



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 certain 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 is an oversight item for the 111th Congress. Other recent inspection issues could receive continued attention in the 111th Congress, which currently appears to be focused on broader legislation to reform food safety programs—notably those of the U.S. Food and Drug Administration (FDA), which oversees all foods other than meat and poultry. Issues relevant to FSIS programs include the following.

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, recalls due to pathogen problems continue to occur, and the significant rates of decline in the incidence of some major foodborne pathogens have not been sustained 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 authority to mandate recalls of 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, with some user fees authorized to cover plant overtime and holiday inspection costs. Congress has denied successive Administrations' proposals for additional user fees. Congress also has used annual appropriations measures to direct FSIS's administration of its programs. Examples include prohibiting implementation of a rule that would allow imports of some Chinese poultry products; prohibiting the use of funds to inspect horses to be used for food for humans; and slowing the agency's implementation of a controversial “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 certain 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, 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.

These incidents have fueled interest in a number of bills in the 110th and 111th Congresses to change other elements of USDA's authorizing statutes. What, if any, additional changes should lawmakers 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. As noted, the 2008 farm bill makes catfish an amenable species.

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).

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 (name redacted), and CRS Report R40443, *Food Safety: Selected Issues and Bills in the 111th Congress*, by (name redacted).

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.

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.

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).

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. For FY2010, FSIS received an annual appropriation of approximately \$1 billion. 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 FY2010, revenue from the fees is expected to add approximately \$150 million in additional program support.

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 nearly 1,900 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 \$65 million of the total FSIS budget annually. 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 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

² A new state inspection option authorized by the 2008 farm bill is discussed later in this report.

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

The U.S. Centers for Disease Control and Prevention (CDC) observed in April 2009:

Despite numerous activities aimed at preventing foodborne human infections, including the initiation of new control measures after the identification of new vehicles of transmission (e.g., peanut butter-containing products), progress toward the national health objectives has plateaued, suggesting that fundamental problems with bacterial and parasitic contamination are not being resolved. Although significant declines in the incidence of certain pathogens have occurred since establishment of FoodNet, these all occurred before 2004. Of the four pathogens with current Healthy People 2010 targets, *Salmonella*, with an incidence rate of 16.2 cases per 100,000 in 2008, is farthest from its target for 2010 (6.8). The lack of recent progress toward the national health objective targets and the occurrence of large multistate outbreaks point to gaps in the current food safety system and the need to continue to develop and evaluate food safety practices as food moves from the farm to the table.⁴

Not all of these infections are from consumption of meat and poultry products. A more recent CDC article reported that, among 243 foodborne disease outbreaks attributed to a single commodity in 2006, the most outbreaks were attributed to fish (47), poultry (35), and beef (25). However, the most cases were attributed to poultry (1,355), leafy vegetables (1,081) and fruits/nuts (1,021). Pairing pathogens with commodities, the CDC found that the most outbreak-related cases were *Clostridium perfringens* in poultry (902 cases), *Salmonella* in fruits nuts (776), norovirus in leafy vegetables (657), shiga-toxin *E. coli* in leafy vegetables (398), *Salmonella* in vine-stalk vegetables (331), and *V. parahaemolyticus* in mollusks (223).⁵

Nonetheless, 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.⁶

³ As of December 2009, 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 (name redacted).

⁴ "Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food—10 States, 2008," *Morbidity and Mortality Weekly Report*, April 10, 2009.

⁵ "Surveillance for Foodborne Disease Outbreaks—United States, 2006," *Morbidity and Mortality Weekly Report*, June 12, 2009. A case is a single person; and outbreak is two or more cases.

⁶ Some discussion of the more recent data is contained in the sections of this CRS report on selected pathogens.

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.

In 1995, under existing statutes, FSIS published a proposed rule to systematize these 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, and taking corrective actions when necessary. Record-keeping and verification 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.⁷

Pathogen Performance Standards and *Salmonella*

The CDC has noted that poultry is an important source of human *Salmonella* infections. The pathogen also periodically has been found in beef, as well as non-animal foods such as fresh produce. According to CDC reports, the overall incidence of *Salmonella* infections through all types of food has not decreased significantly.⁸ CDC also has reported that *Salmonella* has been the most common foodborne pathogen, although exposure to live animals also has been 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 failure to meet *Salmonella* standards as the basis for withdrawing inspection. 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.

⁷ The final rule appeared in 61 *Federal Register* 38805-38855.

⁸ 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; “...—10 States, 2007,” *Morbidity and Mortality Weekly Report*, April 11, 2008; and “...—10 States, 2008,” *Morbidity and Mortality Weekly Report*, April 10, 2009.

