

CRS Report for Congress

Food Safety: Selected Issues and Bills in the 110th Congress

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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, foodborne illness outbreaks linked to the bacterium *E. coli* O157:H7 on leafy produce from California, and a national recall of peanut butter due to *Salmonella* contamination, have made food safety a top issue for a number of lawmakers in the 110th Congress. Several Members have introduced bills to alter the current U.S. food safety system and/or increase spending, which they assert is needed to meet current obligations to protect consumers from unsafe food. This report describes a number of these measures.

Reorganization of Food Safety Responsibilities. The Government Accountability Office has concluded that the current federal safety system should be fundamentally re-examined because it is fragmented and inefficient, threatening food safety. H.R. 1148 and S. 654 would consolidate federal food safety responsibilities under a new, independent Food Safety Administration.

Food Import Oversight. U.S. food imports have increased significantly in recent years, raising questions about whether U.S. safeguards, which generally were created at a time when most Americans obtained their foods domestically, sufficiently protect public health. H.R. 2997 and S. 1776 would require foreign countries and establishments to receive U.S. certifications before importing into the United States, and charge fees on food imports to cover oversight costs. H.R. 1148, S. 654, H.R. 2108, and S. 1274 also contain import pre-certification requirements. H.R. 3100 and S. 1082 include other provisions to bolster food import safety.

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. H.R. 2108/S. 1274, Title VI of S. 1082, and S. 1148/S. 654 contain various provisions for mandatory recall authority and/or notification requirements when adulterated foods are suspected to be in commerce. S. 1292 would require USDA to establish a meat and poultry traceability system.

State-Inspected Meat and Poultry. Federal law prohibits state-inspected meat and poultry from being shipped across state lines, a ban that many states and small plants want to overturn. Bills seeking to allow such shipments include H.R. 2315/S. 1150, H.R. 1760, S. 1149, and H.R. 2419 (Section 11103).

Other food-safety related measures include H.R. 962/S. 549, to curtail the non-medical use of antibiotics in animal feeds; H.R. 992/S. 414 and H.R. 1396/S. 536, addressing the labeling of products from cloned animals; H.R. 912 and S. 1082 (Section 604), encouraging produce safety; and H.R. 3161 and S. 1859, which provide FY2008 appropriations for FDA and FSIS food safety activities. Also, the House Energy and Commerce Committee Chairman in August 2007 was circulating for discussion a wide-ranging food safety bill covering but not limited to imports.

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Food Safety: Selected Issues and Bills in the 110th 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 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 At issue is whether the current system has the resources and structural organization to protect consumers from these dangers. 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.

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 last fall 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. In February 2007, 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.²

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 all 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.

¹ 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.

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

³ FDA requires the same general safety standards for human foods and animal feeds, including pet food.

These and other developments have made food safety a top issue for a number of lawmakers in the 110th Congress. Several 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. Perceived gaps in federal safeguards are being explored at a number of congressional hearings in 2007. A number of bills addressing various aspects of the issue have been introduced, as described in this report. (The body of this report discusses these bills according to the issues they appear to address; Appendix A summarizes them by number.)

If any of these bills progress through the committees of jurisdiction (see below) and onto the House and Senate floors, they could conceivably be considered either independently, or attached to other, larger measures which Congress is considering. For example, food safety provisions were added to the Senate version of a Food and Drug Administration (FDA) bill (S. 1082) as described later in this report. Other potential vehicles are annual appropriations for agriculture and FDA (such as H.R. 3161 and S. 1859) and an omnibus farm bill (such as H.R. 2419).

The Food Safety System

The Government Accountability Office (GAO) has identified 15 federal agencies collectively administering at least 30 laws related to food safety. 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 comprise the majority of both the total funding and the total staffing of the government's food regulatory system.⁴ 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.).

Among other agencies with smaller but still significant shares of the food safety portfolio are the National Marine Fisheries Service (NMFS), which is part of the U.S. Department of Commerce (DOC), the Environmental Protection Agency (EPA), and the Centers for Disease Control and Prevention (CDC) in HHS. USDA's Animal and Plant Health Inspection Service (APHIS) and the Department of Homeland Security's Customs and Border Protection also have important roles with regard to imports of food and agricultural products.

