CRS Report for Congress

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, designed in the early 1900s, has kept pace with changes in the food production and marketing industries. Current issues include:

Is enough being done to address longstanding concerns about naturally occurring microbiological contamination? In 1996, FSIS added a sweeping new system known as Hazard Analysis and Critical Control Point (HACCP)—essentially plant-specific contamination prevention plans — on top of the traditional "sight, smell-, and touch-based" inspection system. However, large recalls due to pathogen problems are still occurring, and significant declines in the incidence of major foodborne pathogens have not occurred in recent years, according to government data. Proposals to delineate pathogen performance standards and/or safe tolerance levels are part of H.R. 1148, S. 654, and H.R. 3624.

Should USDA have new authority to recall suspect meat and poultry products? Recall provisions are in H.R. 1148/S. 654, H.R. 2108/S. 1274, H.R. 3484, and H.R. 5762. The Senate but not the House-passed farm bill (H.R. 2419) would require USDA to establish a notification system for companies to report potentially adulterated meat and poultry.

Is legislation needed to improve the ability to trace animals, meat, and poultry products? One bill (H.R. 1018) would prohibit a mandatory animal ID system; another (H.R. 2301) would set up a producer-run program. S. 1292 and H.R. 3485 both would require more extensive farm-to-fork traceability systems.

Does FSIS have adequate funding and resources, and/or should industry pay more for inspection? FSIS inspection is mainly funded through USDA's annual appropriation. Congress has denied successive Administrations' proposals for new user fees. Separately, Congress has delayed implementation of a controversial new "risk based inspection system" (RBIS) aimed at shifting some existing FSIS resources from processing plants and products that pose relatively lower safety risks to others posing relatively higher risks. Division A of the Consolidated Appropriations Act, 2008 (P.L. 110-161) delays the RBIS until USDA can address any findings in a forthcoming Office of Inspector General report on it. On February 4, 2008, the FY2009 budget cycle began with submission of the President's budget, which includes a modest increase for FSIS.

Should state-inspected meat and poultry products be allowed in interstate commerce? Both the House-passed and Senate-passed farm bills authorize state-inspected shipments, but under divergent approaches. A final version of this provision could be decided in the House-Senate conference on the farm bill.

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Meat and Poultry Inspection: Background and Selected Issues

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

Recently, the effectiveness of the FSIS inspection system has been compared favorably (by some) to FDA's, particularly with regard to its import safety program. At the same time, large recalls of fresh and processed meat and poultry products, often due to microbiological contamination, and illness outbreaks caused by such products, continue to challenge the industry and government regulators.

FSIS policies also came under renewed scrutiny in early 2008 after the agency announced the largest meat recall ever, after evidence emerged that a California beef plant had slaughtered for food a number of nonambulatory cattle, in violation of both a humane slaughter law and food safety rules (see discussion on page 23).

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

Statutory Authorities

Federal Meat Inspection Act of 1906. This law as amended (21 U.S.C. 601 *et seq.*) has long required USDA to inspect all cattle, sheep, swine, goats, horses, mules, and other equines brought into any plant to be slaughtered and processed into products for human consumption. Since passage of the FY2006 USDA appropriation (P.L. 109-97, Section 798), these types of animals are now called "amenable species," and the Secretary of Agriculture now has the discretion to add additional species to the list (but has not yet done so).

¹ This report does not compare and contrast FSIS responsibilities with those of FDA, which are separately authorized and operate under a considerably different regulatory framework. These differences could have significance in the longstanding debate over the need, if any, for reorganizing U.S. food safety authorities and programs. See CRS Report RS22600, *The Federal Food Safety System: A Primer*, by Geoffrey S. Becker and Donna V. Porter.

Poultry Products Inspection Act of 1957. This law as amended (21 U.S.C. 451 *et seq.*) makes poultry inspection mandatory for any domesticated birds intended for use as human food. The current list of included species is chickens, turkeys, ducks, geese, guineas, ratites (ostrich, emu, and rhea), and squabs (pigeons up to one month old).

