

# CRS Report for Congress

## Food Safety: Selected Issues and Bills in the 110<sup>th</sup> Congress

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Prepared for Members and  
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## Summary

A series of widely publicized incidents — from adulterated Chinese seafood imports to bacteria-tainted spinach, meat, and poultry produced domestically — have made food safety an issue in the 110<sup>th</sup> Congress. Numerous proposals were introduced in 2007 that would alter aspects of the current U.S. food safety system; some of these bills could receive consideration in 2008. This report provides an overview of the current system, highlights major issues in the debate to improve it, and describes the bills.

**Reorganization of Food Safety Responsibilities.** Critics believe that the current system is fragmented and inefficient, threatening food safety; others believe that, while improvements could be made, reorganization is not the most appropriate response. The Senate-passed version of H.R. 2419, the omnibus farm bill, would establish a commission to recommend changes.

**Food Import Oversight.** U.S. food imports have been increasing significantly, raising questions about whether U.S. safeguards, generally established at a time when most Americans obtained their foods domestically, sufficiently protect public health. Pending proposals would variously require foreign countries and establishments to seek U.S. certification before importing into the United States; expand oversight of food imports; and/or charge fees on such imports to cover oversight costs.

**Notification and Recall Authority; Traceability.** Generally, neither the Food and Drug Administration (FDA) nor USDA's Food Safety and Inspection Service (FSIS) has explicit statutory authority to order a recall of adulterated foods, to require a company to notify them when it has distributed such foods, or to impose penalties if recall requirements are violated. P.L. 110-85, which comprises wide-ranging FDA amendments, includes a requirement that FDA establish a registry for reporting potentially adulterated foods. The Senate-passed version of the farm bill contains a similar requirement for FSIS-regulated foods. Still pending are numerous bills containing provisions for mandatory recall authority. Several bills also would require agencies to set up systems for tracing foods from their source of production to final sale.

**State-Inspected Meat and Poultry.** Federally but not state-inspected meat and poultry may be shipped across state lines. Both the Senate- and House-passed versions of the pending farm bill would allow state-inspected products into interstate commerce, but under very different approaches.

**Other Proposals.** Other pending food safety-related measures would curtail the non-medical use of antibiotics in animal feeds; address the labeling of products from cloned animals; and provide incentives aimed at improving the safety of fresh fruits and vegetables.

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# Food Safety: Selected Issues and Bills in the 110<sup>th</sup> Congress

## Introduction

The combined efforts of the food industry and the 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, 76 million people become sick, 325,000 are hospitalized, and 5,000 die from foodborne illnesses caused by contamination from any one of a number of microbial pathogens.<sup>1</sup>

Food safety-related incidents frequently heighten public and media scrutiny of the U.S. food safety system in general, as a number of developments in 2006 and 2007 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. Large recalls of various meat and poultry products due to findings of *E. coli* O157:H7, *Listeria*, and other problems occurred throughout 2007. In February of that year, the U.S. Food and Drug Administration (FDA) announced a nationwide recall of Peter Pan and Great Value brands peanut butter produced in a Georgia ConAgra plant due to *Salmonella* contamination, after hundreds of illnesses, dating back to August 2006 and linked to the bacterium, were reported by public health officials.

At issue is whether the current food safety system has the resources, authority, and structural organization to safeguard the health of American consumers, who spend more than \$1 trillion on food each year.<sup>2</sup> Also at issue is whether federal food safety laws, first enacted in the early 1900s, have kept pace with the significant changes that have occurred in the food production, processing, and marketing sectors since then.

Attention 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

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<sup>1</sup> U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, "Foodborne Illness: Frequently Asked Questions," accessed at [<http://www.cdc.gov/foodsafety/>]. However, this estimate appears to be based primarily on 1997 and earlier data in a report by Paul S. Mead et al., "Food-related Illness and Death in the United States," *Emerging Infectious Diseases*, vol. 5, pp. 607-625, 1999.

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

cats and subsequently were found in some hog, chicken, and fish feed.<sup>3</sup> In June 2007, FDA announced that it was detaining all imports of certain types 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.

These and other developments made food safety a top issue for a number of lawmakers in the first session of the 110<sup>th</sup> Congress. Several of them called for 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 were explored at a number of congressional hearings in 2007. Several reports and studies released in 2007 by the Bush Administration also called for changes or increased resources in the system.

Bills addressing various aspects of the issue have been introduced. Many appear to focus on ensuring the safety of imported foods, and/or on strengthening the ability of federal agencies to identify and recall contaminated products. Several call for a more sweeping overhaul of existing statutes, including one that would combine responsibility for all food safety under a single new agency. This report describes many of these bills, both in tabular format (see **Appendix A** and **Appendix B**) and in the text that follows. First, however, the report offers an overview of the current system.

## The Food Safety System

The Government Accountability Office (GAO) has identified 15 federal agencies collectively administering at least 30 laws related to food safety. The Food and Drug Administration (FDA), which is part of the U.S. Department of Health and Human Services (HHS), and the Food Safety and Inspection Service (FSIS), which is part of the U.S. Department of Agriculture (USDA), together compose the majority of both the total funding and the total staffing of the government's food regulatory system.<sup>4</sup> FSIS's annual budget is approximately \$1 billion, at least 90% of it appropriated funds and the balance industry-paid user fees. FDA's annual budget for human foods is less than \$500 million. FDA oversight of animal drugs and feeds totals another approximately \$100 million, of which approximately 90% is appropriated and the balance user fees.<sup>5</sup>

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<sup>3</sup> FDA requires the same general safety standards for human foods and animal feeds, including pet food. A subsequent survey commissioned by the American Association of Veterinary Laboratory Diagnosticians and conducted by Michigan State University counted 347 cases (235 cats and 112 dogs) of pets dying from contaminated pet food. Michigan State University, "MSU survey determines that more than 300 pets may have died from contaminated pet food; culprit may be lethal combination of contaminants," news release, November 29, 2007, accessed at [<http://newsroom.msu.edu/site/indexer/3263/content.htm>].

<sup>4</sup> *High Risk Series: An Update* (GAO-07-310), January 2007.

<sup>5</sup> *Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for 2007*, hearings before a Subcommittee of the Committee on Appropriations, House of Representatives, 109<sup>th</sup> Cong., 2<sup>nd</sup> sess. Also, *Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for* (continued...)

**Food and Drug Administration (HHS).** FDA is responsible for ensuring that all domestic and imported food products — except for most meat and poultry derived from the major animal species — are safe, nutritious, wholesome, and accurately labeled.<sup>6</sup> FDA shares responsibility for the safety of eggs with FSIS. FDA has jurisdiction over establishments that sell or serve eggs or use them as an ingredient in their products (FSIS generally is responsible for processed eggs). FDA is also responsible for ensuring that seafood products, including those from aquaculture, do not endanger public health. The primary statutes governing FDA’s activities are the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 et seq.); the Public Health Service Act, as amended (42 U.S.C. 201 et seq.); and the Egg Products Inspection Act, as amended (21 U.S.C. 1031 et seq.).

FDA’s food safety staff (FY2007) numbers approximately 1,900 in field offices throughout the United States, plus more than 800 in its headquarters offices near Washington, DC. FDA regulates food manufacturers’ safety practices by relying on companies’ self-interest in producing safe products, by working with the industry to improve production practices, and by making periodic (although infrequent) inspections of the approximately 60,700 active food establishments subject to FDA oversight. According to FDA, unannounced compliance inspections of individual establishments by its officials now occur roughly once every five years. FDA relies on notifications from within the industry or from other federal or state inspection personnel, as well as other sources, to alert it to situations calling for increased inspection.

The FDA headquarters offices are the focal point for food safety-related activities. The Center for Food Safety and Applied Nutrition (CFSAN) is responsible for (1) conducting and supporting food safety research; (2) developing and overseeing enforcement of food safety and quality regulations; (3) coordinating and evaluating FDA’s food surveillance and compliance programs; (4) coordinating and evaluating cooperating states’ food safety activities; and (5) developing and disseminating food safety and regulatory information to consumers and industry. FDA’s Center for Veterinary Medicine (CVM) is responsible for ensuring that all animal drugs, feeds (including pet foods), and veterinary devices are safe for animals, are properly labeled, and produce no human health hazards when used in food-producing animals.