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 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.⁹

FSIS on January 28, 2008 issued a notice on new policies and procedures for *Salmonella* sampling and testing.¹⁰ One change was to begin posting 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%);

⁹ *Food Chemical News*, July 3, 2006. A notice and request for comments on this initiative were published in the February 27, 2006, *Federal Register*.

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

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. The December (fourth quarter) 2009 report showed 12 establishments in category 2 and four in category 3.¹¹

The CDC in 2009 credited the industry's response to the FSIS *Salmonella* initiative with a decrease in the percent-positive rate for *Salmonella* in raw broiler chicken, from 11.4% in 2006 to 7.3% in 2008.¹² The rate was 8.6% in the fourth quarter of 2009.

Another *Salmonella* initiative developed by FSIS is on a list of Obama Administration food safety actions announced by the President's Food Safety Working Group (FSWG) on July 7, 2009. The group said that FSIS would, by the end of 2009, "develop new standards to reduce the prevalence of *Salmonella* in turkeys and poultry" (more specifically, young chickens, or broilers) and "establish a *Salmonella* verification program with the goal of having 90 percent of poultry establishments meeting the new standards by the end of 2010."¹³ On December 31, 2009, the agency announced that it would "issue a *Federal Register* notice in the very near future that will provide specific details" on the new standards, and invite public comments on them, with implementation by July 2010. FSIS also for the first time is developing new standards for the pathogen *Campylobacter* in young chickens (broilers) and turkeys, the announcement stated.

Concerns regarding *Salmonella* contamination are not limited to poultry, as illustrated by recalls of 825,769 pounds of ground beef products in August 2009 and another 22,723 pounds of ground beef products in December 2009, both by a California establishment, Beef Packers Inc. The recalls were associated with investigations of *Salmonella* illness outbreaks, according to FSIS.¹⁴ Media reports in late 2009 on these recalls by the company, a supplier of beef to the federal school lunch program, and on pathogens found in ground beef produced by another school lunch supplier, Beef Products Inc., raised questions about the safety of these USDA-purchased commodities (see discussion later in this report).

(FSIS's quarterly *Salmonella* reports also list performance standards and testing results for, in addition to broilers and turkeys, market hogs, steers and heifers, cows and bulls, and ground products—chicken, turkey and beef.)

In another recent incident, Danielle International of Rhode Island had, through February 2010, recalled approximately 30 Italian-style meat products totaling nearly 1.4 million pounds after reports of a multistate outbreak of *Salmonella* Montevideo infections in 252 persons in 44 states and the District of Columbia.¹⁵ Samples of black pepper used on the products tested positive for

¹¹ 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 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>.

¹² *Morbidity and Mortality Weekly Report*, April 10, 2009.

¹³ "Food Safety Working Group: Key Findings." FSWG is an interdepartmental effort to advise the President on how to improve the U.S. food safety system; its website is <http://www.foodsafetyworkinggroup.gov/>.

¹⁴ FSIS, "Constituent Update," December 31, 2009.

¹⁵ U.S. Centers for Disease Control (CDC) and Prevention, "Investigation Update: Multistate Outbreak of Human (continued...)"

Salmonella, indicating that outside ingredients can be a source of concern. FDA, which oversees pepper and other spices, has been coordinating with FSIS regarding the recall.

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

Illness outbreaks continue to be linked to the pathogen *E. coli* O157:H7 in beef products. This has led to calls from critics for improvements in testing for *E. coli* and for minimizing its presence. Some consumer groups have argued that more tests should be mandated; meat industry representatives counter that while an effective sampling and testing program is important to help determine whether a plant's pathogen control measures are working, testing itself cannot assure safety.

CDC noted that "*E. coli* O157:H7 is one of hundreds of strains of the bacterium *Escherichia coli*. Although most strains are considered 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."¹⁶

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 2004.¹⁷

The CDC 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."¹⁸ The CDC reported an increase in the percentage of ground beef samples yielding O157:H7—from 0.24% in 2007 to 0.47% in 2008—but said it was unknown whether this was related to focused sampling of higher-risk facilities, improved laboratory detection, or an actually higher microbial load.¹⁹

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.²⁰ In 2005, the agency

(...continued)

Salmonella Montevideo Infections," update for March 17, 2010.

¹⁶ Background information on this pathogen may be viewed at the following CDC website: http://www.cdc.gov/nczved/dfbmd/disease_listing/stec_gi.html.

¹⁷ *Morbidity and Mortality Weekly Report*, April 13, 2007.

¹⁸ *Morbidity and Mortality Weekly Report*, April 11, 2008.

¹⁹ *Morbidity and Mortality Weekly Report*, April 10, 2009.

²⁰ Source: FSIS press releases on recalls posted at http://www.fsis.usda.gov/Fsis_Recalls/index.asp.

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 box, “Topps Recall”).²¹

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.²² 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.,²³ 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.

