



Food Safety: Selected Issues and Bills in the 111th Congress

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Summary

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

In the 111th Congress, several food safety bills have been introduced, and wide-ranging legislation (H.R. 2749) has passed the House. The Senate also has a comprehensive bill (S. 510). Both of these bills mainly focus on the U.S. Food and Drug Administration's (FDA's) food regulation rather than that of the U.S. Department of Agriculture (USDA, which has oversight of most meat and poultry). The bills would use the agency and its existing FDA authorities rather than create a new food safety structure or authorities. H.R. 2749 is a revised version of H.R. 759, and was amended and approved by a House Energy and Commerce subcommittee on June 10, 2009. The full committee further amended and approved H.R. 2749 on June 17, 2009, and the full House approved the bill on July 30, 2009, with a number of additional amendments intended to satisfy the concerns of agricultural interests. The Senate Health, Education, Labor, and Pensions Committee amended and approved S. 510 on November 18, 2009. Floor action had not been scheduled as of this writing.

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

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

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Introduction

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

In 2007, the Government Accountability Office (GAO) added food safety to its biennially published list of high risk areas, one of 29 needing concerted attention by Congress and the Administration.³ GAO has identified 15 federal agencies collectively administering at least 30 laws related to food safety. The majority of both total funding and total staffing, however, is with the Food Safety and Inspection Service (FSIS) at the U.S. Department of Agriculture (USDA), which regulates most meat and poultry, and the Food and Drug Administration (FDA) at the U.S. Department of Health and Human Services (HHS), which regulates virtually all other foods. FSIS's annual budget in FY2009 was approximately \$972 million in appropriated funds plus an estimated \$140 million in industry-paid user fees. FDA's annual budget for foods in FY2009 was \$643 million, all of it appropriated.⁴

Food Safety Incidents

Food safety-related incidents frequently heighten public and media scrutiny of the U.S. food safety system, as a number of developments in recent years have illustrated. For example, more than 200 confirmed illnesses and three deaths were linked in the autumn of 2006 to the consumption of bagged fresh spinach grown in California and carrying the bacterium *E. coli* O157:H7. The incident raised public concerns about the safety of all fresh leafy produce and stimulated a number of industry and government initiatives to limit future contamination. During April-July 2008, more than 1,300 persons in 43 states, the District of Columbia, and Canada,

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

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

³ GAO, *High Risk Series: An Update* (GAO-07-310), January 31, 2007. Food safety remains on GAO's 2009 high-risk list.

⁴ Source: USDA and HHS budget materials for FY2010. The FDA figure does not include an additional \$89 million in appropriated funds for FDA's Center for Veterinary Medicine (CVM), which regulates animal drugs and feeds (plus additional monies for user fees). When CVM and several other FDA activities related to food safety are added, the total FY2009 budget for FDA food safety is approximately \$891 million, according to these budget materials. For more information on current food safety authorities and agencies, with sources, see CRS Report RS22600, *The Federal Food Safety System: A Primer*, by Geoffrey S. Becker. Also see CRS Report R40721, *Agriculture and Related Agencies: FY2010 Appropriations*, coordinated by Jim Monke.

were found to be infected with the same unusual strain of bacteria (*Salmonella* Saintpaul). Officials first suspected fresh tomatoes as the vehicle, but later genetic tests confirmed the pathogen on samples of a serrano pepper and irrigation water from a farm in Mexico. Large recalls of various FSIS-regulated meat and poultry products, including many million pounds of ground beef, due to findings of *E. coli* O157:H7, *Listeria*, and other problems occurred throughout 2007 and 2008.

A major outbreak of *Salmonella* Typhimurium infections has been linked to the consumption of an institutional brand of peanut butter and of other products containing peanut ingredients from a single firm, the Peanut Corporation of America. None of the major retail peanut butter brands have been implicated. Between September 1, 2008, and April 20, 2009, the U.S. Centers for Disease Control and Prevention (CDC) had identified more than 700 cases in 46 states; the infection may have contributed to the deaths of nine people, according to the CDC. A series of expanding recalls was announced by FDA in early 2009, involving thousands of peanut-containing products from more than 200 companies. These developments were unfolding some two years after a February 2007 nationwide recall due to *Salmonella* contamination of Peter Pan and Great Value brands of peanut butter produced in a Georgia ConAgra plant; hundreds of illnesses, dating back to August 2006 and linked to the bacterium, were reported by public health officials.⁵

In late March 2009, the FDA announced that Setton Pistachio was recalling 1 million pounds of pistachios after one of its buyer-processors found samples that tested positive for multiple strains of *Salmonella*. Additional recalls of more than 600 pistachio-containing products were noted by FDA through late April 2009.

Attention had shifted to the safety of food imports in early 2007 when pet food ingredients imported from China sickened or killed an unknown number of dogs and cats and subsequently were found in some hog, chicken, and fish feeds. Also, in June 2007, FDA announced that it was detaining imports of farm-raised seafood from China (specifically, shrimp, catfish, basa, dace, and eel) until the shippers could confirm that they are free of unapproved drug residues, after repeated contamination problems.

Administration Views

The Bush Administration had issued several reports and studies calling for major changes in the system. Two Bush Administration initiatives were unveiled in November 2007 and were critiqued and debated extensively during the 110th Congress. They were the *Food Protection Plan: An integrated strategy for protecting the nation's food supply*, issued by FDA, and the *Action Plan for Import Safety: A roadmap for continual improvement*, part of which dealt extensively with food product imports, issued by the Interagency Working Group on Import Safety. 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.

⁵ For sources and updates see the FDA website: <http://www.cfsan.fda.gov/~news/whatsnew.html>. For updates on meat and poultry recalls and alerts see the USDA website: http://www.fsis.usda.gov/fsis_recalls/index.asp. Also see CRS Report R40916, *Food Safety: Foodborne Illness and Selected Recalls of FDA-Regulated Foods*, by Sarah A. Lister and Geoffrey S. Becker.

President Obama, in a March 14, 2009, weekly radio address, called the food safety system a “hazard to public health.” He announced a Food Safety Working Group (FSWG) of Cabinet secretaries and senior officials “to advise me on how we can upgrade our food safety laws for the 21st century; foster coordination throughout government; and ensure that we are not just designing laws that will keep the American people safe, but enforcing them.”⁶ The FSWG announced on July 7, 2009, a number of steps the Administration was taking, under existing authorities, to improve government safeguards. Administration officials have testified on aspects of the House legislation,⁷ and issued a formal statement supporting passage of the House bill, H.R. 2749.⁸

In more recent testimony on the Senate bill, FDA Commissioner Margaret Hamburg called S. 510 a “major step in the right direction.” Provisions in the bill address a key policy concern by refocusing FDA’s food safety system on prevention, the Commissioner stated. She added that the bill also generally meets another key policy concern, the need for adequate FDA legal tools to implement the new requirements, although some additional provisions, such as effective enforcement mechanisms, should be added. Finally, the Commissioner stated, the legislation must provide or anticipate adequate resources, but it “does not provide a guaranteed consistent funding source to help FDA fulfill its new responsibilities.” The Commissioner recommended the inclusion of registration fees, flexibility to adjust facility inspection frequencies, and use of accredited third parties to ensure adequate resources.⁹ (These issues are among those discussed later in this report.)

Congressional Response

These and other developments have made food safety a top issue for many lawmakers. Several have called for major changes in the U.S. food safety system and/or funding increases that they assert are needed to meet current obligations to protect consumers from unsafe food. Perceived gaps in federal safeguards have been explored at more than two dozen congressional hearings since 2007 (through early 2009). The 110th Congress adopted some amendments to current programs and increased funding for the primary food safety agencies, but more comprehensive food safety legislation was not enacted.

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

In the Senate, the principal bill is S. 510 by Senator Durbin. The Senate Health, Education, Labor, and Pensions Committee amended and approved the bill on November 18, 2009. A final measure

⁶ The working group established a public website at <http://foodsafetyworkinggroup.gov/>, where the full text of these remarks may be viewed.

⁷ See the June 3, 2009, testimony of FDA Commissioner Margaret Hamburg before the House Energy and Commerce Subcommittee on Health; and the July 16, 2009, testimony of Mr. Mike Taylor, Senior Advisor to the FDA Commissioner, before the House Agriculture Committee.

⁸ The Statement of Administration Policy can be viewed at http://www.whitehouse.gov/omb/111/legislative_sap_date/.

⁹ October 22, 2009, testimony of FDA Commissioner Margaret Hamburg before the Senate Committee on Health, Education, Labor, and Pensions.

will depend on the outcome of full Senate action (which had not been scheduled as of this writing) and then a House-Senate conference committee. At an October 22 hearing on the bill, the HELP Committee's chairman expressed his hope that food safety legislation could reach the President's desk by the end of 2009. Several other lawmakers and various stakeholders have predicted that work on a measure could extend into 2010 and the second session of the 111th Congress.

Both H.R. 2749 and H.R. 510 focus primarily on FDA-regulated foods, and would achieve their proposed reforms through the agency's existing structure and authorities, in particular the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. 301 *et seq.*).

Two other comprehensive House bills have been H.R. 875 by Representative DeLauro, a blueprint for a new, independent Food Safety Administration (FSA), separated from the current FDA but still within HHS, which would operate a comprehensive new food safety program (but would not include the meat and poultry inspection programs operated by FSIS); and H.R. 1332 by Representative Costa, which is similar in design to the Senate bill (S. 510). However, as noted, H.R. 2749 has overtaken these other House bills.

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

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

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

The bills seek to increase the frequency of plant inspections, taking into account risk factors. To aid in such inspections, and to improve the ability to rapidly trace food products through the production and marketing chain in the event of a foodborne illness outbreak, suspected

contamination, or other problems, the bills generally seek to strengthen record-keeping requirements and food traceability systems. Industry participants would be required to maintain records for certain time periods and in formats to be prescribed by the agency. The importance of adequate records has been demonstrated in recent food safety incidents, particularly in the case of outbreaks eventually linked to fresh produce. Food establishments, which are already subject to a one-time registration requirement under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188; 21 U.S.C. 350d), would have to re-register more frequently under the bills, which ask for additional registration information (and the House bill requires a \$500-per-facility registration fee).