Agricultural Marketing Act of 1946. Under this law as amended (7 U.S.C. 1621), FSIS also provides voluntary inspection for buffalo, antelope, reindeer, elk, migratory waterfowl, game birds, and rabbits, which the industry can request on a fee-for-service basis. These meat and poultry species (which are not specifically covered by the mandatory inspection statutes) are still within the purview of FDA under the Federal Food, Drug, and Cosmetic Act (FFDCA, 21 U.S.C. 301 et seq.), whether or not inspected under the voluntary FSIS program. FDA has jurisdiction over meat products from such species in interstate commerce, even if they bear the USDA inspection mark.

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

USDA Meat Grading

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

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

System Basics

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

Plant Sanitation. No meat or poultry establishment can slaughter or process products for human consumption until FSIS approves in advance its plans and specifications for the premises, equipment, and operating procedures. Once this

approval is granted and operations begin, the plant must continue to follow a detailed set of rules that cover such things as proper lighting, ventilation, and water supply; cleanliness of equipment and structural features; and employee sanitation procedures.

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

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.

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. A federal court ruling in 2000, upheld on appeal in 2001, made such enforcement illegal. Nonetheless, FSIS inspectors still test samples for *Salmonella* and use the results as one of a number of indicators of plant performance.²

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

² FSIS also samples meat tissues for drug and pesticide residues, but FDA and the FFDCA, along with the Environmental Protection Agency and its statutes, are the guiding authorities for such residues.

plant conditions or procedures are found to be unsanitary, an FSIS inspector can, by refusing to perform inspection, temporarily halt the plant's operation until the problem is corrected. FSIS can condemn contaminated, adulterated, and misbranded products, or parts of them, and detain them so they cannot progress down the marketing chain. FSIS does not have mandatory recall authority; if potentially dangerous or mislabeled products do enter commerce, the agency relies on establishments to voluntarily recall them.

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

Funding. Federal appropriations pay for most, but not all, mandatory inspection. In FY2008, FSIS received an annual appropriation of \$930 million. In addition, FSIS uses revenue from fees paid by the meat and poultry industries for FSIS inspection that occurs beyond regularly scheduled shifts and on holidays, and by private laboratories that apply for FSIS certification to perform official meat testing and sampling. In FY2008, revenue from the fees was expected to amount to approximately \$141 million in additional program support, for a combined funding level of more than \$1 billion. Combined spending levels are estimated to increase in FY2008 and FY2009, respectively.

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

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

Import Inspection. FSIS conducts evaluations of foreign meat safety programs and visits establishments to determine that they are providing a level of safety equivalent to that of U.S. safeguards. No foreign plant can ship meat or poultry to the United States unless its country has received such an FSIS determination. Once they reach U.S. ports of entry, meat and poultry import shipments must first clear Department of Homeland Security (DHS) inspection to assure that only shipments from countries free of certain animal and human disease hazards are allowed entry. This function was transferred to DHS from USDA's Animal and Plant Health Inspection Service (APHIS) when DHS was established by

the Homeland Security Act of 2002 (P.L. 107-296). After DHS inspection, imported meat and poultry shipments go to one of approximately 150 nearby FSIS inspection facilities for final clearance into interstate commerce.³

Microbiological Contamination and HACCP

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

Twenty recalls tied to *E. Coli* O157:H7 in 2007 were more than in any year since the early 2000s. The largest in 2007 was of nearly 22 million pounds of frozen ground beef products in September (see below). This recall and others have caused some in Congress to question not only the effectiveness of USDA's pathogen prevention programs but also its recall policies. (The record 2008 recall of 143 million pounds of beef was not triggered by pathogen concerns; see page 23.)

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 program changes in a mandatory program called the Hazard Analysis and Critical Control Point (HACCP) system. In this system, firms must analyze risks in each phase of production, identifying and then monitoring "critical control points" for preventing such hazards, with corrective actions taken when necessary. Record keeping and verification are used to ensure that the system is working. FSIS published the final rule on July 25, 1996, and since January 2000 all slaughter and processing operations are required to have HACCP plans in place. HACCP is

³ As of late 2007, FSIS had determined the equivalency of meat or poultry programs in 38 countries. See also CRS Report RL34198, *U.S. Food and Agricultural Imports: Safeguards and Selected Issues*, by Geoffrey S. Becker.