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.²⁴

For 2009, a total of 15 *E. coli*-related recalls were announced by FSIS, four of which were linked to an illness outbreak investigation. The others generally were the result of routine testing. Two large recalls late in the year included 545,699 pounds of fresh ground beef products from a New York State establishment in October, following an investigation of 26 *E. coli*-related illnesses

²¹ Recall updates are at the FSIS website, http://www.fsis.usda.gov/Fsis_Recalls/index.asp. Also, CRS has tallied recalls, by product type and reason, for 1994 through 2009; see the appendix in CRS Report RL34313, *The USDA’s Authority to Recall Meat and Poultry Products*, by Cynthia Brougher and (name redacted).

²² See for example, *Cattle Buyers Weekly*, October 8, 2007; *Feedstuffs*, October 8, 2007.

²³ Source: *Cattle Buyers Weekly*, various 2007 issues.

²⁴ “Nebraska Beef *E. coli* recall gets a sequel,” *Food Chemical News*, August 18, 2008.

among 26 persons from eight states;²⁵ and 248,000 pounds of primarily whole beef cuts from an Oklahoma establishment in December, linked to 21 illnesses in 16 states.²⁶

FSIS had begun testing samples of raw ground beef for *E. coli* O157:H7 in October 1994, declaring 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.²⁷

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.²⁸

Additional FSIS *E. coli* initiatives were announced as one of the items on the FSWG list of actions on July 7, 2009. The working group stated that FSIS is increasing its sampling, focusing

²⁵ CDC, “Multistate Outbreak of *E. coli* O157:H7 Infections Associated with Beef from Fairbank Farms Final Update,” November 24, 2009; at <http://www.cdc.gov/ecoli/2009/>.

²⁶ The December recall was of products that had been mechanically tenderized. Consumer advocates argue that this process can transfer surface pathogens into the center of the meat, which, if not cooked thoroughly, can sicken those who eat it. FSIS also stated in its December 24, 2009, recall announcement “that there is an association between non-intact steaks (blade tenderized prior to further processing) and illnesses” in a number of states. See also “*E. coli*-Tainted Beef Infects 21 in 16 States,” *Washington Post*, December 30, 2009.

²⁷ 67 *Federal Register* 62325.

²⁸ 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.

on the components that go into ground beef, and also improving its instructions to field staff on how to verify beef establishment controls over the pathogen. These beef components are typically referred to as “bench trim” and are the trimmings from larger cuts of primal and sub-primal cuts of beef. A notice on sampling bench trim and a directive on *E. coli* verification activities were issued on July 31, 2009.²⁹ Meanwhile, FSIS reportedly was considering whether to define all cuts of beef as adulterated if they test positive for *E. coli* O157:H7, something a number of groups requested after a recent recall of 421,000 pounds of such “muscle cuts.”³⁰

The agency also is planning or contemplating a number of other efforts aimed at addressing *E. coli* O157:H7, including directing its enforcement investigators to gather more information within 48 hours of a presumed positive test for the pathogen (to improve ability to trace contaminated products back to their source); proposing rules requiring products to be held until testing results are completed; requiring labels on whole meat cuts that have been mechanically tenderized; and possibly instituting new record-keeping requirements aimed at enhancing traceback capabilities.³¹

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. FSIS and other food safety experts were speculating as to whether the increase was due to a higher prevalence of the bacteria, or simply to the fact that the agency had changed its testing method in 2008. It is possible, for example, that the newer method is more sensitive to the presence of *E. coli*.³² In 2009, through December 27, a total of 41 or 0.32% out of 12,685 ground beef samples tested positive. In 2009 testing of ground beef components, FSIS reported that 30 or 0.86% out of 3,496 samples tested positive.

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.

²⁹ FSIS Notice 51-09 and FSIS Directive 10,010.1, Revision 2, respectively.

³⁰ Source, “USDA Mulls *E. coli* As Adulterant on Cuts,” *Cattle Buyers Weekly*, August 24, 2009.

³¹ The agency’s “current thinking” on *E. coli* O157:H7 actions was discussed at a public meeting in Washington, D.C., on March 10, 2010. See for example: “FSIS surprises attendees with details on new *E. coli* policies,” *Food Chemical News*, March 15, 2010; and “USDA to mandate test and hold, non-intact meat labels,” *Meatingplace.com*, March 19, 2010.

³² “Explanation to higher number of *E. coli* positives may be in broth,” *Food Chemical News*, October 20, 2008. A March 12, 2009, FSIS Notice (18-09) announced that the agency was “increasing sampling at high volume ground beef establishments because these establishments produce product that is most widely consumed. The increase in sampling will allow the Agency to estimate the amount of uncontaminated raw ground beef with a higher degree of certainty.” A new sampling notice (44-09) dated June 1, 2009, modifies and clarifies some of the provisions in the March notice it replaced.

