



Meat and Poultry Inspection: Background and Selected Issues

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Summary

The U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) must inspect most meat, poultry, and processed egg products for safety, wholesomeness, and labeling. Federal inspectors or their state counterparts are present at all times in virtually all slaughter plants and for at least part of each day in establishments that further process meat and poultry products. Debate has ensued for decades over whether this system, first designed in the early 1900s, has kept pace with changes in the food production and marketing industries.

Several significant changes in meat and poultry inspection programs were included in the 2008 farm bill (P.L. 110-246), signed into law in June 2008. These include permitting some state-inspected meat and poultry products to enter interstate commerce, just like USDA-inspected products; bringing catfish under mandatory USDA inspection; requiring an inspected establishment to notify USDA if it believes that an adulterated or misbranded product has entered commerce; and requiring establishments to prepare and maintain written recall plans. USDA's implementation of these provisions in 2009 is likely to be an oversight item for the 111th Congress. The following are among other recent inspection issues that could receive continued attention in the 111th Congress, which also could consider broader legislation to reform food safety programs—including those of the U.S. Food and Drug Administration (FDA), which oversees all foods other than meat and poultry. (Among the more sweeping options has been a proposal to consolidate federal food safety responsibilities, including those of FSIS, under a single, independent food agency.)

Is enough being done to address longstanding concerns about naturally occurring microbiological contamination? In 1996, FSIS added a sweeping new system known as Hazard Analysis and Critical Control Point (HACCP)—essentially plant-specific contamination prevention plans—on top of the traditional “sight-, smell-, and touch-based” inspection system. However, large recalls due to pathogen problems are still occurring, and significant declines in the incidence of major foodborne pathogens have not occurred in recent years, according to government data. Past proposals to delineate pathogen performance standards and/or safe tolerance levels could again be offered.

Should USDA have new authority to mandate recalls of suspect meat and poultry products, as advocates have requested? FSIS now relies on the establishments to recall adulterated products but asserts that this approach, along with other enforcement tools, is sufficient to protect consumers. Those wanting mandatory recall authority also contend that an improved ability to trace animals, meat, and poultry products should be built into the system to make recalls more effective.

Does FSIS have adequate funding and resources, and/or should industry pay more for inspection? FSIS inspection is mainly funded through USDA's annual appropriation. Congress has denied successive Administrations' proposals for new user fees. Separately, Congress slowed FSIS's implementation of a controversial new “risk based inspection system” (RBIS, now being retooled as the “Public Health Based Inspection System”) aimed at shifting some existing FSIS resources from processing plants and products that pose relatively lower safety risks to others posing relatively higher risks.

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Background on the Programs

The U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) is responsible for inspecting most meat, poultry, and processed egg products for safety, wholesomeness, and proper labeling. Federal inspectors or their state counterparts are present at all times in virtually all slaughter plants and for at least part of each day in establishments that further process meat and poultry products. The Food and Drug Administration (FDA), within the U.S. Department of Health and Human Services (HHS), is responsible for ensuring the safety of virtually all other human foods, including seafood, and for animal drugs and feed ingredients.¹

Several significant changes in meat and poultry inspection programs were included in the 2008 farm bill (P.L. 110-246), signed into law in June 2008. These include permitting some state-inspected meat and poultry products to enter interstate commerce, just like USDA-inspected products; bringing catfish under mandatory USDA inspection; requiring an inspected establishment to notify USDA if it believes that an adulterated or misbranded product has entered commerce; and requiring establishments to prepare and maintain written recall plans.

Recently, the effectiveness of the FSIS inspection system has been compared favorably (by some) to FDA's, particularly with regard to its import safety program. At the same time, large recalls of fresh and processed meat and poultry products, often due to microbiological contamination, and illness outbreaks caused by such products, continue to challenge the industry and government regulators. FSIS policies came under renewed scrutiny in early 2008 after the agency announced the largest meat recall ever, after evidence emerged that a California beef plant had slaughtered for food a number of nonambulatory cattle, in violation of both a humane slaughter law and food safety rules.

These incidents fueled interest in a number of bills in the 110th Congress to change other elements of USDA's authorizing statutes. What, if any, additional changes should the 111th Congress consider to improve safety oversight of meat and poultry production?

Statutory Authorities

Federal Meat Inspection Act of 1906

This law as amended (21 U.S.C. 601 *et seq.*) has long required USDA to inspect all cattle, sheep, swine, goats, horses, mules, and other equines brought into any plant to be slaughtered and processed into products for human consumption. Since passage of the FY2006 USDA appropriation (P.L. 109-97, Section 798), these types of animals are now called "amenable species." P.L. 109-97 also gave the Secretary of Agriculture the discretion to add additional species to the list, but none have been added under this discretionary authority. As noted, the 2008 farm bill makes catfish an amenable species.

¹FSIS responsibilities are separately authorized and operate under a considerably different regulatory framework than those of FDA. These differences could have significance in the longstanding debate over the need, if any, for reorganizing U.S. food safety authorities and programs. See CRS Report RS22600, *The Federal Food Safety System: A Primer*, by Geoffrey S. Becker and Donna V. Porter.

Poultry Products Inspection Act of 1957

This law as amended (21 U.S.C. 451 *et seq.*) makes poultry inspection mandatory for any domesticated birds intended for use as human food. The current list of included species is chickens, turkeys, ducks, geese, guineas, ratites (ostrich, emu, and rhea), and squabs (pigeons up to one month old).

Agricultural Marketing Act of 1946

Under this law as amended (7 U.S.C. 1621), FSIS also provides voluntary inspection for buffalo, antelope, reindeer, elk, migratory waterfowl, game birds, and rabbits, which the industry can request on a fee-for-service basis. These meat and poultry species (which are not specifically covered by the mandatory inspection statutes) are still within the purview of FDA under the Federal Food, Drug, and Cosmetic Act (FFDCA, 21 U.S.C. 301 *et seq.*), whether or not inspected under the voluntary FSIS program. FDA has jurisdiction over meat products from such species in interstate commerce, even if they bear the USDA inspection mark.

Egg Products Inspection Act

This law as amended (21 U.S.C. 1031 *et seq.*) is the authority under which FSIS assures the safety of liquid, frozen, and dried egg products, domestic and imported, and the safe disposition of damaged and dirty eggs. FDA holds regulatory authority over shell eggs in restaurants and stores.

USDA Meat Grading

USDA meat and poultry grading is distinct and separate from the FSIS safety inspection program. Upon request, firms may request that inspectors from a separate USDA agency, the Agricultural Marketing Service (AMS), grade their products for quality attributes, but only after it has been cleared by FSIS for safety and wholesomeness. Unlike safety inspection, which is mandatory and largely covered by appropriated funds, grading services are voluntary and funded by industry user fees.

Nationally uniform quality grades are used to convey, to buyers and sellers, such traits as tenderness, flavor, and juiciness, and so forth. For example, AMS now grades beef carcasses as prime, choice, select, standard and commercial, utility, cutter, and canner; these grades are not usually visible on individual retail cuts but can appear on the packages. Grades are also available for veal, lamb, and poultry. Legislative authority for quality (and yield) grades comes through the Agricultural Marketing Act (7 U.S.C. 1621).

System Basics

Coverage

FSIS's legal inspection responsibilities begin when animals arrive at slaughterhouses, and they generally end once products leave processing plants. Certain custom slaughter and most retail store and restaurant activities are exempt from federal inspection; however, they may be under state inspection.

Plant Sanitation

No meat or poultry establishment can slaughter or process products for human consumption until FSIS approves in advance its plans and specifications for the premises, equipment, and operating procedures. Once this approval is granted and operations begin, the plant must continue to follow a detailed set of rules that cover such things as proper lighting, ventilation, and water supply; cleanliness of equipment and structural features; and employee sanitation procedures.

HACCP

Plants are required to have a Hazard Analysis and Critical Control Point (HACCP) plan for their slaughter and/or processing operations. Essentially, a plant must identify each point in the process where contamination could occur, called a “critical control point,” have a plan to control it, and document and maintain records. Under HACCP regulations, all operations must have site-specific standard operating procedures (SOPs) for sanitation. USDA inspectors check records to verify a plant’s compliance.

Slaughter Inspection

FSIS inspects all meat and poultry animals to look for signs of disease, contamination, and other abnormal conditions, both before and after slaughter (“antemortem” and “postmortem,” respectively), on a continuous basis—meaning that no animal may be slaughtered and dressed unless an inspector has examined it. One or more federal inspectors are on the line during all hours the plant is operating.

