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Meat and Poultry Inspection Issues

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SUMMARY

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. The Food and Drug Administration (FDA) is responsible for ensuring the safety of all other foods, including seafood.

In the early 1990s, food safety officials recognized that most foodborne illness cases traced to meat and poultry products were being caused by naturally occurring microbiological contamination that was not being adequately addressed by the traditional, sight-, smell-, and touch-based system of inspection. Through the federal rule-making process, FSIS developed and initiated the Hazard Analysis and Critical Control Point (HACCP) system at all federally inspected slaughtering and processing plants. HACCP regulations require all firms to implement preventive actions at each point along the manufacturing chain where microbial contamination is likely to occur. FSIS inspectors monitor the performance of firms' HACCP systems in addition to performing traditional inspection under the existing statutes.

Despite data suggesting HACCP-related reductions in pathogen levels, periodic recalls of very large amounts of product continue to illustrate the difficulty of preventing contamination in processed products. Several bills addressing aspects of this issue were introduced in the 108th Congress, and could resurface in the 109th Congress. These include proposals to give FSIS the authority to (1) mandate recalls of suspected contaminated products; (2) set and enforce performance standards for foodborne pathogens under HACCP; and (3) impose civil penalties for violations of inspection laws and regulations.

In December 2003, USDA announced the first confirmed U.S. case of bovine spongiform encephalopathy (BSE). On January 12, 2004, FSIS published interim rules banning potentially higher BSE-risk cattle parts and non-ambulatory ("downer") cattle from food, prohibiting the labeling as "meat" of mechanically removed muscle tissue; and banning a form of pre-slaughter stunning that can potentially spread infective brain and nervous system tissue into the meat.

Since January 12, any carcass tested for BSE must be held until negative results are received. In June 2004, USDA began a 12-18 month program to test 200,000-268,000 cattle for BSE (compared with 20,000 in 2003).

The Administration has been criticized for its handling of some aspects of the BSE situation. For example, USDA officials acknowledged last year that they had failed to follow proper rulemaking procedures in readmitting certain types of beef from Canada, which reported its own BSE cases in early 2003 and late 2004. Final rules to permit younger Canadian live cattle and additional types of Canadian beef to enter the United States were published by USDA in the January 4, 2005, *Federal Register*.

The FY2005 agriculture appropriation (Division A of H.R. 4818; P.L. 108-447) provides $823.8 million for FSIS. Congressional deliberations on the FY2006 FSIS budget are expected to begin in February with submission of the Administration's budget proposal.

MOST RECENT DEVELOPMENTS

The U.S. Department of Agriculture (USDA) on January 4, 2005, published final rules to permit younger Canadian live cattle and additional types of Canadian beef to enter the United States. These rules, scheduled to take effect in early March, are subject to a 60-day Congressional review period, during which committee hearings on them are likely.

The rules were unveiled as Canada was investigating the discovery of its second case of BSE, in another Alberta dairy cow. U.S. and Canadian officials said that the discovery did not present any food safety danger, and that it would not slow implementation of the import rule — despite criticism by some lawmakers that opening the border was premature.

BACKGROUND AND ANALYSIS

Current Standard Inspection and HACCP Systems

FSIS carries out its duties with total staff of nearly 10,000, and an annual appropriation of more than $800 million. In addition, FSIS uses revenue from fees paid by the packing industry for overtime (above three shifts) and holiday inspection services, and by private laboratories that apply for FSIS certification to perform official meat testing and sampling (they originally were authorized in 1919). Revenue from the fees amounts to more than $100 million annually in additional program support. More than 7,500 of FSIS's employees, roughly 1,000 of them veterinarians, are at some 6,200 plants and import stations nationwide.

Traditional inspection under the original statutes comprises constant organoleptic inspection (for appearance, odor, and feel) at slaughter operations and daily inspection of sample products and operations at processing plants. 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, hazards are identified and risks are analyzed in each phase of production, "critical control points" for preventing such hazards are identified and monitored, and corrective actions are taken when necessary. Record keeping and verification are used to ensure that the system is working. FSIS published the final rule in 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.

Authorities. The Federal Meat Inspection Act of 1906, as amended (21 U.S.C. 601 et seq.), requires USDA to inspect all cattle, sheep, swine, goats, and horses brought into any plant to be slaughtered and processed into products for human consumption. The 1957 Poultry Products Inspection Act, as amended (21 U.S.C. 451 et seq.), made 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).

FSIS also offers voluntary, fee-for-service inspection for buffalo, antelope, reindeer, elk, migratory water fowl, game birds, and rabbits, which is authorized under the Agricultural Marketing Act (7 U.S.C. 1621). These so-called "exotic" meat species are regulated by the FDA (under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq.) if they are not inspected under the voluntary FSIS program. FDA has jurisdiction over meat products from exotic species in interstate commerce, even if they bear the USDA inspection mark.

