



# The FDA Food Safety Modernization Act (P.L. 111-353)

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## Summary

The 111<sup>th</sup> Congress passed comprehensive food safety legislation in December 2010 (the FDA Food Safety Modernization Act, or FSMA, P.L. 111-353). Although numerous agencies share responsibility for regulating food safety, this newly enacted legislation focused on foods regulated by the Food and Drug Administration (FDA) and amended FDA's existing structure and authorities, in particular via the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. §§ 301 et seq.). The new law does not directly affect activities at the U.S. Department of Agriculture (USDA), which oversees the safety of most meat and poultry.

FSMA generally expands or modifies existing FDA authorities rather than creating a new food safety structure or authorities. Among its many provisions, the new law will increase frequency of inspections at food facilities, tighten record-keeping requirements, extend more oversight to certain farms, and mandate product recalls if a firm fails to institute them voluntarily. The new law will require food processing, manufacturing, shipping, and other regulated facilities to conduct an analysis of the most likely safety hazards and to design and implement risk-based controls to prevent them. FSMA also will facilitate the establishment of science-based "performance standards" for the most significant food contaminants. Other provisions in the new law are also intended to improve the nation's foodborne illness surveillance systems. FSMA also mandates increased scrutiny of food imports, which account for a growing share of U.S. consumption; food import shipments will 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. FSMA also contains provisions for certifying or accrediting laboratories, including private laboratories, to conduct sampling and testing of food, among other provisions. This report provides a detailed overview of these and other major provisions in the newly enacted law.

The 112<sup>th</sup> Congress will likely provide oversight and scrutiny of how the law is implemented, including FDA's coordination with other federal agencies. Implementation of the law will depend largely on the availability of discretionary appropriations, and some have questioned whether funding should be provided in the current budgetary climate. In addition, the 112<sup>th</sup> Congress may consider changes to other food safety laws and policies that continue to be actively debated in Congress. Continued congressional interest in reforming the nation's food safety laws and in monitoring food safety issues is expected, given other perceived problems with the current food safety system.

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## Introduction

The combined efforts of the food industry and government regulatory agencies often are credited with making the U.S. food supply among the safest in the world. Nonetheless, public health officials have estimated that each year in the United States, many millions of people become sick and thousands die from foodborne illnesses caused by any of a number of microbial pathogens and other contaminants.<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 in FY2010 for its human foods program was \$784 million, all of it appropriated.<sup>4</sup>

After discussing several recent food safety incidents and the systemic food safety problems that they illustrate, this report describes the existing food safety legal and regulatory landscape and presents an overview of efforts by the 111<sup>th</sup> Congress to revise federal food safety authorities and activities, principally at FDA. It then provides a detailed overview of the major provisions in the newly enacted law—the FDA Food Safety Modernization Act (FSMA, P.L. 111-353). The report is organized around a number of selected food safety issues, describing how they are addressed in previously existing law and regulations, and describing their treatment in the newly enacted law. Finally, appendixes provide a crosswalk of all provisions in FSMA, followed by a side-by-side comparison of each of these provisions with previously existing law.

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<sup>1</sup> The Centers for Disease Control and Prevention (CDC) estimates that each year roughly 1 out of 6 Americans (or 48 million people) get sick, 128,000 are hospitalized, and 3,000 die from foodborne diseases. CDC, “Estimates of Foodborne Illness in the United States,” <http://www.cdc.gov/foodborneburden/index.html>.

<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*.



## 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 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 outbreaks have been linked to FDA-regulated foods. For example, in 2006 more than 200 confirmed illnesses and three deaths were linked to bagged fresh spinach grown in California and contaminated with *E. coli* O157:H7. In 2008, more than 1,400 persons were infected with an unusual strain of bacteria, *Salmonella* Saintpaul. Officials first suspected fresh tomatoes, but later tests found the pathogen in serrano peppers and irrigation water from a farm in Mexico. These incidents raised public concerns about the safety of all fresh produce and stimulated a number of industry and government initiatives to limit future incidents.

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

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

In July 2010, health officials noticed a spike in cases of infection with *Salmonella* Enteritidis, a strain commonly associated with shell eggs, which are regulated by FDA.<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 about the apparent lack of coordination between USDA's egg quality inspection activities and FDA's food safety activities, because both agencies have regulatory responsibility for egg products.<sup>10</sup>

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<sup>5</sup> See CRS Report R40916, *Food Safety: Foodborne Illness and Selected Recalls of FDA-Regulated Foods*. For other information on "Recalls, Market Withdrawals, & Safety Alerts," see FDA's website: <http://www.fda.gov/Safety/Recalls/default.htm>.

<sup>6</sup> See CRS Report RL34313, *The USDA's Authority to Recall Meat and Poultry Products*. For other information on meat and poultry recalls, see FSIS's website: [http://www.fsis.usda.gov/fsis\\_recalls/index.asp](http://www.fsis.usda.gov/fsis_recalls/index.asp).

<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/>.

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

## Food Safety Legal and Regulatory Landscape

Federal responsibility for food safety rests primarily with FDA and USDA.<sup>11</sup> FDA is responsible for ensuring that most domestic and imported food products—except for most meats and poultry—are safe, nutritious, wholesome, and accurately labeled. FDA also has oversight of all seafood, fish, and shellfish products. USDA’s FSIS regulates most meat and poultry and some egg products. State and local food safety authorities collaborate with federal agencies for inspection and other food safety functions, and they regulate retail food establishments.

The division of food safety responsibility between FDA and USDA is rooted in the early history of U.S. food regulation. Congress created separate statutory frameworks when it enacted, in 1906, both the Pure Food and Drugs Act and the Meat Inspection Act. The former addressed the widespread marketing of intentionally adulterated foods, and its implementation was assigned to USDA’s Bureau of Chemistry. The latter law addressed unsafe and unsanitary conditions in meatpacking plants, and implementation was assigned to the USDA’s Bureau of Animal Industry. This bifurcated system has been perpetuated and split further into additional food safety activities under additional agencies (for example, the Environmental Protection Agency, the National Marine Fisheries Service, and others) by a succession of statutes and executive directives. The separation of the two major food safety agencies was further reinforced when, in 1940, the President moved responsibilities for safe foods and drugs, other than meat and poultry, from USDA to the progenitor of HHS, the Federal Security Agency. Meat inspection remained in USDA. There has been discussion over time regarding whether this dispersal of food safety responsibilities has been problematic, or whether a reorganization would divert time and attention from other fundamental problems in the system.<sup>12</sup>

In the 111<sup>th</sup> Congress, major food safety legislation—the subject of this report—was passed, focusing 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 of 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 FFDCA by, for example, introducing an adulterated or misbranded product into interstate commerce, commit what is referred to as a prohibited act under FFDCA § 301 (21 U.S.C. § 331). Persons who commit prohibited acts are subject to criminal and civil penalties.

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<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*.

<sup>12</sup> For a discussion of the history of federal food safety organization and of efforts to change it, see Richard A. Merrill and Jeffrey K. Francer, “Organizing Federal Food Safety Regulation,” *Seton Hall Law Review*, vol. 31:61, 2000. See also GAO, *High Risk Series: An Update* (GAO-07-310), January 31, 2007; and *Ensuring Safe Food From Production to Consumption*, Committee to Ensure Safe Food from Production to Consumption, Institute of Medicine, National Research Council, National Academy Press, 1998.

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

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

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

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

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

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

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

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

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

**Prohibited Acts:** Prohibited acts are listed in FFDCA § 301 [21 U.S.C. § 331]. Along with other specified prohibited acts in FFDCA § 301, paragraphs (a) through (c) provide that introducing adulterated or misbranded food into commerce; adulterating or misbranding food that is in commerce; or the receipt and delivery of adulterated or misbranded food in commerce is prohibited. Pursuant to FFDCA § 303 [21 U.S.C. § 333], in general, any person who violates a provision of FFDCA § 301 may be subject to civil or criminal penalties, including imprisonment, fines, or both. Criminal penalties provided for in 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 FFDCA. A version of 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>13</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 Barack Obama, in a March 14, 2009, weekly radio address, called the food safety system a “hazard to public health.”<sup>14</sup> 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>15</sup> In July 2009, the FSWG announced a number of steps the Obama Administration was taking, under existing authorities, to improve government safeguards.<sup>16</sup> The group released a one-year progress report in July 2010.<sup>17</sup> 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>

The Obama Administration weighed in on the principal bills that were considered by the House and Senate during the 111<sup>th</sup> Congress (and that are the subject of this report). The Administration declared its support for the primary food safety bill in the House of Representatives, H.R. 2749, which had been passed in June 2009.<sup>19</sup> Also, in a July 2010 statement, the Administration urged the Senate to complete its work on its principal food safety bill, S. 510.<sup>20</sup> In November 2010, the Administration expressed its continued support of the Senate's efforts on its bill.<sup>21</sup> In addition,

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<sup>13</sup> FDA, *Food Protection Plan: 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>14</sup> The White House, Remarks of President Barack Obama, “Reversing a Troubling Trend in Food Safety,” weekly address, Washington, DC, March 14, 2009, <http://www.whitehouse.gov/briefing-room/weekly-address>.

<sup>15</sup> The working group established a public website at <http://foodsafetyworkinggroup.gov/>, where the full text of these remarks may be viewed.

<sup>16</sup> FSWG, “Food Safety Working Group: Key Findings,” July 7, 2009, <http://www.foodsafetyworkinggroup.gov/>.

<sup>17</sup> FSWG, “Food Safety Working Group: Progress at 1 Year,” July 9, 2010, <http://www.foodsafetyworkinggroup.gov/>.

<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> The White House, Statement of Administration Policy, “S. 510—The FDA Food Safety Modernization Act,” November 16, 2010, [http://www.whitehouse.gov/sites/default/files/omb/legislative/sap/111/saps510s\\_20101116.pdf](http://www.whitehouse.gov/sites/default/files/omb/legislative/sap/111/saps510s_20101116.pdf).

Administration officials 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>22</sup>

In October 2009 testimony on the Senate bill, FDA Commissioner Hamburg called S. 510 a “major step in the right direction.” Provisions in the bill addressed a key policy concern by refocusing FDA’s food safety system on prevention, the Commissioner stated. She added that the bill also generally met 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 the use of accredited third parties to ensure adequate resources.<sup>23</sup> These issues are among those discussed later in this report.

## Congressional Action

Perceived gaps in federal safeguards have been explored at more than two dozen congressional hearings since 2007.<sup>24</sup> The 110<sup>th</sup> Congress made several amendments to FDA’s food safety authorities,<sup>25</sup> and increased funding for the primary food safety agencies, but more comprehensive food safety legislation was not enacted.

### Committee Jurisdiction for Key Food Safety Issues

#### House Authorizing Committees

The House Committee on Energy and Commerce has jurisdiction over all FDA-regulated products, including foods. The House Committee on Agriculture claims the lead on USDA’s meat and poultry inspection programs.

#### Senate Authorizing Committees

The Senate Committee on Health, Education, Labor, and Pensions (HELP) has jurisdiction over FDA-regulated foods and other products. The Senate Committee on Agriculture, Nutrition and Forestry has jurisdiction over USDA inspection programs.

#### Congressional Appropriations Committees

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.

<sup>22</sup> Dr. Hamburg’s comments were based on the introduced version of H.R. 2749; Mr. Taylor’s were based on the version reported by the full Energy and Commerce Committee (H.Rept. 111-234) in June 2009.

<sup>23</sup> Statement of FDA Commissioner Margaret Hamburg, U.S. Congress, Senate Committee on Health, Education, Labor, and Pensions, *Keeping America’s Families Safe: Reforming the Food Safety System*, 111<sup>th</sup> Cong., 1<sup>st</sup> sess., October 22, 2009, <http://help.senate.gov/hearings/index.cfm>.

