



# Food Safety in the 111<sup>th</sup> Congress: H.R. 2749 and S. 510

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## Summary

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 one of a number of microbial pathogens and other contaminants. 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. 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 the 111<sup>th</sup> Congress, several food safety bills have been introduced, and wide-ranging legislation (H.R. 2749) has passed the House. The Senate also has reported a comprehensive bill (S. 510). Both of these 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 has oversight of most meat and poultry). The bills would generally expand or modify existing FDA authorities rather than create a new food safety structure or authorities. H.R. 2749 is a revised version of H.R. 759, and was amended and approved by a House Energy and Commerce subcommittee on June 10, 2009. The full committee further amended and approved H.R. 2749 on June 17, 2009, and the full House approved the bill on July 30, 2009, with a number of additional amendments intended to satisfy the concerns of agricultural interests. The Senate Health, Education, Labor, and Pensions Committee amended and approved S. 510, and later reported it in December 2009. In mid-July 2010, potential amendments to the bill were being discussed, aimed at addressing issues of continued interest to various Senators. In August 2010, a group of Senate leaders released a manager's amendment to S. 510. Senate floor action has been held up by objections about the projected cost of the bill, as well as attempts to further amend it.

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 rarely visits food manufacturing and other facilities to check sanitary and other conditions. In response, the bills would require (although in different ways) 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.

The 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 do so voluntarily. Major portions of the bills are devoted to more scrutiny of food imports, which account for an increasing 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-passed bill and Senate amendment 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 one of a number of microbial pathogens and other contaminants.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup> 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.<sup>4</sup>

## Food Safety Incidents

Food safety-related incidents frequently heighten public and media scrutiny of the U.S. food safety system.<sup>5</sup> Large recalls of FSIS-regulated meat and poultry products (including ground beef) due to findings of *E. coli* O157:H7, *Listeria*, and other problems occur each year.<sup>6</sup> In addition, in recent years, several large multi-state foodborne 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 the bacterium *E. coli* O157:H7.

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<sup>1</sup> 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.

<sup>2</sup> 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.

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

<sup>4</sup> 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*.

<sup>5</sup> 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*.

<sup>6</sup> For updates on meat and poultry recalls and alerts, see the FSIS website: [http://www.fsis.usda.gov/fsis\\_recalls/index.asp](http://www.fsis.usda.gov/fsis_recalls/index.asp).

Attention shifted to 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 subsequently were found in some hog, chicken, and fish 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 2008, more than 1,400 persons in 43 states, the District of Columbia, and Canada were found to be infected with the same unusual strain of bacteria, *Salmonella* Saintpaul. Officials first suspected fresh tomatoes as the vehicle, but later tests confirmed 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 contamination incidents.

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. According to the U.S. Centers for Disease Control and Prevention (CDC), 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, CDC noticed a spike in cases of infection with *Salmonella* Enteritidis, a strain commonly associated with shell eggs, which are regulated by FDA.<sup>7</sup> 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.<sup>8</sup> In July 2009, FDA had published a long-awaited egg safety regulation, which became effective in July 2010 as the outbreak was well underway.<sup>9</sup> 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.<sup>10</sup>

## Existing Food Safety Legal and Regulatory Landscape

Federal responsibility for food safety rests primarily with FDA and USDA.<sup>11</sup> The FDA is responsible for ensuring that all domestic and imported food products—except for most meats

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<sup>7</sup> 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.

<sup>8</sup> FDA, "Salmonella Enteritidis Outbreak in Shell Eggs," <http://www.fda.gov/Food/NewsEvents/WhatsNewinFood/ucm222684.htm>.

<sup>9</sup> 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>.

<sup>10</sup> Alicia Mundy and Bill Tomson, "Egg Inspectors Failed to Raise Alarms," *The Wall Street Journal*, September 10, 2010.

<sup>11</sup> 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*.

and poultry—are safe, nutritious, wholesome, and accurately labeled. USDA’s Food Safety and Inspection Service (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, on the same day in 1906, both the Pure Food and Drugs Act and the Meat Inspection Act. The former was passed to address the widespread marketing of intentionally adulterated foods, and its implementation was assigned to USDA’s Bureau of Chemistry. The latter law was passed to deal with unsafe and unsanitary conditions in meat packing plants, and implementation was assigned to a different USDA agency, the 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.<sup>12</sup>

There has been discussion over time regarding whether this dispersal of food safety responsibilities has been problematic,<sup>13</sup> or whether a reorganization would divert time and attention from other fundamental problems in the system. Neither the House-passed bill nor the Senate amendment 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.

Both the House and Senate proposals 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.<sup>14</sup> Persons who commit prohibited acts are subject to criminal and civil penalties.

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<sup>12</sup> 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.

<sup>13</sup> See 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.

<sup>14</sup> 21 U.S.C. § 331.

## 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, introduction of adulterated food into commerce, adulteration of food that is in commerce, or receipt and delivery of adulterated food in commerce are prohibited. (See “Prohibited Acts” below.) Adulteration is defined in FFDCA § 402(a), 21 U.S.C. § 342(a), as follows:

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, introduction of misbranded food into commerce, misbranding of food that is in commerce, or receipt and delivery of misbranded food in commerce are 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.

**Person:** FFDCA § 201(e), 21 U.S.C. § 321(e), defines *person* to include an individual, partnership, corporation, or 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 CFR 123.3(k)].”

**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 introduction of adulterated or misbranded food into commerce; adulteration or misbranding of food that is in commerce; or receipt and delivery of adulterated or misbranded food in commerce are 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 110<sup>th</sup> 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.<sup>15</sup> 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 Obama, in a March 14, 2009, weekly radio address, called the food safety system a "hazard to public health." 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 21<sup>st</sup> century; foster coordination throughout government; and ensure that we are not just designing laws that will keep the American people safe, but enforcing them."<sup>16</sup> In July 2009, the FSWG announced a number of steps the Administration was taking, under existing authorities, to improve government safeguards.<sup>17</sup> The group released a one-year progress report in July 2010. 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](http://www.foodsafety.gov) site to provide consumers rapid access to information on food recalls."<sup>18</sup>

To date, the Obama Administration has not provided recommended language for changes in authorizing statutes. The Administration declared its support for H.R. 2749 in its official Statement of Administration Policy on the bill.<sup>19</sup> In a July 2010 statement, the Administration further urged the Senate to complete its work on S. 510.<sup>20</sup> In addition, Administration officials have testified on aspects of the legislation. Testimony 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.<sup>21</sup>

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<sup>15</sup> 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/importsafety/report/actionplan.pdf>.

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

<sup>17</sup> FSWG, "Food Safety Working Group: Key Findings," July 7, 2009, [http://www.foodsafetyworkinggroup.gov/FSWG\\_Key\\_Findings.pdf](http://www.foodsafetyworkinggroup.gov/FSWG_Key_Findings.pdf).

<sup>18</sup> The White House, Statement by the President on Food Safety, July 7, 2010, <http://www.whitehouse.gov/the-press-office/statement-president-food-safety>.

<sup>19</sup> 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>.

<sup>20</sup> The White House, Statement by the President on Food Safety, July 7, 2010, <http://www.whitehouse.gov/the-press-office/statement-president-food-safety>.

<sup>21</sup> Dr. Hamburg's comments were based on an earlier version of H.R. 2749, i.e., prior to markup by the subcommittee; Mr. Taylor's were based on the version reported by the full Energy and Commerce Committee (H.Rept. 111-234).

In October 2009 testimony on the Senate bill, FDA Commissioner Margaret 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.<sup>22</sup> (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. Several 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.<sup>23</sup> The 110<sup>th</sup> Congress adopted some amendments to current programs 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.

## **Legislative Overview**

In the 111<sup>th</sup> Congress, nearly a dozen food safety bills, several of them comprehensive, have been introduced. However, the major vehicle in the House has been H.R. 2749 by Representative Dingell. This bill was amended and approved by the Subcommittee on Health of the House Energy and Commerce Committee on June 10, 2009; by the full committee on June 17, 2009 (H.Rept. 111-234, July 29, 2009); and by the full House on July 30, 2009.<sup>24</sup>

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<sup>22</sup> October 22, 2009, testimony of FDA Commissioner Margaret Hamburg before the Senate Committee on Health, Education, Labor, and Pensions.