In May 1995, the authority for processed egg inspection was transferred from USDA's Agricultural Marketing Service to FSIS. The Egg Products Inspection Act, 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 used in restaurants and sold in stores.

State Inspection. Twenty-eight states currently have their own meat and/or poultry inspection programs covering about 2,100 small or very small establishments. The states run the programs cooperatively with FSIS, which provides up to 50% of the funds for operating them, or about $50 million annually. A state program operating under a cooperative agreement with FSIS must demonstrate that its system is equivalent to federal inspection. However, meat and poultry products produced under state inspection are limited to intrastate commerce only. About half of the states have discontinued their inspection systems for meat or poultry (or both). In these states FSIS has assumed responsibility for inspection at the formerly state-inspected plants, although actual inspection is performed by state personnel.

Import Inspection. FSIS conducts overseas evaluations to determine that imports from foreign countries are processed under equivalent inspection systems; agency officials also verify equivalency by visiting various foreign slaughtering and processing operations. A plant seeking to export meat or poultry to the United States must first receive FSIS certification. At 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)). After DHS inspection, imported meat and poultry shipments go to nearby FSIS inspection facilities for final clearance into interstate commerce.

Basic Features of Inspection Systems.

Coverage. FSIS's legal inspection responsibilities do not begin until animals arrive at slaughterhouses, and they generally end once products leave processing plants. Most of the very large slaughter/packer firms also have on-site rendering operations to process certain edible by-products from inspected carcasses (chiefly tallow). These operations are regulated by FSIS under the Federal Meat Inspection Act, and are subject to the same sanitation and HACCP requirements as the packing plant. (FDA regulates packer/renderer and independent rendering operations that handle non-edible by-products from slaughtering and processing.) Also, 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.

Plants are required under the HACCP rule to have a HACCP plan for their slaughter and/or processing operations. Simply put, this means that at each point in the process where contamination could occur, called a "critical control point," the plant must have a plan to control it, and must document and maintain records. USDA inspectors check the records to verify the plant's compliance. (Under HACCP regulations, all operations must have site-specific standard operating procedures (SOPs) for sanitation).

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. Plants pay user fees to have an inspector on duty on overtime and holiday shifts.

Processing Inspection. The inspection statutes give the Secretary discretion to determine how often a USDA inspector must visit facilities that produce processed products like hot dogs, lunch meat, prepared dinners, and soups. Under current regulations, processing plants that are 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 *Campylobactor* and *E. coli* O157:H7, as well as *Salmonella* itself. Test results 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 court ruling in 2000, upheld on appeal in late 2001, made such enforcement illegal (see below). Nonetheless, FSIS inspectors still test samples for *Salmonella* and use the results as one of a number of indicators of plant performance.

Enforcement Authority. 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. 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.

Meat Safety and BSE

Bovine spongiform encephalopathy (BSE, or "mad cow disease") entered the U.S. public policy spotlight in 2003, with the discovery of the first native North American cases in 2003. (Canadian officials found a third case in December 2004, announcing confirmation of the disease on January 2, 2005.)

First diagnosed in Britain in 1986, BSE is a slowly progressive, incurable disease affecting the central nervous system of cattle. Scientists consider BSE to be related to similar diseases, called transmissible spongiform encephalopathies (TSEs), that occur in other species. Investigators in the British BSE outbreak connected the use in cattle feeds of animal protein from TSE-infected sheep with the appearance of BSE in cattle. In 1997, European scientists determined that there was a possible link between consumption of infected tissue from BSE cattle and an outbreak in humans of a newer variant of a fatal brain disease called Creutzfeldt-Jakob disease (nvCJD) that had begun in Europe in the late 1980s.

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 APHIS and the FDA (part of the Department of Health and Human Services). The Centers for Disease Control and Prevention (CDC) also play a role regarding public health protection. (For more in-depth coverage of BSE and related livestock industry and public health issues, see CRS Issue Brief IB10127, *Mad Cow Disease: Agricultural Issues for Congress*; and CRS Report RL32199, *Bovine Spongiform Encephalopathy (BSE): Current and Proposed Safeguards.)*

APHIS, which (among other things) is responsible for protecting U.S. agriculture from foreign diseases, in 1989 imposed a ban on the import of all live ruminants from countries where BSE is known to exist. In 1991, APHIS banned the import of rendered by-products from ruminants, and then it banned, as of December 2000, the import of all rendered animal protein products (whether from ruminants or not).

