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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 no longer 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 have been introduced in the 108th Congress. These include proposals to give FSIS the authority to (1) mandate recalls of suspected contaminated products (H.R. 2273); (2) set and enforce performance standards for foodborne pathogens under HACCP (S. 1103/H.R. 2203); and (3) impose civil penalties for violations of the inspection laws and regulations (H.R. 1003).

In December 2003, USDA announced the first confirmed case in the United States of bovine spongiform encephalopathy (BSE). On January 12, 2004, FSIS published interim rules, effective immediately, banning high BSE-risk, non-ambulatory ("downer") cattle from slaughtering facilities; imposing new disposal requirements for certain potentially hazardous animal parts and organs; 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.

Also since January 12, any carcass being tested for BSE must be held until negative results are received. In June 2004, USDA began a retooled testing program to test 200,000-268,000 cattle for BSE over 12-18 months (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 they had failed to follow proper rulemaking procedures in readmitting certain types of beef from Canada, which had its own BSE case in early 2003. USDA's BSE testing procedures also have come under criticism.

On July 13, 2004, the House passed an agriculture appropriations bill (H.R. 4766) for FY2005 that recommends $824.7 million for FSIS. The Administration had requested an appropriation of $838.7 million for FSIS, a $59 million increase from the FY2004 enacted level. As passed, H.R. 4766 does not include the Administration proposal to impose new inspection user fees of $124 million (which would require legislation to be implemented). Senate action on the measure is pending.

MOST RECENT DEVELOPMENTS

On July 13, the House passed an agriculture appropriations bill (H.R. 4766) for FY2005 that recommends $824.7 million for FSIS. Senate action is pending.

On July 14, USDA and FDA jointly published an advance notice of proposed rulemaking seeking comments on additional BSE preventive measures that are now under consideration by the agencies. These include a possible FDA rule to ban certain higher-risk cattle parts from all animal feed.

Also on July 14, the House Government Reform and Agriculture Committees held a joint hearing on USDA's BSE surveillance plan, where the Department's Inspector General testified that officials had made mistakes in failing to test a suspect cow for BSE in Texas in April 2004, and in describing the condition of the BSE-affected cow in Washington in December 2003. However, there was no intentional misconduct, she told the panels.

On July 28, USDA announced a recall of 170,000 pounds of ground beef patties after their manufacturer inadvertently included 41,000 pounds of Canadian product that should not have been imported. Although officials stressed that the product was safe and simply had been mislabeled in Canada, the incident brought renewed criticism of the Department over its oversight of beef imports from Canada, where both of the North American BSE cows were born.

BACKGROUND AND ANALYSIS

Special Section: Meat Safety and BSE

Bovine spongiform encephalopathy (BSE), is a slowly progressive, incurable disease affecting the central nervous system of cattle. It was first diagnosed in Britain in 1986. 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.

USDA's Food Safety and Inspection Service (FSIS) is one of the three federal agencies primarily responsible for keeping BSE out of the food supply. The other two agencies involved are USDA's Animal and Plant Health Inspection Service (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 many other things) is responsible for protecting U.S. animal 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 a cow with BSE was announced in Canada in May 2003, APHIS banned all ruminants and products from that country, but in August 2003 it announced it was permitting 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 and products from "minimal risk" regions, including Canada. A final rule was expected sometime this year.

Meanwhile, on April 19, 2004, APHIS posted on its website but did not publicize 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 his concerns about food safety and USDA's apparent failure to follow proper administrative rulemaking procedures. By May, USDA acknowledged that it had not followed proper administrative 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 last August 8. The 7.3 million pounds were among a total of 518.6 million pounds of Canadian beef that the United States has admitted since September 1, 2003. It also promised not to further permit any of these additional types of beef from Canada until after it issues a final rule on what it proposed last November (see above).