<sup>23</sup> 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.

<sup>24</sup> Two other comprehensive House bills have been H.R. 875 by Representative DeLauro, a blueprint for a new, independent Food Safety Administration (FSA), separated from the current FDA but still within HHS, which would (continued...)

In the Senate, the principal bill was originally introduced as S. 510 by Senator Richard Durbin. The HELP Committee amended and approved the bill on November 18, and reported it (without a written report) on December 18, 2009. During the summer of 2010, potential amendments to the bill were being discussed, aimed at addressing issues of continued interest to various Senators. These include a proposal by Senator Dianne Feinstein to phase out the use of bisphenol-A (BPA) in food packaging<sup>25</sup> and a proposal by Senator Jon Tester to exempt small facilities from certain requirements, if they make less than \$500,000 in annual sales and if the majority of those sales are sold directly to qualified end-users.<sup>26</sup>

On August 12, 2010, several members of the Senate HELP Committee, including its 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.<sup>27</sup> Following the release of the proposed amendment, Senate floor action was widely anticipated. However, as of mid-September 2010, further action on the measure had stalled. Senator Tom Coburn has objected to the projected cost of the measure.<sup>28</sup> Although the Senate manager’s proposal (referred to as the “Senate amendment” in this report) does not include either of the changes proposed by Senators Tester and Feinstein, versions of these could be offered as amendments if the proposal is considered by the full Senate. In addition, a bill approved by the Senate Judiciary Committee on September 23, 2010 (S. 3767, introduced by Senator Patrick Leahy), which would increase penalties for persons who knowingly distribute tainted food products, could also be offered as an amendment.

## Overview of Major Provisions

Both H.R. 2749 and S. 510 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 the House and Senate bills seek to address many of the same 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. 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 its widely acknowledged funding and staffing constraints, and no explicit requirement for

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(...continued)

operate a comprehensive new food safety program (but would not include the meat and poultry inspection programs operated by FSIS); and H.R. 1332 by Representative Costa, which is similar in design to the version of the Senate bill originally introduced by Senator Durbin (S. 510).

<sup>25</sup> Alan K. Ota, “Food Safety Bill Held Up By Split Over Fine Lining,” *CQ Today Online News*, July 21, 2010. See also CRS Report RS22869, *Bisphenol A (BPA) in Plastics and Possible Human Health Effects*.

<sup>26</sup> Press release, Senator Tester, “Updated Food Safety amendment protects small producers,” September 24, 2010, [http://tester.senate.gov/Newsroom/pr\\_092410\\_foodsafety.cfm](http://tester.senate.gov/Newsroom/pr_092410_foodsafety.cfm). See also CRS Report RL34612, *Food Safety on the Farm: Federal Programs and Legislative Action*.

<sup>27</sup> 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/>.

<sup>28</sup> Senator Tom Coburn, Unanimous Consent Request, S. 510, *Congressional Record*, daily edition, vol. 156 (September 23, 2010), pp. S7394-S7397.

the frequency of inspections, the agency rarely visits food manufacturing and other facilities to check sanitary and other conditions.

Both 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 are similar conceptually to the so-called hazard analysis and critical control point, or HAACP, 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.

The bills seek to increase the frequency of plant inspections, taking into account the risks posed by specific foods or processors. 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 bill requires 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 bills differ somewhat on how such authority might be applied, and on related requirements for notification when adulterated or misbranded food threatens public health.

The 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 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 by an accrediting body recognized by FDA; again, the House and Senate bills differ in detail on how to accomplish these objectives. The bills 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 bills is how the proposed program changes would be funded. Specifically, H.R. 2749 would institute a new \$500 annual facility registration fee that would help offset the cost of various FDA activities in the bill; a similar fee is not included in S. 510. 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 FFDCAs would increase by \$10 million over the same period.<sup>29</sup> 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.”<sup>30</sup> Despite higher offsetting fee revenues proposed in the House bill, CBO scored higher net federal costs for the House bill than for the Senate amendment due to higher costs in the House bill for FDA activities (principally related to facility inspections) that would not be supported by fees.

**Table 1** provides a crosswalk of the House and Senate provisions. A comparison of key provisions in the House-passed bill and Senate amendment with current law is provided in the **Appendix** at the end of this report.

**Table 1. Crosswalk of Food Safety Provisions in H.R. 2749 (House-Passed) and S. 510 (Manager’s Amendment of August 12, 2010)**

Topic	Sections in H.R. 2749 (House-passed)	Sections in S. 510 (manager’s amendment)
Food Facility Registration Requirements (not including imported foods)	101	102
Record-keeping requirements	102 (HACCP), 106 (access), 107 (traceability), 204 and 205 (imports)	101 (access), 103 (HACCP), 204 (traceability), 301 and 307 (imports)
Record-keeping; Records Access and Inspection	106, 107, 205	101
Hazard Analysis and Risk-Based Preventive Controls and Food Safety Plans	102	103, 114 (seafood)
Performance Standards	103	104
Standards for Produce, other Raw Agricultural Commodities	104	105
Targeting of Inspection Resources	105, 207	201, 306
Third Party Accreditation	307	109
Laboratory Accreditation, Testing	110, 209	202, 203
Recall Authority	102 and 108 (facility and importer recall plans), 105 (inspection frequency), 111 (mandatory recall authority), 204 (fees)	103 (facility recall plans), 107 (fees), 201 (inspection frequency), 206 (mandatory recall authority)
Notification; Reportable Food Registry	111 and 112 (notification and Reportable Food Registry)	211 (Reportable Food Registry)

<sup>29</sup> 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.

<sup>30</sup> 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.

Topic	Sections in H.R. 2749 (House-passed)	Sections in S. 510 (manager's amendment)
Food Traceability	102 (HACCP), 107 (tracing system), 206(unique facility identifier)	110 (report on traceback capability), 204 (tracing system), 302 (importer tracing plans)
Foodborne Illness Surveillance and Education	121, 122	205
Administrative Detention of Food	132	207
Intentional Adulteration and Domestic Food Defense	102	106, 108, 109, 110
State and Local Food Safety Roles and Training	214	209, 210
Whistleblower Protection	212	402
Other Enforcement Provisions (including provisions not comparable between House and Senate bills)	131 (Procedures for seizure), 133 (Authority to prohibit or restrict the movement of food), 134 (Criminal penalties), 135 (Civil penalties), 210 (False or Misleading Reporting to FDA), 211 (Subpoena Authority)	—
Import Certification	109	303
Inspection of Foreign Facilities	105, 207	306
Foreign Supplier Verification	204, 205, 206, 136	301
Expedited Imports	113	302
FDA Foreign Offices	208	308
Other importer provisions (including provisions not comparable between House and Senate bills)	202 (Country of Origin Labeling)	304 (Prior Notice of Imported Food Shipments), 305 (Building Capacity of Foreign Governments with Respect to Food), 115 (Port Shopping), 309 (Smuggled Food)
HHS-USDA Jurisdiction	4, 5, 6, 213	403, 116, 404
Funding and Fees	101, 108, 203, 204	107, 401
Research	123	210
Miscellaneous provisions (including provisions not comparable between House and Senate bills)	114 (Infant Formula), 201 (Food Substances Generally Recognized As Safe), 215 (Bisphenol A in Food and Beverage Containers), 216 (Lead Content Labeling Requirement for Ceramic Tableware and Cookware)	111 (Sanitary Transportation of Food), 112 (Food Allergy and Anaphylaxis Management), 113 (New Dietary Ingredients), 208 (Decontamination and disposal standards and plans)

**Source:** Table prepared by the Congressional Research Service based on the text of H.R. 2749, as passed by the House, and the August 2010 manager's amendment to S. 510 in the Senate.