After the Canadian BSE announcement of the first North American case in May 2003, APHIS banned all ruminants and products from Canada. In August 2003 APHIS announced it was permitting the entry of some products (notably boneless beef from cattle under 30 months) after determining that they were low-risk. In November 2003, APHIS proposed a rule to allow imports of primarily younger live ruminants, along with additional types of beef and other ruminants and ruminant products, from a new category of BSE "minimal risk" regions, the first one to be Canada.

U.S. Case. While this proposed rule was pending, the U.S. case was discovered in December 2003. Officials reassured the public that any human health risks were minimal, and that no high-risk tissues had entered the food supply. However, they announced, out of "an abundance of caution," a voluntary recall of 38,000 pounds of meat from 20 animals slaughtered at the same plant that day, and acknowledged that some of it likely had been consumed. FSIS also 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 federally inspected or state-inspected slaughter and processing facilities.
- 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.

FDA, which regulates animal feed ingredients domestically, banned the feeding of most mammalian proteins to ruminants in August 1997. Until recently, periodic surveys indicated less than full compliance with the regulations. A February 2002 Government Accountability Office (GAO) study reported that 364 out of 10,576 firms inspected by FDA (out of at least 11,741 total firms potentially handling ruminant material) were still out of compliance with FDA's labeling, record keeping, and commingling requirements. In July 2003, however, FDA reported that compliance had reached 99%.

Nevertheless, the animal feed ban remains a focus of efforts to improve U.S. BSE safeguards. The FDA had announced on January 26, 2004, that it would tighten feed ingredient and processing rules. On July 14, 2004, FDA took tentative steps to do so with an advance notice of proposed rulemaking (ANPR), in which it said it was considering a ban on specified risk materials (SRMs, which are designated higher-risk cattle parts such as brains and spinal cords) from all animal feeds. Industry groups said they were pleased that the agency was proceeding carefully but concerned about compliance costs. Consumer advocates argued that rulemaking was moving too slowly. The July 14 ANPR was issued jointly with USDA and sought comments on a number of additional BSE preventive steps being considered.

Canada Rule. Earlier, on April 19, 2004, while the November 2003 proposal to expand Canadian imports was still under consideration, APHIS posted on its website a decision to add bone-in beef from under-30-month cattle to the list of permitted imports. On April 26, a federal judge in Montana issued a temporary restraining order banning these additional imports, citing concerns about food safety and USDA's failure to follow proper rulemaking procedures. By May 2004, USDA acknowledged that it had not followed such procedures in allowing some 7.3 million pounds of certain types of Canadian beef products into the United States that were not on the list of so-called "low-risk" beef products USDA first publicized widely in August 2003. The 7.3 million pounds were among a total of 518.6 million pounds of Canadian beef that the United States has admitted from September 2003 through April 2004. It also promised not to permit any of these additional types of beef from Canada until after it issued a final rule on what it proposed in November 2003.

USDA published the final rule on BSE "minimal risk" regions, and on permitted Canadian imports, in the January 4, 2005, *Federal Register*, to take effect March 7, 2005. The rule makes Canada eligible to export to the United States live cattle under the age of 30 months, along with other ruminants, most types of beef (including from cattle over 30 months) and other cattle and ruminant products. Importers must adhere to strict branding and tracking requirements, and slaughter the cattle by 30 months of age, among other requirements. USDA said Canada qualified as minimal risk because it had specified BSE safeguards in place, such as adequate ongoing surveillance for BSE, a ban on high-risk materials in the food and feed supply, appropriate risk assessment measures, and strong restrictions on imports from other BSE countries.

Some congressional critics, notably several from northern cattle-producing states, argued that USDA should not have opened the border to live cattle at a time when yet another Canadian BSE case was being investigated, and when U.S. negotiators are trying to convince the Japanese and other important foreign markets to begin accepting U.S. beef. USDA officials countered that the new rule is based on a thorough scientific analysis of the potential risks, that denying Canada entry of safe products was inconsistent with the U.S. negotiating stance that U.S. beef is safe, and that a few new BSE cases were always possible, particularly in older cattle born prior to the 1997 feed ban (see below). All three North American cases were in such cattle, according to authorities.

BSE Surveillance. Prior to the appearance of the first U.S. case of BSE in December 2003, FSIS's role in keeping the disease out of the food supply was to put the agency's inspection force on alert to detect and divert from processing any cattle showing suspicious clinical symptoms, and to contact an APHIS inspector to evaluate the animal and dispatch a brain tissue sample to the National Veterinary Services Laboratory in Ames, Iowa, for testing. USDA (APHIS) by 2003 was testing approximately 20,000 cattle annually for BSE, focusing particularly on high-risk animals, including downers (animals that cannot walk at slaughter establishments), those that die on farms, older animals, and those with signs of neurological distress.