<sup>24</sup> This includes hearings conducted by the House and Senate Agriculture Committees; the House Committee on Energy and Commerce; the Senate Committee on Health, Education, Labor, and Pensions (HELP); the House Committee on Small Business; the House Committee on Oversight and Government Reform; the House Committee on Homeland Security; the House Committee on Ways and Means; the Senate Appropriations Committee; and the Senate Committee on Commerce, Science, and Transportation.

<sup>25</sup> CRS Report RS22779, *Food Safety: Provisions in the Food and Drug Administration Amendments Act of 2007*.

In the 111<sup>th</sup> Congress, nearly a dozen food safety bills, several of them comprehensive, were introduced. The major vehicle in the House was H.R. 2749, introduced by Representative John Dingell. This bill was amended and approved by the Subcommittee on Health of the House Energy and Commerce Committee on June 10, 2009; and by the full committee on June 17, 2009 (H.Rept. 111-234, July 29, 2009). After failing to reach the needed two-thirds majority under suspension of the rules on July 29, 2009, the bill passed the House under regular order, with a recorded vote of 283 to 142, on July 30, 2009.<sup>26</sup>

In the Senate, S. 510 was introduced by Senator Richard Durbin. The Senate Committee on Health, Education, Labor, and Pensions (HELP) amended and reported the bill (without a written report) on December 18, 2009. During 2010, a series of substitute amendments to the bill were offered and debated. On November 30, 2010, a substitute version of the bill (S.Amdt. 4715) passed the Senate with a recorded vote of 73-25.<sup>27</sup> However, a procedural issue held up final action on the legislation; it was resolved when the Senate inserted its version of the bill into an earlier House bill (H.R. 2751) that was cleared by the House. This bill was signed by the President in January 2011 as the FDA Food Safety Modernization Act (FSMA, P.L. 111-353).

FSMA generally expands or modifies existing FDA authorities under the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. §§ 301 et seq.). Among its many provisions, the new law increases frequency of inspections at food facilities, tightens record-keeping requirements, extends more oversight to certain farms, and mandates product recalls if a firm fails to institute them voluntarily.

FDA has identified five key elements to the new law.<sup>28</sup>

- **Preventive Controls.** For the first time, FDA has a legislative mandate to require comprehensive, prevention-based controls across the food supply. FSMA requires 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. This provision is similar conceptually to the so-called hazard analysis and critical control point, or HACCP, plans required of meat and poultry establishments. The new law requires the establishment of science-based “performance standards” for the most significant food contaminants. To aid in determining such risks and hazards, the new law seeks to improve foodborne illness surveillance systems, aiming for better data reporting, analysis, and usefulness, with the CDC playing a lead role.

Provisions in FSMA extend safeguards to the farm level, generally calling for new, science-based “performance standards” for safe production mainly of fruits, vegetables, and related products, and expanding enforcement and record-keeping authorities. The new law facilitates the establishment of science-based regulations for the most significant food contaminants.

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<sup>26</sup> Two other comprehensive House bills were introduced by Representative Rosa DeLauro (H.R. 875) and by Representative Jim Costa (H.R. 1332).

<sup>27</sup> Senator Tom Harkin, “Proposed Amendment, S. 510,” *Congressional Record*, November 18, 2010, pp. S8069-S8093.

<sup>28</sup> FDA, “Questions and Answers on the Food Safety Modernization Act,” <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm238506.htm>. Other supplemental information is from CRS.

- **Inspection and Compliance.** FSMA reflects the fact that inspection is an important means of holding industry accountable for its responsibility to produce safe food. FSMA seeks to increase the frequency of plant inspections, specifying how often FDA should inspect food producers, while taking into account the risks posed by specific foods or processes. To aid in such inspections, and to improve the ability to rapidly trace food products through the production and marketing chain in the event of a foodborne illness outbreak, suspected contamination, or other problems, the new law generally seeks to strengthen record-keeping requirements and food traceability systems. Food processing, manufacturing, shipping, and other regulated facilities are required to conduct an analysis of the most likely safety hazards and to design and implement risk-based controls to prevent them. FDA has said that it is “committed to applying its inspection resources in a risk-based manner and adopting innovative inspection approaches.”<sup>29</sup>

Industry participants will 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 (Bioterrorism Act, P.L. 107-188; 21 U.S.C. § 350d), will need to re-register more frequently than they have previously. The new law also requires that additional registration information be submitted.

- **Imported Food Safety.** FSMA increases scrutiny of food imports, which account for a growing share of U.S. consumption; food import shipments must be accompanied by documentation that they can meet safety standards that are at least equivalent to U.S. standards. Such certifications may be provided by foreign governments or other so-called third parties accredited in advance. FSMA also contains provisions for certifying or accrediting laboratories, including private laboratories, to conduct sampling and testing of food, among other provisions. For example, for the first time, importers must verify that their foreign suppliers have adequate preventive controls in place to ensure safety, and FDA will be able to accredit qualified third party auditors to certify that foreign food facilities are complying with U.S. food safety standards.
- **Response.** For the first time, FDA has mandatory recall authority for all food products, if a firm with suspect products fails to recall them voluntarily. FDA had lacked such authority for food, except for infant formula. FDA has said that it expects that “it will only need to invoke this authority infrequently since the food industry largely honors our requests for voluntary recalls.”<sup>30</sup>
- **Enhanced Partnerships.** FSMA directs FDA to improve training of state, local, territorial, and tribal food safety officials. The law strengthens existing collaboration among all food safety agencies—federal, state, local, territorial, tribal, and foreign—to achieve its public health goals.

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<sup>29</sup> Ibid.

<sup>30</sup> Ibid.

Certain food processing operations are exempt from the proposed HACCP requirements, and some farms are also exempt from the new produce standards. Specifically, farms and food facilities that qualify for an exemption are those businesses with an “average annual monetary value” of less than \$500,000 for all food sold during the previous three-year period, provided that the food is sold directly to “qualified end users” such as consumers, restaurants, or retail food establishments located in the same state where the facility sold the food or within 275 miles of the facility, among other requirements. In addition, among the types of businesses that are considered to be “retail food establishments” and therefore generally not subject to the facility registration requirements, FSMA also exempts roadside stands, farmers’ markets, and foods sold through a community-supported agriculture (CSA) program.

FSMA is explicit in maintaining the separate jurisdictions between FDA and USDA.<sup>31</sup>

The Congressional Budget Office (CBO) has estimated that implementing the new law will increase net federal spending subject to appropriation by about \$1.4 billion over a five-year period (FY2011-FY2015).<sup>32</sup> Although the law authorized appropriations when it established the new food safety system, it did not provide the actual funding needed for FDA to perform these activities. The law provides for limited amounts of fees and other offsets; its implementation will depend largely on discretionary appropriations. Some have already questioned whether an expanded investment in this area is appropriate in the current budgetary climate.<sup>33</sup> FDA’s deputy commissioner for foods, Michael Taylor, has indicated that FDA has “already done a lot of work in anticipation of the new law,” but that funding will continue to be an issue and that building a new preventive system will require new resources and investment.<sup>34</sup>

For a comprehensive listing of all sections and topics addressed in the new law, see the two appendix tables at the end of this report. The first table, **Appendix A**, provides a snapshot of each section and topic covered by the new law. The second table, **Appendix B**, contains a side-by-side comparison of FSMA’s provisions with previous law.

## Selected Issues

The following sections provide a discussion of the key provisions in the FDA Food Safety Modernization Act (FSMA, P.L. 111-353). Unless otherwise noted, references to “the Secretary” mean the HHS Secretary.

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<sup>31</sup> See FSMA § 403. Past debates have examined proposals to combine all federal food safety agencies and authorities under a single, possibly Cabinet-level, agency. For example, a bill introduced by Representative DeLauro (H.R. 875) proposed to transfer FDA’s food safety activities to a new food safety agency within HHS, creating a Food Safety Administration with an Administrator appointed to a five-year term by the President and confirmed by the Senate.

<sup>32</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. Reflecting the August 2010 Senate amendment to S. 510.

<sup>33</sup> See Helena Bottemiller, “Food Safety Bill Advocates Expect Funding Fight,” *Food Safety News*, January 4, 2011.

<sup>34</sup> Helena Bottemiller, “FDA’s Taylor: ‘We’ll Hit the Ground Running’,” *Food Safety News*, January 28, 2011.



## Facility Registration

Prior to passage of FSMA, the FFDCA required domestic and foreign food facilities to register with FDA.<sup>35</sup> Excepted were farms, restaurants, retailers, and certain types of nonprofit food establishments and fishing vessels. Renewal was not required on any periodic basis, but registrants were required to notify the HHS Secretary in a timely manner of relevant changes in their status. The FFDCA (§ 801(l); 21 U.S.C. § 381(l)) provided that imported food may not be delivered to the importer, owner, or consignee of the article unless the foreign facility is registered.

**FSMA Provisions.** FSMA (§ 102) amends FFDCA § 415 to 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. It provides for new 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.” FSMA also provides for procedures for vacating such a suspension. Importing or introducing such food into commerce is prohibited, and subject to possible civil and criminal penalties and other enforcement actions. FSMA does not change existing exemptions from the registration requirement for farms, restaurants, retailers, and certain types of nonprofit food establishments and fishing vessels. It also does not impose new registration fees for food facilities.

FSMA clarifies the types of facilities included as a “retail food establishment”<sup>36</sup> and therefore generally not subject to the registration requirements. It requires the HHS Secretary to amend the definition of “retail food establishment” to include food sold directly to consumers by a roadside stand or farmers’ market, food sold through a community-supported agriculture (CSA) program, or sale and distribution of food at any other such direct sales platform as determined by the Secretary (§ 102(c)).

## Record-Keeping and Documentation Requirements

Prior to passage of FSMA, the FFDCA authorized 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.”<sup>37</sup> 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>38</sup>

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<sup>35</sup> Pursuant to P.L. 107-188, the Bioterrorism Act (FFDCA § 415; 21 U.S.C. § 350d).

<sup>36</sup> 21 C.F.R. 1.227(b)(11).

<sup>37</sup> Pursuant to P.L. 107-188, the Bioterrorism Act (FFDCA § 414; 21 U.S.C. § 350c).

<sup>38</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.

Prior to passage of FSMA, advocates of food safety reform argued that record-keeping requirements needed to be strengthened to help regulators determine whether firms are complying with the law, and to facilitate outbreak investigations and product recalls. Among their concerns has been that records do not have to be maintained in electronic format, which, these advocates assert, delays outbreak response. Related concerns have included 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. 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.

**FSMA Provisions.** FSMA (§ 101) amends FFDCFA § 414 to expand the Secretary’s authority to inspect and copy relevant records of a food facility in two ways. It requires 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 has greater flexibility under the second provision, no longer needing a reasonable belief that food is adulterated in order to access records. The Secretary may allow access to records regarding foods likely to be affected in a similar manner, but will need to believe there is at least a risk of harm. Farms and restaurants (as under previous law) remain fully exempt from this provision. For other facilities, written notification is still required to gain access.

(See the subsequent section on “Notification of Contaminated Products and Product Tracing” for additional provisions relating to record-keeping and documentation.)

## Hazard Analysis and Risk-Based Preventive Controls

Prior to passage of FSMA, a broad consensus of policymakers agreed that FDA’s system of food safety safeguards should be more proactive in addressing the nation’s complex food supply.<sup>39</sup> 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 had been expected to abide by the rules; generally it was only when a problem was detected—often after an illness outbreak was reported or testing found a contaminant in a product—that officials would step in to correct it, or order the industry to do so.

A recurring theme in these discussions was the need for prevention. Virtually all stakeholders, including regulators, the regulated industries, consumer advocates, and food safety scientists agreed 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.<sup>40</sup> A popular version of this approach is the so-called Hazard Analysis and Critical

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<sup>39</sup> Emily Ethridge, “Food Safety Bill Advances,” *CQ Markup and Vote Coverage*, Senate Health, Education, Labor and Pensions Committee Markup of S. 510, November 18, 2009.