Congressional oversight of this system is complicated somewhat because a number of committees have jurisdiction over food safety. In the Senate, such matters can come before any of three committees: Agriculture, Nutrition and Forestry; Homeland Security and Governmental Affairs; and Health, Education, Labor and Pensions. In the House, food safety can fall within the purview of any of four

⁴ *High Risk Series: An Update* (GAO-07-310), January 2007. For more information on federal oversight roles see CRS Report RS22600, *The Federal Food Safety System: A Primer*, by Geoffrey S. Becker and Donna V. Porter, from which portions of this section are taken.

committees: Agriculture; Energy and Commerce; Science and Technology; and/or Government Oversight and Reform. The subject and responsible agency typically determine which particular committee will have sole or joint jurisdiction. The agriculture subcommittees of the House and Senate Appropriations Committees also address annual funding for the agencies and in this capacity conduct close oversight.

Reorganization of Food Safety Responsibilities

Proponents 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 proponents. 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.⁵

Opponents of major food safety system changes, including many 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.

Safe Food Act of 2007 (H.R. 1148/S. 654)

Representative DeLauro and Senator Durbin introduced in February 2007 companion bills that would consolidate federal food safety responsibilities under a new Food Safety Administration (FSA). The FSA would be responsible for administering the existing major food safety laws including the FFDCa, FMIA and PPIA. The wide-ranging bills also include requirements for determining food-borne contaminants, setting performance standards, registering and inspecting establishments; they also contain provisions covering enforcement activities such as detention, notification and recall, as well as research and education activities. More specifically, the bills would:

- Establish an independent FSA headed by an administrator appointed by the President and confirmed by the Senate. Agencies and their functions to be transferred include USDA’s FSIS and APHIS; 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; USDA’s research related to food safety and animal feed; NMFS seafood inspection; and any other offices or services designated by the President.

⁵ *High Risk Series: An Update.*

- Require FSA to administer a national food safety system for humans and other animals that is based on a comprehensive analysis of food hazards, to register all domestic and foreign food establishments (with the exception of farms, fishing vessels that do not process food, and retail establishments), and to conduct regular unannounced inspections of them. The bills would require the establishments to implement process controls based on FSA-promulgated, science and health-based regulations and to maintain detailed, accessible records; and require FSA to develop and enforce health-based performance standards to protect against all food-borne contaminants. Inspection fundamentals and frequencies also are spelled out in the bills.
- Create a certification program for imports (see next section for details).
- Require FSA to develop a national system for tracing food and food animals from their point of origin to retail sale.
- Direct FSA to sample and analyze foods for contaminants, in order to assess their relative public health risks and to identify ways to minimize such risks. FSA also would have to develop public education and research programs for food safety.
- Specify prohibited acts; provide authority to detain, seize, condemn, and/or recall foods suspected of being unsafe or misbranded (see also next section for details). The proposed bills also spell out enforcement and hearings procedures and include “whistleblower protection” for public and private employees who report safety problems.

Food Import Oversight

Concerns about perceived gaps in import safeguards, including what many believe have been insufficient funds, 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) and \$39 billion in FY1996 to 46.1 MMT and \$76.9 billion in FY2006, and they continue to rise. At issue is whether U.S. safeguards, which generally were created at a time when most Americans obtained their foods domestically, sufficiently protect public health.

The issue has been 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 are subject to the same safety standards as — and/or that pose no greater hazards than — domestically produced foods. They

also contend that smarter allocation of existing resources, and the food industry's own controls, should address any problems which arise.⁶

Assured Food Safety Act of 2007 (H.R. 2997)

Introduced in July 2007 by Representative Kaptur, H.R. 2997 would require USDA and FDA jointly to establish a program requiring all imported food items to be accompanied by a certificate of safety issued by the government of the exporting country. (The bill does not reference existing food safety authorities.) Items could be excepted if they were from a country that has not been the source of a contaminated food item involved in a health or safety recall in the preceding five years.