FDA also cooperates with over 400 state agencies across the nation that carry out a wide range of food safety regulatory activities. The state agencies are primarily responsible for actual inspection. FDA works with the states to set the safety standards for food establishments and commodities and evaluates the states’ performance in upholding such standards as well as any federal standards that may

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<sup>5</sup> (...continued)

2008, hearings before a Subcommittee of the Committee on Appropriations, House of Representatives, 110<sup>th</sup> Cong., 1st sess.

<sup>6</sup> FDA does have jurisdiction over meats from animals or birds that are not under the regulatory jurisdiction of FSIS. FSIS’s legislative mandate extends only to “amenable species,” currently defined as cattle, sheep, goats, swine, equines, and the following poultry species: chickens, turkeys, ducks, geese, ratites, and guineas.

apply. FDA also contracts with states to use their food safety agency personnel to carry out certain field inspections in support of FDA's own statutory responsibilities.

**Food Safety and Inspection Service (USDA).** FSIS regulates the safety, wholesomeness, and proper labeling of most domestic and imported meat and poultry and their products sold for human consumption. Under the Federal Meat Inspection Act (FMIA) of 1906, as amended (21 U.S.C. 601 et seq.), FSIS inspects all cattle, sheep, swine, goats, and equines both before and after they are slaughtered, and maintains oversight during their processing into food products. Under the Poultry Products Inspection Act (PPIA) of 1957, as amended (21 U.S.C. 451 et seq.), FSIS is required to inspect "any domesticated bird" both before and after slaughter and while being processed for human consumption. However, USDA regulations implementing this law limit the definition of domesticated birds to chickens, turkeys, ducks, geese, ratites (emus, ostriches, and rheas), and guineas. FDA has jurisdiction over exotic and alternative meats not inspected by FSIS, and shares responsibility for egg safety with FSIS. FSIS is responsible for the safety of liquid, frozen, and dried egg products, domestic and imported, and for the safe use or disposition of damaged and dirty eggs under the Egg Products Inspection Act, as amended (21 U.S.C. 1031 et seq.).

FSIS staff numbers around 9,400; roughly 8,000 of them, including about 1,000 veterinarians, are in about 6,300 meat and poultry slaughtering and/or processing plants nationwide. FSIS personnel inspect all meat and poultry animals at slaughter on a continuous basis, and at least one federal inspector is on the line during all hours the slaughter plant is operating. During processing operations — that is, when meat from animals is being transformed into cuts, ground products, and other consumable items — an FSIS inspector may not be constantly on the production line or inspect every item. Instead, the inspector visits the site on a daily basis to monitor the plant's adherence to the standards for sanitary conditions, ingredient levels, and packaging, and to conduct statistical sampling and testing of products. Because all plants are visited daily, processing inspection also is considered to be continuous.

FSIS also is responsible for certifying that foreign meat and poultry plants are operating under an inspection system equivalent to the U.S. system before they can export their products to the United States. FSIS inspectors located at U.S. ports of entry carry out a statistically based sampling program to verify the safety of imported meats from cattle, sheep, swine, goats, and equines and imported poultry meat from chickens, turkeys, ducks, geese, quail, ratites, and guineas before they are released into domestic commerce. FDA is responsible for ensuring the safety of imported meat from any other species.

Twenty-seven states operate their own meat and/or poultry inspection programs. FSIS is statutorily responsible for ensuring that the states' programs are at least equal to the federal program. The approximately 2,100 plants that slaughter animals and/or process meat and poultry under state supervision can market their products only within the state. If a state chooses to discontinue its own inspection program, or if FSIS determines that it does not meet the agency's equivalency standards, FSIS must assume the responsibility for inspection if the formerly state-inspected plants are to remain in operation. Under a separate program, FSIS also has cooperative agreements with more than two dozen states under which state inspection personnel

are authorized to carry out federal inspection in meat and/or poultry plants. Products from these so-called Talmadge-Aiken plants (named for the sponsors of the law that created the program) may travel in interstate commerce.<sup>7</sup>

**Centers for Disease Control and Prevention (HHS).** CDC is responsible for (1) monitoring, identifying, and investigating foodborne disease to determine the contributing factors; (2) working with FDA, FSIS, and other federal agencies, state and local public health departments, universities, and industry to develop control methods; and (3) evaluating the effectiveness of control methods. In 1995, CDC launched “FoodNet,” a collaborative project with FDA and USDA to improve data collection on foodborne illnesses. FoodNet includes active surveillance of clinical microbiology laboratories to obtain a more accurate accounting of positive test results for foodborne illness; a physician survey to determine testing and laboratory practices; population surveys to identify illnesses not reported to doctors; and research studies to obtain new and more precise information about which food items or other exposures may cause diseases. FoodNet data allows CDC to have a clearer picture of the incidence and causes of foodborne illness and to establish baseline data against which to measure the success of changes in food safety programs. The Public Health Service Act, as amended (42 U.S.C. 201 et seq.), provides the legislative authority for CDC’s food safety related activities.

**National Marine Fisheries Service (Department of Commerce).** Although FDA is the primary agency responsible for ensuring the safety, wholesomeness, and proper labeling of domestic and imported seafood products, the National Marine Fisheries Service (NMFS) conducts, on a fee-for-service basis, a voluntary seafood inspection and grading program that focuses on marketing and quality attributes of U.S. fish and shellfish. The primary legislative authority for NMFS’s inspection program is the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621 et seq.). NMFS has approximately 160 seafood safety and quality inspectors, and inspection services are funded with user fees.

**Environmental Protection Agency.** The Environmental Protection Agency (EPA) has statutory responsibility for ensuring that the chemicals used in the production and processing of food do not endanger public health. EPA’s Office of Pesticide Programs (1) registers new pesticides and determines residue levels for regulatory purposes; (2) performs special reviews of pesticides of concern; (3) reviews and evaluates all the health data on pesticides; (4) reviews data on pesticides’ effects on the environment and on other species; (5) analyzes the costs and benefits of pesticide use; and (6) interacts with EPA regional offices, state regulatory counterparts, other federal agencies involved in food safety, the public, and others to keep them informed of EPA regulatory actions. The Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136 et seq.), and the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301 et seq.), are the primary authorities for EPA’s activities in this area.

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<sup>7</sup> A more extensive explanation of FSIS is available in CRS Report RL32922, *Meat and Poultry Inspection: Background and Selected Issues*, by Geoffrey S. Becker.



**Other Federal Agencies with Food Safety Responsibilities.** Among the other agencies that play a role in food safety, USDA's Agricultural Research Service (ARS) performs food safety research in support of FSIS's inspection program. ARS has scientists working in animal disease bio-containment laboratories in Plum Island, NY, and Ames, IA. USDA's Animal and Plant Health Inspection Service (APHIS) indirectly protects the nation's food supply through programs to protect plant and animal resources from domestic and foreign pests and diseases, such as brucellosis and bovine spongiform encephalopathy (BSE, or "mad cow" disease). The Department of Homeland Security (DHS), working with other agencies, is responsible for coordinating federal preparedness for and response to a terrorist attack, major disease outbreak, or other disaster affecting the national agriculture or food infrastructure, and has additional routine food safety inspection responsibilities at U.S. borders.<sup>8</sup>

## Congressional Jurisdiction

Congressional oversight of the diverse federal food safety system is further complicated because of the number of committees that have jurisdiction over one or more aspects. For example, the congressional authorizing committees that direct FDA activities are those with jurisdiction over public health issues: the Senate Committee on Health, Education, Labor, and Pensions and the House Committee on Energy and Commerce. Other committees that exercise oversight roles regarding FDA include the House Committee on Oversight and Government Reform, and the Senate committees on Aging, Homeland Security, and the Judiciary. With regard to FSIS authorization and oversight, the House and Senate Agriculture Committees have primary jurisdiction.

Annual funding decisions originate in the House and Senate appropriations subcommittees on Agriculture, Rural Development, FDA, and Related Agencies, which have jurisdiction not only over FSIS, a USDA agency, but also over FDA's appropriations. This latter arrangement reflects, in part, the agency's origin within the Department of Agriculture as the Bureau of Chemistry in 1862. Since 1940, however, FDA has been administratively part of federal public health agencies, specifically HHS and its predecessors.

## Administration Food Safety Strategy

The Administration released, on November 6, 2007, two separate but related reports with an impact on food safety. The broader of the two covers the safety of most imports for consumers, including but not limited to food. This *Action Plan for Import Safety* was prepared for the President by the Interagency Working Group on Import Safety.<sup>9</sup> The other report is FDA's *Food Protection Plan*, which focuses on food, whether imported or domestically produced, and which contains

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<sup>8</sup> See also CRS Report RL32521, *Agroterrorism: Threats and Preparedness*, by Jim Monke.