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 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.³³ 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 seven deaths and three 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.³⁴ 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.³⁵

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.³⁶

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.³⁷

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

³³ Source: *Food Chemical News*, various issues.

³⁴ The guidelines can be found on the FSIS website at <http://www.fsis.usda.gov>.

³⁵ See the FSIS website for more details on the rule.

³⁶ CFA website: <http://www.consumerfed.org/>.

³⁷ *Morbidity and Mortality Weekly Report*, April 13, 2007, and April 11, 2008.

posted six *Listeria* recalls in 2006 and another 11 in 2007, including, in January and February 2007, 2.8 million pounds of Oscar Mayer/Louis Rich chicken breast cuts and strips.³⁸ Fifteen *Listeria*-related recalls were posted in 2008, and eight in 2009.

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.³⁹ 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."⁴⁰

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.⁴¹

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.⁴²

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 FY2009.⁴³

³⁸ FSIS recall website: http://www.fsis.usda.gov/FSIS_Recalls/index.asp.

³⁹ See "In Congress" later in this section of the report.

⁴⁰ "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.

⁴¹ Comments by Dr. Richard Raymond, USDA Under Secretary for Food Safety, February 22, 2007, press teleconference.

⁴² 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.

⁴³ 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."⁴⁴ 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 Risk-Based Inspection System" (PHRBIS)—to address the OIG recommendations and those of public commenters. FSIS issued a report outlining the elements of and scientific basis for the evolving PHRBIS on April 2008.⁴⁵ The agency has been implementing the OIG recommendations, and has predicted that implementation will begin in late FY2010.

The agency also asked the National Academy of Sciences (NAS) to evaluate the data and methodology underlying its PHRBIS initiative. On March 23, 2009, a committee of the NAS Institute of Medicine issued its report, commending FSIS for its commitment to develop a risk-based system and agreeing with the "general concept of using process control indicators as part of an algorithm to rank establishments in different levels of inspection." However, the committee also "found it a challenge to evaluate the adequacy of indicators of process control to rank establishments and allocate agency inspection resources without a clear understanding of the rationale for the general approach," which the FSIS technical report did not articulate. For example, the agency did not clearly define the meaning of "process control indicators," or provide in-depth consideration of the underlying statistics for specific microbiological testing protocols, among other uncertainties or limitations found by the committee.⁴⁶

In Congress

Provisions in several successive appropriations measures (including P.L. 110-28 and P.L. 110-161, Division A, in the 110th Congress, and P.L. 111-8, Division A, in the 111th Congress) have 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. This prohibition is continued under the FY2010 appropriations measure (P.L. 111-80).

⁴⁴ USDA, OIG, *Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments* (Report. No. 24601-07-Hy).

⁴⁵ 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.

⁴⁶ Committee on Review of the Use of Process Indicators in the FSIS Public Health Risk-Based Inspection System, Institute of Medicine. *Review of the Use of Process Control Indicators in the FSIS Public Health Risk-Based Inspection System: Letter Report* (National Academies Press, 2009).

Several freestanding bills were introduced late in the first session of the 111th Congress that aimed to address microbiological contamination. They include S. 2792, which would direct USDA to require beef slaughterhouses, processing establishments, and grinding facilities to meet minimum testing requirements for *E. coli* O157:H7. The new provisions would be applied to imported as well as domestic beef, require positive *E. coli* O157:H7 test results to be reported to USDA within 24 hours, and exempt facilities that process or grind 25,000 pounds or less per day. Also, S. 2819 would prohibit the marketing of any processed food regulated under the meat and poultry inspection laws (as well as any processed food regulated by FDA under the Federal Food, Drug, and Cosmetic Act) that either has not undergone a pathogen reduction treatment or is certified not to contain verifiable traces of pathogens.

In the second session, H.R. 4750, introduced March 3, 2010, would subject firms and other entities to up to three years in prison, a \$10,000 fine, or both, if they prohibit—whether by contract or other means—another firm or entity from further examining carcasses, carcass parts, or the meat or poultry products from them to ensure that they are not adulterated. The measure follows reports that some firms were prohibiting those who bought their products from testing them to ensure they were free of pathogens; at issue, among other things, is who might be liable for such products if they are found to be contaminated.

Other Selected Issues

Safety of Meats in School Meals Programs

As noted earlier, media reports appeared in late 2009 that raised questions about the safety of the meat being supplied to school meals programs. Meanwhile, several lawmakers also have called for a review of how USDA screens meat and poultry destined for school meals and/or for consideration of legislation in the second session of the 111th Congress that would require the Department to enforce more rigorous testing, recall, and other procedures for products to be used in the programs.

