of the regulations do not appear to be as prescriptive as in the House-passed bill. The Senate bill would encourage coordination with USDA and would require, as appropriate, coordination with state agricultural agencies when enforcing standards. Enforcement could be in the form of audit-based verification systems or other inspection methods. The bill includes language to enable a state or foreign government to request a variance from HHS if needed to account for local growing conditions. It would also require that any standards address growing, harvesting, sorting, and storage; soil amendments, hygiene, packaging, temperature controls, animal encroachment and water; and that the Secretary convene at least three public meetings to seek input on the proposals.

In addition, the Senate bill would exempt some farms from the requirements under certain conditions, as discussed in the next section, “Mitigating Effects on Small Business and Farming Operations”.

Mitigating Effects on Small Business and Farming Operations

How Might Food Safety Proposals Affect Small Farms and Food Businesses?

Concerns among farm and rural groups about the potential effects of new food safety requirements on farms and food processors surfaced early in the debate over how to reform U.S. food safety laws. Most vocal were small farms and processors; organizations representing small, organic, direct-to-market, and sustainable farming operations; and small livestock operations.⁵⁵ At issue is whether numerous proposed requirements would be more costly and burdensome to small farms and other small businesses than could be justified by the potential public health protections such requirements are intended to provide.

Considerations for small business could take many forms, including waiving certain requirements, providing additional time for compliance, providing grants and/or technical assistance to aid in compliance, and exempting certain types of businesses from meeting the requirements. Currently the FFDCFA exempts some types of businesses from certain food safety requirements. For example, farms, restaurants, other retail food establishments, and certain

⁵⁵ See CRS Report RL34612, *Food Safety on the Farm: Federal Programs and Legislative Action*.

nonprofit food establishments and fishing vessels are exempt from facility registration requirements under FFDCA § 415.

Various approaches might be used to define whether a farm or food processor is a “small” business. Often, a definition may be based on a particular threshold value for a financial or business measure, such as annual income or value of sales, numbers of employees, or other measures.

With respect to farming operations, USDA typically relies on measures of *gross cash income* as a measure of the size of a farm business. Gross cash income refers to the sum of all receipts from the sale of crops, livestock, and farm-related goods and services, including any direct payments from the government. For purposes of classifying farms, USDA defines a “small commercial farm” as an operation with gross cash income of \$10,000 to less than \$250,000 annually; “large farms” are defined as farms with gross cash income of \$250,000 to less than \$1 million.⁵⁶ USDA defines farms with gross cash income of less than \$10,000 annually as very small, non-commercial farms. Under these definitions, USDA data indicate that about one-third of all crop and livestock producers are considered “small commercial” farms (**Table 2**). The share of small commercial farms will vary depending on commodity. For example, among fruit and vegetable producers who might be affected by requirements under the House and Senate food safety measures, the share of small commercial farms is roughly 10% of all growers in this category.⁵⁷

The size threshold used and the type of income counted to define a small business varies in legislation and by agency. For example, the Small Business Administration (SBA) has set different thresholds for defining a small business that vary considerably from USDA: among most crop and livestock producers, SBA defines as a small business those who make no more than \$750,000 in sales per year.⁵⁸ In some cases, however, USDA uses SBA’s definition for defining a small business. Specifically, SBA’s threshold of \$750,000 in annual sales is used by USDA to determine small and very small meat and poultry plants as part of FSIS’s outreach and oversight activities under its HACCP implementation and laboratory testing programs.⁵⁹ Under SBA’s business size standards, more facilities would be considered small businesses, with up to one-half of all commercial crop and livestock producers defined as small.⁶⁰

⁵⁶ Hoppe, R.A., “U.S. Farm Structure: Declining—But Persistent—Small Commercial Farms,” *Amber Waves*, USDA, September 2010; and Hoppe, R.A., *Small Farms in the United States: Persistence Under Pressure*, EIB-63, USDA, February 2010. Based on 2007 survey data.

⁵⁷ *Ibid.*, Figure 3.

⁵⁸ Small Business Size Regulations, Title 13 C.F.R. Part 121.

⁵⁹ Correspondence between CRS personnel and askFSIS (<http://www.fsis.usda.gov/>).

⁶⁰ Based on data on farms that make up to \$1 million. USDA survey data are not published for farms that generate between \$500,000 and \$750,000 in annual sales.

Table 2. U.S. Farms and Food Manufacturers, 2007
(by size based on average annual sales receipts)

Farms and Food Manufacturing Establishments	Number	Percent
All Farms, Total	2,204,792	100.0%
Less than \$10,000 (defined by USDA as “very small, non-commercial” farms)	1,271,735	57.7%
Between \$10,000-\$249,000 (defined by USDA as “small commercial” farms)	715,947	32.5%
Between \$250,000-\$499,000	96,251	4.4%
More than \$500,000	120,859	5.5%
All Food Manufacturing, Total^a		
Total, All Food Manufacturers	25,796	100.0%
Less than \$500,000	8,906	34.5%
Selected Food Manufacturing Sectors^b		
Grain and Oilseed Milling, Total	830	100.0%
Less than \$500,000	71	8.6%
Fruit/Vegetable Manufacturing, Total	1,668	100.0%
Less than \$500,000	203	12.2%
Dairy Product Manufacturing, Total	1,612	100.0%
Less than \$500,000	174	10.8%
Animal Slaughtering and Processing, Total	3,817	100.0%
Less than \$500,000	784	20.5%
Seafood Preparation/Packaging, Total	685	100.0%
Less than \$500,000	114	16.6%
Bakeries/Tortilla Manufacturing, Total	10,269	100.0%
Less than \$500,000	5,835	56.8%
Other Food Manufacturing, Total	3,310	100.0%
Less than \$500,000	671	20.3%

Source: Data for farms are from USDA, *2007 Census of Agriculture*, Table 58, December 2009. Data for manufacturing establishments are from the U.S. Census Bureau’s *2007 County Business Patterns* based on annual survey data for all food manufacturers on the number of establishments by “enterprise receipt size,” <http://www.census.gov/econ/sub/>.

Notes: “Average annual sales” includes market value of agricultural products sold and government payments. Farm size designations are those described by USDA in *Small Farms in the United States: Persistence Under Pressure*, EIB-63, February 2010, <http://www.ers.usda.gov/publications/eib63/>. For manufacturing, industry classification is based on 2002 North American Industry Classification System (NAICS) codes.

- a. Included in this total, but not shown separately are data for sugar and confectionery and animal food manufacturing.
- b. Ranked in order by NAICS code but including sugar and confectionery and animal food manufacturing.

Elsewhere in farm legislation, such as in the periodic omnibus farm bill,⁶¹ *adjusted gross income (AGI)* is an alternative income measure that is generally used to differentiate farm size. AGI is a common measure of income for tax purposes, combining income from all sources. Business income contributes to AGI on a net basis, that is, after business expenses. Thus, it is comparable to profit: sales minus expenses and also taxable deductions. In the farm bill, an AGI limit is used to differentiate wealthier farm households as a means test for the maximum amount of income that an individual can earn and still remain eligible for commodity program benefits, including any direct payments from the government. The 2008 farm bill tightened these limits by reducing the AGI limit to \$500,000 of non-farm AGI and \$750,000 of farm AGI.⁶² Given that most business information is proprietary, data are limited on the share of commodity producers (farms and food processors) that have an annual AGI of less than \$500,000. Information for U.S. farms indicates that farms with less than \$500,000 AGI account for more than 95% of all farms.⁶³

Data are not available indicating what share of all farms also engage in food processing. Such operations might include fruit and vegetable producers that pack or further process the produce they grow by making products such as jams, jellies, or juices, or other processed fruit and vegetable products; other examples might include dairies that are also producer-handlers that bottle their own milk. Also, only limited data are available that generally characterize the market and producer channels for so-called locally or sustainably produced foods, or other direct-to-market foods.⁶⁴

For food processors and manufacturers, often different business measures are used to define small businesses. SBA definitions of small food processors are based on the number of employees at a business. Given that most farms do not employ large numbers of workers, size standards based on the number of employees are generally not applicable to farming operations. Among most food processors, a small business is defined by the SBA as a business with no more than 500 employees.⁶⁵ By this definition, nearly all (97%) of all food processors would be considered small businesses based on U.S. Census Bureau data.⁶⁶ The U.S. Census Bureau also tabulates data for manufacturing facilities based on annual sales receipts (**Table 2**).

FDA regulations also define certain small food processing businesses, but they are case by case and not inclusive. For example, FDA's current HACCP regulations exempt "small" juice processors as those "employing fewer than 500 persons."⁶⁷ Accordingly, available data indicate that as many as 84% of businesses that make juice are not covered by the HACCP requirements.⁶⁸

⁶¹ The most recent farm bill was the Food, Conservation, and Energy Act of 2008, P.L. 110-246. For more information, see CRS Report RL34594, *Farm Commodity Programs in the 2008 Farm Bill*.

⁶² *Ibid.*

⁶³ The White House, "Strengthening the Rural Economy—Improving America's Support of Agriculture," <http://www.whitehouse.gov/administration/eop/cea/factsheets-reports/strengthening-the-rural-economy/improving-americas-support-of-agriculture>. Based on USDA data from the 2007 Department of Agriculture's Agricultural Resource Management Survey: <http://www.ers.usda.gov/Briefing/FarmIncome/govtpaybyfarmtype.htm>.

⁶⁴ See for example Martinez, S. et al., *Local Food Systems, Concepts, Impacts, and Issues*, ERR-97, USDA, May 2010, <http://www.ers.usda.gov/Publications/ERR97/ERR97.pdf>; and Hoppe, R.A. et al., *Small Farms in the United States, Persistence Under Pressure*, EIB-63, USDA, February 2010, <http://www.ers.usda.gov/Publications/EIB63/EIB63.pdf>.

⁶⁵ Small Business Size Regulations, Title 13 C.F.R. Part 121.

⁶⁶ Based on annual survey data for all food manufacturers on the number of firms broken out by employment size of the enterprise. U.S. Census Bureau, *2007 County Business Patterns*, <http://www.census.gov/econ/sub/>.

⁶⁷ Hazard Analysis And Critical Control Point (HACCP) Systems, Title 21 C.F.R. Part 120.

⁶⁸ U.S. Census Bureau, *2007 County Business Pattern*. Data for "Frozen Fruit, Juice, and Vegetable Manufacturing."

Very small businesses are also exempt, and so defined by FDA if they meet one of the following three criteria: “annual sales of less than \$500,000, total annual sales greater than \$500,000 but total food sales less than \$50,000, or operations that employ fewer than an average of 100 full-time equivalent employees and sell fewer than 100,000 units of juice in the United States.”⁶⁹ Available data indicate that about 12% of all fruit and vegetable manufacturers have annual sales less than \$500,000 (**Table 2**). Producers of “raw agricultural ingredients of juice,” such as fruit and vegetable growers, are not covered by the HACCP requirements.

Legislative Proposals

Although both the House- and Senate-passed bills contain requirements that might affect small business and farming operations, both bills also seek to take into account the needs of small businesses and provide for coordination of enforcement and education activities with others such as USDA and state authorities.

Several provisions in the House and Senate bills could potentially affect agricultural producers, including smaller farms and food processors, as well as organic, direct-to-market, and sustainable farming operations. The provisions that could have the most direct effect on on-farm activity, especially produce growers, concern the establishment of new standards for produce safety (§ 104 and § 105, respectively). In addition, both bills would require the issuance of updated good agricultural practices. Other bill provisions that could potentially affect small businesses and farming operations include facility registration requirements (§ 101 of the House-passed bill; § 102 of S. 510); records access and/or inspection requirements (§ 106 of H.R. 2749; § 101 and § 204 of S. 510); food traceability requirements (§ 107 of H.R. 2749; § 204 of S. 510); hazard analysis and risk-based preventive controls (§ 103 of S. 510); targeting of inspection resources (§ 201 of S. 510); and changes in the reportable food registry (§ 112 of H.R. 2749). For more information, see CRS Report RL34612, *Food Safety on the Farm: Federal Programs and Legislative Action*.

The extent to which these other provisions might actually affect small business and farming operations remains unclear, since the specific business requirements under these provisions would be subject to agency rulemaking. In addition, what constitutes a “small” and a “very small” business would be “as defined by the [HHS] Secretary” (see, for example, § 102 of the House-passed bill, and §§ 103, 105, and 204 of S. 510).

The House-passed bill contains additional provisions intended to address potential effects of the food safety requirements on small, organic, direct-to-market, and sustainable farming operations. In particular, it would exempt from the facility registration requirements most commodity producers that sell directly to consumers, including an “operation that sells food directly to consumers if the annual monetary value of sales of the food products from the farm or by an agent of the farm to consumers exceeds the annual monetary value of sales of the food products to all other buyers” (§ 101(b)(1)). The House-passed bill also would require that any regulations governing performance standards “take into consideration, consistent with ensuring enforceable public health protection, the impact on small-scale and diversified farms, and on wildlife habitat, conservation practices, watershed-protection efforts, and organic production methods” (§ 104(b)).

⁶⁹ Hazard Analysis And Critical Control Point (HACCP) Systems, Title 21 C.F.R. Part 120.

S. 510 was first modified by the Senate HELP Committee to require that the HHS Secretary “provide sufficient flexibility to be applicable to various types of entities engaged in the production and harvesting of raw agricultural commodities, including small businesses and entities that sell directly to consumers, and be appropriate to the scale and diversity of the production and harvesting of such commodities” (§ 103 and § 105, among other sections). Other committee modifications required consideration of federal conservation and environmental standards and policies including wildlife conservation, and assurances that these provisions will not conflict with or duplicate those of the national Organic Foods Production Act (also § 105). These provisions were retained in the Senate’s August 2010 manager’s amendment to S. 510.

The Senate manager’s amendment of August 2010 included additional modifications to address the potential effects of the food safety requirements on small business and other farming operations. These included allowances for HHS to exempt or limit compliance requirements for certain types of farming operations and food processors, along with provisions that would allow the HHS Secretary the discretion to exclude certain operations, if it is determined that these are low risk and/or do not present a risk of “serious adverse health consequences or death.” Also included were assurances that any new regulations would not conflict with or duplicate other federal policies and standards, and that they would minimize regulatory burden and unnecessary paperwork and the number of separate standards imposed on the facility (for example, the registration, HACCP, produce standards, and traceability requirements in §§ 101, 103, 105, and 204). In addition, HHS would be required to publish “small entity compliance policy guides” to assist small entities in complying with some proposed requirements, such as those regarding registration, HACCP, produce standards, and traceability. Implementation would be delayed for small and very small businesses (as defined by the Secretary) for the HACCP and produce standards requirements, and there would be assurances of “sufficient flexibility” for producers, including small businesses and entities that sell directly to consumers, for the HACCP, produce standards, and traceability provisions.

Despite these additional modifications, Senator Jon Tester continued to push for further amendments to address small farm interests. Senator Tester had first announced in spring 2010 that he planned to introduce two amendments to the Senate committee-reported bill, S. 510.⁷⁰ Under one amendment, certain commodity producers would face limited traceback and record-keeping requirements if the “average annual adjusted gross income [AGI] of such facility for the previous 3-year period is less than \$500,000”; another amendment would have exempted producers who sell directly to market if “the annual value of sales of food directly to consumers, hotels, restaurants, or institutions exceeds the annual value of sales of food to all other buyers.”⁷¹ These amendments were not included in the Senate manager’s amendment of August 2010.

In September 2010, Senator Tester, along with Senator Kay Hagan, announced an updated version of this amendment.⁷² The modified Tester-Hagan amendment would establish “modified requirements for qualified facilities” for so-called “very small” businesses, among other provisions for both small and very small businesses (to be defined by HHS in regulation). Under

⁷⁰ Senator Tester press release, “Tester to Introduce ‘Common Sense’ Amendments to Food Safety Bill,” April 14, 2010, http://tester.senate.gov/Newsroom/pr_041410_foodsafety.cfm (bill language is posted at website).

⁷¹ *Ibid.*

⁷² Press release, Senator Tester, “Updated Food Safety Amendment Protects Small Producers,” September 24, 2010, http://tester.senate.gov/Newsroom/pr_092410_foodsafety.cfm. Bill language is available at <http://tester.senate.gov/Legislation/upload/Tester-Food-Safety-Amendment.pdf>.

this proposed amendment, certain qualified facilities would not be subject to certain food safety requirements; instead they would be required to submit to HHS relevant documentation showing that they have implemented preventive food safety controls and evidence that they are in compliance with state, local, county, or other applicable non-federal food safety laws, among other documentation. Such modified requirements would apply to producers considered “very small” and would include operations that have annual sales of less than \$500,000 (defined not as AGI, but as the three-year average “annual monetary value of sales,” adjusted for inflation) and whose value of sales directly to “qualified end-users” *exceeds* all other sales. Qualified end-users would include consumers or a restaurant or retail food establishment that is located in the same state or less than 400 miles⁷³ from the qualified facility, or that is buying food for sale directly to consumers. Implementation deadlines would also be delayed for small and very small businesses, following promulgation of any applicable regulations under the newly enacted law. The provision also would require that HHS conduct a study of the food processing sector, in conjunction with USDA.

During the Senate floor debate in November 2010, a modified version of this amendment was adopted as part of the substitute Senate amendment (S.Amdt. 4715) to S. 510. This version was passed off the Senate floor on November 30, 2010. Consequently, the Senate-passed bill would exempt certain food processing operations from the proposed HACCP requirements and also would exempt certain farms from the new produce standards. Food facilities would qualify for an exemption from the HACCP requirements under § 103 if they are either a “very small business” as defined by FDA in rulemaking, or if the facility’s “average annual monetary value” of all food sold during the previous three year period was less than \$500,000, provided that the food is sold directly to “qualified end users” such as consumers, restaurants, or retail food establishments located in the same state where the facility sold the food or within 275 miles of the facility. Such a facility would need to demonstrate that it either has “identified potential hazards associated with the food being produced,” and is implementing and monitoring these preventive controls, or that it is “in compliance with State, local, county, or other applicable non-Federal food safety law.” Foods produced from such a facility would also need to provide the facility’s name and address on a food packaging label or at the point of purchase.

Farms that would be exempt from the produce standards under § 105 also include those with a three-year average monetary value of the food they sold of less than \$500,000, provided that the food is sold directly to the similarly defined “qualified end users” and if the farm provides similar notification to consumers. The exemption for both facilities and farms may be revoked in the event that a foodborne illness outbreak is directly linked to an exempted facility or farm, or based on a determination by the HHS Secretary.

In addition, as discussed in the “Registration” section, although both the House and Senate bills clarify the types of businesses that should be considered to be “retail food establishments” and therefore generally not subject to the facility registration requirements, the Senate bill specifies that roadside stands, farmers’ markets, and foods sold through a community-supported agriculture (CSA) program would also not be subject to the requirements.

⁷³ The 400-mile designation is similar to the distance specified in a provision of the Food, Conservation, and Energy Act of 2008 (P.L. 110-246, Section 6015). That provision defines a “Locally or Regionally Produced Agricultural Food Product” as any agricultural food product that is grown, produced, and distributed near where it is marketed such that “the total distance that the product is transported is less than 400 miles from the origin of the product.”

It is not possible to estimate what share of all food processing operations might be exempt from the proposed HACCP requirements, how many farms might be exempt from the new produce standards, or how other small business considerations might possibly mitigate the effects of these and other requirements in the proposal. In part, this is because the definition of small and very small business would be determined by HHS in future agency rulemaking and subject to other requirements specified in the measures. Even though farms would continue to be exempt from the proposed facility registration requirements, there are farms that also engage in food processing that might be affected. Data are not available to determine what share of farms also engage in food processing. In addition, other stipulations in S. 510 would require that foods be sold locally and to certain qualified end-users. Data are also not available to determine what share of grower-processors might qualify for such an exemption; such a determination would likely be made on a case-by-case basis.

Throughout this debate, many farm groups have expressed support for the Tester-Hagan amendment.⁷⁴ However, one of the leading produce industry groups, United Fresh Produce Association (UFPA), opposed the amendment and urged the Senate not to add “exemptions based on the size of the operation, production practices, or geographic location for food being sold in the commercial market” to its food safety proposal.⁷⁵ In November during the floor debate, a letter circulated from UFPA and 19 other producer associations again urging the Senate not to adopt the amendment.⁷⁶ In addition to broader industry concerns about the need to preserve consumer confidence in the safety of all marketed produce, another industry concern is whether small foreign producers might also be exempt, if small U.S. producers were to be exempt (given prevailing U.S. equivalency standards).⁷⁷

Meanwhile, some public health and consumer groups expressed concern that the Tester-Hagan amendment would create “too great a loophole” in the food safety requirements, among other concerns.⁷⁸ In October 2010, a coalition of these groups expressed its opposition to the modified version of the Tester-Hagan amendment.⁷⁹ The groups cited concern that the exemption was based only on sales volume and could result in certain high-risk foods being exempted from food safety protections, and whether labeling requirements were needed for such foods. They argued that it is unclear how many facilities would be exempted under the proposed sales threshold, and

⁷⁴ See, for example, letter from more than 100 farm groups under the Small Holder Alliance, “Support Fresh, Safe Local Food in the Food Safety Bill,” April 15, 2010, [http://smallholdersalliance.com/Amend-S510-April-15%20\(2\).pdf](http://smallholdersalliance.com/Amend-S510-April-15%20(2).pdf); and articles in *Food Safety News* (<http://www.foodsafetynews.com/>) by Helena Bottemiller, “Tester Amendment Picks Up Cosponsor,” May 3, 2010, and “Farmers Gain in Senate Food Safety Battle,” April 15, 2010.

⁷⁵ United Fresh Produce Association, 2010 Issues Brief, http://www.unitedfresh.org/assets/Issue_Brief_United_Fresh_Produce_Association_2010.pdf.

⁷⁶ Letter to Senators Reid, McConnell, Harkin, and Enzi from United Fresh Produce Association, Produce Marketing Association, Northwest Horticultural Council, and other national and state groups, November 18, 2010, available at <http://www.unitedfresh.org/>.

⁷⁷ *Ibid.*, comments by industry representatives at the UFPA’s 2010 Washington Public Policy Conference, September 15, 2010; and Helena Bottemiller, “Group Breaks Ranks on Small Farm Exemptions,” *Food Safety News*, September 10, 2010.

⁷⁸ Letter to Senator Tester from the Consumers Union regarding Amendments to S. 510, the FDA Food Safety Modernization Act, April 20, 2010, <http://www.consumersunion.org/campaigns//notinmyfood/016345indiv.html>; and articles in *Food Safety News* (<http://www.foodsafetynews.com/>); Helena Bottemiller, “Public Health Opposition to Tester Amendment,” April 28, 2010; Helena Bottemiller, “Farmers Gain in Senate Food Safety Battle,” April 15, 2010; and Alex Ferguson, “What’s Wrong with the Tester Amendments,” May 4, 2010.

⁷⁹ Make Our Food Safe coalition, October 19, 2010, <http://www.makeourfoodsafesafe.org/>. The coalition’s white paper on the Tester-Hagan amendment is at <https://ssl.capwiz.com/pew/attachments/TesterResponsefactsheetfinal.pdf>.

that FDA should conduct market analyses to determine appropriate thresholds for exemption in both the produce and processed food sectors. They also questioned the appropriateness of the then 400-mile designation and other aspects of what would constitute a “direct sale” under the proposed amendment, such as whether grocery stores and restaurants should be included.

Targeting of Inspections

How Often Should Plants Be Visited?

Reform advocates argue that many of the recent problems that have led to illness outbreaks and recalls might have been avoided if inspectors were more frequently present in plants to monitor sanitary conditions and processes.⁸⁰ Due to the differing laws and circumstances that apply to FSIS, for example, the agency’s inspectors are in meat and poultry slaughter and processing plants every day, where they must organoleptically (by the senses) examine every live animal and every carcass for defects, and must pass every item before it can enter commerce. The FFDCA authorizes but does not require FDA to inspect food facilities. Therefore, no periodic inspection frequency is currently stipulated. On the other hand, nothing in current law appears to prohibit FDA from setting an inspection frequency, or prioritizing inspections based on risk.

Some, including former and current FDA officials, have argued that the agency lacks sufficient resources to conduct the number of inspections required to ensure the safety of the food supply, particularly in light of the increasing number of registered food facilities.⁸¹ (See **Table 3**.)

According to FDA budget documents, while the number of registered facilities has increased each year since FY2004, the number of food inspectors decreased by about 15% from FY2004 to FY2008. Due in part to arguments for increased funding, appropriations for the agency’s field activities and full time equivalents (FTEs) have risen each fiscal year since FY2007. (In FDA budget documents, inspection-related items appear under the *field* heading, and employees are counted as *FTEs*.) According to the same budget documents, the number of inspections of food facilities has increased each year since FY2008, yet is not projected to return to FY2004 levels until FY2011.

One additional issue is how FDA can best target its available inspection resources to protect the public health. Different facilities may not merit the same frequency of inspection. For example, facilities that process and package food may create a greater opportunity for contamination than warehouses that merely store foods. Companies and facilities that have a record of meeting all FDA requirements may present less of a risk than those that do not. Foods produced in countries with food processing and handling standards at least as rigorous as those of the United States may present less of a health risk than those with less rigorous standards.

⁸⁰ Lyndsey Layton, “FDA Inspections of Food Plants, Enforcement Down, Officials Say,” *The Washington Post*, April 7, 2010. This story refers to an HHS Inspector General report finding “significant weaknesses” in FDA’s domestic food facility inspections program, including a significant decline in the number of inspections as well as a decline in the number of violations identified by inspectors. HHS Office of Inspector General, “FDA Inspections of Domestic Food Facilities,” OEI-02-08-00080, April, 2010, p. iii, <http://oig.hhs.gov>.

⁸¹ See, e.g., Hubbard, William, Former FDA Associate Commissioner for Policy and Planning, and Advisor, Alliance for a Stronger FDA, March 11, 2009, testimony before the House Energy and Commerce Subcommittee on Health; FDA Science Board, *FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology*, November 2007; and “Science and Mission at Risk: FDA’s Self-Assessment,” January 29, 2008 Testimony of Peter Barton Hutt before the Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce.

Table 3. FDA Food-Related Inspection Data, FY2004-FY2011

(budget for field salaries and expenses (S&E), number of field full-time equivalents (FTEs), total number of FDA and state inspections, and cumulative number of domestic and foreign facilities registered under FDCA § 415)

	FY2004	FY2005	FY2006	FY2007	FY2008	FY2009	FY2010	FY2011
Field S&E (\$ in millions) ^a	\$299.3	\$283.3	\$285.3	\$298.0	\$340.6	\$479.9	\$547.5	\$705.2
Field FTEs ^a	2,172	2,059	1,962	1,806	1,861	2,166	2,505	2,902
Inspections ^b	21,876	19,774	17,730	17,038	16,277	17,972	20,542	22,205
Domestic Facilities ^c	121,534	148,451	172,190	194,245	214,584	236,398	252,433 ^d	N/A
Foreign Facilities ^c	92,719	104,555	115,902	129,345	141,703	154,883	164,805 ^d	N/A

Source: Compiled by CRS from FDA annual budget documents for FY2006-FY2011.

- Food field S&E and FTE data are from the FY2007-FY2011 annual Food and Drug Administration, *President's Budget Request* "All Purpose Table—Total Program Level," except that the FY2004 numbers are from the FY2006 annual Food and Drug Administration, *President's Budget Request*, "Narrative by Activity, Foods—Center for Food Safety and Applied Nutrition." Appropriated funds are shown for FY2010; requested funding levels are shown for FY2011. Actual funding levels are shown for FY2004-FY2009.
- Inspection data are the reported Total FDA and State Contract Inspections, from the FY2006-FY2011 annual Food and Drug Administration, *President's Budget Request*, Field Activities—Office of Regulatory Affairs (ORA), "Foods Field Program Outputs—Domestic Inspections." Numbers for FY2010 are appropriated; for FY2011 are requested; all others are actual.
- Source, FDA Office of Legislation on September 22, 2010.
- Number of registrants as of September 22, 2010.

Legislative Proposals

The major proposals seek to improve both the targeting and frequency of in-plant inspections, but in different ways. In general, the House-passed bill would require FDA to conduct inspections more frequently than would the Senate bill. Both measures would allow the Secretary to prioritize inspection resources according to the potential risk posed by particular types of foods, facilities, and/or processes, although the House-passed bill is more prescriptive in its approach. (Relevant sections in the House-passed bill are 105 and 207, and in the Senate-passed bill are 201 and 306.)

The House-passed bill would require the HHS Secretary to establish, within 18 months, a risk-based schedule for inspecting each foreign and domestic food facility, following these prescribed categories and frequencies: category 1, a high-risk food facility that manufactures or processes food, must be inspected at least every 6-12 months; category 2, a low-risk facility that manufactures or processes food or a facility that packs or labels food, must be inspected at least every 18 months to three years; and category 3, a food facility that holds food, must be inspected at least every five years.

The House-passed bill also would authorize the Secretary to modify the types of food facilities within each category, and to alter inspection frequencies if needed to respond to illness outbreaks and recalls. In doing so, the Secretary would be required to consider the type of food at the facility, its compliance history, whether an importing facility is certified (under the new certification requirements the bill would set; see below), and other factors determined relevant by the Secretary.

The House-passed bill also would authorize the Secretary to recognize a federal, state, or local official to conduct domestic facility inspections and an agency or representative of a foreign government to conduct foreign facility inspections. Foods would be deemed to be adulterated if inspection were delayed, limited, or refused by either the owner, operator, or agent of an establishment in which the foods were held, or by any agent of a governmental authority of a foreign country within which an establishment that held the food were located.

Finally, the House-passed bill would require the Secretary to submit to Congress (1) annually, a report containing the number and cost of risk-based inspections; and (2) within three years of enactment, a report containing recommendations about the risk-based inspection schedule.

The Senate-passed bill would require the HHS Secretary to increase the inspection rate for any food facility required to register under FFDCFA § 415. In addition, the Secretary would be required to identify high-risk facilities and to allocate resources to inspect facilities according to known safety risks. Risks would include the type of food, the facility's history of food recalls, the facility's hazard analysis and preventive controls, and others. The Secretary would be required to inspect domestic high-risk facilities not less than once in the five-year period following enactment, and not less than once every three years thereafter. The Secretary would be required to inspect domestic non-high-risk facilities not less than once in the seven-year period following enactment, and not less than once every five years thereafter. Also, the Secretary would be required to inspect at least 600 foreign facilities in the year following enactment, and in each of the subsequent five years to double the number of foreign facilities inspected. In meeting the inspection requirements, the Secretary would be authorized to rely on inspections conducted by other federal, state, or local agencies.