<sup>9</sup> Accessed at [<http://www.importsafety.gov/report/actionplan.pdf>].

recommendations for food imports that generally parallel those in the broader report.<sup>10</sup>

Both plans are oriented toward assessing and prioritizing risks regardless of where they occur (starting at a product's point of origin), and preventing rather than waiting for problems to occur. A number of the recommendations — such as mandatory recall authority for FDA-regulated products (but not FSIS), electronic certification of imports, and new user fees if products must be reinspected — would require congressional authorization. Among other recommended statutory changes are more explicit authority to require additional preventive (HACCP-like) controls for high-risk foods (authority some believe FDA already has); and authority for FDA accreditation of qualified third parties to conduct some types of inspections.

HACCP is the acronym for hazard analysis and critical control point, whereby a production system is analyzed to determine its potential risks and hazards and where they are most likely to occur. Preventive controls are then instituted at the appropriate points, and continually monitored to ensure they are effective. Each meat and poultry plant must have developed and must continue to follow its own HACCP plan, which FSIS inspectors then review on an ongoing basis to ensure it is in place and effective. Currently, only a few types of FDA-regulated food products must follow HACCP rules.

Many other changes are to be implemented through administrative action, or cooperative activities with foreign countries and industry stakeholders. Most cite FDA as the lead agency; few would appear to involve FSIS-regulated products. Many of the changes are expected to necessitate more spending, which neither report quantified. The lack of specific funding requests was among the criticisms leveled against the Administration strategy by some Members of Congress. Administration officials stated that they would seek additional funds to help pay for these initiatives as part of the upcoming FY2009 budget request.

Other perceived shortcomings in the strategy were cited by critics, including some Members of Congress, consumer advocacy groups, and several food safety experts. Several observed, for example, that the plan is not comprehensive because it did not propose any specific food safety improvements on farms or at the retail level, where problems often occur; that it relies too much on voluntary cooperation with industry when stronger mandatory controls are called for; and that it fails to emphasize badly needed improvements in information technology.<sup>11</sup>

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<sup>10</sup> Accessed at [<http://www.fda.gov/oc/initiatives/advance/food/plan.html>].

<sup>11</sup> See, for example, the December 4, 2007, testimony of Michael R. Taylor, Research Professor of Health Policy, The George Washington University, before the Senate Committee on Health, Education, Labor, and Pensions hearing, “Developing a Comprehensive Response to Food Safety.” Also, *FDA Week*, November 9, 2007.

## Selected Issues

### Reorganize Food Safety Responsibilities

**Issue.** Critics have argued for decades that U.S. food safety activities are dispersed over too many agencies and are poorly coordinated. GAO has been among these critics. In its annual (January 2007) report, GAO designated food safety oversight as one of 29 “high risk” federal program areas. The report concluded that the current federal safety system is “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.<sup>12</sup>

Opponents of major food safety system 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.

**Legislation.** The Senate-passed version of the omnibus farm bill (H.R. 2419) would establish a Congressional Bipartisan Food Safety Commission to recommend statutory changes to modernize the food safety system and ways to harmonize food safety requirements across agencies. The language provides extensive guidance on commission membership and on the programs to be examined, sets timelines for completion, and provides \$3 million annually in funding.<sup>13</sup>

If the commission language is maintained in the final farm bill (the House version lacks it), this initiative could sideline further action in this Congress on companion bills (H.R. 1148/S. 654) to reorganize the federal agencies responsible for food safety, as well as to overhaul the safeguards themselves.

These two comprehensive companion bills would consolidate federal food safety responsibilities under a new Food Safety Administration (FSA). The new FSA would be responsible for administering all the major food safety laws. Agencies and their functions to be transferred include FSIS and APHIS from USDA, as well as the Department’s food safety research activities; the FDA’s Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM), as well as portions of other FDA offices that support these centers; resources of the EPA that regulate pesticide residues in food; NMFS seafood inspection; and any other offices or services designated by the President.

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<sup>12</sup> *High Risk Series: An Update.*

<sup>13</sup> The omnibus FY2008 appropriation measure (H.R. 2764), which the President signed into law on December 26, 2007, also contains a number of directives to USDA and FDA to study and recommend changes in the food safety system; see the next section of this report, “Funding and Resources.”

H.R. 1148/S. 654 also would authorize a new food safety system to be based on a comprehensive analysis of food hazards. They would require the registration and regular inspections of all establishments (except farms, fishing vessels that do not process food, and retail establishments), which would have to follow process controls tied to science and health-based regulations, including performance standards. Inspection fundamentals and frequencies also are spelled out in the bills. Among other provisions, the bills specify prohibited acts; provide authority to detain, seize, condemn, and/or recall foods suspected of being unsafe or misbranded (see page 14 for details), and include “whistleblower protection” for public and private employees who report safety problems. They also include a certification system for imports, and a mandatory national system for tracing food and food animals from their point of origin to retail sale, which are described elsewhere in this CRS report.

Another comprehensive bill (H.R. 3624) proposes major changes in how the current system is administered by the FDA — although it would not establish a new single food agency. The bill would require establishment of a new “National Food Safety Program” to be based on a comprehensive analysis of food safety hazards throughout the production and marketing chain; the analysis would consider the distinctive characteristics of food production and processing. The proposed bill would mandate process control regulations, require quarterly inspections of processors and importers, except those that have negligible risk or meet exceptional standards, and spell out procedures for detaining and condemning adulterated or misbranded products.

The bill also would require, among other things, tolerances for contaminants in food tied to health-based standards, and a comprehensive public health assessment system that includes active foodborne illness surveillance and sampling of food products to test for contaminants. The bill’s import inspection and recall provisions are described elsewhere in this CRS report.

## **Increase Funding and Staffing**

**Issue.** Some critics argue that — irrespective of the need, if any, to reform food safety statutes and organization — the primary problem is the lack of sufficient funding and staff to carry out congressionally mandated responsibilities to ensure a safe food supply. From time to time in the past, FSIS has had difficulty in adequately staffing its service obligations to the meat and poultry industries. Usually a combination of factors causes these shortages, such as new technologies that increase plant production speeds and volume, or insufficient funds to hire additional inspectors at times of unexpected increases in demand for inspections, for example.

According to a report released in early December 2007 by the FDA Science Board, the FDA Commissioner’s expert advisory panel, a critical lack of resources has seriously weakened the FDA’s scientific basis generally and its mission to protect the food supply particularly. The report, prepared by a board subcommittee, concluded in part, “... the Agency suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities.” The subcommittee 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.<sup>14</sup>

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 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 has forced FDA to impose a 78 percent reduction in food inspections, at a time when the food industry has been rapidly expanding and food importation has exponentially increased.<sup>15</sup>

The FDA food safety budget has declined from almost half of the agency's total spending in 1971 to about one-fourth of the budget currently, partly because the drug budget has expanded due to collection of drug approval user fees. FDA staffing in programs not funded by user fees, including but not limited to food safety, has decreased significantly, according to a former high-level official.<sup>16</sup> This has occurred at a time when FDA faces new challenges such as rising food imports due to globalization of the U.S. food supply.

Although it requested modest increases for both FDA and FSIS in its FY2008 budget, the Administration stressed that it could meet these challenges by strengthening the scientific basis of its programs, improving risk-based targeting of inspection resources, and developing stronger partnerships with domestic and international stakeholders. At 2007 hearings, some Members of Congress expressed skepticism that these efforts could succeed without additional funds. More recently, the HHS Secretary and FDA officials said that they had asked the White House to include significant increases as part of the President's FY2009 budget request.<sup>17</sup>

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<sup>14</sup> *FDA Science and Mission at Risk*, Report of the Subcommittee on Science and Technology, prepared for the FDA Science Board, November 2007.

<sup>15</sup> *Ibid.* The report cited an estimate by an advocacy group, the Coalition for a Stronger FDA, that more than \$130 million is needed to devise and implement a new food import system alone.

<sup>16</sup> Statement of William K. Hubbard, former FDA Associate Commissioner, before the House Energy and Commerce Subcommittee on Oversight and Investigations, July 17, 2007.