If a certified item is found to be unsafe, imports would be prohibited until U.S. officials receive an opportunity to inspect the production facility to assess whether corrections have been made, and determine that the country has taken adequate correction actions. Another provision would require USDA and FDA to prepare a report on, and implement, the minimum amount of inspection necessary to assure the safety of imports.

A key provision in the bill would require the collection of user fees to defray the increased costs of such inspections, including the costs of hiring additional inspectors. The fees would be assessed beginning in FY2008 on each line item of food imported, up to \$20 per line (USDA and FDA would define the meaning of this). The bill also provides for fee adjustments, including for inflation.

Imported Food Safety Act of 2007 (S. 1776)

Also introduced in July 2007, S. 1776 by Senator Durbin is similar in intent to H.R. 2997. However, it amends the FFDCA and applies only to FDA-regulated food imports with regard to certifications and user fees. The bill would require HHS to establish a certification system within two years of enactment, which would apply to a foreign government or foreign food establishment seeking to import food to the United States. Before granting a certificate to a foreign government, HHS would have to review, audit, and certify that its food safety program is at least equivalent to the U.S. program. Before granting a certificate to a foreign establishment, HHS would have to certify, based on an onsite inspection, that the establishment has equivalent food safety programs and procedures.⁷

Certifications would be valid for no more than five years; HHS would be required to audit foreign governments and establishments at least every five years to determine their continued compliance. S. 1776 would authorize HHS to withdraw certification of a food if it is linked to an outbreak of a human illness, if the foreign

⁶ See also CRS Report RS22664, *U.S. Food and Agricultural Imports: Safeguards and Selected Issues*, by Geoffrey S. Becker.

⁷ Establishments generally are defined here as any place that processes, holds, or transports food or food ingredients, with the explicit exceptions of farms, and of restaurants and other retailers.

program is no longer equivalent to the U.S. program, or if U.S. officials are not permitted to conduct an audit or investigation.

Like H.R. 2997, S. 1776 would set a user fee of up to \$20 per line item with adjustments for inflation, among other similarities. Unlike H.R. 2997, the Senate bill provides more detail on how the fees will be used. S. 1776 directs that not less than 50% be used for border inspections and not more than 50% be used for a newly authorized research program under the bill. Such research would focus on improved testing and sampling techniques to check for adulteration of imported foods.

Import Safety Act of 2007 (H.R. 3100)

This bill was introduced in July 2007 by Representative Kirk. The measure would amend the FFDCFA to significantly increase civil penalties for violations of the act and also would increase the authorization of appropriations for FDA inspection of imported processed foods (and toothpaste) by \$20 million annually through FY2012.

Safe Food Act of 2007 (H.R. 1148/S. 654)

Section 208 of these comprehensive bills (described in the prior section) would require foreign governments or foreign establishments that want to export food to the United States to be certified by the new FSA. Such certification would be granted to a foreign government and/or establishment if it could demonstrate that its food safety programs are at least equivalent to the U.S. program; certification of a foreign establishment would have to be based on an onsite inspection. Certifications would be valid for no more than five years. Certification of a food establishment could be revoked any time if it is linked to a foodborne illness, if the country's or establishment's safeguards are found to be no longer equivalent, or if U.S. officials are refused permission to conduct an audit or investigation.

FSA also is to "routinely inspect" food and food animals via a physical examination before they enter the United States to ensure they are safe and properly labeled. Section 402 of the bills provides for holding a food at ports of entry for up to 24 hours if there is reason to believe it is unsafe or misbranded.

Human and Pet Food Safety Act of 2007 (H.R. 2108/S. 1274)

Section 419 of these companion bills (which are described in more detail in the next section) contain certification and auditing requirements similar to those in S. 1776, including the five-year limit on approvals and a requirement to routinely inspect imports (see above). Another provision in H.R. 2108/S. 1274 requires importers to give HHS representatives access to inspection-related records.