Processing Inspection

The inspection statutes appear to be silent on how frequently USDA inspector must visit facilities that produce processed products like hot dogs, lunch meat, prepared dinners, and soups. Under current policies, processing plants visited once every day by an FSIS inspector are considered to be under continuous inspection in keeping with the laws. Inspectors monitor operations, check sanitary conditions, examine ingredient levels and packaging, review records, verify HACCP processes, and conduct statistical sampling and testing of products during their on-site visits.

Pathogen Testing

The HACCP rule also mandates two types of microbial testing: for generic *E. coli* and for *Salmonella*. Levels of these two organisms are indicators of conditions that either suppress or encourage the spread of such potentially dangerous bacteria as *Campylobacter* and *E. coli* O157:H7, as well as *Salmonella* itself. Test results (plants test for *E. coli* and FSIS for *Salmonella*) help FSIS inspectors verify that plant sanitation procedures are working, and to identify and assist plants whose process controls may be underperforming.

Enforcement

FSIS has a range of enforcement tools to prevent adulterated or mislabeled meat and poultry from reaching consumers. On a day-to-day basis, if plant conditions or procedures are found to be unsanitary, an FSIS inspector can, by refusing to perform inspection, temporarily halt the plant’s

operation until the problem is corrected. FSIS can condemn contaminated, adulterated, and misbranded products, or parts of them, and detain them so they cannot progress down the marketing chain. FSIS does not have mandatory recall authority; if potentially dangerous or mislabeled products do enter commerce, the agency relies on establishments to voluntarily recall them.

Other tools include warning letters for minor violations; requests that companies voluntarily recall a potentially unsafe product; a court-ordered product seizure if such a request is denied; and referral to federal attorneys for criminal prosecution. Prosecutions under certain conditions may lead to the withdrawal of federal inspection from offending firms or individuals, which results in plant closure.

Funding

Federal appropriations pay for most, but not all, mandatory inspection. In FY2008, FSIS received an annual appropriation of \$930 million. In addition, FSIS uses revenue from fees paid by the meat and poultry industries for FSIS inspection that occurs beyond regularly scheduled shifts and on holidays, and by private laboratories that apply for FSIS certification to perform official meat testing and sampling. In FY2008, revenue from the fees was expected to amount to approximately \$141 million in additional program support, for a combined funding level of more than \$1 billion. The agency began FY2009 under a continuing resolution (P.L. 110-329), which provides appropriations through March 6, 2009.

Staffing

FSIS carries out its duties with about 9,400 total staff (full-time equivalent). Approximately 7,800 of FSIS's employees, roughly 1,000 of them veterinarians, are in approximately 6,200 establishments and import inspection facilities nationwide.

State Inspection

Twenty-seven states have their own meat and/or poultry inspection programs covering approximately 2,000 small or very small establishments. The states run the programs cooperatively with FSIS, which provides up to 50% of the funds for operating them, comprising about \$50 million of the total FSIS budget annually (plus an additional \$7.5 million in indirect costs for FSIS state-related activities). A state program operating under a cooperative agreement with FSIS must demonstrate that its system is equivalent to federal inspection. However, state-inspected meat and poultry products are limited to intrastate commerce only. In states that have discontinued their inspection systems for meat or poultry (or both), FSIS has assumed responsibility for inspection at the formerly state-inspected plants. However, actual inspection is performed by state personnel.²

Approximately 360 meat and poultry establishments in nine states are covered by a separate federal-state program, the so-called Talmadge-Aiken plants. Under this program, USDA has signed cooperative agreements with states whereby state employees are used to conduct federal inspections, and passed products carry the federal mark of inspection. Established by the

² See page 17 for a discussion of the new state inspection option authorized by the 2008 farm bill.

Talmadge-Aiken Act of 1962 (7 U.S.C. 450), the arrangement was intended to achieve federal coverage in remote locations to offset the higher cost of assigning federal inspectors there.

Import Inspection

FSIS conducts evaluations of foreign meat safety programs and visits establishments to determine that they are providing a level of safety equivalent to that of U.S. safeguards. No foreign plant can ship meat or poultry to the United States unless its country has received such an FSIS determination. Once they reach U.S. ports of entry, meat and poultry import shipments must first clear Department of Homeland Security (DHS) inspection to assure that only shipments from countries free of certain animal and human disease hazards are allowed entry. This function was transferred to DHS from USDA's Animal and Plant Health Inspection Service (APHIS) when DHS was established by the Homeland Security Act of 2002 (P.L. 107-296). After DHS inspection, imported meat and poultry shipments go to one of approximately 150 nearby FSIS inspection facilities for final clearance into interstate commerce.³

Microbiological Contamination and HACCP

Large recent recalls of meat and poultry products, often due to microbiological contamination, have brought closer attention to USDA's and industry's record in detecting harmful pathogens and preventing them from reaching consumers and making them sick. Although government officials had asserted that the number of both recalls and illnesses had declined over the long term, illness data from the past several years appear to indicate that this overall decline has not continued.⁴

Twenty recalls tied to *E. coli* O157:H7 in 2007 were more than in any year since the early 2000s. The largest in 2007 was of nearly 22 million pounds of frozen ground beef products in September (see below). This recall and others have caused some in Congress to question not only the effectiveness of USDA's pathogen prevention programs but also its recall policies. (The record 2008 recall of 143 million pounds of beef was not triggered by pathogen concerns; see page 22.)

Development of HACCP

In the early 1990s, following years of debate over how to respond to mounting evidence that invisible, microbiological contamination on meat and poultry posed greater public health risks than visible defects (the focus of traditional inspection methods), FSIS began to add testing for pathogenic bacteria on various species and products to its inspection system.

³ As of July 2008, meat or poultry products from 33 countries were eligible for import. An August 2008 audit report by USDA's Office of Inspector General made a number of recommendations for improving oversight of imports, including on the methodology for selecting foreign establishments for review and on production reinspections at the border. *Followup Review of Food and Safety Inspection Service's Controls Over Imported Meat and Poultry Products*, at <http://www.usda.gov/oig/webdocs/24601-08-Hy.pdf>. See also CRS Report RL34198, *U.S. Food and Agricultural Imports: Safeguards and Selected Issues*, by Geoffrey S. Becker.

⁴ See for example Richard Raymond, Under Secretary of Food Safety, comments at an October 23, 2007, news conference regarding recent USDA actions on *E. coli* O157:H7. Some discussion of the more recent data is contained in the sections of this CRS report on selected pathogens.

In 1995, under existing statutes, FSIS published a proposed rule to systematize these program changes in a mandatory program called the Hazard Analysis and Critical Control Point (HACCP) system. In this system, firms must analyze risks in each phase of production, identifying and then monitoring “critical control points” for preventing such hazards, with corrective actions taken when necessary. Record keeping and verification are used to ensure that the system is working. FSIS published the final rule on July 25, 1996, and since January 2000 all slaughter and processing operations are required to have HACCP plans in place. HACCP is intended to operate as an adjunct to the traditional methods of inspection, which still are mandatory under the original statutes.⁵

Pathogen Performance Standards and *Salmonella*

The U.S. Centers for Disease Control and Prevention (CDC) has noted that poultry is an important source of human *Salmonella* infections. It also occasionally has been found in beef. According to CDC reports, the overall incidence of *Salmonella* infections through all types of food has not decreased significantly.⁶ CDC also reported that *Salmonella* has been the most common foodborne pathogen, although exposure to animals also is an important nonfood source.

In the initial years of HACCP implementation, plants that failed three consecutive *Salmonella* tests could have their USDA inspectors withdrawn. This would effectively shut down the plant until the problem could be remedied. However, a federal court ruled in 2000 that the meat and poultry inspection statutes do not give USDA the authority to use *Salmonella* standards as the basis for withdrawing inspection from a plant that has not met them. An appeals court upheld this decision in 2001. Subsequently, USDA has adopted the position that the court decision did not affect the agency’s ability to use the standards as part of the verification of plants’ sanitation and HACCP plans.

Nonetheless, the appeals court ruling supports arguments of those who say that pathogen testing results should not be a basis for enforcement actions until scientists can determine what constitutes an unsafe level of *Salmonella* in ground meat and a number of other meat and poultry products. Consumer groups and other supporters of mandatory testing and microbiological standards, as well as of increased enforcement powers, have used the case to bolster their argument for amending the meat and poultry inspection statutes to expressly require microbiological standards.