⁴ See for example Richard Raymond, Under Secretary of Food Safety, comments at an October 23, 2007, news conference regarding recent USDA actions on *E. coli* O157:H7, at [http://www.usda.gov/wps/portal/!ut/p/_s.7_0_A/7_0_1OB/.cmd/ad/.ar/sa.retrieveconten t/.c/6_2_1UH/.ce/7_2_5JM/.p/5_2_4TQ/.d/1/_th/J_2_9D/_s.7_0_A/7_0_1OB?PC_7_2_5JM_contentid=2007%2F10%2F0301.xml&PC_7_2_5JM_parentnav=TRANSCRIPTS_SPEECHES&PC_7_2_5JM_navid=TRANSCRIPT#7_2_5JM]. Some discussion of the more recent data is contained in the sections of this CRS report on selected pathogens.

intended to operate as an adjunct to the traditional methods of inspection, which still are mandatory under the original statutes.⁵

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].)

Pathogen Performance Standards and Salmonella

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

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

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

The meat and poultry inspection statutes do not give USDA the authority to use *Salmonella* standards as the basis for withdrawing inspection from a plant that has not met them, a federal court ruled in 2000, and an appeals court upheld 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 specify microbiological standards.

FSIS had reported its concern about "increases in Salmonella rates observed over the past three years (2003-2005) among the three poultry product categories, broiler carcasses, ground chicken, and ground turkey. Increases were observed for all three classes in 2003 and 2005 and in each year for broiler carcasses."

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.⁸

Salmonella testing results for 2006, posted on the agency's website, offered a mixed picture. On the one hand, the data indicated that the incidence of the bacterium found in broiler chickens was down significantly from 2005 and at or near the lowest levels found. On the other hand, the rate of positives in ground chicken climbed substantially from 2005 to 2006, and the year-to-year changes for other tested products and animals varied.

For 2007, the incidence of positive *Salmonella* tests on broilers was 8.5% (out of 9,408 samples), compared with 11.4% (out of 10,206 samples) for all four quarters of 2006. The *Salmonella* incidence for ground chicken was 26% (out of 506 samples) for 2007, compared with 45% (out of 222 samples) for 2006, according to FSIS.⁹

⁷ Report on FSIS testing results for *Salmonella*, posted with those for *E. coli* O157:H7 on the Internet at [http://www.fsis.usda.gov/Science/Microbiology/index.asp]. In July 2006 the advocacy group Food & Water Watch released the names of 106 broiler plants in 27 states and Puerto Rico that failed to reach federal *Salmonella* standards between 1998 and 2005.

⁸ Food Chemical News, July 3, 2006. A notice and request for comments on this initiative were published in the February 27, 2006, Federal Register.

⁹ At [http://www.fsis.usda.gov/Science/Microbiology/index.asp] FSIS cautions that "the restructuring of *Salmonella* set scheduling means that comparison of results from 2006 (continued...)

FSIS on January 28, 2008 issued a notice on new policies and procedures for *Salmonella* sampling and testing. One change is to post on its website, beginning March 28, 2008, sample 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 are not testing consistently for low *Salmonella* rates. ¹⁰

Another change is a new "Salmonella Initiative Program," under which poultry slaughter plants with relatively low Salmonella positives could effectively increase line speeds — i.e., process their chickens faster — in exchange for providing more microbial data to help study the links between FSIS-regulated products and human illness. Further, FSIS also is restructuring how it conducts verification sampling.¹¹

E. coli 0157:H7

CDC noted that "E. coli O157:H7 is one of hundreds of strains of the bacterium Escherichia coli. Although most strains are harmless and live in the intestines of healthy humans and animals, this strain produces a powerful toxin and can cause severe illness. E. coli O157:H7 was first recognized as a cause of illness in 1982 during an outbreak of severe bloody diarrhea; the outbreak was traced to contaminated hamburgers. Since then, most infections have come from eating undercooked ground beef." CDC also noted that "... people have also become ill from eating contaminated bean sprouts or fresh leafy vegetables such as lettuce and spinach. Person-to-person contact in families and child care centers is also a known mode of transmission. In addition, infection can occur after drinking raw milk and after swimming in or drinking sewage-contaminated water."¹²

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

⁹ (...continued)

onwards to previous years will be inappropriate. Similarly, the changes to the verification program will prevent valid comparisons of testing results over time (e.g., quarter-to-quarter or year-to-year trends). For such comparisons, the results of upcoming nationwide baseline studies can be used to provide valid estimates of the prevalence of certain pathogens of public health concern and permit valid statistical comparisons to be made over time."