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

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

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

Selected Issues¹⁰

Following is a discussion of selected issues. A comparison of key provisions in the major House and Senate bills is provided in **Table 1** at the end of this report.¹¹

Hazard Analysis and Risk-Based Preventive Controls

Reactive vs. Preventive Intervention

A broad consensus of policymakers agrees that FDA's system of safeguards, which is based on a law first written early the last century, is primarily reactive. By and large, the agency's statute and regulations spell out the reasons a food article is to be considered adulterated or misbranded and therefore unfit for consumption. In effect, industry players are expected to abide by the rules;

¹⁰ Some information in this section is adapted from CRS materials prepared or coordinated in 2008 by Sarah A. Lister, Specialist in Public Health and Epidemiology, Domestic Social Policy Division.

¹¹ For a CRS congressional distribution memorandum comparing the provisions of H.R. 2749 and S. 510 in greater detail, contact Geoffrey S. Becker at 7-7287.

generally it is only when a problem is detected—often after an illness outbreak is reported or testing finds a contaminant in a product—that officials step in to correct it, or order the industry to do so.

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

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

The balance of progress in reduction of certain human foodborne illnesses following implementation of [HACCP] in various areas of the food industry is decidedly favorable.... The committee believes that the emphasis of food safety regulatory agencies must continue to be on prevention, reduction, or elimination of foodborne hazards along the food continuum.¹²

The National Advisory Committee on Microbiological Criteria for Foods, established to offer ongoing advice to the FDA and USDA, agreed with the NAS recommendations, which have dated at least to the early 1990s. The advisory committee also noted that HACCP principles should be standardized to provide uniformity in training and applicability, but also must be developed by each food establishment so they can be tailored to individual products, processing, and distribution conditions.¹³

Legislative Proposals

The House-passed and Senate HELP Committee (hereinafter, Senate) bills contain somewhat similar provisions requiring each owner, operator, or agent of a facility to evaluate the hazards that could affect food manufactured, processed, packed, transported, or held there; identify and implement preventive controls to significantly minimize, prevent, or eliminate such hazards; and monitor and maintain records on these controls once they are in place. The bills further specify types of hazards that should be evaluated, require facilities to conduct a reanalysis at specified intervals, and to maintain for at least two years records to document and verify their control measures, among other details (which differ somewhat between the bills, with the House version appearing to be somewhat more prescriptive). Written HACCP-type and/or broader written food safety plans containing HACCP are also elements of the bills. Under the House-passed bill, higher-risk facilities must submit test results when finished products are found to contain

¹² 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.

¹³ National Advisory Committee on Microbiological Criteria for Foods, *Hazard Analysis and Critical Control Point Principles and Application Guidelines*, adopted August 14, 1997.

contaminants “posing a risk of severe adverse health consequences or death” (although there are some limitations on the extent of the Secretary’s authority here).

Performance Standards

Can Safety Be Better Measured?

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

tolerances (which set legal limits) on the presence of chemicals in food, prohibitions on specific microbial pathogens in specific foods, standards for process control, and standards defining the acceptable outcome of a food process for reducing pathogenic contamination. All of these are performance standards in the sense that they define what must be achieved in controlling risk factors for food safety.¹⁴

The FFDCFA does authorize FDA to promulgate standards for certain hazards, such as tolerances for pesticide or drug residues in foods, but does not grant explicit authority to develop standards solely as a means to verify that processing is done in a manner that ensures safe food.¹⁵

Legislative Proposals

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

¹⁴ *Scientific Criteria to Ensure Safe Food*, p. 17.

¹⁵ FSIS in 1996 had established two performance standards to verify the microbial safety of meat and poultry products as part of its HACCP regulation. FSIS’s efforts to take enforcement action when its standard upper limit for *Salmonella* contamination were constrained by a successful legal challenge, but it still interprets non-compliant *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*, by Geoffrey S. Becker.

Registration

Keeping Track of Food Facilities

The FFDCa already requires domestic and foreign food facilities to register with FDA, pursuant to provisions in P.L. 107-188, bioterrorism act (21 U.S.C. 350d). Excepted are farms, retailers, and certain types of nonprofit food establishments and fishing vessels. Renewal is not required on any periodic basis, but registrants must notify the HHS Secretary in a timely manner of relevant changes in their status. The FFDCa [at 21 U.S.C. 381(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.) Some assert that registration requirements should be strengthened so that authorities will be notified when a firm moves, undertakes a new food business, or changes product lines. Otherwise, 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 industry.

Legislative Proposals

The Senate bill contains a provision requiring domestic and foreign facilities to register every two years, with some additional types of contact information, and with an abbreviated renewal process available to those with no changes. The HHS Secretary would be authorized to suspend a facility's registration if its food could reasonably cause serious adverse health consequences or death to humans or animals; there are provisions for a hearing opportunity and for submitting a corrective action plan to end suspension. Those with suspended registrations are barred from importing or introducing food into commerce. The House-passed bill would require annual registration and spell out additional types of information to be required of registrants; new fees would be imposed (discussed later in this report). The House-passed bill also would provide conditions for suspension of registrations.

Recordkeeping

Should Documentation Requirements and Access to Records Be Strengthened?

Many advocates of reform argue that recordkeeping requirements must be strengthened to improve the ability of regulators to determine whether firms are complying with the law and to facilitate efforts to find the source of problems (including during product recalls) when they do occur. One of their concerns has been that records do not have to be maintained in electronic format, which, 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, is the current "trigger" for accessing records (see next paragraph), 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.

Presently the FFDCa (at 21 U.S.C. 350c) authorizes the HHS 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,” then 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.¹⁶

Legislative Proposals

The major food safety bills contain recordkeeping requirements, but each proposal’s conditions for doing so, while seemingly nuanced, may be significant in impact. The House-passed bill would expand authority for the Secretary to access and copy all relevant records of a food company in order to determine whether a food is adulterated or misbranded by removing the requirement that the Secretary have “a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.” (Drafters of the bill view this as authority to access records during routine inspections.) The bill would remove the requirement to provide written notice before having such access, and would authorize the Secretary to require that records be kept for up to three years and be maintained in standardized electronic format.

The Senate bill would require that access be provided to the HHS Secretary if he or she “believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals.” (The Secretary would no longer be required also to have a reasonable belief as well of adulteration.) Access to records would have to be provided by “each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports such article.” Written notification and presentation of appropriate credentials would still be required to gain access.

Targeting of Inspections

How Often Should Plants Be Visited?

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

FDA inspection frequencies have been declining significantly, as the number of facilities rises and the agency’s workforce declines or remains flat. FDA reports that it has oversight of more than 136,000 registered domestic food facilities, which include more than 44,000 manufacturers and

¹⁶ FDA’s regulations on recordkeeping were promulgated in “Final Rule on Establishment and Maintenance of Records,” 69 *Federal Register* 71561, December 9, 2004.

processors and approximately 113,000 food warehouses, grain elevators and other storage facilities.¹⁷ A former FDA official set the number of currently registered facilities subject to regulation at 150,000 and added that the agency now conducts about 7,000 inspections of them per year—suggesting that plants are not visited, on average, more than once every 10 years. Because 6,000 are designated as high risk facilities to be visited at least yearly, that means that most others “never see an FDA inspector.”¹⁸

A key underlying problem, policymakers and stakeholders agree, has been the lack of resources, (also as discussed later in this report). For example, the overall number of FDA field investigators and compliance officers to inspect facilities and carry outbreak investigations (for foods, drugs and medical devices) dropped from approximately 4,000 in 2003 to 3,354 at the start of 2008, according to the Hubbard testimony.¹⁹

Legislative Proposals

The major bills seek to improve both the targeting and frequency of in-plant inspections, but in diverging ways. The House-passed bill would require the HHS Secretary to establish, within 18 months, a risk-based schedule for inspecting each food facility, following these prescribed categories and frequencies: Category 1, a high-risk food facility that manufactures or processes food must be inspected at least every 6-12 months; Category 2, a low-risk facility that manufactures or processes food or a facility that packs or labels food, must be inspected at least every 18 months to three years; and Category 3, a food facility that holds food, must be inspected at least every five years. The House bill would authorize the Secretary to modify the types of food facilities within each category, and to alter inspection frequencies if needed to respond to illness outbreaks and recalls. In doing so, the Secretary is to consider the type of food at the facility, its compliance history, whether an importing facility is certified (under the new certification requirements the bill would set; see below), and other factors determined relevant by the Secretary. The bill would authorize the Secretary to recognize a federal, state, or local official to conduct domestic facility inspections and an agency or representative of a foreign government to conduct foreign facility inspections.

¹⁷ *Food Protection Plan: An integrated strategy for protecting the nation's food supply*. These statistics do not include another approximately 2 million farms, 935,000 restaurants and other food service establishments, and 114,000 supermarkets and grocery stores, which may be subject to some, but not all, of the FDA requirements which apply to the 136,000 entities that were required to register. The agency relies heavily on state and local authorities to ensure safety in these facilities. Moreover, FDA counts an additional 189,000 registered foreign facilities that manufacture, process, pack or hold food for U.S. consumption (although the actual number of foreign facilities is likely much higher).

¹⁸ Hubbard, William, Former FDA Associate Commissioner for Policy and Planning, and Advisor, Alliance for a Stronger FDA, March 11, 2009, testimony before the House Energy and Commerce Subcommittee on Health. In the 1970s, there were 70,000 official establishments, and FDA was able to inspect 35,000 per year, which means each was inspected an average of every two years, he testified.

¹⁹ *Ibid.* The loss overall of FDA staff, which occurred during a period when Congress was mandating a number of new responsibilities for the agency, was documented in more detail in a major 2007 report by an FDA advisory board. See FDA Science Board, *FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology*, November 2007. Also see “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.

The Senate bill requires the HHS Secretary to allocate resources to inspect facilities according to their risk profiles based on such factors as the type of food, the facility's history of food recalls, outbreaks and violations, and so forth. Registered facilities must be inspected at least once every four years; high-risk facilities within two years of enactment and then annually; coordination with USDA is stipulated in order to target food resources. A provision in the Senate bill requires an annual report to Congress similar to that in the House measure.

