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CRS Report for Congress

Food Safety: Oversight and Current Issues

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Summary

A series of widely publicized food safety problems, including concerns about adulterated pet food ingredients and farmed seafood from China, illnesses linked to *E. coli* O157:H7 on leafy produce from California and in meat products, and a national recall of peanut butter due to *Salmonella* contamination, have made food safety an issue in the 110th Congress. Oversight hearings are underway, and various bills have been proposed to alter the current food safety system and/or increase spending.

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 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.[1] Today an increasing proportion of the U.S. population is older and immune-compromised, heightening their risk from these hazards. At the same time, more consumers than ever are either eating out or buying ready-to-eat and prepared foods including pre-cut produce, which may come from many distant sources, often overseas. At issue is whether the current system of federal food safety laws and agencies has kept pace with the significant changes that have occurred in food production, marketing, and consumption.

Food safety-related incidents frequently heighten congressional, public, and media scrutiny of the issue, as a number of developments in 2006 and 2007 have illustrated. For example, more than 200 confirmed illnesses and three deaths were linked last fall to the consumption of bagged fresh spinach grown in California and that was found to carry *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. In February 2007, the U.S. Food and Drug Administration (FDA)

[1] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, data accessed at [http://www.cdc.gov/foodsafety/]. 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, 1999, pp. 607-625.

announced a nationwide recall of peanut butter due to *Salmonella* contamination, after hundreds of illnesses, dating back to August 2006, were linked to the bacterium.[2] In late September 2007, the U.S. Department of Agriculture (USDA) announced a voluntary recall of nearly 22 million pounds of ground beef products after reports of illnesses were linked to *E .coli* O157:H7 in some of them. This was the largest of 19 reported beef recalls related to the pathogen in 2007, through early November.

Attention shifted to the safety of food imports in early 2007 when adulterated 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 feed.[3] In June 2007, FDA announced that it was detaining imports of certain types of farm-raised seafood from China (specifically, shrimp, catfish, basa, dace, and eel) until their shippers could confirm that they are free of unapproved drug residues.

Perceived gaps in federal safeguards were being explored at a number of hearings in 2007. Several lawmakers have 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. Some proposed bills focus on ensuring the safety of imported foods and/or strengthening the ability of federal agencies to identify and recall contaminated products; others have called for a reorganization of food safety agencies and responsibilities, or for increased funding for current programs. Each of these bills seeks to address one or more of the broad policy concerns outlined below. Members' attention could next turn to the food protection strategy released by the Administration on November 7, 2007, that in part calls for several new legislative authorities (see page 6).

Earlier in 2007, some food safety provisions were added to an FDA drug bill (H.R. 3580) signed into law as P.L. 110-85. Other potential vehicles are annual appropriations for agriculture and FDA (H.R. 3161 and S. 1859) and the farm bill. For example, both the House-passed and Senate committee versions of the farm bill (H.R. 2419) would lift (in divergent ways) a ban on the interstate shipment of state-inspected meat and poultry.

The Food Safety System

The Government Accountability Office (GAO) has identified 15 federal agencies collectively administering at least 30 laws related to food safety.[4] 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 USDA, together comprise the majority of both the total funding and the total staffing of the government's food regulatory system. Primary statutes governing FDA's activities are the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 et seq.) and the Public Health Service Act, as amended (42 U.S.C. 201 et seq.). FSIS's primary authorities are the Federal Meat Inspection Act (FMIA), as amended (21 U.S.C. 601 et seq.), and the Poultry Products Inspection Act (PPIA), as amended (21 U.S.C. 451 et seq.).

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[2] For sources and updates see the FDA website: [http://www.fda.gov/opacom/7alerts.html].

[3] FDA has the same basic safety standards for human foods and animal feeds, including pet food.

[4] *High Risk Series: An Update* (GAO-07-310), January 2007. See also CRS Report RS22600, *The Federal Food Safety System: A Primer*.

Reorganization of Food Safety Responsibilities

Critics have argued for decades that food safety has been compromised by what many maintain is fragmented oversight that is dispersed over too many agencies, poorly coordinated, and inefficient. Defenders of the current system assert that it already is scientifically based with adequate statutory authority, and that food companies already produce and distribute safe food, making the United States a model for the world.

Companion bills H.R. 1148 and S. 654 seek to reorganize the federal agencies responsible for food safety, as well as to overhaul the safeguards themselves. Another bill (H.R. 3624) — although it would not transfer authorities and agency responsibilities as in H.R. 1148/S. 654 — does propose major changes in how the current system is administered by FDA.[5] Among other developments, the Senate Agriculture Committee reported a farm bill that would establish a bipartisan congressional commission on food safety to recommend improvements, which is also the thrust of S. 2245. A potential Senate floor amendment would sunset authority for all U.S. food safety agencies in order to encourage scrutiny of and changes in the current system.

Funding

Some critics argue the primary problem today is that food safety agencies lack sufficient funding and staff to carry out their congressionally mandated responsibilities. From time to time in the past, FSIS has had difficulty in adequately staffing its service obligations to the meat and poultry industries. At FDA, officials concede that they lack the necessary resources to expand in some areas, notably import safety. Although it requested modest FY2008 increases for both FDA and FSIS, the Administration also has stressed that it can meet its 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 recent hearings, some Members of Congress have expressed skepticism that these efforts can succeed without additional funds. Besides increased appropriations, new user fees have been proposed — the latter viewed with suspicion by those who argue that food safety should not be funded by the regulated industries. H.R. 3161 and S. 1859 would provide FY2008 appropriations for FDA and FSIS food safety activities, but had not yet passed Congress in early November 2007. (P.L. 110-92) funds them at FY2007 levels through mid-November. (See CRS Report RL34132, *Agriculture and Related Agencies: FY2008 Appropriations*.)