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 is likely to be a primary focus of efforts to improve U.S. safeguards against BSE. The FDA had announced on January 26, 2004, soon-to-be-published rules for boosting safeguards at and tightening inspections of feed mills, and of renderers that manufacture the bone meal used in feeds. On July 14, 2004, FDA took tentative steps to do so, by indicating, in an advance notice of proposed rulemaking (ANPR), that it was considering a move to ban specified risk materials (SRMs, which are designated higher-risk cattle parts such as brains and spinal cords) from all animal feeds. While industry groups said they were pleased that the agency was proceeding carefully, consumer advocates argued that FDA was moving too slowly. The possible ban was part of a broader ANPR issued jointly with USDA that sought public comments on a number of additional BSE preventive steps now under consideration.

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) on average has tested 20,000 head of cattle annually for BSE, focusing particularly on high-risk animals, including downers (animals that cannot walk at slaughter establishments), animals that die on farms, older animals, and those showing signs of neurological distress. USDA announced initially that APHIS would test 40,000 head of cattle for BSE in FY2004. On March 15, 2004, the Secretary announced a new 12- to 18-month surveillance program to test as many as 268,000 or more mostly higher-risk animals, which got under way in June of this year. (Ongoing test results are being posted on the agency's website.) An international scientific panel, which the Secretary had asked to review U.S. BSE safeguards and recommend enhancements, recommended such an expansion in its February 2004 report, in order to determine the extent, if any, of BSE in U.S. herds.

On July 14, 2004, the House Government Reform and Agriculture Committees held a joint hearing on BSE surveillance. USDA's Inspector General testified that officials had 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 Inspector General also provided criticisms of USDA's ongoing BSE surveillance program with recommendations for strengthening it. Several lawmakers at the hearing were highly critical of the Department's efforts, while others were more supportive of them. (Statements from the hearing are posted on both committees' websites.)

USDA has been approving various "rapid tests" for initial BSE screening in designated laboratories around the country. If these tests indicate any samples may be BSE-positive, the samples will be forwarded to Ames for confirmation through a more sophisticated test. USDA and many in the meat industry believe that such testing is useful for surveillance purposes but not safety assurance.

USDA in April 2004 denied a request by a private meat company, Creekstone Farms, to test 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 falsely imply 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.

Concerning imports, an APHIS rule prohibits cattle and meat imports from any country where BSE has been confirmed, and FSIS's foreign meat inspection program will not certify establishments in such countries to ship beef to the United States. Nonetheless, GAO issued a report in February 2002 criticizing FSIS's inspection procedure for imported meats from non-BSE countries, stating that it could fail to catch shipments purposely or accidentally containing product from a country where BSE is known or newly determined to be present.

FSIS import policies came under renewed scrutiny after it announced on July 28, 2004, a recall of 170,000 pounds of ground beef patties after their U.S. manufacturer inadvertently included 41,000 pounds of Canadian beef in them that should not have been imported. FSIS stressed that the product was safe and simply had been mislabeled by a Canadian inspector.

Many of the policy changes that have been announced since the U.S. BSE case was found were already under discussion among FSIS officials, the meat industry, and

policymakers. In addition, FSIS already had taken some steps intended to lessen the risk of BSE-infected tissue coming in contact with, or being processed for, human consumption. In 2003 the agency announced a regulatory sampling program to test meat that has been mechanically removed from bones to ensure that no spinal cord tissue is present (known as advanced meat recovery, or AMR), as this tissue would carry the risk of BSE. FSIS also was investigating the practice of air-injection stunning as a risk factor.

The new regulations that Secretary Veneman announced on December 30, 2003, were published as interim final rules in the January 12, 2004, *Federal Register*, and became effective immediately. Among the actions to provide additional safeguards and bolster U.S. protection systems:

- Downer (nonambulatory) cattle are no longer allowed into federally inspected or state-inspected slaughter and processing facilities.
- Cattle selected for BSE 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 entering 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.
- 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.