<sup>40</sup> Testimony of Margaret A. Hamburg, FDA Commissioner, before the U.S. Senate Committee on Health, Education, Labor, and Pensions, October 22, 2009; Committee on the Review of the Use of Scientific Criteria and Performance Standards for Safe Food, National Research Council, *Scientific Criteria to Ensure Safe Food*, National Academies (continued...)

Control Points (HACCP) system, which was incorporated in the 1990s by FSIS as a regulatory requirement for all meat and poultry slaughtering and processing establishments.<sup>41</sup> Variations of the HACCP system also had been required by FDA in the processing of seafood, juices, and low-acid canned foods, but not other product categories.

In a number of reports, the committees of the National Academy of Sciences' National Research Council (NAS-NRC) recommended the HACCP approach for food safety.<sup>42</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 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>43</sup>

**FSMA Provisions.** FSMA (§ 103) creates new FFDCAs requirements for each owner, operator, or agent of a food facility to evaluate the hazards that could affect food manufactured, processed, packed, transported, or held there; to identify and implement preventive controls to significantly minimize, prevent, or eliminate such hazards; and to monitor and maintain records on these controls once they are in place. It further specifies the types of hazards that should be evaluated, and requires 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. FSMA requires written HACCP-type and/or broader written food safety plans containing certain requirements as part of its so-called Hazard Analysis and Risk-Based Preventive Controls.

FSMA also contains requirements regarding available FDA guidance documents for seafood (see § 114 and § 103; also see section of this report titled “Targeting of Inspections”). Some facilities are exempt from the requirements under certain conditions, as discussed in more detail in the section below titled “Mitigating Effects on Small Business and Farming Operations.”

## Performance Standards

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

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(...continued)

Press, 2003; Center for Science in the Public Interest (CSPI), “Building a Modern Food Safety System for FDA Regulated Foods,” May 2009; Consumers Union, August 1, 2008, letter to the U.S. House of Representatives.

<sup>41</sup> Robert A. Savage and Daniel Lafontaine, “HACCP Principles: Benchmark for Food Safety,” *Food Quality* magazine, February/March 2010, <http://www.foodquality.com/>. Also see CRS Report RL32922, *Meat and Poultry Inspection: Background and Selected Issues*.

<sup>42</sup> Committee on the Review of the Use of Scientific Criteria and Performance Standards for Safe Food, *Scientific Criteria to Ensure Safe Food*, NAS-NRC, 2003. The report notes: “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.... [T]he emphasis of food safety regulatory agencies must continue to be on prevention, reduction, or elimination of foodborne hazards along the food continuum.” A more recent report in this series is from the Committee on the Review of the Food and Drug Administration’s Role in Ensuring Safe Food, *Enhancing Food Safety: The Role of the Food and Drug Administration*, NAS-NRC, 2010.

<sup>43</sup> National Advisory Committee on Microbiological Criteria for Foods, *Hazard Analysis and Critical Control Point Principles and Application Guidelines*, adopted August 14, 1997.

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>44</sup> The committee added that regulators like FDA, USDA, and the Environmental Protection Agency (EPA) have employed specific standards for diverse reasons and conditions, based on numerous scientific, legal and practical constraints.<sup>45</sup> FFDCA authorizes FDA to promulgate standards for certain hazards, such as tolerances (or legal limits) for pesticide or drug residues in foods, but had not granted explicit authority to develop standards solely as a means to verify that processing is done in a manner that ensures safe food.<sup>46</sup>

**FSMA Provisions.** FSMA (§ 104) amends 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. It places conditions on the issuance of standards, requiring them to be "[b]ased on such review and evaluation, and when appropriate to reduce the risk of serious illness or death to humans or animals or to prevent the adulteration of food" under FFDCA. It further requires that this review and evaluation of "health data and other relevant information" be conducted in coordination with USDA.

## On-Farm Safety Standards; Safety of Produce

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

FDA's "current good manufacturing practice" (CGMP) requirements (at 21 C.F.R. Part 110) apply to manufacturing, packing, or holding human food, but establishments engaged solely in

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<sup>44</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.

<sup>45</sup> *Ibid.*, p. 17. Includes: "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>46</sup> In 1996, USDA's Food Safety and Inspection Service (FSIS) 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*.

harvesting, storing, or distributing raw agricultural commodities generally are excluded.<sup>47</sup> Farms are among those exempted from a requirement that food facilities be registered with FDA, pursuant to the Bioterrorism Act.<sup>48</sup> Further, FFDCCA 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 presents a serious health threat.<sup>49</sup>

Historically, FDA’s general approach has been not to impose mandatory on-farm safety standards or inspections of agricultural facilities.<sup>50</sup> Rather, the agency has tended 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.<sup>51</sup> For example, in July 2009, the Obama Administration released new draft guidances on three specific types of produce: tomatoes, melons, and leafy greens.<sup>52</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>53</sup>

**FSMA Provisions.** FSMA (§ 105) creates new FFDCCA requirements for farms as well as food processors. The provision that could have the most direct effect on on-farm activity—particularly growers of fresh produce—is the establishment of new standards for produce safety. The law requires 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

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<sup>47</sup> 21 C.F.R. 110.19(b). FFDCCA 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>48</sup> P.L. 107-188; 21 U.S.C. 350(d).

<sup>49</sup> 21 U.S.C. 350c and 21 U.S.C. § 374. Dr. Andrew C. von Eschenbach, former FDA Commissioner, observed that produce farms generally do pack and hold food for introduction into interstate commerce, so it can and does inspect them periodically, usually in areas associated with illness outbreaks or to conduct surveillance sampling. Source: U.S. Congress, House Committee on Appropriations, Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, *Appropriations for 2008*, 110<sup>th</sup> Cong., 1<sup>st</sup> sess., February 28, 2007 (Washington: GPO, 2007), pp. Part 5, p. 479.

<sup>50</sup> The FDA advisory panel acknowledged that “[t]he Agency conducts no inspections of retail food establishments or of food-producing farms.” *FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology*, November 2007, p. 21.

<sup>51</sup> Most FDA guidance documents include the following statement: “FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.” Sources: FDA, *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens*, Draft Guidance, July 2009; and FDA, *Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables*, February 2008.

<sup>52</sup> FDA, “Guide to Minimize Microbial Food Safety Hazards of Tomatoes,” “Guide to Minimize Microbial Food Safety Hazards of Melons,” and “Guide to Minimize Microbial Food Safety Hazards of Leafy Greens.” Available at FDA’s website: <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/default.htm>. 74 *Federal Register* 38437-38440, August 3, 2009. See also FDA, “FDA Issues Draft Guidances for Tomatoes, Leafy Greens and Melons,” July 31, 2009.

<sup>53</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>.

Secretary has determined that such standards minimize the risk of serious adverse health consequences or death. Coordination with USDA is encouraged, along with coordination with state agricultural agencies when enforcing standards, as appropriate. Enforcement could be in the form of audit-based verification systems or other inspection methods. FSMA also includes language to enable a state or foreign government to request a variance from HHS if needed to account for local growing conditions. It requires 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.

FSMA exempts some farms from the requirements under certain conditions, as discussed in the next section, “Mitigating Effects on Small Business and Farming Operations”.

## Mitigating Effects on Small Business and Farming Operations

Concerns among farm and rural groups about the potential effects of new food safety requirements on farms and food processors surfaced early in the food safety legislative debate. Most vocal were small farms and processors; organizations representing small, organic, direct-to-market, and sustainable farming operations; and small livestock operations. At issue was 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. For more detailed information, CRS Report RL34612, *Food Safety on the Farm*.

Among the options considered during the debate were 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. FFDCA 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 FFDCA § 415.

**FSMA Provisions.** As discussed, some provisions in FSMA will directly affect farms and food processors (§§ 105 and 103, respectively). Other provisions that could potentially affect farms and food processors include facility registration requirements (§ 102); records access and/or inspection requirements (§§ 101 and 204); food traceability requirements (§ 204); and targeting of inspection resources (§ 201). FSMA, however, provides extensive consideration of the needs of small businesses and provides for coordination of enforcement and education activities with others such as USDA and state authorities.

FSMA explicitly exempts certain food processors from the newly enacted HACCP-type requirements and also exempts certain farms from the new produce standards. Food facilities would qualify for an exemption from the HACCP requirements under § 103 if they are either a “very small business” as defined by FDA in rulemaking, or if the facility’s “average annual monetary value” of all food sold during the previous three year period was less than \$500,000, provided that the food is sold directly to “qualified end users” such as consumers, restaurants, or retail food establishments located in the same state where the facility sold the food or within 275 miles of the facility. Such a facility must demonstrate that it either has “identified potential hazards associated with the food being produced,” and is implementing and monitoring these preventive controls, or that it is “in compliance with State, local, county, or other applicable non-

Federal food safety law.” Foods produced from such a facility will also need to provide the facility’s name and address on a food packaging label or at the point of purchase.

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

In addition, as discussed in the “Facility Registration” section, FSMA clarifies the types of businesses that should be considered to be “retail food establishments” and specifies that roadside stands, farmers’ markets, and foods sold through a community-supported agriculture (CSA) program also are not subject to the requirements.

It is difficult to estimate what share of all food processing operations might be exempt from the new HACCP requirements, how many farms might be exempt from the new produce standards, or how other small business considerations might possibly mitigate the effects of these and other requirements in the new law. In part, this is because the definition of small and very small business would be determined by HHS in future agency rulemaking and subject to other requirements specified in the measures (see, for example, §§ 103, 105, and 204). Even though farms would continue to be exempt from the facility registration requirements, some farms that also engage in food processing might be affected, but data are not available on what share of farms also engage in food processing. In addition, other stipulations in FSMA require that the foods sold from exempted facilities and farms be sold locally and to certain qualified end-users. Data are not available to determine what share of grower-processors might qualify for such an exemption; such a determination will likely be made on a case-by-case basis.

## **Targeting of Inspections**

Reform advocates had long argued that many recent problems leading to illness outbreaks and recalls might have been avoided if inspectors were more frequently present in plants to monitor sanitary conditions and processes.<sup>54</sup> Due to the differing laws and circumstances that apply to FSIS, for example, the agency’s inspectors are in meat and poultry slaughter and processing plants every day, where they must organoleptically (by the senses) examine every live animal and every carcass for defects, and must pass every item before it can enter commerce. Prior to FSMA, FFDCA authorized but did not require FDA to inspect food facilities. Therefore, periodic inspection frequencies were not stipulated, although nothing appeared to prohibit FDA from setting an inspection frequency, or prioritizing inspections based on risk.

Leading up to passage of FSMA, some, including former and current FDA officials, argued that the agency lacked 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

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<sup>54</sup> Lyndsey Layton, “FDA Inspections of Food Plants, Enforcement Down, Officials Say,” *The Washington Post*, April 7, 2010. This story refers to an HHS Inspector General report finding “significant weaknesses” in FDA’s domestic food facility inspections program, including a significant decline in the number of inspections as well as a decline in the number of violations identified by inspectors. HHS Office of Inspector General, “FDA Inspections of Domestic Food Facilities,” OEI-02-08-00080, April, 2010, p. iii, <http://oig.hhs.gov>.

facilities.<sup>55</sup> (See **Table 1.**) According to FDA budget documents, while the number of registered facilities increased each year from FY2004 to FY2010, the number of food inspectors decreased by about 15% from FY2004 to FY2008. Due in part to the resource arguments, appropriations for the agency’s field activities and full-time equivalents (FTEs) rose each fiscal year from FY2007 to FY2010.<sup>56</sup> The number of inspections of food facilities increased each year between FY2008 and FY2010, but remained below FY2004 levels.

