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Meat and Poultry Inspection Issues

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Meat and Poultry Inspection Issues

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.

After September 11, 2001, much of Congress' and food inspection agencies' attention focused on assuring that food and the U.S. agricultural production system are adequately protected from bioterrorism. On June 12, 2002, the President signed into law the Public Health Security and Bioterrorism Preparedness and Response Act (P.L. 107-188). The act authorizes such sums as may be necessary for enhanced FSIS inspection activities in FY2003 and beyond. The act contains extensive provisions concerning FDA food inspection activities.

Preceding the concern with bioterrorism, Congress for years has paid close attention to the efforts of FSIS and the meat and poultry industry to address the ongoing problem of naturally occurring microbiological contamination, which is responsible for outbreaks of severe and sometimes fatal foodborne illness.

Since January 2000, all federally inspected slaughtering and processing plants are operating under a system of inspection called HACCP (for Hazard Analysis and Critical Control Point). The system is intended to prevent meat contamination by microbial pathogens at points along the manufacturing chain where it is most likely to occur. The HACCP system complements, but does not replace, the traditional system of inspection under existing statutes.

Despite data showing that HACCP may reduce the presence of pathogens in *facilities* that produce meat and poultry products, outbreaks of foodborne illness and very large recalls of ground beef and turkey lunch meats, starting in spring 2002, indicate the ongoing difficulty of preventing contamination of the products themselves. Toward the end of the 107th Congress, new legislation to give FSIS mandatory recall authority was introduced in both chambers (S. 2803/H.R. 5230), and debate recommenced on recall proposals introduced earlier (H.R. 3127, H.R. 4834).

Lawmakers in the 107th Congress also reintroduced measures intended to consolidate and modernize the inspection of *all* foods, including meat and poultry (S. 1501, Durbin), as well as new proposals to establish the Secretary's authority to prescribe performance standards for pathogen reduction (S. 2013, S. 2532). The first was prompted by bioterrorism concerns (but is not a new idea), and the second relates to a federal court ruling in December 2001 that holds that FSIS does not have the statutory authority to use *Salmonella* bacteria test results as a basis for enforcement actions under HACCP.

The law establishing a Department of Homeland Security (P.L. 107-296/H.R. 5005) does not contain provisions directly affecting FSIS's or FDA's food safety and protection responsibilities. The Administration has stated that it might consider this issue at some point in the future.

MOST RECENT DEVELOPMENTS

On December 9, 2002, FSIS issued a directive to its inspection personnel on new procedures to verify that plants producing ready-to-eat (RTE) hot dogs, and poultry and roast beef lunch meats, are effectively controlling Listeria monocytogenes *on their premises. The* Listeria *bacterium can cause illness, death, miscarriages, and stillbirths, and is the leading cause of meat and poultry recalls, including a 27.5 million pound recall (the largest ever) in 2002. In 2000, the Clinton Administration launched an initiative to halve* Listeria*-caused deaths by 2005. FSIS held two public meetings and solicited comments on a revised action plan issued in May 2000, but no final regulation has been published.*

On December 12, 2002, FSIS held a public meeting on improving the recall process, a topic that has received significantly more attention since the major foodborne illness outbreaks and massive recalls in the summer of 2002. Several bills to give FSIS mandatory recall authority were introduced at the end of the 107th Congress and may be reintroduced in the 108th.

BACKGROUND AND ANALYSIS

Overview

FSIS inspects most meat, poultry, and processed egg products sold for human consumption for safety, wholesomeness, and proper labeling. FSIS carries out its inspection duties with a total staff of about 10,000, funded in FY2002 by an annual appropriation of $715.6 million (P.L. 107-76). In addition, the agency can use for program support the user fees paid by the packing industry for overtime and holiday inspection services – estimated at $101 million in FY2002. P.L. 107-76 also makes an additional $1 million available from user fees collected for laboratory accreditation services. P.L. 107-117, the Defense supplemental law containing funds for anti-terrorism activities, provides an additional $15 million for increased FSIS inspection to protect meat and poultry products from bioterrorism. About 7,600 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.

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 in the early 1990s 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 new inspection system 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 the system is working. The final rule was

published 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.

The packing industry was generally receptive to HACCP at the outset. Numerous plants, particularly the ones with 500 or more employees (which account for 75% of all U.S. slaughter production and 45% of all processed product output), already were using HACCP-type processes in their operations. However, since full implementation, the mandatory HACCP system has proved to be controversial. Although records show that packing plants for the most part have been abiding by the mandatory standards for pathogen levels, major players in the industry argue that the regulations exceed the HACCP concept by establishing what they view as impractical, expensive testing regimes and unrealistic standards.