For foreign food facilities registered under FFDCFA § 415, the Senate bill would permit the Secretary to enter into arrangements and agreements with foreign governments to facilitate the inspection of those facilities. The Secretary would be required to direct resources for inspection of such foreign facilities, suppliers, and food types, particularly those identified as high-risk, to help ensure the safety of the U.S. food supply. Notwithstanding any other provision of law, foreign foods would be refused entry into the United States if inspectors were refused entry to a facility, warehouse, or other establishment by the owner, operator, or agent in charge, or the government of the foreign country. The Senate bill would also require the Secretary to allocate resources to identify and inspect imported foods at ports of entry, according to the known safety risks of the article of food, based on certain factors.

The Senate bill includes three provisions specific to seafood that focus on (1) establishing interagency agreements to improve seafood safety (§ 201); (2) assessing changes to regulations for post-harvest processing of raw oysters (§ 114); and (3) sending inspectors to assess production of seafood imported into the United States (§ 306). The scope of interagency agreements identified in § 201 includes examining and testing seafood; coordinating inspections; standardizing data; modifying existing processes; sharing enforcement and compliance information; and conducting joint training and outreach. Section 114 would require the Secretary of HHS to submit a report to Congress before issuing guidance, regulation, or suggested amendments related to post-harvest processing of oysters. It would also require GAO to review the Secretary's report and report its findings to Congress. These reports would be waived if a consensus agreement is reached among federal and state regulators and the oyster industry, acting through the Interstate Shellfish Sanitation Conference. Section 306 would permit the Secretary of Commerce, in coordination with the Secretary of HHS, to send inspector(s) to a country or facility of an exporter of seafood imported into the United States to assess practices and processes

used in farming, cultivation, harvesting, preparation for market, and transportation of seafood. Inspectors also may provide technical assistance related to these activities. Reports would be required for each inspection to provide findings to the country or exporter and for use by the Secretary of HHS.

The Senate bill would require the Secretary to submit to Congress not later than February 1 of each year, and to make available to the public via FDA's website, a report including certain information about food facilities, food imports, and FDA foreign offices.

Use of Third Parties for Imports and for Laboratory Accreditation

Can Non-FDA Entities Help Ensure Safety?

Although FDA regulates importers and imported products, the agency does not have express statutory authority to regulate private laboratories that sample or test imported foods, nor does FDA accredit food laboratories or use others to certify the safety of imported foods. Presently, laboratory accreditation is voluntary, and several domestic and international accreditation organizations accredit laboratories.⁸² FDA may conduct voluntary, on-site assessments of private accredited laboratories.⁸³ FDA's own laboratories are accredited and, according to FDA, "the laboratory industry favors accreditation."⁸⁴ Industry participation in third-party certification programs, such as those that help foreign and domestic producers meet FDA requirements through certification, is also voluntary, although FDA has indicated that participation in such programs may "be beneficial."⁸⁵ The FDA has also indicated that "there is extensive support for certification programs that audit to determine compliance with internationally recognized criteria," and that domestic suppliers use third-party certification programs "in part because of customer demand."⁸⁶

The Government Accountability Office testified in 2008 that private laboratory accreditation "could leverage outside resources while providing FDA greater assurance about the quality of the laboratories importers use to demonstrate that their products are safe."⁸⁷ In January 2009, FDA issued draft guidance on accreditation standards for private laboratories and the test data that such labs should submit to the agency for imported FDA-regulated products that were either detained or subject to an FDA Import Alert.⁸⁸ The guidance document encouraged importers to notify the FDA in advance of their submission of a sample to an accredited laboratory, so as "to discourage importers from withholding bad test results, re-testing, or re-sampling."⁸⁹ In January 2009, FDA also issued a final guidance document on voluntary third-party certification programs for foods

⁸² FDA, "Guidance for Industry: Submission of Laboratory Packages by Accredited Laboratories," 74 *Federal Register* 3056-3057, January 16, 2009, hereinafter Draft Guidance.

⁸³ *Ibid.*

⁸⁴ *Ibid.*

⁸⁵ FDA, "Guidance for Industry: Voluntary Third-Party Certification Programs for Foods and Feeds," 74 *Federal Register* 3058-3059, January 16, 2009.

⁸⁶ *Ibid.*

⁸⁷ Draft Guidance, *supra* note 54 (citing GAO, *Federal Oversight of Food Safety—FDA's Food Protection Plan Proposes Positive First Steps, but Capacity to Carry Them Out is Critical*, GAO-08-435T, at 7).

⁸⁸ Draft Guidance.

⁸⁹ *Ibid.*

and animal feeds, which set forth attributes for third-party certification programs and procedures for preventing conflicts of interest.

The use of third parties has been promoted as a method for helping FDA to carry out its responsibilities and target enforcement and inspections while better using existing personnel. Concerns have been expressed regarding testing and certification by third parties, and there has been criticism regarding the autonomy given to the importers and private laboratories. Such criticism varies from the manner in which the samples are collected for testing, to the reporting of test results by the importers to the FDA, to whether test results accurately reflect all information obtained, such as evidence of FFDCAs violations, to potential or actual conflicts of interest. Additionally, critics contend that although third-party certification may be useful as a commercial marketing tool, it does not necessarily ensure safety, as manufacturers involved in recent foodborne illness outbreaks have passed private third-party and state inspections. For example, in two of the most publicized recalls over the last two years—the recall of 380 million eggs by a single company and the recall of over 3,900 peanut products associated with another—both companies had used outside labs and reportedly knew of positive test results for *Salmonella* in their products prior to the recalls.⁹⁰

Both the House and Senate bills address various ways to curb the potential for such problems through laboratory accreditation and third-party certification programs. The question remains as to whether industry will opt to use third parties.

Legislative Proposals

Under § 109 of the House-passed bill, qualified certifying entities are to be accredited and given the responsibility to provide import certifications when the Secretary determines such certifications are needed; generally, the specifics of that certification, including its format, would be left to the Secretary’s regulatory discretion. The bill defines “qualified certifying entity” as “an agency or a representative of the government from which the article originated, as designated by such government or the Secretary; or an individual or entity determined by the Secretary or an accredited body recognized by the Secretary to be qualified to provide a certification.” The House bill would require the Secretary to issue regulations to ensure that certifying entities and their auditors are free from conflicts of interest, and it contains extensive language on what these regulations are to cover. The Secretary would have to require that, to the extent applicable, any certification provided by a certifying entity be renewed whenever the Secretary deems it appropriate; and the Secretary would have to refuse to accept any certification determined to be no longer valid or reliable.

Section 110 of the House-passed bill also contains requirements for new laboratory accreditation programs, testing of imported food by accredited laboratories, recognition of laboratory accreditation bodies, advance notice to the Secretary prior to sample collection for testing, and direct submission to the Secretary of laboratory analyses for certain analytical testing of food.

The Senate-passed bill (§ 303) also would create a system of accreditation of third-party auditors and audit agents, who would certify that importing entities are meeting applicable FDA

⁹⁰ FDA, Update on the *Salmonella* Typhimurium Investigation, FDA/CDC Joint Media Teleconference, (Jan. 28, 2009), at 9, <http://www.fda.gov/downloads/NewsEvents/Newsroom/MediaTranscripts/UCM169176.pdf>; Gardiner Harris and William Neuman, *Salmonella Found in '08 at Egg Farm*, N.Y. Times, (September 15, 2010), at B1.

requirements. Foreign governments, foreign agricultural cooperatives, and other third parties could apply to an accreditation body to be a third party auditor or audit agent, after the accreditation body performs certain reviews. Accreditation bodies could not accredit a third-party auditor unless it agrees to issue a written food or facility certification to accompany each food shipment for import into the United States from an eligible entity. Accredited third-party auditors or audit agents would be required to issue audit reports and immediately notify the Secretary of discoveries during an audit of “a condition that could cause or contribute to a serious risk to the public health.” The Senate bill also contains language regarding revocation of accreditation and avoidance of conflicts of interest.

Section 202 of the Senate bill also includes provisions that would require the Secretary to establish a program for testing of food by accredited laboratories and the recognition of accreditation bodies to accredit laboratories, including state and local government laboratories. The bill would require the development of model accreditation standards, re-evaluation of accreditation bodies at least every five years, and a requirement that laboratory test results be sent to the FDA unless the Secretary exempts the submission of test results after making a determination that the results “do not contribute to the protection of public health.”

Mandatory Recall Authority

Removing Unsafe Foods from Commerce

Currently, neither FDA nor FSIS has explicit statutory authority to mandate a recall of most adulterated foods, or to impose penalties if recall requirements are violated. FDA can order food recalls only for infant formula.⁹¹ GAO and others have contended that these gaps increase the possibility that unsafe food will not be recovered, and will be consumed.⁹² Significantly, reversing their earlier opposition, many major food industry groups now endorse legislative proposals to grant FDA mandatory recall authority for food.⁹³

Defenders of the current system counter that the agencies already have sufficient authority to keep tainted products from reaching consumers. FSIS’s statutory authority enables it to detain meat and poultry products of concern for up to 20 days, and FDA’s authority enables it to detain the foods it regulates for up to 30 days. Both agencies can, with a court’s permission, seize, condemn, and destroy unsafe food.⁹⁴ However, given FDA’s finite resources, these authorities may not be practical or effective when large amounts of product are in wide distribution. Private companies rarely fail to order a voluntary recall when problems arise, and some contend that

⁹¹ FDA has the authority to order recalls of four types of products: infant formula, medical devices, human tissue products, and tobacco products. The agency may request that a company voluntarily recall other FDA-regulated products, such as other foods, drugs, and cosmetics. See also discussion of the melamine contamination incident in CRS Report R40916, *Food Safety: Foodborne Illness and Selected Recalls of FDA-Regulated Foods*.

⁹² See, for example, GAO, *Food Safety: USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food* (GAO-05-51), October 2004; and HHS Office of Inspector General (OIG), “FDA Inspections of Domestic Food Facilities,” OEI-02-08-00080, April, 2010, <http://oig.hhs.gov>.

⁹³ In reaction to a news story on an OIG report, representatives from the food industry noted the need for mandatory recall in some instances. See “OIG Says Better FDA Traceback May Require New Legislation,” *FDA Week*, March 27, 2009.

⁹⁴ A court’s permission may not be needed in all cases; for example, the FFDCA [§ 801(j)(1)] empowers officials to hold an import for up to 24 hours if there is “credible evidence or information indicating that an article of food presents a threat of serious adverse health consequences or death to humans or animals.”

providing FDA with mandatory recall authority might foster a counterproductive adversarial relationship between industry and government, slowing response times. Nonetheless, a number of Members of Congress have supported GAO's recommendation that legislation be considered to strengthen the notification and recall authorities of both agencies.

Legislative Proposals

The House-passed bill (§ 111) would authorize the Secretary to request a voluntary recall by any person who distributes an article of food that the Secretary has reason to believe is adulterated, misbranded, or otherwise in violation of the FFDCFA. It would further authorize the Secretary to issue an order to cease distribution of any article of food if he/she has reason to believe that the use or consumption of, or exposure to, that article of food may cause adverse health consequences or death to humans or animals. An appeal process and other administrative matters are specified. The Secretary would be required to issue a mandatory recall order if he/she determined that problems were not adequately addressed through the procedures described above. The Secretary could proceed directly to a mandatory recall order if he/she has credible evidence that an article of food subject to an order to cease distribution presents an imminent threat of serious adverse health consequences or death to humans or animals. In such case, the person would have to immediately recall the food while stipulated appeal procedures were carried out. Failure to comply with a mandatory recall order would be prohibited under FFDCFA § 301. The House-passed bill also would require the Secretary to provide notice of a recall order to consumers and to state and local health officials; and to refuse admission to foods offered for import into the United States if subject to a recall order or an order to cease distribution.

Other sections of the House-passed bill would require facilities to describe food recall procedures in their food safety plans (§ 102), and importers to have adequate recall procedures (§ 108). In addition, FDA could alter the frequency for risk-based inspection schedules based on the need to respond to food recalls (§ 105), and could assess and collect fees from entities for any fiscal year in which the entity is subject to a food recall (§ 204).

The Senate-passed bill (§ 206) would require the HHS Secretary, if he/she has information “that there is a reasonable probability that an article of food (other than infant formula) is adulterated ... or misbranded ... and the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals,” to provide an opportunity to the responsible party to cease distribution and recall the food. If the party did not do so “within the time and in the manner prescribed by the Secretary,” authority would be provided to require such person to cease distribution, or to immediately notify everyone involved in handling or receiving the food. The Secretary would be required to provide specified notifications to the public of any recall orders, and to establish an incident command or similar operation within the department to assure coordinated communications during a recall. The bill provides for the assessment of civil penalties as well as criminal penalties with regard to failure to comply with or follow a recall order. The assessment of civil penalties for failure to comply with a recall order may preclude the assessment of criminal penalties. If the FDA assesses a civil penalty, the agency would not be able to seek seizures or injunctions for the adulterated food.

Notification of Contaminated Products and Product Tracing

Improving Notification and Traceability Capabilities

Notification and traceability are viewed as tools to make recalls more effective. Some have argued that improved notification and traceability capabilities would enable either FSIS (in the

case of meat and poultry products) or FDA (in the case of other foods) to determine more quickly a product's source and whereabouts, in order to prevent or contain foodborne outbreaks. Traceability has also been debated in connection with defense against agroterrorism, and for verifying the origin of live animals and their products for marketing, trade, and/or animal health purposes, for example. In some recent highly publicized outbreaks, it appears that food company representatives were aware of a food safety problem for a prolonged period of time before notifying FDA.⁹⁵

The 110th Congress responded to some of these concerns by including a provision in the Food and Drug Administration Amendments Act of 2007 (P.L. 110-85) that requires the responsible party for a food facility (i.e., registered under FFDCA § 415) to notify the Secretary of any food “for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals,” and that requires the Secretary to establish a Reportable Food Registry of such reports.⁹⁶ Also, the enacted 2008 farm bill (P.L. 110-246) amends the meat and poultry laws to require an establishment to notify USDA if it has reason to believe that an adulterated or misbranded product has entered commerce. (See also the earlier discussion of current record-keeping requirements under FFDCA § 414.)

Legislative Proposals

The House-passed bill (§ 112) would amend current authority for the Reportable Food Registry to expand the definition of who must report problem foods. In addition to persons who register facilities under FFDCA § 415, persons who own or operate farms and retail establishments would also have to report, as would persons who register importing facilities under FFDCA § 801. In addition, the bill would require submission of results of any sampling or testing of a reported food, including tests conducted pursuant to the bill's proposed hazard analysis and preventive controls provisions, food safety plans, performance standards, or testing by accredited laboratories.

The House-passed bill (§ 107) also would require the Secretary to establish by regulation a tracing system for food in, or to be imported into, the United States, in order to enable the Secretary “to identify each person who grows, produces, manufactures, processes, packs, transports, holds, or sells such food in as short a timeframe as practicable but no longer than 2 business days.” Before promulgating regulations, the Secretary would be required first to identify tracing technologies and methodologies that can enable each of the food industry sectors to maintain the full pedigree of the food from source through subsequent distribution, to make traceback interoperable with other systems, and to use a unique identifier for each facility. Also prior to proposing regulations, the Secretary would first have to, as practicable, assess costs, benefits, and feasibility of adopting such technologies; conduct at least two public meetings; and conduct one or more pilots.

The House bill's traceback requirements would apply to agricultural producers, fisheries (both wild and aquaculture), and retailers, but there is extensive language intended to limit the

⁹⁵ See, for example, documentation on the 2010 Wright County egg recall available at the House Committee on Energy and Commerce website: “Chairmen Request More Details on Salmonella Contamination at Wright County Egg Publications,” September 14, 2010. See also discussion of the melamine contamination incident in CRS Report R40916, *Food Safety: Foodborne Illness and Selected Recalls of FDA-Regulated Foods*.

⁹⁶ FFDCA § 417; 21 U.S.C. 350f. After some delays, the Reportable Food Registry was implemented in September 2009. See the FDA website at <http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/RFR/default.htm>.

applicability to farms. For example, the bill would exempt food produced on a farm or fishery and sold directly to a consumer, restaurant, or grocery store. However, restaurants and grocery stores would be required to keep records documenting the farm or fishery source. Farms or fisheries would have to keep records for at least six months documenting the restaurants and groceries to which they sold their food. The Secretary could also exempt a food or a type of facility, farm, or restaurant from the regulations, or modify the requirements for these entities, if he/she “determines that a tracing system for such food ... is not necessary to protect the public health.” For this latter category of exemptions, each person who produces, manufactures, processes, packs, transports, or holds such food still would have to maintain records that identify the immediate previous sources of the food and its ingredients and the immediate subsequent recipients. The Secretary would be required to coordinate with USDA, and tracing authority would be constrained with regard to growers of grains or similarly handled commodities.

The Senate-passed bill (§ 211) would amend current authority for the Reportable Food Registry to allow the Secretary to require the submission by a responsible party of additional types of information about a reportable food in order to improve consumers’ ability to identify it. The bill also would require grocery stores to conspicuously post one-page information sheets about reportable foods, to be developed by FDA and made available for copying on the agency’s website. A store’s failure to comply would be prohibited.

The Senate bill (§ 204) proposes a food tracing system that is generally similar to the one proposed by the House-passed bill, although different in numerous details. Rather than calling for a tracing system for all foods, from which low-risk foods may be exempted, it would require the Secretary, through rulemaking, to impose enhanced recordkeeping requirements (under FFDCa § 414) for foods that the Secretary determines to pose a higher food safety risk. A number of limitations of such requirements are stipulated, especially with respect to farms and agricultural commodities. Effective dates for the record-keeping requirements would be delayed for small businesses. The bill also would require the Secretary to conduct pilot studies and assessments of food tracing systems to inform the rulemaking process.

Foodborne Illness Surveillance and Outbreak Response

How Might Data Collection and Use Be Strengthened?

Foodborne illness surveillance is carried out by the states, with assistance from CDC. States also investigate foodborne disease outbreaks, in coordination with CDC, either or both FDA or FSIS (depending on implicated or suspected foods), and other federal agencies, if appropriate. FDA is authorized to carry out such investigations, or to coordinate with states in doing so, under broad, permanent authorities in the FFDCa and in Title III of the Public Health Service Act (PHS Act), among other authorities.⁹⁷ A foodborne disease outbreak is not defined in law or in regulations. In public health practice, a foodborne disease outbreak is “the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food.”⁹⁸ As a practical matter, particularly for less serious hazards, outbreak investigations are rarely launched when only two people are affected. (There are exceptions for serious illnesses such as botulism.)

⁹⁷ FFDCa at 21 U.S.C. § 372 and 21 U.S.C. § 399; Public Health Service Act at 42 U.S.C. § 241, 42 U.S.C. § 243, 42 U.S.C. § 247b, 42 U.S.C. § 247b-20, and 42 U.S.C. § 264.

⁹⁸ CDC, “Surveillance for Foodborne-Disease Outbreaks: United States, 1998–2002,” *Morbidity and Mortality Weekly Report (MMWR)*, vol. 55 (Surveillance Summary 10), pp. 1-34, November 10, 2006.

The nation's public health capacity for foodborne illness surveillance and outbreak response is a mix of significant strengths and significant gaps.⁹⁹ In the last decade or so, the linkage of previously unrelated illnesses through genetic "fingerprinting" has revolutionized the ability to identify large multistate outbreaks and mount an urgent response. However, the epidemiological approaches used to identify the food associated with an outbreak can be labor-intensive and time-consuming. Also, especially for FDA-regulated foods, information about common contaminants that may be present in foods during production and in commerce, as well as how to test for them, is limited. As a result, "attribution"—identifying the types of foods that cause foodborne illnesses—remains a significant challenge. The daunting outbreaks of the past few years underscore the problem, but are not the only evidence. Based on data from FoodNet, its active surveillance system, CDC reported that as of 2009, the incidence of several of the foodborne diseases under surveillance had reached a plateau, instead of declining, and that national 2010 health targets for three out of four targeted pathogens—*Campylobacter*, *Listeria*, and *Salmonella*—may not be met.¹⁰⁰

Because regulators regulate foods, rather than food contaminants, many contend that closing the attribution gap is paramount in order to target preventive strategies efficiently and mount a more nimble response to outbreaks. The President's Food Safety Working Group stated one of its three core food safety principles as follows: "High-quality information will help leading agencies know which foods are at risk; which solutions should be put into place; and who should be responsible."¹⁰¹ Achieving this goal is a challenge, raising concerns about available technologies, scientific soundness, intellectual property, "trade secret" protections, liability, and other issues. Stakeholders discussed these issues at an FDA-sponsored public workshop in March 2010.¹⁰²

Legislative Proposals

The House-passed bill (§ 121) would, for purposes of surveillance, define a foodborne illness outbreak as two or more cases of a similar illness resulting from the ingestion of a food. The bill would require the Secretary, acting through the CDC, to enhance foodborne illness surveillance systems, including coordinating federal, state, and local systems; facilitating timely sharing of agency findings; ensuring early notification of the food industry when a particular food is suspected in an outbreak; developing improved epidemiological tools; and other prescribed methods. The bill also would mandate a review of and strategies to enhance the food safety and defense capabilities of state and local agencies.

The Senate-passed bill (§ 205) contains provisions that generally mirror the House bill. It contains additional provisions that would establish a working group to improve foodborne illness surveillance and outbreak investigations, and would reauthorize food safety capacity-building grants to states and Indian tribes under the PHS Act. It also would authorize the appropriation of \$24 million for each fiscal year for FY2011 through FY2015 for efforts to enhance foodborne illness surveillance.

⁹⁹ See CRS Report R40916, *Food Safety: Foodborne Illness and Selected Recalls of FDA-Regulated Foods*.

¹⁰⁰ CDC, "Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food—10 States, 2009," *MMWR*, vol. 59, no. 14 (April 16, 2010), pp. 418-422, <http://www.cdc.gov/foodnet/>. CDC reported that the target for harmful strains of *E. coli* had been met.

¹⁰¹ President's Food Safety Working Group, "Key Findings," March 2009, <http://www.foodsafetyworkinggroup.gov/Content/KeyFindings/HomeKeyFindings.htm>.

¹⁰² FDA, "Measuring Progress on Food Safety: Current Status and Future Directions; Public Workshop," *75 Federal Register* 9232, March 1, 2010.

Criminal Penalties

Existing Criminal Penalties Under FFDCA § 303(a)

The concepts of “adulteration” and “misbranding” are two of the basic statutory components of the FFDCA. 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.

Persons who violate the FFDCA by, for example, introducing an adulterated or misbranded product into interstate commerce, commit what is referred to as a prohibited act under FFDCA § 301.¹⁰³ Persons who commit prohibited acts are subject to criminal and civil penalties. The penalties vary, depending on the offense. Most criminal liability provisions are found in the “Penalties” section of the FFDCA, § 303. Injunctions and seizures may also be sought for adulterated or misbranded products. In light of a number of deaths that appear to have resulted from contaminated food, such as nine deaths linked to tainted peanut butter products, some have called for stronger criminal penalties than the current fines and maximum of three years’ imprisonment.¹⁰⁴

Presently, upon conviction for a misdemeanor violation of the prohibited acts section, a person¹⁰⁵ faces the penalties authorized in FFDCA § 303(a).¹⁰⁶ These are presented in **Table 4**. The maximum criminal penalty for individuals (as adjusted by 18 U.S.C. §§ 3559 and 3571) is imprisonment for one year and/or either \$100,000 if the misdemeanor does not result in death, or \$250,000 if the misdemeanor results in death. The maximum criminal penalty for organizations (as adjusted by 18 U.S.C. §§ 3559 and 3571) is \$200,000 if the offense does not result in death and \$500,000 if the offense results in death. There are exceptions to the misdemeanor penalties provisions in FFDCA § 303(a)(1). A person could avoid being subject to penalties for certain violations of the prohibited acts section under the good faith exception, and persons may also avoid liability for violations of certain prohibited acts if they receive a guaranty from the manufacturer or the person from whom they received the product.¹⁰⁷

¹⁰³ 21 U.S.C. § 331.

¹⁰⁴ See U.S. Congress, House Committee on Energy and Commerce, *Do You Fix Our Ailing Food Safety System*, 111th Cong., 1st sess., March 11, 2009 (http://energycommerce.house.gov/Press_111/20090311/testimony_dewaal.pdf); see also U.S. Congress, Senate Committee on the Judiciary, *statement of Sen. Patrick Leahy, Chairman*, Executive Business Meeting of the S. Comm. on the Judiciary, 111th Cong., 2nd sess., September 23, 2010 (http://judiciary.senate.gov/hearings/testimony.cfm?id=4808&wit_id=2629).

¹⁰⁵ The FFDCA defines “person” to include individuals, partnerships, corporations, and associations, though criminal statutes distinguish between individuals and organizations in setting fine amounts. FFDCA § 201(e); 18 U.S.C. §§ 3559, 3571.

¹⁰⁶ 21 U.S.C. § 333(a)(1). In *United States v. Dotterweich*, the U.S. Supreme Court held that the government need not prove that the defendant intended to commit a FFDCA violation in order to obtain a misdemeanor conviction. Misdemeanor violations of the FFDCA are strict liability offenses. *United States v. Dotterweich*, 320 U.S. 277, 284 (1943); see also *United States v. Park*, 421 U.S. 658 (1975).

¹⁰⁷ 21 U.S.C. § 303(c)(1)-(3). FFDCA § 301(h) prohibits a person from giving a false guaranty to another person that a food is not adulterated.

Table 4. Criminal Penalties for Violations of FFDCA § 303(a)

Statute	Description of Statutory Provision	Maximum Criminal Penalty for Individuals (as adjusted by 18 U.S.C. §§ 3559 and 3571)	Maximum Criminal Penalty for Organizations (as adjusted by 18 U.S.C. §§ 3559 and 3571)
Current Law provisions			
Federal Food, Drug, and Cosmetic Act (FFDCA) § 303(a)(1) (21 U.S.C. § 333(a)(1))	Violation of FFDCA prohibited acts provisions, FFDCA § 301	Imprisonment for one year and/or either \$100,000 if the misdemeanor does not result in death, or \$250,000 if the misdemeanor results in death.	\$200,000 if the offense does not result in death, \$500,000 if the offense results in death.
FFDCA § 303(a)(2) (21 U.S.C. § 333(a)(2))	Violation of FFDCA prohibited acts provisions after a prior conviction under FFDCA § 303 or a violation committed with the intent to defraud or mislead	Imprisonment for not more than 3 years or a fine of not more than \$250,000, or both.	A fine of not more than \$500,000.
Proposed changes			
Proposed FFDCA § 303(a)(3), as set forth in H.R. 2749	Knowing violation of certain FFDCA prohibited acts provisions with respect to any food that is misbranded or adulterated	Imprisonment for not more than 10 years or a fine of not more than \$250,000, or both.	A fine of not more than \$500,000.
Proposed FFDCA § 303(a)(3), as set forth in S. 3767 ^a	Knowing violation of certain FFDCA prohibited acts provisions with respect to any food and with conscious or reckless disregard of a risk of death or serious bodily injury	Imprisonment for not more than 10 years or a fine of not more than \$250,000, or both.	A fine of not more than \$500,000.

Source: Prepared by CRS.

a. Not included in the Senate-passed bill, S. 510.

A violation of the FFDCA's prohibited acts section is a felony offense if it occurs after a prior conviction for violating the FFDCA's prohibited acts section or if it is committed with the intent to defraud or mislead. The maximum criminal penalty for individuals convicted of a felony violation of the FFDCA (as adjusted by 18 U.S.C. §§ 3559 and 3571) is imprisonment for not more than three years or a fine of not more than \$250,000, or both. The maximum criminal penalty for organizations (as adjusted by 18 U.S.C. §§ 3559 and 3571) is a fine of not more than \$500,000.

Criminal liability may also extend to persons who aid and abet criminal violations of the FFDCA, or who conspire to violate the FFDCA, as federal criminal law generally makes it a separate crime to aid or abet any criminal offense against the United States or to conspire to commit a criminal offense against the United States.¹⁰⁸ The decision to seek criminal sanctions against individuals and corporations suspected of violating the FFDCA is within the FDA's discretion.¹⁰⁹

¹⁰⁸ 18 U.S.C. §§ 2, 371.

¹⁰⁹ Heckler v. Chaney, 470 U.S. 821 (1985) (holding that "[t]he FDA's decision not to take the enforcement actions (continued...)

Prosecution may be more likely if the case involves “gross, flagrant, or intentional violations, fraud, or danger to health” or “a continuous or repeated course of violative conduct.”¹¹⁰

Legislative Proposals

Section 134 of the House-passed bill would amend the penalties provisions of FFDCa § 303(a) to provide for fines and a maximum prison sentence of 10 years if any person knowingly violated any one of five listed prohibited acts with respect to food that is misbranded or adulterated. The five prohibited acts listed in § 134 are (1) FFDCa § 301(a), which prohibits “the introduction or delivery for introduction into interstate commerce” of any food that is adulterated or misbranded; (2) FFDCa § 301(b), which prohibits adulteration or misbranding of food in interstate commerce; (3) FFDCa § 301(c), which prohibits the “receipt in interstate commerce” as well as “the delivery or proffered delivery thereof for pay or otherwise” of adulterated or misbranded food; (4) FFDCa § 301(k), which prohibits the “alteration, mutilation, destruction, obliteration, or removal of the whole or part of the labeling of, or the doing of any other act with respect to, a food ... if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in the article being adulterated or misbranded”; and (5) FFDCa § 301(v), which prohibits the “introduction or delivery for introduction into interstate commerce” of an unsafe dietary supplement.

The maximum criminal penalty for individuals convicted of a felony violation of the FFDCa for knowingly violating any one of these five parts of the FFDCa’s prohibited acts section, with respect to any adulterated or misbranded food, would be a fine of not more than \$250,000. Such individuals would also face a maximum prison sentence of 10 years in addition to the fine, as the individual could be fined, imprisoned, or both. The maximum criminal penalty for organizations for such violations would be a fine of not more than \$500,000.

The Senate-passed bill would not alter the criminal penalties under FFDCa § 303(a). It had been reported that if S. 510 were to be considered by the Senate, another bill, S. 3767 (the Food Safety Accountability Act of 2010, introduced by Senator Patrick Leahy), could be offered as a further amendment to it. A substitute amendment to S. 3767 was approved by the Senate Judiciary Committee on September 23, 2010, and the bill as amended was reported by the committee on the same day. However, S. 3767 does not appear to have been included in the Senate amendment to S. 510 that passed off the Senate floor on November 30, 2010.