**Table 1. FDA Food-Related Inspection Data, FY2004-FY2010**

(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
Field S&E (\$millions) <sup>a</sup>	\$299.3	\$283.3	\$285.3	\$298.0	\$340.6	\$479.9	\$546.8
Field FTEs <sup>a</sup>	2,172	2,059	1,962	1,806	1,861	2,166	2,516
Inspections <sup>b</sup>	21,876	19,774	17,730	17,038	16,277	17,972	19,024
Domestic Facilities <sup>c</sup>	121,534	148,451	172,190	194,245	214,584	236,398	252,433 <sup>d</sup>
Foreign Facilities <sup>c</sup>	92,719	104,555	115,902	129,345	141,703	154,883	164,805 <sup>d</sup>

**Source:** Compiled by CRS from FDA annual budget documents for FY2006-FY2012. This table extends through FY2010, the most recent year for which actual numbers are available.

- a. Food field S&E and FTE data are actual numbers, and are from the FY2007-FY2012 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.”
- b. Inspection data are actual numbers of “Grand Total Food Establishment Inspections” (which include FDA and State Contract Inspections), from the FY2006-FY2012 annual Food and Drug Administration, *President’s Budget Request*, Field Activities—Office of Regulatory Affairs (ORA), “Field Foods Program Activity Data.”
- c. Source: FDA Office of Legislation on September 22, 2010.
- d. Number of registrants as of September 22, 2010.

A related issue raised during the food safety debate in the 111<sup>th</sup> Congress was how FDA could best target its available inspection resources to protect the public health. Different facilities might not merit the same frequency of inspection. For example, facilities that process and package food might create a greater opportunity for contamination than warehouses that merely store foods. Companies and facilities that have a record of meeting all FDA requirements might present less of a risk than those that do not. Foods produced in countries with food processing and handling

<sup>55</sup> See, e.g., William Hubbard, 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.

<sup>56</sup> In FDA budget documents, inspection-related items appear under the field heading, and employees are counted as FTEs.



standards at least as rigorous as those of the United States might present less of a health risk than those with less rigorous standards.

***FSMA Provisions.*** FSMA requires the HHS Secretary to increase the inspection rate for any food facility required to register under FFDCa § 415. In addition, the Secretary is required to identify high-risk facilities and to allocate resources to inspect facilities according to known safety risks. Risks include the type of food, the facility's history of food recalls, the facility's hazard analysis and preventive controls, and others. The new law requires the Secretary 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 is 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 is 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 is authorized to rely on inspections conducted by other federal, state, or local agencies.

For foreign food facilities registered under FFDCa § 415, FSMA permits the Secretary to enter into arrangements and agreements with foreign governments to facilitate the inspection of those facilities. The Secretary is 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 are to be refused entry into the United States if inspectors are 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 new law requires 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. It requires 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.

With regard to seafood and other fish products, FSMA includes three specific provisions: establishing interagency agreements to improve seafood safety (§ 201); assessing changes to regulations for post-harvest processing of raw oysters (§ 114); and sending inspectors to assess production of seafood imported into the United States (§ 306). The scope of interagency agreements identified in § 201 includes examining and testing seafood; coordinating inspections; standardizing data; modifying existing processes; sharing enforcement and compliance information; and conducting joint training and outreach. Section 114 requires that two reports (one by the Secretary of HHS and one by the GAO) be submitted to Congress and published when the Secretary issues guidance, regulation, or suggested amendments related to post-harvest processing of oysters. The requirement for the Secretary's report is waived if a consensus agreement is reached among federal and state regulators and the oyster industry, acting through the Interstate Shellfish Sanitation Conference. Section 306 permits the Secretary of Commerce, in coordination with the Secretary of HHS, to send inspector(s) to a country or facility of an exporter of seafood imported into the United States to assess practices and processes used in farming, cultivation, harvesting, preparation for market, and transportation of seafood. Inspectors also may provide technical assistance related to these activities. For each inspection, the Secretary of HHS must prepare and deliver a report to the subject of the inspection, which may then provide a rebuttal or other comments as specified.

## Use of Third Parties for Imports and for Laboratory Accreditation

Prior to passage of FSMA, FDA lacked express statutory authority to regulate private laboratories that sample or test imported foods, nor did it have authority to accredit food laboratories or use others to certify the safety of imported foods. Laboratory accreditation was voluntary, and several domestic and international accreditation organizations could accredit laboratories.<sup>57</sup> FDA may conduct voluntary, on-site assessments of private accredited laboratories.<sup>58</sup> FDA's own laboratories are accredited and, according to FDA, "the laboratory industry favors accreditation."<sup>59</sup> Industry participation in third-party certification programs, such as those that help foreign and domestic producers meet FDA requirements through certification, has been voluntary, although FDA has indicated that participation in such programs may "be beneficial."<sup>60</sup> 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>61</sup>

GAO 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>62</sup> In January 2009, FDA issued draft guidance on accreditation standards for private laboratories and the test data that such labs should submit to the agency for imported FDA-regulated products that were either detained or subject to an FDA Import Alert. The guidance document encouraged importers to notify the FDA in advance of their submission of a sample to an accredited laboratory, so as "to discourage importers from withholding bad test results, re-testing, or re-sampling."<sup>63</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 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 have contended 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 recent recalls—the recall of 380 million eggs by a single

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<sup>57</sup>FDA, "Guidance for Industry: Submission of Laboratory Packages by Accredited Laboratories," 74 *Federal Register* 3056-3057, January 16, 2009, hereinafter Draft Guidance.

<sup>58</sup> *Ibid.*

<sup>59</sup> *Ibid.*

<sup>60</sup> FDA, "Guidance for Industry: Voluntary Third-Party Certification Programs for Foods and Feeds," 74 *Federal Register* 3058-3059, January 16, 2009.

<sup>61</sup> *Ibid.*

<sup>62</sup> Draft Guidance, 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, p. 7).

<sup>63</sup> *Ibid.*

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>64</sup>

**FSMA Provisions.** FSMA addresses various ways to curb the potential for such problems through laboratory accreditation and third-party certification programs. FSMA (§ 303) creates a system of accreditation of third-party auditors and audit agents, who certify that importing entities are meeting applicable FDA requirements. Foreign governments, foreign agricultural cooperatives, and other third parties can apply to an accreditation body to be a third-party auditor or audit agent, after the accreditation body performs certain reviews. Accreditation bodies cannot 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 are required to issue audit reports and to 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 new law also contains language regarding revocation of accreditation and avoidance of conflicts of interest. The question remains as to whether industry will opt to use third parties.

FSMA (§ 202) also includes provisions that require the Secretary to establish a program for testing of food by accredited laboratories and to recognize accreditation bodies to accredit laboratories, including state and local government laboratories. It requires the development of model accreditation standards, as well as re-evaluation of accreditation bodies at least every five years, and it requires that laboratory test results be sent to FDA unless the Secretary exempts the submission of test results after making a determination that the results “do not contribute to the protection of public health.”

## Mandatory Recall Authority

Prior to passage of FSMA, neither FDA nor FSIS had explicit statutory authority to mandate a recall of most adulterated foods, or to impose penalties if recall requirements were violated. FDA could order food recalls only for infant formula.<sup>65</sup> GAO and others contended that these gaps increased the possibility that unsafe food would not be recovered, and would be consumed.<sup>66</sup> Reversing their earlier opposition, many major food industry groups endorsed legislative proposals to grant FDA mandatory recall authority for food.<sup>67</sup>

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<sup>64</sup> FDA, Update on the *Salmonella* Typhimurium Investigation, FDA/CDC Joint Media Teleconference, (Jan. 28, 2009), p. 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), p. B1.

<sup>65</sup> FDA had the authority to order recalls of four types of products: infant formula, medical devices, human tissue products, and tobacco products. The agency could request that a company voluntarily recall other FDA-regulated products, such as other foods, drugs, and cosmetics. See also discussion of the melamine contamination incident in CRS Report R40916, *Food Safety: Foodborne Illness and Selected Recalls of FDA-Regulated Foods*.

<sup>66</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; and HHS Office of Inspector General (OIG), “FDA Inspections of Domestic Food Facilities,” OEI-02-08-00080, April, 2010, <http://oig.hhs.gov>.

<sup>67</sup> In reaction to a news story on an OIG report, representatives from the food industry noted the need for mandatory recall in some instances. See “OIG Says Better FDA Traceback May Require New Legislation,” *FDA Week*, March 27, 2009.

**FSMA Provisions.** FSMA (§ 206) requires 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 does not do so “within the time and in the manner prescribed by the Secretary,” authority is provided to require such person to cease distribution, or to immediately notify everyone involved in handling or receiving the food. The Secretary is 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 law provides for the assessment of civil penalties as well as criminal penalties for failure to comply with or follow a recall order. The assessment of civil penalties for failure to comply with a recall order may preclude the assessment of criminal penalties. If the FDA assesses a civil penalty, the agency would not be able to seek seizures or injunctions for the adulterated food.

## Notification of Contaminated Products and Product Tracing

Notification and traceability are viewed as tools to make recalls more effective. Some had 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 was also debated in connection with defense against agroterrorism, and for verifying the origin of live animals and their products for marketing, trade, and/or animal health purposes, for example. In some recent highly publicized outbreaks, it appears that food company representatives were aware of a food safety problem for a prolonged period of time before notifying FDA.<sup>68</sup>

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) requiring the responsible party for a food facility (i.e., one registered under FFDC § 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 requiring the Secretary to establish a Reportable Food Registry of such reports.<sup>69</sup> Also, the enacted 2008 farm bill (P.L. 110-246) amended the meat and poultry laws to require an establishment to notify USDA if it has reason to believe that an adulterated or misbranded product has entered commerce. (See also the earlier discussion of record-keeping requirements under FFDC § 414.)

**FSMA Provisions.** FSMA (§ 211) amends 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. It also requires 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.

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<sup>68</sup> See, for example, documentation on the 2010 Wright County egg recall available at the House Committee on Energy and Commerce website: “Chairmen Request More Details on Salmonella Contamination at Wright County Egg Publications,” September 14, 2010. See also discussion of the melamine contamination incident in CRS Report R40916, *Food Safety: Foodborne Illness and Selected Recalls of FDA-Regulated Foods*.

<sup>69</sup> FFDC § 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>.

FSMA (§ 204) also provides for an enhanced food tracing system that requires the Secretary, through rulemaking, to impose enhanced record-keeping requirements (under FFDCA § 414) for foods that the Secretary determines to pose a higher food safety risk. Low-risk foods may be exempted. A number of limitations of such requirements are stipulated, especially with respect to farms and agricultural commodities. Effective dates for the record-keeping requirements are delayed for small businesses. The Secretary is also required to conduct pilot studies and assessments of food tracing systems to inform the rulemaking process.

## Foodborne Illness Surveillance and Outbreak Response

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. A foodborne disease outbreak is not defined in law or in regulations. In 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>70</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>71</sup> The ability to link seemingly unrelated illnesses through genetic “fingerprinting” has revolutionized the identification of large multistate outbreaks. However, the epidemiological approaches used to identify the food associated with an outbreak can be labor-intensive and time-consuming. Also, especially for FDA-regulated foods, information about common contaminants that may be present in foods during production and in commerce, as well as how to test for them, is limited. As a result, “attribution”—identifying the types of foods that cause foodborne illnesses—remains a significant challenge. The 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>72</sup>

**FSMA Provisions.** FSMA (§ 205) contains provisions that, 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 law requires the Secretary, acting through the CDC, to enhance foodborne illness surveillance systems, including coordinating federal, state, and local systems; facilitating timely sharing of agency findings; ensuring early notification of the food industry when a particular food is suspected in an outbreak; developing improved epidemiological tools; and other prescribed methods. It also contains provisions to establish a working group to improve foodborne illness surveillance and outbreak investigations, and to reauthorize food safety capacity-building grants

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<sup>70</sup> CDC, “Surveillance for Foodborne-Disease Outbreaks—United States, 2007,” *Morbidity and Mortality Weekly Report (MMWR)*, vol. 59, pp. 973-979, August 13, 2010.

<sup>71</sup> See CRS Report R40916, *Food Safety: Foodborne Illness and Selected Recalls of FDA-Regulated Foods*.

<sup>72</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.

to states and Indian tribes under the PHS Act. It authorizes the appropriation of \$24 million for each fiscal year for FY2011-FY2015 for efforts to enhance foodborne illness surveillance.