In past hearings and debates on bills to ban downers from federal inspection, lawmakers, animal health and food safety experts, and livestock industry groups have expressed concern that such a ban could result in FSIS inspectors and APHIS veterinarians being unable to evaluate and test those animals at greatest risk for BSE (i.e., downers and diseased cattle dying on farms).

Current Standard Inspection and HACCP Systems

FSIS carries out its inspection duties with a total staff of about 10,000, and an annual appropriation level of slightly less 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 these fees amounts to an estimated $101 million annually in additional program support. About 7,700 of FSIS's employees, roughly 1,000 of them veterinarians, are located 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 system (HACCP). 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 has a voluntary, fee-for-service inspection program 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-seven 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 $43 million in total annually (plus training and other assistance). A state inspection 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. Twenty-six states have discontinued their state inspection systems for meat or poultry (or both). In these states

FSIS has assumed responsibility for inspection at the formerly state-inspected plants, although the actual inspection is performed by state inspection 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. Each packing 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 used to be performed by APHIS). After DHS inspection, imported meat and poultry shipments go to nearby FSIS inspection facilities for final clearance before being released 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.

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.

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 the user fee proposal 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 release of the FY2005 budget (February 2004) reiterated 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. According to testimony presented by Dr. Elsa Murano, USDA Under Secretary for Food Safety, at a hearing of the House Appropriations Committee's Agriculture Subcommittee on March 18, 2004, the Department sent proposed legislation authorizing

expanded user fees to Congress in August 2003. To date, no Member has introduced the bill, and new fees are not assumed in the FY2005 appropriation (see below).

The Administration's formal FY2005 budget request proposes an $838.7 million appropriation for meat, poultry, and egg inspections (with no offsets from expanded user fees). It assumes that an additional $113 million in revenue from existing user fees will be available for program support. Dr. Murano testified that FSIS would allocate about half of the $59 million proposed increase to the basic inspection program, including hiring about 80 more employees, and continuing to improve enforcement of the Humane Methods of Slaughter Act. The balance of the increase would support several components of a new initiative on defense of U.S. agriculture and the food supply, including improving biosurveillance and expanding the network of federal and state diagnostic labs and their electronic data-sharing capability. The FY2005 budget also proposes a 50% increase in funds to provide formal classroom training to all new inspectors and supplemental training to the current workforce in the field.

On July 13, 2004, the House passed an agriculture appropriations bill (H.R. 4766) for FY2005 that recommends $824.7 million for FSIS in FY2005. H.R. 4766 provides for the following specific FSIS increases for FY2005 as requested by the Administration: $17.3 million for frontline inspectors and humane slaughter enforcement; $3 million for BSE surveillance (see the section below on BSE funding); $7.2 million for inspector training; and $15.5 million for increased pay costs. Also in the House-passed bill is an increase of $9.6 million for food defense activities, including $2.5 million for biosurveillance, $3.6 million for the Food Emergency Response Network, $3 million for the network's data systems support, and $500,000 for laboratory equipment and additional training. The bill also includes $2.7 million for Codex Alimentarius activities, $1.65 million for outsourcing microbiological testing, and a reduction of $7.7 million in information technology savings as requested in the budget. Senate action on the measure is pending.

P.L. 108-199, the FY2004 Consolidated Appropriations Act, which includes USDA, provides the current funding of $780 million for FSIS (after rescission).

Other Legislative and Administrative Action

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 into 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 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 Humane Methods of Slaughter Act 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 directs FSIS to continue this process. The FY2005 budget request would provide another $5 million to this issue.

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.

Equine Slaughter. Some 50,000 or more U.S. horses are slaughtered each year for human food, mainly for European and Asian markets. Pending bills (H.R. 857 and S. 2352) would ban such slaughter. Debate has focused on the acceptability of this practice, and whether existing facilities could provide sufficient care for such horses if they no longer went for human food. (For background 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 have been introduced in the second session of the 108th Congress since the discovery of the first U.S. case of BSE in December 2003. 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 diagnosis in December 2003, the industry, USDA, and Congress have been moving toward adoption of a national animal ID system, focused on animal disease control rather than on 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*.)