S. 3767, as reported, would also amend the penalties provisions of FFDCa § 303(a) to provide for fines and a maximum prison sentence of 10 years if a person knowingly violated one of five parts of the FFDCa’s prohibited acts section. S. 3767 lists the same five prohibited acts that appear in H.R. 2749, § 134. However, S. 3767 differs from the criminal provisions in the House bill in that it contains an additional requirement that the knowing violation be “with respect to food and with conscious or reckless disregard of a risk of death or serious bodily injury.”

(...continued)

requested by respondents is therefore not subject to judicial review under the [Administrative Procedure Act]” and that the FFDCa enforcement provisions do not overcome the agency’s “decisions not to institute proceedings”).

¹¹⁰ FDA, *Regulatory Procedures Manual*, § 6-5-1, March 2010, <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucml176738.htm>.

The maximum criminal penalties for violations would be the same as proposed by the House-passed bill. The maximum criminal penalty for individuals convicted of a felony violation of the FFDCAs for knowingly violating these parts of the FFDCAs's prohibited acts section, "with respect to food and with conscious or reckless disregard of a risk of death or serious bodily injury," would be a fine of not more than \$250,000, imprisonment for up to 10 years, or both. The maximum criminal penalty for organizations for such violations "with respect to food and with conscious or reckless disregard of a risk of death or serious bodily injury" would be a fine of not more than \$500,000. Changes proposed by the House-passed bill and by S. 3767 are presented in **Table 4**.

Food Imports

Concerns About Import Oversight

A steady increase in food imports, a result of globalization and consumer desire for a wider variety of foods year-round, has generated growing concerns about whether current federal programs sufficiently ensure the safety of these imports.¹¹¹ FDA import alerts in 2007 and 2008 targeting adulterated pet food ingredients, farmed seafood, and dairy products and ingredients, all from China, have been among the incidents that have heightened interest in this issue. Most of the recent debate has included extensive discussion about how to improve current import safeguards, within resource constraints, and without unduly restraining free trade.¹¹²

The FFDCAs (at 21 U.S.C. § 381(a)) empowers FDA to refuse entry to any food import if it "appears," based on a physical examination or otherwise, to be adulterated, misbranded, or otherwise in violation of the law. In exercising its oversight, the agency relies on a system of prior notifications by importers and document reviews at ports of entry. Importers must have an entry bond and file a notification for every shipment. An FDA database, the Operational and Administrative System for Import Support (OASIS), helps inspectors to determine a shipment's relative risk and whether it needs closer scrutiny (i.e., a physical examination, and/or testing). In practice, import inspections are relatively infrequent. The agency recorded more than 8.2 million imported food "lines" in FY2007 (compared with fewer than 2.8 million entry lines in FY1997), of which approximately 1% were physically examined and/or tested.¹¹³ Among the cited reasons for this low incidence in inspections are limited and declining resources, including too few inspectors to cover the more than 360 U.S. ports of entry despite ever-increasing import volumes.¹¹⁴ Current law also does not explicitly authorize, or require, import verification.

¹¹¹ GAO, *Food Safety: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food*, GAO-09-873, September 15, 2009; GAO, *Food Safety: FDA Could Strengthen Oversight of Imported Food by Improving Enforcement and Seeking Additional Authorities*, GAO-10-699T, May 6, 2010. See also CSPI, "Building a Modern Food Safety System for FDA Regulated Foods, May 2009.

¹¹² Additional information is available in CRS Report RL34198, *U.S. Food and Agricultural Imports: Safeguards and Selected Issues*.

¹¹³ FDA briefing for Senate staff, February 8, 2008. FDA FY2009 budget materials state that 94,743 import food field exams were conducted in FY2007.

¹¹⁴ See, for example, Testimony of Caroline Smith DeWaal, CSPI Director of Food Safety, before the House Energy and Commerce Committee's Subcommittee on Oversight and Investigations, July 17, 2007.

In addition, some have questioned whether FDA has what is called “equivalence authority”, such as that governing U.S. imports of meat and poultry products under USDA’s FSIS jurisdiction.¹¹⁵ “Equivalency” refers to the requirement that all imported meat and poultry products meet all safety standards applicable to similar products produced in the United States. Foreign meat and poultry food regulatory systems may apply “equivalent sanitary measures to eliminate or abate food safety hazards” if those measures provide the same “level of public health protection” achieved by U.S. measures.¹¹⁶ Under laws governing meat inspection,¹¹⁷ no foreign establishment can ship its products to the United States until FSIS has determined that the establishment’s country has a meat and/or poultry safety program that provides a level of protection that is at least equivalent to the U.S. system. FSIS visits the exporting country to review its rules and regulations, meets with foreign officials, and accompanies them on visits to establishments. In addition, FSIS operates a reinspection program at 150 import houses located near approximately 35 border entry points. FDA does not have a program like that of FSIS. Some have suggested that the FDA program should operate more like that of FSIS, although they acknowledge the difficulties and resource demands of attempting to regulate many more different types of foods from many countries of origin.¹¹⁸

Legislative Proposals

Both the House-passed and Senate-passed bills seek tighter controls over imports, and both would use certification or verification systems involving so-called third parties. More specifically, under the House-passed bill (§ 109), the Secretary would have 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 the date of enactment. However, such certification would apply only in the following situations:

- for food imported from a particular country or region, based on the adequacy of government controls there or other relevant information, if such certification would assist in determining the admissibility of the food;
- for a food type that could pose a significant risk to health, if such certification would assist in determining whether the article poses such risk; or
- for an article imported from a particular country, if the Secretary has an agreement with that government providing for such certification.

Another section of the House-passed bill (§ 204) would require a food importer to register annually with the Secretary, to submit an appropriate unique facility identification as a condition of such registration, and to meet “good importer practices;” the latter to include verification of good manufacturing practices and preventive controls of the importer’s foreign suppliers, as applicable, among other things. A provision in this section would require every person importing,

¹¹⁵ *Ibid.*

¹¹⁶ According to USDA, the concept that different sanitary measures can achieve the same level of protection is called equivalence. See: USDA, Food Safety And Inspection Service, “Process for Evaluating the Equivalence of Foreign Meat and Poultry Food Regulatory Systems,” October 2003, <http://www.fsis.usda.gov/oppde/ips/eq/eqprocess.pdf>.

¹¹⁷ Federal Meat Inspection Act, 21 U.S.C. §§ 601-695; and Poultry Products Inspection Act, 21 U.S.C. §§ 451-471.

¹¹⁸ See for example Testimony of Caroline Smith DeWaal, CSPI Director of Food Safety, before the House Energy and Commerce Committee’s Subcommittee on Oversight and Investigations, July 17, 2007.

or brokering for import of, a food to permit an officer or employee of the Secretary to “inspect the facilities of such person and have access to, and to copy and verify, any related records.” Any food offered for import that is not from a duly registered person would be misbranded. (Fees are to be charged and are discussed later in this report.)

The Senate-passed bill (§ 303) contains a provision that would authorize the HHS Secretary, based on public health considerations, including risks associated with food or its place of origin, to require food imports to be accompanied by “certification or such other assurances as the Secretary determines appropriate” that the food complies with some or all requirements of the act. Among other provisions, certifications would be used for designated food imported from countries where FDA has an agreement for a certification program. Certifying entities would be an agency or representative from the originating country or such other persons as accredited elsewhere (see section titled “Use of Third Parties for Imports and for Laboratory Accreditation”).

The Senate bill (§ 301) also would authorize a “Foreign Supplier Verification Program,” generally requiring each importer to perform foreign supplier verification activities in accordance with regulations the Secretary would issue to ensure compliance with relevant FFDC provisions. Each importer’s program would be able to assure that each of its foreign suppliers produces the imported food employing processes and procedures, “including reasonably appropriate risk-based preventive controls” that are documented in a written plan and equivalent in preventing adulteration and reducing hazards as required by other relevant provisions of the FFDC. Verification activities would include monitoring records, lot-by-lot certification of compliance, annual on-site inspections, checking the preventive control plan of the foreign supplier, and periodically testing and sampling shipments. Importers would maintain import verification program records for at least two years and make them available to the Secretary upon request. The House bill also contains provisions regarding foreign supplier verification (including provisions in §§ 204, 205, 206, and 136).

Among separate but related provisions in both the House and Senate bills are specific authorizations for the Secretary to review the equivalence of a foreign country’s safety standards, regulations, statutes, and controls and to conduct audits to verify their implementation; and to enter into arrangements with foreign countries to facilitate inspection of foreign facilities. Another feature of both bills would require the establishment of a program to expedite imports from those who voluntarily agree to certain higher safety standards. This program is called a “Safe and Secure Food Importation Program” in the House-passed bill (§ 113) and a “Voluntary Qualified Importer Program” in the Senate bill (§ 302).

Bisphenol A (BPA)

Are Food Containers with BPA Safe? Are Alternatives Available?

Bisphenol A (BPA) is a component of certain plastics. When used in food containers, such as plastic bottles or metal can liners, BPA is regulated by the FDA. Scientific disagreement about possible human health effects that may result from BPA exposure has led to conflicting regulatory decisions regarding the safety of these food containers, especially when intended for use by infants and children.¹¹⁹ FDA’s conclusion in 2008 that BPA use is safe conflicted with findings of

¹¹⁹ For additional background information, see CRS Report RS22869, *Bisphenol A (BPA) in Plastics and Possible Human Health Effects*.

advisory panels. This prompted some to question FDA's risk assessment process, and its ability to conduct such assessments. Recently, FDA expressed concern about possible health effects from BPA exposure, and announced that it was conducting new studies on the matter, pending possible changes in its regulatory approach.

In March 2009, several manufacturers of baby bottles announced that they would stop selling BPA-containing bottles in the United States, partly in response to growing numbers of retailers that would no longer carry the products.¹²⁰ However, manufacturers of cans maintain that suitable alternatives to BPA are not available and are not likely to become available in the immediate future. Until alternatives for all uses are developed, they argue that BPA-containing liners will be necessary to ensure a tight seal on cans and lids, and thus to prevent food spoilage and food poisoning risks to consumers. Manufacturers are seeking alternatives to meet consumer demand, but development will take time as new containers are produced and tested for diverse foods with different properties.¹²¹

Legislative Proposals

The House-passed bill (§ 215) would require FDA to determine whether there was “a reasonable certainty of no harm for infants, young children, pregnant women, and adults, for approved uses of polycarbonate plastic and epoxy resin made with bisphenol A in food and beverage containers ... under the conditions of use prescribed in current [FDA] regulations.” FDA would be required to notify Congress about any uses of BPA for which a determination of safety could not be made, and how the agency would regulate such uses to protect public health.

The Senate-passed bill does not contain a provision regarding BPA. It is reported that Senator Dianne Feinstein had sought unsuccessfully to incorporate S. 593, the Ban Poisonous Additives Act of 2009, a bill she sponsored that would ban BPA in all FDA-regulated food containers, or a modification of that bill.¹²²

Paying for Food Safety with User Fees

How Much Is Needed and Who Should Pay?

Many critics have argued that—irrespective of the need, if any, to reform food safety statutes and organization—a fundamental problem has been FDA's stated lack of sufficient funding and staff to carry out congressionally mandated (and existing) responsibilities to ensure a safe food supply.¹²³ Responding to a request from Democratic leaders of the House Energy and Commerce Committee, a subcommittee of the FDA Science Board¹²⁴ estimated that, in order to address these

¹²⁰ Lyndsey Layton, “No BPA for Baby Bottles in U.S.,” *The Washington Post*, March 6, 2009.

¹²¹ Lyndsey Layton, “Replacing BPA in Cans Gives Foodmakers Fits; FDA Safety Concerns Prompt Scramble to Remove the Chemical,” *The Washington Post*, February 23, 2010.

¹²² Ben Moscovitch, “Food Safety Passage Hurdles Persist as Senate Begins Deliberations,” *InsideHealthPolicy.com*, November 18, 2010.

¹²³ See, e.g., FDA Science Board, *FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology*, November 2007.

¹²⁴ The Science Board is one of several advisory committees to FDA. It consists of experts from academia and industry, and advises the Commissioner on specific complex and technical issues, as well as emerging issues within the scientific community, in industry and academia. It also provides advice to the Agency on keeping pace with technical and (continued...)

deficiencies, the food-related portion of FDA's appropriation should be increased.¹²⁵ In fact, congressional appropriators have increased funding for FDA food activities in recent years.¹²⁶ (See **Table 5**.)

Table 5. FDA Direct Appropriations for Foods, FY2005-FY2011

(dollars in millions)

	FY2005 actual	FY2006 actual	FY2007 actual	FY2008 actual	FY2009 actual	FY2010 appropriation	FY2011 request
Appropriations	435.5	438.7	457.1	507.8	712.8	784.1	1,041.9

Source: Compiled by CRS from FDA annual budget documents. Data are from the FY2007-FY2011 annual Food and Drug Administration, *President's Budget Request* "All Purpose Table—Total Program Level."

Proposed increases in program spending raise a variety of policy issues. Requests for higher appropriations compete with other priorities throughout the federal discretionary budget. The programs do not operate as mandatory authorizations as do farm support programs, for example, and currently are being made during a period of budget deficits.

An alternative approach to direct appropriations that has been used in some other areas of FDA is to fill perceived shortfalls through new user fees on the regulated industry. User fees related to foods have been proposed in legislation and in budget requests over time. The FY2011 President's budget request proposed \$6.467 million for reinspection fees, \$4.307 million for export certification fees, and \$182.783 million in inspection and registration fees. To date, no such user fees for foods have been explicitly authorized.

Currently, FDA's authority to collect user fees extends to human and animal prescription drugs and human medical devices (21 U.S.C. 379g - 379j-12);¹²⁷ human biologics (42 U.S.C. 262 note); and tobacco products (21 U.S.C. 387s). Some of these user fees are paid annually, and some are paid when submitting certain applications to FDA. The fees collected are intended to be used to fund approval-related activities; with the exception of tobacco fees, they can not be used to fund enforcement or inspection activities for products on the market, except to a very limited extent. (Unlike foods and some food additives, prescription drugs, medical devices, and animal drugs require FDA's advance permission before they can be legally marketed.) The user fee programs have generally been authorized in five-year increments (except for tobacco fees, which are permanently authorized). Each authorization specifies the fee amounts FDA may collect annually, among other legislative direction.

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scientific evolutions in the fields of regulatory science, formulating appropriate research agendas, and upgrading its scientific and research facilities to keep pace with these changes. FDA, *Science Board to the Food and Drug Administration*, October 6, 2010, <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/ScienceBoardtotheFoodandDrugAdministration/default.htm>.

¹²⁵ *Estimated Resources Required for Implementation*, report of the Science Board's Subcommittee on Science and Technology in response to the request of Representatives Dingell, Waxman, Stupak, and Pallone, February 25, 2008.

¹²⁶ See CRS Report R40792, *Food and Drug Administration Appropriations for FY2010*.

¹²⁷ See CRS Report RL34571, *Medical Device User Fees and User Fee Acts*; CRS Report RL33914, *The Prescription Drug User Fee Act (PDUFA): History, Reauthorization in 2007, and Effect on FDA*; and CRS Report RL34459, *Animal Drug User Fee Programs*.

FDA is also authorized to collect export certification fees for drugs, animal drugs, medical devices and biological products (21 U.S.C. 381(e)(4)). A person who exports any of these products may request that the Secretary certify in writing that the product meets FFDC requirements. If the Secretary issues a written export certification, a fee of up to \$175 may be charged.

The introduction of user fees for other FDA-regulated products has added to the agency's budget. Fees have provided additional resources for the agency to hire reviewers to conduct premarket reviews; to hire support personnel and field investigators to speed up the application review process for drugs, biological products, and medical devices; and to acquire and support critical information technology infrastructure.¹²⁸

The introduction of fees has also raised the following four issues, among others, which are applicable to policy discussions about food fees. First, proposals for new user fees typically meet with resistance, both from the companies that would have to absorb such costs and from consumer advocates, who argue that industry funds might cause conflicts of interest by having industry pay the salaries of some of its regulators. (Certain types of fees, such as for facility registration, have not been as vociferously opposed by some consumer advocates.) To help address the issues that underlie this resistance, clear conflict-of-interest guidelines as well as certain restrictions on how funds may be expended have been created in other areas.

Second, concerns are sometimes expressed that user fees, once authorized, comprise an ever-increasing proportion of the budget, and may supplant rather than supplement funding for the agency. For that reason, certain fees carry the requirement that direct appropriations meet a certain threshold before user fees can be collected.¹²⁹

Third, the funding generated by some types of fees—those that are periodic and associated with external events such as the submission of marketing applications—can be difficult to predict. However, FDA's highly trained staff can not easily be increased or trimmed to conform to short-term activity levels and associated available funds. One example of the dilemma of unpredictable fee funding comes from the area of medical device user fees. In FY2002, when they were initially authorized, the fees were all periodic, which led to unpredictable funding for the device program and caused some budgetary shortfalls.¹³⁰ In FY2007, in order to make user fee funding more consistent and reliable, certain annual fees (such as annual registration fees) were enacted to help resolve the issue.¹³¹

A fourth set of concerns has been raised by small businesses. In the area of drugs and devices, small businesses claim to be drivers of innovation, and caution that fees imposed on them have a disproportionate and chilling effect on their work. For that reason, many of the drug- and device-related user fees have reductions for small businesses.

¹²⁸ For an example regarding drugs, see U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Health, *Prepared Statement of Hon. Lester M. Crawford, Deputy Commissioner, Food and Drug Administration, Reauthorization of the prescription Drug User Fee Act, 107th Cong., 2nd sess., March 6, 2002, f:78503.wais* (Washington: GPO, 2002), pp. 30-31.

¹²⁹ See CRS Report RL34334, *The Food and Drug Administration: Budget and Statutory History, FY1980-FY2007*.

¹³⁰ See Barbara Zimmerman, *Medical Device Review Program Performance*, FDA, Webcast, 2010, <http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM224256.wmv>.

¹³¹ *Id.*, and see CRS Report RL34571, *Medical Device User Fees and User Fee Acts*; and CRS Report RL34465, *FDA Amendments Act of 2007 (P.L. 110-85)*.

Legislative Proposals

Each proposal would fund some FDA food safety activities through the collection of user fees, though the types of fees and details differ. (See **Table 6**.) The House-passed bill would establish two annual fees (a facility registration fee and an importer registration fee), and two fees related to periodic activities (a reinspection and recall fee, and an export certification fee). The Senate bill would establish one annual fee (for participants in the voluntary qualified importer program (VQIP)), and three fees for periodic activities (a reinspection fee, a recall fee, and an export certification fee). Details of these fees are presented in **Table 7** and **Table 8**, including, where specified, who pays the fee, the fee amount, restrictions on the fee amount, the result of nonpayment, how funds may be used, required reports and meetings, authorizations, appropriations-related restrictions on fee collection, and expiration dates. For fees paid annually, see **Table 7**. For periodic fees, see **Table 8**.

Table 6. Fees in the House-Passed Bill (H.R. 2749) and the Senate-Passed Bill (S. 510)

	H.R. 2749, House-passed	S. 510, Senate-passed
Facility Registration Fee	§ 101	None
Importer Registration Fee	§ 204	None
Reinspection Fee	§ 108	§ 107
Recall Fee	§ 108 (for all recalls)	§ 107 (for noncompliance with recall)
Export Certification Fee	§ 203	§ 401
VQIP Fee	None	§ 107

Source: Prepared by CRS based on the text of the House-passed and Senate-passed bills (H.R. 2749 and S. 510).

The House-passed bill would authorize higher fees, would carry a higher total price tag, and would mandate more frequent inspections than the Senate bill (as discussed in the front matter and inspection-related sections of this report). Regarding fees, the Congressional Budget Office (CBO) estimates that over five years, the House-passed bill would collect \$1.4 billion and the Senate bill would collect \$241 million (based on an assessment of the August 2010 manager’s amendment).¹³² CBO also estimates that covering the five-year cost of new requirements, including more frequent inspections, would require additional outlays of \$2.2 billion under the House-passed bill, and \$1.1 billion under the Senate bill.¹³³

The Senate-passed bill would exclude certain small businesses from FFDCA § 415 registration requirements, as discussed in the “Mitigating Effects on Small Business and Farming Operations” section. While this exclusion would not reduce the amount of fees collected under the Senate-passed bill (which has no registration fee), it would reduce the fees collected under the House-passed bill (which has a registration fee). As the Senate has passed S. 510, as amended by S.Amdt. 4715, the issue of which facilities must register and whether and how many fees would be collected could remain an issue to be reconciled between the House and Senate, and could affect the CBO score of the resulting legislation.

¹³² Ellen Werble, Rebecca Yip, and Zachary Epstein et al., *H.R. 2749: Food Safety Enhancement Act of 2009*, Congressional Budget Office, July 24, 2009, p. 5, <http://www.cbo.gov/ftpdocs/104xx/doc10478/hr2749.pdf>. Ellen Werble, Stephanie Cameron, and Susanne Mehlman et al., *S. 510: Food Safety Modernization Act*, Congressional Budget Office, August 12, 2010, p. 6, <http://www.cbo.gov/ftpdocs/117xx/doc11794/s510.pdf>.

¹³³ Note that the CBO scores in this paragraph are specific to FDA costs. For that reason, they are somewhat lower than amounts discussed earlier this report, which reflect estimated total federal costs.

Table 7. Comparison of Annual Fees in the House-Passed Bill (H.R. 2749) and the Senate-Passed Bill (S. 510)

Category	H.R. 2749, House-passed		S. 510, Senate-passed
	Facility Registration Fee	Importer Registration Fee	VQIP Fee
Who Pays	Facilities required to register under amended FFDCa § 415.	Importers required to register under new FFDCa § 801(s).	Importers participating in the voluntary importer certification program, under new FFDCa § 806.
Fee Amount	\$500/facility (inflation adjusted annually).	\$500/importer (inflation adjusted annually).	Amounts estimated as specified to cover 100% of the VQIP costs for that year.
Fee Amount Cap	\$175,000/person with multiple facilities (not inflation-adjusted).	None.	None.
	(Note: The Secretary must waive either the facility or importer fee for persons otherwise required to pay both.)		
Result of Nonpayment	Fees over 30 days past due treated as a claim of the U.S. Government under 31 U.S.C., chapter 37, subchapter II (Claims of the United States Government).	Nothing fee-specific, but registration under new FFDCa § 801(s) may be suspended or cancelled for FFDCa violations; foods are deemed misbranded if imported by an importer not duly registered under § 801(s).	Fees over 30 days past due treated as a claim of the U.S. Government under 31 U.S.C., chapter 37, subchapter II (Claims of the United States Government).
How Funds May Be Used	For food safety activities, as defined.	For registering importers under new FFDCa § 801(s) and ensuring compliance with good food importer practices.	For administering the VQIP program.
Required Reports, Meetings	Secretary must: (1) submit to Congress an annual report on the implementation of the authority and use of the fee; (2) hold an annual public meeting on how the fees would be used and collected.	None.	Secretary must: (1) publish within 180 days of enactment a proposed set of guidelines related to the burden of fee amounts on small businesses; (2) submit to Congress, not later than 120 days after each fiscal year in which fees are assessed, a specified report describing fees assessed and collected, entities paying such fees, and their types of business.
Authorization	Such sums as may be necessary for each of FY2010 through FY2014.	Such sums as may be necessary for each of FY2010 through FY2014.	For FY2010 and each FY thereafter, an amount equal to the revenue amount determined as specified.
Appropriations-Related Restrictions on Fee Collection	Fees must be refunded if appropriations for FDA's salaries and expenses (total, not just for food) are less than the preceding year's appropriations adjusted for inflation, as specified.	None.	Fees must be refunded if appropriations for FDA's food safety activities, excluding fees, are less than the preceding year's appropriations adjusted for inflation, as specified.
Expiration Date	Fee sunsets after FY2014.	None.	None.

Source: Prepared by the CRS based on the text of the House-passed and Senate-passed bills (H.R. 2749 and S. 510).

Table 8. Comparison of Periodic Fees in the House-Passed Bill (H.R. 2749) and the Senate-Passed Bill (S. 510)

Category	H.R. 2749, House-passed		S. 510, Senate-passed		
	Reinspection and Recall Fee	Export Certification Fee	Reinspection Fee	Recall Fee	Export Certification Fee
Who Pays	Facilities that must undergo an additional inspection for violating the FFDCA; or are subject to a food recall.	Exporters who voluntarily request and receive within 20 days Secretary's export certification under amended FFDCA § 801(e)(4).	If subject to reinspection in a fiscal year: the responsible party for a domestic facility (defined in new FFDCA § 415(b)), the U.S. registered agent for a foreign facility, or the importer.	If noncompliant with a recall order under FFDCA § 412(f) or new § 423: the responsible party for domestic facilities (defined in new FFDCA § 415(b)), or the importer.	Exporters who voluntarily request and receive within 20 days Secretary's export certification under amended FFDCA § 801(e)(4).
Fee Amount	Secretary sets fees at a level to fully cover cost of reinspections and/or recalls.	Secretary sets inflation-adjusted fee annually.	Secretary annually establishes fees for facilities and for importers so each fee covers 100% of the respective estimated reinspection-related costs.	Secretary annually establishes fees to cover 100% of estimated cost of food recall activities associated with such order performed by the Secretary.	Fees may cover the cost of certification.
Fee Amount Cap / Waiver	Secretary waives / refunds fees resulting from inappropriately ordered recalls.	Fee may not exceed amount reasonably related to the cost of issuing certificates.	The amount of fees collected may not exceed \$25 million in a given FY, except that if a domestic facility or importer becomes subject to a fee in a given year, the Secretary may collect it.	The amount of fees collected may not exceed \$20 million in a given FY, except that if a domestic facility or importer becomes subject to a fee in a given year, the Secretary may collect it.	Fee may not exceed \$175 per certification.
Result of Nonpayment	No provision in § 108 of bill.	No provision in § 203 of bill.	Fees over 30 days past due treated as a claim of the U.S. Government under 31 U.S.C., chapter 37, subchapter II (Claims of the United States Government).		No provision in § 107.
How Funds May Be Used	For recall and reinspection.	For issuing certifications.	For reinspection-related activities.	For food-recall-related costs associated with the recall order, for activities performed by the Secretary.	For issuing certifications.

Category	H.R. 2749, House-passed		S. 510, Senate-passed		
	Reinspection and Recall Fee	Export Certification Fee	Reinspection Fee	Recall Fee	Export Certification Fee
Required Reports, Meetings	None.	None.	Secretary must: (1) publish within 180 days of enactment a proposed set of guidelines related to the burden of fee amounts on small businesses; (2) submit to Congress, not later than 120 days after each fiscal year in which fees are assessed, a specified report describing fees assessed and collected, entities paying such fees, and their types of business.		None.
Authorization	Such sums as may be necessary for each of FY2010 through FY2014.	Fees shall be collected in each FY in an amount equal to the amount specified in appropriations acts.	For FY2010 and each FY thereafter, an amount equal to the revenue amount determined as specified.		No provision in § 107.
Appropriations-Related Restrictions on Fee Collection	None.	None.	Fees must be refunded if appropriations for FDA's food safety activities, excluding fees, are less than the preceding year's appropriations adjusted for inflation, as specified.		None.
Expiration Date	None.	None.	None.	None.	None.

Source: Prepared by the CRS based on the text of the House-passed and the Senate-passed bills (H.R. 2749 and S. 510).