On-Farm Safety Standards; Safety of Produce

Should Agricultural Producers Get More Scrutiny? ²⁰

Food safety experts agree that an effective, comprehensive food safety system should include consideration of potential hazards at the farm level. From this point, viewpoints diverge. Should farmers and ranchers be subject to mandatory safety standards, enforced through certification of their practices, periodic inspections, and penalties for noncompliance? Or, should public policy continue to encourage voluntary strategies for producing safe foods on farms and ranches, through education, cooperation, and market-based incentives? Historically, the federal and state governments have relied on the latter “carrot” approach that, in the view of some critics, is no longer effective. It also could be argued that numerous existing laws and regulations already impose restrictions, both direct and indirect, on producers of food commodities, which effectively meet food safety objectives—and also involve significant compliance costs. These restrictions include requirements on the use of animal drugs, feed additives, and pesticides.

FDA's “current good manufacturing practice” (CGMP) requirements (at 21 C.F.R. Part 110) apply to manufacturing, packing, or holding human food, but establishments engaged solely in harvesting, storing, or distributing raw agricultural commodities generally are excluded.²¹ Further, the 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 presenting a serious health threat.²² Such requirements pertain to anyone who “manufactures, processes, packs, distributes, receives, holds, or imports.” Farms are among those exempted from a requirement that food facilities be registered with FDA, pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.²³

²⁰ See also CRS Report RL34612, *Food Safety on the Farm: Federal Programs and Selected Proposals*, by Geoffrey S. Becker, and CRS Report RS22939, *FDA Authority to Regulate On-Farm Activity*, by Vanessa K. Burrows.

²¹ 21 C.F.R. 110.19(b). The 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.”

²² 21 U.S.C. 350c and 21 U.S.C. § 374. FDA has observed that produce farms generally do pack and hold food for introduction into interstate commerce, so it can and does inspect them periodically, usually in areas associated with illness outbreaks or to conduct surveillance sampling. Source: U.S. Congress, House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, Appropriations for 2008, Hearings, Part 5, p. 479.

²³ P.L. 107-188; 21 U.S.C. 350(d).

FDA's general approach has been not to impose mandatory on-farm safety standards or inspections of agricultural facilities.²⁴ Rather, the agency relies on farmers' adoption of so-called good agricultural practices to reduce hazards prior to harvest. Such practices are issued as FDA guidance, not regulations; they are advisory and not legally enforceable responsibilities.²⁵ In July 2009, the Obama Administration released new draft guidances on three specific types of produce: tomatoes, melons, and leafy greens.²⁶

Legislative Proposals

Pending food safety bills seek to bring more oversight to the farm level, but at varying intensity of regulation. The most extensive would have been the approach in the DeLauro bill, which would authorize the FSA Administrator to visit and inspect U.S. and foreign "food production facilities"—explicitly defined as "any farm, ranch, orchard, vineyard, aquaculture facility, or confined animal-feeding operation;" to review food safety records as required to be kept for purposes of food tracebacks and other purposes; and to set good practices standards, among several other specified activities.

The House-passed bill would require the Secretary to publish a notice of proposed rulemaking, and within three years after such date, final rules, establishing scientific and risk-based standards for the safe growing, harvesting, processing, packing, sorting, transporting, and holding of those types of raw agricultural commodities that are a fruit, vegetable, nut, or fungi, and for which the Secretary has determined such standards are reasonably necessary to minimize the risk of serious adverse health consequences or death to humans or animals.

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

The Senate bill also focuses on fresh produce, by requiring within one year proposed regulations for the safe production, harvesting, handling and packing of those fruits and vegetables (that are raw agricultural commodities) for which the HHS Secretary has determined that such standards minimize the risk of serious adverse health consequences or death. Required contents of the regulations do not appear to be as prescriptive. The bill would encourage coordination with

²⁴ The FDA advisory panel acknowledged that the agency "conducts only limited inspections of food-producing farms, except in emergencies." *FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology*.

²⁵ Sources: FDA, *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*, October 26, 1998, at <http://www.cfsan.fda.gov/~dms/prodguid.html>; and *Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables*, February 2008, at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm064458.htm>.

²⁶ Comments were accepted until October 2, 2009; see 74 *Federal Register* pp. 38437-38440.

USDA and would require, as appropriate, coordination with state agricultural agencies when enforcing standards. Enforcement may be in the form of audit-based verification systems or other inspection methods, and it includes language to enable a state or foreign government to request a variance from HHS if needed to account for local growing conditions. The Senate bill also 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.

Both the House-passed and Senate bills would require the issuance of updated good agricultural practices. Both seek to take into account the needs of small businesses and provide for coordination of enforcement and education activities with others such as USDA and state authorities. S. 510 was modified by the HELP Committee to require that the HHS Secretary “provide sufficient flexibility to be applicable to various types of entities engaged in the production and harvesting of raw agricultural commodities, including small businesses and entities that sell directly to consumers, and be appropriate to the scale and diversity of the production and harvesting of such commodities.” Other committee modifications to this section require consideration of federal conservation and environmental standards and policies including wildlife conservation, and assurances that these provisions will not conflict with or duplicate those of the national Organic Foods Production Act.

Food Imports

Concerns About Import Oversight²⁷

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. Import alerts in 2007 and 2008 targeting adulterated pet food ingredients, farmed seafood, and dairy products and ingredients, all from China, have been among the incidents that have heightened interest in this issue. Most of the recent debate has included extensive discussion about how to improve current import safeguards, within resource constraints, and without unduly restraining free trade.

The FFDCA [at 21 U.S.C. 381(a)] empowers the FDA to refuse entry to any food import if it “appears,” based on a physical examination or otherwise, to be adulterated, misbranded, or in violation of the law. In exercising its oversight, the agency relies on a system of prior notifications by importers and document reviews at points of entry (ports). Importers must have an entry bond and file a notification for every shipment. An FDA database, the Operational and Administrative System for Import Support (OASIS), is to help inspectors to determine a shipment’s relative risk and whether it needs closer scrutiny (i.e., a physical examination, and/or testing). In practice, import inspections are relatively infrequent. The agency recorded more than 8.2 million imported food “lines” in FY2007 (compared with fewer than 2.8 million entry lines in FY1997), of which approximately 1% were physically examined and/or tested.²⁸ In 2007

²⁷ This discussion is based in part on material in CRS Report RL34198, *U.S. Food and Agricultural Imports: Safeguards and Selected Issues*, by Geoffrey S. Becker, where more information can be found.

²⁸ Source: FDA briefing for Senate staff, February 8, 2008. FDA FY2009 budget materials state that 94,743 import food field exams were conducted in FY2007.

congressional hearings, witnesses testified that 450 inspectors must cover more than 300 ports of entry.²⁹

Current law does not explicitly authorize, or require, import verification, and whether FDA has what is often called “equivalence authority” has been a matter of debate. Regardless, it does not have a program like that of FSIS. Under the FMIA and PPIA, no foreign establishment can ship its products to the United States until FSIS has determined that the establishment’s country has a meat and/or poultry safety program that provides a level of protection that is at least equivalent to the U.S. system. FSIS visits the exporting country to review its rules and regulations, meets with foreign officials, and accompanies them on visits to establishments. In addition, FSIS operates a reinspection program at 150 import houses located near approximately 35 border entry points. Some have suggested that the FDA program should operate more like that of FSIS, although they acknowledge the difficulties and resource demands of attempting to regulate many more different types of foods from many countries of origin.

Legislative Proposals

The two bills seek tighter controls over imports, and both would use certification or verification systems involving so-called third parties (see below) to do so. More specifically, for example, under the House-passed bill, the Secretary would have to require, as a condition of granting admission for an imported food article, that a “qualified certifying entity provide a certification that the article complies with specified requirements” of the FFDCA. This requirement is to take effect on or after three years from the date of enactment. However, such certification would apply only in the following situations:

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

Another section of the House-passed bill would require an importer of foods to register annually with the Secretary, to submit an appropriate unique facility identification as a condition of such registration, and to meet “good importer practices” (the latter to include verification of good manufacturing practices and preventive controls of the importer’s foreign suppliers, as applicable), among other things. A provision in this section would require every person importing, or brokering for import of, a food to permit an officer or employee of the Secretary to “inspect the facilities of such person and have access to, and to copy and verify, any related records.” Any food offered for import that is not from a duly registered person would be misbranded under FFDCA § 403. (Fees are to be charged and are discussed later in this report.)

The Senate bill contains a provision authorizing the HHS Secretary, based on public health considerations, including risks associated with food or its place of origin, to require food imports

²⁹ See for example hearings held before subcommittees of the House Committee on Energy and Commerce, July 17, September 26, and October 11, 2007.

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 shall be used for designated food imported from countries where FDA has an agreement for a certification program. Certifying entities are to be an agency or representative from the originating country or such other persons as accredited elsewhere (see also “Use of Third Parties for Imports and for Laboratory Accreditation,” below). Among separate but related provisions in both bills is specific authorization 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 Senate bill also contains a “Foreign Supplier Verification Program,” generally requiring each importer to perform foreign supplier verification activities in accordance with regulations the Secretary must issue to ensure compliance with relevant FFDCAs provisions. Each importer’s program must be able to assure that each of its foreign suppliers produces the imported food employing processes and procedures, “including risk-based reasonably appropriate preventive controls, that are documented in a written plan ... and equivalent in preventing adulteration and reducing hazards as those required” by other relevant provisions of the FFDCAs. Verification activities may 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 must maintain import verification program records for at least two years and make them available to the Secretary upon request. The House bill also contains provisions for foreign supplier verification.

A feature of both major bills would require the establishment of a program to expedite imports from those who voluntarily agree to certain higher safety standards. This program is called a “Safe and Secure Food Importation Program” in the House-passed bill and a “Voluntary Qualified Importer Program” in the Senate bill.

Use of Third Parties for Imports and for Laboratory Accreditation

Can Non-FDA Entities Help Ensure Safety?