¹⁰ Twenty-one plants, out of 195 tested, were named in the first report, accessed April 2008 at [http://www.fsis.usda.gov/science/Salmonella_Verification_Testing_Program/index.asp].

¹¹ 73 Federal Register pp. 4767-4774. Public comments were due by February 27, 2008.

¹² Background information on this pathogen may be viewed at the following CDC website: [http://www.cdc.gov/nczved/dfbmd/disease_listing/stec_gi.html].

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.¹³

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.

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 2004.¹⁴ The report on 2007 concluded that "additional efforts are needed" to control the pathogen in cattle "and to prevent its spread to other food animals and food products, such as produce." ¹⁵

During calendar 2006, FSIS announced eight recalls due to *E. coli* O157:H7 contamination, mostly of ground beef products, and none were related to human illness. In 2005, the agency announced five recalls. In 2007 FSIS announced 20 recalls, totaling more than 33 million pounds, mostly ground beef products, due to *E. coli* concerns. At least nine of the 2007 recalls were related to human illnesses (the rest came about after routine testing). Although many of the recalls were relatively small, a June recall involved nearly 6 million pounds of beef, and the Topps recall 21.7 million pounds (see below).¹⁶

¹³ 67 Federal Register 62325.

¹⁴ Morbidity and Mortality Weekly Report, April 13, 2007.

¹⁵ Morbidity and Mortality Weekly Report, April 11, 2008.

¹⁶ Some information is from the October 23, 2007, Raymond press conference. Recall updates are at the FSIS website, [http://www.fsis.usda.gov/Fsis_Recalls/index.asp]; a list of both FSIS and FDA recalls is at [http://www.recalls.gov/food.html].

USDA Actions in 2007. USDA stated that after it had identified by June 2007 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%. It also began or accelerated implementation of several other *E. coli* prevention initiatives that had been under development. Announced actions affecting federally inspected raw beef plants include the following:¹⁷

- FSIS began in March 2007 to test beef trim (which is used in ground beef), on assumptions that contamination of ground beef is related to contaminated beef trim.
- FSIS notified beef companies that starting in November 2007 all plants would have to verify that they are effectively controlling *E. coli* O157:H7 during slaughter and processing; and it has provided the industry with examples of controls that would meet the minimum criteria for effectiveness.
- The agency directed its inspectors to use a new checklist to review establishment control procedures to help the agency identify changes in each one's production controls and corrective action procedures.
- FSIS said it would begin testing other types of materials used in ground beef in addition to beef trim, and require importing countries to conduct equivalent sampling.
- FSIS will attempt, starting in January 2008, to better target its routine *E. coli* testing, with more frequent sampling of larger plants, and other adjustments based on checklist data.
- The agency stated that it would work to speed up recalls.

USDA Actions in 2008. At a public meeting on April 9-10, 2008, FSIS discussed its deliberations over whether to consider *E. coli* O157:H7 an adulterant in whole cuts of beef, as it is now for ground products only. Although FSIS believes this might possibly be an additional way to reduce the risk of *E. coli* O157:H7 contamination, meat industry officials are opposed. They argue, among other things, that whole cuts have not been linked to illness incidents, and that such a change would conflict with longstanding FSIS policy.¹⁸

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. On October 6, USDA notified the public that several more product labels (but no additional pounds of products) were being added to the recall.

¹⁷ 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].

¹⁸ "FSIS plans meeting to discuss 'strong moves' against *E. coli*, *Food Chemical News*, April 7, 2008; and "Industry Opposes *E. coli* moves by USDA, *Cattle Buyers Weekly*, April 14, 2008.

USDA officials said that this recall case was unusual in that it arose from a patient-reported illness (forwarded on August 31, 2007) thought to be caused by *E. coli*. The same day, according to USDA, a field investigator collected a sample of leftover product from the patient's freezer for testing, and the laboratory returned a positive finding of *E. coli* O157:H7 from that sample on September 7. It took a series of follow-up tests and meetings before USDA was ready to tie the illness — and a number of other similar illnesses — to the Topps plant, with the recall announced on September 25. By October 6, the Centers for Disease Control (CDC) had cited 32 illnesses that appeared to be 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. 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., ²⁰ 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.