## Selected Issues

The following sections provide a discussion of the key provisions in H.R. 2749 as passed by the House and the Senate manager's amendment to S. 510. Unless otherwise noted, the House bill provisions discussed in this section refer to provisions in the House-passed H.R. 2749, and the

Senate provisions refer to provisions in the Senate manager's amendment ("amendment") to S. 510, released August 12, 2010. 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 amendment (§ 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 amendment 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 amendment would not change the current exemptions from the registration requirement for farms, restaurants, retailers, and certain types of nonprofit food establishments and fishing vessels. The amendment would not impose registration fees.

## 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.<sup>31</sup>

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 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.” (Drafters of the bill view the removal of the “reasonable belief” requirement as authority to access 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.

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<sup>31</sup> 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.



The Senate amendment (§ 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 amendment 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 that are likely to be affected in a similar manner, but would need to believe that 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 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 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. 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. 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.<sup>32</sup>

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.<sup>33</sup>

### ***Legislative Proposals***

The House-passed bill and Senate amendment (§ 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 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 amendment contains additional requirements regarding available FDA guidance documents for seafood (§ 114).

## **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.”<sup>34</sup> The committee added that regulators like the FDA, USDA, and the Environmental Protection Agency

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<sup>32</sup> 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.

<sup>33</sup> National Advisory Committee on Microbiological Criteria for Foods, *Hazard Analysis and Critical Control Point Principles and Application Guidelines*, adopted August 14, 1997.

<sup>34</sup> 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.

(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.<sup>35</sup>

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.<sup>36</sup>

### ***Legislative Proposals***

The House bill and Senate amendment both include language on performance standards (§ 103 and § 104, respectively). Although differing in detail, the House-passed bill and Senate amendment 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 amendment conditions the issuance of standards, requiring them “[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 amendment 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. From this point, viewpoints diverge. 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 relied on the latter “carrot” approach that, in the view of some critics, is no longer effective. It also could be argued that numerous existing laws and regulations already

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<sup>35</sup> Ibid, p. 17.

<sup>36</sup> 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 CRS Report RL32922, *Meat and Poultry Inspection: Background and Selected Issues*.

impose restrictions, both direct and indirect, on producers of food commodities, which effectively meet food safety objectives—and also involve significant compliance costs. These restrictions 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.<sup>37</sup> 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.<sup>38</sup> 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 officials access to these records if a food is suspected of being adulterated and presenting a serious health threat.<sup>39</sup>

FDA's general approach has been not to impose mandatory on-farm safety standards or inspections of agricultural facilities.<sup>40</sup> 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; they are advisory and not legally enforceable.<sup>41</sup> In July 2009, the Obama Administration released new draft guidances on three specific types of produce: tomatoes, melons, and leafy greens.<sup>42</sup> 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.<sup>43</sup>

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<sup>37</sup> 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."

<sup>38</sup> P.L. 107-188; 21 U.S.C. 350(d).

<sup>39</sup> 21 U.S.C. 350c and 21 U.S.C. § 374. FDA has 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 Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, Appropriations for 2008, Hearings, Part 5, p. 479.

<sup>40</sup> The FDA advisory panel acknowledged that the agency "conducts only limited inspections of food-producing farms, except in emergencies." *FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology*.

<sup>41</sup> Sources: FDA, *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*, October 26, 1998, at <http://www.cfsan.fda.gov/~dms/prodguid.html>; and *Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables*, February 2008, at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm064458.htm>.

<sup>42</sup> FDA, "Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Tomatoes; Availability;" FDA, "Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons;" and FDA, "Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens; Availability" (74 *Federal Register* 38437-38440, August 3, 2009). See also FDA, "FDA Issues Draft Guidances for Tomatoes, Leafy Greens and Melons," July 31, 2009, <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/FruitsVegetablesJuices/FDAProduceSafetyActivities/ucm174086.htm>.

<sup>43</sup> 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>.

## ***Legislative Proposals***

Several provisions in the in the House-passed bill and Senate amendment 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 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. These regulations could set forth procedures and practices that the Secretary determines to be reasonable to prevent known or reasonably foreseeable biological, chemical, and physical hazards, including natural ones, that may be intentionally or unintentionally introduced. The 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.”

The Senate amendment 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 amendment would encourage coordination with USDA and would require, as appropriate, coordination with state agricultural agencies when enforcing standards. Enforcement may be in the form of audit-based verification systems or other inspection methods. The amendment 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.

## **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.<sup>44</sup> 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.

Several provisions in the House-passed bill and Senate amendment 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). In addition, both bills would require the issuance of updated good agricultural practices, among other bill provisions that could potentially affect small businesses and farming operations. These include facility registration requirements (§ 101 of the House-passed bill; § 102 of the Senate amendment); records access and/or inspection requirements (§ 106 of H.R. 2749; § 101 and § 204 of the Senate amendment); food traceability requirements (§ 107 of H.R. 2749; § 204 of the Senate amendment); hazard analysis and risk-based preventive controls (§ 103 of the Senate amendment); targeting of inspection resources (Section 201 of the Senate amendment); 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, as well as the discretion of the HHS Secretary.

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 nonprofit food establishments and fishing vessels are exempt from facility registration requirements under FFDCFA § 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 gross cash income (or sales receipts), adjusted gross income (AGI), numbers of employees, or other measures. 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.<sup>45</sup> Under these definitions, USDA data indicate that 22% of all crop and livestock producers were considered to be small commercial farms. The share of small 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

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<sup>44</sup> For information, see CRS Report RL34612, *Food Safety on the Farm: Federal Programs and Legislative Action*.

<sup>45</sup> Robert A. Hoppe, “U.S. Farm Structure: Declining—But Persistent—Small Commercial Farms,” *Amber Waves*, USDA, September 2010, <http://www.ers.usda.gov/AmberWaves/September10/Features/USFarm.htm>; and USDA, *Small Farms in the United States: Persistence Under Pressure*, EIB-63, February 2010, <http://www.ers.usda.gov/publications/eib63/>. Based on 2007 survey data.

farms is roughly 10% of all growers in this category.<sup>46</sup> Small business definitions for farms, established by the Small Business Administration (SBA), also are based on annual sales receipts but vary considerably from USDA's definitions: among most crop producers, SBA defines as a small business those who make no more than \$750,000 in sales per year.<sup>47</sup> By these standards, more farms would be considered small businesses, with up to one-half of all crop and livestock producers defined as small.<sup>48</sup>

Elsewhere in farm legislation, adjusted gross income (AGI) is 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 periodic omnibus farm bill,<sup>49</sup> 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. 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 indicate that farms with less than \$500,000 AGI account for the vast majority (more than 95%) of farm numbers.<sup>50</sup>

For food processors, 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. Among most food processors, a small business is defined by the SBA as a business with no more than 500 employees.<sup>51</sup> By this definition, nearly all (97%) of all food manufacturers would be considered small businesses based on U.S. Census Bureau data.<sup>52</sup>

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 "employing fewer than 500 persons."<sup>53</sup> Accordingly, available data indicate that as many as 84% of businesses that make juice would be not be covered by the HAACP requirements.<sup>54</sup> Very small businesses would also be exempt, and so defined 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."<sup>55</sup> Producers of "raw

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<sup>46</sup> Ibid., Figure 3.

<sup>47</sup> Small Business Size Regulations, Title 13 C.F.R. Part 121.

<sup>48</sup> Based on data on farms that make up to \$1 million. USDA survey data are not published for this increment.

<sup>49</sup> 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*.

<sup>50</sup> 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>.

<sup>51</sup> Small Business Size Regulations, Title 13 C.F.R. Part 121.

<sup>52</sup> 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/susb/>.

<sup>53</sup> Hazard Analysis And Critical Control Point (HAACP) Systems, Title 21 C.F.R. Part 120.

<sup>54</sup> U.S. Census Bureau, *2007 County Business Pattern*. Data for "Frozen Fruit, Juice, and Vegetable Manufacturing."

<sup>55</sup> Hazard Analysis And Critical Control Point (HAACP) Systems, Title 21 C.F.R. Part 120.

agricultural ingredients of juice,” such as fruit and vegetable growers, would not be covered by the HACCP requirements.