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 being asked to stretch and carefully target limited numbers of inspection dollars and personnel. Among many complex 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), which certify primarily food-quality and marketing traits and which are funded through user fees.³⁰

FDA does not currently regulate or otherwise accredit private laboratories that analyze imported, FDA regulated goods, nor does it accredit or use others to certify the safety of imported foods. (The agency does have agreements with state authorities upon which it relies to conduct many of its plant inspections, for example.) In January 2009, the agency issued a new guidance document setting criteria for others’ use of voluntary third-party certification programs for foods and animal feeds (hereinafter foods), noting that

An increasing number of establishments that sell foods to the public, such as retailers and food service providers, are independently requesting, as a condition of doing business, that their suppliers, both foreign and domestic, become certified as meeting safety (as well as other) standards. In addition, domestic and foreign suppliers (such as producers, co-manufacturers, or re-packers) are increasingly looking to third-party certification programs to assist them in meeting U.S. regulatory requirements. The Federal government supports voluntary certification programs as one way to help ensure products meet U.S. safety and security standards and to allow Federal agencies to target their resources more effectively.³¹

However, the use of third parties, and FDA’s apparent desire to rely more heavily on them, remains controversial, for a number of reasons. Critics contend that although third-party certification may be useful as a commercial marketing tool, it does not ensure safety, as recent food contamination incidents have illustrated. For example, the Peanut Corporation of America plant, cited as the source of the *Salmonella* Typhimurium infections in late 2008 and early 2009, had passed several private third party and state inspections. At the same time, private laboratory tests of its products, even when they indicated pathogens were present, were not reported (and were not required to be reported) to government authorities.

“An examination of the largest food poisoning outbreaks in recent years—in products as varied as spinach, pet food, and a children’s snack, Veggie Booty—show that auditors failed to detect problems at plants whose contaminated products later sickened consumers,” reported an article critical of such private inspections.³² The Chairman of the House Energy and Commerce Committee commented that the *New York Times* “report raises issues of conflict of interest and shows auditors don’t catch problems at these plants, even appearing to award bad actors like PCA superior and excellent ratings.”³³ Other import questions besides “who inspects” include what third-party qualifications and other expectations should be, and exactly what type of inspection

³⁰ These programs are described on the AMS website <http://www.ams.usda.gov/AMSV1.0/>, under “Grading, Certification, and Verification.”

³¹ FDA, *Guidance for Industry: Voluntary Third-Party Certification Programs for Foods and Feeds*, accessed March 12, 2009 at <http://www.fda.gov/oc/guidance/thirdpartycert.html#I>. FDA stated that the “guidance is intended as one of the steps in FDA’s future recognition of one or more voluntary third-party certification programs for particular product types.” The document also defines a third party here as “an organization other than the establishment or FDA (or another governmental entity acting under our authority, such as a State regulatory authority, with which FDA has a contract, partnership arrangement, or MOU for the purpose of conducting inspections that pertain to the establishment’s compliance status with FDA requirements). A third party could include a Federal, State, local, or foreign government authority that is not conducting inspections under our authority, as well as a private entity.”

³² Moss, Michael, and Andrew Martin, “Food Safety Problems Slip Past Private Inspectors,” *The New York Times*, March 6, 2009.

³³ House Energy and Commerce Committee Chairman Henry Waxman, comments during a March 11, 2009, hearing before the Subcommittee on Health, entitled “How Do We Fix Our Ailing Food Safety System?”

procedures are going to be the most effective—at the least, such questions cannot be answered independently of one another, some food safety experts have argued.

Legislative Proposals

The major bills take a number of approaches toward incorporating third party certifications into import inspections and laboratory accreditation. The Senate bill would require third party auditors and audit agents to issue written and electronic certifications to accompany each food shipment import. The HHS Secretary would have to develop model accreditation standards and to establish a system for the “recognition of accreditation bodies that accredit third-party auditors and audit agents to certify that eligible entities meet the applicable requirements” of the FFDCA. (The HELP Committee altered S. 510 to authorize the HHS Secretary to directly accredit third parties if the Secretary has not recognized an accrediting body within one year of the program’s establishment.) Foreign governments, foreign agricultural cooperatives and other third parties the Secretary deems appropriate could apply to an accreditation body to be a third party auditor or audit agent, after the accreditation body performs the reviews prescribed in the bill. The bill also contains extensive language regarding required reports, to include detailed notification by a third-party auditor any time a condition is discovered that could cause or contribute to a serious public health risk, terms for withdrawal of accreditation, and avoidance of conflicts of interest.

The Senate bill includes provisions mandating the recognition of accreditation bodies to accredit laboratories, including laboratories of states and localities. These provisions call for the development of model accreditation standards, re-evaluation of accreditation bodies at least every five years, the delisting of those not in compliance, and a requirement that laboratory test results be sent to the FDA, among other things.

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

The House-passed bill also contains requirements for new laboratory accreditation programs. Both the Senate and House bills further stipulate the purposes for which accredited laboratories are to be used.

Notification and Recall; Product Tracing

Removing Unsafe Foods From Commerce

Currently, neither FDA nor FSIS has explicit statutory authority to order a recall of adulterated foods, require a company to notify them when it has distributed such foods, or impose penalties if recall requirements are violated. (FDA can order such recalls for infant formula, and for unsafe medical devices, such as pacemakers, as can other agencies for unsafe toys or automobiles.) These gaps increase the possibility that unsafe food will not be recovered and will be consumed, GAO and others have contended.³⁴

Defenders of the current system counter that the agencies already have sufficient authorities to keep such products from reaching consumers. FSIS's statutory authority enables it to detain meat and poultry products of concern for up to 20 days, and FDA's authority enables it to detain the foods it regulates for up to 30 days. Both agencies can, with a court's permission, seize, condemn, and destroy unsafe food.³⁵ Private companies rarely if ever fail to order a voluntary recall when problems arise; creating mandatory authority might foster a counterproductive adversarial relationship between industry and government, slowing response times, it is argued. Nonetheless, a number of Members of Congress support GAO's recommendation that legislation be considered to strengthen the notification and recall authorities of both agencies.

The Bush Administration's November 2007 strategy for food safety called for mandatory recall authority (for FDA, not FSIS) in cases where firms (whether foreign or domestic) are unwilling to do so voluntarily or expeditiously. FDA notes that it already has the authority to seize adulterated or misbranded food, but this may not be practical once a product is in wide distribution. Significantly, the Grocery Manufacturers Association (GMA), among other major food industry groups, has endorsed the proposal for mandatory recall authority.

Notification and traceability are viewed as tools for making recalls more effective. Some have argued that improved notification and traceability capabilities would enable either FSIS (in the case of meat and poultry products) or FDA (in the case of other foods) to determine more quickly a product's source and whereabouts, to prevent or contain foodborne illness outbreaks. The traceability issue has also been debated in connection with protecting against agroterrorism, and for verifying the U.S. origin of live animals and their products for marketing, trade, and/or animal health purposes, for example.

The 110th Congress addressed this issue by including provisions in the Food and Drug Administration Amendments Act of 2007 (P.L. 110-85) which require the HHS Secretary both to establish a food registry for the reporting of food adulteration, and to encourage more coordination and communication when recalls occur.³⁶ The enacted 2008 farm bill (P.L. 110-246)

³⁴ See, for example, *Food Safety: USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food* (GAO-05-51), October 2004. For additional background, see CRS Report RL34167, *The FDA's Authority to Recall Products*, by Vanessa K. Burrows, and CRS Report RL34313, *The USDA's Authority to Recall Meat and Poultry Products*, by Cynthia Brouger and Geoffrey S. Becker.

³⁵ A court's permission may not be needed in all cases; for example, the FFDCA [§801(j)(1)] empowers officials to hold an import for up to 24 hours if there is "credible evidence or information indicating that an article of food presents a threat of serious adverse health consequences or death to humans or animals."

³⁶ In May 2008, FDA reported a delay in implementing the provision, saying that it planned to integrate the reporting mechanism for foods (including foods for humans as well as animal feeds) into an agency-wide reporting system under (continued...)

amends the meat and poultry laws to require an establishment to notify USDA if it has reason to believe that an adulterated or misbranded product has entered commerce. Another farm bill provision requires meat and poultry establishments to prepare and maintain written recall plans.

Legislative Proposals for Notification and Recall

Notification and recall and authorities are key elements of the major food safety proposals offered in the 111th Congress. For example, the House-passed bill would require a responsible party, or a person required to register in order to import food, to notify the Secretary if there is reason to believe that an article of food when introduced into or while in interstate commerce, or while held for sale (regardless of whether the first sale) after shipment in interstate commerce, is adulterated or misbranded in a manner that presents a reasonable probability that the use or consumption of, or exposure to, the article (or an ingredient or component used in any such article) will cause a threat of serious adverse health consequences or death to humans or animals. (This language is similar to the reporting threshold currently established under the FFDCA.) This section of the House bill would authorize the Secretary to request a voluntary recall by any person who distributes an article of food that the Secretary has reason to believe is adulterated, misbranded, or otherwise in violation of the FFDCA. It would further authorize the Secretary to issue an order to cease distribution of any article of food if the Secretary has reason to believe that the use or consumption of, or exposure to, that article of food may cause adverse health consequences or death to humans or animals, with an appeal process and other administrative matters specified (including limits on the Secretary's authority to delegate decisions regarding orders). The Secretary would be required to issue a mandatory recall order if the Secretary determined that problems have not been adequately addressed through the procedures described above.

Other language in this section of the House bill would authorize the Secretary to proceed directly to a mandatory recall order if the Secretary has credible evidence that an article of food subject to an order to cease distribution presents an imminent threat of serious adverse health consequences or death to humans or animals. In such case, the person would have to immediately recall the food while stipulated appeal procedures were being carried out, among other provisions in this section.

Regarding the reportable food registry, the House bill would extend reporting requirements to farms where food is produced for sale or distribution in interstate commerce, to restaurants and other retail food establishments, and to those required by this bill to register as importers. The bill would also newly require the reporting of documented results of any sampling and testing of a reportable food article and of a component of a food article, including tests conducted pursuant to the new hazard analysis and preventive controls provisions, the new food safety plan, the new performance standards, or the testing by accredited laboratories.

The Senate bill also would require the HHS Secretary, if he/she has information “that there is a reasonable probability that an article of food (other than infant formula) is adulterated ... or misbranded ... and the use of or exposure to such article will cause serious adverse health

(...continued)

development. In June 2009, FDA announced a further delay in the implementation of the registry until September 8, 2009, in order to consider any comments received on draft guidance and through the agency's planned outreach initiatives, and to allow for further testing of the electronic portal for reportable foods. The registry is now in place; see the FDA website at <http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/RFR/default.htm>.