## Criminal Penalties

Under pre-existing law, the concepts of “adulteration” and “misbranding” are two basic statutory components of 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 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>73</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 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.<sup>74</sup>

Upon conviction for a misdemeanor violation of the prohibited acts section, a person<sup>75</sup> faces the penalties authorized in FFDCA § 303(a).<sup>76</sup> These are presented in **Table 2**. The maximum criminal penalty for individuals (as adjusted by 18 U.S.C. §§ 3559 and 3571) is imprisonment for one year and/or either \$100,000 if the misdemeanor does not result in death, or \$250,000 if the misdemeanor results in death. The maximum criminal penalty for organizations (as adjusted by 18 U.S.C. §§ 3559 and 3571) is \$200,000 if the offense does not result in death and \$500,000 if the offense results in death. There are exceptions to the misdemeanor penalty 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>77</sup>

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<sup>73</sup> 21 U.S.C. § 331.

<sup>74</sup> See U.S. Congress, House Committee on Energy and Commerce, *How Do You Fix Our Ailing Food Safety System*, 111<sup>th</sup> Cong., 1<sup>st</sup> sess., March 11, 2009 ([http://democrats.energycommerce.house.gov/Press\\_111/20090311/testimony\\_dewaal.pdf](http://democrats.energycommerce.house.gov/Press_111/20090311/testimony_dewaal.pdf)); see also U.S. Congress, Senate Committee on the Judiciary, statement of Sen. Patrick Leahy, Chairman, Executive Business Meeting of the S. Comm. on the Judiciary, 111<sup>th</sup> Cong., 2<sup>nd</sup> sess., September 23, 2010 ([http://judiciary.senate.gov/hearings/testimony.cfm?id=4808&wit\\_id=2629](http://judiciary.senate.gov/hearings/testimony.cfm?id=4808&wit_id=2629)).

<sup>75</sup> 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>76</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 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>77</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 food is not adulterated.

**Table 2. Criminal Penalties for Violations of FFDCa § 303(a)**

Statute	Description of Statutory Provision	Maximum Criminal Penalty for Individuals (as adjusted by 18 U.S.C. §§ 3559 and 3571)	Maximum Criminal Penalty for Organizations (as adjusted by 18 U.S.C. §§ 3559 and 3571)
Federal Food, Drug, and Cosmetic Act (FFDCA) § 303(a)(1) (21 U.S.C. § 333(a)(1))	Violation of FFDCA prohibited acts provisions, FFDCA § 301	Imprisonment for one year and/or either \$100,000 if the misdemeanor does not result in death, or \$250,000 if the misdemeanor results in death	\$200,000 if the offense does not result in death, \$500,000 if the offense results in death
FFDCA § 303(a)(2) (21 U.S.C. § 333(a)(2))	Violation of FFDCA prohibited acts provisions after a prior conviction under FFDCA § 303 or a violation committed with the intent to defraud or mislead	Imprisonment for not more than three 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 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 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 FFDCA, or who conspire to violate 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>78</sup> The decision to seek criminal sanctions against individuals and corporations suspected of violating FFDCA is within FDA's discretion.<sup>79</sup> 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>80</sup>

**FSMA Provisions.** FSMA does not alter the criminal or civil penalties under FFDCA. During the food safety debate in Congress, another Senate bill, S. 3767 (the Food Safety Accountability Act of 2010, as introduced by Senator Patrick Leahy), was considered for inclusion in the final Senate version of the food safety bill (S. 510). The provisions of S. 3767 would have amended the penalties provisions of FFDCA § 303(a) to provide for fines and a maximum prison sentence of 10 years, if a person knowingly violated FFDCA's prohibited acts section.<sup>81</sup> However, these provisions were not included in the final enacted law.

<sup>78</sup> 18 U.S.C. §§ 2, 371.

<sup>79</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 FFDCA enforcement provisions do not overcome the agency's "decisions not to institute proceedings").

<sup>80</sup> FDA, *Regulatory Procedures Manual*, § 6-5-1, March 2010, <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucml176738.htm>.

<sup>81</sup> S. 3767, as reported, would have amended 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 FFDCA's prohibited acts section, provided that the knowing violation be "with respect to food and with conscious or reckless disregard of a risk (continued...)

FSMA 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 violations of FFDC. This would include employees who testify, assist, or participate in a proceeding on such a violation, or who refuse to participate in an activity reasonably believed to violate the FFDC. The new law also contains extensive language on the procedures for treating and protecting whistleblowers.

## Dietary Supplements

Survey data show that about half of American consumers report using dietary supplements.<sup>82</sup> Supplements are subject to routine regulations for foods under FFDC (including new requirements under FSMA, such as mandatory recall authority). Supplements are also subject to an additional set of regulations under the Dietary Supplement Health and Education Act of 1994 (DSHEA), as amended. Among other things, DSHEA requires that manufacturers and distributors who wish to market 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. Since passage of DSHEA, some confusion has existed regarding the criteria for defining new dietary ingredients and evaluating their safety. Also, there is growing concern about the illegal addition of anabolic steroids to certain performance enhancing supplements.<sup>83</sup>

**FSMA Provisions.** In addition to the general provisions of FSMA that apply to most foods, including supplements, FSMA includes two provisions specifically focused on supplements (both found in FSMA, Section 113). The first provision requires FDA to notify the Drug Enforcement Administration (DEA) if, when reviewing the safety of a new dietary ingredient, FDA determines that the ingredient may contain an anabolic steroid or its analogue. (DEA regulates anabolic steroids as controlled substances.<sup>84</sup>) The second provision requires that FDA publish guidelines, within 180 days of enactment, to clarify the definition of a new dietary ingredient, and explain how a product so categorized is to be evaluated for safety.

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(...continued)

of death or serious bodily injury.” The maximum criminal penalty for individuals convicted of a felony violation of FFDC for knowingly violating these parts of FFDC’s prohibited acts section, “with respect to food and with conscious or reckless disregard of a risk of death or serious bodily injury,” would have been a fine of not more than \$250,000, imprisonment for up to 10 years, or both. The maximum criminal penalty for organizations for such violations “with respect to food and with conscious or reckless disregard of a risk of death or serious bodily injury” would not be more than \$500,000.

<sup>82</sup> Centers for Disease Control and Prevention, National Center for Health Statistics, National Health and Nutrition Examination Survey (NHANES), key statistics, Table 96, “Dietary supplement use among persons 20 years of age and over ..., United States, ... 2003–2006,” [http://www.cdc.gov/nchs/data/09.pdf#096](http://www.cdc.gov/nchs/data/hus/09.pdf#096).

<sup>83</sup> Testimony of Michael Levy, FDA Center for Drug Evaluation and Research, U.S. Congress, Senate Committee on the Judiciary, Subcommittee on Crime and Drugs, hearing on “Body-building Products and Hidden Steroids: Enforcement Barriers,” 111<sup>th</sup> Cong., 1<sup>st</sup> sess., September 29, 2009, <http://www.fda.gov/NewsEvents/Testimony/ucm071783.htm>.

<sup>84</sup> CRS Report RL34635, *The Controlled Substances Act: Regulatory Requirements*.



## Food Imports

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.<sup>85</sup> FDA import alerts in 2007 and 2008 targeting adulterated pet food ingredients, farmed seafood, and dairy products and ingredients, all from China, are among the incidents that have heightened interest in 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>86</sup>

Before enactment of FSMA, FFDC (21 U.S.C. § 381(a)) empowered 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, under the provisions of the Bioterrorism Act, the agency relied on a system of prior notifications by importers and document reviews at ports of entry. Importers needed an entry bond and had to file a notification for every shipment. An FDA database, the Operational and Administrative System for Import Support (OASIS), helped inspectors to determine a shipment’s relative risk and whether it needed closer scrutiny (i.e., a physical examination, and/or testing). In practice, import inspections were 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>87</sup> Among the cited reasons for this low incidence of inspections were limited and declining resources, including too few inspectors to cover the more than 360 U.S. ports of entry despite ever-increasing import volumes.<sup>88</sup> Prior law did not explicitly authorize, or require, import verification.

**FSMA Provisions.** FSMA provisions on food imports (Title III) place tighter controls over imports, and use certification or verification systems involving so-called third parties. FSMA (§ 303) authorizes 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 are to be used for designated food imported from countries where FDA has an agreement for a certification program. Certifying entities include an agency or representative from the originating country or other persons accredited elsewhere (see section titled “Use of Third Parties for Imports and for Laboratory Accreditation”).

FSMA (§ 301) authorizes a “Foreign Supplier Verification Program,” generally requiring each importer to perform foreign supplier verification activities in accordance with regulations the Secretary may issue to ensure compliance with relevant FFDC provisions. Each importer’s

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<sup>85</sup> GAO, *Food Safety: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food*, GAO-09-873, September 15, 2009; GAO, *Food Safety: FDA Could Strengthen Oversight of Imported Food by Improving Enforcement and Seeking Additional Authorities*, GAO-10-699T, May 6, 2010. See also Center for Science in the Public Interest, “Building a Modern Food Safety System for FDA Regulated Foods,” May 2009.

<sup>86</sup> Additional information is available in CRS Report RL34198, *U.S. Food and Agricultural Imports: Safeguards and Selected Issues*.

<sup>87</sup> 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>88</sup> See, for example, Testimony of Caroline Smith DeWaal, CSPI Director of Food Safety, before the House Energy and Commerce Committee’s Subcommittee on Oversight and Investigations, July 17, 2007.

program will 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 to requirements of other relevant provisions of FFDCA. Verification activities 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 are required to maintain import verification program records for at least two years and to make them available to the Secretary upon request.

Other FSMA provisions include 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. The law also requires the establishment of a program to expedite imports from those who voluntarily agree to certain higher safety standards under the “Voluntary Qualified Importer Program” (§ 302).

Some have questioned whether FSMA will provide FDA with so-called “equivalence authority,” such as that governing U.S. imports of meat and poultry products under USDA’s FSIS jurisdiction. “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.<sup>89</sup> Under laws governing meat inspection,<sup>90</sup> 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 at least equivalent to the U.S. system. FSIS visits the exporting country to review its rules and regulations, meets with foreign officials, and accompanies them on visits to establishments. In addition, FSIS operates a reinspection program at 150 import houses located near approximately 35 border entry points. FDA does not have a program like that of FSIS. Some have suggested that the FDA program should operate more like that of FSIS, although they acknowledge the difficulties and resource demands of attempting to regulate many more different types of foods from many countries of origin.<sup>91</sup> How FDA is able to exercise its new authority under FSMA regarding food imports under the agency’s jurisdiction remains to be seen.

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<sup>89</sup> 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>.

<sup>90</sup> Federal Meat Inspection Act, 21 U.S.C. §§ 601-695; and Poultry Products Inspection Act, 21 U.S.C. §§ 451-471.

<sup>91</sup> See, for example, testimony of Caroline Smith DeWaal, Director of Food Safety, Center for Science in the Public Interest, before the House Energy and Commerce Committee’s Subcommittee on Oversight and Investigations, July 17, 2007.

## Paying for Food Safety with User Fees

Many critics have argued that a fundamental problem has been FDA's lack of sufficient funding and staff to carry out congressionally mandated (and existing) responsibilities to ensure a safe food supply.<sup>92</sup> Responding to a request from Democratic leaders of the House Energy and Commerce Committee, a subcommittee of the FDA Science Board<sup>93</sup> estimated that, in order to address these deficiencies, the food-related portion of FDA's appropriation should be increased.<sup>94</sup> In fact, congressional appropriators increased funding for FDA food activities each year from FY2005 to FY2010.<sup>95</sup> (See **Table 3.**)

**Table 3. FDA Direct Appropriations for Foods, FY2005-FY2010**

(dollars in millions)

	FY2005	FY2006	FY2007	FY2008	FY2009	FY2010
Appropriations	435.5	438.7	457.1	507.8	712.8	783.2

**Source:** Compiled by CRS from FDA annual budget documents. Data are from the FY2007-FY2012 annual Food and Drug Administration, *President's Budget Request*, "All Purpose Table—Total Program Level." All dollar amounts are actual; FY2010 is the most recent year for which actual numbers are available.