<sup>17</sup> See, for example, "House members grill FDA chief over produce safety, increased inspections," *Food Chemical News*, March 5, 2007; "FDA Chief Pressed on Below-Inflation Budget Hike for Food Safety," *CQ Budget Tracker News*, March 1, 2007. The more recent HHS and FDA remarks were made at a December 4, 2007, hearing on imported food safety before the Senate Committee on Health, Education, Labor, and Pensions.

FSIS and FDA receive most of their funding through the annual Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act. Some funds also are provided through user fees. In FY2007, for example, more than 12% (\$130 million) of the FSIS budget of approximately \$1 billion was from user fees charged to establishments, mostly for inspections conducted after regularly scheduled shifts. As noted, the \$457 million FDA food safety budget (FY2007) was virtually all from appropriated funds.

Proposed increases in program spending raise a variety of policy issues. Requests for higher appropriations must compete with other priorities throughout the federal discretionary budget (the programs do not operate, like farm support programs, for example, as mandatory authorizations). 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. Nonetheless, a number of pending food safety bills discussed in this report include proposed user fees to pay for such various new activities as certification of food imports, re-inspection of products initially kept out of commerce, and the auditing of private food testing laboratories.

**Legislation.** The first session of the 110<sup>th</sup> Congress did not clear a freestanding Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act for FY2008 (H.R. 3161, S. 1859). Rather, the programs operated for nearly the first three months of the fiscal year under a series of continuing resolutions, and are now operating for the balance of FY2008 under the Consolidated Appropriations Act, 2008 (H.R. 2764).

Division A of this omnibus measure provides new budget authority in FY2008 of \$509.9 million for the FDA foods program area, or \$52.8 million more than the FY2007 enacted level of \$457.1 million and the Administration FY2008 request of \$466.7 million. Of this, \$28 million is to be spent from July 1, 2008, through September 30, 2009, for implementation of a detailed plan for a comprehensive overhaul of FDA’s food safety operations. Accompanying report language further directs that nearly \$327 million of the agency appropriation be spent for food-related field activities; and that FDA make at least \$18.3 million available immediately to hire additional domestic and import inspectors, including \$8 million “for the deployment of inspectors with rapid response capabilities who will be responsible for immediate attention to outbreaks of food-related disease as well as providing technical assistance to states and others, as appropriate, to support overall practices to increase the safety of food and food products.”

The report also states that FDA should contract with the National Academy of Sciences for a comprehensive study of gaps in public health protection provided by the food safety system, including a response to the recommendations of the FDA Food Protection Plan released in November 2007. Moreover, both FDA and USDA were separately directed to also submit their own plans addressing the weaknesses that caused GAO to place food safety on its 2007 high-risk list.

The FY2008 measure provides new budget authority for FSIS of \$930.1 million, or nearly \$38 million more than the enacted FY2007 level. (Currently authorized

user fees were expected to provide another \$135 million for the year.) The increase is in part to be used to hire additional inspectors in FY2008.

**Table 1. Appropriated Funds for FSIS and FDA**  
(millions)

	FY2007 Enacted	FY2008 Request	FY2008 Enacted
FSIS	\$892.1	\$930.1	\$930.1
FDA (food)	\$457.1	\$466.7	\$509.9

**Source:** House Appropriations Committee documents. FSIS total excludes user fees (estimated to be approximately \$135 million FY2008).

## Improve Oversight of Food Imports

**Issue.** Concerns about perceived gaps in import safeguards, including what many believe have been insufficient funds, are not new. However, they have gained wider attention in recent years as U.S. food imports log significant increases, fueled by the globalization of production and processing, and by consumers' desire for a wider variety of nutritious and inexpensive foods year-round. The value of total imports of agricultural and seafood products increased from \$39 billion in FY1996 to \$83.7 billion in FY2007, a 115% increase. At issue is whether U.S. safeguards, which generally were created at a time when most foods were supplied domestically, can protect public health in a global marketplace.

The Bush Administration's food safety and import safety strategies (see pages 6-7) assert that imported foods generally do not pose a greater food safety risk than domestic foods. However, the increase in import volume, along with the changing makeup — from largely unprocessed bulk ingredients for subsequent processing by domestic establishments, to an increasing variety of ready-to-eat products, fresh produce, and seafood — have taxed FDA's ability to monitor them for safety, the Administration reports said.

Among legislative changes recommended in the Administration food safety and import strategies is the authority for FDA to require electronic import certificates for shipments of products deemed to be of high risk. For such products, FDA would have to negotiate and implement government-to-government agreements whereby an importer would obtain certificates from either the appropriate foreign agency or an accredited third party. This new certification system, which appears to be based at least in part on the concept of the FSIS foreign equivalency determinations, presumably would have to be consistent with international trade obligations, and likely would be one of the initiatives requiring additional resources.<sup>18</sup> The strategies also entail new authority for FDA to block entry of foods imported from foreign firms that impede entry by FDA inspectors to their facilities.

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<sup>18</sup> See also CRS Report RL34198, *U.S. Food and Agricultural Imports: Safeguards and Selected Issues*, by Geoffrey S. Becker.

The imports issue was explored at a number of congressional hearings in 2007, and several bills have been offered to change the current system. Those who oppose major changes assert that imported foods already are subject to the same safety standards as — and/or pose no greater hazards than — domestically produced foods. They also contend that smarter allocation of existing resources, and the food industry's own controls, can and should be capable of addressing any problems that arise.<sup>19</sup>

**Legislation.** As of late 2007, at least a dozen food safety bills were pending that contain provisions addressing some aspect of food import safety. About half of them — H.R. 2997, H.R. 3100, H.R. 3610, H.R. 3937, H.R. 3967, S. 1776, and S. 2418 — focus almost exclusively on the import issue.

A number of the bills would require that importing establishments, and/or the foreign countries in which they are located, first receive formal certification from U.S. authorities that their food safety systems demonstrably provide at least the same level of safety assurances as the U.S. system. Some would direct that certifications be denied or revoked if foreign safeguards are found to be insufficient, unsafe imports are discovered, and/or foodborne illnesses are linked to such products. H.R. 2997 takes a somewhat different tack, by requiring that food imports (both FDA- and FSIS-regulated) be certified by the government of their country of origin.

A number of the bills also propose the collection of user fees — for example, up to \$20 per shipment in one bill, up to \$50 per shipment in another — from importers to cover the costs of inspecting foreign products at the borders. Some of the bills seek to require more physical inspections and testing by FDA at the border or within other countries, to authorize more research into inspection and testing technologies, or to restrict imports to specific ports.

A controversial provision in H.R. 3610 (introduced by House Energy and Commerce Committee Chairman Dingell) would restrict imports of all FDA-regulated foods to ports of entry located in metropolitan areas that have one of the 13 FDA laboratories, although waivers could be granted under some circumstances.<sup>20</sup> At a July 17, 2007, hearing before the House Energy and Commerce Subcommittee on Oversight and Investigations, the panel's investigators testified that FDA border inspectors currently had to cover 326 ports of entry, greatly straining the existing workforce. Those opposed to the port restrictions in H.R. 3610 argue that it would result in severe economic dislocation and huge costs for industries and consumers.<sup>21</sup> A separate provision in the Dingell bill would require the HHS Department to establish a voluntary "Safe and Secure Food Importation Program" under which food

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<sup>19</sup> Ibid.

<sup>20</sup> FDA had initially proposed to consolidate its 13 labs into six, but backed away from that plan due in part to strong opposition by some key Members of Congress. The Consolidated Appropriations Act, 2008, prohibits the agency from closing or consolidating these labs.

<sup>21</sup> See, for example, the testimony on H.R. 3610 by the Food Marketing Institute and by the American Association of Exporters and Importers, September 26, 2007, before the House Energy and Commerce Committee, Subcommittee on Health.



importing companies could receive expedited movement of their products in exchange for abiding by HHS-developed food safety and security guidelines.

Meanwhile, Title X of the Food and Drug Administration Amendments Act of 2007 (H.R. 3580; signed into law as P.L. 110-85), requires an annual report to Congress on the number and amount of FDA-regulated food products imported by country and by type of food, the number of inspectors and inspections performed, and aggregated data on inspection findings, including violations and enforcement actions.

## **Strengthen Authorities for Notification, Recall, and Product Tracing**

**Issue.** 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 one food, 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 has concluded.<sup>22</sup>

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.<sup>23</sup> Finally, private companies rarely if ever fail to order a voluntary recall when problems arise; these are frequently announced by the government, and become widely publicized, it is argued. Nonetheless, a number of Members of Congress support GAO's recommendation that legislation be considered to strengthen notification and recall authorities.