Listeria monocytogenes

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

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

¹⁹ See for example, *Cattle Buyers Weekly*, October 8, 2007; *Feedstuffs*, October 8, 2007.

²⁰ Source: Cattle Buyers Weekly, various 2007 issues.

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.²¹ Interest increased significantly after October 2002, when Pilgrim's Pride Corporation recalled a record-breaking 27.5 million pounds of poultry lunch meats for possible *Lm* contamination after a July 2002 outbreak of listeriosis in New England. CDC confirmed 46 cases of the disease, with 7 deaths and 3 stillbirths or miscarriages. The recall covered products made as early as May 2002, and officials stated that very little of the meat was still available to be recovered.

In December 2002, FSIS issued a directive to inspection program personnel giving new and specific instructions for monitoring processing plants that produce hot dogs and deli meats.²² 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.²³

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.²⁴

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.²⁵

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

²¹ Source: *Food Chemical News*, various issues.

²² The guidelines can be found on the FSIS website at [http://www.fsis.usda.gov].

²³ See the FSIS website for more details on the rule.

²⁴ CFA website: [http://www.consumerfed.org/].

²⁵ Morbidity and Mortality Weekly Report, April 13, 2007, and April 11, 2008.

lunchmeat products by ConAgra. Another 28 *Listeria*-related recalls were announced during 2005, involving approximately 649,000 pounds of processed meat and poultry products, according to the agency's website. The website had posted six *Listeria* recalls in 2006 and another 11 in 2007, including, in January and February 2007, 2.8 million pounds of Oscar Mayer/Louis Rich chicken breast cuts and strips. ²⁶ Through March 2008, four had been posted covering *Listeria*.

In Congress

In recent years, bills have been offered to add language to the inspection laws clarifying the Secretary's authority to set enforceable performance standards. In the 110th Congress, for example, pending bills to establish a single food agency (H.R. 1148/S. 654) include provisions requiring the new agency to set such standards. Another bill (H.R. 3624) would require FDA to set tolerance levels to limit the quantity of contaminants, including harmful pathogens, in foods.

Other Selected Issues

Recall and Enforcement Proposals

Currently, the Agriculture Secretary must go to the courts to obtain an order to seize and detain suspected contaminated products if a firm refuses to issue a recall voluntarily. The GAO has criticized agencies' efforts to ensure that companies carry out recalls quickly and efficiently, particularly of products that may carry severe risk of illness. A 2004 GAO report concluded that the agencies do not know how well companies are carrying out recalls and are ineffectively tracking them. As a result, most recalled items are not recovered and thus may be consumed, GAO reported.²⁷

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.

²⁶ FSIS recall website: [http://www.fsis.usda.gov/FSIS_Recalls/index.asp].

²⁷ 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 Geoffrey S. Becker.

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

In August 2004, the consumer group Center for Science in the Public Interest (CSPI) began a national campaign to urge USDA to publicize the names of retail outlets where recalled meat has been distributed, so that consumers can learn more quickly whether they have purchased potentially contaminated products. USDA and industry leaders have contended that distribution records are proprietary, and exempt from provisions of the Federal Freedom of Information Act; such information, they argue, should be limited mainly to public officials so that they can monitor recalls. However, in the March 7, 2006, *Federal Register*, FSIS proposed posting on its website the names of retailers who have products subject to a voluntary recall. A final rule had not been issued as of early April 2008.

In Congress. Bills to address meat and poultry recalls have been introduced in the 110th 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. However, the Senate-passed version of the farm bill includes a provision (H.R. 2419, in Title XI) requiring reportable food registries for FSIS-regulated meat and poultry products as well. The House version lacks this provision, so the final language could be determined in a House-Senate conference committee that was underway in April 2008. H.R. 5762, H.R. 2108/S. 1274, H.R. 3484, H.R. 3610, H.R. 3624, S. 2081, and H.R. 1148/S. 654 are among other pending bills that contain various provisions for mandatory recall authority and/or notification requirements when adulterated foods are suspected to be in commerce.