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

An alternative approach to direct appropriations is to fill perceived shortfalls through user fees on the regulated industry. For several years before the introduction of FMSA, such user fees related to foods had been proposed in legislation and in budget requests. For example, the President's FY2011 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.

Before FSMA added the authority for FDA to collect food-related user fees, the agency already had the authority to collect user fees related to human and animal prescription drugs and human medical devices (21 U.S.C. 379g - 379j-12);<sup>96</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

<sup>92</sup> See, e.g., FDA Science Board, *FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology*, November 2007.

<sup>93</sup> The Science Board is one of several advisory committees to FDA. It consists of experts from academia and industry, and advises the Commissioner on specific complex and technical issues, as well as emerging issues within the scientific community, in industry and academia. It also provides advice to the agency on keeping pace with technical and scientific evolutions in the fields of regulatory science, formulating appropriate research agendas, and upgrading its scientific and research facilities to keep pace with these changes. FDA, *Science Board to the Food and Drug Administration*, October 6, 2010, <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/ScienceBoardtotheFoodandDrugAdministration/default.htm>.

<sup>94</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>95</sup> See CRS Report R40792, *Food and Drug Administration Appropriations for FY2010*.

<sup>96</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*.

submitting certain applications to FDA. The fees collected are intended to fund approval-related activities; with the exception of tobacco fees, they cannot 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.

Since before the FMSA was enacted, FDA has also been explicitly 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 FDCA requirements. If the Secretary issues a written export certification, a fee of up to \$175 may be charged.

The introduction of user fees for these FDA-regulated products has added to the agency's budget. Fees have provided additional resources for the agency to hire reviewers to conduct premarket reviews; to hire support personnel and field investigators to speed up the application review process for drugs, biological products, and medical devices; and to acquire and support critical information technology infrastructure.<sup>97</sup>

The introduction of fees raises several issues. First, proposals for new user fees typically meet with resistance, both from the companies that would have to absorb such costs and from consumer advocates, who argue that industry funds might cause conflicts of interest by having industry pay the salaries of some of its regulators. 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 established.

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>98</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 cannot easily be increased or trimmed to conform to short-term activity levels and associated available funds. One example of the dilemma of unpredictable fee funding comes from the area of medical device user fees. In FY2002, when they were initially authorized, the fees were all periodic, which led to unpredictable funding for the device program and caused some budgetary shortfalls.<sup>99</sup> In FY2007, in order to make user fee funding more

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<sup>97</sup> For an example regarding drugs, see U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Health, prepared statement of Hon. Lester M. Crawford, Deputy Commissioner, Food and Drug Administration, *Reauthorization of the Prescription Drug User Fee Act*, 107<sup>th</sup> Cong., 2<sup>nd</sup> sess., March 6, 2002 (Washington: GPO, 2002), pp. 30-31.

<sup>98</sup> See CRS Report RL34334, *The Food and Drug Administration: Budget and Statutory History, FY1980-FY2007*.

<sup>99</sup> See Barbara Zimmerman, *Medical Device Review Program Performance*, FDA, Webcast, 2010, <http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM224256.wmv>.

consistent and reliable, certain annual fees (such as annual registration fees) were enacted to help resolve the issue.<sup>100</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.

**FSMA Provisions.** FSMA funds some FDA food safety activities through the collection of user fees. (See **Table 4.**) It establishes 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 annual and periodic fees are presented in **Table 5**, 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. FSMA does not impose new facility registration fees.

**Table 4. Fees in the FDA Food Safety Modernization Act (FSMA, P.L. 111-353)**

	FSMA, P.L. 111-353
Reinspection Fee	§ 107
Recall Fee	§ 107
Export Certification Fee	§ 401
VQIP Fee	§ 107

**Source:** Prepared by CRS.

Regarding fees, the Congressional Budget Office (CBO) estimated that over five years, the new requirements would collect \$241 million (based on an assessment of the August 2010 manager's amendment of the Senate version of the food safety bill).<sup>101</sup> CBO also estimated that covering the five-year cost of new requirements, including more frequent inspections, would require additional outlays of \$1.1 billion.<sup>102</sup>

<sup>100</sup> Ibid., and see CRS Report RL34571, *Medical Device User Fees and User Fee Acts*; and CRS Report RL34465, *FDA Amendments Act of 2007 (P.L. 110-85)*.

<sup>101</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>102</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.

**Table 5. Select Details of Fees Authorized in the FDA Food Safety Modernization Act (FSMA, P.L. 111-353)**

	<b>VQIP Fee</b>	<b>Reinspection Fee</b>	<b>Recall Fee</b>	<b>Export Certification Fee</b>
<b>Who pays</b>	Importers participating in the voluntary importer certification program, under new FFDCCA § 806.	If subject to reinspection in a fiscal year: the responsible party for a domestic facility (defined in new FFDCCA § 415(b)), the U.S. registered agent for a foreign facility, or the importer.	If noncompliant with a recall order under FFDCCA § 412(f) or new § 423: the responsible party for domestic facilities (defined in new FFDCCA § 415(b)), or the importer.	Exporters who voluntarily request and receive within 20 days Secretary's export certification under amended FFDCCA § 801(e)(4).
<b>Fee Amount</b>	Amounts estimated as specified to cover 100% of the VQIP costs for that year.	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 issuing export certifications.
<b>Fee Amount Cap</b>	None.	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. Fees may not be retained in an amount that exceeds the cost of issuing export certifications for the respective fiscal year.
<b>Result of Nonpayment</b>	Fees over 30 days past due treated as a claim of the U.S. Government under subchapter II (Claims of the United States Government).			No provision in § 107.
<b>How Funds May Be Used</b>	For administering the VQIP program.	For reinspection-related activities.	For food-recall-related costs associated with the recall order, for activities performed by the Secretary.	For FDA's export certification costs.
<b>Required Reports, Meetings</b>	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.
<b>Authorization</b>	For FY2010 and each FY thereafter, an amount equal to the revenue amount determined as specified.			No provision in § 107.
<b>Appropriations-Related Restrictions on Fee Collection</b>	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.
<b>Expiration Date</b>	None.	None.	None.	None.

**Source:** Prepared by CRS based on the text of FSMA (P.L. 111-353).

# Appendix A. FDA Food Safety Modernization Act (P.L. 111-353) Provisions

Subject Matter	Section(s)	FDA Food Safety Modernization Act (FSMA), P.L. 111-353
<b>Title I—Improving Capacity to Prevent Food Safety Problems</b>		
Record-keeping Requirements and FDA Access to Records	101	Inspections of Records (§ 101)
Facility Registration	102	Registration of Food Facilities
Hazard Prevention Plans	103	Hazard Analysis and Risk-Based Preventive Controls (§ 103)
Performance Standards	104	Performance Standards (§ 104)
Produce Safety Standards	105	Standards for Produce Safety (§ 105)
Intentional Adulteration and Domestic Food Defense	106, 108, 109, 110	Protection Against Intentional Adulteration (§ 106); National Agriculture and Food Defense Strategy (§ 108); Food and Agriculture Coordinating Councils (§ 109); Building Domestic Capacity (§ 110)
Export Certification Fees	107	Authority to Collect Fees (§ 107)
Sanitary Transportation of Food	111	Sanitary Transportation of Food (§ 111)
Food Allergy and Anaphylaxis	112	Food Allergy and Anaphylaxis Management (§ 112)
Vitamins and Minerals Containing Anabolic Steroids	113	New Dietary Ingredients (§ 113)
Seafood	114, 103, 201, 306	Requirements for Guidance Relating to Post-Harvest Processing of Raw Oysters (§ 114); Updating Guidance Relating to Fish and Fisheries Products Hazards and Controls (§103, part); Targeting of Inspection Resources for Domestic Facilities, Foreign Facilities, and Ports of Entry; Annual Report (§ 201); Inspection of Foreign Food Facilities (§ 306)
Port Shopping	115	Port Shopping (§ 115)
Jurisdiction	116	Alcohol-Related Facilities (§ 116)
<b>Title II—Improving Capacity to Detect and Respond to Food Safety Problems</b>		
Inspection of Facilities	201	Targeting of Inspection Resources for Domestic Facilities, Foreign Facilities, and Ports of Entry; Annual Report (§ 201)
Laboratory Accreditation	202	Recognition of Laboratory Accreditation for Analyses of Foods (§ 202)
Other Laboratory Provisions	203	Integrated Consortium of Laboratory Networks (§ 203)
Traceability of Food	204	Enhancing Tracking and Tracing of Food and Recordkeeping (§ 204)
Foodborne Illness Surveillance and Education	205	Surveillance (§ 205)
Mandatory Recall Authority	206	Mandatory Recall Authority (§ 206)
Administrative Detention of Food	207	Administrative Detention of Food (§ 207)

<b>Subject Matter</b>	<b>Section(s)</b>	<b>FDA Food Safety Modernization Act (FSMA), P.L. 111-353</b>
Food Decontamination and Disposal	208	Decontamination and Disposal Standards and Plans (§ 208)
State and Local Food Safety Roles and Training	209, 210	Improving the Training of State, Local, Territorial, and Tribal Food Safety Officials (§ 209); Enhancing Food Safety (§ 210)
Research	210	Food Safety Integrated Centers of Excellence (§ 210)
Reportable Food Registry	211	Improving the Reportable Food Registry (§ 211)
<b>Title III—Improving the Safety of Imported Food</b>		
Foreign Supplier Verification	301	Foreign Supplier Verification Program (§ 301)
Expediting Imports	302	Voluntary Qualified Importer Program (§ 302)
Import Certification	303	Authority to Require Import Certifications for Food (§ 303)
Prior Notice of Imports	304	Prior Notice of Imported Food Shipments (§ 304)
Foreign Capacity Building	305	Building Capacity of Foreign Governments with Respect to Food (§ 305)
Inspection of Foreign Facilities	306	Inspection of Foreign Food Facilities (§ 306)
Third Party Accreditation	307	Accreditation of Third-Party Auditors (§ 307)
FDA Foreign Offices	308	Foreign Offices of the Food and Drug Administration (§ 308)
Smuggled Food	309	Smuggled Food (§ 309)
<b>Title IV—Miscellaneous Provisions</b>		
Funding and Fees	401	Authority to Collect Fees (§ 107); Funding for Food Safety (§ 401)
Whistleblower Protection	402	Employee Protections (§ 402)
Jurisdiction	403, 404	Jurisdiction; Authorities (§ 403); Compliance With International Agreements (§ 403)
Pay-As-You-Go	405	Determination of Budgetary Effects (§ 405)

**Source:** Table created by CRS.



# Appendix B. Comparison of Provisions in the FDA Food Safety Modernization Act (FSMA, P.L. 111-353), with Previously Existing Law

**Background, Applicable Law, and Administration Statements**      **FDA Food Safety Modernization Act (FSMA), P.L. 111-353**

## Title I—Improving Capacity to Prevent Food Safety Problems

**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 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.

The Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. §§ 301 et seq.) § 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. 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 Food Safety Working Group (FSWG) stated that the Administration would work with Congress on “critical legislation that will provide key tools ... to keep food safe.” One tool it cited was “the ability to access basic food safety records at facilities.”

## 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 “(j) 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 “(i) 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 Law, and Administration Statements

**Facility Registration.** 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.

Both domestic and foreign food facilities are required to register with FDA pursuant to FFDCA § 415. Farms, restaurants, other retail food establishments, and most nonprofit food establishments and fishing vessels are excluded from the requirement. Renewal is not required on any periodic basis, but registrants must notify the Secretary in a timely manner of any relevant changes in their status. FFDCA § 301 (dd) designates failure to register as a prohibited act. FFDCA § 801 (l) provides that imported food may not be delivered to the importer, owner, or consignee of the article until the foreign facility is registered. FDA does not have explicit authority to require a registration fee.