Appendix A. Snapshot of Provisions in the House-Passed Bill (H.R. 2749) and the Senate-Passed Bill (S. 510), Ranked by Section Number

Subject Matter	H.R. 2749 (House-passed)	S. 510 (Senate-passed)
PROVISIONS ACCORDING TO SECTIONS OF H.R. 2749, IN NUMERICAL ORDER		
Jurisdiction	Rules of Construction (§ 4); USDA Exemptions (§ 5); Alcohol-Related Facilities (§ 6); Extraterritorial Jurisdiction (§ 213)	Jurisdiction; Authorities (§ 403); Alcohol-Related Facilities (§ 116); Compliance With International Agreements (§ 404)
Food Facility Registration Requirements	Changes in Registration of Food Facilities (§ 101)	Registration of Food Facilities (§ 102)
Hazard Prevention Plans	Hazard Analysis, Risk-Based Preventive Controls, Food Safety Plan, Finished Product Test Results from Category I Facilities (§ 102)	Hazard Analysis and Risk-Based Preventive Controls (§ 103)
Performance Standards	Performance Standards (§ 103)	Performance Standards (§ 104)
Produce Safety Standards	Safety Standards for Produce and Certain Other Raw Agricultural Commodities (§ 104)	Standards for Produce Safety (§ 105)
Inspection of Facilities	Risk-Based Inspection Schedule (§ 105)	Targeting of Inspection Resources for Domestic Facilities, Foreign Facilities, and Ports of Entry; Annual Report (§ 201)
Recordkeeping Requirements and FDA Access to Records	Access to Records (§ 106). See also the records provisions in “Traceability of Food,” § 107, and “Registration for Customs Brokers,” § 205	Inspections of Records (§ 101). See also “Enhancing Tracking and Tracing of Food and Recordkeeping,” § 204
Traceability of Food	Traceability of Food (§ 107); Unique identification number for food facilities, importers, and custom brokers (§ 206)	Enhancing Tracking and Tracing of Food and Recordkeeping (§ 204)
Funding and Fees	Changes in Registration of Food Facilities (§ 101); Reinspection and Food Recall Fees Applicable to Facilities (§ 108); Exportation Certificate Program (§ 203); Registration for Commercial Importers of Food; Fee (§ 204)	Authority to Collect Fees (§ 107); Funding for Food Safety (§ 401)
Third Party Accreditation	Certification and Accreditation (§ 109, part)	Accreditation of Third-Party Auditors (§ 307)
Laboratory Accreditation	Testing by Accredited Laboratories (§ 110)	Recognition of Laboratory Accreditation for Analyses of Foods (§ 202)
Mandatory Recall Authority	Notification, Nondistribution, and Recall of Adulterated or Misbranded Food (§ 111)	Mandatory Recall Authority (§ 206)
Reportable Food Registry	Reportable Food Registry: Exchange of Information (§ 112)	Improving the Reportable Food Registry (§ 211)
Expediting Imports	Safe and Secure Food Importation Program (§ 113)	Voluntary Qualified Importer Program (§ 302)

Subject Matter	H.R. 2749 (House-passed)	S. 510 (Senate-passed)
Infant Formula	Infant Formula (§ 114)	No comparable provision.
Foodborne Illness Surveillance and Education	Surveillance (§ 121) Public Education and Advisory System (§ 122)	Surveillance (§ 205)
Research	Research (§ 123)	Food Safety Integrated Centers of Excellence (§ 210)
Seizure of Food	Procedures for Seizure (§ 131)	No comparable provision.
Administrative Detention of Food	Administrative Detention (§ 132)	Administrative Detention of Food (§ 207)
Quarantine Authority	Authority to Prohibit or Restrict the Movement of Food (§ 133)	No comparable provision.
Criminal Penalties	Criminal Penalties (§ 134)	No comparable provision.
Civil Penalties	Civil Penalties for Violations Relating to Foods (§ 135)	No comparable provision.
Import Entry Filings (See also “Foreign Supplier Verification,” below.)	Improper Import Entry Filings (§ 136)	No comparable provision.
Food Substances Generally Recognized As Safe (GRAS)	Food Substances Generally Recognized As Safe (§ 201)	No comparable provision.
Country-of-Origin Labeling (COOL)	Country of Origin Labeling (§ 202)	No comparable provision.
Export Certification Fees	Exportation Certificate Program (§ 203)	Authority to Collect Fees (§ 107)
Foreign Supplier Verification	Registration for Commercial Importers of Food; Fee (§ 204); Registration for Customs Brokers (§ 205); Unique Identification Number for Food Facilities, Importers and Customs Brokers (§ 206); Improper Import Entry Filings (§ 136)	Foreign Supplier Verification Program (§ 301)
Inspection of Foreign Facilities	Prohibition Against Delaying, Limiting, or Refusing Inspection (§ 207); Risk-Based Inspection Schedule (§ 105, part); Certification and Accreditation (§ 109, part)	Inspection of Foreign Food Facilities (§ 306)
FDA Foreign Offices	Dedicated Foreign Inspectorate (§ 208)	Foreign Offices of the Food and Drug Administration (§ 308)
Other Laboratory Provisions	Plan and Review of Continued Operation of Field Laboratories (§ 209)	Integrated Consortium of Laboratory Networks (§ 203)
False or Misleading Reporting to FDA	False or Misleading Reporting to FDA (§ 210)	No comparable provision.
FDA Subpoena Authority	Subpoena Authority (§ 211)	No comparable provision.
Whistleblower Protection	Whistleblower Protections (§ 212)	Employee Protections (§ 402)

Subject Matter	H.R. 2749 (House-passed)	S. 510 (Senate-passed)
See “Jurisdiction” row of Appendix B for § 213 of H.R. 2749 regarding extraterritorial jurisdiction.		
State and Local Food Safety Roles and Training	Support for Training Institutes (§ 214)	Improving the Training of State, Local, Territorial, and Tribal Food Safety Officials (§ 209); Enhancing Food Safety (§ 210)
Bisphenol A (BPA)	Bisphenol A in Food and Beverage Containers (§ 215)	No comparable provision.
Lead in Ceramics	Lead Content Labeling Requirement for Ceramic Tableware and Cookware (§ 216)	No comparable provision.
PROVISIONS ACCORDING TO SECTIONS IN S.Amdt. 4715 to S. 510 THAT HAVE NOT ALREADY BEEN LISTED, IN NUMERICAL ORDER		
Intentional Adulteration and Domestic Food Defense	Hazard Analysis, Risk-Based Preventive Controls, Food Safety Plan, Finished Product Test Results from Category I Facilities (§ 102)	Protection Against Intentional Adulteration (§ 106); National Agriculture and Food Defense Strategy (§ 108); Food and Agriculture Coordinating Councils (§ 109); Building Domestic Capacity (§ 110)
Sanitary Transportation of Food	No comparable provision.	Sanitary Transportation of Food (§ 111)
Food Allergy and Anaphylaxis	No comparable provision.	Food Allergy and Anaphylaxis Management (§ 112)
Vitamins and Minerals Containing Anabolic Steroids	No comparable provision.	New Dietary Ingredients (§ 113)
Seafood	No comparable provisions.	Requirements for Guidance Relating to Post Harvest Processing of Raw Oysters (§ 114); Updating Guidance Relating to Fish and Fisheries Products Hazards and Controls (§103, part)
Port Shopping	No comparable provision.	Port Shopping (§ 115)
See “Jurisdiction” row of Appendix B for § 116 of S. 510 regarding alcohol.		
Food Decontamination and Disposal	No comparable provision.	Decontamination and Disposal Standards and Plans (§ 208)
Import Certification	Certification and Accreditation (§ 109, part)	Authority to Require Import Certifications for Food (§ 303)
Prior Notice of Imports	No comparable provision.	Prior Notice of Imported Food Shipments (§ 304)
Foreign Capacity Building	No comparable provision.	Building Capacity of Foreign Governments with Respect to Food (§ 305)
Smuggled Food	No comparable provision.	Smuggled Food (§ 309)
Pay-As-You-Go	No comparable provision.	Determination of Budgetary Effects (§ 405)

Source: Table created by CRS based on the text of the House-passed and the Senate-passed bills (H.R. 2749 and S. 510). Provisions are listed in numerical order by section number, beginning with sections in H.R. 2749, followed by sections in S. 510 not yet presented.

Appendix B. Comparison of Current Law with Provisions in the House-Passed Bill (H.R. 2749) and the Senate-Passed Bill (S. 510)

Background, Applicable Current Law, and Administration Statements	H.R. 2749 (House-passed)	S. 510 (Senate-passed)
PROVISIONS ACCORDING TO SECTIONS OF H.R. 2749, IN NUMERICAL ORDER		
JURISDICTION		
<p>The preemption doctrine is derived from the Supremacy Clause of the U.S. Constitution, which establishes that the laws of the United States “shall be the supreme law of the land; and the judges in every state shall be bound thereby, any thing in the Constitution or laws of any State to the contrary notwithstanding.” In general terms, federal preemption occurs when a validly enacted federal law supersedes any inconsistent state law. Courts’ application of this may involve such factors as whether or not a federal statute has explicitly stated Congress’ intent on the matter. This issue is discussed regarding medical devices in CRS Report R40534, <i>Riegel v. Medtronic, Inc.: Federal Preemption of State Tort Law Regarding Medical Devices with FDA Premarket Approval</i>.</p> <p>Separately, FFDCa § 902(b) generally exempts meat and meat food products from the provisions of the FFDCa; § 24 of the Poultry Products Inspection Act (PPIA) generally exempts poultry and poultry products from FFDCa provisions.</p> <p>Alcohol</p> <p>The Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) provides for regulation of those engaged in the alcohol beverage industry, and for the protection of consumers.</p>	<p>Rules of Construction (§ 4)</p> <p>The preemption provision states that “Nothing in this Act or the Amendments made by this Act shall be construed to prohibit or limit—(1) any cause of action under State law; or (2) the introduction or evidence of compliance or noncompliance with” the FFDCa.</p> <p>Also clarifies that nothing in this Act is to limit or otherwise alter the current jurisdiction or authorities between the Secretaries of HHS and of Agriculture, including those under the FFDCa, Public Health Service Act, the Federal Meat Inspection Act (FMIA), the PPIA, or the Egg Products Inspection Act (EPIA).</p> <p>USDA Exemptions (§ 5)</p> <p>Explicitly exempts from this Act foods and establishments to the extent that they are regulated under the FMIA, PPIA, or EPIA. Exempts a farm “to the extent such farm raises animals from which” such foods are derived. Clarifies that livestock and poultry intended for slaughter under the FMIA, PPIA, as well as milk-producing cows, sheep, or goats are exempt.</p> <p>Alcohol-Related Facilities (§ 6)</p> <p>Similar to the Senate provision, except that it contains a shorter list of provisions excepted from the exemption. Notably, mandatory recall and administrative detention provisions are not excepted from the exemption. Therefore, they would not apply to alcohol-related beverages and facilities.</p>	<p>Jurisdiction; Authorities (§ 403)</p> <p>Not a preemption provision; provides that this Act, and any amendment made by it, would not: (1) alter jurisdiction between HHS and USDA under applicable statutes, regulations, or agreements regarding products eligible for voluntary inspection under the Agricultural Marketing Act (7 U.S.C. 1621 et seq.); (2) alter the jurisdiction between the Administration of the Alcohol and Tobacco Tax and Trade Bureau and the HHS Secretary; (3) limit the authority of the HHS or Agriculture Secretary under specified existing statutes (including the FFDCa); or (4) impede, minimize, or affect the authority of the Secretary of Homeland Security under the Homeland Security Act (6 U.S.C. 101 et seq.).</p> <p>Alcohol-Related Facilities (§ 116)</p> <p>Generally exempts from this Act (the Manager’s Amdt.) beverages and facilities that are primarily regulated under the Alcohol Administration Act. Certain of the act’s provisions are excepted from this exemption, including those related to registration, mandatory recall, and administrative detention, among others; these provisions would apply to alcohol-related beverages and facilities.</p>

Background, Applicable Current Law, and Administration Statements	H.R. 2749 (House-passed)	S. 510 (Senate-passed)
	<p>Extraterritorial Jurisdiction (§ 213)</p> <p>Makes the following a prohibited act under the FFDCa: “The production, manufacture, processing, preparation, packaging, holding, or distribution of an adulterated or misbranded food with the knowledge or intent that such article will be imported into the United States.”</p> <p>Adds a new § 312 to the FFDCa stating that “There is extraterritorial Federal jurisdiction over any violation of this Act relating to any food if such article was intended for import into the United States or if any act in furtherance of the violation was committed in the United States.”</p>	<p>Compliance With International Agreements (§ 404)</p> <p>Nothing in this Act shall be construed in a manner inconsistent with the agreement establishing the World Trade Organization or any other agreement or treaty to which the United States is a party.</p>
<p>FOOD FACILITY REGISTRATION REQUIREMENTS (See also “Registration”, “Mitigating Effects on Small Business and Farming Operations” and “Paying for Food Safety with User Fees” sections of this report.)</p>		
<p>Some assert that registration requirements should be strengthened so that FDA is notified when a firm moves, undertakes a new food business, or changes product lines. Otherwise, the FDA’s records on what facilities are manufacturing and marketing food are continually out of date, it is argued. Others have argued that additional registration requirements would be needlessly intrusive and costly for the industry.</p> <p>Both domestic and foreign food facilities are required to register with FDA pursuant to FFDCa § 415. Farms, restaurants, other retail food establishments, and most nonprofit food establishments and fishing vessels are excluded from the requirement. Renewal is not required on any periodic basis, but registrants must notify the Secretary in a timely manner of any relevant changes in their status. FFDCa § 301(dd) designates failure to register as a prohibited act. FFDCa § 801(l) provides that imported food may not be delivered to the importer, owner, or consignee of the article until the foreign facility is registered. FDA does not have explicit authority to require a registration fee.</p> <p>Obama Administration: The Hamburg and Taylor testimonies express support for § 101 of the House bill.</p>	<p>Changes in Registration of Food Facilities (§ 101)</p> <p>Amends FFDCa § 415 both to require facilities to register annually, by each December 31, and to pay an annual registration fee of \$500. The Secretary is authorized to suspend the registration of any facility for an FFDCa violation that could result in serious adverse health consequences or death to humans or animals. Where the Secretary exercises this discretionary suspension authority, the Secretary must first provide the facility a notice of intent and opportunity for an informal hearing, after which a suspension order may be written for finding a violation, with timelines for doing so specified. A suspended registration could be reinstated based on criteria published by the Secretary. Places limitations on the Secretary’s authority to delegate suspension decisions.</p> <p>Makes failure to register an act of “misbranding” under FFDCa § 403.</p> <p>Also amends the information requirements of registrants to include: the name, address, and emergency contact of each facility being registered; its primary purpose and business activity, including dates of operation if seasonal; the category of food manufactured, processed, packed or held there; all business trade names; and the name, address and 24-hour emergency contact information of the U.S.</p>	<p>Registration of Food Facilities (§ 102)</p> <p>Amends FFDCa § 415 to require biennial facility registration, with an abbreviated process for registrants whose information has not changed. Registrants are required to provide additional contact information, including an e-mail address and, for foreign facilities, the United States agent for the facility. Registrants must also provide an assurance that the Secretary will be permitted to inspect the facility. The Secretary is authorized or required to suspend and/or reinstate registrations, based on the Secretary’s determination that “food manufactured, processed, packed, or held by a facility registered under this section has a reasonable probability of causing serious adverse health consequences or death to humans or animals” for a facility that “created, caused, or was otherwise responsible” or “that knew of, or had reason to know of, such reasonable probability.” The bill delineates an appeal process, including a requirement for an informal hearing generally within two business days, and procedures for submission of a corrective action plan and for lifting a suspension. The Secretary shall review corrective action plans “not later than 14 days after the submission” of such plans. The Secretary also shall promulgate regulations regarding suspension and reinstatement procedures. If its registration is suspended, a facility may not import food, or</p>

Background, Applicable Current Law, and Administration Statements	H.R. 2749 (House-passed)	S. 510 (Senate-passed)
	<p>distribution agent. Further requires registrants to notify the Secretary of any changes in products, function or legal status within 30 days of a change, unless otherwise specified by the Secretary, who may cancel a registration that is improperly updated or contains false, misleading, or inaccurate information, or if the required fee is not paid within 30 days.</p> <p>Contains extensive language defining what is and is not a facility. A facility is “any factory, warehouse, or establishment (including a factory, warehouse or establishment of an importer) that manufactures, processes, packs or holds food.” Stipulates that a facility is not a farm, a private residence, a restaurant or other retail food establishment, a nonprofit establishment that prepares or serves food directly, or a fishing vessel, and further clarifies what is meant by these exceptions. Also specifies what a farm may or may not do to be exempted from facility registration requirements.</p> <p>Clarifies that a “retail food establishment” includes an establishment that, as its primary function, “sells food products (including those food products that it manufactures, processes, packs, or holds) directly to consumers (including by Internet or mail order),” and also includes grocery stores, convenience stores, vending machine locations, and stores that sell bagged feed, pet food, and feed ingredients or additives over-the-counter directly to consumers and final purchasers for their own personal animals.</p> <p>See also “Funding and Fees” and “Foreign Supplier Verification” below regarding importer registration requirements and fees.</p>	<p>introduce food into interstate or intrastate commerce, in the United States. The Secretary’s authority to suspend registration shall not be delegated to anyone other than the FDA Commissioner. The Secretary may require that registration be submitted electronically, but not earlier than 5 years after enactment.</p> <p>Contains provisions for consideration of small businesses. Requires the Secretary to issue a “small entity compliance policy guide” setting forth the requirements of such regulations to assist small entities in complying with the registration requirements and other activities (no later than 180 days after the issuance of the regulations under this section).</p> <p>Requires the Secretary to amend the definition of “retail food establishment” (21 CFR 1.227(b)(11)) to clarify that, in determining the primary function of such an establishment, the sale of food directly to consumers would include sales by a roadside stand or farmers’ market, sales through a community supported agriculture (CSA) program, or other types of direct food sales as determined by the Secretary.</p>
<p>HAZARD PREVENTION PLANS (See also “Hazard Analysis and Risk-Based Preventive Controls”, “Mitigating Effects on Small Business and Farming Operations”, and “Mandatory Recall Authority” sections of this report.)</p>		
<p>A broad consensus of policymakers agrees that FDA’s system of safeguards, which is based on a law first written early the last century, is primarily reactive. By and large, the agency’s statute and regulations spell out the reasons a food article is to be considered adulterated or misbranded and</p>	<p>Hazard Analysis, Risk-Based Preventive Controls, Food Safety Plan, Finished Product Test Results from Category I Facilities (§ 102)</p> <p>Establishes a new FFDCA § 418, with provisions broadly similar to those in S. 510, but differing somewhat in detail</p>	<p>Hazard Analysis and Risk-Based Preventive Controls (§ 103)</p> <p>Establishes a new FFDCA § 418, requiring the owner, operator, or agent in charge of a facility to develop a written plan and carry out certain preventive activities in</p>

Background, Applicable Current Law, and Administration Statements	H.R. 2749 (House-passed)	S. 510 (Senate-passed)
<p>therefore unfit for consumption. In effect, industry players are expected to abide by the rules; generally it is only when a problem is detected—often after an illness outbreak is reported or testing finds a contaminant in a product—that officials step in to correct it, or order the industry to do. So virtually all stakeholders, including regulators, the regulated industries, consumer advocates, and food safety scientists now agree that the foundations of any new program should be an understanding of what, and how, hazards can enter the food supply, followed by implementation of measures to prevent these hazards.</p> <p>FDA currently requires that managers of certain food facilities—those producing or processing seafood, some juices, and low-acid canned foods—prepare Hazard Analysis and Critical Control Point (HACCP) plans for their operations. HACCP is a preventive approach that incorporates hazard analysis, appropriate process controls, verification, and other steps throughout the production process. A cornerstone of HACCP is the identification of hazards by industry that are “reasonably likely to occur.” The emphasis on hazards that are reasonably likely to occur assures that such hazards—such as microbial contamination in fresh juices, or botulism in low-acid canned foods—are systematically and consistently addressed.</p> <p>There is no explicit statutory authority or requirement regarding HACCP systems for FDA-regulated foods. FDA regulations requiring HACCP plans and systems for seafood, fruit and vegetable juices, and low-acid canned foods cite the applicable statutory authority as FFDCA § 402(a), which defines adulteration, and the Secretary’s general authority to promulgate regulations to assure the safety of foods, at FFDCA § 701(a).</p> <p>At the U.S. Department of Agriculture, the Food Safety and Inspection Service (FSIS) in 1996 began implementing rules to establish a mandatory HACCP for meat and poultry, using its authority to regulate major meat and poultry species under the Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA). Record keeping and verification are used to ensure that the system is working. Following a phase-in period to accommodate</p>	<p>and organization. Like S. 510, requires the owner, operator, or agent of a facility to analyze hazards and implement controls to prevent or reduce them, but unlike S. 510, requires a food safety plan to be developed and implemented before a facility introduces or delivers for introduction into interstate commerce any shipment of food.</p> <p>Requires (under § 418A) that this plan include a hazard analysis to identify whether there are hazards, including those due to the source of ingredients, that are reasonably likely to occur in the absence of preventive controls. The plan also must include descriptions of:</p> <ul style="list-style-type: none"> • preventive controls being implemented including those to address hazards identified by the Secretary; • procedures for monitoring preventive controls; • procedures for taking corrective actions; • verification activities including validation that such controls are effective (to include use of environmental and product testing programs); • monitoring of such preventive controls to verify effectiveness; • record keeping procedures (records must be kept for at least two years); • both established recall procedures and traceback procedures; • procedures to ensure the safety of the supply chain for ingredients; • procedures to implement performance standards issued by the Secretary (under a new FFDCA § 419). <p>The owner, operator, or agent must conduct a reanalysis of hazards (and revise preventive controls if necessary): (1) at least every two years (S. 510 is every three years); (2) if there is a change in the process or product that could affect the hazard analysis; and (3) if the Secretary determines it is appropriate to protect public health. Limits</p>	<p>the plan, including:</p> <ul style="list-style-type: none"> • conducting an analysis to identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility, hazards that may be intentionally introduced, including by acts of terrorism; and preparing a written analysis; • identifying and implementing preventive controls, including at critical control points, if any, to provide assurances that identified hazards will be prevented or minimized, and that food is not adulterated or misbranded; • developing a means to verify the effectiveness of these preventive controls; • implementing corrective actions if controls are found, through monitoring, not to have been effective (specifies that corrective actions ensure “(1) appropriate action is taken to reduce the likelihood of recurrence of the implementation failure; (2) all affected food is evaluated for safety; and (3) all affected food is prevented from entering into commerce if the owner, operator or agent in charge of such facility cannot ensure that the affected food is not adulterated,” as defined by law) • verifying that preventive controls are effective, that monitoring is ongoing, that corrective actions are taken when needed, and that the plan is periodically reviewed for continued relevance; • keeping and maintaining, for at least two years, records documenting the monitoring of preventive controls, relevant instances of nonconformance, instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions. <p>Applicable definitions are provided in this section for “critical control point,” “facility,” and “preventive controls.” The required plan and associated documentation of performance must be made promptly available to an authorized representative of the Secretary upon oral or written request. The hazards must be reanalyzed at least every three years, or sooner if there is a change in</p>

Background, Applicable Current Law, and Administration Statements	H.R. 2749 (House-passed)	S. 510 (Senate-passed)
<p>smaller sized establishments, and since January 2000, all slaughter and processing operations have been required to have HACCP plans in place. HACCP is intended to operate as an adjunct to the traditional methods of facility inspection, which still are mandatory under the original statutes.</p> <p>Obama Administration: The Administration's Food Safety Working Group (FSWG) stated that the Administration would work with Congress on "critical legislation that will provide key tools to keep food safe." One tool it cited was the ability to require sanitation and preventive controls at food facilities, based on a scientific hazard analysis. The Hamburg and Taylor testimonies express support for § 102 of the House bill.</p>	<p>the Secretary's ability to delegate the authority to order revisions. Contains applicable definitions (including one not in S. 510 defining "hazard that is reasonably likely to occur"), the same deemed compliance for seafood, juice, and low-acid canning facilities, and the same effective dates based on business size as in S. 510.</p> <p>Also as is similar in S. 510, the Secretary is required to issue guidance or regulations on standards for conducting a hazard analysis and establishing preventive controls. However, the Secretary must allow the facility to implement an alternative preventive control if it is able to demonstrate that it effectively addresses the hazard. Food from facilities not in compliance with these provisions are to be considered adulterated under the FFDCa.</p> <p>In issuing guidance or regulations, the Secretary must, to seek consistency, review relevant international standards for hazard analysis and preventive controls. The Secretary also must consider their impact on small businesses and must issue guidance to assist small businesses in complying.</p> <p>The Secretary is authorized to exempt from or modify, by regulation, the requirements with respect to facilities engaged solely in the production of food for nonhumans (and may take into account differences between human and animal foods), facilities that store packaged foods not exposed to the environment, or facilities that store raw agricultural commodities for further distribution or processing.</p> <p>Further, under a new FFDCa § 418B, the Secretary must require submission of finished product test results by the owner, operator, or agent of each category I facility (see "Risk-Based Inspection Schedule," below, for definition of such facility) "...documenting the presence of contaminants in food in the possession or control of such facility posing a risk of severe adverse health consequences or death." Such submissions are those determined by the Secretary to be feasible and appropriate and taking into consideration available information on potential risks; and this section is not to: construe a requirement for mandated "testing or submission of test results that the Secretary determines</p>	<p>processes or practices that could create or worsen a hazard. The Secretary may require a revision of the plan based on a new hazard or new scientific information, including, as appropriate, "results from the Department of Homeland Security biological, chemical, radiological, or other terrorism risk assessment." Failure to comply with the requirements of this section is prohibited under FFDCa § 301.</p> <p>Seafood, juice, and low-acid canned-food facilities that are already in compliance with applicable FDA regulations are deemed to be in compliance with this section. Facilities subject to requirements in FFDCa § 419, as established by this act (regarding safety standards for produce), are not subject to this section. The Secretary may, by regulation, exempt or modify the requirements of this section for facilities that are solely engaged in the production of food for animals other than man, the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing, or the storage of packaged foods that are not exposed to the environment. This section does not limit the Secretary's authority to revise, issue or enforce regulations for specific types of foods, such as the HACCP regulations currently in effect for certain foods. This section does not apply to dietary supplements.</p> <p>Considering existing regulatory hazard analysis and preventive control programs to determine applicable internationally recognized standards, the Secretary shall promulgate regulations not later than 18 months after enactment regarding the implementation of requirements under this section, and shall issue an applicable guidance document. Regulations shall be sufficiently flexible to be applicable in all situations, including the operations of small businesses. This section does not provide the Secretary with the authority to apply specific technologies, practices, or critical controls to an individual facility.</p> <p>Contains clarifying language regarding the promulgation of FDA regulations, including consideration for various types of businesses and activities (on-farm and at processing facilities). Contains provisions for consideration of small</p>

Background, Applicable Current Law, and Administration Statements	H.R. 2749 (House-passed)	S. 510 (Senate-passed)
	<p>would not provide useful information in assessing the potential risk presented by a facility or product category”; or to limit the Secretary’s authority under other provisions to access information or test results including in the course of an investigation of an illness or contamination incident.</p> <p>This requirement is to take effect on the sooner of either 2 years from date of enactment or the completion of a feasibility study and at least two pilot projects that are required. Food from a facility not in compliance with the requirements of new § 418B is adulterated.</p>	<p>businesses. Requires the Secretary to issue a “small entity compliance policy guide” setting forth the requirements of such regulations to assist small entities in complying with the registration requirements and other activities (no later than 180 days after the issuance of the regulations under this section), along with other flexibility and extended implementation deadlines for small and very small businesses. Requirements become effective in stages according to the size of the business: businesses must be compliant 18 months after the date of enactment, except small businesses (as defined by the Secretary) are to have 2 years after enactment, and very small businesses (as defined by the Secretary) 3 years after enactment.</p> <p>Under added language in S. Amdt. 4715 certain facilities would not be subject to the requirements. Food facilities would qualify for an exemption from the HACCP requirements if they are either a “very small business” as defined by FDA in rulemaking, or if the facility’s “average annual monetary value” of all food sold during the previous 3 year period was less than \$500,000, provided that the food is sold directly to “qualified end users” such as consumers, restaurants, or retail food establishments that are located in the same state where the facility sold the food or within 275 miles of the facility. Such a facility would need to demonstrate that it either has “identified potential hazards associated with the food being produced,” and is implementing and monitoring these preventive controls, or that it is “in compliance with State, local, county, or other applicable non-Federal food safety law.” Foods produced from such a facility would also need to provide the facility’s name and address on a food packaging label or at the point of purchase. Requires FDA to conduct a study of the food processing sector, in conjunction with USDA.</p>
PERFORMANCE STANDARDS (See also “Performance Standards” section of this report.)		
<p>Performance standards are typically specific, quantitative measurements of a property of, or a substance in, food. They may apply strictly to the property being measured, or serve as benchmarks for whether the food is safe in a broader sense. For example, a performance standard for a</p>	<p>Performance Standards (§ 103)</p> <p>Similar in intent but not identical to S. 510. Under a new FFDC § 419, the Secretary must at least every two years review and evaluate epidemiological data and other appropriate information, including research under § 123</p>	<p>Performance Standards (§ 104)</p> <p>In coordination with USDA, the Secretary shall, at least every two years, review and evaluate relevant health data and other relevant information, including epidemiological and toxicological data and other appropriate information to</p>

Background, Applicable Current Law, and Administration Statements	H.R. 2749 (House-passed)	S. 510 (Senate-passed)
<p>single microbe might be used to determine whether a product is contaminated with microbes in general. (This approach is sometimes called process verification.) Such a finding could indicate a problem with the product’s processing, and prompt a review of processing activities. The FFDCA (in various provisions in Chapter IV, regarding food) authorizes FDA to promulgate standards for certain hazards, such as maximum permissible levels (called tolerances) for residues of pesticides or drugs in foods. The FFDCA does not grant FDA the explicit authority to develop standards solely as a means to verify that processing is carried out in a manner that assures the safety of the food.</p> <p>Obama Administration: The FSWG stated that the Administration would work with Congress on “critical legislation that will provide key tools to keep food safe.” One tool it cited was the ability to establish performance standards to measure the implementation of proper food safety standards. The Hamburg and Taylor testimonies express support for § 103 of the House bill.</p>	<p>(the research section) of the bill, to identify the most significant food-borne contaminants and resulting hazards. Following each review, the Secretary must publish in the Federal Register a list of contaminants that have the greatest adverse impact on public health (and must consider the number and severity of illnesses and deaths associated with the contaminant in a food).</p> <p>The Secretary must issue, “as soon as practicable” through guidance or by regulation, science-based performance standards (which may include action levels) to significantly minimize, prevent, or eliminate such hazards. The standards shall apply to foods and food classes. Foods not meeting required standards are to be considered adulterated. The Secretary is authorized to make recommendations to industry on product sampling. Finally, the Secretary must report to Congress on the review including how the Secretary will address significant hazards and any resource or data limitations that preclude further action.</p>	<p>determine the most significant foodborne contaminants.</p> <p>Based on such review and evaluation and when appropriate to reduce the risk of serious illness or death to humans or animals, or to prevent the adulteration of the food under FFDCA § 402 or the spread of communicable disease under PHS Act § 361, the Secretary shall issue contaminant-specific and science-based guidance documents, actions levels, or regulations. Such standards shall apply to products and product classes, may differentiate between food for humans and food for animals, and shall not be written to be facility-specific. HHS shall coordinate with USDA to avoid duplication of effort regarding guidance documents for the same contaminant. The Secretary will issue and periodically review/revise all guidance documents and regulation.</p>
<p>PRODUCE SAFETY STANDARDS (See also “On-Farm Safety Standards; Safety of Produce” and “Mitigating Effects on Small Business and Farming Operations” sections of this report.)</p>		
<p>As noted earlier, the FFDCA authorizes FDA to promulgate standards for certain hazards, some of which, such as maximum permissible levels (called tolerances) for residues of pesticides, may apply to produce. The FFDCA does not grant FDA explicit authority to develop standards solely as a means to verify that processing is carried out in a manner that assures the safety of the food. FDA has several voluntary efforts in place to address safety in the produce industry. For example, in February 2008, the agency issued the final version of the Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables, which contains non-binding recommendations regarding: primary production and harvesting of fresh fruits and vegetables; personnel; buildings and equipment; sanitation operations; production and process controls; documentation and records; traceback; and recall. On September 2, 2008, FDA published a notice in the Federal</p>	<p>Safety Standards for Produce and Certain Other Raw Agricultural Commodities (§ 104)</p> <p>Under a new FFDCA § 419A, within 18 months of enactment, the Secretary (in coordination with the Secretary of Agriculture) must publish a notice of proposed rulemaking, and within three years after such date, final rules establishing scientific and risk-based standards for the safe growing, harvesting, processing, packing, sorting, transporting, and holding of those types of raw agricultural commodities that are from a fruit, vegetable, nut, or fungus, and for which the Secretary has determined such standards are reasonably necessary to minimize the risk of serious adverse health consequences or death to humans or animals</p> <p>These regulations may set forth procedures and practices that the Secretary determines reasonable to prevent</p>	<p>Standards for Produce Safety (§ 105)</p> <p>Subsection (a) of this section establishes a new FFDCA § 419, regarding safety standards for produce. Within one year of enactment, the Secretary (in consultation with USDA and state agriculture departments, including with regard to the national organic foods program, and in consultation with DHS), is required to publish a notice of proposed rulemaking for science-based minimum standards for the safe production and harvesting of those fruits and vegetables that are raw agricultural commodities (including mixes and specific categories of fruits and vegetables), for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death. The Secretary may exclude from such rulemaking commodities determined to be low risk when produced or harvested by small or very small businesses. The Secretary shall hold at least 3 public meetings on such rulemaking in</p>

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<p>Register seeking comments and data to assist the agency in its revision, now underway, of its 1998 Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables. Also, FDA asserts that it has been engaged in efforts to identify hazards commonly associated with fresh produce, and to develop tracking and tracing methods.</p> <p>Under the Agricultural Marketing Agreement Act of 1937 (7 U.S.C. § 601 et seq.), producers and handlers can organize themselves under legally binding marketing orders that can include quality (and possibly, safety) standards. The act is overseen by USDA's Agricultural Marketing Service (AMS). In an advance notice of proposed rulemaking, AMS in October 2007 invited comments on whether to create such a federal marketing program that specifically would require handlers (packers, processors, shippers) of leafy greens, including lettuce and spinach, to meet prescribed safety standards. A similar state order was adopted by California growers in 2006.</p> <p>Obama Administration: The FSWG announced, and FDA issued on July 31, 2009, new draft guidances on three specific types of produce: Guide to Minimize Microbial Food Safety Hazards of Tomatoes, Guide to Minimize Microbial Food Safety Hazards of Melons, and Guide to Minimize Microbial Food Safety Hazards of Leafy Greens, which, when finalized (and as is the case for all FDA guidance documents), will be nonbinding and will represent FDA's current thinking on these topics.</p> <p>Also, the Hamburg and Taylor testimonies express support for § 104 of the House bill.</p>	<p>known or reasonably foreseeable biological, chemical, and physical hazards, including natural ones, that may be intentionally or unintentionally introduced. The regulations may include minimum safety standards, and address manure use, water quality, employee hygiene, sanitation and animal control, and temperature controls, as the Secretary determines to be reasonably necessary. They may provide for coordination of education and enforcement activities and must provide a reasonable time for compliance, taking into account the needs of small businesses for additional time, among other permitted activities. The Secretary is required to take into consideration (consistent with public health) "the impact on small-scale and diversified farms, and on wildlife habitat, conservation practices, watershed-protection efforts, and organic production methods." The Secretary shall coordinate with the Secretary of Agriculture and may contract and coordinate with a Governor-designated state agency for education and compliance activities (emphasis added to distinguish from S. 510, which mandates use of state agencies).</p> <p>Under this new provision, a food is adulterated if it is grown, harvested, packed, sorted, transported or held under conditions that do not meet these new requirements. The bill appears to lack the variance procedures, and the express exemption for those required to meet hazard analysis and prevention standards that are in S. 510.</p> <p>Requires the Secretary to update the 1998 guidance for minimizing hazards in fresh fruits and vegetables.</p>	<p>diverse geographic areas.</p> <p>Proposed rulemaking shall "provide sufficient flexibility to be applicable to various types of entities...including small businesses and entities that sell directly to consumers, and be appropriate to the scale and diversity" of production and harvesting. The proposed rule also shall address minimum standards for other specified elements, including soil amendments, hygiene, packaging, temperature controls, animal encroachment and water, as well as hazards that occur naturally or that may have been introduced, intentionally or unintentionally. The proposal shall take into consideration, consistent with public health protection, "conservation and environmental practice standards and policies established by Federal natural resource conservation, wildlife conservation, and environmental agencies," and also "in the case of production that is certified organic, not include any requirements that conflict with or duplicate the requirements of" the national organic foods program, while providing the same level of protection as required under this act. Priority is to be given to those raw fruits and vegetables that have been associated with food-borne illness outbreaks.</p> <p>Subsection (b) states that within a year of the closing of the comment period, the Secretary shall adopt a final rule to provide for minimum standards for certain types of fruits and vegetables, as needed to minimize the risk of serious adverse health consequences. Among other requirements, the final rule shall provide for coordination of education and enforcement activities with state and local officials, minimize recordkeeping burdens, and describe the variance process and the types of permissible variances that the Secretary may grant to states and foreign countries to address local growing conditions. Effective dates for compliance are phased in for small and very small business (see below). The Secretary may coordinate with USDA and shall contract as appropriate with states to conduct compliance activities (emphasis added). Not later than one year after enactment, the Secretary shall publish updated good agricultural practices and guidance for the safe production and harvesting of specific types of produce,</p>

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after consultation with stakeholders (as specified). This section shall not apply to facilities subject to FFDCa § 418 (Hazard Analysis and Risk-based Preventive Controls), as established by this act.