USDA began, in June 2004, a new 12- to 18-month surveillance program to test as many as 268,000 or more mostly higher-risk animals. USDA's aim is to measure the extent, if any, of BSE in U.S. herds; officials assert it is not a safety assurance program *per se*. USDA has approved various "rapid tests" for the initial BSE screening in designated laboratories around the country. If these tests indicate samples may be BSE-positive, the samples are forwarded to Ames for confirmation through a more sophisticated test. More than 167,000 had been tested through December 31, all negative for BSE. (Test results are posted on the agency website.)

USDA in April 2004 denied a request by a private meat company, Creekstone Farms, to use a rapid test to screen all of its cattle for BSE as a way to re-establish the firm's foreign markets lost after the U.S. BSE finding. USDA has argued that such "100% testing" is unscientific, would imply falsely that meat from BSE-tested animals is safer than that from untested cattle, and would undermine government-to-government negotiations to reopen markets. Creekstone has argued that it would test merely to satisfy marketing demands.

On July 14, 2004, the House Government Reform and Agriculture Committees held a joint hearing on BSE surveillance. USDA's Inspector General (IG) testified that USDA

officials erred — but did not engage in intentional misconduct or knowingly provide misleading information — when they failed to test a suspicious cow for BSE in Texas in April 2004, and when they characterized the Washington BSE cow as nonambulatory in December 2003. The IG also testified on weaknesses in USDA's BSE surveillance and ways to strengthen it.

The new nominee for Secretary of Agriculture, Governor Johanns of Nebraska, was peppered with a variety of questions and comments about BSE at his January 6 confirmation hearing before the Senate Committee on Agriculture. The committee chairman announced that he will convene another hearing specifically on the Canadian import rule, which Congress has 60 legislative days to review and can overturn (unless vetoed by the President). However, Members might raise additional topics, such as the difficulties of reopening additional foreign markets to U.S. beef, progress on implementing a national animal identification program (see "Meat Traceability," below), complaints from some USDA meat inspectors and others that packers are not fully complying with the new in-plant BSE safeguards, and the status of possible changes in the FDA feed ban, for example.

Inspection Funding Issues

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, problems in finding qualified people to work in dangerous or unpleasant environments or at remote locations, etc. These staffing problems have been exacerbated by the addition of HACCP requirements on top of the traditional carcass-by-carcass inspection duties. In order to monitor the staffing situation more closely, Congress included language in the conference report to accompany the FY2000 USDA appropriations law (P.L. 106-78), requiring FSIS to prepare a quarterly report on budget execution, staffing levels, and staffing needs (these are available on the FSIS website under "Communications to Congress"; see [http://www.fsis.usda.gov/oa/congress/congress.htm#Annual]).

In order to address staffing problems, most administrations over the past 20 years have proposed in their annual budget requests to charge the meat-packing industry new user fees sufficient to cover the entire cost or a portion of federal inspection services. The primary rationale for more comprehensive 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. Congressional appropriators have rejected new user fee proposals every year, stating that the safety of the food supply is a legitimate responsibility of the government. In addition, some Members have argued that the large meat recalls that have occurred since HACCP was implemented illustrate why the government should retain taxpayer-funded regulatory oversight.

The Bush Administration's initial FY2005 budget proposal (February 2004) reiterated user fee proposals made in FY2003 and FY2004 to increase the industry's reimbursement for FSIS inspection beyond one shift per day. The Administration's rationale is that the regular working day should be considered standard inspection, and any services provided beyond that time should be considered additional, hence subject to a higher fee schedule. Congressional appropriators traditionally have rejected these proposals, and in recent years

they have included report language stating that they will not consider offsetting FSIS appropriations with greater revenue from user fees unless authorizing legislation has first been passed. No new fees are assumed in the FY2005 appropriation (see below).

The FY2005 Consolidated Appropriations Act (P.L. 108-447, H.R. 4818) sets a level of $823.8 million for FSIS in FY2005, close to the Senate-reported (S. 2803) level and a $43.9 million increase from the FY2004 enacted level. The House-passed bill (H.R. 4766) recommended $824.7 million. In P.L. 108-447, and also part of the FSIS overall total, are $17.3 million for frontline inspectors and humane slaughter enforcement; $20.7 million for regulatory and scientific training; $3 million for overseeing BSE-related FSIS rules; $7.2 million for inspector training; and increases for food defense activities, including $2.1 million for biosurveillance, $2 million for the Food Emergency Response Network, and $1.5 million for the network's data systems support. Conferees also included $2.7 million for Codex Alimentarius activities.

Congressional review of the FY2006 FSIS budget will begin with submission of the President's FY2006 proposal in early February 2005.