## FDA Food Safety Modernization Act (FSMA), P.L. 111-353

### Registration of Food Facilities (§ 102)

Amends FFDCA § 415 to require biennial facility registration, with an abbreviated process for registrants whose information has not changed. Registrants are required to provide additional contact information, including an e-mail address and, for foreign facilities, the United States agent for the facility. Registrants must also provide an assurance that the Secretary will be permitted to inspect the facility. The Secretary is authorized or required to suspend and/or reinstate registrations, based on the Secretary's determination that "food manufactured, processed, packed, or held by a facility registered under this section has a reasonable probability of causing serious adverse health consequences or death to humans or animals" for a facility that "created, caused, or was otherwise responsible" or "that knew of, or had reason to know of, such reasonable probability." 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.

Provides 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). Requires the Secretary to amend the definition of "retail food establishment" (21 CFR 1.227(b)(11)) to clarify that, in determining the primary function of such an establishment, the sale of food directly to consumers would include sales by a roadside stand or farmers' market, sales through a community supported agriculture (CSA) program, or other types of direct food sales as determined by the Secretary.

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

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

**Hazard Analysis.** 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. 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—

## Background, Applicable Law, and Administration Statements

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, as 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.

**Obama Administration:** The Administration’s 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.

## FDA Food Safety Modernization Act (FSMA), P.L. 111-353

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 section’s requirements is prohibited under FFDCA § 301.

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). Provides 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 enactment, and very small businesses (as defined by the Secretary) 3 years after enactment. Certain facilities would not be subject to the requirements. Food facilities would qualify for an exemption from the HACCP requirements if they are either a “very small business” as defined by FDA in rulemaking, or if the facility’s “average annual monetary value” of all food sold during the previous 3-year period was less than \$500,000, provided that the food is sold directly to “qualified end users” such as consumers, restaurants, or retail food establishments that are located in the same state where the facility sold the food or within 275 miles of the facility. Such a facility would need to demonstrate that it either has “identified potential hazards associated with the food being produced,” and is implementing and monitoring these preventive controls, or that it is “in compliance with State, local, county, or other applicable non-Federal food safety law.” Foods produced from such a facility would also need to provide the facility’s name and address on a food packaging label or at the point of purchase. Requires FDA, with USDA, to conduct a study of the food processing sector.

**Performance Standards (§ 104)**

In coordination with the U.S. Department of Agriculture (USDA), the Secretary of the Department of Health and Human Services (HHS) 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 FFDCA § 402 or the spread of communicable disease under Public Health Service (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 will 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.

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

Subsection (a) of this section establishes a new FFDCA § 419, regarding safety standards for produce. Within one year of enactment, the Secretary (in consultation with USDA and state agriculture departments, including with regard to the national organic foods program, and in consultation with DHS), is required to publish a notice of proposed rulemaking for science-based minimum standards for the safe production and harvesting of those fruits and vegetables that are raw agricultural

**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. FFDCA (in various provisions in Chapter IV, regarding food) authorizes FDA to promulgate standards for certain hazards, such as maximum permissible levels (called tolerances) for residues of pesticides or drugs in foods. FFDCA does not grant FDA the explicit authority to develop standards solely as a means to verify that processing is carried out in a manner that assures the safety of the food.

**Obama Administration:** The Food Safety Working Group (FSWG), established by the Administration in 2009, 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.

**Produce Standards.** As noted earlier, FFDCA authorizes FDA to promulgate standards for certain hazards, some of which, such as maximum permissible levels (called tolerances) for residues of pesticides, may apply to produce. FFDCA does not grant FDA explicit authority to develop standards solely as a means to verify that processing is carried out in a manner that assures the safety of the food. FDA has several voluntary efforts in place to address safety

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in the produce industry. For example, in February 2008, the agency issued the final version of the Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables, which contains non-binding recommendations regarding: primary production and harvesting of fresh fruits and vegetables; personnel; buildings and equipment; sanitation operations; production and process controls; documentation and records; traceback; and recall. On September 2, 2008, FDA published a notice in the Federal 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.

**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.

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commodities (including mixes and specific categories of fruits and vegetables), for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death. The Secretary may exclude from such rulemaking commodities determined to be low risk when produced or harvested by small or very small businesses. The Secretary shall hold at least 3 public meetings on such rulemaking in 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 businesses (see below). The Secretary may coordinate with USDA and shall contract as appropriate with states to conduct compliance activities. 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 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 FFDCA or the PHS Act [42 U.S.C. § 201 et seq.] to revise, issue, or enforce product and category-specific regulations, such as those for existing HACCP programs.

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. Certain farms would not be subject to the requirements. Farms would qualify for an exemption from the HACCP requirements if the farm's "average annual monetary value" of all food sold during the previous 3 year period was less than \$500,000, provided that the food is sold directly to "qualified end users" such as consumers, restaurants, or retail food establishments that are located in the same state where the facility sold the food or within 275 miles of the facility. Foods produced from such a farm would also need to provide the farm's name and address on a food packaging label or at the point of purchase. Such a farm would also need to be in compliance with State, local, county, or other applicable non-Federal food safety laws. Foods produced from such a farm would also need to provide the facility's name and address on a food packaging label or at the point of purchase.

**Protection Against Intentional Adulteration (§ 106)**

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

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

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

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

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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.” (CRS Report RL 30153, *Critical Infrastructures: Background, Policy, and Implementation*)

At present, DHS has identified several critical infrastructure and key resources sectors, including “Agriculture and Food.” For each sector, a Government Coordinating Council and a (private) Sector Coordinating Council have been established to share data and best practices, and to support risk-based planning.

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.

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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 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. Within two years of enactment, the Secretary (in coordination with USDA and DHS) must report to Congress regarding measures to promote food safety and supply chain security, and prevent foodborne illness outbreaks, covering certain identified areas. In preparing the initial report, the Secretary shall describe ways to improve laboratory capability and capacity, information systems, risk assessment systems for food, and include an analysis of FDA’s handling of foodborne outbreaks during the five years prior to enactment that involved fruits and vegetables that are raw agricultural commodities, as defined in FFDCA § 201(f).

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 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.

### 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 FFDCA, and would thus enable the associated fee to be charged to the exporter. The food user fees are established by

**Fees and Funding.** 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.

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Requests for higher appropriations always compete with other priorities throughout the federal discretionary budget. (The food safety programs do not operate like farm support programs, which have mandatory authorizations). Such requests currently are being made during a period of huge budget deficits. Efforts to fill perceived shortfalls through new fees on the food industry always meet with resistance, both from the companies that would have to absorb such costs, and from consumer advocates, who have long argued that industry funds might compromise public health programs.

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

In general, FDA's fee-funded programs for drugs and devices have finite appropriations authorities that sunset, prohibiting the agency from collecting fees beyond the authorized time frame. These authorities do not apply to food safety programs at this time. In addition, some discretionary-funded grant programs have finite appropriations authorities, and may or may not continue to be funded if authority expires. But, in general, FDA's enforcement activities, such as those for food safety, are based in broad, permanent authorities in FFDCA. These authorities do not expire, and they are not accompanied by authorized levels of appropriations. Decisions to apportion 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

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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, 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 enacted food safety user fees are different from existing user fees in several ways. First, the newly enacted fee is authorized indefinitely, while each of the existing user fees has 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 enacted law 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



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certify in writing that the product meets FFDCAs requirements. If the Secretary issues a written export certification, a fee may be charged.

**Obama Administration:** In addition to requesting increased funds for FDA, the Administration has endorsed the need for registration, reinspection, and export certification fees.

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 increasing staff levels to a total 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.

**Transportation.** FFDCAs § 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.

### Sanitary Transportation of Food (§ 111)

Requires the Secretary, within one year of enactment, to promulgate regulations described in FFDCAs § 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."

**Allergens.** FFDCAs § 403(w) requires food products that contain any of the eight most common food allergens (defined in FFDCAs § 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.

### Food Allergy and Anaphylaxis Management (§ 112)

Requires the Secretary, within one year of enactment and in consultation with the Secretary of Education, to develop, and make available to local educational agencies (LEAs), guidelines to develop plans for individuals to manage the risk of food allergy and anaphylaxis in schools and early childhood education programs. The voluntary guidelines shall address specified elements, as follows: (1) parental obligation to provide the school with information regarding a student's food allergy; and risk of anaphylaxis; (2) an individual plan created with the parent and tailored to each student with a documented risk for anaphylaxis; (3) communication strategies between schools and emergency medical services; (4) strategies to reduce the risk of exposure to anaphylactic causative agents in classrooms and common areas for affected students; (5) training and education for school and program personnel, parents, and children; (6) authority and training of program personnel to administer epinephrine when the nurse is not immediately available, and the availability of epinephrine for this purpose; (7) as part of an individual plan, a plan that addresses the response to an anaphylactic incident in a child engaged in extracurricular programs; (8) maintenance of information for each administration of epinephrine to a child, and prompt notification of parents; and (9) other elements the Secretary determines to be necessary. An individual management plan developed pursuant to this section shall be considered an education record for the purpose of the Family Educational Rights and Privacy Act of 1974 (FERPA) [20 U.S.C. § 1232g]. Nothing in this section or the guidelines developed by the Secretary shall be construed to preempt state law, including any state law regarding whether students at risk for anaphylaxis may self-administer medication.

Authorizes the Secretary to award non-renewable food allergy management incentive grants for up to two years to assist LEAs with adoption and implementation of the voluntary food allergy management guidelines. LEAs must provide matching funds of at least 25% of the amount of the grant and report to the Secretary with information on how the grant money was spent and the status of implementation of the guidelines. In awarding grants under this subsection, the Secretary shall give priority to LEAs with the highest percentages of economically disadvantaged children, as defined by §

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1124(c) of the Elementary and Secondary Education Act of 1965 [20 U.S.C. § 6333(c)]. The grant program is authorized for \$30 million for FY2011, and such sums as may be necessary for each of four succeeding fiscal years. Though the guidelines developed by the Secretary are voluntary, the Secretary is authorized to enforce an agreement by an LEA to implement such guidelines as a condition of receipt of a grant authorized by this section.

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

#### New Dietary Ingredients (§ 113)

**Dietary Supplements.** FDCA 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.

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.

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

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

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

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. Requires any report prepared under the section to be made public.

**Updating Guidance Relating to Fish and Fisheries Products Hazards and Controls (§103, part)** Requires the Secretary to update the Fish and Fisheries Products Hazards and Control Guidance to take into account advances in technology since its previous publication.

**Seafood.** 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. NSSP participants include agencies from shellfish producing and non-producing states, FDA, EPA, NOAA, and the shellfish industry.

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

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

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.

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**Port Shopping.** 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 (P.L. 107-188)

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### Port Shopping (§ 115)

Until the Secretary promulgates a final rule that implements the amendments made by section 308 of the Bioterrorism Act requires the Secretary to notify the Secretary of Homeland Security of instances of import refusals under FFDCA section 801(a) (Imports; list of registered foreign establishments; samples from unregistered foreign establishments; examination and refusal of admission) to alert U.S. Customs and Border Protection and prevent imports refused at one port from being admitted by another port.

### Alcohol-Related Facilities (§ 116)

Generally exempts from this act beverages and facilities that are primarily regulated under the Alcohol Administration Act. Certain of the act's provisions are exempted 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.

## Title II—Improving Capacity to Detect and Respond to Food Safety Problems

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

Current law, which derives from FFDCA § 704 (in the General Authority chapter of 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, FDA Administrator Margaret A. Dr. Hamburg's testimony noted the large amount of resources needed to meet the inspection goals 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, FDA Deputy Administrator Michael Taylor expressed support for the agency's flexibility to adjust inspection 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 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 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.

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

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

In January 2009, FDA issued guidance regarding voluntary third-party certification programs for foods and animal 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.