Food and Drug Administration Revitalization Act (S. 1082)

A provision in the Food Safety title (VI) of this Senate-passed bill would require an annual report to Congress on the number and amount of FDA-regulated food products imported by country and type of food, the number of inspectors and

inspections performed, and aggregated data on inspection findings, including violations and enforcement actions. Elsewhere in the bill, Section 513 would prohibit imports of food products from any foreign facility that refuses to admit (upon request) U.S. inspectors to their facility, or delays such access.⁸

Food and Drug Import Safety Act of 2007 (Dingell Draft)

Representative Dingell, Chairman of the House Energy and Commerce Committee, in August 2007 began circulating a “discussion draft” of his legislation to reform and fund food import inspections, among other provisions, most of which would be amendments to the FFDCFA. The draft bill would require the collection of user fees on imported foods, beginning in FY2008. As in other proposed bills, the fees would be based on the number of entry lines of food, but HHS-FDA could set them as high as \$50 per line, with provisions for inflation adjustments. At least 90% of the fee revenue would have to be used to carry out import inspection activities, with priority on inspections at ports of entry and on detection of intentionally adulterated food. Not more than 10% of the revenue could be used for the bill’s newly authorized research into testing techniques for use in import inspections.⁹

This section of the Dingell draft reiterates that all imported foods must meet the same standards as U.S.-produced foods; entry would be denied to foods that do not. Each foreign facility from which imported food originated would have to obtain an HHS-issued certification that it maintains a program using reliable analytical methods to ensure compliance with all U.S. standards. Failure to do so could result in revocation of the certificate. HHS would be charged with enforcing the provision through random inspections, sampling and testing.

Another proposed amendment would require HHS-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 allowing other ports to be used if the food in question poses no increased likelihood of adverse health consequences. 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. Another topic of the hearing was FDA’s tentative decision to close a number of its 13 field laboratories, which many subcommittee Members strongly criticized. The Dingell draft would prohibit HHS from closing any of these laboratories, as well as any of the 20 FDA district offices or their compliance or inspection activities.

⁸ This bill is now in conference; the House bill which lacks these Senate provisions is H.R. 2900. See Table 13, Food Safety, in CRS Report RL34102, *FDA Legislation in the 110th Congress: A Side-by-Side Comparison of S. 1082 and H.R. 2900*, by Erin D. Williams, Susan Thaul, Sarah A. Lister, Donna V. Porter, and C. Stephen Redhead. Also see CRS Report RL34098, *FDA Legislation in the 110th Congress: A Guide to S. 1082 and H.R. 2900*, by Erin D. Williams, Susan Thaul, and Donna V. Porter.

⁹ The draft bill also would implement a similar fee system for imported drugs.

The Dingell draft also would require labeling of all foods to identify the country of origin, with implementation details left to HHS; and require the department to establish a voluntary “Safe and Secure Food Importation Program” under which food importing companies could receive expedited movement of their products in exchange for abiding by HHS-developed food safety and security guidelines.

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, the GAO has concluded.¹⁰

Others counter that the agencies already have sufficient authorities to keep such products from reaching consumers. FSIS’ 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.¹¹ 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 GAO’s recommendation that legislation be considered to strengthen notification and recall authorities.

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 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.¹²

Human and Pet Food Safety Act of 2007 (H.R. 2108/S. 1274)

These companion bills were introduced in May 2007 by Representative DeLauro and Senator Durbin, respectively. A key provision in the bills would require any

¹⁰ 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.

¹¹ 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 ...”

¹² See also CRS Report RS22653, *Animal Identification: Overview and Issues*, by Geoffrey S. Becker.

person with reason to believe that a food introduced into interstate commerce may be in violation of the FFDCA (i.e., adulterated or mislabeled) to notify HHS of the identity and location of the food. Whenever HHS determines that a food is in violation, it would have to give appropriate persons (retailers, manufacturers, importers or distributors) an opportunity to cease distribution, recall it, and notify all persons involved including consumers and public health officials. Civil and criminal penalties would be spelled out for violations of the notification and recall standards. Persons would not be liable for penalties if they had a guaranty signed by the food provider that it was not adulterated or misbranded.

In cases where a person did not carry out prescribed actions in a voluntary recall, HHS could conduct a mandatory recall. More specifically, it would be authorized to seize the food, order that distribution be ceased, notify all persons to immediately cease its distribution, and to notify affected consumers and public health officials. Anyone producing or otherwise handling a recalled food would have to make available any necessary records. Also, HHS would be required 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 Internet website.