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 would be provided to require such person to cease distribution, or to immediately notify everyone involved in handling or receiving the food.

Legislative Proposals for Traceability

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

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

The Senate bill does not contain the House requirement for as extensive a tracing system. Rather, it requires the Secretary, in consultation with USDA and state departments of agriculture, to improve FDA’s capacity to effectively and rapidly track and trace, in the event of an outbreak, fruits and vegetables that are raw agricultural commodities. It would require proposed rules within three years of enactment for standards on the type of information, format, and time frame for persons to submit records to aid in such tracebacks, and would also mandate three pilot projects, in coordination with the produce industry, to evaluate new methods for more effectively conducting such tracebacks.

The HELP Committee also altered S. 510 to require the HHS Secretary, when promulgating rules, to consider their impact on farms and small businesses, as well as the findings of the pilot projects and international trade obligations. The committee version further included language limiting the types of records that the Secretary could request. Finally, the committee added a new provision to S. 510 requiring a pilot project to evaluate methods for more effectively tracing processed foods in the event of an illness outbreak.

Foodborne Illness Surveillance and Outbreak Response

How Might Data Collection and Use Be Strengthened?³⁷

Surveillance for foodborne illness is carried out by the states, with federal assistance from the CDC. States also conduct investigations of foodborne illness outbreaks, in coordination with CDC, either FDA or FSIS, or both (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, under broad, permanent authorities in the FFDCA (at 21 U.S.C. 372 and 21 U.S.C. 399) and Title III of the Public Health Service (PHS) Act (at 42 U.S.C. 241, 42 U.S.C. 243 and 247b, and 42 U.S.C. 247b-20), among others.

A foodborne disease outbreak is not defined in law or in regulations. In public health practice, a “foodborne disease outbreak” is “the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food.”³⁸ As a practical matter, particularly for less serious hazards, outbreak investigations are rarely launched when only two people are affected, although there are exceptions, such as for botulism.

The nation’s public health capacity for foodborne illness surveillance and outbreak response is a mix of significant strengths and significant gaps. In the last decade or so, the linkage of previously unrelated illnesses through genetic “fingerprinting” has revolutionized the ability to identify large multistate outbreaks and mount an urgent response.³⁹ However, the epidemiological tools used to find the food associated with an illness can be cumbersome. Also, especially for FDA-regulated foods, information about common contaminants that may be present during production and in commerce, as well as how to test for them, is limited. As a result, “attribution”—identifying the types of foods associated with outbreaks or isolated foodborne illnesses—remains a significant challenge. The daunting outbreaks of the past few years underscore the problem, but are not the only evidence. Based on data from its active surveillance system, FoodNet, CDC reported that in 2007, the incidence of several of the foodborne diseases under surveillance since 1996 had reached a plateau, instead of declining, and that national 2010 health targets for these diseases may not be met.⁴⁰

“For all actors in the food safety system—public and private—the effectiveness of what they do depends on the quality of information they have on potential hazards and how to minimize them. Thus, any effort to improve the food safety system must address how a wide range of institutions and individuals meet their information needs.”⁴¹ Ultimately, because regulators regulate foods, and not the contaminants in isolation, many contend that closing the “attribution” gap is paramount in order to target preventive strategies efficiently, and mount a more nimble response

³⁷ Prepared by Sarah A. Lister, Specialist in Public Health and Epidemiology, Domestic Social Policy Division.

³⁸ CDC, “Surveillance for Foodborne-Disease Outbreaks: United States, 1998–2002,” *Morbidity and Mortality Weekly Report (MMWR)*, vol. 55 (Surveillance Summary 10), pp. 1-34, November 10, 2006.

³⁹ See, for example, the CDC PulseNet program, <http://www.cdc.gov/pulsenet/>.

⁴⁰ Centers for Disease Control and Prevention, “Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food—10 States, 2007,” *MMWR*, vol. 57, no. 14 (April 11, 2008), pp. 366-370.

⁴¹ Taylor, Michael R., and Michael B. Batz, *Harnessing Knowledge to Ensure Food Safety: Opportunities to Improve the Nation’s Food Safety Information Infrastructure*, 2008, Food Safety Research Consortium, Gainesville, Florida, and School of Public Health and Health Services, The George Washington University, Washington, D.C.

to outbreaks. But doing so is a challenge, raising concerns about available technologies, scientific soundness, intellectual property and “trade secret” protections, liability, and others.

Legislative Proposals

The Senate bill defines, for purposes of surveillance, a “foodborne illness outbreak” as two or more cases of a similar illness resulting from the ingestion of a food. The bill would require the Secretary, acting through the CDC, to enhance foodborne surveillance systems to improve the collection, analysis, reporting and usefulness of foodborne illness data, including by coordinating federal, state, and local systems, facilitating the sharing of agency findings on a more timely basis, ensuring early notification of the food industry when a particular food is suspected in an outbreak, developing improved epidemiological tools, and other prescribed methods. The bill also would require the establishment of an advisory group on improving foodborne illness surveillance and outbreak investigations; mandate strategies to leverage and enhance the food safety and defense capabilities of state and local agencies; and renew authority for food safety capacity-building grants, as has been authorized under the PHS Act.⁴²

The House-passed bill generally mirrors the Senate bill except that it lacks the provisions establishing an advisory group and renewing capacity-building grants.

Paying for Food Safety

How Much Is Needed and Who Should Pay?

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. According to the report released in late 2007 by the FDA Science Board, the FDA Commissioner’s expert advisory panel, a critical lack of resources has seriously weakened the FDA’s scientific basis generally and its mission to protect the food supply particularly. The report concluded in part, “... the Agency suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities.” The report tied these deficiencies to two sources: (1) demands on FDA have soared due in part to major advances in science and in the complexity of new products, and to the globalization of the industries the agency regulates; and (2) resources have not increased in proportion to the demands. Such demands include an accumulation of unfunded legislative mandates imposed by Congress, the report stated.⁴³

The report singled out the FDA’s two food safety centers, CFSAN and CVM, where crisis management has “drawn attention and resources away from FDA’s ability to develop the science base and infrastructure needed to efficiently support innovation in the food industry, provide

⁴² The HELP Committee added a new provision to S. 510 that would require the HHS Secretary to establish regulatory training and education programs for state, local, and tribal food safety officials. The provision would authorize the use of those officials to conduct examinations, testing, and investigations. A related new section would authorize appropriations for grants to such entities for these and related activities.

⁴³ FDA Science Board, *FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology*, November 2007.

effective routine surveillance, and conduct emergency outbreak investigation activities to protect the food supply.” Also, it noted that “[a]n appallingly low inspection rate” leaves FDA unable to

sufficiently monitor either the tremendous volume of products manufactured domestically or the exponential growth of imported products. During the past 35 years, the decrease in FDA funding for inspection of our food supply forced FDA to impose a 78 percent reduction in food inspections, at a time when the food industry has been rapidly expanding and food importation has exponentially increased.⁴⁴

Responding to a subsequent request from Democratic leaders of the House Energy and Commerce Committee, a Science Board subcommittee estimated that, in order to address the deficiencies detailed in the report, the FDA’s appropriated (non-user fee) budget should be significantly but gradually increased overall, from an estimated \$1.5 billion in FY2008, to \$3.7 billion by FY2013. The FDA budget for foods was \$577 million in FY2008; the subcommittee recommended that the food-related portion of the appropriation should be increased by \$128 million in FY2009, \$283 million in FY2010, \$441 million in 2011, \$598 million in FY2012, and \$755 million in 2013.⁴⁵

In fact, congressional appropriators have increased funding for FDA food safety activities for FY2008 and FY2009. For example, the Omnibus Appropriations Act, 2009 (P.L. 111-8) provided a \$325 million increase for the agency, including more than \$140 million for food safety. Congress appears likely to provide further increases in the FY2010 budget, in line with the Obama Administration’s request for more than \$1 billion for FDA food safety activities. This would be an increase of nearly \$260 million above the FY2009 level.

Proposed increases in program spending raise a variety of policy issues. Requests for higher appropriations always compete with other priorities throughout the federal discretionary budget (the programs do not operate, like farm support programs, for example, as mandatory authorizations), and currently are being made during a period of huge budget deficits. Efforts to fill perceived shortfalls through new user 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 “taint” programs that are first and foremost public health programs. (Certain types of fees, such as for facility registration, have not been as vociferously opposed by some consumer advocates.) Nonetheless, a number of pending food safety bills discussed in this report include proposed industry fees—some quite extensive—to pay for such activities as facility registration, certification of food imports, re-inspection of products initially kept out of commerce, and the auditing of private food testing laboratories.

Currently, FDA is authorized to collect several types of fees. Among them are user fees and import 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, (21 U.S.C. 379g - 379j-12). These fees are intended to be used to fund approval-related activities; they can be used to fund enforcement or inspection activities for products on the market only to a very limited extent, if at all. (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 been authorized in five-year increments. Each

⁴⁴ Ibid.

⁴⁵ *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.

authorization specifies the fee amounts FDA may collect annually, among other legislative direction. FDA's authority to collect export certification fees extends to drugs, medical devices and biological products [21 U.S.C. 381(e)(4)]. A person who exports a human drug, animal drug, or device may request that the Secretary certify in writing that the product meets FFDC requirements. If the Secretary issues a written export certification, a fee may be charged.

Legislative Proposals

The House-passed bill would establish a variety of fees to help fund food safety activities, including

- a facility registration fee collected each year from facilities required to register under FFDC § 415. This fee is to be set at \$500 per facility in FY2010; for FY2011 and each subsequent fiscal year, the fee is to be adjusted to reflect the cost of inflation, under a specified formula. The bill also would set a maximum annual fee payment of \$175,000 for those who have multiple facilities.
- a fee from each facility that either violates any food-related requirement of the FFDC and therefore must undergo additional FDA inspection; or is subject to a food recall. The Secretary would have to set the fee at a level to fully cover the reinspection and/or recall costs and use the collection solely for that purpose.
- an export certification fee the Secretary may impose if an export certificate is required of U.S. exporters of foods and animal feeds. The fee shall be “reasonably related” to the cost of issuing such certificates.
- an annual fee for the registration of an importer of food, also set at \$500.