Meat Traceability

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

Some argue that improved traceability capabilities would have enabled USDA to determine the whereabouts of all related cattle of potential interest in the three U.S. case of BSE (bovine spongiform encephalopathy, or "mad cow disease"). The traceability issue has also been debated in connection with protecting against

agroterrorism; verifying the U.S. origin of live cattle and meat products for export; and facilitating recalls to prevent or contain foodborne illness outbreaks, among other things.

Supporters of animal ID and meat traceability point out that most major meat-exporting countries already have domestic animal ID systems. The U.S. meat industry argued in the past that such a system would not be based on sound science, and would be technically unworkable. However, since the domestic BSE case, the industry, USDA, and some Members of Congress have been actively pursuing adoption of a national animal ID (but not meat traceability) system, focused on animal disease control rather than food safety *per se*. Among other issues are cost, need for a mandatory rather than voluntary system, potential producer liability, and privacy of records.

In Congress. Animal ID proposals have emerged in the 110th Congress. For example, H.R. 1018 would prohibit the establishment of a mandatory ID system. H.R. 2301 would create a livestock identification board with members from industry to oversee a national program.²⁸ S. 1292 and H.R. 3485, separate bills, are broader traceability proposals. S. 1292 would require the Secretary of Agriculture to establish a traceability system for all stages of production, processing, and marketing of meat and poultry, and would require animal producers and meat and poultry processors to maintain records sufficient to enable the Secretary to trace a product forward to the consumer or backward to where the animal originated. H.R. 3485 covers both FSIS and FDA-regulated food traceability.

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

Elsewhere, a provision in Title X of the farm bill (H.R. 2419) approved in December 2007 by the Senate would require USDA to issue regulations addressing "the protection of trade secrets and other proprietary and/or confidential business information that farmers and ranchers disclose in the course of participation" in an ID system. The bill was in a House-Senate conference in April 2008.

²⁸ See also CRS Report RS22653, *Animal Identification: Overview and Issues*, by Geoffrey S. Becker.

Funding and Resources

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.

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.²⁹ 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."³⁰

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.³¹

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

²⁹ See "In Congress" later in this section of the report.

³⁰ "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].

³¹ Comments by Dr. Richard Raymond, USDA Under Secretary for Food Safety, February 22, 2007, press teleconference. The start of implementation appears to have been delayed; in April FSIS was holding a series of public meetings on aspects of RBIS. For information see [http://www.fsis.usda.gov/regulations_&_policies/Risk_Based_Inspection/index.asp].

strengthen safety oversight, and wondered whether the agency has the statutory authority to change inspection frequency.³²

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 FY2009.³³

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 currently 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." 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 or 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.³⁵ FSIS said it has been retooling RBIS — which it now calls a "public health-based inspection system" — to address the OIG recommendations and those of public commenters.

In Congress. Representative DeLauro and several other lawmakers have expressed their own concerns about RBIS, such as during testimony before her House Appropriations Subcommittee on Agriculture by Dr. Raymond on March 29 and April 19, 2007. A provision (§6102) in the fiscal 2007 Iraq War supplemental appropriation (P.L. 110-28) prohibited USDA from implementing 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. Both the House and Senate

³² 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.

³³ Sources: various statements as reported in *Food Chemical News*, February 26, 2007, and April 23, 2007.

³⁴ USDA, OIG, *Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments* (Report. No. 24601-07-Hy).

³⁵ Meeting materials were posted by USDA-FSIS on the Internet at [http://www.fsis.usda. gov/News_&_Events/Meetings_&_Events/index.asp]; a copy of the January 2008 FSIS Risk Assessment for Guiding Public Health-Based Poultry Slaughter Inspection was posted at [http://www.fsis.usda.gov/PDF/Poultry_Slaughter_Risk_Assess_Jan2008.pdf].

reports on USDA's FY2008 appropriation also had expressed concern about RBIS. The final FY2008 appropriation for USDA (P.L. 110-161, Division A) reiterates the directive that the Department not implement RBIS until after the OIG reported its evaluation to Congress and FSIS revolved any issues raised.

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

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

In Congress. FSIS inspection costs are mainly funded through USDA's annual appropriation. For the current FY2008, the Senate-reported bill had recommended \$930.6 million for FSIS, or \$38.5 million above the FY2007 level. The House-passed bill and the final version (Division A of P.L. 110-161) provide \$930.1 million in appropriations for FSIS for FY2008, the same as the Administration's request. The congressional appropriation is to be supplemented in FY2008 by an estimated \$141 million in existing user fees.