Food and Drug Administration Revitalization Act (S. 1082)

Introduced in April 2007 by Senator Kennedy as the Prescription Drug User Fee Amendments of 2007, S. 1082 was extensively amended and retitled prior to full Senate passage in May 2007. One of the sections added before passage is a new Title VI on food safety that among other things requires HHS to establish, within FDA, an “Adulterated Food Registry.” Responsible parties and importers would be required to report detailed information (outlined in the bill) about cases of actual or suspected food adulteration.¹³ HHS in turn would have to issue an alert if the Registry shows that a reportable adulterated food “has been associated with repeated and separate outbreaks of illness or has been repeatedly determined to be adulterated.” The responsible party or importer would have to maintain records on such foods and permit their inspection by the FDA. HHS would have to issue regulations for reporting to the Registry.

Another recall-related provision in Title VI would require HHS 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 Internet website.¹⁴

¹³ Responsible parties are defined to mean facilities that have to register with FDA under Section 415 of the FFDCA, 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.

¹⁴ Other food-related provisions in S. 1082 include a required annual FDA report on the Administration’s Pesticide Residue Monitoring Program; a required FDA report on whether substances used to preserve the appearance of fresh meat may create any health risk or mislead consumers; authorization for HHS to enhance as necessary FDA inspection of
(continued...)

Safe Food Act of 2007 (H.R. 1148/S. 654)

Section 403 of both bills would require any person with reason to believe that a food entering commerce to be in violation of the law to immediately notify FSA. Section 210 would require establishment of a national system to trace food and food animals from point of origin to retail sale.

Meat and Poultry Products Traceability and Safety Act of 2007 (S. 1292)

Introduced by Senator Schumer in May 2007, S. 1292 would require USDA to establish a meat and poultry traceability system covering all stages of production, processing, and marketing, from live animals before slaughter to distribution of finished products to the ultimate consumer. The bill also would require persons and companies to maintain records and allow access to them when needed to trace products.

Food and Drug Import Safety Act of 2007 (Dingell Draft)

The Dingell draft bill would provide the Secretary of HHS with the authority to require appropriate persons to cease distribution of a food if he/she finds there is a reasonable probability that it would cause serious, adverse health consequences.

State-Inspected Meat and Poultry

Federal law currently prohibits state-inspected meat and poultry plants from shipping their products across state lines, a ban that many states and small plants want to overturn. 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. State-inspected plants cannot ship interstate. 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-only-inspected products into interstate commerce argue that state programs are not required to 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 28 state

¹⁴ (...continued)

seafood and aquaculture products; 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. The House-passed version of the FDA user fee legislation (H.R. 2900) lacks food safety provisions. For more information see references to the CRS reports in footnote 8.

programs to be at least equal to the U.S. program, was based largely on self-assessments.¹⁵

New Markets for State-Inspected Meat and Poultry Act of 2007 (H.R. 2315/S. 1150)

These companion bills were introduced, respectively, by Representative Pomeroy in May and Senator Hatch in April 2007. They would authorize USDA to approve state-inspected meat and poultry products to enter interstate commerce, so long as the state program enforces all of the mandatory requirements in place for the federal program, among other stipulations. One of these stipulations would be a requirement that the states also implement all recommended changes identified by USDA as necessary to enable transition to a state-run program using USDA standards. States could continue to receive federal reimbursements for up to 50% of their inspection program costs. The bills also contain language that could enable currently federally-inspected plants to opt for state inspection.

Farm, Nutrition, and Bioenergy Act of 2007 (H.R. 2419)

This omnibus farm bill was reported by the House Agriculture Committee and passed by the House in July 2007. Section 11103 encompasses the key provisions of H.R. 2315/S. 1150 (see above).

H.R. 1760/S. 1149

Introduced in March 2007 by Representative Kind and in April 2007 by Senator Kohl, these companion bills would strike the provisions in the FMIA and PPIA that prohibit the interstate shipment of state-inspected meat and poultry. The bills also would set the federal reimbursement rate for state costs at no less than 50% and no more than 60%.