FSIS Bioterrorism Preparedness

Since September 11, 2001, concern has been voiced about the potential for terrorist attacks on the U.S. agricultural base and food supply through intentional contamination by organisms or chemicals injurious to crop, animal, or human health. FSIS received $15 million in funds for increased oversight of meat and poultry safety in the Defense emergency supplemental act (P.L. 107-117, enacted January 10, 2002) which allocated the remaining $20 billion from the September 11, 2001, disaster relief act (P.L. 107-38). The Public Health Security and Bioterrorism Preparedness and Response Act (P.L. 107-188) authorized an additional $15 million in FY2002 and such sums as necessary in subsequent years to strengthen FSIS's inspection force. The FY2004 agriculture appropriations conference report (H.Rept. 108-401) allocated a portion of the increased appropriation to hire additional inspectors and increase laboratory testing for pathogens causing foodborne illness.

FSIS's Food Biosecurity Action Team (F-BAT) has conducted mock exercises to improve response time and communication in emergency situations. FSIS made security guidelines available to food processors in August 2002 (accessible on the FSIS website). The Food Threat Preparedness Network (PrepNet) is a joint FSIS/FDA group that works on threat prevention and emergency response.

Other Legislative and Administrative Issues

Humane Slaughter. Under provisions in the Federal Meat Inspection Act (21 U.S.C. 603(b), 610(b), 620(a)), FSIS inspectors are responsible for enforcing the Humane Methods of Slaughter Act (7 U.S.C. 1901-1906). This act requires that all livestock (but not poultry) be rendered unconscious before slaughter. FSIS inspectors have the authority to stop slaughter lines and order plant employees to take corrective actions to ensure compliance with the act. Legislative proposals to include poultry under the act were introduced in the 102nd through 104th Congresses, but none was acted upon.

Until recently, the issue of humane slaughter has been closely connected with the issue of humane treatment of downer cattle at federally inspected slaughtering facilities and other locations. During action on the FY2004 agriculture appropriations bill, lawmakers debated amendments that reflected the content of companion bills in the House and Senate (the Downed Animal Protection Act; H.R. 2519/S. 1298). These would have amended the 2002 farm act to require that downed animals at stockyards, market agencies, livestock dealer facilities, and slaughter facilities be euthanized immediately and barred from federal inspection. The Senate adopted the downed animal provision in its funding bill, but it was dropped in conference. The January 2004 USDA regulatory ban on slaughtering downers for human food was adopted in response to BSE concerns, but some lawmakers remain interested in writing the ban into law.

Concerns persist about FSIS enforcement of compliance with the Humane Methods of Slaughter Act (HMSA) regarding healthy, ambulatory animals. These concerns arose in early 2002 when media reports alleged widespread violations of the act, which prompted a number of administrative and congressional actions.

In February 2002, FSIS placed 17 veterinarians in its district offices, specifically to monitor humane slaughter and handling procedures and to report to headquarters on compliance. The conference agreement on the 2002 farm act contains a provision expressing the sense of Congress that FSIS should fully enforce the HMSA and report the number of violations to Congress annually. In the FY2003 omnibus appropriation act, Congress designated $5 million of FSIS funding specifically for hiring 50 additional inspectors to oversee the agency's compliance, and language in the FY2004 Consolidated Appropriations Act directed FSIS to continue this process.

On January 31, 2004, GAO released a report to Congress stating that it had found it difficult to assess FSIS's performance on enforcing the act because of incomplete and inconsistent inspection records (GAO-04-247, *Humane Methods of Slaughter Act: USDA Has Addressed Some Problems but Still Faces Enforcement Challenges).* GAO also reported that inspectors' knowledge of regulatory requirements varied, documentation did not consistently reflect the scope and severity of incidents, and enforcement action varied depending upon whether it was one animal or several that had not been rendered completely unconscious by stunning. FSIS issued new guidelines to its field personnel in November 2003, and indicated it would follow up on GAO's recommendations for improvement. On September 9, 2004, the agency published a *Federal Register* notice outlining a "systematic approach" to meeting humane slaughter requirements.

USDA's FY2005 budget request asked for another $5 million to address this issue. The final appropriations measure includes language, generally as proposed by the Senate, which directs that no less than 63 full-time equivalent positions (above the FY2002 level) be devoted to enforcement of the Humane Methods of Slaughter Act, and that $3 million (rather than the $4 million in the Senate bill) be provided to incorporate the agency's Humane Animal Tracking system into its field computer systems. Also in the appropriation (P.L. 108-447), as part of the FSIS overall total, are $17.3 million combined for frontline inspectors and humane slaughter enforcement.