Some argue 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.<sup>24</sup>

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<sup>22</sup> 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.

<sup>23</sup> A court's permission may not be needed in all cases; for example, the FFDCFA [§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."

<sup>24</sup> See also CRS Report RS22653, *Animal Identification: Overview and Issues*, by Geoffrey S. Becker.

The Administration's November 2007 strategy for food safety calls for mandatory recall authority 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. The agency also is seeking authority to give it more access to records in cases of food emergencies. Significantly, a major food industry group, the Grocery Manufacturers Association (GMA), endorsed the proposal for mandatory recall authority.<sup>25</sup> The day after the Administration proposed it for FDA, a USDA official asserted that FSIS does not need similar mandatory recall authority for meat and poultry products. Responding to questions, the official stated that USDA already has sufficient enforcement tools and that the voluntary approach now in place works well.<sup>26</sup>

**Legislation.** Title X of P.L. 110-85, which was signed into law on September 27, 2007, requires FDA, within one year, to establish a "Reportable Food Registry." Responsible parties and importers will be required to report to this registry detailed information (outlined in the bill) about cases of actual or suspected food adulteration, generally within 24 hours.<sup>27</sup> The measure contains a number of explicit provisions regarding the types of records that must be maintained and the specific data that must be provided. Another recall-related provision, in Title VI of the bill, will require FDA to work with companies, professional associations, and other organizations to collect and communicate information about recalls of human or pet food and to post information regarding the products on an accessible FDA website.<sup>28</sup>

Before passing its version of the omnibus farm bill (H.R. 2419) in December 2007, the Senate adopted a managers' amendment that also establishes reportable food registries for FSIS-regulated meat and poultry products. A House-Senate conference committee, anticipated in early 2008, is likely to determine the outcome of these registries, which are not in the House version.

Many pending food safety bills introduced during 2007 also contain provisions dealing with notification, recall, and/or traceability: H.R. 1148/S. 654, H.R. 2108/S. 1274, H.R. 3484, H.R. 3485, H.R. 3610, H.R. 3624, H.R. 3937, S. 1292, S. 2081, and

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<sup>25</sup> "GMA Applauds Bush Administration's Focus on Prevention in Effort to Improve Safety of Imported Food," November 6, 2007, press release, at [<http://www.gmaonline.org/news/docs/NewsRelease.cfm?DocID=1806&>].

<sup>26</sup> Dr. Richard Raymond, Undersecretary for Food Safety, November 7, 2007, testimony before the House Agriculture Subcommittee on Livestock, Dairy, and Poultry.

<sup>27</sup> Responsible parties are defined to mean facilities that have to register with FDA under Section 415 of the FFDCFA, i.e., "any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States ..." Exempted are farms, restaurants, and other retail establishments.

<sup>28</sup> Other food-related provisions in H.R. 3580, which primarily deals with FDA non-food issues, include a required annual FDA report on the Administration's Pesticide Residue Monitoring Program; a required report on seafood safety risks, seafood inspection activities, and the feasibility of a traceability system to trace the plant of origin for all domestic and imported seafood products; and authority to partner with states to implement inspection programs for imported seafood and aquaculture to ensure they meet federal standards.

S. 2418. Several of these would require any person to immediately notify authorities if he or she has reason to believe that a food entering commerce is in violation of the law; and would provide either FDA and/or FSIS with the authority to mandate recalls if an establishment refused to do so voluntarily or sufficiently. Several bills also would require establishment of a national system to trace food and food animals from point of origin to retail sale.

One proposal would newly require all manufacturers of foods (and of other non-food products like auto parts, drugs, and other consumer products) to have “recall responsibility certificates” issued by U.S. Customs and Border Protection (CBP). The document is to certify that the manufacturer, for a five-year period, has the resources to cover the entire cost of any recall of its product, plus compensatory damages and costs that may arise from product liability claims due to defects.

## **Allow State-Inspected Meat and Poultry in Interstate Commerce**

**Issue.** Federal law currently prohibits meat and poultry plants that operate under one of the 27 state inspection programs from shipping their products across state lines. Many of the states and small plants want to overturn that ban. Limiting state-inspected products to intrastate commerce is unfair, these states and plants argue, because their programs must be, and are, “at least equal” to the federal system. Foreign plants operating under FSIS-approved foreign programs, which must be “equivalent” to the U.S. program, can export meat and poultry products into and sell them anywhere in the United States.

Those who oppose allowing state-inspected products into interstate commerce argue that state programs are not required to have, and do not have, the same level of safety oversight as the federal or even some foreign systems. For example, foreign-processed products are subject to U.S. import reinspection at ports of entry. These opponents of interstate shipment note that a recent FSIS review, which found all but one of the state programs to be at least equal to the U.S. program, was based largely on self-assessments.<sup>29</sup>

**Legislation.** Both the House- and Senate-passed versions of H.R. 2419, the omnibus farm bill, would amend the meat and poultry inspection acts to permit interstate shipment of state-inspected products — but under divergent approaches. It would replace the current federal-state cooperative inspection program with a new program that would enable meat and poultry that is not federally inspected to be shipped across state lines, so long as the state programs adopt standards identical to those of FSIS along with any additional changes FSIS required. Moreover, the bill would enable many plants currently under federal inspection to apply for state inspection and continue to ship interstate.

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<sup>29</sup> Until it ceded its inspection responsibilities to the federal government in August 2007 after USDA deferred a finding of “equal to” status, New Mexico had been the 28<sup>th</sup> state with a program. See also CRS Report RL34202, *State-Inspected Meat and Poultry: Issues for Congress*, by Geoffrey S. Becker; and *FSIS Review of State Programs: Summary Report* (January 2007) at [[http://www.fsis.usda.gov/PDF/Review\\_of\\_State\\_Programs.pdf](http://www.fsis.usda.gov/PDF/Review_of_State_Programs.pdf)].

The Senate version would supplement rather than replace the current federal-state cooperative inspection program with an alternative whereby state-inspected plants with 25 or fewer employees could opt into a new program that subjects them to federally directed but state-operated inspection, thus allowing them to ship interstate. The Senate version reportedly was developed as a compromise by those on both sides of the issue, suggesting that it would more likely prevail in any upcoming conference on the farm bill.

## Strengthen Produce Safety

**Issue.** Increased consumption of fresh produce, particularly of leafy vegetables such as spinach and lettuce, is viewed as a positive trend from a nutritional perspective, but it has presented new challenges with regard to food safety. These challenges have been underlined by reports, starting in September 2006, of foodborne illnesses linked to California spinach and lettuce contaminated with the bacterium *E. coli O157:H7*, among other recent incidents.<sup>30</sup> There is ongoing debate regarding the extent to which FDA, which oversees the safety of all produce, has the authority to regulate safety on the farm, one of the potential sources of such contamination.

The agency and other public officials have been encouraging the industry to develop and follow voluntary guidelines for growing and packing safe products. A majority of California producers signed, in early 2007, a state Leafy Greens Marketing Agreement. This binds them to implement and maintain safety standards in growing and handling spinach, lettuce, and other leafy greens. Assessments of 2 cents per carton are to fund operations of the agreement, including periodic inspections.<sup>31</sup>

Nationally, USDA's Agricultural Marketing Service (AMS) published in the October 4, 2007, *Federal Register* an advance notice of proposed rulemaking on whether to establish a "marketing program to address the handling of fresh and fresh-cut leafy green vegetables. The program would allow packers, processors, shippers, and marketers (collectively referred to as handlers) to maintain the quality of their products by reducing the risk of pathogenic contamination during the production and handling of leafy greens."<sup>32</sup> Consumer advocates criticized the proposal because it might deter FDA from taking a more aggressive regulatory approach to protecting consumers from unsafe produce, despite AMS assertions that it was not intended to do so.

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<sup>30</sup> See also archived CRS Report RL33722, *Food Safety: Federal and State Response to the Spinach E. coli Outbreak*, by Donna V. Porter.

<sup>31</sup> The agreement can be accessed at [<http://www.caleafygreens.ca.gov/>].