Antibiotic Use in Animals

Public health experts have expressed concern about the increasing problem of patients who do not respond to certain medical treatments because the microorganisms causing their illness are resistant to the antibiotics being used. 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. Animal producers administer antibiotics in feed for chickens, cattle, hogs, and farmed seafood not only to treat and prevent diseases but also to encourage growth and efficient use of feed rations. Some argue that nontherapeutic uses — which have increased as more animals are raised in large-scale confinement facilities — should be severely

¹⁵ This section is from CRS Report RL32922, *Meat and Poultry Inspection: Background and Selected Issues*. See also *FSIS Review of State Programs: Summary Report* (January 2007) at [http://www.fsis.usda.gov/PDF/Review_of_State_Programs.pdf].

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.¹⁶

Preservation of Antibiotics for Medical Treatment Act of 2007 (H.R. 962/S. 549)

H.R. 962 was introduced in February by Representative Slaughter; S. 549 was introduced the same month by Senator Kennedy. These companion measures would amend the FFDCFA to define a nontherapeutic use of a critical antimicrobial animal drug (which is also defined) 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, HHS 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.

Biotechnology

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 been rapidly adopting 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.

Cloned Food Labeling Act (H.R. 992/S. 414)

Senator Mikulski introduced S. 414 in January 2007; Representative DeLauro introduced the House version (H.R. 992) in February 2007. The bills would amend the FFDCFA and FMIA (but not the PPIA) to require that products from cloned animals or their progeny be so labeled. USDA and HHS would have to require that anyone who “handles, or distributes a cloned product for retail sale [to] maintain a verifiable recordkeeping audit trail” to verify compliance.

¹⁶ This discussion is based largely on a section in archived CRS Report RL31853, *Food Safety Issues in the 109th 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>].

H.R. 1396/S. 536

The House version of these companion bills was introduced in March 2007 by Representative Woolsey. The Senate version was introduced in February 2007 by Senator Kohl. The bills 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.

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 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. 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.¹⁷

Spinach Research and Recovery Act of 2007 (H.R. 912)

Introduced by Representative Farr in February 2007, this bill would authorize the appropriation in FY2008 of \$20 million for USDA-sponsored research and \$6 million for FDA research on enhancing the safety of perishable agricultural commodities (fresh and fresh frozen fruits and vegetables). Growers and first handlers unable to market spinach crops as a result of the FDA Public Health Advisory issued on September 14, 2006 would be eligible for payments of up to 75% of the value of the unmarketed crop.

Food and Drug Administration Revitalization Act (S. 1082)

Section 604 directs HHS to work with states on programs and activities to improve the safety of fresh and processed produce with the goal of strengthening state programs.

Appropriations

Some critics argue that — irrespective of the need, if any, to reform food safety statutes and organization — the primary problem is that the agencies lack sufficient funding and staff to carry out their congressionally-mandated responsibilities to ensure a safe food supply. From time to time in the past, FSIS has had difficulty in

¹⁷ See also archived CRS Report RL33722, *Food Safety: Federal and State Response to the Spinach E. coli Outbreak*, by Donna V. Porter.

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 appropriated funds to hire additional inspectors at times of unexpected increases in demand for inspections, for example. At FDA, the 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.¹⁸ 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 in both FDA and FSIS in its FY2008 budget, the Administration also has stressed that it can 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 recent hearings, some Members of Congress have expressed skepticism that these efforts can succeed without additional funds.¹⁹

Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2008 (H.R. 3161, S. 1859)

FDA and FSIS receive their annual funding through this appropriations act. The House measure was reported by the Appropriations Committee in late July 2007 (H.Rept. 110-258) and passed by the full House in early August 2007. The Senate version was reported by the Appropriations Committee also in late July 2007 (S.Rept. 110-134).