A lawsuit brought against FSIS at the end of 1999 and reaffirmed on appeal in December 2001 challenges the agency's authority to carry out HACCP reforms and pathogen testing under existing statutes. These events raise the question of whether the original laws sufficiently undergird FSIS's stated intention to move to a more science-based inspection system.

Performance data on HACCP gradually are becoming available and generally indicate that HACCP is having a measurable beneficial impact on levels of microbiological contamination in processing plants. Combined FSIS data for the 1998-2001 period show that despite minor fluctuations, *Salmonella* prevalence in all classes of products have decreased to levels below the baseline prevalence estimates determined prior to HACCP implementation. The latest data indicate that young chickens average 10.7% under HACCP compared to 20% prior to HACCP; market hogs average 5.4% compared to 8.7%; cows and bulls average 2.2% compared to 2.7%; steers and heifers average 0.4% compared to 1%; ground beef averages 3.4% compared to 7.5%; ground chicken averages 15.7% compared to 44.6%; and ground turkey averages 29.2% compared to 49.9%.

Reductions in *Salmonella* levels mean reductions in the presence of other foodborne pathogens as well, according to FSIS. Data that the Centers for Disease Control and Prevention (CDC) released in April 2002, showing a 23% overall drop in bacterial foodborne illnesses since 1996, would appear to substantiate this. According to the new CDC data, the four major bacterial foodborne illnesses – *Campylobacter*, *Salmonella*, *Listeria*, and *E. coli* O157:H7 – posted a 21% decline in the past 6 years. However, despite the decline in the incidence of those four illnesses, the rate of positive tests for *E. Coli* O157:H7 bacteria in the raw product has been increasing steadily since FSIS began testing in 1994. This suggests that such factors as testing and more widespread knowledge among restaurant chefs and household consumers about proper cooking methods may be preventing people from becoming ill, but that not much progress is being made in reducing the presence of the bacteria in meat products themselves.

CDC officials emphasize that several food safety improvements – in addition to HACCP in meat and poultry plants – have been implemented over the same period (e.g., HACCP regulation of fruit and vegetable juices and seafood, and industry adoption of FDA guidelines on *Salmonella* prevention in egg production), and that the data collected have limitations and do not reflect the entire U.S. population. FDA officials state that there is probably some connection between HACCP implementation in meat and poultry plants and

the decline in foodborne illness, but it likely never will be possible to say how exactly how much.

Standard and HACCP Inspection Authority and Requirements

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 original Meat Inspection Act did not cover the poultry industry, which at the time was mainly small-scale production by independent farmers. The 1957 Poultry Products Inspection Act, as amended [21 U.S.C. 451 et seq.], made poultry inspection mandatory. 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 use or disposition of damaged and dirty eggs.

The primary goals of the FSIS inspection program are to prevent adulterated or misbranded animals and products from being sold as food, and to ensure that meat and poultry are slaughtered and processed under sanitary conditions. Uninspected and condemned products cannot be sold for human consumption in domestic or foreign commerce. Requirements also apply to intrastate commerce (for which either USDA programs or federally approved state programs must be in place). 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. All firms seeking to export meat or poultry to the United States must first receive FSIS certification. After passing through Customs and inspection by USDA's Animal and Plant Health Inspection Service (APHIS) for possible animal or human disease hazards, all imports go to FSIS inspection facilities for final clearance.

The following are the basic requirements of FSIS standard and HACCP 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. The agency has no regulatory jurisdiction at the farm level. Also, certain custom slaughter and most retail store and restaurant activities are exempt from federal inspection; however, they may be under state inspection. Most exotic meats – including venison, rabbit, and buffalo – are under the Food and Drug Administration's (FDA) regulatory oversight and not subject to mandatory inspection under the meat and poultry acts, although producers of these meats may request USDA inspection on a fee-for-service basis. FDA also is responsible for seafood (even those fish and shellfish raised through aquaculture), milk, and for the safety of shell eggs in retail stores and restaurants. Beginning April 26, 2001, FSIS inspection is mandatory for meat from ratites (ostrich, emu, rhea) and quail. A provision in the USDA appropriations act for FY2001 (P.L. 106-387) amended the Poultry Products Inspection Act

to include these animals, and the interim final rule was published in the *Federal Register* May 1, 2001 (66 FR 21631).