FSIS had reported its concern about increases in *Salmonella* rates observed over a three-year period (2003-2005) among the three poultry product categories, broiler carcasses, ground chicken, and ground turkey. To address the problem, in early 2006 the agency launched an initiative to reduce the pathogen in raw meat and poultry products, including the concentration of more inspection resources at establishments with higher levels, and quarterly rather than annual reporting of *Salmonella* test results. Sampling frequency was to be based on a combination of factors such as a plant’s regulatory history and its incidence of the pathogen.⁷

⁵ The final rule appeared in 61 *Federal Register* 38805-38855.

⁶ CDC, “Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food—10 States, 2006,” *Morbidity and Mortality Weekly Report*, April 13, 2007; and “... —10 States, 2007,” *Morbidity and Mortality Weekly Report*, April 11, 2008.

⁷ *Food Chemical News*, July 3, 2006. A notice and request for comments on this initiative were published in the February 27, 2006, *Federal Register*.

Scientific Advice on Performance Standards

National Advisory Committee on Microbiological Criteria for Foods. The committee, established in 1988 to provide scientific advice to the Secretaries of Agriculture and of Health and Human Services on public health issues, concluded in a report issued in October 2002 that “performance standards that meet the principles as outlined in this document [i.e., standards that are based on quantitative rather than qualitative data] are valuable and useful tools to define an expected level of [pathogen] control in one or more steps in the process.” (The report is at http://www.fsis.usda.gov/OPHS/nacmcf/rep_stand.htm.)

Institute of Medicine-NRC. A second review of microbiological performance standards, *Scientific Criteria to Ensure Safe Food*, was released in 2003 by the Institute in collaboration with the National Research Council (NRC). Among many recommendations, this report calls on Congress to “grant the regulatory agencies clear authority to establish, implement, and enforce food safety criteria, including performance standards, and the flexibility needed within the administrative process to update these criteria.”

The Institute report also makes specific recommendations for FSIS to improve meat and poultry safety, including (1) to conduct surveys to evaluate changes over time in the microbiological status of certain components of processed meats and poultry; (2) to expand *E. coli* O157:H7 testing, identify control points for *E. coli* O157:H7 back to the farm level, and inform consumers that even irradiated ground beef must be cooked to a temperature that kills the pathogen; and (3) to greatly expand generic *E. coli* criteria, and *Salmonella* performance standards, for beef trim intended for grinding. (This report may be accessed at <http://www.nap.edu/catalog/10690.html>.)

FSIS on January 28, 2008 issued a notice on new policies and procedures for *Salmonella* sampling and testing.⁸ One change has been to post on its website sampling test results from establishments, with their names and locations—beginning with young chicken slaughter establishments—that have substandard or variable records in meeting *Salmonella* performance standards. The agency stated that it was taking this unprecedented action in part because at least 90% of such establishments were not testing consistently for low *Salmonella* rates.

The FSIS performance standard for *Salmonella* in young chickens is 20%, i.e., 12 positive samples out of 51 taken. Tested plants are placed in one of three categories, as follows:

Category 1 establishments have results from their two most recent completed sample sets that are at or below half of the standard (i.e., at or below 10%);

Category 2 establishments have results from their most recent completed sample set that are higher than half of the standard but do not exceed the standard (i.e., above 10% but below 20%);

Category 3 establishments have results from their most recent completed sample set that exceed the standard (i.e., above 20%).

Twenty-one category 2 or category 3 plants, out of 195 tested, were named in the first report, accessed in April 2008. In the agency’s June 2008 posting, a total of 17 plants—15 in category 2 and two in category 3—were listed. In the September 2008 posting, 13 category 2 and no category 3 plants were posted. The December 2008 report showed 15 establishments in category 2 and two in category 3.⁹

⁸ 73 *Federal Register* pp. 4767-4774.

⁹ The testing results are posted monthly. A description of the testing and the most recent results can be accessed at http://www.fsis.usda.gov/science/Salmonella_Verification_Testing_Program/index.asp. Another description of, and more critical look at, the *Salmonella* testing program is in *More Foul Fowl: An Updated Analysis of Salmonella* (continued...)

Another recent change is a “*Salmonella* Initiative Program,” under which poultry slaughter plants with relatively low *Salmonella* positives could effectively increase line speeds—i.e., process their chickens faster—in exchange for providing more microbial data to help study the links between FSIS-regulated products and human illness.

***E. coli* O157:H7**

CDC noted that “*E. coli* O157:H7 is one of hundreds of strains of the bacterium *Escherichia coli*. Although most strains are harmless and live in the intestines of healthy humans and animals, this strain produces a powerful toxin and can cause severe illness. *E. coli* O157:H7 was first recognized as a cause of illness in 1982 during an outbreak of severe bloody diarrhea; the outbreak was traced to contaminated hamburgers. Since then, most infections have come from eating undercooked ground beef.” CDC also noted that “... people have also become ill from eating contaminated bean sprouts or fresh leafy vegetables such as lettuce and spinach. Person-to-person contact in families and child care centers is also a known mode of transmission. In addition, infection can occur after drinking raw milk and after swimming in or drinking sewage-contaminated water.”¹⁰

In October 1994, FSIS began testing samples of raw ground beef for *E. coli* O157:H7 and declared that any such product found with this pathogen would be considered adulterated—the first time a foodborne pathogen on raw product was declared an adulterant under the meat inspection law. Industry groups immediately asked a Texas federal court for a preliminary injunction to halt this effort, on the grounds that it was not promulgated through appropriate rulemaking procedures, was arbitrary and capricious, and exceeded USDA’s regulatory authority under law. In December 1994, the court denied the groups’ request, and no appeal was filed, leaving the program in place. FSIS has taken tens of thousands of samples since the program began; to date, hundreds of samples have tested positive.

In September 2002, FSIS issued a press release stating that “[t]he scientific data show that *E. coli* O157:H7 is more prevalent than previously estimated,” and in October 2002 the agency published a notice requiring manufacturers of all raw beef products (not just ground beef) to reassess their HACCP plans and add control points for *E. coli* O157:H7 if the reassessment showed that the pathogen was a likely hazard in the facility’s operations. FSIS inspectors are to verify that corrective steps have been taken and conduct random testing of all beef processing plants, including all grinders (some previously had been exempted). In addition, the agency announced guidelines for grinding plants advising them to increase the level of pathogen testing by plant employees, and to avoid mixing products from different suppliers.¹¹

(...continued)

Contamination in Broiler Chickens, March 2008, by the advocacy group Food and Water Watch. It was accessed in July 2008 at <http://www.foodandwaterwatch.org/food/pubs/reports/more-foul-fowl>.

¹⁰ Background information on this pathogen may be viewed at the following CDC website: http://www.cdc.gov/nczved/dfbmd/disease_listing/stec_gi.html.

¹¹ 67 *Federal Register* 62325.

Topps Recall

On September 25, 2007, USDA announced that Topps Meat Company, LLC, an Elizabeth, N.J., establishment, was voluntarily recalling approximately 331,582 pounds of frozen ground beef products because they might be contaminated with *E. coli* O157:H7. On September 29, the recall was expanded to 21.7 million pounds, making it one of the largest in history. By October 6, the Centers for Disease Control (CDC) had cited 32 illnesses apparently related to the recall.

According to trade press reports, the initial (September 25) recall covered three days of ground beef production (on June 22, July 12, and July 23, 2007). The expansion to 21.7 million pounds covered one year of production (back to September 25, 2006), because the plant was carrying over each day's production to the next, rather than processing the ground meat in separate batches, which would create a clean break in production, as industry experts have stressed should be done. In addition, the plant had not followed its own HACCP plan, according to the reports.¹² More specifically, for example, reports indicated that the plant appeared to be grinding meat that did not carry the necessary documentation showing that it had been tested by the supplier for contamination. At the same time, the USDA inspector who visited the plant daily (but was not there continuously) reportedly did not uncover the problem, either. The plant has since ceased operations.

By early November 2007, the Topps recall was linked to beef trim supplied by an Alberta, Canada, packer, Ranchers Beef Ltd.,¹³ which had closed in August 2007. On November 9, 2007, FSIS began to hold Canadian beef products at the border until they could be tested for *E. coli*; by December 2007 it had eased this policy but continued heightened testing of these products destined for ground beef.