The Congressional Budget Office (CBO) has estimated that the House bill would collect fees totaling approximately \$1.4 billion over five years, but that an additional \$2.2 billion in discretionary outlays would be needed over those five years to cover the cost of the bill's new requirements including more inspections.⁴⁶

The Senate bill would require the assessment of differing fees to cover the costs of reinspections of facilities, including those subjected to a food recall to cover such recall costs, of importers subject to reinspections, and of importers participating in the voluntary qualified importer program. The bill provides the methodology for determining the amounts of such fees (generally to be designed to cover all costs); includes limitations on such fees, including an annual limit on annual total collections related to recalls to \$20 million and on annual collections for reinspections to \$25 million; and authorizes the collection of export certification fees for food, including animal feed.

The Senate bill also authorizes, for FDA's food safety and veterinary medicine activities and related field activities, appropriations of \$825 million for FY2010 and such sums as may be necessary for FY2011 through FY2014. Also, the Secretary is required to increase field staff, with a goal of not fewer than 3,800 staff members in FY2010, 4,000 in FY2011, 4,200 in FY2012, 4,600 in FY2013, and 5,000 in FY2014. Within these increases, 150 new field staff by 2011 are to be devoted to food defense activities. (CBO had not scored the Senate bill as of this writing.)

⁴⁶ The CBO estimate and supporting details are in the July 29, 2009, House report on H.R. 2734 (H.Rept. 111-234).

Organization of Food Safety Responsibilities

Would Restructuring Improve Oversight?

The current divisions of federal responsibility for food safety are rooted in the early history of U.S. food regulation. Congress created separate statutory frameworks when it enacted, on the same day in 1906, both the Pure Food and Drugs Act and the Meat Inspection Act. The former was passed to address the widespread marketing of intentionally adulterated foods, and its implementation was assigned to USDA's Bureau of Chemistry. The latter law was passed to deal with unsafe and unsanitary conditions in meat packing plants, and implementation was assigned to a different USDA agency, the Bureau of Animal Industry. This bifurcated system has been perpetuated and split further into additional food safety activities under additional agencies (for example, the Environmental Protection Agency, the National Marine Fisheries Service, and others) by a succession of statutes and executive directives. The separation of the two major food safety agencies was further reinforced when, in 1940, the President moved responsibilities for safe foods and drugs, other than meat and poultry, from USDA to the progenitor of HHS, the Federal Security Agency. Meat inspection remained in USDA.⁴⁷

Critics have argued for decades that this dispersal of food safety responsibilities has been problematic. In its annual (January 2007) report, where it designated food safety oversight as a "high risk" federal program area, the Government Accountability Office called the current federal safety system "fragmented," resulting in:

inconsistent oversight, ineffective coordination, and inefficient use of resources. GAO has recommended that Congress consider a fundamental reexamination of the system and other improvements to help ensure the rapid detection of and response to any accidental or deliberate contamination of food before public health and safety is compromised.⁴⁸

The GAO echoed the observations and recommendations of a number of other reports and studies. For example, a committee of the National Academy of Sciences-National Research Council concluded in a 1998 report that a strong federal role "requires central management of now-dispersed efforts," noting that the various agencies report to different congressional committees, sometimes compete for resources and public attention, and all lack direct access to the White House.⁴⁹

Opponents of major structural changes, including some in the food and agricultural industries, assert that the system already is scientifically based, that the statutes are adequate, and that food companies already produce and distribute safe food, making the U.S. system a model for food safety around the world. A number of those pressing for food safety reform have cautioned that a reorganization, while it might have merit, could divert time and attention from other fundamental problems in the system.

⁴⁷ For an extensive discussion of the history of federal food safety organization and of efforts to change it, see Merrill, Richard A. and Jeffrey K. Francer, "Organizing Federal Food Safety Regulation," *Seton Hall Law Review*, Vol. 31:61, 2000.

⁴⁸ *High Risk Series: An Update*.

⁴⁹ *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.

Legislative Proposals

Past debates have examined proposals to combine all federal food safety agencies and authorities under a single, possibly Cabinet-level, agency. Recent discussions have focused on more limited options such as transferring FDA's food safety activities to a new food safety agency within HHS. This option is encompassed by the DeLauro bill (H.R. 875), creating a Food Safety Administration with an Administrator appointed to a five-year term by the President and confirmed by the Senate. Among other provisions, the measure would transfer all functions, personnel, and assets of the following offices: FDA's Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, and National Center for Toxicological Research; all portions of both the FDA Office of Regulatory Affairs and the FDA Commissioner's Office devoted to food safety; and the seafood inspection program operated by the National Marine Fisheries Service in the Department of Commerce.

Neither the House-passed nor Senate measure encompasses a major reorganization of food safety agencies, and the Obama Administration had not announced its position on this question as of late November 2009.

Table I. Comparison of Selected Provisions of Major Food Safety Bills

S. 510 as Approved by Committee	H.R. 2749 as Passed by House
Facility Registration Changes	
<p>Requires domestic and foreign food facilities to register every 2 years, with some additional types of contact information; abbreviated renewal process for those with no changes. No registration fee. Authorizes suspension of registration when a food presents “a reasonable probability of causing serious adverse health consequences or death to humans or animals.” No changes in definition of “facility” (i.e., farms and retail food establishments continue to be exempt). [Sec.102]</p>	<p>Requires domestic and foreign food facilities to register every year, with some additional types of contact information; no abbreviated renewal process. Annual registration fee of \$500 per facility; maximum is \$175,000 for multiple facilities. Authorizes suspension “for a violation of this Act [FFDCA] that could result in serious adverse health consequences or death to humans or animals.” Farms and retail food establishments continue to be exempt, but extensive new language defines these terms to clarify exemptions. [Sec. 101]</p> <p>Other sections set new registration requirements for food importers. Commercial importers but not customs brokers are subject to \$500 annual registration fee. [Secs. 204, 205, 206]</p>
Access to Records	
<p>Requires that access be provided if the HHS Secretary (hereinafter, 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.” (Reasonable belief of adulteration also is no longer required.) Appropriate credentials and written notice still required, among other access limitations. Applies to all records related to manufacture, processing, packing, distribution, receipt, holding, or importation of a food. Farms and restaurants continue to be exempted. [Sec. 101]</p>	<p>Broadens existing authority to access records by deleting the following condition in current law: “If the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals...” (Appears to authorize access during routine inspections.) No longer requires written notice before accessing records. Applies to all records related to manufacture, processing, packing, distribution, receipt, holding, or importation of a food. Spells out conditions for Secretary’s remote access to records. Restaurants are newly subjected to some records access requirements. New records access provisions do not apply to farms—except where the article of food is a fruit, vegetable, or fungus that has a standard or is the subject of an active foodborne illness investigation and is not a grain or similarly handled commodity (basically, a price-supported row crop). [Sec. 106]</p>
Hazard Analysis and Preventive Controls	
<p>Requires the facility owner, operator, or agent in charge to develop a written plan and carry out certain preventive activities in the plan, to include: identification and evaluation of known or reasonably foreseeable hazards, identification and implementation of appropriate controls with verification, monitoring of effectiveness, corrective actions when controls are not effective, and maintenance of records for 2 years. Written plans with documentation must be made promptly available to the Secretary’s representative upon an oral or written request.</p> <p>The plan must be reanalyzed at least every 3 years, or sooner if there is a change in processes/practices that could create or increase a hazard or if the Secretary requires it. Both unintentionally and intentionally introduced hazards must be analyzed.</p> <p>Within 18 months of enactment, the Secretary <i>must</i> issue regulations with science-based <i>minimum</i> standards for such plans, to include sufficient flexibility for all situations, including small businesses (small and very small businesses as defined by the Secretary <i>must</i> receive additional time to comply). The Secretary <i>may</i> exempt or modify compliance</p>	<p>Sets broadly similar requirements to those in the Senate bill, but differs in organization and appears to be more detailed and somewhat more prescriptive. For example: a written plan must be developed and implemented <i>before</i> a facility introduces food into commerce; a <i>description</i> of verification activities must be in the plan, with validation of effectiveness to include the use of environmental and testing programs; the plan must also include procedures to ensure the safety of supply chain ingredients. Records must be maintained for 2 years.</p> <p>The plan must be reanalyzed every 2 years, or sooner if there is a change in processes/practices or the Secretary requires it to protect public health. Another difference is that higher-risk facilities will have to submit finished product test results to the Secretary for contaminants “posing a risk of severe adverse health consequences or death.”</p> <p>The Secretary <i>must</i> issue regulations with science-based standards for such plans, and <i>may</i> by regulation or guidance identify reasonably likely hazards and also may do so for specific product types. However, a facility owner, operator, or agent must be allowed to implement an alternative preventive control program if it can be demonstrated to be as effective. Also, the</p>

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requirements for facilities engaged solely in food production for animals or solely in the storage of raw agricultural commodities for further distribution (other than fruits and vegetables), or for storage of packaged foods not exposed to the environment. [Sec. 103]

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Secretary *must* take into account both international standards for consistency, and impact on small businesses (with guidance to assist them in complying). Also permits the Secretary to exempt or modify compliance requirements for animal food production and for storage of foods, as well as to exempt the storage of raw agricultural commodities for further distribution or processing.

Addresses *intentional* adulteration by requiring facilities to have written food defense plans before introducing food into commerce. [Sec.102]

Performance Standards

Requires the Secretary at least every 2 years to review relevant health data and other information to determine the most significant foodborne contaminants. Requires the Secretary to issue science-based documents, action levels, or regulations “when appropriate to reduce the risk of serious illness or death to humans or animals.” These must apply to products or product classes, not facilities. [Sec. 104]

Requires the Secretary at least every 2 years to review epidemiological and other appropriate data to identify the most significant foodborne contaminants. Requires the Secretary to both publish a list of those contaminants with the greatest adverse impact on public health, and to issue (through guidance or regulation)

“as soon as practicable” science-based *performance standards* (which may include action levels) “as appropriate, to minimize to an acceptable level, prevent, or eliminate the occurrence of such hazards.” Standards must be “as necessary to protect public health” and be applicable to foods and food classes. [Sec. 103]

On-Farm Safety (Produce)

Requires rules “to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death.” The Secretary must consult with the Secretary of Agriculture and state agriculture departments (including with regard to the national organic foods program) and conduct at least three public meetings on the proposals.