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. In addition, under HACCP regulations, all operations must have site-specific standard operating procedures (SOPs) for sanitation. For each "critical control point" along the production line, plants must document and maintain records on all cleaning procedures being used to prevent contamination before, during and after production. USDA inspectors check the records to verify the plant's compliance.

Slaughter Inspection. FSIS inspects all meat and poultry animals at slaughter on a continuous basis; that is, no animal may be slaughtered and dressed unless an inspector has examined each carcass. 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. Slaughter inspection under the original statutes consists primarily of *organoleptic* detection procedures – sight, touch, and smell – to look for signs of disease, contamination, and/or other abnormal conditions, both before and after slaughter.

In addition to standard inspection, 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, the plant must have a plan to control it. FSIS's role is to verify that the plant's plan effectively maintains sanitation standards at all the control points.

The HACCP rule also mandates two types of microbial testing to verify that plant safety procedures are working and to measure plant performance in reducing pathogens:

- All meat and poultry slaughter plants must regularly test carcasses for generic *E. coli* in order to verify that their systems are effectively controlling fecal contamination. The testing is intended as a process verification tool for plants and inspectors and is not to be used as a standard for enforcement purposes. However, plants are required to follow approved testing procedures and methods, and failure to meet specified performance criteria will result in USDA's working with the plant to improve sanitation and process controls. Testing frequency varies, from many tests daily in high volume plants to once a week in the smallest ones.

  USDA states that generic *E. coli* was chosen because it is the best microbial indicator of fecal contamination, the primary vehicle for such potentially dangerous bacteria as *Salmonella, Campylobactor*, and *E. coli* O157:H7.

- Both slaughter plants and those that produce raw ground product must meet or stay below a national standard incidence rate for *Salmonella* contamination. USDA states that it chose *Salmonella* for testing over other bacteria because: (1) it is the leading cause of foodborne illness; (2) it is one

of the most common foodborne bacteria; (3) it is easy to test for; and (4) its reduction also will cause reductions in other foodborne pathogens. The national standard varies by product. For example, it is set initially at 1% of samples testing positive for steers and heifers, 7.5% for ground beef, 20% for broilers, and 49.9% for ground turkey. Plants with higher levels than the standard are required to take remedial actions in order to meet the targets; failure to meet USDA standards by a third testing series can lead to suspension of inspection, which effectively closes the plant. USDA inspectors conduct the *Salmonella* testing.

Processing Inspection. Inspection of processed products like hot dogs, lunch meat, prepared dinners, and soups does not require an FSIS inspector to remain constantly on the production line or to inspect each and every processed item. Instead, inspectors are on site daily to monitor operations, check sanitary conditions, examine ingredient levels and packaging, review records, and conduct statistical sampling and testing of products. Such plants also are required to have HACCP plans, which are verified daily by USDA inspectors. Processing inspectors often have responsibility for two or more plants that must be visited each day; consequently, these plants are processing meat or poultry without on-site federal oversight for a large portion of their workday. Nonetheless, because each plant is visited daily, processing inspection is considered to be continuous.

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. Without inspection, plants are prohibited from operating.

Challenges to the HACCP Rule

Reaction to the mandatory HACCP regulations has been mixed. A significant portion of the packing industry already was using HACCP-type processes and conducting its own pathogen testing before those activities became mandatory. Nonetheless, after implementation, several major meat industries have contended that the *Salmonella* standard, in particular, oversteps the intent of HACCP and is impractical, expensive, and sets unrealistic microbiological goals. They also maintain that adding HACCP onto existing requirements increases the regulatory burden for meat and poultry processors, with no tangible improvement in public health. On the other hand, consumer advocacy organizations such as the Center for Science in the Public Interest and Safe Tables Our Priority have remained supportive of the HACCP rule, contending, among other things, that the testing program is effective at reducing pathogens because it forces companies to emphasize prevention in their operating plans.

HACCP-related Legal Action. In December 1999, FSIS attempted to withdraw inspectors from a processing firm in Texas (**Supreme Beef**) whose ground beef products had repeatedly violated *Salmonella* levels (withdrawing inspectors effectively closes down a plant). 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) that the *Salmonella* came in with the product from the slaughterhouse and thus could not be removed, and (3) that 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, in part because Supreme Beef had gone of business and the May 2000 decision applied only to meat plants in the original court's district. However, on December 11, 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.