### *Legislative Proposals*

Although both the House-passed bill and the Senate amendment 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.

The House-passed bill contains additional provisions that are intended to address potential effects of the food safety requirements on small, organic, direct-to-market, and sustainable farming operations, among other related provisions. 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)).

Initially, S. 510 was 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 require 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).

The Senate amendment includes additional provisions intended to address the potential effects of the food safety requirements on small business and other farming operations. These include 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”; and assurances that any new regulations do not conflict with or duplicate other federal policies and standards, and that they 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 considerations in the Senate amendment, Senator Jon Tester has stated that he intends to offer further amendments to address small farm interests if the Senate food



safety measure reaches the Senate floor in the 111<sup>th</sup> Congress.<sup>56</sup> Senator Tester first announced in spring 2010 that he planned to introduce two amendments to the Senate committee-reported bill, S. 510.<sup>57</sup> 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 exempt 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.” These amendments were not ultimately included in the Senate manager’s amendment.

In September 2010, Senator Tester, along with Senator Kay Hagan, announced an updated version of this amendment.<sup>58</sup> 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 in regulation). Under this proposed amendment, qualified facilities would not be subject to the facility registration requirements under FFDCA § 415; instead they would be required to submit to HHS relevant documentation showing that they have implemented preventative 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 miles<sup>59</sup> 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 Tester-Hagan amendment also includes other clarifying language with respect to the exemption for direct farm marketing and sales. The provision further would require that HHS conduct a study of the food processing sector, in conjunction with USDA.

Many farm groups have expressed support for these proposed amendments.<sup>60</sup> However, one of the leading produce industry groups, United Fresh Produce Association (UFPA), is urging 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.<sup>61</sup> In addition to

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<sup>56</sup> Senator Tester press release, “Updated Food Safety Amendment Protects Small Producers,” September 24, 2010, [http://tester.senate.gov/Newsroom/pr\\_092410\\_foodsafety.cfm](http://tester.senate.gov/Newsroom/pr_092410_foodsafety.cfm).

<sup>57</sup> 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](http://tester.senate.gov/Newsroom/pr_041410_foodsafety.cfm) (bill language is posted at website).

<sup>58</sup> Press release, Senator Tester, “Updated Food Safety Amendment Protects Small Producers,” September 24, 2010, [http://tester.senate.gov/Newsroom/pr\\_092410\\_foodsafety.cfm](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>.

<sup>59</sup> 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.”

<sup>60</sup> 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.

<sup>61</sup> United Fresh Produce Association, 2010 Issues Brief, <http://www.unitedfresh.org/assets/> (continued...)

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).<sup>62</sup> Some consumer groups, including the Consumers Union, have expressed concern that the proposed amendments would create “too great a loophole” in the food safety requirements, among other concerns.<sup>63</sup>

## 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. 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. The FFDCFA 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.<sup>64</sup> (See **Table 2**.)

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.

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(...continued)

Issue\_Brief\_United\_Fresh\_Produce\_Association\_2010.pdf.

<sup>62</sup> Comments by industry representatives at the UFPA’s 2010 Washington Public Policy Conference, September 15, 2010; Helena Bottemiller, “Group Breaks Ranks on Small Farm Exemptions,” *Food Safety News*, September 10, 2010.

<sup>63</sup> 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.

<sup>64</sup> 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 2. 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 FFCA § 415)

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

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

- a. 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." Numbers for FY2010 are appropriated; for FY2011 are requested; all others are actual.
- b. 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.
- c. Source, FDA Office of Legislation on September 22, 2010.
- d. Number of registrants as of September 22, 2010.

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 U.S. may present less of a health risk than those with less rigorous standards.

### *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 amendment. 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 amendment 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 amendment would require the HHS Secretary to increase the inspection rate for any food facility required to register under FFDCCA § 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 FFDCCA § 415, the Senate amendment 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 amendment 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.

Regarding seafood, the Senate amendment would permit the heads of various agencies to enter into specified types of agreements to improve seafood safety. In order to target food inspection resources, the Secretary would be required to coordinate and cooperate with the Secretaries of

Agriculture and Homeland Security, and would be permitted to consult with any relevant HHS advisory committee, as appropriate. For foreign seafood, the Senate amendment would permit the Secretary of Commerce to send inspector(s) to a country or facility of an exporter from which seafood imported into the United States originates. Such inspector(s) would conduct a specified assessment of practices and processes used in connection with the farming, cultivation, harvesting of such seafood. Based on each assessment, the Secretary of HHS, in coordination with the Secretary of Commerce, would be required to prepare and inspection report, provide it to the relevant country or exporter, and provide a 30-day period for rebuttal.

The Senate amendment 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.<sup>65</sup> FDA may conduct voluntary, on-site assessments of private accredited laboratories.<sup>66</sup> FDA's own laboratories are accredited and, according to FDA, "the laboratory industry favors accreditation."<sup>67</sup> 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."<sup>68</sup> 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."<sup>69</sup>

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."<sup>70</sup> In January 2009, FDA issued a 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.<sup>71</sup> The guidance document encouraged importers to notify the FDA in advance of their submission of a sample to an accredited laboratory, so as "to

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<sup>65</sup> FDA, Draft Guidance, Guidance for Industry: Submission of Laboratory Packages by Accredited Laboratories (Jan. 2009), hereinafter Draft Guidance.

<sup>66</sup> Ibid.

<sup>67</sup> Ibid.

<sup>68</sup> FDA, Guidance for Industry: Voluntary Third-Party Certification Programs for Foods and Feeds (Jan. 2009).

<sup>69</sup> Ibid.

<sup>70</sup> 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).

<sup>71</sup> Draft Guidance.

discourage importers from withholding bad test results, re-testing, or re-sampling.”<sup>72</sup> In January 2009, FDA also issued a final guidance document on voluntary third-party certification programs for foods 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.<sup>73</sup>

House and Senate legislative proposals 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.

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<sup>72</sup> Ibid.

<sup>73</sup> 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.

The Senate amendment (§ 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 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 amendment also contains language regarding revocation of accreditation and avoidance of conflicts of interest.

Section 202 of the Senate amendment 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 Senate amendment would require the development of model accreditation standards, re-evaluation of accreditation bodies at least every five years, and submission of laboratory test results to the FDA unless the Secretary exempts such submission 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. It can also order recalls of unsafe medical devices such as pacemakers.) GAO and others have contended that these gaps increase the possibility that unsafe food will not be recovered, and will be consumed.<sup>74</sup>

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.<sup>75</sup> FDA notes, however, that its authority to seize adulterated or misbranded food may not be practical or effective once a product is in wide distribution. Private companies rarely fail to order a voluntary recall when problems arise, and some contend that 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.

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<sup>74</sup> 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. See also CRS Report RL34167, *The FDA’s Authority to Recall Products*; and CRS Report RL34313, *The USDA’s Authority to Recall Meat and Poultry Products*.

<sup>75</sup> 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.”

The Bush Administration's November 2007 strategy for food safety called for mandatory recall authority (for FDA, not FSIS) in cases where firms (whether foreign or domestic) are unwilling to do so voluntarily or expeditiously. Similarly, President Obama's Food Safety Working Group recommends granting FDA the authority to mandate food recalls.<sup>76</sup> Significantly, reversing their earlier opposition, many major food industry groups now endorse legislative proposals to grant FDA mandatory recall authority.

### *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 amendment (§ 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 amendment 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.

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<sup>76</sup> President's Food Safety Working Group, "Key Findings," March 14, 2009, <http://www.foodsafetyworkinggroup.gov>.



## **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 (such as the melamine contamination of pet food), it appears that food company representatives were aware of a food safety problem for a prolonged period of time before notifying FDA.

The 110<sup>th</sup> 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.<sup>77</sup> Also, the enacted 2008 farm bill (P.L. 110-246) amends the meat and poultry laws to require that an establishment 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 about 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 the 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 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, 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,

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<sup>77</sup> 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>.

benefits, and feasibility of adopting such technologies; conduct at least two public meetings; and conduct one or more pilots.