Failure to comply with requirements under this section is prohibited. Amendments made by this section do not limit the authority of the Secretary under the FFDCa or the Public Health Service (PHS) Act [42 U.S.C. § 201 et seq.] to revise, issue, or enforce product and category-specific regulations, such as those for existing HACCP programs.

This section contains provisions for consideration of small businesses. As noted above, small and very small businesses may be exempted from regulation if the Secretary has determined these “are low risk and do not present a risk of serious adverse health consequences or death.” Extended implementation deadlines for small and very small businesses apply: small businesses (as defined by the Secretary) are to have 1 year after final regulation are promulgated, and very small businesses (as defined by the Secretary) 2 years after final regulations. Requires the Secretary to issue a “small entity compliance policy guide” setting forth the requirements of such regulations to assist small entities in complying with the registration requirements and other activities (no later than 180 days after the issuance of the regulations under this section), along with other flexibility for small businesses. Requires the Secretary to ensure any updated guidance comply with the Paperwork Reduction Act (PRA) and minimize regulatory burden and unnecessary paperwork and the number of separate standards on the facility, among other clarification regarding acknowledgment of risk differences and compliance burden.

Under added language in S. Amdt. 4715 certain farms would not be subject to the requirements. Farms would qualify for an exemption from the HACCP requirements if the farm’s “average annual monetary value” of all food sold during the previous 3 year period was less than \$500,000, provided that the food is sold directly to “qualified end users” such as consumers, restaurants, or retail food establishments that are located in the same state where the

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facility sold the food or within 275 miles of the facility. Foods produced from such a farm would also need to provide the farm's name and address on a food packaging label or at the point of purchase. Such a farm would also need to be in compliance with State, local, county, or other applicable non-Federal food safety laws. Foods produced from such a farm would also need to provide the facility's name and address on a food packaging label or at the point of purchase.

INSPECTION OF FACILITIES (See also "Targeting of Inspections" and "Mandatory Recall Authority" sections of this report, and "Inspection of Foreign Facilities" row of this table.)

Reform advocates argue that many of the recent problems that have led to illness outbreaks and recalls might have been avoided if inspectors were more frequently present in plants to monitor sanitary conditions and processes. Due to the differing laws and circumstances that apply to FSIS, for example, that agency's inspectors are in meat and poultry slaughter and processing plants every day, where they must organoleptically (by the senses) examine every live animal and every carcass for defects, and must pass every item before it can enter commerce.

Current law, which derives from FFDC § 704 (in the General Authority chapter of the FFDC), authorizes but does not require FDA to inspect food facilities. Therefore, no periodic inspection frequency is currently required.

Obama Administration: The FSWG stated that the Administration would work with Congress on "critical legislation that will provide key tools to keep food safe." One tool it cited was "the ability to use resources flexibly to target food at the highest risk and achieve the maximum gain for public health." However, Dr. Hamburg's testimony noted several issues regarding § 105 of the House bill (as introduced prior to subcommittee markup), including both the large amount of resources needed to meet the inspection goals in the bill and the difficulty of hiring and training the additional staff that would be needed. She recommended modification "to take into account the

Risk-Based Inspection Schedule (§ 105)

Amends § 704 (Inspection, in the General Authority chapter of the FFDC) to require each § 415-registered facility to be inspected randomly by officers duly designated by the Secretary at a frequency based on the risk of the facility. The Secretary may use federal, state, or local officials for domestic inspections and foreign country representatives for foreign ones. The inspection schedule must be implemented within 18 months of enactment and follow these prescribed categories and frequencies:

- Category 1, a high-risk food facility that manufactures or processes food, must be inspected at least every 6-12 months;
- Category 2, a low-risk facility that manufactures or processes food or a facility that packs or labels food, must be inspected at least every 18 months to 3 years;
- Category 3, a food facility that holds food, must be inspected at least every 5 years.

Authorizes the Secretary to modify the types of food facilities within each category, to alter inspection frequencies if needed to respond to illness outbreaks and recalls, and to inspect a facility more frequently than specified. In doing so, the Secretary is to consider the type of food at the facility, its compliance history, whether an

Targeting of Inspection Resources for Domestic Facilities, Foreign Facilities, and Ports of Entry; Annual Report (§ 201)

Subsection (a) of this section establishes a new FFDC § 421 (in the food chapter of the FFDC), requiring the Secretary, with respect to facilities that must register under FFDC § 415, to allocate inspection resources according to the "known safety risks" of the food and countries involved, as well as the facility's compliance history, the rigor of its hazard analysis and risk-based preventive controls, among other stated criteria. Establishes separate inspection frequencies and increasing frequency rates for domestic and foreign facilities for both high-risk and non-high-risk entities. Establishes requirements for identification and inspection at ports for imported foods, including consideration of whether the shipment has been certified under a voluntary qualified importer program or other criteria.

The Secretary shall improve coordination and cooperation with the Secretaries of Agriculture and Homeland Security to target food inspection resources. It also authorizes interagency agreements regarding seafood (involving HHS, DHS, Commerce Department, and the Federal Trade Commission, among other agencies); such agreements may include examining and testing seafood imports, coordinating inspections of foreign facilities, standardizing data, among

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<p>operational challenges involved, such as by changing these inspection frequencies flexibility to modify the inspection requirements based on the best available data on risk,” among other things. In his subsequent testimony on the House committee-approved bill, Mr. Taylor expressed support for its flexibility to adjust inspection frequencies.</p>	<p>importing facility is certified (under the new certification requirements the bill would set; see below), and other factors determined relevant by the Secretary. The Secretary is authorized to publish in the Federal Register adjustments to inspection frequencies in category 2 and 3 facilities, and is required to publish in the Federal Register any proposed modifications of the categorization of any facility or facility type. The Secretary must submit an annual report on the inspections to Congress, which is to include numbers inspected and cost estimates, and also to submit a 3-year report on any needed adjustments to the risk-based inspection schedule. These recommendations must consider a number of factors listed in this section such as the nature of the food product and how it is handled; its association with food-borne illnesses, and others.</p>	<p>others. Provides for advisory committee consultation within HHS with respect to allocating inspection resources.</p> <p>Subsection (b) of this section requires the Secretary to report to Congress, by February 1 of each year, providing specified information regarding: domestic and foreign food facility inspections (including those scheduled but not completed); food imports; and FDA foreign offices. Such reports shall be made publicly available.</p>

RECORDKEEPING REQUIREMENTS AND FDA ACCESS TO RECORDS (See also “Record-Keeping” and “Mitigating Effects on Small Business and Farming Operations” sections of this report.)

Many advocates of reform argue that recordkeeping requirements must be strengthened to improve the ability of regulators to determine whether firms are complying with the law and to facilitate efforts to find the source of problems (including during product recalls) when they do occur. One of their concerns has been that records are not required to be maintained in electronic format, which if required, these advocates assert, would greatly speed outbreak response. Related issues include the types of records to be kept, how detailed they should be, how long they should be kept, and access and use of these records by authorities. For example, are the current legal premises for accessing records (see below), adequate? Proposals for increased recordkeeping requirements often raise questions about the intrusiveness of government, privacy concerns, and the protection of sensitive commercial information (trade secrets), for example.

FFDCA § 414 currently authorizes the Secretary, by regulation, to require that food establishments (except farms and restaurants) maintain certain records regarding foods, including immediate previous sources, and immediate subsequent recipients. “If the Secretary has a reasonable

Access to Records (§ 106)

Broader than S. 510; amends FFDCA § 414(a) regarding Records Inspection. Although much of the amended language appears similar to existing language, several qualifying phrases are now absent. For example, the bill broadens the ability to access records by deleting the following conditional phrase in the current law: “If the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals...” (Drafters of the bill view this as new authority to access records during routine inspections.) The bill also no longer requires that “written notice” be provided in advance of accessing records. However, records not required to be immediately available at the start of a records inspection must be immediately available if requested in advance by letter. Also, relevant records (i.e., for access and copying) are to be all those “relating to such article bearing on whether the food is adulterated, misbranded, or otherwise in violation of this Act...” rather than the higher current threshold—which is those records “needed to assist the Secretary in determining whether a food is adulterated and presents a

Inspections of Records (§ 101)

Amends FFDCA § 414, which contains one standard (trigger) for records access, by creating two such standards. The first is somewhat similar to current law by authorizing access “If the Secretary has a reasonable belief that an article of food and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner is adulterated and presents a threat of serious adverse health consequences or death to humans or animals...” The second standard authorizes access “If the Secretary believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals...” It appears that by invoking the second standard, the Secretary would no longer be required to have a reasonable belief that a food is adulterated in order to have access to records.

Also apparently new under both standards would be the ability to access records if “any other article of food” could be similarly affected, such as food produced on the same

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<p>belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals,” such records must be made available for inspection and copying upon written notice. (Emphasis added.) The Secretary is required to take appropriate measures to ensure that unauthorized disclosure of any trade secret or confidential information is prevented.</p> <p>Obama Administration: The FSWG stated that the Administration would work with Congress on “critical legislation that will provide key tools to keep food safe.” One tool it cited was “the ability to access basic food safety records at facilities.” The Hamburg and Taylor testimonies express support for § 106 of the House bill.</p>	<p>threat of serious adverse health consequences.”</p> <p>New provisions spell out the conditions under which the Secretary could require remote access to records (i.e., not appear at a facility to review them), notably where “...the Secretary has reasonable belief that an article of food presents a threat of serious adverse health consequences or death to humans or animals.”</p> <p>Restaurants would be subject to some records access requirements. However, the only distribution of records which may be required of restaurants under this subsection are those showing the restaurant’s suppliers and subsequent distribution other than to consumers.</p> <p>Also, states that access to records provisions do not apply to farms—except that a farm owner, operator, or agent must permit an officer or employee of the Secretary to have access to and copy all records relating to an article of food that is produced, manufactured, processed, packed, or held on the farm. This exception applies only if the article of food either: is a fruit, vegetable, nut or fungus that is subject to a standard under new § 419A (see Safety Standards for Produce and Certain Other Raw Agricultural Commodities, §104); or is the subject of an active investigation by the Secretary of a foodborne illness outbreak and is further not a grain or similarly handled commodity (generally, the list in the bill encompasses the row crops covered by USDA price supports).</p> <p>Additionally for farms, that Secretary must as soon as practicable (in coordination with the Secretary of Agriculture) identify and issue guidance on one or more fruits, vegetables, nuts, or fungi where access to records will be used. This section also requires such identification to be based on illness outbreaks, requires its expiration when the new § 419A rules take effect, and requires the Secretary to consult with the Secretary of Agriculture in issuing regulations “with respect to farms under this subsection and shall take into account the nature of and impact on farms,” among other things.</p> <p>(See also the records provisions in “Traceability of Food,” § 107, and “Registration for Customs Brokers,” § 205.)</p>	<p>manufacturing line as an implicated food, or food produced using implicated ingredients. Under either trigger, a designee of the Secretary is to be granted access to records upon presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner. Requirements apply to all records relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of a food, in any format (including paper and electronic formats), and at any location. No specific format is required. Farms and restaurants would continue to be excluded under FFDCA § 414.</p> <p>See also “Enhancing Tracking and Tracing of Food and Recordkeeping” (§ 204)</p>

TRACEABILITY OF FOOD (See also “Mitigating Effects on Small Business and Farming Operations” and “Notification of Contaminated Products and Product Tracing” sections of this report.)

Traceability means the ability to follow the movement of a product through its stages of production and distribution. As a food safety tool, traceability helps government authorities and industry officials to locate the source of contamination (traceback) and to locate those who may have received the contaminated food (trace forward). Records sufficient to identify products and to trace them quickly are considered to be important prerequisites for a successful recall. (see below.) Among other issues are the potential administrative and cost burdens that a more extensive regulatory program might impose on those in the food system, as well as privacy concerns about records.

§ 306 of the Public Health Security and Bioterrorism Response Act of 2002 amended the FFDCA to require any person who manufactures, processes, packs, transports, receives, holds or imports foods into the United States to keep records that enable the identification of the immediate previous supplier and the immediate subsequent recipient of the food (FFDCA § 414; see also “Records Access and Records Inspection,” above).

Obama Administration: In July 2009, the FSWG announced a number of steps the Obama Administration was taking, under existing authorities, to improve traceability, including:

- issue draft guidance on what industry could do to establish product tracing systems;
- require federal agencies are to implement a new “incident command system to address outbreaks of foodborne illness;
- increase FSIS capacity of its public health epidemiology liaison program to State public health departments through new hires and expanded outreach;
- ask State and local agencies to update their emergency operations procedures to be consistent with new food disease outbreak guidelines being issued by the Council to

Traceability of Food (§ 107); Unique identification number for food facilities, importers, and custom brokers (§ 206)

Amends FFDCA § 414 to require the Secretary to establish by regulation a tracing system for food in, or to be imported into, the United States. These regulations are to enable the Secretary “to identify each person who grows, produces, manufactures, processes, packs, transports, holds, or sells such food in as short a timeframe as practicable but no longer than 2 business days.” The Secretary is authorized to include in such regulations the use of lot numbers, a standardized format for pedigree information, and the use of a common food nomenclature.

However, before promulgating regulations the Secretary is required to first identify tracing technologies and methodologies that can enable each of the food industry sectors to: maintain the full pedigree of the food from source through subsequent distribution; make traceback interoperable with other systems; and use a unique identifier for each facility. Prior to proposing regulations, the Secretary also first must, to the extent practicable, assess costs, benefits and feasibility of adopting such technologies; conduct at least two public meetings; and conduct one or more pilots.

The traceback regulations will apply to agricultural producers (and retailers), but the provision specifically exempts food that is produced on a farm or fishery (wild or farmed) and sold by that farm or fishery directly to a consumer, restaurant, or grocery store. However, such farms and fisheries must keep records for at least 6 months documenting the restaurants or grocery stores to which it sold; and the restaurants and grocery stores are required to keep records documenting the farm source. The Secretary may also exempt a food or a type of facility, farm, or restaurant from the regulations, or modify the requirements for these entities, if the Secretary “determines that a tracing system for such food ... is not necessary to protect the public

Enhancing Tracking and Tracing of Food and Recordkeeping (§ 204)

The Secretary, in coordination with USDA and state officials, shall improve the capacity of FDA to effectively and rapidly track and trace foods in the event of an outbreak. Within 270 days of enactment, the Secretary is required to establish pilot projects in coordination with the food industry to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or mitigate a foodborne illness outbreak and to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated or misbranded.

Participants are to include one or more projects with the processed food sector and one or more projects coordinating processors or distributors of fruits and vegetables that are “raw agricultural commodities,” reflecting the diversity of the food supply and include at least three different types of foods that have been the subject of significant outbreaks during the 5-year period preceding enactment, among other criteria for project selection intended to inform future rule promulgation. The Secretary shall report to Congress its findings for improving the tracking and tracing of food within 18 months of enactment.

The Secretary, in coordination with USDA and state departments of health and agriculture, shall collect additional data to assess product tracing technologies, among other information. The Secretary, in consultation with USDA, shall also establish within FDA a product tracing system to receive information needed to track and trace food.

The Secretary shall publish a notice of proposed rulemaking to establish additional recordkeeping requirements for high-risk foods, subject to certain specified conditions (no later than two years after enactment). The Secretary shall designate such high-risk foods within one year after

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<p>Improve Foodborne Outbreak Response;</p> <ul style="list-style-type: none"> improve collaboration between the CDC and the States to evaluate and optimize best practices for more effective outbreak investigations, and launch a new system to facilitate information-sharing and adoption of best practices. <p>In its July 2010 progress report, the Administration announced that “FDA has conducted a pilot study on a tracing system, and HHS, in collaboration with USDA, has rolled out an enhanced and updated www.foodsafety.gov site to provide consumers rapid access to information on food recalls,” among other actions.</p> <p>Also, the Hamburg and Taylor testimonies express support for § 107 of the House bill.</p>	<p>health.” For this latter category of exemptions, each person who produces, manufactures, processes, packs, transports, or holds such food still must maintain records that identify the immediate previous sources of the food and its ingredients and the immediate subsequent recipients.</p> <p>Contains language limiting applicability to farms, including requirements that the Secretary coordinate with the Secretary of Agriculture when conducting pilot projects with respect to farms and when issuing regulations that will impact farms. Furthermore, any new tracing system with respect to grain or any “similarly handled commodities” (generally, those row crops that have been covered by USDA price supports) must be “limited to enabling the Secretary to identify those who received, processed, packed, transported, distributed, held, or sold” such a commodity “from the initial warehouse operator that held” it “for any period of time to the ultimate consumer.”</p>	<p>enactment based on criteria specified in the provision, and shall publish the list of foods designated as high-risk, which may be subject to updates and revision. The provision addresses information protection; requirements for public input; rules on retention of records; and less restrictive requirements (as specified) for: farm-to-school or farm-to-institution programs of USDA and other related programs; “identity-preserved labels” with respect to farm sales of food that is produced and packaged on a farm; food that is produced through the use of a fishing vessel; producers of commingled raw agricultural commodities; grocery stores; direct farm sales to consumers or grocery store; and others. The Secretary may modify requirements, or exempt a food or facility from them, if product tracing requirements are not needed to protect public health.</p> <p>The Secretary shall submit a report to Congress “taking into consideration the costs of compliance and other regulatory burdens on small businesses, and federal, state, and local food safety practices and requirements, that evaluates the public health benefits and risks” of limiting the product tracing requirements to certain identified foods and also limiting the participation of restaurants in the recordkeeping requirements.</p> <p>The provision also specifies the information the Secretary may request from U.S. farms, subject to certain limitations, but specifies that the Secretary is not authorized to impose any limitations on comingled foods. With the exception of farms, failure to comply with recordkeeping provisions under this section is prohibited.</p> <p>This section contains provisions for consideration of small businesses. Requires the Secretary to issue a “small entity compliance policy guide” setting forth the requirements of such regulations to assist small entities in complying with the registration requirements and other activities (no later than 180 days after the issuance of the regulations under this section), along with phased-in compliance deadlines for small and very small businesses. Small businesses (as defined by the Secretary) will have 1 year after final regulations are promulgated, and very small businesses (as defined by the Secretary) 2 years after final regulations.</p>

FUNDING AND FEES (See also “Paying for Food Safety with User Fees” and “Mandatory Recall Authority” sections of this report.)

Many critics argue that—irrespective of the need, if any, to reform food safety statutes and organization—a fundamental problem has been the lack of sufficient funding and staff to carry out congressionally mandated (and existing) responsibilities to ensure a safe food supply.

Proposed increases in program spending raise a variety of policy issues. Requests for higher appropriations always compete with other priorities throughout the federal discretionary budget (the programs do not operate, like farm support programs, for example, as mandatory authorizations). Such requests currently are being made during a period of huge budget deficits. Efforts to fill perceived shortfalls through new fees on the food industry always meet 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 compromise public health programs.

Congressional appropriators have steadily increased funding for FDA food activities in recent years: from about \$440 million FY2005 and FY2006; \$510 million in FY2008; \$710 million in FY2009; and \$780 million in FY2010. \$1.04 billion was requested for FY2011.

In general, FDA’s fee-funded programs for drugs and devices have finite appropriations authorities that sunset, prohibiting the agency from collecting fees beyond the authorized time frame. These authorities do not apply to food safety programs at this time. In addition, some discretionary-funded grant programs have finite appropriations authorities, and may or may not continue to be funded if authority expires. But, in general, FDA’s enforcement activities, such as those for food safety, are based in broad, permanent authorities in the FFDCA. These authorities do not expire, and they are not accompanied by authorized levels of appropriations. Decisions to apportion annual appropriations among FDA’s various programs and activities are made through the annual appropriations process without explicit directives in authorizing legislation.

Various Sections (§ 101, § 108, § 203, § 204)

Authority to assess new types of food-related fees appear in four sections of the House bill.

Under **§ 101, Changes in Registration of Food Facilities**, the Secretary is required to assess and collect a facility registration fee each year from facilities required to register under FFDCA § 415. This fee is to be set at \$500 per facility in FY2010; for FY2011 and each subsequent fiscal year, the fee is to be adjusted to reflect the cost of inflation, under a specified formula. § 101 also sets a maximum annual fee payment of \$175,000 for those who have multiple facilities. Other provisions in this section: require the Secretary to hold a public meeting each fiscal year to explain the fees’ use and to solicit stakeholder views; are intended to ensure that these fees do not supplant FDA appropriations or reduce HHS Department staffing; address their collection, crediting and availability vis a vis appropriations; sunset the fees after FY2014; and require annual reports to Congress. “Food safety activities” and “costs of food safety activities” are extensively defined in this section. The provisions in this section are modeled in part on existing user fee authorities for drugs and devices.

Under **§ 108, Reinspection and Food Recall Fees Applicable to Facilities**, the Secretary is required to assess and collect a fee from each facility that either: violates any food-related requirement of the FFDCA and therefore must undergo additional FDA inspection; or is subject to a food recall. The Secretary must set the fee amount at a level to fully cover the reinspection and/or recall costs and use the collection solely for that purpose. If the Secretary determines that a recall “was inappropriately required,” the fee must be waived or refunded. Other language here addresses their collection, crediting and availability vis a vis appropriations, with a sunset for the fees after FY2014.

Under **§ 203, Exportation Certificate Program**, the

Authority to Collect Fees (§ 107)

Authorizes FDA to collect two types of fees related to food: export certification fees and user fees. The export certification provisions in current law are amended to allow food exporters to request that the Secretary certify that exported foods comply with provisions in the FFDCA, and would thus enable the associated fee to be charged to the exporter. The food user fees are established by inserting a new FFDCA § 743 : “Part 6—Fees Related to Food.” The new part authorizes, indefinitely, the assessment and collection of four user fees:

- fees paid by domestic facilities subject to a reinspection (to cover reinspection-related costs);
- fees paid by domestic facilities and importers subject to food recalls (to cover food recall activities performed by the Secretary);
- fees paid by importers participating in the voluntary qualified importer program (to cover administrative costs of the program); and
- fees paid by importers subject to reinspection (to cover reinspection-related costs).

Overdue fees are treated as claims of the United States Government under 21 U.S.C. § 37. The Secretary is required to report annually to Congress describing the entities paying fees, and the fees assessed and collected for each year.

The Secretary is required to establish and publish the fee amounts annually, setting fees so that each one covers 100% of the cost of the associated activity, with certain caveats. For the first five years that user fees are assessed, the Secretary is to include a surcharge in order to recoup the costs associated with establishing the user fee programs. Fees collected for a given fiscal year for food recall activities may not exceed \$20 million. Fees collected for a given fiscal year for reinspection of both domestic

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<p>FDA is currently authorized to collect several types of fees. Among them are user fees and export certification fees, neither of which may currently be collected for food-related activities. FDA’s authority to collect user fees extends to human prescription drugs, medical devices, and animal drugs, under FFDCa Chapter VII, Subchapter C, §§ 735-740. Generally, these fees can only be used to fund the “process for the review of applications.” (FDA reviews applications to determine whether to permit drugs, medical devices, and animal drugs to be legally marketed. Prior approval is not required for most foods, which can be legally marketed without the agency’s prior permission.) The user fee programs have been authorized in five-year increments. Each authorization specifies the fee amounts FDA may collect annually, and makes the authority to collect these fees contingent upon “triggers,” which require that appropriated and internally allocated funding amounts for certain activities meet specified threshold levels.</p> <p>FDA’s authority to collect export certification fees extends to drugs, medical devices and biological products, according to FFDCa § 801(e)(4). A person who exports a human drug, animal drug, or device may request that the Secretary certify in writing that the product meets FFDCa requirements. If the Secretary issues a written export certification, a fee may be charged.</p> <p>Obama Administration: In addition to requesting increased funds for FY2010 (see above), the Administration has endorsed the registration, reinspection, and export certification fees in §§ 101, 108, and 203 of the House bill.</p>	<p>Secretary is authorized to impose a fee for food export certifications that meet the specifications of a foreign purchaser and that do not conflict with the destination country’s laws. (Such fees already may be charged for certifications of some other FDA-regulated products.) The fee shall be “reasonably related” to the cost of issuing such certificates; this fee authority is permanent.</p> <p>Section 204 establishes a new FFDCa § 744, requiring the Secretary to assess and collect a \$500 annual fee for the registration of an importer of food, with administrative provisions somewhat comparable to those set under § 101 (above). (This fee is to be tied to the new requirement that such importers begin to register with FDA within one year of enactment.) Importers that already must pay the facility fee under § 101 are exempt from this importer registration fee. This fee authority sunsets after FY2014.</p>	<p>facilities and importers may not exceed \$25 million combined. Despite these limitations, the Secretary may collect fees from facilities or importers who become subject to the fees after the limitations are reached. The Secretary must credit to the following year any fees collected in excess of actual costs, and adjust fee amounts for that following year to account for the excess fees and other factors the Secretary determines are appropriate.</p> <p>The Secretary is authorized to collect fees only to the extent that amounts have been specified in advance in appropriations acts. Additional “triggers” apply. Fees collected in a given year must be refunded unless appropriations to FDA for food safety activities are maintained at the FY2009 level, with specified adjustments. Fees can be used solely to fund the specified food safety activity.</p> <p>Note: The proposed food user fee is different from existing user fees in several ways. First, the proposed fee would be authorized indefinitely, while each of the existing user fees have been authorized in five-year increments. Second, the fees would be used to fund inspection and enforcement activities for foods on the market. For other products, the existing user fees only fund application-review related activities, as defined in the law—though, as noted above, FDA does not inspect foods before they can be marketed as it does some of the other products that it regulates. Third, the act does not authorize specific fee levels in advance, but rather allows the Secretary to set fee levels based upon estimated costs. For currently authorized fees, the amounts are articulated in law, either individually, or in aggregate, for a given type of fee.</p> <p>Funding for Food Safety (§ 401)</p> <p>This section authorizes, for activities of FDA’s Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, and related field activities in the Office of Regulatory Affairs, such sums as may be necessary for FY2011-FY2014. In addition, the Secretary is required to increase the field staff of these three entities with a goal of not fewer than: (1) 4,000 staff members in FY2011; (2)</p>

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4,200 staff members in FY2012; (3) 4,600 staff members in FY2013; and (4) 5,000 staff members in FY2014. Within the total, field staff for food defense activities and for smuggled food detection and removal shall be increased by 150 employees by FY2011.