The House-passed bill would provide new budget authority in FY2008 of \$503.7 million for the FDA foods program area, compared with an FY2007 enacted level of \$457.1 million and an Administration FY2008 request of \$466.7 million. The accompanying House report directs the agency to develop a performance plan that establishes measurable benchmarks for improvements in its food safety activities, and provides, within the overall increase, \$28 million for its implementation. The report also directs that \$319.1 million of the agency appropriation be spent for food-related field activities. The Senate-reported bill would provide \$522.5 million for the food program area. Within that amount, at least \$21 million is to be used to hire inspectors for both imported and foreign products and at least \$11 million to create federal and state rapid response teams for food safety problems (specifically with produce), among other directives in the Senate report. FDA food safety activities are not supplemented by user fees.

¹⁸ Statement of William K. Hubbard, former FDA Associate Commissioner, before the House Energy and Commerce Subcommittee on Oversight and Investigations, July 17, 2007.

¹⁹ 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.

For FSIS, the House-passed bill provides \$930.1 million in FY2008 appropriations, the same as the Administration request. The Senate-reported bill recommends \$930.6 million for FSIS, or \$38.5 million above the FY2007 level. The congressional appropriation would be supplemented in FY2007 by an estimated \$135 million in existing user fees. Neither the House nor Senate version endorses new user fees; the Administration was seeking another \$96 million in such fees, although not beginning until FY2009. The accompanying House and Senate committee reports state that the appropriation includes \$28.3 million and \$27.3 million for pay costs and related cost of living increases, respectively. The House report states that an increase of \$6.5 million is to fill FSIS inspector vacancies; the Senate report notes that its funding level will enable FSIS to hire 78 additional inspectors and 13 additional investigative staff in FY2008.²⁰

²⁰ See CRS Report RL3413, *Agriculture and Related Agencies: FY2008 Appropriations*, coordinated by Jim Monke.

Appendix A: Selected Food Safety Bills at a Glance

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 2007 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 FFDCA and the FMIA to deem as misbranded a food or meat food product that does not bear a conspicuous label stating that it is derived from a cloned animal; 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>	Transfers the responsibilities and resources of existing food safety agencies into a new independent Food Safety Administration to administer and enforce all federal food safety laws. Requires the Administrator to: (1) administer a national food safety program based on an analysis of the food hazards; (2) establish standards for processors of food and food establishments; (3) establish a certification system for foreign governments or food establishments seeking to import food; (4) establish requirements for tracing food and food-producing animals from point of origin to retail sale; (5) maintain an active surveillance system of food, food products, and epidemiological evidence; (6) establish a sampling system to monitor contaminants in food; (7) rank and analyze hazards in the food supply; (8) establish a national public education campaign on food safety; and (9) conduct 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

Bill	Contents	Status
		2/8/07; referred to Agriculture
H.R. 1760/S. 1149 (Kind/Kohl) <i>(no title)</i>	Amends the FMIA and the PPIA 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 FFDCFA to require a person that has reason to believe that any food introduced into interstate commerce may be in violation of the FFDCFA to immediately notify HHS of its identity and location. If a food may pose a threat to public health, authorizes and requires HHS 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 HHS 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
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. Also provides ability for federally inspected plants to convert to the new state inspection program. Also provides for annual USDA 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. Exempts from inspection provisions retail stores and restaurants (including specified central kitchen facilities).	H.R. 2315 introduced 5/15/07; referred to Agriculture S. 1150 introduced 4/18/07; referred to Agriculture Similar provisions incorporated by Agriculture Committee into H.R. 2419, the omnibus farm bill (<i>Farm, Nutrition, and Bioenergy Act of 2007</i> ; see below)
H.R. 2419 (Peterson) <i>Farm, Nutrition, and Bioenergy Act of 2007</i>	Omnibus farm bill includes above provisions similar to those in H.R. 2315/S. 1150 (see above)	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
H.R. 2997 (Kaptur) <i>Assured Food Safety</i>	Directs USDA and FDA to jointly establish a certification program required for all food imports, to be issued by the	Introduced 7/11/07; referred to Energy and