<sup>32</sup> 72 *Federal Register*, pp. 56678-56680. The Agricultural Marketing Agreement Act of 1937 as amended (7 U.S.C. 601-674) authorizes AMS to implement federal marketing orders and agreements, which are designed to establish and maintain orderly marketing conditions for the regulated commodities. Both orders (which are mandatory for affected parties) and agreements (which, like the one discussed in this *Federal Register*, are voluntary) can be used for such purposes as setting grade, size, or other quality attributes of a commodity, for determining marketing conditions, and for providing research and promotional activities, among other things.

**Legislation.** Bills taking a variety of approaches to improving fresh produce safety have been offered in the 110<sup>th</sup> Congress. One of the more comprehensive (S. 2077), introduced by Senate Agriculture Committee Chairman Harkin, would require HHS-FDA to promulgate rules on good manufacturing practices (GMPs) for “minimally processed produce” (i.e., fresh-cut produce). The bill also would require FDA, in consultation with USDA, to issue rules on good agricultural practices for growers of fresh produce. Both processing establishments and growers would have to implement written plans detailing controls for limiting contaminants, and submit to periodic FDA inspections. Among other provisions, the bill provides for research and public education on produce safety, and for equivalency procedures for countries exporting produce to the United States.

Elsewhere, a provision in Title X of P.L. 110-85 directs FDA to work with states on programs and activities to improve food safety, including the safety of fresh and processed produce with the goal of strengthening state programs.

## Restrict Antibiotic Use in Animals

**Issue.** Public health experts have expressed concern about increasing antibiotic resistance among sick patients. Such antimicrobial resistance has been linked to a number of causes such as overuse by medical professionals and their patients, and the wide use of antibiotics for nontherapeutic (essentially nonmedical) purposes in food animals. Farmers administer antibiotics in feed for some types of food-producing animals not only to treat and prevent diseases but also to encourage growth and efficient use of feed rations. Some argue that nontherapeutic uses should be severely constrained and/or limited to drugs not associated with human medical treatments. Others oppose this approach, arguing that many animal production operations would not be commercially viable without the drugs’ routine use and/or that the linkage between such use and antimicrobial resistance lacks a strong scientific basis.<sup>33</sup>

**Legislation.** As of late 2007, one major proposal had been offered affecting agricultural use of antibiotics. Companion bills H.R. 962/S. 549 would amend the food and drug act to define a nontherapeutic use of a critical antimicrobial animal drug (i.e., a drug that is important in treating human illnesses) as “any use of the drug as a feed or water additive for an animal in the absence of any clinical sign of disease in the animal for growth promotion, feed efficiency, weight gain, routine disease prevention, or other routine purpose.” Within two years, FDA would have to withdraw approval of such nontherapeutic drug use unless the drug application holder can demonstrate there is “reasonable certainty that no harm to human health” will occur. The bills also contain data collection and reporting requirements for drug manufacturers.

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<sup>33</sup> This discussion is based largely on a section in archived CRS Report RL31853, *Food Safety Issues in the 109<sup>th</sup> Congress*. Also see the FDA website “New Guidance for Industry on Antimicrobial Drugs for Food Animals: Questions and Answers,” accessed at [<http://www.fda.gov/oc/antimicrobial/questions.html>].

## Increase Biotechnology Oversight

**Issue.** Since genetically engineered (GE, sometimes called genetically modified, or GM) crop varieties first became commercially available in the mid-1990s, U.S. soybean, cotton, and corn farmers have rapidly adopted them to lower production costs and raise crop yields. A number of animal biotechnologies (including cloning) also are becoming available. Members of Congress, particularly from agricultural areas, generally favor the adoption of such technologies, along with publicly supported research and other activities aimed at gaining their acceptance in foreign and domestic markets. Others question the food safety impacts of GE crops and animals, and whether the current U.S. regulatory framework, which is based primarily upon statutory authorities enacted before the rise of agricultural biotechnology, is still adequate.

**Legislation.** The Senate-passed omnibus farm bill (H.R. 2419) would prohibit FDA from issuing a final risk assessment and from lifting the voluntary moratorium on marketing products of cloned animals until completion of newly mandated studies on the safety and on the market impacts of introducing such products. The outcome of this language could depend upon decisions in a House-Senate conference committee in early 2008. Meanwhile, language accompanying the omnibus appropriation for 2008 (H.R. 2764) also calls on the FDA to continue the voluntary moratorium until more studies can be completed.

S. 414/H.R. 992 would amend the food and drug act and the meat inspection act (but not the poultry inspection act) to require that products from cloned animals or their progeny be so labeled. FSIS and FDA would have to require that anyone who “handles, or distributes a cloned product for retail sale maintain a verifiable recordkeeping audit trail” to verify compliance. A separate proposal (H.R. 1396/S. 536) would amend the Organic Foods Production Act of 1990 (7 U.S.C. 6504) to prohibit the use of the “organic” label on food products from cloned livestock or their progeny.

## Appendix A: Overview of Selected Food Safety Bills

Bill	Contents	Status
H.R. 912 (Farr) <i>Spinach Research and Recovery Act of 2007</i>	Authorizes new appropriations for produce safety research; provides for payments for spinach industry losses after the FDA September 2006 health advisory on fresh produce.	Introduced 2/8/07; referred to Agriculture
H.R. 962/S. 549 (Slaughter/Kennedy) <i>Preservation of Antibiotics for Medical Treatment Act of 2007</i>	Requires FDA to withdraw approval of nontherapeutic uses in food animals of drugs used to treat human diseases, unless manufacturer can reasonably demonstrate no harm to human health due to antimicrobial resistance.	H.R. 962 introduced 2/8/07; referred to Energy and Commerce Committee  S. 549 introduced 2/12/07; referred to Health, Education, Labor, and Pensions
H.R. 992/S. 414 (DeLauro/Mikulski) <i>Cloned Food Labeling Act</i>	Amends the food and drug act and the meat inspection act to deem as misbranded a food or meat food product derived from a cloned animal if it does not bear a conspicuous label stating this fact; requires verifiable recordkeeping.	H.R. 992 introduced 2/12/07; referred to Agriculture and to Energy and Commerce  S. 414 introduced 1/26/07 and referred to Health, Education, Labor, and Pensions
H.R. 1148/S. 654 (DeLauro/Durbin) <i>Safe Food Act of 2007</i>	Establishes a new independent Food Safety Administration to administer and enforce all federal food safety laws. Requires: (1) a national food safety program based on an analysis of the food hazards; (2) standards for processors of food and food establishments; (3) a certification system for foreign governments or food establishments seeking to import food; (4) a system for tracing food and food-producing animals from point of origin to retail sale; (5) maintaining an active surveillance system of food, food products, and epidemiological evidence; (6) a sampling program to monitor contaminants in food; (7) an analysis of hazards in the food supply; (8) a national public education campaign on food safety; and (9) research relating to food safety. Sets forth provisions regarding prohibited acts, administrative detention, condemnation, recall, penalties for violations of food safety laws, whistle blower protection.	H.R. 1148 introduced 2/16/07; referred to Energy and Commerce and to Agriculture  S. 654 introduced 2/15/07; referred to Agriculture
H.R. 1396/S. 536 (Woolsey/Kohl) <i>(no title)</i>	Amends the Organic Foods Production Act of 1990 to prohibit the labeling of cloned livestock and products derived from cloned livestock as organic.	H.R. 1396 introduced 3/7/07; referred to Agriculture  S. 536 introduced 2/8/07; referred to Agriculture