Requires rules that “establish by regulation scientific and risk-based food safety standards for the growing, harvesting, processing, packing, sorting, transporting, and holding of those types of raw agricultural commodities (1) that are a fruit, vegetable, nut, or fungus; and (2) for which the Secretary has determined that such standards are reasonably necessary to minimize the risk of serious adverse health consequences or death to humans or animals.” The Secretary must coordinate with the Secretary of Agriculture, including on education and compliance activities.

Regulations *must* include minimum standards for safety deemed “reasonably necessary,” standards related to soil amendment, hygiene, packaging, temperature controls, animal encroachments, and water; and address natural, unintentional, and intentional hazards. The Secretary *must* prioritize implementation for fruits and vegetables that have been associated with foodborne illness outbreaks. Regulations also *must* provide a reasonable time for compliance, taking into account the needs of small businesses; provide for coordination of education and enforcement with state and local officials, as well as contracting and coordination with states for enforcement. The Secretary *must* permit states and foreign countries to request “variances” from these regulations where it is determined necessary “in light of local growing conditions.” Requires procedures for considering such variances. Further requires the proposed rules to provide sufficient flexibility for application to various types of entities, including small businesses and those selling directly to consumers, and to “be appropriate to the scale and diversity of the production and harvesting of such commodities.” The proposed rules

Regulations *may* cover such elements as actions reasonably necessary to prevent both unintentional and intentional hazards; standards for safety deemed “reasonably necessary”; standards for manure use, water quality, employee hygiene, sanitation and animal control, and temperature controls; and provide for coordination of education and training with other government agencies, universities, private entities and others with experience working directly with farmers; among other cited elements. Regulations *must* provide a reasonable time for compliance, taking into account the needs of small businesses, and taking into consideration (consistent with public health) the impact on “small-scale and diversified farms, and on wildlife habitat, conservation practices, watershed-protection efforts and organic production methods.” [Sec. 104]

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must also take into consideration federal conservation and environmental practices and policies. Finally, the requirements in the proposed rules cannot conflict with or duplicate those established under the national Organic Foods Production Act. (Such stipulations must, however, continue to provide for public health.) [Sec. 105]

Traceability

Requires the Secretary to improve his/her capacity to effectively and rapidly track and trace, *in the event of an outbreak, fruits and vegetables that are raw agricultural commodities*. Requires the Secretary to publish, within 3 years, rules for standards on the type of information, format and timeframe for persons to submit records to aid the Secretary in such tracking and tracing. These regulations shall consider the impact on farms and small businesses, and the bill sets some limitations on the types of records the Secretary may require. Also details requirements for a pilot project with report to Congress, and for public meetings on the regulations. [Sec. 204]

Establishes a pilot program to evaluate methods for more effectively tracking processed foods in the event of a foodborne illness outbreak. [Sec. 205]

Requires the Secretary to establish by regulation a tracing system for *domestic and imported food*, which must enable the Secretary to identify each person who grows, produces, manufactures, processes, packs, transports, holds or sells such food as soon as possible but no longer than 2 business days. Prior to proposing rules, the Secretary must identify tracing technologies that among other things enable each food industry sector to maintain full pedigree; assess costs and benefits; and conduct at least one pilot and two public meetings.

Contains extensive language intended to limit the applicability to farms. For example, food that is produced on a farm (or fishery) and sold directly to a consumer, restaurant, or grocery store is exempt, except that farms and fisheries must keep records for at least 6 months on who they sold to (and the restaurants and grocery stores must keep records on their farm/fishery sources). Permits the Secretary to exempt a type of food, facility, farm or restaurant from, or modify, the regulations upon a determination that tracing “is not necessary to protect the public health,” although such exempted persons would still have to have records on their immediate prior sources and immediate subsequent recipients.

Other farm-related considerations include a requirement to coordinate with the Secretary of Agriculture and limitations on traceback as it affects growers of grains or “similarly handled commodities” (basically, price-supported row crops). [Sec. 107]

Food Registry Changes

No changes.

Extends food registry reporting requirements to farms where food is produced for interstate commerce, to restaurants and other retail food establishments, and to importers; also requires the reporting of certain food testing results. [Sec. 112]

Recall Authority

Requires the Secretary to request a responsible party to recall a food if the Secretary determines, based on information gathered through the reportable food registry or any other means “that there is a reasonable probability that an article of food” (other than infant formula) is adulterated or misbranded “and the use or exposure to such article will cause serious adverse health consequences or death to humans or animals.” Authorizes the Secretary to require a responsible party to take certain actions leading to a recall (including to cease distribution), and requires the Secretary (after an informal hearing opportunity), to order a recall if he/she deems it necessary. Contains extensive language on the procedures for a hearing, recall order, and public notification. [Sec. 207]

Requires a responsible party, or a person who must register a facility, to notify the Secretary whenever they have “reason to believe that an article of food” in commerce “is adulterated or misbranded in a manner that presents a reasonable probability that the use or consumption of, or exposure to, the article (or an ingredient or component used in any such article) will cause a threat of serious adverse health consequences or death to humans or animals.” Authorizes the Secretary to request that a person recall an article of food if the Secretary *has reason to believe it is adulterated, misbranded, or otherwise in violation of this act* [FFDCA]; and to require a person to cease distribution if the Secretary has reason to believe the article of food “may cause serious adverse health consequences or death to humans or animals.” Requires the Secretary to order a recall if he/she determines (after an informal hearing opportunity) it is necessary. Authorizes the Secretary to proceed directly to a

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mandatory recall order if the Secretary has credible evidence that an article of food subject to an order to cease distribution presents an imminent threat of serious adverse health consequences or death to humans or animals. Contains extensive (but not identical) language on the procedures for a hearing, recall order, and public notification. [Sec. 111]

Other Enforcement Provisions

Generally, expands the circumstances whereby the Secretary may detain a food that poses a threat. [Sec. 208]

Also generally expands the circumstances whereby the Secretary may detain a food, but language is broader than that of the Senate bill. [Sec. 132]

Creates new authority aimed at protecting “whistleblowing” employees who provide information on possible violations of food safety law. [Sec. 402]

Also creates new authority aimed at protecting “whistleblowing” employees who provide information on possible violations of food safety law; however, this language differs from the Senate version. [Sec. 212]

Other enforcement-related provisions (not in the Senate bill) include an expedited process for seizing adulterated or misbranded food [Sec 131]; new authority (with limitations) to prohibit or restrict the movement of food within a state [Sec. 133]; expanded authorities for criminal and civil penalties [Secs. 134, 135]; and expanded FDA Commissioner’s subpoena authority for certain purposes [Sec. 211].

Facility Inspections

Requires the Secretary to increase the inspection of all facilities, and to allocate inspection resources based on their risk profiles, including such factors as the type of food at the facility, its past involvement in recalls, outbreaks and violations, and the rigor of its hazard analysis and preventive controls, among others. High-risk facilities must be inspected within the first 2 years and thereafter every year; non-high-risk facilities must be inspected at least every 4 years.

Requires that each domestic and foreign facility be randomly inspected under a risk-based inspection schedule with the following frequencies: high-risk facilities that manufacture or process food (category 1) at least every 6-12 months; low-risk facilities that manufacture or process food, and facilities that pack or label food (category 2) at least every 18 months to 3 years; and facilities that hold food (category 3) at least every 5 years. Authorizes the Secretary to use federal, state, or local officials for domestic inspections and foreign country representatives for foreign ones.

Also contains directions for increasing inspections at ports of entry, based on an imported food’s risk profile. *Authorizes* the Secretary to enter into arrangements with foreign governments to facilitate the inspection of foreign facilities and *requires* the Secretary to direct resources to inspecting them, particularly high-risk ones. *Requires* the Secretary to establish FDA offices in foreign countries (as FDA has already been doing) to assist foreign governments there on food safety; such FDA activities may include performing risk-based inspections and supporting foreign government inspections. [Secs. 201, 307, 309]

Authorizes the Secretary to modify the types of facilities within each category and to alter the frequency if needed to respond to illness outbreaks and recalls. The Secretary must consider, when determining inspection frequencies, the type of food, the facility’s compliance history, and other specified factors. Permits *Federal Register* notification of changes in inspection frequencies and requires such notification when modifying how facilities are categorized.

Requires establishment of a corps of inspectors dedicated to inspecting foreign facilities at a level sufficient to help the Secretary achieve the frequency required in this act. [Secs. 105, 208]

Import Certifications and Use of Third Parties

Authorizes the Secretary (based on public health considerations including product risks or origin) to require that an article of food offered for import provide certification “or such other assurances” deemed appropriate that it complies with applicable requirements of this act. Certifications or assurances *may* be provided in any form the Secretary specifies, such as shipment-specific certificates or a listing of certified entities. Certification must be used for food

Authorizes the Secretary to require that a food article offered for entry has a certification from a qualified entity that it meets specified requirements of the act, but *only in the following situations* where certification would assist in determining the admissibility of the food article: (1) for food from a particular country, territory, or region, where the Secretary has scientific, risk-based evidence that the foreign government’s controls are inadequate; (2) for a food type where there is scientific evidence

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from countries where FDA has an agreement to establish a certification program. The Secretary is authorized to require periodic renewals of certifications. [Sec. 303]

Requires the Secretary to establish a system of third-party auditors and audit agents that are accredited to certify that entities involved with imports are meeting applicable FDA requirements. Generally, the Secretary would first recognize accreditation bodies, which in turn would accredit third-party auditors or audit agents, which in turn would be tasked with doing the certifications. (The HHS Secretary is authorized to directly accredit third parties if an accrediting body is not recognized within one year of the system's establishment.) Contains extensive language requiring development of model accreditation standards, issuance of regulations designed to protect against financial conflicts of interest, re-evaluation of accreditation bodies at least every 4 years, and auditing of third-party performance, among other things. Also details requirements that each player in this system must meet to remain eligible. [Sec. 308]

that it presents the risk of a threat of serious adverse health consequences or death; or (3) where the Secretary has an agreement with the foreign government to provide such certification. Certification may take any form specified by the Secretary such as a statement that the article, facility, or farm involved complies with applicable FFDC requirements, or a listing of certified facilities or other entities.