Bill	Contents	Status
<i>Act of 2007</i>	country of origin. Directs USDA and FDA to prohibit importation of a product that fails safety standards until they can inspect the foreign production facilities and 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.	Commerce, to Agriculture, and to Ways and Means
H.R. 3100 (Kirk) <i>Import Safety Act of 2007</i>	Amends the FFDCA 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.	Introduced 7/19/07; referred to Energy and Commerce
H.R. 3161, S. 1859 (DeLauro/Kohl) <i>Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2008</i>	Makes FY2008 appropriations for the: (1) U.S. Department of Agriculture; (2) Food and Drug Administration; (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)	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 S. 1859 introduced and reported 7/24/07 by Appropriations (S.Rept. 110-134)
Dingell Draft <i>Food and Drug Import Safety Act of 2007</i>	Reiterates that all imported foods must meet the same standards as U.S.-produced foods; entry would be denied to foods that do not. Each foreign facility producing food for U.S. import must obtain an HHS-issued certification that it has a program, using reliable analytical methods, to ensure compliance with all U.S. standards. Failure to do so could result in revocation of the certificate. Charges HHS with enforcing the provision through random inspections, sampling and testing. Requires user fees on imported foods, beginning in FY2008, of as much as \$50 per line. At least 90% of the fee revenue must be used to carry out import inspection, 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 a newly authorized research into testing techniques for use in import inspections. Also requires HHS-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 HHS from closing any of the current FDA laboratories, or any of the 20 FDA district offices. Also requires the labeling of all foods to identify the country of origin; establishment of a voluntary "Safe and Secure Food	Not yet introduced; draft released for discussion 8/3/07.

Bill	Contents	Status
	Importation Program” under which food importing companies could receive expedited movement of their products.	
S. 1082 (Kennedy) <i>Food and Drug Administration Revitalization Act</i>	<p>Requires regulations on processing and ingredient standards for pet food, animal waste and ingredient definitions, 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 HHS 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 for fresh and processed produce, including at retail food establishments, and to establish procedures and requirements for processed produce.</p> <p>Also amends the FFDCA, to require a registry on adulterated foods, and spells out notification and recordkeeping requirements, including standards and thresholds for reporting instances of suspected reportable food adulteration and notification procedures. Also bans imports from any foreign food facility that denies access to U.S. inspectors; requires the preparation of various food safety-related reports; and provides for enhanced FDA inspection of aquaculture and seafood through partnerships.</p>	<p>Introduced 4/10/07; referred to Health, Education, Labor, and Pensions, which reported it 4/24/07 Kennedy with an amendment in the nature of a substitute and an amendment to the title. Kennedy with an amendment in the nature of a substitute and an amendment to the title. (No written report)</p> <p>Passed by Senate 5/9/07</p>
S. 1292 (Schumer) <i>Meat and Poultry Products Traceability and Safety Act of 2007</i>	Amends the FMIA and PPIA to require USDA 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 FFDCA to require HHS Secretary to establish within two years a certification system for foreign governments and foreign establishments seeking to import food into the United States. Requires HHS 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 line item imported, 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

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. These and other developments made food safety a top issue for a number of lawmakers in the first session of the 110th 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. The issue of import safety was the focus of numerous congressional hearings and bills in the 110th Congress, and remains high on the policy agenda of the 111th Congress. Attention is now focused on two pending food safety bills, which seek to address the safety primarily of foods regulated by the U.S. Food and Drug Administration (FDA). After rising nearly 11 percent from 2007 to 2008, the number of food-insecure people in the developing countries analyzed by ERS researchers is estimated to rise to 833 million in 2009, an almost 2-percent rise from 2008 to 2009. Despite a decline in food prices in late 2008, deteriorating purchasing power and food security are expected in 2009 because of the growing financial deficits and higher inflation that have occurred in recent years. Food Safety (including the Leahy bill as a probable amendment) appears to be on a fast track in the Senate. We expect to see a vote to shut off debate, the procedural first hurdle, as early as Wednesday. Consideration of amendments and final vote could come very rapidly thereafter. We were able to change some noxious Codex language (about international harmonization of food and supplement regulation) in the larger Senate Food Safety Bill S. 510. But despite this tremendously important improvement (thank you, Senator Hatch), we still regard it as a bad bill. Right now, our job is to stop the Leahy bill. Please take immediate action to let Congress know you are opposed.