Bill	Contents	Status
H.R. 1760/S. 1149 (Kind/Kohl) <i>(no title)</i>	Amends the meat inspection act and the poultry products inspection act to authorize the interstate distribution of state inspected meat and poultry if the Secretary of Agriculture determines that state inspection requirements are at least equal to federal inspection requirements; provides for partial reimbursement for inspection costs.	H.R. 1760 introduced 3/29/07; referred to Agriculture  S. 1149 introduced 4/18/07; referred to Agriculture
H.R. 2108/S. 1274 (DeLauro/Durbin) <i>Human and Pet Food Safety Act of 2007</i>	Amends the food and drug act to require a person who has reason to believe that any food (including pet food) introduced into interstate commerce may be in violation of the act to immediately notify FDA of its identity and location. If a food may pose a threat to public health, authorizes and requires FDA to implement a series of specific notification, detention, and recall procedures. Sets forth certification and inspection requirements for foreign governments and foreign firms seeking to import food into the United States. Also requires new FDA measures to prevent contamination of pet food.	H.R. 2108 introduced 5/2/07; referred to Energy and Commerce  S. 1274 introduced 5/2/07; referred to Health, Education, Labor, and Pensions  Some provisions included in P.L. 110-85 (see below)
H.R. 2315/S. 1150 (Pomeroy/Hatch) <i>New Markets for State-Inspected Meat and Poultry Act of 2007</i>	Directs USDA to review each state's meat and poultry inspection program for effectiveness and steps needed to convert to program described as follows. Amends the FMIA and PPIA to authorize USDA to approve a qualifying state meat and/or poultry inspection program and allow the shipment in commerce (including interstate) of meat and poultry products so inspected (replaces current federal-state inspection program). Also provides ability for federally inspected plants to convert to the new state inspection program.  Provides for annual FSIS reviews of state plans; federal-state cooperative agreements and partial reimbursement for costs of meeting federal requirements; and limitations on size of plants permitted to enter the new program. Prohibits from state inspection plan participation establishments with more than 50 employees, with some exceptions.	H.R. 2315 introduced 5/15/07; referred to Agriculture  S. 1150 introduced 4/18/07; referred to Agriculture  Like provisions incorporated by House Agriculture Committee into H.R. 2419, the omnibus farm bill (see below)
H.R. 2419 (Peterson) <i>Farm, Nutrition, and Bioenergy Act of 2007</i>	<b>House</b> version of omnibus farm bill includes provisions on state inspection like those in H.R. 2315/S. 1150 (see above).  <b>Senate</b> version supplements current rules with program enabling products inspected by state personnel who are under federal supervision to be shipped in interstate commerce. Limits eligible establishments to those with 25 or fewer employees; state-inspected establishments with more than 25 employees could shift to regular federal inspection. Current federal establishments ineligible for the new state program. Contains 60% federal cost share and 100% in states with high level of pathogen testing; provides for new training and outreach programs.	H.R. 2419 introduced 5/22/07; referred to Agriculture, which reported it as amended on 7/23/07 (H.Rept. 110-256). Passed by full House on 7/27/07  Full Senate considered H.R. 2419 beginning 11/5/07, substantially amended it, and passed the bill 12/14/07; House-Senate conference pending



Bill	Contents	Status
	<p><b>Senate</b> version also establishes new Bipartisan Food Safety Commission (see S. 2245); extends mandatory FSIS inspection to farm-raised domestic catfish; establishes reportable (i.e., adulterated) food registries for meat and poultry; prohibits FDA from issuing a final risk assessment and lifting the voluntary moratorium on marketing products of cloned animals until completion of new studies on the safety and on the market impacts of introducing such products.</p>	
<p>H.R. 2997 (Kaptur) <i>Assured Food Safety Act of 2007</i></p>	<p>Directs USDA and FDA to jointly establish a mandatory certification program required for all food imports, to be issued by the country of origin. Directs USDA and FDA to prohibit importation of a product that fails safety standards until the foreign production facilities can be inspected to determine that sufficient corrections have been made, to be followed by more rigorous inspections for three years. Establishes user fees on food imports of up to \$20 per line item imported, to pay for inspections.</p>	<p>Introduced 7/11/07; referred to Energy and Commerce, to Agriculture, and to Ways and Means</p>
<p>H.R. 3100 (Kirk) <i>Import Safety Act of 2007</i></p>	<p>Amends the food and drug act to authorize additional appropriations for FDA of \$20 million for each of FY2008 through FY2012 for import inspections of processed food (and toothpaste). Significantly increases civil penalties for food-safety related violations.</p>	<p>Introduced 7/19/07; referred to Energy and Commerce</p>
<p>H.R. 3161, S. 1859 (DeLauro/Kohl) <i>Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2008</i></p>	<p>Makes FY2008 appropriations for the: (1) USDA; (2) FDA; (3) Commodity Futures Trading Commission; and (4) Farm Credit Administration. Specifies certain uses and limits on or prohibitions against the use of funds appropriated by this act. (See text of this CRS report for details on food safety-related funding for FDA and USDA)</p>	<p>H.R. 3161 introduced and reported as an original measure 7/24/07 by Appropriations (H.Rept. 110-258) Passed by House 8/2/07</p> <p>S. 1859 introduced and reported 7/24/07 by Appropriations (S.Rept. 110-134)</p> <p>FY2008 funding for these agencies incorporated into H.R. 2764 as Division A. Signed into law December 26, 2007</p>
<p>H.R. 3484 (DeGette) <i>Safe and Fair Enforcement and Recall (SAFER) for Meat, Poultry, and Food Act of 2007</i></p>	<p>Establishes new notification and recall authorities for meat, poultry, and other foods, including a requirement that USDA or FDA be notified any time there is reason to believe that a food is adulterated or misbranded. Provides USDA and FDA with mandatory recall authorities if specified voluntary actions are not undertaken.</p>	<p>Introduced 9/6/07; referred to Agriculture and to Energy and Commerce</p>

Bill	Contents	Status
	Other provisions make it easier for FSIS to refuse to provide or to withdraw inspection from meat or poultry establishments; and provide new monetary penalties for violations of food safety laws.	
H.R. 3485 (DeGette) <i>Tracing and Recalling Agricultural Contamination Everywhere (TRACE) Act of 2007</i>	Requires, within one year of enactment, the establishment of new traceability systems for both FDA and USDA regulated food products, through all stages of production, processing, and marketing; includes record keeping and access requirements for producers, processors and others.	Introduced 9/6/07; referred to Agriculture and to Energy and Commerce
H.R. 3580 (Dingell); P.L. 110- 85 <i>Food and Drug Administration Amendments Act of 2007</i>	<p>Title X requires regulations on processing and ingredient standards for pet food, and on updated standards for pet food labeling; also requires an early warning and surveillance system to identify pet food adulteration and associated disease outbreaks. Requires FDA to collect, aggregate, and disseminate information on recalls of either human or pet foods; to coordinate activities, provide assistance and support staff training for states to improve food safety programs, including for fresh and processed produce, and including at retail food establishments.</p> <p>Title X also amends the food and drug act to require a registry on potentially contaminated human and animal foods, and spells out notification and recordkeeping requirements, including standards and data elements for reporting instances of suspected food adulteration, including notification within 24 hours by processors. Also requires the preparation of various food safety-related reports; and provides for enhanced FDA inspection of aquaculture and seafood through partnerships.</p>	<p>Introduced 9/19/07; referred to Energy and Commerce. Bill reflects compromise between House and Senate versions of FDA bills (H.R. 2900; S. 1082); only Senate version contained food safety provisions</p> <p>Passed House under suspension 9/19/07; passed Senate by unanimous consent on 9/20/07 and cleared for White House; signed into law 9/27/07 (P.L. 110-85)</p>
H.R. 3610 (Dingell) <i>Food and Drug Import Safety Act of 2007</i>	Reiterates that all FDA-regulated imported foods must meet the same standards as U.S.-produced foods; entry would be denied to foods that do not. All food imports must originate from facilities or countries that have been certified by FDA as having safety standards that provide the same level of safety as U.S. standards. Failure to do so could result in revocation of the certificate. Charges FDA with enforcing the provision through random inspections, sampling and testing. Requires user fees on imported foods, beginning in FY2008, of up to \$50 per recorded import load. At least 90% of the fee revenue must be used to carry out import and overseas inspections, with priority on inspections at ports of entry and on detection of intentionally adulterated food. Not more than 10% of the revenue may be used for newly authorized research into testing techniques for use on import inspections.	Introduced 9/20/07; referred to Energy and Commerce