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, which was established in 1988 to provide scientific advice and recommendations to the Secretary of Agriculture and the Secretary 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 available 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 online 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 (see [http://www.fsis.usda.gov/oa/news/2003/fsisinitiatives.htm]).

A CDC report issued on April 29, 2004, seems to bolster the agency's assertions. The CDC announced 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. While 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 the 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's jurisdiction). Representatives of major consumer groups said that the proposed rule would not require enough testing in small processing plants and that products that are not tested for *Lm* should not be labeled "ready-to-eat" because they would still require cooking to be 100% safe. No final rule pursuant to the February 2001 rule was ever published.

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. FSIS inspectors will conduct random tests to verify establishments' programs. Plants will be 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).

On June 5, 2003, Senator Clinton introduced a bill (S. 1187) to require ready-to-eat foods not processed under a science-based *Lm* control plan to bear a label advising pregnant women and other at-risk consumers how to handle them so as to avoid contracting listeriosis.

Recall and Civil Penalty Proposals. Bills to enhance the effectiveness of meat and poultry recalls have been introduced or reintroduced in successive congresses for several years. In the 108th Congress, Representative Lowey has reintroduced the Meat and Poultry Inspection Accountability Act (H.R. 1003), which would give FSIS the authority to impose substantial civil money penalties on slaughtering and processing operations that violated the meat and poultry inspection laws and regulations. Representative Udall reintroduced the Unsafe Meat and Poultry Recall Act (H.R. 2273), which would authorize FSIS to recall suspected contaminated products directly if the product owner did not comply with the agency's request for a voluntary recall. On November 20, 2003, Representative DeGette introduced a bill that would give 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.

An August 2000 GAO study on FSIS and FDA recalls (*Food Safety — Actions Needed by USDA and FDA to Ensure that Companies Promptly Carry Out Recalls)* criticized both the agencies' efforts to ensure that companies carry out recalls quickly and efficiently,

particularly of products that may carry severe risk of illness. GAO also stated that neither FDA nor FSIS compiled sufficient information on companies' recall schedules or methods, and that determining the need for mandatory recall authority could not be done until such data were available.

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 the voluntary recall system moved too slowly or was not comprehensive enough. In a speech at the Food Safety Summit in March 2003, Secretary Veneman said that USDA is weighing the merits of amending the meat and poultry inspection laws to (1) require slaughtering and processing firms to inform the department if they suspect adulteration or misbranding of their product; (2) obtain authority to impose civil penalties on a firm if, after a written warning, it remains out of compliance; and (3) permit FSIS inspectors to issue cease-and-desist orders or to withdraw inspection on the basis of HACCP violations at an earlier stage than currently is the practice.

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.

FSIS Bioterrorism Preparedness

Since September 11, 2001, widespread 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) allocates 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.

The FY2005 budget request for FSIS would designate two-thirds of a proposed $59 million total increase for FSIS for bioterrorism preparedness activities: $23.5 million for detecting and responding to intentional contamination of the food supply; $10 million for expanding the number of federal, state, and local labs currently participating in the Food Emergency Response Network (FERN) from 60 (currently) to 100; $3.6 million for linking more of the FERN labs into an electronic information exchange system (eLEXNET); $2.3 million for purchasing laboratory equipment to improve testing capacity; and $1.9 million for further bio-security training for FSIS inspectors.

LEGISLATION

H.R. 1003 (Lowey)

The Meat and Poultry Inspection Accountability Act would expand the enforcement options under the federal meat and poultry inspection laws to include the imposition of civil money penalties; and would amend 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 Committee on Agriculture and Committee on Energy and Commerce.

H.R. 2203 (Eshoo)

The Meat and Poultry Pathogen Reduction and Enforcement Act would clarify the authority of the USDA Secretary 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 the 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 amend 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 the authority of the USDA Secretary 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* be required 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.