Equine Slaughter. Some 50,000 or more U.S. horses are slaughtered each year for human food, mainly for European and Asian markets. Bills in the 108th Congress would

have banned such slaughter. Debate focused on the acceptability of this practice, and whether adequate care could be provided for such horses if they no longer went for human food. (See CRS Report RS21842, *Horse Slaughter Prevention Bills and Issues*).

Meat Traceability. USDA's Office of Inspector General (OIG) on September 30, 2003, released an audit report on a 2002 meat recall by Con Agra (see "*E. coli* O157:H7," below). 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." Several bills intended to create an animal ID and tracking system were introduced in the second session of the 108th Congress, following the discovery of the first U.S. case of BSE. The issue has also been debated in connection with protecting against bioterrorism; 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 Congress have been moving toward 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, and privacy of records. (For more information on this subject, see CRS Report RL32012, *Animal Identification and Meat Traceability*.)

HACCP-Related Legal Action. In December 1999, FSIS attempted to withdraw inspectors from a processing firm in Texas whose ground beef products had repeatedly violated *Salmonella* levels. However, the firm obtained a federal court injunction to prevent FSIS's action. The firm argued that (1) high *Salmonella* levels did not indicate the presence of other dangerous pathogens, (2) the *Salmonella* came in with the product from the slaughterhouse and thus could not be removed, and (3) the plant had never failed to meet standards for sanitation. In May 2000, the federal judge ruled that the meat and poultry inspection statutes did not give FSIS authority to use the *Salmonella* standard as the basis for withdrawing inspection.

In 2001, USDA asked an appeals court to overturn the ruling. However, in December 2001, the appeals court upheld the district court's decision. Shortly afterwards, Secretary Veneman issued a statement saying that although the decision limited FSIS's ability to enforce performance standards, it did not affect the agency's ability to use the standards as part of the verification of plants' sanitation and HACCP plans. In late July 2002, FSIS issued a notice to its employees instituting detailed procedures for reporting and taking action on failed generic *E. coli* tests in slaughtering plants, and on failed *Salmonella* tests in slaughter and grinding operations. The notice requires more documentation of test information, faster and more standardized notification of higher level managers, a procedural schedule for corrective actions, and instructions on what steps FSIS inspectors are to take if the corrective actions do not result in a negative test. The notice can be found on the FSIS website at [http://www.fsis.usda.gov/].

The appeals court ruling supports the 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. 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 moving ahead quickly with amending the meat and poultry inspection statutes to specify microbiological standards.

Pathogen Performance Standards. In part because of the court decision barring the use of *Salmonella* testing as an enforcement trigger, Senator Harkin in recent years has introduced bills to add language to the inspection laws clarifying the Secretary's authority to set enforceable performance standards. On May 22, 2003, he reintroduced the Meat and Poultry Pathogen Reduction and Enforcement Act (S. 1103; H.R. 2203, Eshoo). These bills would require the Secretary to set performance standards for the top illness-causing pathogens in raw meat after a three-year survey and evaluation period. The bill would enforce the standards by not permitting violative products to be labeled "USDA Inspected and Passed," thus preventing them from being sold for human consumption in any form.

The National Advisory Committee on Microbiological Criteria for Foods, 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].)

A second review of microbiological performance standards, *Scientific Criteria to Ensure Safe Food*, was released in late 2003 by the Institute of Medicine in collaboration with the National Research Council of the National Academy of Sciences. The report is available at [http://www.nap.edu/catalog/10690.html]. Among many recommendations, this newest 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 report also makes seven specific recommendations for FSIS to take to improve the safety of meat and poultry products. Among these are (1) conduct surveys to evaluate changes over time in the microbiological status of certain components of processed meats and poultry; (2) 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; (3) greatly expand generic *E. coli* criteria for, and *Salmonella* performance standards for, beef trim intended for grinding.

***E. coli* O157:H7.** In October 1994, FSIS began testing samples of raw ground beef for *E. coli* O157:H7 and declared that any such product found with this pathogen would be considered adulterated — the first time a foodborne pathogen on raw product was declared an adulterant under the meat inspection law. Industry groups immediately asked a Texas federal court for a preliminary injunction to halt this effort, on the grounds that it was not promulgated through appropriate rulemaking procedures, was arbitrary and capricious, and exceeded USDA's regulatory authority under law. In December 1994, the court denied the groups' request, and no appeal was filed, leaving the program in place. FSIS has taken roughly 60,700 samples since the program began; to date, 246 samples have tested positive.

In June and July 2002, 42 people in nine states were sickened by eating ground beef contaminated with *E. coli* O157:H7, due to delays in tracing the tainted meat back to the

original packer (Con Agra) and in having the company issue a recall. The recall, announced July 19, 2002, applied to about 19 million pounds of beef trim and fresh and frozen ground beef products produced as far back as April. Only about 3 million pounds were recovered.