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.

Current Legislative and Administrative Actions

Pathogen Performance Standards. In part because of the *Supreme Beef* case, Senator Harkin made several attempts in both the106th and 107th Congresses to add language to the inspection laws to clarify the Secretary's authority to set enforceable performance standards. In June 2000 he introduced the Microbiological Performance Standards Clarification Act of 2000 (S. 2760). Subsequently he offered the bill for adoption as floor amendment to the FY2001 agricultural appropriations bill, but it failed adoption by one vote. Senator Harkin later offered the proposal as an amendment to the Senate's FY2002 USDA appropriations measure (S. 1191/S.Amdt 1984), but withdrew it when the lawmakers agreed to take up a competing amendment (S.Amdt. 1987) that would have postponed enforcement of microbial standards until two research organizations completed scientific reviews of the issue in 2002.

In March 2002, companion measures containing stronger and more detailed versions of Senator Harkin's earlier amendments were introduced as separate legislation. The Meat and Poultry Pathogen Reduction and Enforcement Act (S. 2013, Harkin; H.R. 3956, Eshoo)

would have required the Secretary to set performance standards for the top illness-causing pathogens in raw meat after a 3-year survey and evaluation period. The bill would have enforced the standards by not permitting violative products to be labeled "USDA Inspected and Passed," which would prevent the product from being sold for human consumption in any form.

In May 2002, Senator Schumer introduced related but more extensive legislation that would have: (1) established microbiological performance standards; (2) established livestock and poultry traceback systems; (3) required states to report illnesses from meat and poultry products to the CDC; (4) protected employees at federally inspected meat and poultry plants who report food safety problems from intimidation by their employers; (5) listed biological threats to the food supply and enhance preparedness and response plans; and (6) conducted studies on how to improve the recruitment of federal meat and poultry inspectors and on whether meat and poultry plants should be required to use rapid detection tests for major pathogens (S. 2532).

In January 2002, the first of the two expected scientific evaluations of microbiological standards was completed; the report was made public in October 2002. The author of this report is 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 relative to the safety and wholesomeness of the U.S. food supply. The Advisory Committee "concluded 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 control in one or more steps in the process." (The report is available at [http://www.fsis.usda.gov/OPHS/nacmcf/rep_stand.htm].) The release date of the second review, being conducted by the Institute of Medicine in collaboration with the National Research Council of the National Academy of Sciences, has been postponed to March 2003.

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 54,023 samples since the program began; to date, 226 samples have tested positive.

In June and July 2002, 42 people in 9 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 and in having the company issue a recall. The recall was announced July 19 and applied to about 19 million pounds of beef trim and fresh and frozen ground beef products produced as far back as April. 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 have until February 4, 2003, and very small plants until April 7, 2003. FSIS inspectors will verify that corrective steps have been taken and conduct random testing of all beef processing plants, including all grinders (some previously had been exempted). The agency is preparing to issue guidelines to grinding plants also advising increased pathogen testing by plant employees, and avoidance of mixing products from different suppliers.

Listeria monocytogenes. In February 2001, FSIS published a proposed rule to establish performance standards that meat and poultry processing firms would have to meet to reduce the presence of *Listeria monocytogenes*, a pathogen in ready-to-eat foods. The proposed rule covered more than 100 different types of dried, salt-cured, fermented, and cooked or processed meat and poultry products. *Listeria* causes an estimated 2,500 illnesses and 499 deaths each year (from listeriosis), and is still the number one cause for meat and poultry product recalls. FSIS and FDA jointly prepared the proposed rule in response to an initiative that the Clinton Administration announced in May 2000 to cut in half the number of listeriosis cases by 2005. The *Federal Register* notice (66 FR 5515) asked the food processing industry for technical comments on a draft risk assessment, and for comment on a risk management action plan. The action plan was built on a previous set of performance standards for selected lunch meats and other products that became effective in March 1999 (64 FR 732).

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 *Listeria* should not be labeled "ready-to-eat" because they would still require cooking to be 100% safe. To date, FSIS has not published a final rule setting performance standards for *Listeria* in ready-to-eat meats.