THIRD PARTY ACCREDITATION (See also “Food Imports” section of this report, and “Laboratory Accreditation” and “Inspection of Foreign Facilities” rows of this table.)

The use of so-called third parties is increasingly being promoted as a method for helping regulators such as the FDA to carry out their oversight responsibilities, particularly when they are being asked to stretch and carefully target finite inspection dollars and personnel. However, the idea is controversial, particularly among food safety advocates, who have expressed concern about potential conflicts of interest between auditors and the companies they audit and about potentially less rigorous oversight. They cite a number of recent food safety crises including the Salmonella contamination of peanut products in late 2008 and early 2009, even though the peanut product supplier had passed several private third-party and state inspections.

Among many questions is the definition of a “third party.” Broadly, it may be any entity or person that is formally assigned one or more responsibilities that otherwise would be performed by another entity. In practice and in proposed legislation, third parties might variously and specifically be defined as a state or local agency, another federal agency, a foreign government, a professional or scientific body, or even a private company, often one that specializes in the task to be performed. Private companies frequently rely on third party auditors, certifying agents and the like, often including provisions in their contracts with suppliers, for example, that a third party verify that certain specifications—whether safety, quality, quantity, or other desired attributes—are being achieved. Within the federal government, examples include a variety of voluntary third-party auditing programs. For example, “Process Verification and Audit Based Programs,” operated by USDA’s Agricultural Marketing Service (AMS) and are funded through user fees. These programs are intended primarily

Certification and Accreditation (§ 109, part)

Appears to be less detailed with regard to how the Secretary is to establish a third-party certification program. As noted, qualified certifying entities are to be accredited and given the responsibility to provide such certifications when the Secretary determines such certifications are needed, and the specifics of that certification, including its format, would be left to the Secretary’s regulatory discretion. § 109 defines “qualified certifying entity” as “an agency or a representative of the government from which the article originated, as designated by such government or the Secretary; or an individual or entity determined by the Secretary or an accredited body recognized by the Secretary to be qualified to provide a certification...”

Requires the Secretary to issue regulations to ensure that certifying entities and their auditors are free from conflicts of interest (in doing so, the Secretary may rely on or incorporate international certification standards). Contains extensive language on what these regulations are to stipulate, such as that entities have written policies; that they obtain and maintain annual declarations of all personnel involved in audits regarding their financial interests in any producer, manufacturer, and other specified types of food companies; that they not be owned, operated, controlled, or have any other financial ties to those or the products they are certifying. (However, the certifying entity could provide consultative services to a facility it is certifying so long as the Secretary has approved its procedures ensuring the separation of these two functions.)

The Secretary must require that, to the extent applicable, any certification provided by a certifying entity be renewed

Accreditation of Third-Party Auditors (§ 307)

Amends FFCA Chapter VIII (regarding imports and exports), adding a new § 808, for a system of third-party auditors and audit agents that are accredited to certify that entities involved with imports are meeting applicable FDA requirements. Generally, the Secretary would first recognize accreditation bodies. Such bodies in turn could accredit the third-party auditors or audit agents, who in turn could be tasked to certify eligible entities. Defines the following terms: audit agent, accreditation body, third-party auditor, accredited third-party auditor, consultative audit, eligible entity, and regulatory audit.

The Secretary must establish the new system within two years of enactment and is required to: promptly revoke recognition of accreditation bodies found not in compliance with this section’s requirements and develop model accreditation standards (within 18 months after enactment), taking into account existing standards so as to avoid duplication of efforts and costs. Accreditation bodies must submit to the Secretary a list of all accredited third-party auditors and audit agents they have accredited.

Accreditation bodies must, prior to accrediting a foreign government or foreign government agency, perform reviews and audits of that government or agency’s food safety programs, systems, and standards, as the Secretary deems necessary, to determine that the foreign government is capable of ensuring that entities or foods it certifies will meet the requirements of the FFCA. Prior to accrediting foreign cooperatives and other third parties, accreditation bodies must perform reviews and audits as the Secretary deems necessary to determine that the entities to be certified have systems in place to ensure the entities or foods will meet the requirements of the FFCA.

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<p>to certify food quality and marketing attributes, as opposed to safety requirements per se.</p> <p>FDA appears to have argued in the past that its authority is broad enough, under the FFDCA and the PHS Act, at least to propose regulations on how independent sampling services and private laboratories can be used to satisfy food import requirements. However, FDA does not currently regulate private laboratories that analyze imported, FDA regulated goods. (Under FFDCA § 704, FDA has been required to have published criteria for accrediting independent persons to conduct inspections related to Class II and III devices.)</p> <p>In January 2009, following a request for information and publication of a draft document, FDA issued guidance setting criteria for others' use of voluntary third-party certification programs for foods and animal feeds, noting that the federal government "supports voluntary certification programs as one way to help ensure products meet U.S. safety and security standards and to allow federal agencies to target their resources more effectively." FDA has also published a notice of a pilot program of voluntary third-party certification for imported shrimp.</p> <p>Obama Administration: Dr. Hamburg's testimony expresses support for relying not only on foreign governments for international inspections but also having the flexibility to explore use of an accreditation system and audit the performance of accredited third parties.</p>	<p>whenever the Secretary deems it appropriate; and he/she must refuse to accept any certification determined to be no longer valid or reliable. The Secretary must provide for the electronic submission of certifications, in coordination with Customs and Border Protection.</p> <p>Authorizes the Secretary, in evaluating an accreditation body, to observe that body's on-site audits of qualified certifying entities, and to conduct on-site audits of certified facilities "upon request. and upon presentation of appropriate credentials, at reasonable times and within reasonable limits and in a reasonable manner" to include access to records.</p>	<p>Accreditation bodies may not accredit a third party auditor unless it agrees to issue a written food or facility certification to accompany each food shipment into the United States from an eligible entity. The Secretary must consider certifications of foods offered for import and participation in the voluntary qualified importer program when targeting inspection resources and must use certification to determine whether food meets the requirements for import and to determine whether facilities are eligible for the voluntary qualified importer program established in § 302 of this act. Accredited third-party auditors can only issue food and facility certifications after conducting certain audits and activities. Only the Secretary and accredited third-party auditors can provide facility certifications. Only the Secretary, a Secretary-designated agency or representative of the country from which the food for import originated, or accredited third-party auditors can provide food certifications.</p> <p>Accredited third-party auditors or audit agents must prepare audit reports, which are to include a number of specified elements; provide, at the Secretary's request, an onsite audit report or other reports or documents required for the audit process for any eligible entity it has certified (with certain exceptions); and immediately notify the Secretary of the discovery during an audit of "a condition that could cause or contribute to a serious risk to the public health" and the identification of the eligible entity subject to the audit. Third-party auditors and audit agents must adhere to a series of explicit prohibitions in this section designed to avoid conflicts of interest. The Secretary is required to promulgate regulations within 18 months of enactment to protect against conflicts of interest between accredited third-party auditors and eligible entities to be certified by such auditors or audit agents.</p> <p>The Secretary must withdraw accreditation from a third-party auditor in certain circumstances, such as if a food certified by the auditor is linked to an outbreak of foodborne illness, and the Secretary must also establish procedures to reinstate accreditations that have been withdrawn. The Secretary must also establish, by regulation, a program similar to that used by USDA, by which third-party auditors and audit agents</p>

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reimburse FDA for the cost of establishing and administering the accreditation system. The reimbursement program must be revenue neutral and not generate surplus revenue.

Eligible entities must apply for annual recertification if they intend to participate in the voluntary qualified importer program or if they are required to provide certification to the Secretary for food offered for import into the U.S. False statements made to or by accredited third-party auditors are subject to criminal penalties. The Secretary must, at least once every 4 years, reevaluate accreditation bodies and evaluate the performance of accredited third-party auditors and audit agents (in part through the compliance history of the entities they certified). The Secretary may conduct onsite audits of certified entities with or without the accredited third-party auditor present. The Secretary must make publicly available a registry of accreditation bodies and third-party auditors. Audits performed are not considered inspections under FFDCA § 704, and this section does not affect the Secretary's authority to inspect any eligible entity.

LABORATORY ACCREDITATION (See also “Third Party Accreditation”, “Inspection of Foreign Facilities” and “Import Certification” rows of this table.)

Neither the FFDCA nor applicable regulations address the accreditation of food laboratories or the establishment of laboratory networks.

FDA continues to support an existing Food Emergency Response Network (FERN), a nationwide network made up of more than 130 federal, state and local public health laboratories that support emergency response activities related to food defense and food safety. The FDA Office of Regulatory Affairs publishes a Laboratory Manual with a section on “Private Laboratory Guidance.” The Guidance seeks to “establish a uniform, systematic, and effective approach to ensuring that private labs performing analyses on FDA-regulated imported commodities submit scientifically sound data.” The Guidance, although unenforceable, provides recommendations on sampling techniques, requirements of lab analysts, reviewing the analyzed packages, and auditing analyzed samples.

In January 2009, FDA issued guidance regarding voluntary

Testing by Accredited Laboratories (§ 110)

Establishes a new FFDCA § 714, which requires the Secretary to establish a standards-based program for the recognition of laboratory accreditation bodies that accredit laboratories to perform analytical testing for the purposes of this section. In evaluating whether such bodies meet the Secretary's standards, the Secretary is authorized to observe these bodies' on-site audits of laboratories, and to conduct an on-site audits under specified conditions. The Secretary is required to publish on the FDA website a list of accreditation bodies.

Any analytical testing must be done by a laboratory that is accredited by an above-accredited body and that samples such articles with adequate controls to ensure the integrity of the samples, except that testing pursuant to FFDCA §801(a) (relating to testimony on refused imports) must be by an independent laboratory. This section contains notification requirements for accreditation bodies and for

Recognition of Laboratory Accreditation for Analyses of Foods (§ 202)

Subsection (a) establishes a new FFDCA § 422, requiring the Secretary, within two years of enactment, to establish a program for food testing by accredited laboratories that meet certain requirements established by the Secretary; to establish a publicly available (subject to national security concerns) registry of accrediting bodies recognized by the Secretary and accredited laboratories (such accredited entities would be required to report any changes to the Secretary). Foreign labs would need to meet the same accreditation standards as domestic labs. The Secretary shall develop model accreditation standards that address sampling and analytic procedures, quality controls, personnel training and qualifications, and other matters. The Secretary shall review accreditation bodies at least once every five years and promptly revoke recognition for an accrediting body that is not in compliance with this section. Food testing shall be conducted by accredited labs no later than 30 months after enactment, unless otherwise

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<p>third-party certification programs for foods and feeds. The guidance does not focus on laboratory accreditation, but rather the ways in which third-party certifiers should use laboratory results in their assessments. The guidance, which also is not enforceable, says that laboratories should conform to existing international standards and guidelines.</p>	<p>others (such as the results of all analyses conducted), among other provisions. Any violation of this section's requirements is considered a prohibited act under the FFDCa.</p>	<p>exempted.</p> <p>Food testing in the following situations shall be conducted by a federal laboratory or a laboratory accredited according to the requirements of this section whenever such testing is: (1) by or for an owner or consignee in response to a specific testing requirement under the FFDCa or its regulations when applied to address an identified or suspected food safety problem and as required by the Secretary as the Secretary deems appropriate; and (2) on behalf of an owner or consignee in support of an imported food submission under Section 801(a) and under an FDA Import Alert that requires successful consecutive tests.</p> <p>Any such testing results must be sent directly to the FDA, unless the Secretary by regulation exempts the submission of those results upon a determination that the results "do not contribute to the protection of public health." Certain exceptions may apply.</p> <p>If testing performed by an accredited state or local government laboratory results in a state recalling a food, the Secretary shall review the sampling and testing results for the purpose of determining the need for a national recall, or other compliance and enforcement activities. This authority does not limit the ability of the Secretary to review and act upon information from food testing, including determining the sufficiency of such information and testing.</p> <p>Subsection (b) requires the Secretary, within 180 days of enactment and biennially thereafter, and in consultation with federal agencies and state, local, and tribal governments, to make a publically available report to Congress regarding progress in implementing a national food emergency response laboratory network. Such a network: (1) provides ongoing surveillance, rapid detection, and surge capacity for large-scale food-related emergencies, including intentional adulteration of the food supply; (2) coordinates the capacities of state, local, and tribal food laboratories, including data sharing to develop national situational awareness; (3) provides accessible, timely, accurate, and consistent food laboratory services</p>

nationwide; (4) develops and implements a methods repository for use by federal, state, and local officials; (5) responds to food-related emergencies; and (6) is integrated with relevant laboratory networks administered by other federal agencies.

MANDATORY RECALL AUTHORITY (See also “Mandatory Recall Authority” section of this report.)

The Secretary does not have mandatory recall authority for foods, except for infant formula under FFDC A § 412(f). A voluntary recall by a manufacturer or distributor may be undertaken at any time for other foods and all other FDA-regulated products. In urgent situations, FDA may request a voluntary recall of an FDA-regulated product [21 CFR 7.40(b)]. The Secretary has authority under FFDC A § 304 to seize foods, drugs, and cosmetics that are adulterated or misbranded when introduced into or while in interstate commerce, or while held for sale after shipment in interstate commerce.

Obama Administration: One of the actions announced by the FSWG was to begin enhancing communication to the public, including through an improved individual alert system allowing consumers to receive food safety information such as notification of recalls. The FSWG, and the Statement of Administration Policy on H.R. 2749, noted support for mandatory recall authority. The Hamburg and Taylor testimonies express support for the House bill provision.

Notification, Nondistribution, and Recall of Adulterated or Misbranded Food (§ 111)

This section establishes a new FFDC A § 420, effective not later than one year after enactment, which requires certain persons who place food in commerce to notify the Secretary of potential food safety problems; provides the Secretary with authority to request a voluntary recall of food and to order that distribution of a food be ceased; and establishes authority of the Secretary to mandate a recall, with procedures reflecting two different levels of threat that may be posed by an affected food.

FFDC A § 420, subsection (a), requires a responsible party [as defined in FFDC A § 417(a)(1)] or a person required to register to import food under § 801(r) (as established by this act), to notify the Secretary if there is reason to believe that an article of food when introduced into or while in interstate commerce, or while held for sale (regardless of whether the first sale) after shipment in interstate commerce, is adulterated or misbranded in a manner that presents a reasonable probability that the use or consumption of, or exposure to, the article (or an ingredient or component used in any such article) will cause a threat of serious adverse health consequences or death to humans or animals. (This language is similar to the reporting threshold currently established under FFDC A § 417.) Failure to notify the Secretary when required is prohibited under FFDC A § 301.

FFDC A § 420, subsection (b), authorizes the Secretary to request a voluntary recall by any person who distributes an article of food that the Secretary has reason to believe is adulterated, misbranded, or otherwise in violation of the FFDC A.

Mandatory Recall Authority (§ 206)

Subsection (a) of this section establishes a new FFDC A § 423 regarding recall of food. If the Secretary determines, based on information gathered through the reportable food registry under FFDC A § 417 or through any other means, that there is a reasonable probability that an article of food (other than infant formula) is adulterated under FFDC A § 402, or misbranded under FFDC A § 403(w) (specifically regarding allergen labeling), and the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals, the Secretary shall provide the responsible party (as defined in FFDC A § 417) with an opportunity to cease distribution and recall such article.

If a person fails to comply voluntarily with a request by the Secretary to cease distribution or sale of, or to recall, an article of food, the Secretary may order the person to cease distribution and sale, and to immediately notify all persons “manufacturing, processing, packing, transporting, distributing, receiving, holding, or importing and selling such article;...and to which such article has been distributed, transported or sold, to immediately cease distribution of such article,” including products distributed to a warehouse-based third party logistics providers. The Secretary shall offer the responsible party an opportunity for an informal hearing within two days of issuance of such an order. If the Secretary subsequently determines that the affected foods should not remain in commerce, the Secretary shall: amend the order to require a recall; specify a timetable for the recall; require periodic reports from the responsible party; and provide notice to consumers to whom the food was or may have been distributed. If, after the informal hearing, the Secretary determines that adequate grounds do not exist for the order’s required actions, the Secretary shall vacate or modify

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FFDCA § 420, subsections (c) and (d), authorize the Secretary to issue an order to cease distribution of any article of food that the Secretary has reason to believe that the use or consumption of, or exposure to, an article of food may cause serious adverse health consequences or death to humans or animals, with an appeal process and other administrative matters specified (including limits on the Secretary's authority to delegate decisions regarding orders). Subsection (e) requires the Secretary to issue a mandatory recall order if the Secretary determines that problems have not been addressed through procedures under subsections (c) and (d). Certain requirements of such order are stipulated.

FFDCA § 420, subsection (f), authorizes the Secretary to proceed directly to a mandatory recall order if the Secretary has credible evidence or information that an article of food subject to an order to cease distribution presents an imminent threat of serious adverse health consequences or death to humans or animals. In such case, the person must immediately recall the food while stipulated appeal procedures are carried out. ("Serious," which distinguishes the thresholds for the routine (subsection (e)) and emergency (subsection (f)) mandatory recall authorities, is not defined.)

The Secretary is required, as the Secretary deems necessary, to notify consumers, and state and local health officials, of any recall order issued under this section. Failure of a person to comply with any order issued by the Secretary under this section is prohibited under FFDCA section 301. Any articles of food intended for import and subject to a cease-distribution or recall order under this section shall be refused entry, under FFDCA section 801. Nothing in this section shall limit the Secretary's authority to assure food safety through any other provisions of the FFDCA, or the Public Health Service Act.

the order.

Alcoholic beverages are exempt from a mandatory recall or any action pending initial action by the Alcohol and Tobacco Tax and Trade Bureau.

The Secretary shall work with state and local public health officials in carrying out this section, as appropriate. In conducting a recall under this section, the Secretary shall issue a press release, and other notices as appropriate, to provide consumers and retailers with information about the affected articles of food and the risks posed; and shall consult USDA policies regarding providing to the public a list of retail consignees receiving products involved in a Class I recall, and consider providing such a list to the public, if appropriate. If available, an image of the recalled article must be published on the FDA website. The Secretary's authority to issue or vacate recall orders shall not be delegated to anyone other than the FDA Commissioner and this section shall not affect the authority of the Secretary to request or participate in a voluntary recall. The Secretary shall establish an "incident command operation" within HHS no later than 24 hours after the initiation of a mandatory recall that will adhere to requirements for coordinated and timely communication. Not later than 90 days after enactment the Secretary shall include on the FDA website a consumer-friendly search engine for locating information about recalled food.

Under subsection (c) of this section, pursuant to FFDCA § 303(f)(2)(A), a person who does not comply with a recall order under this section shall be subject to civil money penalties. Under subsection (d) of this section, failure to comply with such an order is prohibited under FFDCA § 301.

Reporting requirements:

- Requires GAO to submit a report to Congress (no later than 90 days after enactment) that identifies and evaluates federal, state and local agencies with mandatory recall authority of food, considers models for farmer restitution in the case of erroneous recalls, and recommends how to minimize economic costs.

- Depending on the findings in GAO's review, USDA shall

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conduct a feasibility study of implementing a farmer indemnification program to provide restitution to producers for incurred losses as a result of an erroneous mandatory recall. This report will be submitted to the House and Senate Agriculture Committees.

- The Secretary shall submit an annual report to the Senate HELP and House Energy and Commerce Committees on the use of recall authority under § 423. This report shall identify foods subject to a public health advisory; the number of responsible parties given an opportunity to cease distribution of or recall a food; the number of recall orders; and a description of instances in which there was no testing for adulteration.

REPORTABLE FOOD REGISTRY (See also “Notification of Contaminated Products and Product Tracing” section of this report.)

The FDA Amendments Act of 2007 (FDAAA, P.L. 110-85) created FFDC § 417, which required FDA to establish a reportable food registry to facilitate product identification and tracing. Under FFDC § 417, a “reportable food” is “an article of food (other than infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals,” and registered food facilities must notify the FDA electronically about such a reportable food. Although FDA did not meet the deadline to implement the registry within 1 year of enactment of FDAAA, the agency published compliance guidance for industry in September, 2009, and the reporting requirement became effective at that time.

Reportable Food Registry: Exchange of Information (§ 112)

The food registry reporting requirements apply to facilities that are required to register under FFDC § 415. This section of the House bill expands coverage to farms where food is produced for sale or distribution in interstate commerce, to restaurants and other retail food establishments, and to those required by this bill to register as importers. The bill newly requires the reporting also of documented results of any sampling and testing of a reportable food article and of a component of a food article, including: tests conducted pursuant to new § 418 (Hazard Analysis and Risk-Based Preventive Controls), new § 418A (Food Safety Plan), new § 419 (Performance Standards), or new § 714 (Testing by Accredited Laboratories); analytical results of facility environmental testing; or any other information deemed relevant by the Secretary.

This section does not amend the definition of “reportable food,” which establishes the reporting threshold. The Secretary must offer an alternative to electronic reporting for farms, restaurants, and retail food establishments. Finally, § 112 of the bill contains extensive language on the conditions under which food registry information may or

Improving the Reportable Food Registry (§ 211)

Amends FFDC § 417 to require the Secretary to obtain from a responsible party consumer-oriented information regarding reportable foods (except for fruits and vegetables that are raw agricultural commodities), no later than 18 months after enactment: description of the food, affected product identification codes, contact information for responsible parties, and other information deemed relevant by the Secretary. The Secretary shall also prepare a one-page summary of the reportable food, to be available by internet and for grocery stores, as part of its notification process. If a grocery store sold a reportable food subject to posting, the store shall prominently display such summary information for 14 days no later than 24 hours after the one-page notification is published. Within one year of enactment, the Secretary shall publish a list of “conspicuous locations” for posting such notifications. Failure to post a required notification is prohibited.

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may not be shared with or disclosed to others including other agencies and to the public.

Note: The bill here references 21 CFR 1.227(b)(3) to define a farm as "... a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves of, and cooling produce are considered part of harvesting. The term "farm" includes: (i) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and (ii) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership." The bill here also makes the same reference to define a retail food establishment.)

EXPEDITING IMPORTS (See also "Food Imports" section of this report.)

The FFDCA does not explicitly provide authority for expediting imports. Among the questions raised during the policy debate: Should importers, or those foreign facilities which supply them, that have good histories of compliance with U.S. food safety laws, and/or that import relatively low-risk foods, be permitted to follow abbreviated procedural requirements? If so, what if any additional standards should they have to meet?

Safe and Secure Food Importation Program (§ 113)

Amends FFDCA Chapter VIII (regarding imports and exports), adding a new § 805, which appears to leave more aspects of implementation to the Secretary's discretion than does the expedited import program proposed in S. 510. This section authorizes the Secretary (in coordination with Customs and Border Protection) to establish a program to facilitate the movement of food through the import process, if the importer verifies that each facility involved in its production, manufacture, processing, packaging, and holding is in compliance with safety and security guidelines that the Secretary would develop (taking into account a number of prescribed factors). The importer also is to ensure that appropriate safety and security controls are in place throughout the supply chain and to provide supporting information to the Secretary.

Voluntary Qualified Importer Program (§ 302)

Amends FFDCA Chapter VIII (regarding imports and exports), adding a new § 806. It requires the Secretary, within 18 months of enactment: (1) to establish, in consultation with the Secretary of Homeland Security, a voluntary program to expedite review and importation of foods from qualified importers; and (2) to issue applicable program guidance. An importer is defined in this section as "the person that brings food, or causes food to be brought, from a foreign country into the customs territory of the United States." An importer that intends to participate in the program under this section in a fiscal year shall submit a notice to the Secretary of such intent at time and in a manner established by the Secretary. Eligibility is limited to an importer who offers for importation a food from a facility that has a certification under § 809(b), as established by this act. The Secretary shall consider, in making such determinations, the risk posed with respect to: (1) the nature of the food; (2) the compliance history of the foreign supplier; (3) the regulatory system of the country of export; (4) the compliance of the importer with the requirements of the foreign supplier verification program under § 805, as established by this act; (5) recordkeeping,

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		testing, inspections and audits of facilities, traceability of articles of food, temperature controls, and sourcing practices of the importer; (6) the potential risk for intentional adulteration of the food; and (7) other factors that the Secretary determines appropriate. The Secretary shall review each importer’s qualifications at least every three years, and shall promptly revoke an importer’s qualified status if the importer is found not to be in compliance. Making of false statements under this authority may subject an importer to criminal fines and/or imprisonment, pursuant to 18 U.S.C. § 1001.
INFANT FORMULA		
FFDCA § 412 sets forth detailed requirements whereby manufacturers of infant formula are required to provide FDA with assurances of the nutritional quality of their formulations before marketing the formula. FDA has requirements for certain labeling, nutrient content, quality control procedures, and company recordkeeping and reporting. The FDA website states that the agency is also working to finalize a proposed rule for good manufacturing practices, quality control procedures, quality factors, notification requirements, and reports and records, for the production of infant formulas.	Infant Formula (§ 114) Alters several requirements which apply to a manufacturer of a new infant formula; e.g., FDA would have additional time to review certain safety information regarding new ingredients.	No comparable provision.
FOODBORNE ILLNESS SURVEILLANCE AND PUBLIC EDUCATION (See also “Foodborne Illness Surveillance and Outbreak Response” section of this report.)		
Surveillance for foodborne illness is carried out by the states, with assistance from the CDC. States also conduct investigations of foodborne outbreaks, in coordination with CDC, either FDA or FSIS (depending on implicated or suspected foods), and, if appropriate, other federal agencies. FDA is authorized to carry out such investigations, or to coordinate with states in doing so: (1) under broad, permanent authorities in FFDCA § 702 regarding examinations and investigations, and § 909 regarding authority to assist states with examinations and investigations; and (2) under several broad, permanent disease control authorities of the Secretary of HHS in Title III of the PHS Act, which underpin CDC’s activities as well. These include PHS Act § 301 regarding research and investigations, §§ 311 and 317 regarding federal-state	Surveillance (§ 121) This section generally mirrors the language in § 205 of the Senate bill, but lacks two of the provisions: the requirement for a working group on foodborne illness surveillance; and the reauthorization of the food safety capacity grants. Public Education and Advisory System (§ 122) This section of the bill requires the Secretary, in cooperation with private, state and other public organizations, to design and implement a national public education program on food safety. The section describes the elements to be included in the program, and further requires the Secretary to work with states and others to develop and incorporate into the public education program	Surveillance (§ 205) For the purposes of this section, “foodborne illness outbreak” is defined as two or more cases of a similar illness resulting from the ingestion of a certain food. This section requires the Secretary, acting through the Director of the CDC, to enhance foodborne illness surveillance systems by, among other things, enhancing system capacity; improving coordination and information sharing; incorporating research findings; making surveillance data available to the public in appropriate formats; and integrating systems and data with other biosurveillance and related federal, state and local surveillance systems. Appropriations are authorized for these activities at \$24 million annually (FY2011-FY2015). The Secretary must also

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<p>cooperation, and § 361 regarding control of communicable diseases. PHS Act § 317R provides an explicit but expired authority of the Secretary to award grants to state and tribal governments to enhance food safety surveillance and laboratory capacities. Although this authority has expired, the Secretary may carry out this activity under the broad, permanent authorities mentioned earlier.</p> <p>A foodborne illness “outbreak” is not defined in law or regulations. In public health practice, and as used by CDC, a “foodborne disease outbreak” is defined as “the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food.” As a practical matter, particularly for less serious hazards, foodborne disease outbreak investigations are not always launched when only two people are affected. Exceptions may be made for serious problems such as botulism.</p>	<p>regional and national advisories concerning food safety.</p>	<p>establish a working group, comprised of public- and private-sector experts and stakeholders, to meet and report at least annually, and make recommendations for the improvement of foodborne illness surveillance systems.</p> <p>The Secretary shall, within one year of enactment, conduct an assessment of state and local food safety and defense capacities, and shall subsequently develop and implement strategies to enhance these capacities, in order to achieve a number of stated goals. This section also reauthorizes the food safety capacity grants in PHS Act § 317R at \$19.5 million for FY2010, and such sums as may be necessary for FY2011 through FY2015.</p>
RESEARCH		
<p>FDA, along with other federal agencies, is already involved in a variety of research activities, in such areas as how and where food contamination occurs, biotechnology and allergenicity issues, seafood safety, color additives, consumer studies, the detection, characterization, and behavior of foodborne pathogens, for example. Collaborative research efforts have been underway for some time with USDA’s Agricultural Research Service and National Institute of Food and Agriculture, and with academia, state health and agricultural officials, industry and others.</p>	<p>Research (§ 123)</p> <p>Requires the Secretary to conduct research to assist in implementation of the Act, including studies to improve sanitation and food safety practices in food production, harvesting, processing, develop improved monitoring and food inspection techniques, develop efficient and rapid methods for detecting the presence of food contaminants, among other specific areas of emphasis.</p>	<p>Food Safety Integrated Centers of Excellence (§ 210)</p> <p>Section 210(b) of this section, regarding Food Safety Integrated Centers of Excellence, which would, among other things, conduct food safety research. Requires the Secretary and the CDC Director (in consultation with other groups) to designate five “Integrated Food Safety Centers of Excellence” at selected state health departments to serve as resources for federal, state, and local public health professionals. Authorizes the appropriation of such sums as necessary to carry out this provision.</p>
SEIZURE OF FOOD		
<p>FFDCA § 304 spells out the grounds, jurisdiction, and procedures to be used to seize FDA-regulated products through a court order. (This extensive FFDCA provision and the implementing steps involved are detailed in FDA’s</p>	<p>Procedures for Seizure (§ 131)</p> <p>Appears to expedite the process for seizing adulterated or misbranded articles of food by altering the current statutory procedures for doing so.</p>	<p>No comparable provision.</p>

¹³⁴ See <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm>.

Regulatory Procedures Manual.¹³⁴⁾

ADMINISTRATIVE DETENTION OF FOOD

The Secretary has authority for the administrative detention of foods pursuant to FFDCA §§ 304(h) and 801. Under FFDCA § 304(h), an FDA officer or qualified employee may order the detention of an article of food for up to 30 days if the FDA official “has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.” The detention request must be approved by the Secretary or the Secretary’s designated official. Detention orders may be appealed to the Secretary.