Although schools use cash to purchase directly most of the foods used in these programs, a significant amount—by law, at least 12% of the combined value of cash and commodity assistance—is provided through commodities purchased by USDA and transferred to schools through the states. This 12% now amounts to about \$1 billion annually for all types of commodities.⁴⁷ USDA's Agricultural Marketing Service (AMS) handles purchases for most commodities, including meat and poultry, and has purchased approximately 133 million pounds of beef alone in each of the past three years.⁴⁸

USA Today reported that, during the dates covered by the Beef Packers Inc. recall, USDA purchased four orders totaling nearly 450,000 pounds of ground beef for the school lunch program. One order reportedly tested positive for the *Salmonella* strain that triggered the retail recall—and was rejected by USDA. However, it would have been prudent for the Department to reject the other three orders even though they did not produce positive test results, one food safety

⁴⁷ For an explanation of these programs see CRS Report R40397, *Child Nutrition and WIC Programs: A Brief Overview*, by (name redacted).

⁴⁸ Source: AMS e-mail communication, March 18, 2010.

expert told the newspaper.⁴⁹ Such pathogen tests do not guarantee that the pathogen is absent. “Because *Salmonella* is seldom distributed evenly in any lot of beef, ‘94% of the time, I won’t find it even though it’s there,’” the article quoted the expert as saying. On the other hand, the three lots that were not rejected were produced during production runs on days following those that the recalled beef was produced; the assembly lines are cleaned each night, making it very unlikely that the pathogen would have survived, he added.⁵⁰

A subsequent *USA Today* article observed that on the one hand, AMS’s safety rules for school-bound meat and poultry are more stringent than the Department’s (presumably meaning FSIS’s) rules are for commercially marketed products. On the other hand, the article asserted, many of the larger fast food and supermarket chains set testing and safety standards that are far higher than those required by AMS. For example, McDonald’s, Burger King, and Costco test the ground beef they buy five to 10 times more frequently than the Department’s tests for a typical production day.⁵¹

The New York Times reported on a separate case where *E. coli* and *Salmonella* have been found “dozens of times” in meat produced for the school lunch program by Beef Products Inc. The *Times* stated that the meat was diverted before it went into the program. Although one of the company’s facilities reportedly has been suspended from the school lunch buying program three times in three years, USDA (again, presumably FSIS) has allowed the facility to remain in production for other customers.⁵²

The *Times* article outlines the company’s use of “a product made from beef that included fatty trimmings the industry once relegated to pet food and cooking oil.” Because the “trimmings were particularly susceptible to contamination,” the company began treating the product with ammonia gas, which, it said, proved highly effective in killing pathogens. The challenge, according to the *Times*, has been how to keep the ammonia levels high enough to kill the pathogens but not negatively affect the taste of the product. Furthermore, the government reportedly did not require that the ammonia-treated meat be so labeled, because the government agreed with Beef Products’ assertion that it was a processing agent and not an additive.⁵³

The food safety expert quoted by *USA Today*, James Marsden, generally defended the AMS purchasing program in a recent Internet posting. He observed that ground beef destined for schools must be tested for both *Salmonella* and *E. coli* O157:H7, both of which AMS has a “zero-tolerance” policy and thus will not accept any products where it is found. Furthermore, suppliers must hold the product until tests confirm that samples are negative for the pathogens. Marsden added that other provisions in the AMS purchasing program require that slaughter plants include at least two pathogen intervention steps and that carcasses themselves be tested regularly for *E. coli* O157:H7. However, he also reiterated the “potential weakness” in the program that he

⁴⁹ “Why a Recall of Tainted Beef Didn’t Include School Lunches,” *USA Today*, December 2, 2009. James Marsden, the food safety expert quoted in the article, is a Kansas State University professor who among other things serves as senior science advisor for the North American Meat Processors Association, an industry trade association.

⁵⁰ *Ibid.*

⁵¹ “Fast Food Standards for Meat Top Those for School Lunches,” *USA Today*, December 9, 2009. An accompanying article in the newspaper asserted that the Department also buys for the school lunch program “spent hen” meat, from old egg-laying birds that most private companies no longer use, even for soup and other processed foods, out of quality concerns.

⁵² “Safety of Beef Processing Method Is Questioned,” *The New York Times*, December 31, 2009.

⁵³ *Ibid.*

described in the *USA Today* article, namely what he called “an overreliance on microbiological test results.”⁵⁴

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.⁵⁵

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. It is also argued that voluntary procedures encourage cooperation between industry and its regulators, whereas mandatory recall authority might discourage it. Mandatory authority would foster a more adversarial system of mistrust and possible litigation, making recalls less rather than more effective, industry representatives argue.

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

⁵⁴ James Marsden, “The Safety of Ground Beef at Schools,” at <http://www.meatingplace.com/MembersOnly/blog/BlogDetail.aspx?topicID=5213&BlogID=11&pf=true>.