Appears to be less detailed with regard to how the Secretary must establish a third-party certification program. Qualified certifying entities must be accredited and given responsibility to provide such certifications, where they will be required (see above paragraph), but more of the particulars would be left to the Secretary's discretion. Contains somewhat different provisions aimed at protecting against financial conflicts of interest. Also authorizes a number of actions (such as on-site audits and records examinations at certified facilities) that the Secretary may utilize to evaluate an accreditation body. [Sec. 109]

Import Registration

Requires the Secretary to publish a list of importers (which is defined in this section) participating in the supplier verification program described below. [Sec. 301]

Requires commercial food importers and customs brokers to register annually and to submit unique facility identification numbers as a condition of registration. Includes detailed provisions for suspending and cancelling the registration of those that fail to meet safety requirements. [Secs. 204, 205, 206]

Foreign Supplier Verification

Requires each importer to establish a risk-based foreign supplier verification program. The importer's program must assure that imports are not adulterated or misbranded, and are in compliance with new FDA hazard analysis and preventive control requirements, with appropriate verification steps and documentation (records to be maintained for 2 years). [Sec. 301]

Importers (but apparently not customs brokers) must comply with "good importer practices." Requires the Secretary (in consultation with CBP) to issue regulations on measures an importer must take to ensure that the importer has adequate information about a food, its hazards, and applicable requirements, and the ability to verify that the food and each person who produced or otherwise handled it and its components are in compliance, among other stipulations. [Sec. 204]

Expedited Imports

Requires the Secretary to establish, in consultation with the Secretary of Homeland Security, a voluntary qualified importer program that would enable participating importers that meet certain requirements to receive expedited review and importation of foods. Contains detailed factors the Secretary must consider in determining eligibility for the program; includes a requirement that an importer's qualifications be reviewed at least every 3 years. [Sec. 302].

Authorizes the Secretary to establish, in consultation with CBP, a "safe and secure food importation program" to facilitate the movement of food through the import process where the importer verifies that each facility involved in the production, processing, etc. of a food is in compliance with guidelines that the Secretary is to develop for this voluntary program. Also prescribes factors the Secretary is to take into account in developing safety and security guidelines, but generally this section appears to leave more implementation aspects to the discretion of the Secretary than does the Senate bill. [Sec. 113]

Review of Foreign Food Safety Programs

Explicitly authorizes the Secretary to review a foreign country's food safety laws and regulations and conduct on-site audits to verify implementation, to determine whether the country can provide reasonable assurances that its food meets or exceeds U.S. safety standards. [Sec. 305]

Authorizes the Secretary to "recognize Federal, State, and local officials and agencies and representatives of foreign countries as meeting standards established by the Secretary for conducting inspections," which could be limited to specific commodities or food types. [Sec. 105]

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	Under third-party accreditation (see above), a foreign government may be eligible to be a qualified certifying agent. In addition, before import certifications may be required for a food (see above), the Secretary must establish a process for a country or territory to demonstrate that its controls are adequate to ensure that its food is safe for import into the United States; the Secretary cannot require certification for a food from a country or territory that has made such a demonstration. [Sec. 109]
Lab Accreditation & Testing	
Requires the Secretary to provide for the recognition of accreditation bodies to accredit laboratories (including those operated by states and localities and that operate outside the United States) that can conduct sampling and analytical testing of food and to establish a public registry of such accreditation bodies. Requires the Secretary to develop model standards that such bodies shall require laboratories to meet. Provides for review of accreditation bodies at least every 5 years and spells out how food testing results are to be employed (e.g., to support admissibility of a food import). [Sec. 202]	Requires the Secretary to establish and implement a program for the recognition, based on standards the Secretary deems appropriate, of laboratory accreditation bodies that accredit laboratories to perform analytical testing for the purposes specified in this section. Such purposes include testimony on the admissibility of an import that has been denied entry, and other purposes deemed appropriate by the Secretary. The Secretary must publish a list of recognized accreditation bodies, among other provisions in this section regarding the establishment and use of tests by approved laboratories. [Sec. 110]
Foodborne Illness Surveillance	
Contains a provision detailing how the Secretary, acting through the Centers for Disease Control and Prevention, must improve foodborne illness surveillance systems. Requires partnerships with experts and stakeholders in government, private industry, consumer organizations, and academia, among other provisions. [Sec. 206]	Contains similar but not identical language on surveillance. For example, lacks provisions in the Senate bill to require a working group on foodborne illness surveillance and to reauthorize food safety capacity grants. [Sec. 121]
Food Defense (Intentional Adulteration)	
Requires the Secretary in consultation with the Secretaries of Homeland Security and Agriculture to issue regulations to protect against the intentional adulteration of food; describes what types of foods should be covered and how the Secretary is to determine coverage; exempts farms from coverage (except dairy). [Sec. 106]	A portion of the earlier section of the bill on hazard analysis and preventive controls requires facility owners, operators, or agents to develop and implement a written food defense plan before introducing any food shipment into interstate commerce. Lists required elements of such a plan, among other provisions. [Sec. 102]
Requires, in consultation with the Secretaries of Agriculture and Homeland Security, preparation of a National Agriculture and Food Defense Strategy; contains provisions for its development and revision. [Sec. 108]	House bill surveillance section also requires development of strategies to enhance the food safety and defense capabilities of state and local agencies. [Sec. 121]
The surveillance section requires the Secretary to develop and implement strategies to enhance the food safety and defense capabilities of state and local agencies. [Sec. 206]	
HHS-USDA Jurisdiction	
States that nothing in this act is to: alter jurisdiction between HHS and USDA under applicable laws and regulations; affect the HHS Secretary's authority to issue food safety regulations as in effect on the day prior to enactment of this act; impede the Secretary of Agriculture's authorities regarding plant or animal health emergencies or food emergencies or foodborne illness involving products it regulates under the federal meat, poultry products, or egg products inspection acts. [Sec. 403]	Clarifies that nothing in this act is to limit or alter current jurisdiction or authorities between HHS and USDA. Explicitly exempts from this act foods and establishments to the extent they are regulated under the federal meat, poultry products, or egg products inspection acts. Exempts a farm "to the extent such farm raises animals from which" such foods are derived. Clarifies that livestock and poultry intended for slaughter under the meat and poultry products inspection acts, as well as milk producing cows, sheep, or goats, are exempt. [Sec. 4, Sec. 5]

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Funding and Fees

Authorizes new budget authority for FDA’s Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, and related field activities at \$825 million for FY2010, and such sums as may be necessary for FY2011 through FY2014. Requires increases in field staff by specified amounts, to reach 5,000 by FY2014. [Sec. 401]

Authorizes the following fees: to cover the government cost of a reinspection or recall action (see House provision at right); and those paid by importers participating in the qualified voluntary importer program to cover administrative costs. The fee provisions contain specific language regarding collection and use. [Sec. 107]

Does not authorize new budget authority. Authorizes four new types of fees: (1) an annual \$500 registration fee for each facility, with a maximum payment of \$175,000 for those with multiple facilities [Sec. 101]; (2) fees to cover either the government cost of a reinspection due a violation of the FFDCA, or the cost of a food recall [Sec. 108]; (3) a fee to cover the cost of issuing exportation certificates for foods when needed to meet foreign specifications [Sec. 203]; and (4) an annual \$500 fee for the registration of food importers (but not import brokers). [Sec. 204]. Each fee provision contains specific language regarding its collection and use.

Selected Provisions Not in the House Bill

Requires new regulations for sanitary transportation of food. [Sec. 111]

Requires issuance of voluntary guidelines for state and local education agencies to develop plans for managing food allergy and anaphylaxis risks in schools; authorizes incentive grants. [Sec. 112]

Requires the EPA Administrator, in coordination with the Secretaries of HHS, Homeland Security, and Agriculture, to provide support and technical assistance to state, local, and tribal governments in preparing for and recovering from an agriculture or food emergency (“decontamination and disposal standards and plans”). [Sec. 209]

Requires the HHS Secretary to establish regulatory training and education programs for state, local, and tribal food safety officials. Authorizes the use of those officials to conduct examinations, testing, and investigations. Authorizes appropriations for grants to such entities for these and related activities. [Sec. 210; Sec. 211]

Requires the Secretary to develop a comprehensive plan to expand the food safety capabilities of foreign governments. [Sec. 306]

Requires a strategy to identify and prevent smuggled foods from entering the United States. [Sec. 310]

Requires the HHS Secretary, within 6 months of enactment, to update the fish and fisheries HACCP guidelines to take into account recent technology advances. [Sec. 405]

Selected Provisions Not in the Senate Bill

Requires the Secretary to conduct research to assist in implementation of the act. [Sec. 123]

Alters several provisions affecting the submission and review of manufacturers’ information relating to infant formula ingredients. [Sec. 214]

Requires the Secretary to publish within 60 days notice of receipt of a request for a substance to be determined to be “Generally Recognized as Safe” (GRAS; such substances are exempt from the more rigorous premarket approval process required for other food additives). [Sec 201]

Considers a processed food misbranded if its label fails to identify the country in which final processing occurred; and a non-processed food misbranded if its label fails to identify the country of origin. [Sec. 202]

Requires the Secretary to notify Congress by the end of 2009 on whether the science supports the safety (regarding various population groups) for approved uses of the chemical Bisphenol A (BPA) in food and beverage containers. [Sec. 215]

Sets forth lead content labeling requirements for ceramic tableware and cookware. [Sec. 216]

Source: Prepared by CRS based on reviews of S. 510 as modified and approved by the Senate HELP Committee, and H.R. 2749 as passed by the House.

Notes: *Italics* added by the author for emphasis. Unless stated otherwise, “Secretary” is of HHS; the expectation is that FDA will be the implementing agency in most cases. Acronyms used in the table include:

- CBP:** U.S. Customs and Border Protection
- EPA:** Environmental Protection Agency
- FDA:** Food and Drug Administration
- FFDCA:** Federal Food, Drug, and Cosmetic Act
- HHS:** Department of Health and Human Services
- USDA:** U.S. Department of Agriculture

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