The Administration's FY2009 budget proposal recommends \$952 million in new appropriations for FSIS, to be supplemented by about \$140 million in existing user fees (i.e., not counting the proposed \$96 million in new fees described above). This would bring the FSIS program level to approximately \$1.1 billion in FY2009. The House and Senate Appropriations Committees in early 2008 have been holding hearings on the FSIS and other USDA budget proposals, with markups expected to follow.

State-Inspected Products

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

Those who oppose allowing state-inspected products in interstate commerce argue that state programs are not required to have the same level of safety oversight as the federal, or even the foreign, plants. For example, foreign-processed products are subject to U.S. import reinspection at ports of entry. The opponents of interstate shipment note that a recent FSIS review, which had found all 28 state programs to be at least equal to the U.S. program, was based largely on self-assessments.³⁶

In Congress. In the 110th Congress, both the House and Senate versions of H.R. 2419, the omnibus farm bill, would amend the FMIA and the PPIA to permit interstate shipment of these products — but under divergent approaches. The House-passed farm bill would replace the current federal-state cooperative inspection programs with a new program that would enable meat and poultry that is not federally inspected to be shipped across state lines, so long as the state programs adopted standards identical to those of USDA along with any additional changes USDA required. The proposed language is generally taken from pending H.R. 2315 (S. 1150 in the Senate). The farm bill provision further would enable many plants currently under federal inspection to apply for state inspection and continue to ship interstate. Opponents of this change fear that many would seek to opt out of the federal system if they believed that they could receive more lenient oversight by the states — an assertion that state proponents dismiss.

The Senate farm bill would supplement the current federal-state cooperative inspection program with a new provision whereby state-inspected plants with 25 or fewer employees could opt into a new program that subjects them to federally directed but state-operated inspection, and thus could ship interstate. The Senate version reportedly was developed as a compromise by those on both sides of the issue. Nonetheless, some proponents of ending the current ban contend that the Senate language is overly restrictive, while those who support the Senate version contend that it provides appropriate safeguards. A House-Senate farm bill conference committee, which was meeting in April 2008, likely will determine the final version.

Other pending bills that would authorize the shipment of state-inspected products across state lines are H.R. 1760 and S. 1149; they also would set the federal share of state inspection costs at no less than 50% and no more than 60%. A separate measure, H.R. 2876, would authorize interstate shipment if the Secretary determines that the state program is at least equal to the federal program. (For more a more extensive discussion, see CRS Report RL34202, *State Inspected Meat and Poultry: Issues for Congress*, by Geoffrey S. Becker.)

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

"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]).

Food Safety Reorganization

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

In its January 2007 annual report, GAO newly designated food safety oversight as one of 29 "high risk" federal program areas. The report, among other things, recommended that "Congress consider a fundamental reexamination of the system and other improvements to help ensure the rapid detection of and response to any accidental or deliberate contamination of food before public health and safety is compromised."³⁸ Besides GAO, the National Academy of Sciences and the National Commission on the Public Service have studied the issue and recommended options for change.³⁹

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

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

³⁹ See National Research Council, Institute of Medicine, *Ensuring Safe Food From Production to Consumption*, Washington, DC, National Academy Press, 1998; and National (continued...)

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

The omnibus farm bill (H.R. 2419) that cleared the Senate includes a provision establishing a bipartisan congressional food safety commission that is to study the federal food safety system and recommend needed changes. Another provision in the same measure requires the President to consider these changes and report to Congress on legislation needed to effect them.

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

As lawmakers are asked to consider these or other proposals that would either reorganize or consolidate the federal food safety organization, a range of policy options are being debated, including whether the current regulatory approaches and their authorizing statutes remain appropriate, particularly given the diversity of food types, health risks, methods of production, and sources of supply; the continuously evolving science on foodborne illness and how to prevent future outbreaks; the impacts on industry competitiveness, particularly in a global economy; and funding constraints.

Horse Slaughter

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

³⁹ (...continued)

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

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

New bills in the 110th Congress to ban the movement or possession of horses for slaughter include H.R. 503 and S. 311. The Senate Commerce, Science and Transportation Committee approved S. 311 without amendments on April 25, 2007.⁴⁰

Meanwhile, the omnibus appropriation for FY2008 (P.L. 110-161, in Division A, Section 741) both continues the ban on using appropriated funds for inspecting horses and also prohibits the USDA-FSIS rule that enables the collection of user fees for such purposes.