⁵⁵ *Food Safety: USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food*, GAO-05-51. Also see CRS Report RL34313, *The USDA’s Authority to Recall Meat and Poultry Products*, by Cynthia Brougher and (name redacted).

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.⁵⁶

Reviewing FSIS protocols for handling recalls following the Topps case (see box, “Topps Recall”), 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.”⁵⁷

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 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. The proposed implementing rules for these two requirements were still in review at USDA in mid-September 2009.

Several other bills to authorize mandatory recalls for meat and poultry products were introduced but not enacted in the 110th Congress. In the 111th Congress, bills by Representative DeGette (H.R. 815) and by Senator Brown (S. 425) would amend both the FMIA and the PPIA to require “[a] person (other than a household consumer) that has reason to believe” that any carcass, poultry, meat product, or poultry product “transported, stored, distributed, or otherwise handled by the person is adulterated or misbranded shall, as soon as practicable, notify the Secretary of the identity and location of the article.” The bills set forth a series of steps for voluntary recall and consumer notification and, if they are not taken, require the Secretary to order them. The bills (which also would mandate similar requirements for FDA-regulated products) provide for hearing opportunities, among other related language. A bill with similar objectives also was introduced by Senator Udall (S. 1527).

Mandatory recall provisions have been incorporated into food safety legislation (H.R. 2749) that cleared the House on July 30, 2009, as well as into a comprehensive bill (S. 510) approved in November 2009 by a Senate committee, but these bills’ provisions apply to FDA-regulated foods and not to FSIS-regulated meat and poultry products.

⁵⁶ “USDA Will List Retail Stores Receiving Recalled Meat and Poultry Products,” July 11, 2008, press release. A link to retail distribution lists is being posted at the end of FSIS recall press releases; see, for example, http://www.fsis.usda.gov/Fsis_Recalls/Open_Federal_Cases/index.asp?src_location=Content&src_page=FSISRecalls.

⁵⁷ *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>.

Meat Traceability and Animal Identification

Recalls imply the ability to quickly trace the movement of products. Some argue, for example, 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 had argued in the past that such a system would not be based on sound science, and would be technically unworkable. However, following the domestic BSE case, the industry, USDA, and other professionals attempted to implement a universal, although not mandatory, national animal ID (but not meat traceability) system. However, this system was focused on animal disease control rather than on food safety objectives.

Regardless, progress has been slow on this so-called National Animal Identification System (NAIS). Some Members of Congress are among those who believed the programs should be mandatory in order to achieve universal participation. Although many producers themselves appear to be supportive, many also have expressed adamant opposition to the plan. Among other issues are cost, need for a mandatory rather than voluntary system, potential producer liability, and privacy of records.

On February 5, 2010, Secretary of Agriculture Vilsack announced that USDA was revising its approach to achieving a national capability for animal disease traceability. The NAIS is to be abandoned. In its place USDA proposes a new approach that will allow individual states (and tribal nations) to chose their own degree of within-state animal identification (ID) and traceability for livestock populations. Under this revised focus, states may chose to have no mandatory animal ID and traceability capability, or to rely on existing ID systems already in place to fight brucellosis, tuberculosis, and other contagious animal diseases, or to develop their own version of a more detailed birth-to-market ID system as originally proposed under NAIS. The flexibility is intended to allow each state to respond to its own producer needs and interests. However, under the proposed revision USDA will require that all animals moving in interstate commerce have a form of ID that allows traceability back to their originating states.⁵⁸

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. Several other bills establishing broader traceability programs would have applied to animal ID as well. Also in the 110th Congress, both the House and Senate committee reports to accompany USDA’s FY2008 appropriation (H.Rept. 110-258; S.Rept. 110-134) had questioned

⁵⁸ Adapted from CRS Report R40832, *Animal Identification and Traceability: Overview and Issues*, by (name redacted).

USDA's progress and direction in implementing NAIS. Over several years through FY2008, about \$128 million had gone into the development of such a program.

The FY2009 USDA appropriation (P.L. 111-8, Division A), passed near the start of the 111th Congress, provided another \$14.5 million for program, of which \$3.5 million was for information technology, \$9.4 million was for field implementation, and \$1.6 million was for program administration. Explanatory language to accompany the appropriation further directed APHIS "to make demonstrable progress" to implement the program, and to meet a number of specific objectives (regarding 48-hour traceback ability) that were in the agency's 2008 traceability business plan.

The FY2010 appropriation (P.L. 111-80) provided \$5.3 million for NAIS, \$9.1 million less than FY2009. This was in contrast to no funding under the House bill and was \$2 million less than the Senate bill. The conference report expressed concern that the lack of progress by APHIS in registering animal premises in the United States would prohibit APHIS from implementing an effective national animal ID system, and that such a system was needed for animal health and would benefit livestock markets. As of mid-2009, about 37% of premises were registered under NAIS, out of an estimated 1.4 million U.S. animal and poultry operations. USDA had stated that much higher levels of participation were needed to successfully implement NAIS. The conference report stated further that, "[i]f significant progress is not made, the conferees will consider eliminating funding for the program." Since FY2004, approximately \$142 million has been appropriated for NAIS.