## 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 as accredited entities is required to report any changes to the Secretary). Foreign labs must meet the same accreditation standards as domestic labs. The Secretary shall develop model accreditation standards that address sampling and analytic procedures, quality controls, personnel training and qualifications, and other matters. The Secretary shall review accreditation bodies at least once every five years and promptly revoke recognition for an accrediting body that is not in compliance with this section. Food testing shall be conducted by accredited labs no later than 30 months after enactment, unless otherwise 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 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 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.

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**Laboratory Network.** 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 FY2010 levels for FY2011.

**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 (trace back) and to locate those who may have received the contaminated food (trace forward). Records sufficient to identify products and to trace them quickly are considered to be important prerequisites for a successful recall. (See below.) Among other issues are the potential administrative and cost burdens that a more extensive regulatory program might impose on those in the food system, as well as privacy concerns about records.

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

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

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

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### 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.

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

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

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

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

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

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issued by the Council to Improve Foodborne Outbreak Response:

- improve collaboration between the CDC and the states to evaluate and optimize best practices for more effective outbreak investigations, and launch a new system to facilitate information-sharing and adoption of best practices.

In its July 2010 progress report, the Administration announced that “FDA has conducted a pilot study on a tracing system, and HHS, in collaboration with USDA, has rolled out an enhanced and updated [www.foodsafety.gov](http://www.foodsafety.gov) site to provide consumers rapid access to information on food recalls,” among other actions.

See: FSWG, “Food Safety Working Group: Key Findings,” July 7, 2009; FSWG, “Food Safety Working Group: Progress at 1 Year,” July 9, 2010; and The White House, Statement by the President on Food Safety, July 7, 2010.

farm; food that is produced through the use of a fishing vessel; producers of commingled raw agricultural commodities; grocery stores; direct farm sales to consumers or grocery store; and others. The Secretary may modify requirements, or exempt a food or facility from them, if product tracing requirements are not needed to protect public health.

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.

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 commingled foods. With the exception of farms, failure to comply with recordkeeping provisions under this section is prohibited. Provides 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.

### Surveillance (§ 205)

**Surveillance.** Surveillance for foodborne illness is carried out by the states, with assistance from the CDC. States also conduct investigations of foodborne outbreaks, in coordination with CDC, either FDA or FSIS (depending on implicated or suspected foods), and, if appropriate, other federal agencies. FDA is authorized to carry out such investigations, or to coordinate with states in doing so: (1) under broad, permanent authorities in FFDCA § 702 regarding examinations and investigations, and § 909 regarding authority to assist states with examinations and investigations; and (2) under several broad, permanent disease control authorities of the Secretary of HHS in Title III of the PHS Act, which underpin CDC’s activities as well. These include PHS Act § 301 regarding research and investigations, §§ 311 and 317 regarding federal-state cooperation, and § 361 regarding control of communicable diseases. PHS Act § 317R provides an explicit but expired authority of the Secretary to award grants to state and tribal governments to enhance food safety surveillance and laboratory capacities. Although this authority has expired, the Secretary may carry out this activity under the broad, permanent authorities mentioned earlier.

A foodborne illness “outbreak” is not defined in law or regulations. In public health practice, and as used by CDC, a “foodborne disease outbreak” is defined as “the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food.” As a practical matter, particularly for less serious hazards, foodborne disease outbreak investigations are not always launched

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 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.

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when only two people are affected. Exceptions may be made for serious problems such as botulism.

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.

Recalls are actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority. These are classified as follows:

- **Class I recall:** a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.
- **Class II recall:** a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- **Class III recall:** a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

**Market withdrawal:** occurs when a product has a minor violation that would not be subject to FDA legal action. The firm removes the product from the market or corrects the violation. For example, a product removed from the market due to tampering, without evidence of manufacturing or distribution problems, would be a market withdrawal.

Source: FDA, Background and Definitions, <http://www.fda.gov/Safety/Recalls/ucm165546.htm>.

**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 voluntary recalls. The FSWG has noted support for mandatory recall authority.

## 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 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.

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

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

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),

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 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.

**Administrative Detention of Food (§ 207)**

**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."

**Decontamination.** 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)

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.

**Decontamination and Disposal Standards and Plans (§ 208)**

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



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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.

**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).

FDA provides 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. See *Stronger Partnerships for Safer Food: An Agenda for Strengthening State and Local Roles in the Nation's Food Safety System*, at <http://www.rwjf.org/>.

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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.

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

Creates a new FFDCA § 1011 which requires the Secretary to set standards and administer training and education programs for employees of state, local, territorial, and tribal food safety authorities relating to their responsibilities under FFDCA, 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 FFDCA §1011 such sums as necessary for FY2011-FY2015.

Creates a new AREERA § 405, "National Food Safety Training, Education, Extension, Outreach and Technical Assistance Program." USDA shall, through NIFA, award competitive grants to carry out the program authorized above, as specified. Priority shall be given to projects for small and medium-sized farms, beginning farmers, socially disadvantaged farmers, small processors, or small fresh fruit and vegetable merchant wholesalers. Grants are limited to terms of not more than three years. Eligible entities are (1) a state cooperative extension service; (2) a federal, state, local, or tribal agency, a nonprofit community-based or non-governmental organization, or an organization representing owners and operators of farms, small food processors, or small fruit and vegetable merchant wholesalers that meet specified requirements; (3) an institution of higher education (as defined) or a foundation maintained by such institution; (4) a collaboration of 2 or more eligible entities; or (5) other entities as determined by USDA. 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 program. Appropriations are authorized as "such sums as necessary" (FY2011-2015).

## Enhancing Food Safety (§ 210)

Subsection (a) of this section replaces FFDCA § 1009, regarding grants to states for inspections. New language would authorize grants to states, localities, territories, Indian tribes, and certain non profit entities, to be used for: undertaking food safety examinations, inspections and investigations; training

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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. There are authorized to be appropriated for new program "such sums as necessary" for FY2011-2015.

### Enhancing Food Safety (§ 210), Food Safety Integrated Centers of Excellence

Section 210(b) of this section, regarding Food Safety Integrated Centers of Excellence, which would, among other things, conduct food safety research. Requires the Secretary and the CDC Director (in consultation with other groups) to designate five "Integrated Food Safety Centers of Excellence" at selected state health departments to serve as resources for federal, state, and local public health professionals. Authorizes the appropriation of such sums as necessary to carry out this provision.

**Research.** FDA, along with other federal agencies, is already involved in a variety of research activities, in such areas as how and where food contamination occurs, biotechnology and allergenicity issues, seafood safety, color additives, consumer studies, the detection, characterization, and behavior of foodborne pathogens, for example. Collaborative research efforts have been underway with USDA's Agricultural Research Service and National Institute of Food and Agriculture, and with academia, state health and agricultural officials, industry and others.

**Reportable Food Registry.** 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 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.

### 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 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.

## Title III—Improving the Safety of Imported Food

FFDCA does not explicitly authorize, and does not require, the establishment of a foreign supplier verification program. 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.

### 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

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

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 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.

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

### Voluntary Qualified Importer Program (§ 302)

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

**Import Certifications.** The steady increase in food imports, a result of globalization and consumer desire for a wider variety of foods year-round, has generated growing concerns about whether current federal programs sufficiently ensure the safety of these imports. Most of the recent debate has included extensive discussion about how to improve current import safeguards,

### Authority to Require Import Certifications for Food (§ 303)

Amends FFDCA § 801 by authorizing the Secretary to require certification or other assurance of the safety of an article of food imported or offered for import, and to deny entry to any food offered for import that does not meet such a requirement. The Secretary may base such a requirement on

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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. Also, 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, but 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 expressed 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.

**Prior Notice.** 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. 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.

**Capacity Building.** Current law would not prohibit the development of the plan proposed by this section of S. 510 (right). Implementation of certain elements of such a plan may be authorized under: (1) FFDCA § 803, which authorizes an HHS Office of International Relations to, among other things, reach agreements with other governments regarding practices and standards; and (2) PHS Act § 307, authorizing collaborations with foreign governments for the purposes of research and education regarding health-related matters.

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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.

## Prior Notice of Imported Food Shipments (§ 304)

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.

## Building Capacity of Foreign Governments with Respect to Food (§ 305)

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.

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

Amends FDCA 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 FDCA § 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.

**Foreign Facility Inspection.** FDCA § 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 FDCA § 301. “Interstate commerce” is defined under FDCA § 201 to mean “(1) commerce between any State or Territory and any place outside thereof, and 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 FDCA; nor does there appear to be any statutory distinction here between foreign and domestic. Although FDCA 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 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 FDCA, or an import alert. In 2007, FDA issued an import alert with respect to illegal drug residues in specific seafood products

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from China, requiring that importers demonstrate through testing that illegal residues are absent.

**Third-Party Auditors.** 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 concept is controversial, particularly among food safety advocates, who have expressed concern about potential conflicts of interest between auditors and the companies they audit and about potentially less rigorous oversight. They cite a number of recent food safety crises including the Salmonella contamination of peanut products in late 2008 and early 2009, even though the peanut product supplier had passed several private third-party and state inspections.

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

FDA has argued in the past that its authority is broad enough, under 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

## 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 can first recognize accreditation bodies. Such bodies in turn can accredit the third-party auditors or audit agents, who in turn could be tasked to certify eligible entities. Defines the following terms: audit agent, accreditation body, third-party auditor, accredited third-party auditor, consultative audit, eligible entity, and regulatory audit.

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

Accreditation bodies must, prior to accrediting a foreign government or foreign government agency, perform reviews and audits of that government or agency’s food safety programs, systems, and standards, as the Secretary deems necessary, to determine that the foreign government is capable of ensuring that entities or foods it certifies will meet the requirements of 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 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-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

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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:** FDA Commissioner Hamburg’s testimony expressed 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.

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.

**Foreign Offices.** 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.

## Foreign Offices of the Food and Drug Administration (§ 308)

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 foreign offices. Clarifies that nothing in this provision shall affect the Secretary’s authority to issue public notifications under other circumstances.

FFDCA does not appear to address or to define the term “smuggled food,” although Chapter VIII of the act covers imports and exports.

## Smuggled Food (§ 309)

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.”

## Title IV—Miscellaneous Provisions

**Fees and Funding** (see discussion listed above under FSMA, Title I)

**Funding for Food Safety (§ 401)** (provision listed above under FSMA, Title I)

**Whistleblowers Protection.** A variety of federal and state measures have been adopted to protect so-called whistleblowers, or those employees who

**Employee Protections (§ 402)**

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disclose information about illegal or improper activity, generally at their place of employment. Many federal employees, for example, are covered by the Whistleblower Protection Act (P.L. 101-12). FFDCA itself contains no such language regarding a private employee who must, or willingly provides, information related to an FDA-related product.

**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 generally exempts meat and meat food products from the provisions of FFDCA (§ 902(b)); § 24 of the Poultry Products Inspection Act (PPIA) generally exempts poultry and poultry products from FFDCA provisions.

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

The budgetary effects of PAYGO measures are determined by statements inserted into the Congressional Record by the chairmen of the House and Senate Budget Committees and referenced in the measures. The statements are expected to reflect cost estimates prepared by the Congressional Budget Office. If this procedure is not followed, then the budgetary effects are determined by the Office of Management and Budget. If OMB determines after a congressional session ends that a cumulative violation of PAYGO has occurred for the budget year, then sequestration may occur, which is an across-the-board cut in nonexempt direct spending programs. See CRS Report R41157, *The Statutory Pay-As-You-Go Act of 2010: Summary and Legislative History*.

**Source:** Prepared by CRS based on the text of FSMA (P.L. 111-353).

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

### Jurisdiction; Authorities (§ 403)

Not a preemption provision; provides that this act, and any amendment made by it, would not: (1) alter jurisdiction between the Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (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 (hereinafter referred to as “the Secretary”); (3) limit the authority of the HHS or Agriculture Secretary under specified existing statutes (including 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.).

### 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.

### Determination of Budgetary Effects (§ 405)

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

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



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