FSIS reported that, of an average of nearly 10,000 ground beef samples tested annually in 2004, 2005, and 2006, a total of 43 (less than 0.2%) tested positive for *E. coli* O157:H7, part of a significant decline in the percentage of positive samples since 2000, when it was 0.86%. FSIS asserted that the reduction reflected the success of its HACCP-based and related regulatory policies. However, increases were recorded in 2007, when 29 or 0.24% of 12,200 ground beef samples tested positive, and in 2008, when 54 or 0.47% of 11,535 were positive.

By June 2007, after FSIS had identified an increased number of positive *E. coli* O157:H7 beef samples, along with a larger number of recalls and illnesses linked to the pathogen than in recent years, it increased the number of tests on ground beef by more than 75%, the agency stated. It also began or accelerated implementation of several other *E. coli* prevention initiatives that had been under development. Among the actions it cited in October 2007 were the testing (starting in March 2007) of beef trim, which is used in ground beef; requiring beef plants to verify that they are effectively controlling *E. coli* O157:H7 during slaughter and processing; directing its inspectors to use a new checklist to review establishment control procedures; beginning testing other types of materials used in ground beef in addition to beef trim and requiring importing countries to conduct equivalent sampling; better targeting its routine *E. coli* testing; and working to speed up recalls.¹⁴

Nonetheless, as noted, *E. coli* positives climbed in 2008. As the year was ending, FSIS and other food safety experts were speculating as to whether the increase was due to a higher prevalence of

¹² See for example, *Cattle Buyers Weekly*, October 8, 2007; *Feedstuffs*, October 8, 2007.

¹³ Source: *Cattle Buyers Weekly*, various 2007 issues.

¹⁴ USDA, FSIS. "FSIS Takes Aggressive Actions To Combat *E. coli* O157:H7," October 23, 2007, at http://www.fsis.usda.gov/News_&_Events/NR_102307_01/index.asp. FSIS has published an August 2008 report on its findings in *Results of Checklist and Reassessment of Control for Escherichia coli O157:H7 in Beef Operations*, at http://www.fsis.usda.gov/PDF/Ecoli_Reassessment_&_Checklist.pdf.

the bacteria, or simply to the fact that the agency had changed its testing method earlier in the year. It is possible, for example, that the new method is more sensitive to the presence of *E. coli*.¹⁵

The CDC foodborne illness reports for 2006 and 2007 indicated that the incidence of all foodborne infections caused by *E. coli* O157:H7 had declined significantly from the 1996-1998 baseline through 2004, but not since then. The CDC reported that it did not know why reductions had not been maintained, but it did point out that the 2006 outbreaks caused by contaminated spinach and lettuce highlighted the need for more effective prevention. The earlier CDC report (on 2006) stated that the frequency of *E. coli* O157:H7 in ground beef samples taken in 2005 and 2006 had remained about the same as in 2004.¹⁶ The report on 2007 concluded that “additional efforts are needed” to control the pathogen in cattle “and to prevent its spread to other food animals and food products, such as produce.”¹⁷

During calendar 2006, FSIS announced eight recalls due to *E. coli* O157:H7 contamination, mostly of ground beef products, and none were related to human illness. In 2005, the agency announced five recalls. In 2007 FSIS announced 20 recalls, totaling more than 33 million pounds, mostly ground beef products, due to *E. coli* concerns. At least nine of the 2007 recalls were related to human illnesses (the rest came about after routine testing). Although many of the recalls were relatively small, a June recall involved nearly 6 million pounds of beef, and the Topps recall 21.7 million pounds (see page 9).¹⁸

In 2008, 17 *E. coli*-related recalls were listed on the FSIS website. The largest was by Nebraska Beef, of Omaha, of approximately 5.3 million pounds of beef manufacturing trimmings and other products intended for use in raw ground beef produced between May 16 and June 26. Nebraska Beef was involved in another large recall, of 1.36 million pounds of primal cuts, subprimal cuts, and boxed beef, produced on June 24 and on July 8, 2008. Dozens of illnesses were linked to products in the two Nebraska Beef recalls. Nebraska-processed products sold under the Coleman Natural Beef brand were also recalled by the Whole Foods Market chain.¹⁹

Listeria monocytogenes

In February 2001, FSIS published a proposed rule to set performance standards that meat and poultry processing firms would have to meet to reduce the presence of *Listeria monocytogenes* (*Lm*), a pathogen in ready-to-eat foods (e.g., cold cuts and hot dogs). The proposal covered over 100 different types of dried, salt-cured, fermented, and cooked or processed meat and poultry products. *Lm* causes an estimated 2,500 illnesses and 499 deaths each year (from listeriosis), and has been a major reason for meat and poultry product recalls.

The proposed rule raised controversy among affected constituencies. The meat industry argued that the benefits to consumers would not outweigh the cost to packers of additional testing. Representatives of food manufacturers criticized the proposed regulations for covering some

¹⁵ “Explanation to higher number of *E. coli* positives may be in broth,” *Food Chemical News*, October 20, 2008.

¹⁶ *Morbidity and Mortality Weekly Report*, April 13, 2007.

¹⁷ *Morbidity and Mortality Weekly Report*, April 11, 2008.

¹⁸ Some information is from the October 23, 2007, Raymond press conference. Recall updates are at the FSIS website, http://www.fsis.usda.gov/Fsis_Recalls/index.asp.

¹⁹ “Nebraska Beef *E. coli* recall gets a sequel,” *Food Chemical News*, August 18, 2008.

categories of foods too broadly and heavily, while not covering some other high-risk foods at all (such as milk, which is under FDA jurisdiction). Consumer groups said the proposed rule would not require enough testing in small processing plants and that products not tested for *Lm* should not be labeled “ready-to-eat” because they would still require cooking to be 100% safe.

Interest in the *Listeria* issue had grown in 1998 and 1999, following reports of foodborne illnesses and deaths linked to ready-to-eat meats produced by a Sara Lee subsidiary.²⁰ Interest increased significantly after October 2002, when Pilgrim’s Pride Corporation recalled a record-breaking 27.5 million pounds of poultry lunch meats for possible *Lm* contamination after a July 2002 outbreak of listeriosis in New England. CDC confirmed 46 cases of the disease, with 7 deaths and 3 stillbirths or miscarriages. The recall covered products made as early as May 2002, and officials stated that very little of the meat was still available to be recovered.

In December 2002, FSIS issued a directive to inspection program personnel giving new and specific instructions for monitoring processing plants that produce hot dogs and deli meats.²¹ In June 2003, FSIS announced the publication of an interim final rule to reduce *Listeria* in ready-to-eat meats. Rather than set performance standards, as the February 2001 proposed rule would have, the new regulation requires plants that process RTE foods to add control measures specific to *Listeria* to their HACCP and sanitation plans, and to verify their effectiveness by testing and disclosing the results to FSIS. The rule directs FSIS inspectors to conduct random tests to verify establishments’ programs. Plants are subject to different degrees of FSIS verification testing depending upon what type of control steps they adopt in their HACCP and sanitation plans.²²

On January 4, 2005, the Consumer Federation of America (CFA) issued a report sharply criticizing USDA’s *Listeria* rulemaking. CFA asserted that the Department essentially adopted meat industry positions in weakening the final rule, such as by deleting proposed plant testing requirements and by not explicitly requiring that HACCP plans include *Listeria* controls. In 2003, *Listeria* illnesses increased by 22%, CFA contended, citing CDC data.²³

USDA and meat industry officials countered that the number of product recalls related to *Listeria* had declined from 40 in 2002 to 14 in 2003, that the rise in *Listeriosis* cases was quite small in 2003 after four years of declines, and that the interim rule provides more incentives for plants to improve safety. The CDC’s 2006 and 2007 FoodNet reports indicated that the incidence of foodborne illness caused by *Listeria*, which had reached its lowest level in 2002 compared with a 1996-1998 baseline, has not continued to decline significantly in more recent years.²⁴

Recalls of FSIS-regulated products continue. In 2005, the largest was a December 2005 recall of 2.8 million pounds of various bologna, ham, and turkey lunchmeat products by ConAgra. Another 28 *Listeria*-related recalls were announced during 2005, involving approximately 649,000 pounds of processed meat and poultry products, according to the agency’s website. The website had posted six *Listeria* recalls in 2006 and another 11 in 2007, including, in January and February

²⁰ Source: *Food Chemical News*, various issues.