Interest in the *Listeria* issue increased significantly after October 2002, when the Pilgrim's Pride Corporation recalled a record-breaking 27.5 million pounds of poultry lunch meats for possible *Listeria* contamination after a July 2002 outbreak of listeriosis in New England. 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 with new and specific instructions for monitoring processing plants that produce hot dogs and poultry lunch meats (not the 100-plus items in the February 2001 proposed rule). The guidelines can be found at [http://www.fsis.usda.gov/OPPDE/rdad/FSISDir7000.htm].

Both the poultry meat and ground beef recalls prompted renewed demands from a variety of consumer and environmental groups for more federal enforcement and oversight of inspection, and for an end to large-scale livestock operations, which environmental groups argue increase the spread of harmful microorganisms.

Recall and Civil Penalty Proposals. In response to the foodborne illness outbreaks in the summer of 2002 , Senator Harkin and Representative Rivers introduced companion bills on July 26 and August 7, respectively, to not only give recall, civil penalty, and withdrawal of inspection authorities to FSIS, but also to give recall and civil penalty authority to the FDA (S. 2803/H.R. 5230). Similar bills were introduced earlier in the 107th Congress: H.R. 1276, to give FSIS authority to levy civil penalties on packers that violate inspection laws, and H.R. 3127, 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. (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.) In May 2002, a bill similar to H.R. 3127 was introduced, except that it also would have clarified FSIS's authority to withdraw inspection if a company willfully or repeatedly violated meat and poultry inspection laws and regulations, and would have authorize civil penalties of up to $100,000 per day against problem firms (H.R. 4834).

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 the agencies' efforts in making sure 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 compiles 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.

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 which could ultimately be proven false. Some observers argue that much still needs to be done in educating consumers and restaurateurs about safe meat and poultry handling and cooking practices.

Consolidated Federal Food Safety Agency

Concerns about bioterrorism preparedness after September 11, 2001, have brought renewed attention to a decades-long debate over whether the 12 federal agencies and roughly 35 laws governing food safety should be consolidated into a single food safety entity. In the

107th Congress, Senator Durbin, a long-standing proponent of the single agency concept, reintroduced consolidation legislation shortly after the terrorist attacks, stating that such reform was necessary to protect the food supply from terrorist threats (S. 1501, the Safe Food Act of 2001/H.R. 1671). An October 2001 Senate Government Affairs Subcommittee hearing on food safety preparedness included testimony on the single entity concept proposed in S. 1501. In speeches at a major food industry conferences in March and June 2002, Homeland Security Director Tom Ridge stated that the Bush Administration is considering reorganizing or consolidating federal food safety agencies at some point in the future.

Consumer groups are in favor of provisions that make federal regulatory oversight of food safety more consistent across all types of food products, however that might be achieved. Food processors argue that: (1) increased regulation will not result in increased food safety until scientifically valid microbiological standards can be determined; (2) reorganization by itself will not necessarily improve public health; and (3) reorganization or physical restructuring of agencies would create huge logistical problems that could actually interfere with the efficacy of the current system.

The GAO restated its long-standing criticism of the current fragmented food inspection system at the October 2001 hearing, and reemphasized the National Academy of Sciences's (NAS) report calling for greater coordination and statutory reform, *Ensuring Safe Food from Production to Consumption*, which Director Ridge also mentioned in his speech. In the 2002 farm act (Section 10807 of P.L. 107-171, the Farm Security and Rural Investment Act), Congress created a 15-member Food Safety Commission and charged it with making specific recommendations to enhance the U.S. food safety system, including a description of how each recommendation would improve food safety. The report is due one year from the Commissions's first meeting; however, the law authorizes commission members to be appointed only after authorized funds are appropriated. Since the government currently is operating on a continuing resolution providing 2002 level funding, the Commission awaits implementation. (The NAS report is available at [http://books.nap.edu/books/0309065593/html/index.html]; also see the GAO website [http://www.gao.gov/] for links to the October 10 testimony).

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 disaster relief act (P.L. 107-38).

Several bills introduced in the Senate in fall 2001 contained provisions affecting the anti-terrorism activities of FSIS and/or its two primary cooperating USDA agencies, the Animal and Plant Health Inspection Service (APHIS) (which inspects cargo and passengers at U.S. ports of entry for animal and plant pests, and responds to animal disease outbreaks, among other duties) and the Agricultural Research Service (ARS) (which conducts research on animal diseases and food safety to support FSIS's regulatory activities, among other subjects). The USDA-related provisions in these bills were incorporated into S. 1765, the Bioterrorism Preparedness Act of 2001, which the Senate adopted *in toto* as an amendment

in the nature of a substitute to H.R. 3448 in December 2001. The House-passed version (passed the same month) did not contain any USDA-related authorities. The conference report was passed by both chambers in May and the President signed the bill into law in June 2002 (P.L. 107-188, the Public Health Security and Bioterrorism Preparedness and Response Act (H.Rept. 107-481)).