The House-passed 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 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 amendment (§ 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 amendment 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 amendment (§ 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 amendment 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.<sup>78</sup> A foodborne disease outbreak is not defined in law or in regulations. In

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<sup>78</sup> 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.

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.”<sup>79</sup> 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.)

The nation’s public health capacity for foodborne illness surveillance and outbreak response is a mix of significant strengths and significant gaps.<sup>80</sup> 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 tools used to identify the food associated with an outbreak can be cumbersome. 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.<sup>81</sup>

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.”<sup>82</sup> 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.<sup>83</sup>

### *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 surveillance systems, including by 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.

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<sup>79</sup> 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.

<sup>80</sup> See CRS Report R40916, *Food Safety: Foodborne Illness and Selected Recalls of FDA-Regulated Foods*.

<sup>81</sup> 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.

<sup>82</sup> President’s Food Safety Working Group, “Key Findings,” March 2009, <http://www.foodsafetyworkinggroup.gov/Content/KeyFindings/HomeKeyFindings.htm>.

<sup>83</sup> FDA, “Measuring Progress on Food Safety: Current Status and Future Directions; Public Workshop,” *75 Federal Register* 9232, March 1, 2010.

The Senate amendment (§ 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.

## 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.<sup>84</sup> 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.

Presently, upon conviction for a misdemeanor violation of the prohibited acts section, a person<sup>85</sup> faces the penalties authorized in FFDCA § 303(a).<sup>86</sup> These are presented in **Table 3**. The maximum criminal penalty for individuals (as adjusted by 18 U.S.C. §§ 3559 and 3571) is \$100,000 if the misdemeanor does not result in death, \$250,000 if the misdemeanor results in death, and/or imprisonment of one year. 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.<sup>87</sup>

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<sup>84</sup> 21 U.S.C. § 331.

<sup>85</sup> 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.

<sup>86</sup> 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).

<sup>87</sup> 21 U.S.C. § 303(c)(1)-(3). FFDCA § 301(h) prohibits a person from giving a false guaranty to another person that a (continued...)

**Table 3. Criminal Penalties for Violations of FFDCA § 303(a)**

<b>Statute</b>	<b>Description of Statutory Provision</b>	<b>Maximum Criminal Penalty for Individuals (as adjusted by 18 U.S.C. §§ 3559 and 3571)</b>	<b>Maximum Criminal Penalty for Organizations (as adjusted by 18 U.S.C. §§ 3559 and 3571)</b>
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	\$100,000 if the misdemeanor does not result in death, \$250,000 if the misdemeanor results in death; and/or imprisonment of one year	\$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 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	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 violation of the FFDCA's prohibited acts section is a felony offense if it occurs after a prior conviction for violating 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.<sup>88</sup> The decision to seek criminal sanctions against individuals and corporations suspected of violating the FFDCA is within the FDA's discretion.<sup>89</sup>

(...continued)

food is not adulterated.

<sup>88</sup> 18 U.S.C. §§ 2, 371.

<sup>89</sup> *Heckler v. Chaney*, 470 U.S. 821 (1985) (holding that “[t]he FDA’s decision not to take the enforcement actions 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”).

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.”<sup>90</sup>

### *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 amendment would not alter the criminal penalties under FFDCa § 303(a). However, it has been reported that if the measure is considered by the Senate, another bill, S. 3767 (the Food Safety Accountability Act of 2010, introduced by Senator Patrick Leahy), could be offered as an amendment. 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.

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.”

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 FFDCa for knowingly violating these parts of the FFDCa’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

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<sup>90</sup> FDA, REGULATORY PROCEDURES MANUAL § 6-5-1 (March 2010), <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176738.htm>.

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 3**.

## **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. 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.<sup>91</sup>

The FFDCA (at 21 U.S.C. § 381(a)) empowers the FDA to refuse entry to any food import if it “appears,” based on a physical examination or otherwise, to be adulterated, misbranded, or 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), is to help 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.<sup>92</sup> In 2007 congressional hearings, witnesses testified that 450 inspectors must cover more than 300 ports of entry.<sup>93</sup>

Current law does not explicitly authorize, or require, import verification, and whether FDA has what is often called “equivalence authority”<sup>94</sup> has been a matter of debate. Regardless, FDA does not have a program like that of FSIS. 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

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<sup>91</sup> Additional information is available in CRS Report RL34198, *U.S. Food and Agricultural Imports: Safeguards and Selected Issues*.

<sup>92</sup> Source: FDA briefing for Senate staff, February 8, 2008. FDA FY2009 budget materials state that 94,743 import food field exams were conducted in FY2007.

<sup>93</sup> See for example hearings held before subcommittees of the House Committee on Energy and Commerce, July 17, September 26, and October 11, 2007.

<sup>94</sup> “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. 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>.

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 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.

### *Legislative Proposals*

The House-passed bill and Senate amendment 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, 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 amendment (§ 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 amendment (§ 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 FFDCA 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 FFDCFA. 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 bill and the Senate amendment 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 the House bill and the Senate amendment 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 amendment (§ 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.<sup>95</sup> FDA’s conclusion in 2008 that BPA use is safe conflicted with findings of advisory panels. This prompted some to question FDA’s risk assessment process, and its ability to conduct such assessments competently. 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.<sup>96</sup> 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.<sup>97</sup>

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<sup>95</sup> For additional background information, see CRS Report RS22869, *Bisphenol A (BPA) in Plastics and Possible Human Health Effects*.

<sup>96</sup> Lyndsey Layton, “No BPA for Baby Bottles in U.S.,” *The Washington Post*, March 6, 2009.

<sup>97</sup> Lyndsey Layton, “Replacing BPA in Cans Gives Foodmakers Fits; FDA Safety Concerns Prompt Scramble to (continued...)”

## 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 amendment does not contain a provision regarding BPA. It is reported that Senator Dianne Feinstein had sought to include in it a provision that would ban BPA in FDA-regulated food containers, and may instead offer a separate amendment restricting BPA if the manager’s amendment is considered by the Senate before the end of the 111<sup>th</sup> Congress.<sup>98</sup> A proposed BPA amendment has not been made public. It could require a ban on BPA in FDA-regulated food containers (as does S. 593, a bill sponsored by Senator Feinstein), or a phased elimination of the chemical, or elimination of the chemical from only some types of food containers, or some other approach.

## 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 the lack of sufficient funding and staff to carry out congressionally mandated (and existing) responsibilities to ensure a safe food supply.<sup>99</sup> Responding to a request from Democratic leaders of the House Energy and Commerce Committee, a Science Board subcommittee estimated that, in order to address these deficiencies, the food-related portion of FDA’s appropriation should be increased by \$128 million in FY2009, \$283 million in FY2010, \$441 million in 2011, \$598 million in FY2012, and \$755 million in 2013.<sup>100</sup> In fact, congressional appropriators have increased funding for FDA food activities in recent years.<sup>101</sup> (See **Table 4**.)

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(...continued)

Remove the Chemical,” *The Washington Post*, February 23, 2010.

<sup>98</sup> Denise Grady, “In Feast of Data on BPA Plastic, No Final Answer,” *The New York Times*, September 7, 2010; and Elynn Ferguson, “Egg Recall Helps Spur Efforts to Find Consensus on Food Safety Legislation,” *CQ Today Online News*, September 10, 2010.

<sup>99</sup> See, e.g., FDA Science Board, *FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology*, November 2007.

<sup>100</sup> *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.

<sup>101</sup> See CRS Report R40792, *Food and Drug Administration Appropriations for FY2010*.

**Table 4. FDA Direct Appropriations for Foods, FY2005-FY2011**

(dollars in millions)

	FY2005	FY2006	FY2007	FY2008	FY2009	FY2010	FY2011
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." Numbers for FY2010 are appropriated; for FY2011 are requested; all others are actual.

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), 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);<sup>102</sup> 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 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.

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 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 in 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

<sup>102</sup> 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*.