²¹ The guidelines can be found on the FSIS website at <http://www.fsis.usda.gov>.

²² See the FSIS website for more details on the rule.

²³ CFA website: <http://www.consumerfed.org/>.

²⁴ *Morbidity and Mortality Weekly Report*, April 13, 2007, and April 11, 2008.

2007, 2.8 million pounds of Oscar Mayer/Louis Rich chicken breast cuts and strips.²⁵ Fifteen *Listeria*-related recalls were posted in 2008.

Risk-Based Inspection System

Congress in 2007 ordered a halt to FSIS's work on what the agency was calling a more robust "risk-based inspection system" (RBIS), aimed at enabling the agency to rebalance existing inspection resources.²⁶ The objective of this initiative was "to improve public health by placing greater inspection and verification emphasis on federally inspected meat and poultry establishments that pose greater risks. In a more robust RBIS, each establishment's risk could be categorized, and the type and intensity of inspection could be based primarily on that risk."²⁷

More specifically, the initiative was to enable FSIS to shift some processing inspection resources from lower-risk products and plants to relatively higher-risk products (for example, ground poultry), and to plants with relatively poor safety records. USDA in February 2007 had announced a timetable for introducing RBIS, beginning in April 2007 at 30 locations representing about 254 processing (but not yet slaughter) establishments. About a fourth of these plants would come under closer scrutiny, about a fourth less scrutiny, and about half would receive approximately the same level of attention as currently, a USDA official said. He added that all plants will still be under "daily inspection," and full-time employees would not be reduced under RBIS.²⁸

Public comments to FSIS on RBIS, and hearings by a House appropriations subcommittee, indicated that many agreed in concept with risk-based inspection but were concerned that the agency had provided too few specifics on how it would be implemented, lacked the data it needed to implement it, and should consider doing it through formal rulemaking. A few warned that it could undermine rather than strengthen safety oversight, and wondered whether the agency has the statutory authority to change inspection frequency.²⁹

Several interest groups reiterated their concerns following the earlier, February 22, 2007, USDA announcement. The American Meat Institute, representing major meat packers, said in a statement that it was concerned that the "hasty launch" of the initiative could jeopardize consumer confidence in meat and poultry, and that details of exactly how the program would work still were unclear. Several consumer groups questioned the validity of the data that USDA was using to rank product risk and plant performance FY2009.³⁰

²⁵ FSIS recall website: http://www.fsis.usda.gov/FSIS_Recalls/index.asp.

²⁶ See "In Congress" later in this section of the report.

²⁷ "Measuring Establishment Risk Control for Risk-based Inspection," paper for May 23-24, 2006, meeting of the National Advisory Committee on Meat and Poultry Inspection. Information on the meeting (and on other committee meetings) is posted at http://www.fsis.usda.gov/regulations_&_policies/National_Advisory_Committee_on_Meat_&_Poultry/index.asp.

²⁸ Comments by Dr. Richard Raymond, USDA Under Secretary for Food Safety, February 22, 2007, press teleconference.

²⁹ Risk-based inspection comments posted by FSIS, *Food Chemical News*, November 27, 2006; also, *Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for 2007*, hearings before a Subcommittee of the Committee on Appropriations, U.S. House of Representatives, 109th Congress, 2nd session.

³⁰ Sources: various statements as reported in *Food Chemical News*, February 26, 2007, and April 23, 2007.

The Department's Office of Inspector General (OIG) conducted an audit of FSIS's work on RBIS, issuing its report in December 2007. Among other findings, the OIG questioned whether the agency had the systems in place "to provide reasonable assurance that risk can be timely or fully assessed, especially since FSIS lacks current, comprehensive assessments of establishments' food safety systems."³¹ OIG reported that FSIS lacks adequate management control processes or an integrated IT (computer) system to support a program, and the agency had not resolved all of the prior recommendations that OIG said were most critical to successful development of risk-based inspection. The OIG report offered 35 new recommendations around such matters as improving the use of food safety assessment-related data; determining how assessment results will be used to estimate risk; and providing clearer documentation and written procedures and guidance for all stakeholders.

The OIG report was the major item discussed at the February 5-6, 2008, meeting of the National Advisory Committee on Meat and Poultry Inspection. FSIS said it has been retooling RBIS—which it now calls a "Public Health Based Inspection System" (PHBIS)—to address the OIG recommendations and those of public commenters. FSIS issued a report outlining the elements of and scientific basis for the evolving PHBIS on April 2008.³² The agency has been implementing the OIG recommendations; it also has asked the National Academy of Sciences to evaluate the data and methodology underlying its PHBIS initiative.

In Congress

In the 110th Congress, provisions in several appropriations measures (including P.L. 110-28 and P.L. 110-161, Division A) had directed USDA not to implement its risk-based inspection system anywhere until the OIG evaluated the data supporting the system, and the FSIS resolved any issues raised in the evaluation. A number of other bills were offered that contained provisions clarifying the Secretary's authority to set enforceable performance standards. New bills could emerge in the 111th Congress.

Other Selected Issues

Recall and Enforcement Proposals

Currently, the Agriculture Secretary must go to the courts to obtain an order to seize and detain suspected contaminated products if a firm refuses to issue a recall voluntarily. The GAO has criticized agencies' efforts to ensure that companies carry out recalls quickly and efficiently, particularly of products that may carry severe risk of illness. A 2004 GAO report concluded that the agencies do not know how well companies are carrying out recalls and are ineffectively tracking them. As a result, most recalled items are not recovered and thus may be consumed, GAO reported.³³

³¹ USDA, OIG, *Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments* (Report. No. 24601-07-Hy).

³² The report, *Public Health Risk-Based Inspection System for Processing and Slaughter*, along with other materials from the February meeting, are posted on an agency's web page: http://www.fsis.usda.gov/regulations_&_policies/Public_Health_Based_Inspection/index.asp.

³³ *Food Safety: USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food*, (continued...)

At past hearings, consumer and food safety advocacy groups have testified in favor of obtaining these new enforcement tools to improve food safety in general, and to strengthen USDA's enforcement of the new HACCP system in particular. These groups have asserted that civil fines would serve as an effective deterrent and could be imposed more quickly than criminal penalties or the withdrawal of inspection. They also have argued that the authority to assess civil penalties would permit USDA to take stronger—and more rapid—action against “bad actors,” or those processors who persistently violate food safety standards. Food safety advocates argue that FSIS should have the authority to mandate product recalls as a backup guarantee in case voluntary recalls moved too slowly or were not comprehensive enough.

Meat and poultry industry trade associations have testified in opposition to granting USDA new enforcement powers. Both producers and processors argue that current authorities are sufficient and that only once has a plant refused to comply with USDA's recommendation to recall a suspected contaminated product. Industry representatives have testified that USDA's current authority to withdraw inspection, thereby shutting down a plant, is a strong enough economic penalty to deter potential violators and punish so-called bad actors. Furthermore, they say, new enforcement powers would increase the potential for plants to suffer drastic financial losses from suspected contamination incidents that could ultimately be proven false. Some observers argue that much still needs to be done to educate consumers and restaurateurs about safe meat and poultry handling and cooking practices.

In August 2004, the consumer group Center for Science in the Public Interest (CSPI) began a national campaign to urge USDA to publicize the names of retail outlets where recalled meat has been distributed, so that consumers can learn more quickly whether they have purchased potentially contaminated products. USDA and industry leaders have contended that distribution records are proprietary, and exempt from provisions of the Federal Freedom of Information Act; such information, they argue, should be limited mainly to public officials so that they can monitor recalls. However, in the March 7, 2006, *Federal Register*, FSIS proposed posting on its website the names of retailers who have products subject to a voluntary recall. FSIS announced on July 11, 2008, that it would begin to post such names in August 2008. The lists cover retailers involved in the potentially most serious (Class I) recalls only.³⁴

Reviewing FSIS protocols for handling recalls following the Topps case (see page 9), USDA's OIG concluded that while the agency has improved its investigative and recall procedures, it still needed “a science-based sampling protocol to collect and analyze a representative sample of product at an establishment to conclude whether contamination occurred there.”³⁵

In Congress

Provisions of the Food and Drug Administration Amendments Act of 2007 (H.R. 3580; P.L. 110-85) require the Secretary of HHS both to establish a food registry for the reporting of food adulteration, and to encourage more coordination and communication when recalls occur, but it

(...continued)

GAO-05-51. Also see CRS Report RL34313, *The USDA's Authority to Recall Meat and Poultry Products*, by Cynthia Brougher and Geoffrey S. Becker.