The Act authorizes an additional $15 million in FY2002 and such sums as necessary in subsequent years to strengthen FSIS's inspection force. The measure also authorizes $30 million to increase APHIS's border inspection activities, create closer working relationships with state and private veterinarians, and to establish an integrated FSIS/APHIS computer tracking and record-keeping system for livestock and meat imports. (Note: The newly enacted Homeland Security Act of 2002, P.L. 107-296, transfers APHIS's border inspection activities to the Department of Homeland Security. It is unclear how the transfer might affect the implementation of activities specified in P.L. 107-188.) The Bioterrorism Act also contains a provision making it a federal criminal offense intentionally to damage the property or employees of public or private animal enterprises (e.g., a livestock or poultry slaughtering operation, or an animal research laboratory) and authorizes restitution for economic loss resulting from the damage.

Separately, P.L. 107-206, the FY2002 supplemental appropriations bill, which the President signed in August 2002, would have provided $13 million to FSIS to cover the costs of reviewing foreign countries' meat and poultry inspection regimes and visiting additional foreign plants specifically to address security concerns. The GAO has been critical in the past of FSIS's documentation of its reviews of foreign governments' inspection systems, maintaining that it is difficult to determine if such reviews have been sufficiently thorough to guarantee that foreign countries have systems at least equivalent to the United States'. However, the President withheld the release of $5.1 billion of the $28.9 billion appropriation, which included the additional $13 million for FSIS foreign inspection reviews. The funds would become available if the President submitted a formal request for them and declared a budget emergency.

In March 2002, Under Secretary for Food Safety Elsa Murano testified before the House Agriculture Appropriations subcommittee on the steps FSIS and the Department currently are taking administratively to address food biosecurity issues. At the Department level, the USDA Homeland Security Council coordinates anti-terrorism activities across USDA and with other federal agencies. Within FSIS, the Food Biosecurity Action Team (F-BAT) has placed the agency's 7,600 inspectors on high alert to look for ante-mortem and post-mortem irregularities in meat animals and poultry, and 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.

Irradiation

Food irradiation is the process of exposing food to ionizing radiation (e.g., from cobalt-60, cesium-137, x-ray machines, or electron accelerators) that penetrates food and kills insect pests and microorganisms without raising the temperature of the food significantly. In December 1997, FDA approved irradiation for the control of pathogenic microorganisms in

red meats (FDA approval was necessary because irradiation is considered a food additive). In December1999, USDA published a final rule in the *Federal Register* (64 FR 72167) that guides the meat industry in the use of the technology and in labeling irradiated red meat products. The rule also permits poultry processors to irradiate unpackaged as well as packaged poultry (irradiation of packaged poultry has been permitted since 1992). According to FSIS officials, this change gives processors greater flexibility to use irradiation in the context of their overall HACCP plans. Only about 1% of poultry is irradiated currently, according to FSIS.

Supporters of irradiation as a food safety technology claim that it will significantly reduce the public health threat, particularly from ground beef that may be contaminated with *E. coli* O157:H7 (the process also can reduce the levels of *Salmonella* and other major foodborne pathogens). Some consumer groups support irradiation for food safety purposes, but state that it is not a panacea — good sanitary conditions through final preparation still will be necessary — and that it raises other issues concerning worker and environmental safety. Other interest groups remain concerned that it may alter the nutrient content of meat. An August 2000 GAO report to Congress concluded that the cumulative evidence from more than 40 years of research in U.S., European and other laboratories indicates that irradiated food is safe to eat. Red meat processors are interested in the technology, but state that they would like to be assured of consumer acceptance before committing themselves to the high cost of installing the equipment. The technology might be adopted first in institutions that serve high populations of immune-compromised people, such as nursing homes and hospitals. Although some research studies show potential consumer acceptance of irradiated ground beef could be as high as 50%, observers still expect the technology to be adopted slowly.

In the 2002 farm act (P.L. 107-171, Sections 10808-09), Congress passed a provision that requires the FDA to permit the use of the term "pasteurized" on food labels to indicate that products (including meat products) have undergone a treatment process, including irradiation, that reduces pathogen levels and remains effective even if the products are stored improperly. The provision also requires the USDA to conduct a public and industry education program on the availability and effectiveness of processes and treatments that eliminate or significantly reduce the level of pathogens on meat and poultry products.