Under FFDCA § 801, FDA officers and qualified employees must request the Secretary of Homeland Security to hold food at the port of entry for up to 24 hours if they possess “credible evidence or information indicating that an article of food presents a threat of serious adverse health consequences or death to humans or animals,” and that officer or qualified employee “is unable to inspect, examine, or investigate such article upon the article being offered for import.” The request to hold the food must be approved by the HHS Secretary or his or her appropriately designated official. The FDA’s ability to hold such food for up to 24 hours is intended to enable “the Secretary to inspect, examine, or investigate the article as appropriate.”

Obama Administration: The Hamburg and Taylor testimonies express support for § 132 of the House bill.

Administrative Detention (§ 132)

Similar to the Senate measure, this section changes the FFDCA § 304(h) requirement for “credible evidence or information” to “reason to believe” and changes the standard of “a threat of serious adverse health consequences or death to humans or animals” to “adulterated or misbranded,” and also adds “or otherwise in violation of this Act.” Unlike S. 510, the House bill extends the maximum period to detain an article of food under § 304(h) from 30 days to 60 days; strikes a sentence regarding how a subsection may be construed regarding delivery of an article of food pursuant to the execution of a bond while the food is subject to a detention order; and extends the time allowed for the Secretary to act after an appeal of a detention order has been filed from 5 days to 15 days. The Secretary is required to issue regulations or guidance to implement the amendments, and the amendments shall take effect 180 days after enactment.

Administrative Detention of Food (§ 207)

This section amends FFDCA § 304(h) in two ways. First, the requirement for “credible evidence or information” is lowered to “reason to believe.” Second, the standard “a threat of serious adverse health consequences or death to humans or animals” is changed to “adulterated or misbranded.” Thus, FFDCA § 304(h)(1)(A) would read: “An officer or qualified employee of the Food and Drug Administration may order the detention ... of any article of food that is found during an inspection, examination, or investigation under this Act conducted by such officer or qualified employee, if the officer or qualified employee has reason to believe that such article is adulterated or misbranded.” Within 120 days of enactment, the Secretary shall issue an interim final rule to implement the amended authority, and the amendments to FFDCA § 304(h) shall be in effect 180 days after enactment.

QUARANTINE AUTHORITY

The seizure provisions of FFDCA § 304 do not appear to specifically authorize geographical quarantines of an article of food in the United States.

On occasion, FDA does subject certain imports or groups of imports from an entire country or region to “detention without physical examination” until the importer can demonstrate that the product satisfies FDA requirements. Examples of this in 2007 were imports of all Chinese plant protein products (including wheat gluten and rice gluten)

Authority to Prohibit or Restrict the Movement of Food (§ 133)

Amends FFDCA § 304 (seizure section) by adding that where the Secretary, after consulting with the Governor or other appropriate state elected official, “determines that there is credible evidence or information that an article of food presents an imminent threat of serious adverse health consequences or death to humans or animals,” the Secretary is authorized to prohibit or restrict the

No comparable provision.

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<p>after some were found to contain melamine, an unapproved substance; and of all farm-raised shrimp, catfish, basa, dace, and eel from China until the shippers of these products could demonstrate that they were free of unapproved drug residues.</p>	<p>movement of the article of food within the state or a portion of it. The Secretary must determine that “there is no less drastic action that is feasible and that would be adequate to prevent the imminent threat of serious adverse health consequences or death to humans or animals.”</p> <p>Violation of a prohibition or restriction is a prohibited act under FFDCA § 301. The remainder of § 133 describes the notification procedures the Secretary must follow (including public announcement and publication in the Federal Register) for such a prohibition or restriction, requires renewal every 14 days, and includes limitations on the ability to delegate quarantine authority to others.</p>	
CRIMINAL PENALTIES (See also “Criminal Penalties” section of this report.)		
<p>Under FFDCA § 301(a) (as adjusted by 18 U.S.C. §§ 3559 and 3571) the maximum criminal penalty for individuals convicted of a misdemeanor under the act is \$100,000 if it does not result in death; \$250,000 if it results in death; and/or imprisonment of one year. The maximum criminal misdemeanor penalty for organizations (as adjusted by 18 U.S.C. §§ 3559 and 3571) is \$200,000 if the offense does not result in death and \$500,000 if the offense results in death.</p> <p>For felony convictions the maximum criminal penalty for individuals (as adjusted by 18 U.S.C. §§ 3559 and 3571) is imprisonment for not more than three years or a fine of not more than \$250,000, or both. The maximum criminal penalty for organizations (as adjusted by 18 U.S.C. §§ 3559 and 3571) is a fine of not more than \$500,000.</p> <p>Obama Administration: The Hamburg and Taylor testimonies express support for § 134 of the House bill.</p>	<p>Criminal Penalties (§ 134)</p> <p>Any person who knowingly violates specified prohibited acts under FFDCA § 301 would be subject to increased penalties, of up to 10 years in prison and/or fines in accordance with the U.S. Criminal Code (Title 18 of the U.S.C.). This section also requires the revision of penalties for violations of the FFDCA.</p>	<p>No comparable provision.</p>
CIVIL PENALTIES		
<p>FFDCA § 303(f)(2) FFDCA subjects any person who “introduces into interstate commerce or delivers for introduction into interstate commerce an article of food that is adulterated within the meaning of [FFDCA] section 402(a)(2)(B)” to a civil monetary penalty of up to \$50,000 if an individual and up to \$250,000 on any other person, to a</p>	<p>Civil Penalties for Violations Relating to Foods (§ 135)</p> <p>Amends FFDCA § 303(f)(2)) to delete restrictions on civil penalty provisions regarding pesticide chemical residues that result in a food being deemed adulterated under</p>	<p>No comparable provision.</p>

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<p>maximum of \$500,000 for all such violations adjudicated in a single hearing. However, 402(a)(2)(B) applies only to the presence of illegal pesticide residues. The section further exempts from this penalty any person who grew the article of food, and it prohibits use of FDA’s seizure, injunction, or criminal authorities if such a civil monetary penalty is assessed.</p> <p>Currently, there are no maximum civil penalties tied to FFDCA § 303(a), which addresses criminal penalties for prohibited acts under the FFDCA.</p> <p>Obama Administration: The Hamburg and Taylor testimonies express support for § 135 of the House bill.</p>	<p>FFDCA § 402(a)(2)(B). It also amends § 303(f)(2) by authorizing the Secretary to assess a civil penalty of up to \$20,000 (not to exceed \$50,000 in a single proceeding) on an individual and of up to \$250,000 on any other person (not to exceed \$1 million in a single proceeding) for committing a violation of FFDCA § 301 (prohibited acts). For knowing violations, maximum civil penalties for individuals are \$50,000 (not to exceed \$100,000 in a single proceeding), and for any other person \$500,000 (not to exceed \$7.5 million in a single proceeding). Each prohibited act and each day is to be considered a separate offense. The rewording of this section appears to effectively broaden the reasons for which civil penalties could be applied; subjects those growing an article of food that is adulterated under § 402(a)(2)(B) to them; and appears to no longer preclude use of seizure, injunction, or criminal authorities with regard to violations of § 402(a)(2)(B). It does not strike § 303(f)(2)(C) regarding hearings on the assessment of civil penalties.</p>	
IMPORT ENTRY FILINGS (See also “Food Imports” section of this report, and “Foreign Supplier Verification” row of this table.)		
<p>The FFDCA does not require those who are importers or import brokers to register with FDA under the food facility registration provisions of § 415.</p>	<p>Improper Import Entry Filings (§ 136)</p> <p>This section amends FFDCA § 801 (imports and exports) by authorizing the Secretary to require by regulation or guidance the submission of documentation (in certain circumstances, in consultation with Customs and Border Protection) or other information for articles of food that are imported or offered for import into the United States. Failure to submit required information, submission of inaccurate or incomplete information, is prohibited under FFDCA § 301.</p>	<p>No comparable provision.</p>
FOOD SUBSTANCES GENERALLY RECOGNIZED AS SAFE (GRAS)		
<p>This issue revolves around FDA’s exercise of so-called “generally recognized as safe” (GRAS) determinations. Under current law, substances which FDA agrees are GRAS are exempt from the much more rigorous premarket approval process required for other food additives. Under a 1997 proposed rule, FDA proposed creating a notification procedure for GRAS substances</p>	<p>Food Substances Generally Recognized As Safe (§ 201)</p> <p>Requires the Secretary to publish within 60 days on the FDA public website, notice of receipt of a request for a substance to be determined by the Secretary to be Generally Recognized As Safe (GRAS), and supporting scientific justifications, among other provisions. This section</p>	<p>No comparable provision.</p>

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<p>through which manufacturers can notify the FDA of their “determination that a particular use of a substance is GRAS,” thereby bypassing the regular federal rulemaking procedures. In fact, FDA has been using this GRAS notification procedure since the publication of the proposed rule on an “interim policy” basis.</p>	<p>does not appear to address the GRAS notification procedure, as it discusses requests for substances to be determined by the Secretary to be GRAS. In the notification procedure, the manufacturer or other individual makes the conclusion that the substance is GRAS and the FDA states that it has “no questions” about this conclusion, that the notice does not provide a basis for a GRAS status determination, or that the individual has stopped the GRAS notification process.</p>	
COUNTRY OF ORIGIN LABELING (COOL)		
<p>Since the 1930s, § 304 of the Tariff Act of 1930, as amended, has required most imports to carry labels so that the "ultimate purchaser," usually the retail consumer, can determine their country of origin. Certain products, including a number of agricultural commodities in their "natural" state such as meats, fruits and vegetables, were excluded. Effective in 2009, many retail food stores are now required to inform consumers about the country of origin of fresh fruits and vegetables, seafood, peanuts, pecans, macadamia nuts, ginseng, and ground and muscle cuts of beef, pork, lamb, chicken, and goat, under provisions of the 2002 farm bill (P.L. 107-171) as amended by the 2008 farm bill (P.L. 110-246).</p> <p>The FFDCA does not expressly require country-of-origin labeling (COOL) for foods. FFDCA § 403(e) does consider a packaged food misbranded if it lacks a label containing the name and place of business of the manufacturer, packer, or distributor. However, this is not an indicator of the origin of the product itself.</p>	<p>Country of Origin Labeling (§ 202)</p> <p>Amends the misbranding provision of FFDCA § 403 to consider a processed food misbranded if its label fails to identify the country in which final processing occurred. A non-processed food is misbranded if its label fails to identify the country of origin. Processed foods and non-processed foods are deemed to meet the requirements of this section if they are subject to and meet the requirements of, respectively, the U.S. Customs and Border Protection or USDA. The Secretary is required to promulgate final regulations on this provision within 180 days of enactment, and the new requirements take effect two years after enactment.</p>	<p>No comparable provision.</p>
EXPORT CERTIFICATION FEES		
	<p>Exportation Certificate Program (§ 203) is discussed under the “Funding and Fees” section.</p>	<p>Authority to Collect Fees (§ 107) is discussed under “Funding and Fees” above.</p>
FOREIGN SUPPLIER VERIFICATION (See also “Mandatory Recall Authority” and “Food Imports” sections of this report, and “Import Entry Filings” row of this table.)		
<p>The FFDCA does not explicitly authorize, and does not require, the establishment of a foreign supplier verification program. The FFDCA also does not require those who are importers or import brokers to register with FDA under</p>	<p>Registration for Commercial Importers of Food; Fee (§ 204); Registration for Customs Brokers (§ 205); Unique Identification Number for Food Facilities, Importers and Customs Brokers (§ 206)</p>	<p>Foreign Supplier Verification Program (§ 301)</p> <p>Amends FFDCA Chapter VIII (regarding imports and exports) by adding a new § 805, effective two years after</p>

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<p>the food facility registration provisions of § 415. At a House Energy and Commerce Committee hearing on June 3, 2009, U.S. officials acknowledged that they had no firm data on the number of entities that import food.</p> <p>Obama Administration: The Hamburg and Taylor testimonies express support for § 204 of the House bill.</p>	<p>These sections require an importer of foods to register annually with the Secretary and to submit an appropriate unique facility identification as a condition of such registration. Further conditions for importers (but not customs brokers) include compliance with “good importer practices.” Among other provisions in this section is a requirement that importers permit an officer or employee of the Secretary to “inspect the facilities of such person and have access to, and to copy and verify, any related records.”</p> <p>The Secretary (in consultation with Customs and Border Protection) must promulgate regulations on the measures an importer must take to ensure that the importer has adequate information about a food, its hazards, and applicable requirements; the ability to verify that both the food and each person who produced, manufactured, processed, packed, transported, or held the food including its components are in compliance; and procedures to take corrective actions regarding noncompliant foods. This provision also authorizes the Secretary, in promulgating good import practices regulations, to incorporate certification of compliance under FFDCA § 801 (q) and participation in the safe and secure food importation program under FFDCA § 805, and to take into account differences among importers and types of imports.</p> <p>Provisions in this part of the bill provide for conditions for suspending registrations, and for exemptions from the requirements by the Secretary, among other things. Failure to register is prohibited under FFDCA § 301; any food offered for import that is not from a duly registered person is misbranded under FFDCA § 403. Fees must be charged to importers (but apparently not customs brokers, even though “Fee” was in the title of § 205 marked up in committee).</p> <p>Improper Import Entry Filings (§ 136)</p> <p>As previously noted, this section amends FFDCA § 801 (imports and exports) by authorizing the Secretary to require by regulation or guidance the submission of documentation (in certain circumstances, in consultation</p>	<p>the date of enactment, requiring each importer to establish risk-based foreign supplier verification activities. Importing, or offering for importation, a food by an importer who does not have such a program in place is prohibited under FFDCA § 301, and the Secretary shall refuse admission to any such product that appears to be in violation of this requirement. Defines an importer as the U.S. owner or consignee of the article of food at the time of entry of such article into the United States; or the United States agent or representative of a foreign owner or consignee of the article of food at the time of entry of such article into the United States.</p> <p>The importer is required to develop a program that: (1) assures that imported food is not adulterated or misbranded; and (2) complies with the program of hazard analysis and preventive controls in FFDCA § 418, or the produce safety requirements in FFDCA § 419, each as established by this act. Within one year of enactment, the Secretary shall issue guidance and promulgate regulations regarding the development of foreign supplier verification programs, including appropriate verification steps that importers may apply to the products of their foreign suppliers, to assure that safety requirements are met. The importer shall maintain appropriate documentation for not less than two years, and make such records available for inspection. Importers of seafood, juice, or low-acid canned food whose products are currently in compliance with FDA’s relevant standards and regulations are deemed to be compliant with this section. The Secretary shall publish and maintain a current list of participating importers.</p>

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	with Customs and Border Protection) or other information for articles of food that are imported or offered for import into the United States. Failure to submit required information, submission of inaccurate or incomplete information, is prohibited under FFDCa § 301.	
INSPECTION OF FOREIGN FACILITIES (See also “Targeting of Inspections” section of this report, and “Inspection of Facilities”, “Laboratory Accreditation”, “Third Party Accreditation,” and “Import Certification” rows of this table.)		
<p>FFDCA § 704 authorizes officers and employees designated by the Secretary of HHS to, among other things, enter and inspect “any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction.” Inspections must be conducted “at reasonable times and within reasonable limits and in a reasonable manner.” The refusal to permit such inspections is prohibited under FFDCA § 301. “Interstate commerce” is defined under FFDCA § 201 to mean “(1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.” A “factory, warehouse, or establishment” is not defined in the FFDCA; nor does there appear to be any statutory distinction here between foreign and domestic. Although the FFDCA appears neither to expressly include nor to expressly exclude foreign facilities with regard to the right of inspection by the HHS Secretary or designee, the Bush Administration had argued that FDA lacks the authority to refuse food imports when the agency has been denied access to a foreign facility.</p> <p>Note: Whether FDA now has what is often called “equivalency authority” is a matter of debate. “In a May 9, 2007 hearing before the House Agriculture Committee, FDA’s chief food officer, David Acheson, responded to a question 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 Government Accountability Office] had suggested in 1998 that border inspections alone were ineffective, but that FDA lacks the authority to mandate equivalency.”</p>	<p>Prohibition Against Delaying, Limiting, or Refusing Inspection (§ 207); Risk-Based Inspection Schedule (§ 105)</p> <p>Amends FFDCA § 402 by newly considering a food adulterated if it is from any farm, factory, warehouse, or establishment and the owner, operator, or agent,” or any agent of a governmental authority in the foreign country, “delays or limits an inspection or refuses to permit entry or inspection” under FFDCA § 414 (records inspection) or § 704 (factory inspection). (The remainder of the bill’s § 203 consists of similar proscriptions for drugs, devices, and cosmetics.)</p> <p>The general risk-based inspection provisions in § 105 (above) apply to both imported and domestic inspections. As noted above, §105 requires foreign facilities to be inspected by an agency or representative of a foreign country that is recognized by the Secretary as meeting U.S. standards. (See also § 208 of the House bill, below.)</p> <p>Risk-Based Inspection Schedule (§ 105, part); Certification and Accreditation (§ 109, part)</p> <p>The Secretary has authority under § 105 (Risk-Based Inspection Schedule) to “recognize Federal, State, and local officials and agencies and representatives of foreign countries as meeting standards established by the Secretary for conducting inspections” under the FFDCA (recognition for such inspections could be limited to specific commodities or food types); and under § 109 (accreditation of third-party certifying agents), whereby a foreign government may be eligible to be a qualified certifying agent.</p>	<p>Inspection of Foreign Food Facilities (§ 306)</p> <p>Amends FFDCA Chapter VIII (regarding imports and exports), adding a new § 807, authorizing the Secretary to enter into arrangements and agreements with foreign governments to facilitate the inspection of foreign facilities registered under FFDCA § 415; and requiring the Secretary to direct resources to inspections of foreign facilities, suppliers, and food types, especially such facilities, suppliers, and food types that present a high risk (as identified by the Secretary), to help ensure the safety and security of the food supply of the United States.</p> <p>Imported foods shall be refused admission if “from a foreign factory, warehouse, or other establishment of which the owner, operator, or agent in charge, or the government of the foreign country, refuses to permit entry of United States inspectors or other individuals duly designated by the Secretary, upon request, to inspect such factory, warehouse, or other establishment,” if an inspection is refused “during the 24-hour period after such request is submitted, or after such other time period, as agreed upon by the Secretary and the foreign factory, warehouse, or other establishment.”</p> <p>The Secretary of Commerce, in coordination with HHS, may send one or more inspectors to a country or facility of an exporter of seafood imported to the United States. The inspection will assess the practices used in connection with the farming, cultivation, harvesting, preparation for market, transportation of the seafood; technical assistance may be provided for such activities. The Secretary, coordinating with the Secretary of Commerce, shall prepare an inspection report, which will also be provided to the</p>

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<p>However, FDA has visited certain importing countries at their invitation to conduct such reviews, suggesting that current authority does not bar the Secretary from conducting such assessments.</p> <p>FSIS has import equivalency authority, in that most meat, poultry, and processed egg products may only be imported from countries that have demonstrated to FSIS that they maintain regulatory protections for specified products that are equivalent to the U.S. system (34 in March 2008). The United States accepts FDA-regulated products from any country. The FDA may detain or refuse admission to imported products based on physical inspections, the appearance of a violation of the FFDCA, or an import alert. In 2007, FDA issued an import alert with respect to illegal drug residues in specific seafood products from China, requiring that importers demonstrate through testing that illegal residues are absent.</p> <p>Obama Administration: Mr. Taylor’s testimony stated that, “FDA plans to increase inspection of foreign facilities, but we are concerned that the House bill’s foreign inspection mandate may not result in the best use of FDA’s resources, in light of the approximately 200,000 registered foreign facilities and the high cost of overseas inspections. We think we can achieve cost-effective oversight of imports by working with foreign governments, using the bill’s new tools for import oversight, supporting strong third-party inspections, and increasing targeted, risk-based foreign inspections.”</p>	<p>Before requiring certification under § 109, (see above), the Secretary must establish a process for a country or territory to demonstrate that its controls are adequate to ensure that a food destined for the United States is safe. The Secretary cannot require a certification for a food from a country or territory that has made such a demonstration. The application of these certification requirements must be consistent with U.S. international obligations.</p>	<p>exporter who will be given 30 days to provide a rebuttal or comments to HHS.</p>
<p>FDA FOREIGN OFFICES</p> <p>The FFDCA neither prohibits nor requires the establishment of FDA field offices in other countries. FDA reports that it is establishing offices in China, Latin America, India, Europe, and the Middle East, and was implementing a Memorandum of Agreement with China, in order to coordinate food safety activities.</p>	<p>Dedicated Foreign Inspectorate (§ 208)</p> <p>Amends FFDCA § 704 (in the General Authority chapter) to require the Secretary to establish and maintain a corps of inspectors dedicated to inspecting foreign food facilities. This corps is to be staffed and funded at a level to assist the Secretary to achieve the frequency of inspections for food facilities described in this Act.</p>	<p>Foreign Offices of the Food and Drug Administration (§ 308)</p> <p>The Secretary is required, in consultation with the Secretaries of State and Homeland Security and the United States Trade Representative, to establish FDA offices in foreign countries selected by the Secretary, to assist the appropriate governmental entities of those countries regarding measures to provide for the safety of food and other FDA-regulated products exported by those countries</p>

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		to the United States. FDA activities may include the conduct of risk-based inspections of such products, and supporting such inspections by the governmental entity. The Secretary shall report to Congress by October 1, 2011, with respect to the selection of specific countries, the progress of the established offices in assisting those foreign governments, and plans to establish additional foreign offices. Clarifies that nothing in this provision shall affect the Secretary's authority to issue public notifications under other circumstances.
OTHER LABORATORY PROVISIONS		
<p>Several national networks of laboratories are currently in operation. None is explicitly authorized in law. Existing networks include: the Laboratory Response Network (LRN), run by CDC and federal and state partner groups to conduct public health testing during emergencies; the Food Emergency Response Network (FERN), coordinated by FDA; and the National Animal Health Laboratory Network, coordinated by USDA.</p> <p>Obama Administration: Its FY2010 budget requested an increase in the number of chemical laboratories under FERN through cooperative agreements, and to invest in FDA high-volume laboratories for better sample analyses and faster testing. The administration proposed retaining the FY2010 level for FY2011.</p>	<p>Plan and Review of Continued Operation of Field Laboratories (§ 209)</p> <p>The House bill contains no provision comparable to the integrated consortium provision in S. 510. § 209 does require the Secretary to submit, to Congress and the Comptroller General, a reorganization plan at least 90 days prior to terminating or consolidating any of the 13 field laboratories responsible for analyzing food that are operated by FDA's Office of Regulatory Affairs, or terminating or consolidating any of the 20 district offices with responsibility for food safety. This section also subjects such a reorganization plan to the requirements of the Congressional Review Act (5 U.S.C. §§ 801-808), which establishes a special set of expedited or "fast track" legislative procedures, primarily in the Senate, through which Congress may enact joint resolutions disapproving agencies' final rules.</p>	<p>Integrated Consortium of Laboratory Networks (§ 203)</p> <p>The Secretary of Homeland Security, in consultation with the Secretaries of HHS and USDA and the EPA Administrator, shall maintain an agreement whereby relevant laboratory network members: (1) agree on common laboratory methods to facilitate information sharing regarding animal health, agriculture, and human health; (2) identify the means by which each laboratory network member could work cooperatively to optimize national laboratory preparedness and provide surge capacity during emergencies; and (3) engage in ongoing dialogue and build relationships to support a more effective and integrated response during emergencies. The Secretary of Homeland Security shall publish and report biennially to Congress on the progress of this integrated consortium.</p>
FALSE OR MISLEADING REPORTING TO FDA		
<p>FFDCA § 301 delineates prohibited acts under the law, one of which is "With respect to any device, the submission of any report that is required by or under this Act that is false or misleading in any material respect." [§ 301(q)(2)].</p>	<p>False or Misleading Reporting to FDA (§ 210)</p> <p>Expands the FDA-regulated products covered by this prohibited act to include a "food, drug, or biological product."</p>	<p>No comparable provision.</p>
FDA SUBPOENA AUTHORITY		
<p>The FFDCA provides authority for issuing subpoenas under certain specified conditions. For example, in the course of</p>	<p>Subpoena Authority (§ 211)</p> <p>Expands subpoena authority by permitting the FDA</p>	<p>No comparable provision.</p>

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<p>an investigation or hearing leading to either civil penalties or withdrawal of approval for violations of the law related to drug applications under §§ 335(b) and 335(c), the Secretary is authorized, among other things, to issue subpoenas requiring attendance of witnesses and production of evidence. Similar authorities are provided regarding violations related to devices under § 333(f), and regarding debarment proceedings for certain drug applications and for food imports (i.e., preventing entry of a food import), under § 335(a).</p>	<p>Commissioner to issue subpoenas for witnesses and “the production of records and other things” for the purpose of any hearing, investigation, or other proceeding on a violation of the FFDCa. This section contains extensive language on the timing of compliance and service of a subpoena, among other things.</p>	
WHISTLEBLOWER PROTECTION		
<p>A variety of federal and state measures have been adopted to protect so-called whistleblowers, or those employees who disclose information about illegal or improper activity, generally at their place of employment. Many federal employees, for example, are covered by the Whistleblower Protection Act (P.L. 101-12). The FFDCa itself contains no such language regarding a private employee who must, or willingly provides, information related to an FDA-related product.</p>	<p>Whistleblower Protections (§ 212)</p> <p>Creates a new FFDCa § 911, “Protections for Employees Who Refuse to Violate, or Who Disclose Violations of, This Act or Section 351 of the Public Health Service Act.” Extensive language here makes it illegal to “discharge, demote, suspend, threaten, harass, on in any other manner discriminate against an employee in the terms and conditions of employment” if such an employee provides information on a food, relating to a possible violation of the FFDCa or the Public Health Service Act.</p>	<p>Employee Protections (§ 402)</p> <p>Creates a new FFDCa § 1012 prohibiting food businesses from discharging or otherwise discriminating against an employee who provides or causes to be provided information relating to violations of the FFDCa; who testifies, assists, or participates in a proceeding on such a violation; or who refuses to participate in an activity reasonably believed to violate the act. Contains extensive (but different from House) language on the procedures for treating and protecting whistleblowers.</p>
<p>See “Jurisdiction” above for § 213 of H.R. 2749 regarding extraterritorial jurisdiction.</p>		
STATE AND LOCAL FOOD SAFETY ROLES AND TRAINING		
<p>Although federal agencies such as the FDA and FSIS have national responsibility for food safety under their respective authorizing statutes, state and local food safety agencies (usually located within health, agriculture, or environment departments) have long played major, and in some cases lead, roles, with responsibility for illness surveillance, response to local outbreaks, and inspection and oversight of food safety and local public health laws in restaurants and grocery stores. Often these activities may be conducted in collaboration, or under contract, with federal authorities. Notable examples include the Grade A Pasteurized Milk Ordinance and the National Conference of Interstate Milk Shipments (where federal authorities collaborate with state authorities and the milk industry to ensure the safety of milk shipped in interstate commerce), the National Shellfish</p>	<p>Support for Training Institutes (§ 214)</p> <p>Requires the Secretary to provide financial and other assistance to appropriate entities to establish and maintain at least one university-affiliated institute to train federal, state and local officials in food protection activities.</p>	<p>Improving the Training of State, Local, Territorial, and Tribal Food Safety Officials (§ 209)</p> <p>Creates a new FFDCa § 1011 which requires the Secretary to set standards and administer training and education programs for employees of state, local, territorial, and tribal food safety authorities relating to their responsibilities under the FFDCa, and authorizes the Secretary to enter into examination, testing, and investigations partnerships with such officials and their employees.</p> <p>The Secretary shall coordinate with USDA’s extension activities of the National Institute of Food and Agriculture (NIFA) in advising producers and small processors of new requirements under this act. Also, the Secretary, within 180</p>

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<p>Sanitation Program (a federal-state program to ensure the safety of shellfish), and FDA-state contract inspection agreements (where states conduct facility inspections for FDA).</p> <p>Currently no specific legislative language authorizes support for a training institute. FDA does provide funding to state and local agencies through various grants and cooperative agreements to help them conduct such activities as food defense, laboratory improvements, and food safety training; this funding totaled approximately \$11.4 million in FY2008 and was in addition to an estimated \$8 million states received for FDA contracts to conduct food inspection that year. See <i>Stronger Partnerships for Safer Food: An Agenda for Strengthening State and Local Roles in the Nation's Food Safety System</i>, at http://www.rwjf.org/.</p>		<p>days of enactment, shall enter into agreements with the Secretary of Agriculture to provide competitive training and technical assistance grants, through NIFA, for farmers, small food processors, and small fruit and vegetable merchant wholesalers, in accordance with § 405 of the Agricultural Research, Extension, and Education Reform Act of 1998 (AREERA), as established by this act (see below). There are authorized to be appropriated for new FFDCA §1011 such sums as necessary for FY2011-FY2015.</p> <p>Creates a new AREERA § 405, "National Food Safety Training, Education, Extension, Outreach and Technical Assistance Program." The Secretary of Agriculture shall, through NIFA, award competitive grants to carry out the program authorized above, as specified. Priority shall be given to projects for small and medium-sized farms, beginning farmers, socially disadvantaged farmers, small processors, or small fresh fruit and vegetable merchant wholesalers. Grants are limited to terms of not more than three years. Eligible entities are (1) a state cooperative extension service; (2) a federal, state, local, or tribal agency, a nonprofit community-based or non-governmental organization, or an organization representing owners and operators of farms, small food processors, or small fruit and vegetable merchant wholesalers that meet specified requirements; (3) an institution of higher education (as defined) or a foundation maintained by such institution; (4) a collaboration of 2 or more eligible entities; or (5) other entities as determined by the Secretary. Grants may be made to projects involving more than one state. The Secretary may issue best practices or other guidelines based on findings from this grant program. There are authorized to be appropriated for new AREERA § 405 such sums as necessary for FY2011-2015.</p> <p>Enhancing Food Safety (§ 210)</p> <p>Subsection (a) of this section replaces FFDCA § 1009, regarding grants to states for inspections. New language would authorize grants to states, localities, territories, Indian tribes, and certain non profit entities, to be used for: undertaking food safety examinations, inspections and investigations; training to the Secretary's standards for</p>

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		<p>conducting such activities; and building laboratory capacity, among other things. Sets out eligibility and application requirements and procedures; authorizes appropriation of such sums as necessary for grants from FY2011-FY2015. Requirements for eligible entities are specified, including maintenance of effort with respect to grantee funding contributions. Also, the Secretary shall measure the status and success of each grant program, based on information provided by recipients of how grant funds were spent and the status of their efforts.</p> <p>Subsection (b) of this section requires the Secretary and the CDC Director (in consultation with other groups) to designate five “Integrated Food Safety Centers of Excellence” at selected state health departments to serve as resources for federal, state, and local public health professionals. Authorizes the appropriation of such sums as necessary to carry out this provision.</p>
BISPHENOL A (BPA) (See also “Bisphenol A (BPA)” section of this report.)		
<p>Bisphenol A (BPA) is used to produce certain types of plastic, including food containers. In the United States and elsewhere, scientific disagreement about the possibility of human health effects that may result from BPA exposure through food and water has led to conflicting regulatory decisions regarding the safety of food containers, especially those intended for use by infants and children.</p> <p>BPA-containing PC polymers and epoxy resins used in food containers—such as baby bottles and infant formula cans, respectively—are regulated by FDA as food contact substances. Applicable FDA regulations are at 21 CFR §§ 177.1580, 175.300(b)(3)(viii), 177.1440, and 177.2280. A conclusion of safety by FDA conflicted with earlier findings by one panel of scientific advisors, and was later challenged by a second panel. These events have prompted some to question FDA’s process for the assessment of health risks. (See also CRS Report RS22869, <i>Bisphenol A (BPA) in Plastics and Possible Human Health Effects</i>.)</p>	<p>Bisphenol A in Food and Beverage Containers (§ 215)</p> <p>Requires the Secretary to notify Congress by December 31, 2009 on whether available scientific data support “a determination that there is a reasonable certainty of no harm, for infants, young children, pregnant women, and adults, for approved uses” of plastics made with BPA in food and beverage containers. If such a determination cannot be made for any use, the Secretary must inform Congress on what actions will be taken to protect public health.</p>	<p>No comparable provision.</p>

LEAD IN CERAMICS

Pursuant to its FFDCa authority, FDA regulates food contact surfaces as well as food. The FDA has standards regarding the leaching of lead from ceramics that are to be used for food. These are at “Compliance Policy Guide (CPG) Sec. 545.450 Pottery (Ceramics); Import and Domestic—Lead Contamination” (CPG 7117.07).