³⁴ “USDA Will List Retail Stores Receiving Recalled Meat and Poultry Products,” July 11, 2008 press release.

³⁵ *Food Safety and Inspection Service Recall Procedures for Adulterated or Contaminated Product*, August 2008, at <http://www.usda.gov/oig/webdocs/24601-09-HY.pdf>.

applies to FDA-regulated foods. In the Senate but not the House version of the omnibus farm bill (H.R. 2419) was a requirement that USDA establish similar “reportable food registries” for meat and poultry and their products. The final conference substitute, enacted as P.L. 110-246, amends the meat and poultry laws to require an establishment to notify USDA if it has reason to believe that an adulterated or misbranded product has entered commerce. Another conference provision requires meat and poultry establishments to prepare and maintain written recall plans.

Several other bills to authorize mandatory recalls for meat and poultry products were introduced but not enacted in the 110th Congress. Among other bills containing various provisions for mandatory recall authority and/or notification requirements were H.R. 5762, H.R. 2108/S. 1274, H.R. 3484, H.R. 3610, H.R. 3624, S. 2081, H.R. 1148/S. 654, and S. 2952.

Meat Traceability and Animal Identification

Recalls imply the ability to quickly trace the movement of products. On September 30, 2003, USDA’s OIG released an audit report on a 2002 meat recall by Con Agra. The report recommends “that FSIS reassess its management control process over ... recall operations ... by ensuring that ground beef is traceable from manufacturing to point-of-sale and that adequate production records are maintained to facilitate traceback.”

Some argue that improved traceability capabilities would have enabled USDA to determine the whereabouts of all related cattle of potential interest in the three U.S. case of BSE (bovine spongiform encephalopathy, or “mad cow disease”). The traceability issue has also been debated in connection with protecting against agroterrorism; verifying the U.S. origin of live cattle and meat products for export; and facilitating recalls to prevent or contain foodborne illness outbreaks, among other things.

Supporters of animal ID and meat traceability point out that most major meat-exporting countries already have domestic animal ID systems. The U.S. meat industry argued in the past that such a system would not be based on sound science, and would be technically unworkable. However, since the domestic BSE case, the industry, USDA, and other professionals have been attempting to implement a universal, although not mandatory, national animal ID (but not meat traceability) system, focused on animal disease control rather than food safety *per se*. However, progress has been slow; see the discussion of the National Animal Identification System (NAIS) later in this section. Some Members of Congress are among those who believe the programs should be mandatory in order to achieve universal participation. Among other issues are cost, need for a mandatory rather than voluntary system, potential producer liability, and privacy of records.

In Congress

Animal ID proposals were offered but not enacted in the 110th Congress. For example, H.R. 1018 would have prohibited the establishment of a mandatory ID system. H.R. 2301 would have created a livestock identification board with members from industry to oversee a national program. S. 1292 and H.R. 3485, separate bills, were broader traceability proposals. S. 1292 would have required the Secretary of Agriculture to establish a traceability system for all stages of production, processing, and marketing of meat and poultry, and would have required animal producers and meat and poultry processors to maintain records sufficient to enable the Secretary to trace a product forward to the consumer or backward to where the animal originated. H.R. 3485 covered both FSIS and FDA-regulated food traceability.

Both the House and Senate committee reports to accompany USDA's FY2008 appropriation (H.Rept. 110-258; S.Rept. 110-134) had questioned USDA's progress and direction in implementing NAIS. Over several years through FY2007, about \$117.8 million had gone into the development of such a program. Despite this effort, "the direction of this system remains unclear," noted the report on the Senate appropriations bill, which would have designated \$17.4 million in additional funds for NAIS. The House committee report noted that its version would have provided no new funding, and requested that USDA provide "a complete and detailed strategic plan for the program, including tangible outcomes, measurable goals, specific milestones, and necessary resources for the entire program." The final FY2008 appropriation for USDA—contained in Division A of the Consolidated Appropriations Act, 2008 (P.L. 110-161)—provided \$9.75 million to continue NAIS implementation. Appropriators stated that a USDA business plan for the program, issued late in 2007, did not provide sufficient information or justification to grant the entire \$33.2 million requested for the year.

Elsewhere, a provision in the Senate-passed farm bill (H.R. 2419) approved in December 2007 would have required USDA to issue regulations addressing "the protection of trade secrets and other proprietary and/or confidential business information that farmers and ranchers disclose in the course of participation" in an ID system. The provision was removed during the House-Senate conference prior to final passage.

Funding and User Fees

From time to time in the past, FSIS has had difficulty in sufficiently staffing its service obligations to the meat and poultry industries. Usually a combination of factors causes these shortages, including new technologies that increase plant production speeds and volume, insufficient appropriated funds to hire additional inspectors at times of unexpected increases in demand for inspections, and problems in finding qualified people to work in dangerous or unpleasant environments or at remote locations. These staffing problems were complicated somewhat by the addition of HACCP requirements on top of the traditional inspection duties.

To ease funding pressures, most administrations over the past 20 years have proposed to charge the meat-packing industry new user fees sufficient to cover the entire cost, or at least a portion, of federal inspection services. (FSIS has been authorized since 1919 to charge user fees for holiday and overtime inspections, and does so). The primary rationale for more extensive user fees has been that resources would then be adequate to hire new inspectors as necessary. USDA economists estimate that the cost passed on to consumers from such a fee would be no more than one cent per pound. Meat industry and consumer groups have consistently opposed increased fees, arguing that food safety is a public health concern that merits taxpayer support.

As part of its FY2009 budget submitted to Congress in February 2008, the Bush Administration again had asked for new user fees. Its FY2009 proposal would raise \$92 million by collecting licensing fees from meat and poultry establishments, and another \$4 million by charging plants that require additional inspections due to performance failures. These fees also were proposed, unsuccessfully, with the Administration's FY2008 budget.

In Congress

FSIS inspection costs are mainly funded through USDA's annual appropriation. For FY2008, the Senate-reported bill had recommended \$930.6 million for FSIS, or \$38.5 million above the

FY2007 level. The House-passed bill and the final version (Division A of P.L. 110-161) provided \$930.1 million in appropriations for FSIS for FY2008, the same as the Administration's request. The congressional appropriation was to be supplemented in FY2008 by an estimated \$141 million in existing user fees.

The Administration's FY2009 budget proposal recommended \$952 million in new appropriations for FSIS, to be supplemented by about \$140 million in existing user fees (i.e., not counting the proposed \$96 million in new fees described above). This would bring the FSIS program level to approximately \$1.1 billion in FY2009. The 110th Congress did not complete action on the agriculture appropriation measure for the full year. As noted earlier, FSIS and other USDA agencies were operating under a continuing resolution (P.L. 110-329) through March 6, 2009.

State-Inspected Products

As noted, current federal law long prohibited state-inspected meat and poultry plants from shipping their products across state lines, a ban that many states and small plants have wanted to overturn. Limiting state-inspected products to intrastate commerce is unfair, these states and plants argued, because their programs must be, and are, "at least equal" to the federal system. While state-inspected plants could not ship interstate, foreign plants operating under USDA-approved foreign programs, which must be "equivalent" to the U.S. program, have been permitted to export meat and poultry products into and sell them anywhere in the United States.

Those who have opposed state-inspected products in interstate commerce argued that state programs have not been 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. The opponents of interstate shipment note that a recent FSIS review, which had found all 28 state programs to be at least equal to the U.S. program, was based largely on self-assessments.³⁶

"At Least Equal to" vs. "Equivalence"

According to FSIS, "at least equal to" means "that the food safety and other consumer protection measures effected by a State program address the same issues addressed by the Federal (FSIS) program, and the results of the State's approach are to be at least as effective as those of the Federal program. The State program need not take exactly the same action as the Federal program" (FSIS Directive 5720.2, Revision 3, November 16, 2004).