BSE

North American Cases. As of late 2007, 15 cases of BSE had been reported in North America, 12 of them in animals born in Canada, which reported its first native case in May 2003 (one earlier case was imported from Great Britain). The United States reported its first case in December 2003 (it was one of the Canadianborn animals that had been imported into the United States). The United States also found two more cases, the most recent in late February 2006 in a 10-year-old Alabama beef cow.

In epidemiological investigations of the three U.S. cases, the U.S. Department of Agriculture (USDA) was unable to track down all related animals of interest, but

⁴⁰ See CRS Report RS21842, *Horse Slaughter Prevention Bills and Issues*, by Geoffrey S. Becker.

those that were located tested negative for the disease. Despite a beef recall, some meat from the first U.S. BSE cow may have been consumed, USDA said, adding, however, that the highest-risk tissues never entered the food supply. No materials from the other two U.S. cows entered the food supply, USDA also said. In the recent Alabama case, authorities were unable to determine the cow's herd of origin.

Humane Slaughter and the Hallmark/Westland Recall

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

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

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

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.⁴¹ 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

⁴¹ For additional details on the following discussion see CRS Report RL32199, *Bovine Spongiform Encephalopathy (BSE, or 'Mad Cow Disease'): Current and Proposed Safeguards*, by Geoffrey S. Becker and Sarah A. Lister.

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).

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 an intensive, one-time BSE testing program for higher-risk cattle (since completed).

In Congress. Although BSE remains a priority for many Members of Congress, much of the recent interest has focused on trade rather than food safety concerns. Japan and Korea, once among the four leading markets for U.S. beef, did not clear the way for the return of some U.S. beef products until late 2005 and 2006, respectively. Exports to Japan are still well below previous levels, and Korean inspection procedures kept that market largely closed to the United States through much of 2007 and again during early 2008.

An April 18, 2008, U.S.-Korea agreement was announced that could lead to the country's reopening as early as May 2008. If so, it could help to defuse the frustration of many Members of Congress, some of whom were expected to reintroduce legislation calling for sanctions against trading partners that failed to

accept assurances of U.S. beef safety. U.S. access to Korea's beef market has been an issue in the debate over implementation of the U.S.-Korea free trade agreement (FTA). A number of Members signaled that their support for legislation to implement the FTA was contingent on Korea fully opening its market for U.S. beef.

Also of concern to many Members is USDA's gradual reopening of the U.S. border to more types Canadian cattle. Some Members are sympathetic to the arguments of certain cattle organizations, primarily from the Upper Plains, that such cattle continue to pose a BSE threat; resolutions of disapproval (H.J.Res. 55 and S.J.Res. 20) of the most recent USDA rule to expand the types of eligible Canadian imports have been introduced in both chambers. If passed, however, these resolutions would have no force of law. (For background see CRS Report RS21709, *Mad Cow Disease and U.S. Beef Trade*, by Charles E. Hanrahan and Geoffrey S. Becker.)

The FDA "Feed Ban"

The FDA Center for Veterinary Medicine (CVM), responsible for the safety of animal feeds, began prohibiting the use of most mammalian protein in feeds for ruminants in August 1997, a restriction commonly called the "feed ban." This ban did not prohibit the inclusion of potential bovine risk materials such as brain and spinal cord in all animal feeds, but only those feeds intended for ruminants. FDA required that feeds containing ruminant material be labeled with a prohibition against feeding to ruminants, and that firms and farms effectively separate prohibited and non-prohibited feeds in production, shipping and feeding. The ban exempted certain bovine by-products, such as blood, milk, gelatin and restaurant plate waste, on the premise that the exempted materials posed a minimal risk of transmission. On October 6, 2005, FDA published a proposed rule banning some SRM (mainly brains and spinal cords from cattle 30 months of age and older, and from all cattle not passed for human food) 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 public comment period on this rule ended on December 20, 2005; a final rule had not been issued as of mid-April 2008. Meanwhile, Canada finalized a similar but somewhat more extensive amendment to its own feed rules in June 2006.