With regard to proposed authorizing legislation in the 111th Congress, the broader food traceability provisions of H.R. 814 (DeGette) and S. 425 (Brown) both include the requirement that FSIS establish, within one year, a system that can trace each animal to any premises it was held at any time prior to slaughter, and each carcass, carcass part, or meat/poultry product from slaughter through processing and distribution to the ultimate consumer. The bills also would authorize the Secretary to require records to be maintained and to provide access to them for purposes of traceability.

Traceability provisions have been incorporated into food safety legislation (H.R. 2749) approved by the House and into a Senate bill (S. 510), but these provisions would apply to FDA-regulated foods and not to FSIS-regulated meat and poultry products.

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.

For example, as part of its FY2009 budget submitted to Congress in February 2008, the Bush Administration again had asked for new user fees, beginning after FY2009, of \$92 million by collecting licensing fees from meat and poultry establishments, and of another \$4 million by charging plants that require additional inspections due to performance failures. These fees were not adopted by Congress, which also had opposed them when they were in the Administration's FY2008 budget. The \$4 million user fee was again requested by the Obama Administration in its FY2010 proposal, but neither the House nor Senate Appropriations Committee recommended its adoption (which would require a change in authorizing legislation).

In Congress

As noted, the enacted omnibus (P.L. 111-8, Division A) provides \$971.6 million for FSIS, approximately \$41 million above the FY2008 level and approximately \$20 million above the Administration request. This congressional appropriation is being augmented in FY2009 by existing (currently authorized) user fees, which FSIS had earlier estimated would total \$140 million for the fiscal year. For FY2010, the enacted appropriation (P.L. 111-80) provides \$1.019 billion, which is the Administration-requested level and an increase over the enacted FY2009 level. Congressional consideration of the FY2011 budget request was getting underway in March 2010.

Chinese Poultry Rule

The FY2009 omnibus appropriation continued language, which was also in the FY2007 and FY2008 USDA appropriations measures, prohibiting FSIS from implementing rules to allow the importation of poultry products from China into the United States. The explanatory statement accompanying the FY2009 measure expressed "very serious concerns about contaminated foods from China," and called on USDA to submit a report to Congress on the safety implications of such changes and a plan of action to guarantee the safety of Chinese poultry product imports. A final rule to allow certain processed poultry products to enter from China had been published by FSIS rule on April 24, 2006.⁵⁹

The Chinese government in March 2009 strongly criticized the ban as a violation of trade rules and stated that it would challenge it in the World Trade Organization (WTO). It also pointed out that China had "imported 580,000 tons of chicken products from the United States last year, accounting for 73.4% of total chicken imports."⁶⁰ On April 17, 2009, China formally requested formal WTO consultations on the issue, the first step toward referral to a dispute settlement panel (which subsequently was established in July 2009 and composed in September 2009).⁶¹

⁵⁹ 71 *Federal Register* pp. 20867-20871.

⁶⁰ See, for example, "China blasts 'discriminative' U.S. measure on Chinese poultry imports," March 13, 2009, on the Chinese Government's official web portal at http://www.gov.cn/misc/2009-03/13/content_1258409.htm.

⁶¹ The text of the Chinese request and status of the dispute (DS392) can be accessed through the WTO website at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds392_e.htm.

The House-passed FY2010 appropriation for USDA would have continued the Chinese chicken prohibition; the Senate would have permitted such imports but only under specified conditions. House-Senate conferees on the final measure (enacted as P.L. 111-80) adopted language that appears to be closer (but not identical) to the Senate approach. More specifically, Section 743 of the final measure states that funds cannot be used to implement the rule unless the Secretary of Agriculture formally notifies Congress that China will not receive any preferential consideration of any application to export poultry or poultry products to the United States; the Secretary will conduct audits of inspection systems and on-site reviews of slaughter and processing facilities, laboratories, and other control operations before any Chinese facilities are certified to ship products to the United States, and subsequently such audits and reviews will be conducted at least annually (or more frequently if the Secretary determines it necessary); there will be a “significantly increased level” of reinspections at U.S. ports of entry; and a “formal and expeditious” information sharing program will be established with other countries importing Chinese processed poultry products that have conducted audits and plant inspections.