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.<sup>103</sup>

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. In FY2007, in order to make user fee funding more consistent and reliable, certain annual fees (such as annual registration fees) were enacted.<sup>104</sup>

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.

### *Legislative Proposals*

Each major proposal would fund some FDA food safety activities through the collection of user fees, though the types of fees and details differ. (See **Table 5**.) The House-passed bill would authorize higher fees, would carry a higher total price tag, and would mandate more frequent inspections than the Senate amendment (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 amendment would collect \$241 million.<sup>105</sup> 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 amendment.<sup>106</sup>

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 amendment 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

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<sup>103</sup> See CRS Report RL34334, *The Food and Drug Administration: Budget and Statutory History, FY1980-FY2007*.

<sup>104</sup> 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)*.

<sup>105</sup> 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>.

<sup>106</sup> Note that the CBO scores in this paragraph are specific to FDA costs. For that reason, they are somewhat lower than amounts discussed earlier in this report, which reflect estimated total federal costs.

two tables at the end of this report, 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 6**, below. For periodic fees, see **Table 7**, below.

**Table 5. Types of Fees in House-Passed H.R. 2749 and Senate Manager’s Amendment to S. 510**

	<b>H.R. 2749, House-passed</b>	<b>S. 510, Manager’s Amendment</b>
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 the CRS based on the text of the House-passed H.R. 2749 and Senate manager’s amendment to S. 510.

**Table 6. Comparison of Annual Fees in House-Passed H.R. 2749 and Senate Manager’s Amendment to S. 510**

Category	H.R. 2749, House-passed		S. 510, Manager’s Amendment
	Facility Registration Fee	Importer Registration Fee	VICP 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).  (Note: The Secretary must waive either the facility or importer fee for persons otherwise required to pay both.)	None.	None.
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 H.R. 2749 and Senate Manager’s Amendment to S. 510.

**Table 7. Comparison of Periodic Fees in House-Passed H.R. 2749 and Senate Manager’s Amendment to S. 510**

Category	H.R. 2749, House-passed		S. 510, Manager’s Amendment		
	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 of amendment.
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, Manager's Amendment		
	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 of amendment.
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 H.R. 2749 and Senate manager's amendment to S. 510.



# Appendix. Comparison of Provisions in H.R. 2749 (House-Passed) and S. 510 (Senate Manager’s Amendment) with Current Law

Background, Applicable Current Law, and Administration Statements	H.R. 2749 (House-passed)	S. 510 (Manager’s Amendment)
<p><b>Food Facility Registration Requirements</b></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 FFDC A § 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. FFDC A § 301(dd) designates failure to register as a prohibited act. FFDC A § 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><b>Obama Administration:</b> The Hamburg and Taylor testimonies express support for § 101 of the House bill.</p>	<p><b>Changes in Registration of Food Facilities (§ 101)</b></p> <p>Amends FFDC A § 415 both to require facilities to register annually, by each December 31, and to pay an annual registration fee of \$500. (This fee is described in more detail later in this memorandum.) The Secretary is authorized to suspend the registration of any facility for an FFDC A 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 FFDC A § 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. 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</p>	<p><b>Registration of Food Facilities (§ 102)</b></p> <p>Amends FFDC A § 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 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>

**Background, Applicable Current Law, and Administration Statements**

**H.R. 2749 (House-passed)**

**S. 510 (Manager’s Amendment)**

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.

**Records Access and Records Inspection**

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 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.

**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

**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 threat of serious adverse health consequences.”

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.”

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.

**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 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.

**Background, Applicable Current Law, and Administration Statements**

**H.R. 2749 (House-passed)**

**S. 510 (Manager’s Amendment)**

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.

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).

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. (See also the records provisions in Traceability of Food, § 107.)

**Registration for Customs Brokers (§ 205)**

A provision in this section requires every person importing or brokering for import 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.”

**Preventive Control Plans**

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 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

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

Also establishes a new FFDC § 418, with provisions broadly similar to those in S. 510, but differing somewhat in detail 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

**Hazard Analysis and Risk-Based Preventive Controls (§ 103)**

Establishes a new FFDC § 418, requiring the owner, operator, or agent in charge of a facility to develop a written plan and carry out certain preventive activities in the plan, including:

- 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

**Background, Applicable Current Law, and Administration Statements**

**H.R. 2749 (House-passed)**

**S. 510 (Manager’s Amendment)**

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.

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.

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).

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 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.

introduces or delivers for introduction into interstate commerce any shipment of food.

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:

- 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).

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 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.

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.

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 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.

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**H.R. 2749 (House-passed)**

**S. 510 (Manager’s Amendment)**

**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 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.

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.

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.

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.

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 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.

This requirement is to take effect on the sooner of either 2 years from date of enactment or the completion of a feasibility

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.

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.

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 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

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<p><b>Seafood</b></p> <p>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.</p> <p>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.</p> <p>FDA's Seafood HACCP Program regulations are articulated in 21 CFR parts 123 (fish and fishery products) and 1240 (control of communicable diseases).</p> <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>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>No comparable provisions.</p>	<p>enactment, and very small businesses (as defined by the Secretary) 3 years after enactment.</p> <p><b>Requirements for Guidance Relating to Post Harvest Processing of Raw Oysters (§ 114)</b></p> <p>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).</p> <p>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.</p> <p>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 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 (part of §103) 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>

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**Performance Standards**

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 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 FFDCFA (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 FFDCFA 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.

**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.

**Performance Standards (§ 103)**

Similar in intent but not identical to S. 510. Under a new FFDCFA § 419, the Secretary must at least every two years review and evaluate epidemiological data and other appropriate information, including research under § 123 (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).

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.

**Performance Standards (§ 104)**

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 determine the most significant foodborne contaminants.

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 FFDCFA § 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.

**Produce and On-Farm Food Safety**

As noted earlier, the FFDCFA 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 FFDCFA 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

**Safety Standards for Produce and Certain Other Raw Agricultural Commodities (§ 104)**

Under a new FFDCFA § 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

These regulations may set forth procedures and practices that

**Standards for Produce Safety (§ 105)**

Subsection (a) of this section establishes a new FFDCFA § 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

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and records; traceback; and recall. On September 2, 2008, FDA published a notice in the Federal 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.

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. Further action on a federal order had not occurred as of early August 2009.

**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. Comments on the documents are to be accepted until October 2, 2009 (see 74 FR 38437-40).

Also, the Hamburg and Taylor testimonies express support for § 104 of the House bill.

the Secretary determines reasonable to prevent 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).

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.

Requires the Secretary to update the 1998 guidance for minimizing hazards in fresh fruits and vegetables.

Secretary shall hold at least 3 public meetings on such rulemaking in diverse geographic areas.

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.

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, after consultation with stakeholders (as specified). This section shall not apply to



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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 HACCP programs already in place.

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.

**Targeting of Inspection Resources**

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.

**Risk-Based Inspection Schedule (§ 105)**

Amends § 704 (Inspection, in the General Authority chapter of the FFDCa) 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:

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

Subsection (a) of this section establishes a new FFDCa § 421 (in the food chapter of the FFDCa), requiring the Secretary, with respect to facilities that must register under FFDCa § 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

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Current law, which derives from FFDCa § 704 (in the General Authority chapter of the FFDCa), 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 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.

- 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 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.

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 others. Provides for advisory committee consultation within HHS with respect to allocating inspection resources.

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.

**Laboratory Accreditation**

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

**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

**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

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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 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.

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 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.

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 exempted.

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.

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.

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.

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

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**Other Laboratory Provisions**

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.

**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.

**Third-Party Accreditation**

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

**Plan and Review of Continued Operation of Field Laboratories (§ 209)**

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.

**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

tribal food laboratories, including data sharing to develop national situational awareness; (3) provides accessible, timely, accurate, and consistent food laboratory services 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.

**Integrated Consortium of Laboratory Networks (§ 203)**

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.

**Accreditation of Third-Party Auditors (§ 307)**

Amends FFDCA 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

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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 to certify food quality and marketing attributes, as opposed to safety requirements per se.