"Equivalence" is a somewhat different concept. "Meat and poultry products exported from another nation must meet all safety standards applied to foods produced in the United States. However, under international law, food regulatory systems in exporting countries may employ sanitary measures that differ from those applied domestically by the importing country. The United States makes determinations of equivalence by evaluating whether foreign food regulatory systems attain the appropriate level of protection provided by our domestic system. Thus, while foreign food regulatory systems need not be identical to the U.S. system, they must employ equivalent sanitary measures that provide the same level of protection against food hazards as is achieved domestically" (FSIS, "Equivalence Process," at http://www.fsis.usda.gov/regulations_&_policies/equivalence_process/index.asp).

³⁶ The *FSIS Review of State Programs: Summary Report* (January 2007) was accessed on April 27, 2007, at http://www.fsis.usda.gov/PDF/Review_of_State_Programs.pdf. Later in 2007, New Mexico turned its inspection activities over to FSIS.

In Congress

In the 110th Congress, Section 11015 of the enacted farm bill (P.L. 110-246) amends the FMIA and the PPIA to authorize a new opt-in program for state-inspected plants. This program is to supplement rather than replace the existing federal-state cooperative inspection program. In states that choose to participate, a federally employed coordinator would supervise state employees in plants that want to ship across state lines. Eligible plants are limited to those with 25 or fewer employees—except that plants with between 25 and 35 employees can apply for coverage within the first three years of enactment. The law sets federal reimbursement for state costs under the new program at 60%; the current federal-state cooperative inspection program provides reimbursement at 50% of costs. Products inspected under the new program are to carry the federal mark of inspection. Other provisions prohibit federally inspected establishments from participation, establish a new technical assistance division to assist the states, and require periodic audits by USDA, among other things.

The new program, which reflects language in the Senate version of the farm bill, reportedly was developed as a compromise by those on both sides of the issue. It appears to be based in concept on the Talmadge-Aiken program (see page 4). Some proponents of ending the interstate ban on state-inspected meat have contended that the new language is overly restrictive, while those who support the change have countered that it provides appropriate safeguards. The farm bill requires final rules to implement the new state program by December 2009.

Food Safety Reorganization

U.S. food safety oversight, while concentrated in FSIS and FDA, is spread among 15 agencies operating under a variety of statutes. This complex system is supplemented by many state food safety programs. GAO, which has looked at the matter several times, noted in one report that the federal food safety system “emerged piecemeal, over many decades, typically in response to particular health threats or economic crises. The result is a fragmented legal and organizational structure that gives responsibility for specific food commodities to different agencies and provides them with significantly different authorities to enforce food safety laws.”³⁷

In its January 2007 annual report, GAO newly designated food safety oversight as one of 29 “high risk” federal program areas. The report, among other things, 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.”³⁸ Besides GAO, the National Academy of Sciences and the National Commission on the Public Service have studied the issue and recommended options for change.³⁹

³⁷ *Food Safety: Experiences of Seven Countries in Consolidating Their Food Safety Systems*, GAO-05-212, February 2005.

³⁸ *High Risk Series: An Update* (GAO-07-310), January 2007.

³⁹ See National Research Council, Institute of Medicine, *Ensuring Safe Food From Production to Consumption*, Washington, DC, National Academy Press, 1998; and National Commission on the Public Service, *Urgent Business For America: Revitalizing the Federal Government for the 21st Century*, Washington, DC, 2003.

In Congress

In the 110th Congress, “single food agency” bills were introduced in February 2007, as H.R. 1148 by Representative DeLauro and S. 654 by Senator Durbin. The measures would have combined federal food safety programs, including meat and poultry inspection, under a new, independent Food Safety Administration, to be headed by an Administrator appointed by the President and confirmed by the Senate. The new Administrator would have been required to conduct a comprehensive analysis of food safety hazards and to adopt and implement a national program that among other things requires registration of all domestic and foreign food establishments doing business in the United States. The bills would have required the formulation of food safety performance standards, set out inspection procedures for establishments, provided for research and education programs, and included enforcement and penalty provisions.⁴⁰

The omnibus farm bill (H.R. 2419) that cleared the Senate included a provision establishing a bipartisan congressional food safety commission to study the federal food safety system and recommend needed changes. Another provision in the same measure would have required the President to consider these changes and report to Congress on legislation needed to effect them. The provision was removed by farm bill conferees.

Interest in reorganizing the agencies and/or enhancing their resources and authorities, particularly those of FDA, was the topic of numerous 2007 and 2008 congressional hearings, including hearings before Representative DeLauro’s House Appropriations subcommittee and several subcommittees of the House Energy and Commerce Committee. Panels on both sides of Congress held hearings on the safety of imported food products, including meat and poultry, where agency organization and resources were at issue as well.

If, as is possible, lawmakers in the 111th Congress are asked to consider new proposals that would either reorganize or consolidate the federal food safety organization, a range of policy options are likely to be debated, including whether the current regulatory approaches and their authorizing statutes remain appropriate, given the diversity of food types, health risks, methods of production, and sources of supply; the continuously evolving science on foodborne illness and how to prevent future outbreaks; the impacts on industry competitiveness, particularly in a global economy; and funding constraints. Another uncertainty is whether food safety reform efforts would be limited to FDA authorities and programs alone, or would be extended further to those of FSIS (and other agencies). One factor mitigating against the latter approach is that jurisdiction over FDA and FSIS is split between separate committees in both the House and Senate.

Horse Slaughter

Nearly 105,000 horses were slaughtered in the United States in 2006 for human food, mainly for European and Asian consumers. Such slaughter was conducted under federal inspection at two foreign-owned plants in Texas and another foreign-owned plant in Illinois. Debate has focused on the acceptability of using horses for human food, and the costs of long-term care for such horses (or of disposing of their carcasses) if they no longer went for human food.

⁴⁰ A more recent bill (H.R. 7143) introduced by Representative DeLauro on September 26, 2008, also seeks to reorganize food safety, but it focuses on elevating the food safety functions of FDA by creating a new agency within the HHS Department.

Although legislation has been debated in Congress to curtail such slaughter (see below), the plants' activities became constrained in 2007 by the courts and state law. A federal lawsuit filed by the owners of the two Texas slaughter plants, Beltex Corporation and Dallas Crown, Inc., sought to clarify that a Texas state law, first passed in 1949 to prevent the use of horsemeat for human food, was not enforceable and that they should not be prosecuted. The U.S. District Court for the Northern District of Texas in Fort Worth had earlier agreed with the plants' owners that the law had been repealed, was preempted by the FMIA, and violated the dormant Commerce Clause of the U.S. Constitution. However, on January 19, 2007, a panel of the U.S. Court of Appeals for the Fifth Circuit rejected all three arguments in the lower court's ruling, declaring the Texas law to be in force and clearing the way for the state attorney general to prosecute the plant owners if they continued to operate. Elsewhere, the Illinois legislature passed a law banning horse slaughter for food. The U.S. Court of Appeals for the Seventh Circuit by fall 2007 ruled against the argument of the plant (owned by Cavel International) that the Illinois law violates the interstate and foreign commerce clauses of the U.S. Constitution, bringing Cavel's operations there to a close. (The U.S. Supreme Court in 2008 declined to hear the case.)

In Congress

The 109th Congress had debated whether to ban horse slaughter and (in the FY2006 appropriation) had banned the use of federal funds for ante-mortem inspection of horses at meat processing plants. Although supporters of the ban had hoped that the lack of federal funds for such inspection would force an end to horse slaughter, the practice continued, with the three plants paying user fees for the federal service (until legal and state-level developments challenged the plants; see above). Also in the 109th Congress, the full House approved a bill (H.R. 503) to ban horse slaughter, but no action occurred on a Senate version (S. 1915).

Bills in the 110th Congress to ban the movement or possession of horses for slaughter included H.R. 503 and S. 311. The Senate Commerce, Science and Transportation Committee approved S. 311 without amendments on April 25, 2007, but the measure did not advance. Another bill, H.R. 6598, introduced later in the 110th Congress, would have amended the criminal portion (Title 18) of the U.S. Code to make it illegal to knowingly possess, ship, transport, purchase, sell, deliver, or receive any horse, horseflesh, or carcass intended for human consumption. The Judiciary Committee favorably reported H.R. 6598 on September 23, 2008, but it too was not enacted.

Meanwhile, the omnibus appropriation for FY2008 (P.L. 110-161, in Division A, Section 741) had both continued the ban on using appropriated funds for inspecting horses and also prohibited the USDA-FSIS rule that enabled the collection of user fees for such purposes. The continuing resolution for FY2009 also appears to continue the ban. (See CRS Report RS21842, *Horse Slaughter Prevention Bills and Issues*, by Geoffrey S. Becker.)