Lead Content Labeling Requirement for Ceramic Tableware and Cookware (§ 216)

Would deem ceramic tableware and cookware misbranded under the FFDCa if it includes a glaze or decorations containing lead for an intended functional purpose, unless either: it and its package bears statement: “This product is made with lead-based glaze consistent with FDA guidelines for such lead”; or [sic] the product is in compliance with FDA requirements applicable to ornamental and decorative ceramic ware. Further requires the Secretary to educate consumers on the safety of ceramic ware for food use.

No comparable provision.

PROVISIONS ACCORDING TO SECTIONS IN S. 510 THAT HAVE NOT ALREADY BEEN PRESENTED, IN NUMERICAL ORDER

INTENTIONAL ADULTERATION AND DOMESTIC FOOD DEFENSE

Intentional adulteration of foods can occur due to terrorism or out of economic motivation. Examples of the latter include findings in early 2007 of melamine in pet food ingredients from China. Melamine—apparently added to boost the ingredients’ protein readings—sickened or killed many dogs and cats in North America. The ingredients subsequently were found in some hog, chicken, and fish feed. Although a risk assessment by FDA and USDA indicated the problem posed virtually no risk to humans, melamine turned up again in 2008 in milk products, milk-derived ingredients, and finished food products containing milk from China.

FFDCa § 801(h) and (i), regarding imports and exports, require the Secretary to increase the number of import inspections, giving greatest priority to the detection of intentional adulteration of food, and to improve information management systems and develop rapid detection methods to serve this purpose. FDA’s current food regulations do not specifically address intentional contamination of foods. FDA has published some guidance documents regarding protection of the food supply from intentional contamination. The agency also has an internal work group on intentional economic adulteration and

Hazard Analysis, Risk-Based Preventive Controls, Food Safety Plan, Finished Product Test Results from Category I Facilities (§ 102)

Subsection (c) of this section establishes a new FFDCa § 418C, Food Defense, requiring the owner, operator, or agent of a facility to develop and implement a written food defense plan before introducing any shipment of food into interstate commerce. Lists required elements of the plan, including an assessment to identify conditions and practices that may permit a hazard to be intentionally introduced, a description of preventive measures to minimize such risks and of corrective actions to be taken if necessary, and other elements.

Defines “hazard” for the purposes of this section. Authorizes the Secretary to require by regulation or guidance the adoption of preventive measures for specific product types; allows for alternative measures to be approved by the Secretary; contains a number of reassessment, plan revision, recordkeeping, and records access requirements similar to those that facilities must follow under this section of the bill when developing and implementing hazard prevention plans for unintentional

Protection Against Intentional Adulteration (§ 106)

Subsection (a) of this section establishes a new FFDCa § 420, requiring the Secretary, within 18 months of enactment, in coordination with the DHS and in consultation with USDA, to promulgate regulations to protect against the intentional adulteration of food subject to this act. Regulations shall apply only to food: (1) for which the Secretary has identified clear vulnerabilities; and (2) that is in bulk form rather than final packaging. To make such determinations, the Secretary shall conduct vulnerability assessment of the food system (including consideration by DHS), considering uncertainties, risks, costs, benefits, available mitigation strategies, and other factors. This section shall not apply to food produced on farms, except for milk. Failure to comply with the requirements of this subsection is prohibited.

Subsection (b) of this section requires the Secretary, within one year of enactment, to issue appropriate guidance regarding the requirements of this section, and authorizes the Secretary, in coordination with the Secretaries of DHS and USDA, to issue guidance documents related to protection against intentional food adulteration. These guidance documents and the vulnerability assessment of the

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<p>conducted, on May 1, 2008, a public meeting on the issue.</p> <p>There is currently no statutory requirement for the development of a comprehensive agriculture and food defense strategy. There are, however, other examples of required, comprehensive, quadrennial reviews of this type. The Quadrennial Defense Review is perhaps the best-known example. The Implementing Recommendations of the 9/11 Commission Act of 2007 (P.L. 110-53) requires the Secretary of the Department of Homeland Security (DHS) to routinely conduct a Quadrennial Homeland Security Review, beginning in FY2009. The Pandemic and All-Hazards Preparedness Act (P.L. 109-417, December, 2006) requires the Secretary of HHS to routinely prepare a quadrennial National Health Security Strategy and implementation plan, beginning in 2009.</p> <p>“In November 2002, Congress passed legislation creating [DHS]. Among its responsibilities is overall coordination of critical infrastructure protection activities....In June 2006, the Bush Administration released a National Infrastructure Protection Plan. This Plan presents the process by which the Department of Homeland Security intends to identify those specific assets most critical to the United States, across all sectors, based on the risk associated with their loss to attack or natural disaster, and then to prioritize activities aimed at maximizing the reduction of those risks for a given investment.” (CRS Report RL 30153, Critical Infrastructures: Background, Policy, and Implementation, by John D. Moteff.) At present, DHS has identified several critical infrastructure and key resources sectors, including “Agriculture and Food.” For each sector, a Government Coordinating Council and a (private) Sector Coordinating Council have been established to share data and best practices, and to support risk-based planning.</p> <p>With regard to building domestic capacity, in general, requirements in this section are not explicit in current law, but the Secretary would not be prohibited from undertaking these assessments and reporting the findings.</p> <p>FDA has initiated a number of activities focusing on economic adulteration of foods and other products it</p>	<p>contamination.</p>	<p>food system may require limited distribution due to national security concerns. The Secretary will periodically review required regulations and guidance required by this section, and update them if needed.</p> <p>National Agriculture and Food Defense Strategy (§ 108)</p> <p>Within one year of enactment, the Secretary and the Secretary of Agriculture, and in consultation with the Secretary of Homeland Security, shall prepare a National Agriculture and Food Defense Strategy, to be submitted to relevant congressional committees and made public on USDA and HHS websites (in a manner consistent with national security interests). The strategy shall include an implementation plan and a research agenda, and be consistent with the National Incident Management System; the National Response Framework; the National Infrastructure Protection Plan; the National Preparedness Goals; and other relevant national strategies. The strategy must be revised at least every four years. The strategy shall describe the process by which HHS, DHS, and USDA will achieve a set of goals laid out in this act, and evaluate the progress made by federal, state, local, and tribal governments towards achieving those goals. The act lists 17 specific goals, covering preparedness, detection, emergency response, and recovery.</p> <p>Food and Agriculture Coordinating Councils (§ 109)</p> <p>Requires the Secretary of Homeland Security, in coordination with the Secretaries of HHS and Agriculture, within 180 days of enactment and annually thereafter, to report on the activities of the Food and Agriculture Government Coordinating Council and the Food and Agriculture Sector Coordinating Council, regarding their progress in facilitating public-private partnerships; facilitating information exchange; developing best practices for coordinated preparedness and response; and means to protect the U.S. economy and public health in the event of a food or agricultural incident.</p> <p>Building Domestic Capacity (§ 110)</p>

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<p>regulates, including the establishment of an internal working group.</p>		<p>Establishes a number of assessment and reporting requirements regarding domestic capacity to prevent or address food safety threats, as follows:</p> <p>Within two years of enactment, the Secretary (in coordination with USDA and DHS) must report to Congress regarding measures to promote food safety and supply chain security, and prevent foodborne illness outbreaks, covering certain identified areas. In preparing the initial report, the Secretary shall describe ways to improve laboratory capability and capacity, information systems, risk assessment systems for food, and include an analysis of FDA’s handling of foodborne outbreaks during the five years prior to enactment that involved fruits and vegetables that are raw agricultural commodities, as defined in FFDCa § 201(r).</p> <p>HHS and USDA shall, biennially, submit to Congress a joint food safety and food defense research plan, which may include studying the long-term health effects of foodborne illness. The plan shall include a list and description of projects conducted during the previous two-year period, and the plan for projects to be conducted in the following two years.</p> <p>HHS shall, annually, submit to Congress an evaluation of the effectiveness of each HHS-administered program. The evaluation will assess each program’s effectiveness in achieving “legislated intent, purposes, and objectives,” and will include recommendations for consolidation and elimination to reduce duplication and inefficiencies. The report will be made publicly available. (Note: The language of this provision is not limited to food safety programs.)</p> <p>Not later than one year after enactment, the Secretary shall conduct a study of issues associated with developing and implementing a program that requires “unique identification numbers” for each food facility registered with FDA and for each broker that imports to the United States. A report to Congress on “unique identification numbers” is due within 15 months after enactment.</p>

SANITARY TRANSPORTATION OF FOOD

FFDCA § 416, regarding sanitary transportation practices for food, was established in § 7202 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU), P.L. 109-59, August, 2005. The law requires the Secretary to promulgate applicable regulations, but does not state a deadline for doing so.

No comparable provision.

Sanitary Transportation of Food (§ 111)

Requires the Secretary, within one year of enactment, to promulgate regulations described in FFDCA § 416(b), which say, “The Secretary shall by regulation require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices prescribed by the Secretary to ensure that food is not transported under conditions that may render the food adulterated.” Requires FDA conduct a study of the transportation of food for U.S. consumption, addressing certain issues including an examination of the “unique needs of rural and frontier areas with regard to delivery of safe food.”

FOOD ALLERGY AND ANAPHYLAXIS MANAGEMENT

FFDCA § 403(w) requires food products that contain any of the eight most common food allergens (defined in FFDCA § 201(qq)) to declare their presence on the food label. Noncompliant food is deemed misbranded. This requirement was established by the Food Allergen Labeling and Consumer Protection Act of 2004 (P.L. 108-282). The act focused specifically on food labeling and did not address food allergy and anaphylaxis (a severe, whole-body allergic reaction) management in schools or elsewhere. FDA has announced it is developing a long-term strategy to assist manufacturers to better inform food allergic consumers about the allergens in their products.

No comparable provision.

Food Allergy and Anaphylaxis Management (§ 112)

Requires the Secretary, within one year of enactment and in consultation with the Secretary of Education, to develop, and make available to local educational agencies (LEAs), guidelines to develop plans for individuals to manage the risk of food allergy and anaphylaxis in schools and early childhood education programs. The voluntary guidelines shall address specified elements, as follows: (1) parental obligation to provide the school with information regarding a student’s food allergy and risk of anaphylaxis; (2) an individual plan created with the parent and tailored to each student with a documented risk for anaphylaxis; (3) communication strategies between schools and emergency medical services; (4) strategies to reduce the risk of exposure to anaphylactic causative agents in classrooms and common areas for affected students; (5) training and education for school and program personnel, parents, and children; (6) authority and training of program personnel to administer epinephrine when the nurse is not immediately available, and the availability of epinephrine for this purpose; (7) as part of an individual plan, a plan that addresses the response to an anaphylactic incident in a child engaged in extracurricular programs; (8) maintenance

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of information for each administration of epinephrine to a child, and prompt notification of parents; and (9) other elements the Secretary determines to be necessary. An individual management plan developed pursuant to this section shall be considered an education record for the purpose of the Family Educational Rights and Privacy Act of 1974 (FERPA) [20 U.S.C. § 1232g]. Nothing in this section or the guidelines developed by the Secretary shall be construed to preempt state law, including any state law regarding whether students at risk for anaphylaxis may self-administer medication.

Authorizes the Secretary to award non-renewable food allergy management incentive grants for up to two years to assist LEAs with adoption and implementation of the voluntary food allergy management guidelines. LEAs must provide matching funds of at least 25% of the amount of the grant and report to the Secretary with information on how the grant money was spent and the status of implementation of the guidelines. In awarding grants under this subsection, the Secretary shall give priority to LEAs with the highest percentages of economically disadvantaged children, as defined by § 1124(c) of the Elementary and Secondary Education Act of 1965 [20 U.S.C. § 6333(c)]. The grant program is authorized for \$30 million for FY2011, and such sums as may be necessary for each of four succeeding fiscal years. Though the guidelines developed by the Secretary are voluntary, the Secretary is authorized to enforce an agreement by an LEA to implement such guidelines as a condition of receipt of a grant authorized by this section.

Note: This provision authorizes grant-making by the Secretary of HHS to assist LEAs in implementing food allergy and anaphylaxis management guidelines. Because any individual management plans developed pursuant to this funding would be considered as education records, such records may not be available for disclosure to the Secretary of HHS.

VITAMINS AND MINERALS, ANABOLIC STEROIDS

FFDCA section 413 [21 U.S.C. 350b] requires that manufacturers and distributors of dietary supplements who wish to market dietary supplements that contain “new dietary ingredients” (those not marketed in the United States in a dietary supplement before October 15, 1994) notify FDA about these ingredients.

No comparable provision.

New Dietary Ingredients (§ 113)

Amends 21 U.S.C. 350b. Requires the Secretary to notify the U.S. Drug Enforcement Agency, as specified, if s/he determines that the information in a new dietary ingredient notification submitted under this section for an article purported to be a new dietary ingredient is inadequate to establish that a dietary supplement containing such article will reasonably be expected to be safe because the article may be, or may contain, an anabolic steroid or an analogue of an anabolic steroid. Requires the Secretary to publish guidance that clarifies when a dietary supplement ingredient is a new dietary ingredient, among other things.

SEAFOOD (See also “Hazard Analysis and Risk-Based Preventive Controls” section of this report.)

The National Shellfish Sanitation Program (NSSP) is the federal/state cooperative program recognized by FDA and the Interstate Shellfish Sanitation Conference (ISSC; see next paragraph) for the sanitary control of shellfish produced and sold for human consumption. The purpose of the NSSP is to promote and improve the sanitation of shellfish (oysters, clams, mussels and scallops) moving in interstate commerce through federal/state cooperation and uniformity of state shellfish programs. Participants in the NSSP include agencies from shellfish producing and non-producing States, FDA, EPA, NOAA, and the shellfish industry.

No comparable provisions.

Requirements for Guidance Relating to Post Harvest Processing of Raw Oysters (§ 114)

Creates for the Secretary and GAO certain requirements (see below) triggered when the FDA issues—related to the post harvest processing of raw oysters—(1) guidance, regulation, or suggested amendment to the NSSP’s Model Ordinance; or (2) guidance or regulation relating to the Seafood HACCP Program (21 CFR parts 123 and 1240).

Not later than 90 days prior to issuance, requires the Secretary to submit to Congress a report on the projected public health benefits, cost of compliance, feasibility of implementation, and certain other topics. This requirement does not apply to the guidance described in 103(h) (Updating Guidance Relating to Fish and Fisheries Products Hazards and Controls, discussed below). This requirement is waived if the Secretary issues a guidance that is adopted as a consensus agreement between federal and state regulators and the oyster industry, acting through the ISSC.

The ISSC is a voluntary national organization of state shellfish regulatory officials that provide guidance and counsel on matters for the sanitary control of shellfish. The ISSC has adopted formal procedures for state representatives to review shellfish sanitation issues and develop regulatory guidelines. Following FDA concurrence, these guidelines are published in revisions of the NSSP Model Ordinance.

FDA’s Seafood HACCP Program regulations are articulated in 21 CFR parts 123 (fish and fishery products) and 1240 (control of communicable diseases).

Not later than 30 days after the Secretary issues a proposed regulation or guidance described above, requires the GAO to (1) review and evaluate the Secretary’s report and report its findings to Congress, (2) compare such proposed regulation or guidance to similar regulations or

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<p>FDA’s Fish and Fisheries Products Hazards and Controls Guidance was published by the agency to assist processors of fish and fishery products in the development of HACCP plans, which are required under regulations at 21 CFR 12. Despite FDA’s stated intention to update the guidance every 2 to 3 years, the most recent edition is dated June 2001.</p>		<p>guidance for other regulated foods, including a comparison of risk, and (3) evaluate the impact of post harvest processing on the competitiveness of the U.S. oyster industry domestically and in international markets.</p> <p>Requires any report prepared under the section to be made public.</p> <p>Updating Guidance Relating to Fish and Fisheries Products Hazards and Controls (§103, part) Requires the Secretary to update the Fish and Fisheries Products Hazards and Control Guidance to take into account advances in technology since its previous publication.</p>
PORT SHOPPING		
<p>FFDCA section 801(n) provides FDA with the authority to help prevent “port shopping,” whereby importers of refused goods try to import through another port when refused entry at one port. The provision authorizes FDA to require refused food to be marked with the statement “UNITED STATES: REFUSED ENTRY.” This authority was enacted in section 308 of the Bioterrorism Act of 2002 (P.L. 107-188)</p>	<p>No comparable provision.</p>	<p>Port Shopping (§ 115)</p> <p>Until the Secretary promulgates a final rule that implements the amendments made by section 308 of the Bioterrorism Act of 2002, requires the Secretary to notify the Secretary of Homeland Security of instances of import refusals under FFDCA section 801(a) (Imports; list of registered foreign establishments; samples from unregistered foreign establishments; examination and refusal of admission) to alert U.S. Customs and Border Protection and prevent imports refused at one port from being admitted by another port.</p>
<p>See “Jurisdiction” row of this table for § 116 of S. 510 regarding alcohol.</p>		
FOOD DECONTAMINATION AND DISPOSAL		
<p>Depending on the type(s) of contaminant and the type(s) of food involved, several federal agencies and a variety of laws may be involved in various steps in the process of decontamination, disposal, and/or remediation following an agriculture or food emergency. In addition to agencies that provide scientific and technical assistance—particularly EPA, and various agencies in DHS, HHS, and USDA—the Federal Emergency Management Agency (FEMA) may be involved if the incident is sufficiently large in scope, and the Federal Bureau of Investigation may be involved if it resulted from a deliberate act. In addition, state authorities may play a</p>	<p>No comparable provision.</p>	<p>Decontamination and Disposal Standards and Plans (§ 208)</p> <p>Requires the Administrator of the Environmental Protection Agency (EPA), in coordination with the Secretaries of HHS, DHS, and USDA, to provide support and technical assistance to state, local, and tribal governments in preparing for, assessing, decontaminating, and recovering from an agriculture or food emergency. Activities shall include: (1) the development and dissemination of standards and protocols; (2) jointly developed model plans for the decontamination of</p>

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<p>leading role, and may seek technical and other assistance from appropriate federal agencies. Several Emergency Support Function annexes in FEMA's National Response Framework provide insights into the possible roles and coordination of various federal agencies in response to an agriculture or food emergency.</p>		<p>individuals, equipment, and facilities following an intentional incident, and the disposal of large quantities of infected or contaminated animals, plants, or food products; and (3) the conduct of annual exercises, consistent with the mandated DHS national exercise program. Based on findings from exercises, model plans shall be updated at least biennially. The development of standards and plans shall be prioritized, considering: the highest-risk biological, chemical, and radiological threat agents; agents that could cause the greatest economic devastation to the agriculture and food system; and agents that are most difficult to clean or remediate.</p>
<p>IMPORT CERTIFICATION (See also “Use of Third Parties for Imports and for Laboratory Accreditation” and “Food Imports” sections of this report, and “Laboratory Accreditation” and “Inspection of Foreign Facilities” rows of this table.)</p>		
<p>The steady increase in food imports, a result of globalization and consumer desire for a wider variety of foods year-round, has generated growing concerns about whether current federal programs sufficiently ensure the safety of these imports. Most of the recent debate has included extensive discussion about how to improve current import safeguards, within resource constraints, and without unduly restraining free trade.</p> <p>Current law does not explicitly authorize, or require, any certification of imports, and whether FDA has what is often called “equivalence authority” has been a matter of debate (also see below). Regardless, it does not have a program like that of FSIS, which many consider to be a form of certification. Under the FMIA and PPIA, no foreign establishment can ship its products to the United States until FSIS has determined that the establishment’s country has a meat and/or poultry safety program that provides a level of protection that is at least equivalent to the U.S. system. FSIS visits the exporting country to review its rules and regulations, meets with foreign officials, and accompanies them on visits to establishments. In addition, FSIS operates a reinspection program at 150 import houses located near approximately 35 border entry points. Some have suggested that the FDA program should operate more</p>	<p>Certification and Accreditation (§ 109, part)</p> <p>Amends FFDCA § 801 by authorizing the 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 is to take effect on or after three years from date of enactment. However, the Secretary must only require such certification in the following situations:</p> <ul style="list-style-type: none"> • For food imported from a particular country, territory, or region, where the Secretary finds based on scientific risk-based evidence that the government controls there are inadequate and that such certification would assist in determining the admissibility of the food; • For a food type for which there is scientific evidence that there is a particular risk that presents a threat of serious adverse health consequences or death and that such certification would assist in determining whether the article poses such risk; or • For an article imported from a particular country or territory, if the Secretary has an agreement with that government providing for such certification. 	<p>Authority to Require Import Certifications for Food (§ 303)</p> <p>Amends FFDCA § 801 by authorizing the Secretary to require certification or other assurance of the safety of an article of food imported or offered for import, and to deny entry to any food offered for import that does not meet such a requirement. The Secretary may base such a requirement on public health considerations, including risks associated with the food or its place of origin. Such certification shall be used for designated food imported from countries with which the FDA has an agreement to establish a certification program. Certifying entities—those who may provide certification or assurances—include an agency or a representative of the government of the country from which the article of food at issue originated, as designated by such government or the Secretary; or such other persons or entities accredited to conduct audits, pursuant to § 808, as established by this act, to provide such certification or assurance. The Secretary may require periodic renewal, or determine that a current certification is not valid. The Secretary shall provide for electronic submission of required certifications. Certifying agents who make false statements shall be subject to criminal fines or imprisonment pursuant to 18 U.S.C. § 1001. If the</p>

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<p>like that of FSIS, although they acknowledge the difficulties and resource demands of attempting to regulate many more different types of foods from many more countries of origin.</p> <p>Obama Administration: Dr. Hamburg’s testimony expresses support for relying not only on foreign governments for international inspections but also having the flexibility to explore use of an accreditation system and audit the performance of accredited third parties.</p>	<p>The Secretary, in coordination with the Commissioner for Customs and Border Protection, shall provide for the electronic submission of certifications. A certification may take the form of a statement that the article, or the facility or farm “that manufactured, processed, packed, held, grew, harvested, sorted, or transported” it, complies with FFDC A requirements as specified by the Secretary, or take any other form specified by the Secretary including a listing of certified facilities or other entities.</p> <p>Before requiring certification, the Secretary must establish a process for a country or territory to demonstrate that its controls are adequate to ensure that a food destined for the United States is safe. The Secretary cannot require a certification for a food from a country or territory that has made such a demonstration. The application of these certification requirements must be consistent with U.S. international obligations.</p> <p>A qualified certifying entity must 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. Finally, this section is not to limit the Secretary’s authority to conduct random import inspections, issue import alerts for detaining products, or take other steps necessary to determine imports’ admissibility. Other § 109 provisions regarding qualified certifying entities are discussed in a later section, “Third-Party Accreditation.”</p>	<p>Secretary determines that the food safety systems of a foreign country or region do not meet the requirements of this section, the Secretary shall, to the extent practicable, identify such inadequacies and a means for the country or region to notify the Secretary of subsequent improvements. Amendments made by this section shall not limit the Secretary’s authority to conduct inspections of imported food or to take such other steps as the Secretary deems appropriate to determine the admissibility of imported food.</p>
PRIOR NOTICE OF IMPORTS		
<p>FFDCA § 801 (m) requires the Secretary to establish, by regulation, procedures and requirements by which an importer shall give FDA prior notice of shipments of food intended for importation, in order that FDA can make determinations regarding the admissibility of the food. The FFDCA stipulates certain required data elements that must be included in the notice, including the country from which the food originated, and the country from which the food is shipped. In November 2008, FDA published a final regulation to implement the current authority. The final rule does not require that information be provided</p>	<p>No comparable provision.</p>	<p>Prior Notice of Imported Food Shipments (§ 304)</p> <p>Amends the list of elements that must be provided in the notice required under FFDCA § 801 (m) by adding the identity of “any country to which the article has been refused entry.” Within 120 days of enactment, the Secretary shall publish an interim final rule implementing this amendment, which shall take effect 180 days after the date of enactment.</p>

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regarding refusal of an article of food by another country.		
FOREIGN CAPACITY BUILDING		
<p>Current law would not prohibit the development of the plan proposed by this section of S. 510 (right). Implementation of certain elements of such a plan may be authorized under: (1) FFDCA § 803, which authorizes an HHS Office of International Relations to, among other things, reach agreements with other governments regarding practices and standards; and (2) PHS Act § 307, authorizing collaborations with foreign governments for the purposes of research and education regarding health-related matters.</p>	<p>No comparable provision.</p>	<p>Building Capacity of Foreign Governments with Respect to Food (§ 305)</p> <p>Requires the Secretary, within two years of enactment, to develop a comprehensive plan to expand the technical, scientific, and regulatory capacity of foreign governments, and their respective food industries, from which foods are exported to the United States. In developing the plan, the Secretary shall consult with the Secretaries of Agriculture, State, Treasury, Homeland Security, and Commerce, the U.S. Trade Representative, representatives of the food industry, appropriate foreign government officials, and non-governmental organizations that represent the interests of consumers, and other stakeholders. The plan shall include, as appropriate: (1) recommendations for bilateral and multilateral arrangements and agreements, including provisions for responsibility of exporting countries to ensure the food safety; (2) provisions for electronic data sharing; (3) provisions for mutual recognition of inspection reports; (4) training of foreign governments and food producers on U.S. food safety requirements; (5) recommendations to harmonize requirements under Codex Alimentarius; and (6) provisions for multilateral acceptance of laboratory methods and detection techniques. This section does not apply to dietary supplements.</p>
SMUGGLED FOOD		
<p>The FFDCA does not appear to address or to define the term “smuggled food,” although Chapter VIII of the act covers imports and exports.</p>	<p>No comparable provision.</p>	<p>Smuggled Food (§ 309)</p> <p>Requires the Secretary, within 180 days of enactment, in consultation with designated officials in the Department of Homeland Security, to develop and implement a strategy “to better identify smuggled food and prevent its entry into the United States.” Contains notification requirements regarding smuggled food, defined here as “any food that a person introduces into the United States through fraudulent means or with the intent to defraud or mislead.”</p>

DETERMINATION OF BUDGETARY EFFECTS (“PAY-AS-YOU-GO”)

The Statutory Pay-As-You-Go Act of 2010 (Title I of P.L. 111-139) created a budget enforcement tool aimed at preventing, or at least discouraging, increases in the net deficit that could arise from the enactment of direct spending and revenue legislation. The statutory PAYGO process does not apply to discretionary spending, which is provided in annual appropriations acts.

The budgetary effects of PAYGO measures are determined by statements inserted into the Congressional Record by the chairmen of the House and Senate Budget Committees and referenced in the measures. As a general matter, the statements are expected to reflect cost estimates prepared by the Congressional Budget Office (CBO). If this procedure is not followed, then the budgetary effects are determined by the Office of Management and Budget (OMB).

If OMB determines after a congressional session ends that a cumulative violation of PAYGO has occurred for the budget year, then sequestration may occur, which is an across-the-board cut in nonexempt direct spending programs. (See CRS Report R41157, *The Statutory Pay-As-You-Go Act of 2010: Summary and Legislative History*.)

No comparable provision.

Note: The House bill was passed by the chamber before the enactment of the Statutory Pay-As-You-Go Act. Thus, it does not have any reference to paygo or the CBO score like the Senate measure, which originated later.

Nonetheless, there is a CBO score of the House bill, and it estimates direct revenues from civil penalties of \$10 million over 5 years, and \$2 billion of potential discretionary spending over 5 years (in addition to spending offset by new user fees). See Congressional Budget Office, “Cost Estimate of H.R. 2749, Food Safety Enhancement Act of 2009,” July 24, 2009, at <http://www.cbo.gov>.

Determination of Budgetary Effects (§405).

This section complies with requirements in the Statutory Pay-As-You-Go Act by referencing the CBO score for this measure. The CBO score has a zero net direct spending estimate (mandatory spending), and thus no effect on statutory paygo. (See “CBO Estimate of the Statutory Pay-As-You-Go Effects for Senate Amendment 4715 in the Nature of a Substitute to S. 510, FDA Food Safety Modernization Act,” November 19, 2010, at <http://www.cbo.gov/ftpdocs/119xx/doc11970/s510.pdf>.)

This direct spending score is unrelated to the potential for higher future discretionary appropriations that may be needed to implement the law. (E.g., \$1.4 billion over 5 years as estimated in “Congressional Budget Office Cost Estimate of S. 510,” August 12, 2010, at <http://www.cbo.gov/ftpdocs/117xx/doc11794/s510.pdf>.) The budget impact of changes in discretionary appropriations would be determined by discretionary budget limits and allocations placed on future appropriations acts, and decisions by future appropriations committees.

Source: Table created by CRS staff based on the text of the House-passed and the Senate-passed bills (H.R. 2749 and S. 510).

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