Bill	Contents	Status
	<p>Requires FDA to restrict imports of all foods to ports of entry located in a metropolitan area that has an FDA laboratory capable of testing such foods, although waivers could be granted in limited circumstances. Prohibits closing any of the current FDA laboratories, or any of the 20 FDA district offices. Requires the labeling of all foods to identify the country of origin. Requires establishment of a voluntary “Safe and Secure Food Importation Program” under which food importing companies could receive expedited movement of their products.</p>	
<p>H.R. 3624 (Pallone) <i>Consumer Food Safety Act of 2007</i></p>	<p>Requires new “National Food Safety Program” that must be based on a comprehensive analysis of food safety hazards throughout the production and marketing chain. Mandates process control regulations; requires quarterly inspections of processors and importers, except those that have negligible risk or meet exceptional standards. Creates system involving routine FDA inspections of foreign processing facilities and of imports at ports of entry. Authorizes (but does not appear to require) FDA to enter into an agreement with any foreign country desiring to export food to the United States. FDA must certify the specific types of food products covered by the foreign safety system, and review each foreign certification at least once every three years.</p> <p>Includes import inspection provisions and requirements for notification and mandatory recall. Permits FDA to impose traceability requirements on any type or class of food product if necessary to protect public health.</p>	<p>Introduced 9/20/07; referred to Energy and Commerce</p>
<p>H.R. 3937 (DeLauro) <i>Food Import Safety Act of 2007</i></p>	<p>Requires all FDA-regulated food imports from a foreign facility or country that has been certified by HHS as having at least the same level of safety as U.S. standards, to be periodically reviewed by HHS. Permits HHS to revoke certification if a foreign facility or country is linked to illness or no longer meeting requirements. Provides for mandatory notification of problem foods, and for mandatory recall of such foods if voluntary actions to do so are not sufficient. Sets forth civil and criminal penalties.</p>	<p>Introduced 10/23/2007; referred to Committee on Energy and Commerce</p>
<p>H.R. 3967 (Burgess) <i>Imported Food Safety Improvement Act of 2007</i></p>	<p>Authorizes FDA to refuse any food from any country, growing area, producer, manufacturer or shipper due either to repeated foodborne disease outbreaks or repeated adulteration, and if there is a reasonable probability of significant adverse health consequences, and systemic intervention is needed. A lower threshold could be used to refuse an import in an emergency situation.</p>	<p>Introduced 10/23/07; referred to Energy and Commerce</p>

Bill	Contents	Status
S. 1292 (Schumer) <i>Meat and Poultry Products Traceability and Safety Act of 2007</i>	Amends the meat and poultry inspection acts to require FSIS to establish a traceability system for all stages of production, processing, and distribution of meat and meat food products and poultry and poultry food products. The system must be able to trace each animal or group of animals to any location the animal was held before slaughter; and each carcass, carcass part and food product forward from slaughter through processing and distribution to the ultimate consumer. Also authorizes recordkeeping requirements.	Introduced 5/3/07; referred to Agriculture
S. 1776 (Durbin) <i>Imported Food Safety Act of 2007</i>	Amends the food and drug act to require FDA to establish within two years a certification system for foreign governments and establishments seeking to import food into the United States. Requires FDA to review, audit, and certify a foreign government before certifying its program as at least equivalent to the U.S. system; additionally requires an onsite inspection of foreign establishments before certifying equivalency. Requires audits at least every five years to determine continued compliance, and provides for decertification if a food import is linked to human illness outbreaks. Establishes user fees of up to \$20 per recorded import load, with no less than 50% of revenues to be used for border inspections and no more than 50% for research on testing and sampling techniques.	Introduced 7/12/07; referred to Agriculture
S. 2077 (Harkin) <i>Fresh Produce Safety Act</i>	Requires adoption of good manufacturing practices (GMPs) for processors of “fresh cut” produce, covering sanitation procedures and water standards, including testing, and based on a scientific risk assessment; has similar good agricultural practices for growers. Provides for FDA inspections of processors and producers. Other provisions of the bill provide for research and public education on produce safety, and for equivalency agreements with countries exporting produce to the United States.	Introduced 9/20/07; referred to Agriculture
S. 2081 (Brown) <i>Food and Product Responsibility Act of 2007</i>	Provides new recall and notification authorities for FDA and FSIS generally similar to those in H.R. 2108/S. 1274, H.R. 3484 and H.R. 3624 (see above). Also, all manufacturers of foods (and of other non-food products like auto parts, drugs and other consumer products) must obtain “recall responsibility certificates” which certify that they have the resources to cover the entire cost of any recalls, plus compensatory damages and costs that may arise from product liability claims.	Introduced 9/20/07; referred to Agriculture
S. 2192 (Feingold) <i>Food and Product Responsibility Act of 2007</i>	Requires FDA to collect user fees from a manufacturer of a food (or other FDA-regulated product) if it must be reinspected to ensure the correction of a violation found in the original inspection.	Introduced 10/18/07; referred to Health, Education, Labor, and Pensions

<b>Bill</b>	<b>Contents</b>	<b>Status</b>
S. 2245 (Durbin) <i>Food Safety Authority Modernization Act</i>	Establishes a Congressional Bipartisan Food Safety Commission to recommend statutory changes to modernize the food safety system and ways to harmonize food safety requirements across agencies.	Introduced 10/25/07; referred to Homeland Security and to Governmental Affairs; added to Senate version of farm bill (H.R. 2419)
S. 2418 (Casey) <i>Ending Agricultural Threats: Safeguarding America's Food Supply for Everyone (EAT SAFE) Act of 2007</i>	Requires public notification regarding any prohibited imported food products; spells out civil penalties for importing such products; requires certification standards for accrediting imported food safety laboratories; provides for data sharing, public notification regarding recalled food products; authorizes appropriations for foodborne illness education, and for food safety personnel hiring and training.	Introduced 12/5/07; referred to Agriculture

## Appendix B. Selected Food Safety Authorization Bills at a Glance

<i>(Where boxes are empty, bills contain no applicable provision.)</i>	<b>H.R. 912</b> Farr	<b>H.R. 962/S. 549</b> Slaughter/Kennedy	<b>H.R. 992/S. 414</b> DeLauro/Mikulski	<b>H.R. 1148/S. 654</b> DeLauro/Durbin	<b>H.R. 1396 S. 536</b> Woolsey/ Kohl	<b>H.R. 1760/S. 1149</b> Kind/Kohl	<b>H.R. 2108/S. 1274</b> DeLauro/ Durbin	<b>H.R. 2315/S. 1150</b> Pomeroy/Hatch <b>H.R. 2419</b>	<b>H.R. 2997</b> Kaptur	<b>H.R. 3100</b> Kirk	<b>H.R. 3484</b> DeGette	<b>H.R. 3485</b> DeGette	<b>H.R. 3580</b> P.L. 110-85
<b>Bill Focus:</b>	produce	antibiotics (ag use)	cloning	single agency	animal cloning	state meat & poultry	pet/human food	state meat & poultry	imports	imports	recall	trace-ability	FDA
System reorganization				yes				study (Senate)					
Problem notification				yes			yes	yes (Senate)					yes
Mandatory recall				yes			yes				yes		
Tracing/recordkeeping				yes								yes	
Enforcement/penalties				yes					yes	yes	yes		
Performance stndrds.				yes									
New process controls				yes									
Inspection frequency				yes									
Reqd. testing/sampling				yes									
Foreign certification				yes			yes		yes				
Expedite import entry													
New user fees (for)									(imports)				
Labeling					organic								
Research; education	yes			yes									
Other selected provisions	industry loss paymts.	limits on use	require labeling	whistle-blower protect.	“organic” not eligible	interstate shipment permitted	pet food rules required	interstate shipment permitted		addtl. approps. authority			state asst.; misc. on seafoods

<i>(Where boxes are empty, bills contain no applicable provision.)</i>	<b>H.R. 3610</b> Dingell	<b>H.R. 3624</b> Pallone	<b>H.R. 3937</b> DeLauro	<b>H.R. 3967</b> Burgess	<b>S. 1292</b> Schumer	<b>S. 1776</b> Durbin	<b>S. 2077</b> Harkin	<b>S. 2081</b> Brown	<b>S. 2192</b> Feingold	<b>S. 2245</b> Durbin	<b>S. 2418</b> Casey
<b>Bill Focus:</b>	imports	new program	imports	imports	traceability	imports	produce	recalls	user fees	study	smuggled imports
System reorganization		yes								yes (study)	
Problem notification		yes	yes					yes			yes
Mandatory recall	yes	yes	yes					yes			
Tracing/recordkeeping		authorized			meat/poultry						
Enforcement/penalties	yes	yes									yes
Performance stndrds.		yes					Produce growers & processors				
New process controls		yes									
Inspection frequency		yes					yes				
Reqd. testing/sampling	yes						yes				lab certif.
Foreign certification	yes	yes	yes			yes					
Expedite import entry	yes										
New user fees (for)	(imports)					(imports)			(reinspection)		
Labeling	COOL										
Research; education	yes	yes				yes	yes				yes
Other selected provisions	limit ports of entry; no lab closures	whistle-blower protection		new authority to refuse unsafe imports				certify firms' ability to pay for recalls		Commission to study & recommend changes	addtl. approps. authorized; more training