BSE

North American Cases

Through the end of 2008, 19 cases of BSE had been reported in North America. Sixteen of them were cattle born in Canada, which reported its first native case in May 2003 (one earlier case was imported from Great Britain) and its latest case in November 2008. The United States reported its first case in December 2003 (one of the Canadian-born animals, imported into the United States).

The United States also found two additional cases, in U.S.-born cattle. The most recent U.S. case was in late February 2006.

In epidemiological investigations of the three U.S. cases, the U.S. Department of Agriculture (USDA) was unable to track down all related animals of interest, but those that were located tested negative for the disease. Despite a beef recall, some meat from the first U.S. BSE cow may have been consumed, USDA said, adding, however, that the highest-risk tissues never entered the food supply. No materials from the other two U.S. cows entered the food supply, USDA also said. In the recent Alabama case, authorities were unable to determine the cow's herd of origin.

Animal health officials initially indicated that all of the North American cases were caused by the consumption of BSE-contaminated feed. However, USDA reportedly now believes that the two native-born U.S. cattle had "atypical" BSE, which differs from other cases. If these cases are determined to be "spontaneous," that may affect future control strategies.

BSE Safeguards

FSIS is one of the three federal agencies primarily responsible for keeping BSE out of the food supply. The other two agencies involved in BSE are USDA's Animal and Plant Health Inspection Service (APHIS), which handles primarily the animal disease aspects, and FDA, which regulates feed ingredients. After the first U.S. BSE case, FSIS published, as interim final rules in the January 12, 2004, *Federal Register*, several actions to bolster U.S. BSE protection systems, effective immediately:

- Downer (nonambulatory) cattle are no longer allowed into inspected slaughter and processing facilities. (This interim final rule was published in the July 13, 2007 *Federal Register*.)
- Cattle selected for testing cannot be marked as "inspected and passed" until confirmation is received that they have tested negative for BSE.
- Specified risk materials (SRM), which include the skull, brain, trigeminal ganglia, eyes, vertebral column, spinal column, and dorsal root ganglia of cattle over 30 months of age, and the small intestine of cattle of all ages, are now prohibited from the human food supply.
- Slaughter facilities are required to develop and implement procedures to remove, segregate, and dispose of SRM and make information readily available for review by FSIS inspection personnel.
- SRM from cattle 30 months or older cannot be in a product labeled as "meat" if derived from advanced meat recovery (AMR) technology, which USDA said would help ensure it does not contain spinal tissue.
- Mechanically separated meat may not be used for human food.
- Air injection stunning is banned, to ensure that portions of the animal brain are not dislocated into the carcass.

The FSIS actions, which remain in effect, were in addition to other BSE regulatory safeguards that have been in place for several years. These include import controls and ongoing BSE surveillance through carcass testing by APHIS, and restrictions on the feeding of certain mammalian proteins to cattle by FDA (see box on page 23).

Additional USDA actions in the wake of the December 2003 BSE discovery have included more attention to implementing a nationwide animal identification program that would enable all cattle and other animal movements to be traced within 48 hours in cases of animal disease (see prior section on “Meat Traceability and Animal Identification”); and an intensive, one-time BSE testing program for higher-risk cattle (since completed).

Humane Slaughter and the Hallmark/Westland Recall

On February 17, 2008, USDA announced that Hallmark/Westland Meat Packing Co. of California was voluntarily recalling 143 million pounds of fresh and frozen beef products dating to February 1, 2006. About 50 million pounds were distributed to the school lunch and several other federal nutrition programs in at least 45 states. This largest U.S. meat recall ever came after USDA’s Food Safety and Inspection Service (FSIS) found that for at least two years the facility had not always notified inspectors about cattle that had become nonambulatory after they had been inspected, but before they were slaughtered for food. FSIS regulations explicitly prohibit most nonambulatory cattle in human food, because of their higher risk of bovine spongiform encephalopathy (BSE, or “mad cow disease”).

FSIS also cited evidence that the plant had violated the Humane Methods of Slaughter Act (HMSA), which first came to light after animal welfare advocates secretly videotaped what they described as employees inhumanely handling downer cattle before slaughter. The HMSA stipulates, among other things, that “[n]o method of slaughtering or handling in connection with slaughtering shall be deemed to comply with the public policy of the United States unless it is humane.”

The recall was so-called Class II, indicating a remote possibility that consumption of the products could cause adverse health effects. Nonetheless, FSIS suspended operations at the plant, which is not expected to reopen. The 110th Congress held several hearings in which the effectiveness and USDA implementation of the HMSA, and its BSE rules, were challenged. Bills to legislatively prohibit the slaughter of nonambulatory livestock for food included H.R. 661, S. 394, and S. 2770. They were not enacted. For additional details, see CRS Report RS22819, *Nonambulatory Livestock and the Humane Methods of Slaughter Act*, by Geoffrey S. Becker.

In Congress

Although BSE remains a priority for many Members of Congress, much of the recent interest has focused on trade rather than food safety concerns. Japan and Korea, once among the four leading export markets for U.S. beef, have taken years to begin accepting U.S. beef products. Exports to Japan, which restarted in 2005, are still limited to products from younger cattle, and sales remain below previous levels. Korean inspection procedures kept that market largely closed to the United States through much of 2007 and again during early 2008.

An April 18, 2008, a new U.S.-Korea agreement was announced that was to lead to that country’s opening to most U.S. beef in accordance with accepted international veterinary guidelines. However, Korea first delayed implementation and then scaled back the types of products it would accept, following vigorous anti-government protests that grew from this agreement’s announcement. By July, and through the end of 2008, U.S. beef again was moving into Korea. U.S. authorities have been hopeful that such positive developments could help to defuse the frustration of many Members of Congress, some of whom had been expected to reintroduce legislation calling for sanctions against trading partners that failed to accept assurances of U.S. beef safety. U.S. access to Korea’s beef market has been an issue in the debate over implementation of the U.S.-Korea free trade agreement (FTA). A number of Members signaled that their support for legislation to implement the FTA was contingent on Korea fully opening its market for U.S. beef. (See CRS Report RL34528, *U.S.-South Korea Beef Dispute: Agreement and Status*, by Remy Jurenas and Mark E. Manyin.)

Also of concern to many Members has been USDA's gradual reopening of the U.S. border to more types Canadian cattle. Some Members are sympathetic to the arguments of certain cattle organizations, primarily from the Upper Plains, that such cattle continue to pose a BSE threat. In the 110th Congress resolutions of disapproval (H.J.Res. 55 and S.J.Res. 20) of the most recent USDA rule to expand the types of eligible Canadian imports were introduced in both chambers but not enacted. Even if passed, these resolutions would have had no force of law. (For background see CRS Report RS21709, *Mad Cow Disease and U.S. Beef Trade*, by Charles E. Hanrahan and Geoffrey S. Becker.)

The FDA "Feed Ban"

The FDA Center for Veterinary Medicine (CVM), responsible for the safety of animal feeds, began prohibiting the use of most mammalian protein in feeds for ruminants in August 1997, a restriction commonly called the "feed ban." This ban did not prohibit the inclusion of potential bovine risk materials such as brain and spinal cord in all animal feeds, but only those feeds intended for ruminants. FDA required that feeds containing ruminant material be labeled with a prohibition against feeding to ruminants, and that firms and farms effectively separate prohibited and non-prohibited feeds in production, shipping and feeding. The ban exempted certain bovine by-products, such as blood, milk, gelatin and restaurant plate waste, on the premise that the exempted materials posed a minimal risk of transmission. On October 6, 2005, FDA published a proposed rule banning some SRM from all animal feeds, including pet food. The agency said its rule would remove those cattle parts responsible for 90% of potential BSE infectivity.

The final rule appeared in the April 25, 2008, *Federal Register* (its issuance was tied in part to the April U.S.-Korea beef agreement). Under the rule, prohibited materials (i.e., SRM) include the brains and spinal cords from cattle 30 months of age and older, the entire carcasses of BSE-infected cattle, the entire carcass of cattle that has not been inspected and passed for human consumption that is 30 months of age or older from which brains and spinal cords were not removed, tallow derived from BSE-infected cattle and from other prohibited cattle materials, and mechanically separated beef derived from the same prohibited materials.

Canada had finalized a similar but somewhat more extensive amendment to its own feed rules in June 2006.

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