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 in the *Federal Register* (67 FR 62325) 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. The changes at large operations were required to be complete by December 6, 2002; small plants had until February 4, 2003, and very small plants until April 7, 2003. 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 is issuing guidelines to grinding plants advising them to increase the level of pathogen testing by plant employees, and to avoid mixing products from different suppliers. In September 2003, FSIS released data showing that through August 31, 2003, 0.32% of samples tested positive compared with 0.78% in 2002 and 0.84% in 2001.

On September 30, 2003, OIG released an audit report on the 2002 recall, concluding that several FSIS management weaknesses, as well as mistakes on the part of Con Agra, contributed to the problems that arose. The report makes several recommendations for actions FSIS should take. Chief among these is a reiteration of one that the OIG made in 2000; namely, "that FSIS needs to revisit its authorities and establish operating procedures to address the weaknesses disclosed in this audit." Those weaknesses concern data collection and analysis, enforcement actions for repeat violations, performance standards for inspectors, and risk-based performance measures for the *E. coli* O157:H7 testing program, among others. In response to the OIG report, the FSIS Administrator issued a press release on October 2, 2003, detailing the changes the agency has already made in the program and citing recent data showing a reduction in the number of positive test results.

A CDC report issued on April 29, 2004, indicated that the incidence of infections caused by *E. coli* 0157:H7 had declined significantly between 1996 and 2003, with much of that decline occurring in 2002-2003. USDA and meat industry officials credited their pathogen reduction efforts for the decrease; consumer advocates questioned whether the data reflected a sustained reduction or merely year-to-year variability.

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. 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 is still the primary cause of meat and poultry product recalls.

The proposed regulations raised a 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 that 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. The proposed rule has not been finalized.

Interest in the *Listeria* issue 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. The Centers for Disease Control and Prevention confirmed 46 cases of the disease, with 7 deaths and 3 stillbirths or miscarriages. The recall covered products made as long ago 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. (The guidelines can be found on the FSIS website at [http://www.fsis.usda.gov]). 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 (see the FSIS website for more details on the rule).

Recall and Civil Penalty Proposals. Bills to enhance the effectiveness of meat and poultry recalls have been introduced in successive congresses. In the 108th Congress, the Unsafe Meat and Poultry Recall Act was proposed to authorize FSIS to recall suspected contaminated products directly if the product owner did not comply with the agency's request for a voluntary recall. Another bill would have given USDA and FDA recall authority. Currently, the 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. Another bill, the Meat and Poultry Inspection Accountability Act , would have given FSIS the authority to impose substantial civil money penalties on slaughtering and processing operations that violated the meat and poultry inspection laws and regulations. These measures did not advance beyond their committees of referral, but similar proposals could arise in the 109th Congress.

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. For example, an October 2004 GAO report, *Food Safety: USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food*, 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.

At past hearings, consumer groups 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 stated 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 action against "bad actors" — processors who persistently violate food safety standards. Food safety

advocates argue that FSIS should have the authority to mandate product recalls as a backup guarantee in case voluntary recalls moved too slowly or were not comprehensive enough.

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

In August 2004, the consumer group Center for Science in the Public Interest (CSPI) began a national campaign to urge USDA to publicize the names of retail outlets where recalled meat has been distributed, so that consumers can learn more quickly whether they have purchased potentially contaminated products. USDA and industry leaders contend 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. At the state level, the California legislature in August 2004 passed a bill (SB 1585) to require food companies and public agencies to make recall information more widely available. However, the governor vetoed the bill.

Language in the conference report to accompany the FY2005 appropriation for USDA (P.L. 108-447; H.Rept. 108-792) commends FSIS for beginning to include, in its meat and poultry recall notices, photographs of recalled products and website addresses of their manufacturers. Conferees urge the agency to continue this practice and also to ask manufacturers to voluntarily provide information on retail locations of recalled products, for inclusion in the releases.

LEGISLATION

109th Congress

H.R. 187 (Pomeroy)

To prohibit operation during a calendar year of USDA's final rule to establish standards for the designation of minimal-risk regions for the introduction of BSE into the United States, including designation of Canada as a minimal-risk region, unless U.S. access to major markets for United States exports of cattle and beef products is equivalent to or better than the access status accorded such exports as of January 1, 2003. Introduced January 4, 2005; referred to the Committee on Agriculture.

108th Congress

H.R. 1003 (Lowey)

The Meat and Poultry Inspection Accountability Act would expand enforcement options in federal meat and poultry inspection laws to include the imposition of civil money penalties

and amended the Federal Food, Drug, and Cosmetic Act to expand FDA enforcement options to include such penalties with respect to meat and poultry. Introduced February 27, 2003; referred to Committees on Agriculture and on Energy and Commerce.