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.)

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.

**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

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 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.

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.

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 FFDCa. 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 FFDCa.

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.

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-

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use of an accreditation system and audit the performance of accredited third parties.

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.

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 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.

**Food Traceability**

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

**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,

**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

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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:** The FSWG announced in July 2009 the following actions intended to improve traceability:

- within 3 months, FDA is to issue draft guidance on what industry could do to establish product tracing systems;
- within 3 months, federal agencies are to implement a new “incident command system to address outbreaks of foodborne illness;
- within 6-12 months, FSIS is to increase the capacity of its public health epidemiology liaison program to State public health departments through new hires and expanded outreach;
- By July 2009, federal agencies were to 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 Improve Foodborne Outbreak Response;
- A promise that CDC is to work with collaborating States to evaluate and optimize best practices for more effective outbreak investigations, and within 12 months launch a new system to facilitate information-sharing and adoption of best practices.

Also, the Hamburg and Taylor testimonies express support for § 107 of the House bill.

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 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.

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

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 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

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	<p>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>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>
<p><b>Foodborne Illness Surveillance and Education</b></p> <p>Surveillance for foodborne illness is carried out by the states, with assistance from the CDC. States also conduct investigations of foodborne illness 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</p>	<p><b>Surveillance (§ 121)</b></p> <p>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 (see column at left).</p> <p><b>Public Education and Advisory System (§ 122)</b></p> <p>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</p>	<p><b>Surveillance (§ 205)</b></p> <p>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 establish a</p>



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PHS Act § 301 regarding research and investigations, §§ 311 and 317 regarding federal-state cooperation, and § 361 regarding control of communicable diseases. PHS Act § 317R provides an explicit but expired authority of the Secretary of HHS to award grants to state and tribal governments to enhance food safety surveillance and laboratory capacities. Although this authority has expired, the Secretary of HHS may carry out this activity under the broad, permanent authorities mentioned earlier.

A foodborne illness “outbreak” is not defined in law or regulations that apply to either CDC or FDA. In common 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. Botulism is an exception. Because the disease is so often deadly, and usually results from improperly canned products that consumers could keep for years before eating, authorities typically launch an investigation to identify and remove all potentially hazardous products that may be linked to a single case of botulism.

program, and further requires the Secretary to work with states and others to develop and incorporate into the public education program regional and national advisories concerning food safety.

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.

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.

**Mandatory Recall Authority; Reportable Food Registry**

The Secretary does not have mandatory recall authority for foods, except for infant formula under FFDCA § 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 FFDCA § 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.

Also, the FDA Amendments Act of 2007 (FDAAA, P.L. 110-85) created FFDCA § 417, which required FDA to establish a reportable food registry to facilitate product identification and tracing. Under FFDCA § 417, a “reportable food” is “an article of food (other than infant formula) for which there is a

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

This section establishes a new FFDCA § 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.

FFDCA § 420, subsection (a), requires a responsible party [as defined in FFDCA § 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

**Mandatory Recall Authority (§ 206)**

Subsection (a) of this section establishes a new FFDCA § 423 regarding recall of food. If the Secretary determines, based on information gathered through the reportable food registry under FFDCA § 417 or through any other means, that there is a reasonable probability that an article of food (other than infant formula) is adulterated under FFDCA § 402, or misbranded under FFDCA § 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 FFDCA § 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

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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.

**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 § 112 of the House bill.

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 § 417.) Failure to notify the Secretary when required is prohibited under FFDC § 301.

FFDC § 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.

FFDC § 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.

FFDC § 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

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 the order.

Alcohol beverage 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.

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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.

**Reportable Food Registry: Exchange of Information (§ 112)**

The food registry reporting requirements under apply to facilities that are required to register under FFDCa § 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 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

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 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.

**Improving the Reportable Food Registry (§ 211)**

Amends FFDCa § 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

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farm or another farm under the same ownership.” The bill here also makes the same reference to define a retail food establishment.)

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.

**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)**

Like the S. 510 manager’s amendment, this section amends FFDCA § 304(h) to requirement for “credible evidence or information” to “reason to believe” and amends the standard of “a threat of serious adverse health consequences or death to humans or animals” to “adulterated or misbranded,” but the House-passed version of H.R. 2749 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.

**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

**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

**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

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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 conducted, on May 1, 2008, a public meeting on the issue.

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.

“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.” (Source: 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

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 contamination.

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 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.

**National Agriculture and Food Defense Strategy (§ 108)**

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.

**Food and Agriculture Coordinating Councils (§ 109)**

Requires the Secretary of Homeland Security, in coordination with the Secretaries of HHS and Agriculture, within 180 days of

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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.

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.

FDA has initiated a number of activities focusing on economic adulteration of foods and other products it regulates, including the establishment of an internal working group.

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.

**Building Domestic Capacity (§ 110)**

Establishes a number of assessment and reporting requirements regarding domestic capacity to prevent or address food safety threats, as follows:

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 FFDCIA § 201(r).

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.

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.)

Not later than one year after enactment, the Secretary shall

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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.

**State and Local Food Safety Roles and Training**

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 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).

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

Source: Stronger Partnerships for Safer Food: An Agenda for Strengthening State and Local Roles in the Nation’s Food Safety System, accessed February 3, 2010 at <http://www.rwjf.org/files/research/20090417foodsafetyfinalreport.pdf>.

**Support for Training Institutes (§ 214)**

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.

**Improving the Training of State, Local, Territorial, and Tribal Food Safety Officials (§ 209)**

Creates a new FFDC § 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 FFDC, and authorizes the Secretary to enter into examination, testing, and investigations partnerships with such officials and their employees.

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 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 FFDC §1011 such sums as necessary for FY2011-FY2015.

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

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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.

**Enhancing Food Safety (§ 210)**

Subsection (a) of this section replaces FFDC § 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 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.

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.

**Whistleblower Protection**

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

**Whistleblower Protections (§ 212)**

Creates a new FFDC § 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

**Employee Protections (§ 402)**

Creates a new FFDC § 1012 prohibiting food businesses from discharging or otherwise discriminating against an employee who provides or causes to be provided information relating to



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<p>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>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>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><b>Seizure of FDA-Regulated Products</b></p> <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 Regulatory Procedures Manual at <a href="http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm">http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm</a>.)</p>	<p><b>Procedures for Seizure (§ 131)</b></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>
<p><b>Quarantine Authority</b></p> <p>The seizure provisions of FFDCA § 304 do not appear to specifically authorize geographical quarantines of an article of food in the United States.</p> <p>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) 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><b>Authority to Prohibit or Restrict the Movement of Food (§ 133)</b></p> <p>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 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>	<p>No comparable provision.</p>
<p><b>Criminal Penalties</b></p> <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</p>	<p><b>Criminal Penalties (§ 134)</b></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</p>	<p>No comparable provision.</p>

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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.

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.

**Obama Administration:** The Hamburg and Taylor testimonies express support for § 134 of the House bill.

requires the revision of penalties for violations of the FFDCA.

**Civil Penalties**

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 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.

Currently, there are no maximum civil penalties tied to FFDCA § 303(a), which addresses criminal penalties for prohibited acts under the FFDCA.

**Obama Administration:** The Hamburg and Taylor testimonies express support for § 135 of the House bill.

**Civil Penalties for Violations Relating to Foods (§ 135)**

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 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.

No comparable provision.

**False or Misleading Reporting**

FFDCA § 301 delineates prohibited acts under the law, one of which is “With respect to any device, the submission of any

**False or Misleading Reporting to FDA (§ 210)**

Expands the FDA-regulated products covered by this prohibited act to include a “food, drug, or biological product.”

No comparable provision.