Food Import Oversight

Concerns about perceived gaps in import safeguards are not new. However, they have gained wider interest 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. Total imports of agricultural and seafood products increased from 31.7 million metric tons (MMT) valued at $39 billion in FY1996 to 46.1 MMT and $76.9 billion in FY2006, and they continue

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[5] In fact, a number of the bills described in other sections of this CRS report also envision significant system changes.

to rise. At issue is whether U.S. safeguards, which generally were created at a time when most Americans obtained their foods domestically, adequately protect public health.

As of early November 2007, about a dozen food safety bills were pending with provisions addressing some aspect of food import safety. Several focus extensively on the issue. Many of these bills (including H.R. 2997, S. 1776, H.R. 1148/S. 654, H.R. 2108/S. 1274, H.R. 3610, H.R. 3624, and H.R. 3937) propose 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. Under some of these bills, including H.R. 3937 and H.R. 3967, certification could be denied or revoked if foreign safeguards are found to be insufficient, unsafe imports are discovered, or foodborne illnesses are linked to such products.

A number of the bills also propose the collection of user fees from importers to cover the costs of inspecting foreign products at the borders. Another (S. 2192) would require fees of those who must be reinspected because their products fail a first inspection. Some 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. Among other measures with import safety provisions are H.R. 3100, H.R. 3580 (P.L. 110-85), and S. 2077. (See also CRS Report RL34198, *U.S. Food and Agricultural Imports: Safeguards and Selected Issues*).

Notification and Recall Authority; Product Tracing

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 products, 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, some argue.

Others 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.[6] 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. Nonetheless, a number of Members of Congress support legislation to strengthen notification and recall authorities. For example, H.R. 2108/S. 1274, H.R. 3484, H.R. 3580 (P.L. 110-85), H.R. 3610, H.R. 3624, S. 2081, H.R. 1148/S. 654, and H.R. 3937 contain various provisions for mandatory

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[6] 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 ..." For additional background see CRS Report RL34167, *The FDA's Authority to Recall Products*, by Vanessa K. Burrows.

recall authority and/or notification requirements when adulterated foods are suspected to be in commerce.

Recalls imply that industry and government officials have the ability to quickly trace the movement of products. Some argue that improved traceability capabilities would enable either USDA (in the case of meat and poultry products) or FDA (in the case of other foods) to more quickly determine 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. H.R. 3485 and S. 1292 are among the bills that would require agencies to establish food traceability systems.

State-Inspected Meat and Poultry

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 USDA-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 the foreign, plants. 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.[7]

H.R. 2419, the House-passed omnibus farm bill, would permit interstate shipment of these products. It also could enable many federally inspected plants to shift to state inspection. The Senate Agriculture Committee reported a farm bill (S. 2302) that also would permit interstate shipment, but under very different conditions than in the House bill. Other bills to permit interstate shipment include H.R. 2315/S. 1150 and H.R. 1760/S. 1149. (See also CRS Report RL34202, *State-Inspected Meat and Poultry: Issues for Congress*, and CRS Report RL32922, *Meat and Poultry Inspection: Background and Selected Issues*.)

Produce Safety

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 were underlined by reports, starting in September 2006, of foodborne illnesses linked to California spinach and lettuce contaminated with the bacterium *E. coli O157:H7*. There is ongoing debate

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[7] See also *FSIS Review of State Programs: Summary Report* (January 2007) at [http://www.fsis.usda.gov/PDF/Review_of_State_Programs.pdf].

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. Bills intended to improve produce safety include H.R. 912 and S. 2077.

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.[8] The other report is FDA's *Food Protection Plan*, which focuses on food, whether imported or domestically produced, and which contains recommendations for food imports that generally parallel those in the broader report.[9]

Both plans are oriented toward assessing and prioritizing risks regardless of where they occur (starting with a product's origin), and preventing rather than waiting for problems to occur. Many of the 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 them are expected to necessitate more spending, which neither report quantified. Officials stated that they would seek additional funds to help pay for these initiatives as part of the upcoming FY2009 budget request.

Proposed Legislative Changes. One significant legislative change that FDA wants is mandatory recall authority in cases where firms are unwilling to do so voluntarily or expeditiously. (USDA officials continue to assert that they do not need similar authority for meat and poultry.) Another proposed change would be new authorization for FDA to require electronic import certificates for shipments of products deemed to be of high risk. Another would be new authority to block entry of foods imported by foreign firms that impede regulators' access to their facilities.

Among other proposed statutory changes in the plan would be authority for FDA regulations requiring food entities to implement measures solely intended to prevent intentional food adulteration by terrorists or criminals; more explicit authority to require additional preventive (HACCP-like) controls for high-risk foods; authority for FDA accreditation of qualified third parties to conduct some types of inspections; and new user fees for facilities that have to be reinspected because they have failed to meet FDA safety requirements.

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[8] Accessed at [http://www.importsafety.gov/report/actionplan.pdf].

[9] Accessed at [http://www.fda.gov/oc/initiatives/advance/food/plan.html].