Furthermore, USDA must provide a report to the House and Senate Appropriations Committees within 120 days and every 180 days thereafter, indefinitely, that includes both initial and new actions taken to audit and review the Chinese system to ensure it meets sanitary standards equivalent to those of the United States, the level of port of entry reinspections being conducted on Chinese poultry imports, and a work plan incorporating any agreements between FSIS and the Chinese government regarding a U.S. equivalency assessment. USDA also is to meet specified requirements (spelled out in Section 743) for notifying the public about audits and site reviews in China and lists of certified Chinese facilities.

Many food safety advocates were supportive of the House appropriations language banning the poultry rule, arguing that China—the third leading foreign supplier of food and agricultural imports into the United States—lacks effective food safety protections, and that the 2006 rule was rushed into approval without an adequate safety evaluation. Opponents of a ban, particularly those in the U.S. animal industries, argue that it would undermine U.S. trade commitments, and believe it already has led to trade retaliation by the Chinese.⁶²

“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).

⁶² See also CRS Report R40706, *China-U.S. Poultry Dispute*, by (name redacted) and (name redacted).

State-Inspected Products

As noted, 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 opposing 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.⁶³

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 inspectors 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, and meet all FMIA and PPIA requirements. 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 contended that the new language is overly restrictive, while those who supported the change countered that it provides appropriate safeguards.

The farm bill required final rules to implement the new state program by December 2009. FSIS published, on September 16, 2009, the proposed rules, with an initial 60-day comment period.⁶⁴ The proposal spells out standards for determining the average number employees in a plant; clarifies that eligibility is limited to those states that already have a cooperative agreement to operate a meat or poultry inspection program; describes the process for a state to apply for the interstate version; and specifies that an eligible establishment is to apply for participation through

⁶³ 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.

⁶⁴ 74 *Federal Register* pp. 47648-47669.

the state-approved program, not FSIS. Among other provisions, the proposed rule would prohibit a participating establishment from reverting to intrastate inspection if it fails to correct any violations of federal standards that are found. A final rule had not yet appeared as of mid-March 2010.

BSE

North American Cases

Twenty-one cases of BSE have been reported in North America. Eighteen of them were cattle born in Canada, which reported its first native case in May 2003 and its latest case in March 2010 (one earlier case was imported into Canada from Great Britain). 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. The most recent Canadian case was announced by Canadian officials on March 10, 2010, in a six-year-old beef cow in Alberta.

In epidemiological investigations of the three U.S. cases, 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.

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, “The FDA “Feed Ban””).

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).

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. This final rule took effect April 27, 2009, but FDA set a compliance date of October 26, 2009, for those (notably renderers) who needed additional time to comply.

In Congress

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

On 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 had 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 (name redacted) and (name redacted).)

A recent incident inciting U.S. lawmakers and trade officials was a vote in early January 2010 by Taiwan's parliament to effectively reverse provisions in a U.S.-Taiwan agreement that was to permit U.S. ground beef and offal to enter that country. The agreement, reached in October 2009 after lengthy negotiations, also is to permit U.S. bone-in beef, but the parliament reportedly did not change that provision. Taiwan's actions, which U.S. trade officials declared "do not have a basis in science and constitute a unilateral violation of a bilateral agreement,"⁶⁵ could again lead to congressional proposals for some type of sanctions or retaliation.

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 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 and approved—but before they were actually slaughtered—for food. FSIS regulations explicitly prohibit most nonambulatory cattle which are presented for ante-mortem inspection, because of their higher risk of BSE.

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."

FSIS published a final rule in the March 18, 2009, *Federal Register* that now specifically requires cattle slaughter establishments to notify government inspectors when cattle become nonambulatory even if they have already passed ante-mortem inspection. All such cattle must be condemned—that is, diverted from the human food supply—and properly disposed of.

⁶⁵Office of the U.S. Trade Representative (USTR), "Joint Statement from USTR, USDA on Taiwan's Actions to Unjustifiably Restrict U.S. Beef Imports in Violation of Our Bilateral Agreement," January 5, 2010, at <http://www.ustr.gov/>.

In Congress

The 110th Congress had 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.

In the 111th Congress, the Senate-passed version of the American Recovery and Investment Act of 2009 (H.R. 1) included a provision to prohibit permanently the use of federal funds for inspecting any nonambulatory disabled cattle for use as human food, regardless of the reason for becoming nonambulatory. However, the provision was removed by House-Senate conferees prior to final enactment as P.L. 111-5. A freestanding bill (H.R. 4356) to ban such cattle from the food supply and to ensure that they are humanely euthanized was introduced in December 2009; the measure was pending at the start of 2010. A subcommittee of the House Oversight and Government Reform Committee held a hearing on the issue on March 4, 2010, where, among other witnesses, the Government Accountability Office testified on a new GAO report concluding that FSIS inspectors may not be taking consistent actions to enforce the HMSA. For background, see CRS Report RS22819, *Nonambulatory Livestock and the Humane Methods of Slaughter Act*, by (name redacted).

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