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<p>report that is required by or under this Act that is false or misleading in any material respect.” [§ 301(q)(2)].</p>		
<p><b>FDA Subpoena Authority</b></p> <p>The FFDCA provides authority for issuing subpoenas under certain specified conditions. For example, in the course of 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><b>Subpoena Authority (§ 211)</b></p> <p>Expands subpoena authority by permitting the FDA 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>	<p>No comparable provision.</p>
<p><b>Food Decontamination and Disposal</b></p> <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 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>No comparable provision.</p>	<p><b>Decontamination and Disposal Standards and Plans (§ 208)</b></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 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><b>Import Certification</b></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</p>	<p><b>Certification and Accreditation (§ 109, part)</b></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</p>	<p><b>Authority to Require Import Certifications for Food (§ 303)</b></p> <p>Amends FFDCA § 801 by authorizing the Secretary to require certification or other assurance of the safety of an article of food</p>

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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.

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 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.

**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.

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:

- 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.

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 FFDCA requirements as specified by the Secretary, or take any other form specified by the Secretary including a listing of certified facilities or other entities.

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.

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

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 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.

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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.”

**Inspection of Foreign Facilities**

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.

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.” However, FDA has visited certain importing countries at their invitation to conduct such reviews, suggesting that current authority does not bar the Secretary from

**Prohibition Against Delaying, Limiting, or Refusing Inspection (§ 207); Risk-Based Inspection Schedule (§ 105)**

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.)

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.)

**Risk-Based Inspection Schedule (§ 105, part); Certification and Accreditation (§ 109, part)**

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.

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

**Inspection of Foreign Food Facilities (§ 306)**

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.

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.”

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 exporter who will be given 30 days to provide a rebuttal or comments to HHS.

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conducting such assessments.

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.

**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.”

that has made such a demonstration. The application of these certification requirements must be consistent with U.S. international obligations.

**Foreign Supplier Verification**

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 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.

**Obama Administration:** The Hamburg and Taylor testimonies express support for § 204 of the House bill.

**Registration for Commercial Importers of Food; Fee (§ 204); Registration for Customs Brokers (§ 205); Unique Identification Number for Food Facilities, Importers and Customs Brokers (§ 206)**

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.”

The Secretary (in consultation with Customs and Border Protection) must promulgate regulations on the measures an

**Foreign Supplier Verification Program (§ 301)**

Amends FFDCA Chapter VIII (regarding imports and exports) by adding a new § 805, effective two years after 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.

The importer is required to develop a program that: (1) assures

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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.

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). Fees are discussed later in this comparison.

**Improper Import Entry Filings (§ 136)**

This different but somewhat related 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.

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.

**Expediting Imports**

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

**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

**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

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additional standards should they have to meet?	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.	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, 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.
<b>FDA Foreign Offices</b>	<b>Dedicated Foreign Inspectorate (§ 208)</b>	<b>Foreign Offices of the Food and Drug Administration (§ 308)</b>
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.	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.	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 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



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<p><b>Country of Origin Labeling</b></p> <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><b>Country of Origin Labeling (§ 202)</b></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>foreign offices. Clarifies that nothing in this provision shall affect the Secretary’s authority to issue public notifications under other circumstances.</p> <p>No comparable provision.</p>
<p><b>Prior Notice of Imports</b></p> <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 regarding refusal of an article of food by another country.</p>	<p>No comparable provision.</p>	<p><b>Prior Notice of Imported Food Shipments (§ 304)</b></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>
<p><b>Foreign Capacity Building</b></p> <p>Current law would not prohibit the development of the plan</p>	<p>No comparable provision.</p>	<p><b>Building Capacity of Foreign Governments with Respect to Food (§ 305)</b></p>

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<p>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>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>
<p><b>Smuggled Food</b></p> <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><b>Smuggled Food (§ 309)</b></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>
<p><b>Port Shopping</b></p> <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><b>Port Shopping (§ 115)</b></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</p>

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admitted by another port.

**Jurisdiction**

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, *Riegel v. Medtronic, Inc.: Federal Preemption of State Tort Law Regarding Medical Devices with FDA Premarket Approval*.

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.

**Alcohol**

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.

**Rules of Construction (§ 4)**

This so-called 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.

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 FMIA, PPIA, or EPIA.

**USDA Exemptions (§ 5)**

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.

**Alcohol-Related Facilities (§ 6)**

Similar 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.

**Extraterritorial Jurisdiction (§ 213)**

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.”

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.”

**Jurisdiction; Authorities (§ 403)**

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.).

**Alcohol-Related Facilities (§ 116)**

Generally exempts from this ct (the manager’s amendment) 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.

**Compliance With International Agreements (§ 404)**

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.

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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 increased funding for FDA food safety activities for FY2008 and FY2009. The Obama Administration request for FY2010 calls for a more than \$1 billion FDA food safety budget, which would be a \$259 million increase over the FY2009 level of \$785 million. Of this increase, \$165 million is proposed to come from new budget authority (appropriations) and \$94 million through new fees on industry. These fees would include \$75 million raised through an apparently annual food inspection and facility registration fee, \$15 million raised through a re-inspection fee, and \$4 million raised through export certification fees (see below for more on the latter two fees). The FY2010 appropriations bills for USDA (H.R. 2997/S. 1406) that have passed both chambers but not yet been enacted both fully fund the President's request, although both appear to provide the money through new budget authority rather than new user fees.

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

**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 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

**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 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,

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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.

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.

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.

**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.

issuing such certificates; this fee authority is permanent. 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.

and adjust fee amounts for that following year to account for the excess fees and other factors the Secretary determines are appropriate.

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.

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.

**Funding for Food Safety (§ 401)**

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) 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.

**Food Safety Research**

**Research (§ 123)**

**Food Safety Integrated Centers of Excellence (§ 210)**

FDA, along with other federal agencies, is already involved in a

Requires the Secretary to conduct research to assist in

Section 210(b) of this section, regarding Food Safety Integrated

<b>Background, Applicable Current Law, and Administration Statements</b>	<b>H.R. 2749 (House-passed)</b>	<b>S. 510 (Manager's Amendment)</b>
<p>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 Cooperative State Research, Education, and Extension Service, and with academia, state health and agricultural officials, industry and others. The Administration's FY2010 budget proposal anticipates research in high priority areas such as reducing risk of E. coli in produce, speeding response to outbreaks through improved testing and other new technologies, limiting the adverse health effects of both intentional and unintentional food contamination, and upgraded information technology systems.</p>	<p>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>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>
<p><b>Bisphenol A (BPA)</b></p> <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><b>Bisphenol A in Food and Beverage Containers (§ 215)</b></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>

<b>Background, Applicable Current Law, and Administration Statements</b>	<b>H.R. 2749 (House-passed)</b>	<b>S. 510 (Manager's Amendment)</b>
<p><b>Requirements for Infant Formula</b></p> <p>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.</p>	<p><b>Infant Formula (§ 114)</b></p> <p>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.</p>	<p>No comparable provision.</p>
<p><b>Additive and Labeling Requirements</b></p> <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 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><b>Food Substances Generally Recognized As Safe (§ 201)</b></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 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>	<p>No comparable provision.</p>
<p><b>Lead in Ceramics</b></p> <p>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).</p>	<p><b>Lead Content Labeling Requirement for Ceramic Tableware and Cookware (§ 216)</b></p> <p>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.</p>	<p>No comparable provision.</p>

Background, Applicable Current Law, and Administration Statements	H.R. 2749 (House-passed)	S. 510 (Manager's Amendment)
<p><b>Sanitary Transportation of Food</b></p> <p>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.</p>	<p>No comparable provision.</p>	<p><b>Sanitary Transportation of Food (§ 111)</b></p> <p>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.”</p>
<p><b>Food Allergies</b></p> <p>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.</p>	<p>No comparable provision.</p>	<p><b>Food Allergy and Anaphylaxis Management (§ 112)</b></p> <p>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 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</p>



Background, Applicable Current Law, and Administration Statements	H.R. 2749 (House-passed)	S. 510 (Manager's Amendment)
<p><b>Vitamins and Minerals, Anabolic Steroids</b></p> <p>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.</p>	<p>No comparable provision.</p>	<p>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.</p> <p>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.</p> <p>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.</p> <p><b>New Dietary Ingredients (§ 113)</b></p> <p>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.</p>

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## **Acknowledgments**

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