H.R. 2203 (Eshoo)

The Meat and Poultry Pathogen Reduction and Enforcement Act would clarify the authority of USDA to prescribe performance standards for pathogens and to enforce the HACCP system. Introduced May 22, 2003; referred to Committee on Agriculture.

H.R. 2273 (Udall)

The Unsafe Meat and Poultry Recall Act would amend the meat and poultry inspection laws to authorize USDA to order the recall of suspected adulterated, misbranded, or otherwise unsafe products. Introduced May 22, 2003; referred to Committee on Agriculture.

H.R. 3547 (DeGette)

The Safe and Fair Enforcement and Recall for Meat, Poultry, and Food Act would give USDA and FDA authority to order recalls of suspected contaminated food products, and to withdraw inspection until after a hearing on a recall, from plants with a history of recurrent food safety violations. The bill also would authorize civil penalties to be imposed on violators of food safety acts and regulations. Introduced November 20, 2003; referred to Committees on Agriculture and on Energy and Commerce.

H.R. 3705 (Miller)

The Mad Cow Testing Act of 2004 would have amended the Federal Meat Inspection Act to require BSE testing on all cattle for human food, with testing done by APHIS and costs borne by packers/processors. Introduced January 20, 2004; referred to Committee on Agriculture.

H.R. 4121 (Rehberg)

The Consumer and Producer Protection Act of 2004 would amend the Federal Meat Inspection Act to permit inspection of nonambulatory cattle unable to walk due to "fatigue, stress, obdurator nerve paralysis, obesity, or one or more broken or fractured appendages, severed tendons or ligaments, or dislocated joints." Introduced April 1, 2004; referred to Committee on Agriculture.

S. 1103 (Harkin)

The Meat and Poultry Pathogen Reduction and Enforcement Act would clarify USDA authority to prescribe performance standards for the reduction of pathogens in meat and poultry and processed products; and to enforce the existing regulations for HACCP. Introduced May 22, 2003; referred to Committee on Agriculture, Nutrition, and Forestry.

S. 1187 (Clinton)

The At-Risk Consumer Protection Through Food Safety Labeling Act would amend the federal meat and poultry inspection laws to require that ready-to-eat meat or poultry products not produced under a scientifically validated program to address *Listeria monocytogenes* to bear a label advising pregnant women and other at-risk consumers of the USDA and FDA regulations regarding consumption of those products. Introduced June 4, 2003; referred to the Committee on Agriculture, Nutrition, and Forestry.

S. 1298 (Akaka)/H.R. 2519 (Ackerman)

The Downed Animal Protection Act would direct the Secretary of Agriculture to promulgate regulations to provide for the humane treatment, handling, and disposition of nonambulatory livestock by a covered entity, including a requirement that they be humanely euthanized. It would prohibit such animals from being inspected and passed for human food in Federal Meat Inspection Act establishments. S. 1298 introduced June 19, 2003; referred to the Committee on Agriculture. H.R. 2519 introduced June 19, 2003; referred to the Committee on Agriculture. (See H.R. 2673 for related amendments.)

S. 2007 (Durbin)/H.R. 3714 (DeLauro)

The BSE and Other Prion Disease Prevention and Public Health Protection Act would set new restrictions intended to ensure that many imported foods, feeds, nutritional supplements, medicines, cosmetics, and other specified articles do not harbor BSE infectivity; prohibit such articles from entering interstate or foreign commerce if they contain specified risk materials from ruminants; spell out new procedures for FDA oversight of animal feed; mandate a national ruminant identification program; and establish new programs for prion disease monitoring and testing, among other things. S. 2007 introduced January 20, 2004; referred to Committee on Agriculture; H.R. 3714 introduced January 21, 2004; referred to Committees on Agriculture; Energy and Commerce; and Ways and Means.

S. 2051 (Cantwell)

The Animal Feed Protection Act of 2004 would prohibit in interstate or foreign commerce animal feeds, nutritional supplements, and animal medicines that contain specified risk materials from ruminants, any ruminant materials from USDA-designated BSE countries, or any materials from ruminants with neurological disease signs. Introduced February 5, 2004; referred to Committee on Agriculture.

S. 2910 (Durbin)/H.R. 5259 (DeLauro)

The Safe Food Act of 2004 would consolidate federal food safety responsibilities, including those of FSIS and FDA, under a new Food Safety Administration. Introduced October 7, 2004. S. 2910 referred to the Senate Committee on Agriculture; H.R. 5929 referred to the Committees on Energy and Commerce, and on Agriculture.