Other Selected Issues

"Mad Cow" Disease

"Mad cow" disease, or 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. In 1997, European scientists determined that there was a likely link between BSE in cattle and an outbreak in humans of a new type of fatal brain disease called Creutzfeldt-Jakob disease (nvCJD) that had begun in Europe in the late 1980s. Most experts now agree that nvCJD is a human form of BSE that is transmitted to humans who consume meat from BSE-infected cattle.

U.S. federal and state agencies have found no BSE in U.S. cattle since they began surveillance in 1989. That year, APHIS began banning the import of all live ruminants from

countries where BSE is known to exist, and in 1991, the agency banned the importation of rendered by-products from ruminants. As of December 2000, the importation of all rendered animal protein products (whether from ruminants or not) is prohibited. The Food and Drug Administration, which regulates animal feed ingredients domestically, banned the feeding of virtually all mammalian proteins to ruminants in August 1997. Periodic surveys show, however, that full compliance has been difficult to achieve. A June 2001 FDA survey showed that 22% of renderers, feed mills, and other facilities that handle ruminant material were out of compliance with FDA's labeling, recordkeeping, and commingling requirements. A February 2002 GAO study reports that 364 out of 10,576 firms inspected by FDA (out of at least 11,741 total firms potentially handling ruminant material) are still out of compliance. Furthermore, according to GAO, FDA's database for ensuring compliance is so flawed as to be useless [http://www.gao.gov].

Wide differences of opinion on the adequacy of U.S. safeguards against BSE persist. A study issued in November 2001 by the Harvard Center for Risk Analysis, states that the steps that USDA and HHS have taken to date to prevent and prepare for possible BSE introduction are effective, although some improvements could still be made. The February 2002 GAO study states, "Federal actions do not sufficiently ensure that all BSE-infected animals or products are kept out or that if BSE were found, it would be detected promptly and not spread to other cattle through animal feed or enter the human food supply."

FSIS's responsibility regarding BSE requires the agency's inspectors to divert from processing any cattle showing suspicious clinical symptoms and send their brains to an APHIS laboratory in Ames, Iowa, for testing. More than 11,000 cattle brains have been tested since 1990, and no BSE has been found. Under FSIS's foreign meat inspection program, no establishments in countries where BSE has been found are approved to ship beef to the United States. However, the February 2002 GAO report criticizes USDA for not testing the brains of cattle that die on farms, since they may be at higher risk of carrying BSE, and questions the adequacy of the inspection procedures for imported meats.(For additional information on BSE, see CRS Report RS20839, *Mad Cow Disease: Agriculture Issues*).

State Inspection

For more than a decade, Members of Congress have introduced bills that would permit state-inspected meat and poultry plants to ship their products across state lines (the most recent was introduced in the 106th Congress). Currently, plants under state inspection, which must be at least "equal to" (but not necessarily identical to) the federal program, can only market their products intrastate. At past hearings on legislative proposals, representatives of state departments of agriculture, state meat processing associations, the American Farm Bureau Federation, the National Cattlemen's Beef Association, and several major consumer and food safety organizations have testified in support of the measure. The American Meat Institute (AMI), which represents the manufacturers of about 70% of U.S. meat products, has always testified in opposition to such bills, stating that for economic equity and other reasons, state-inspected plants that want to ship interstate should be required to meet the same standards that federally inspected plants must meet. None of the proposals ever progressed to a vote.

The 2002 farm act (P.L. 107-171) contains a provision that requires FSIS to conduct a survey of state inspection programs to determine how they currently compare to the federal

program, and to offer guidance on the changes state inspections systems might expect if the statutory prohibition against interstate shipment were removed (Title X, Subtitle B(65)). The survey and guidelines are to be included in FSIS's next annual report to Congress.

In addition, the conference report on the 2002 USDA appropriations act (P.L. 107-76) asked the Department to consider developing a limited pilot project that would permit Ohio to ship state-inspected meat and poultry interstate. In March 2002, USDA delivered to Congress a report on the feasibility and design of such a pilot program (available on the FSIS website). The report concluded that the pilot: (1) would be a resource-intensive proposition for both FSIS and Ohio inspection officials; (2) would not provide any more information on the results of allowing interstate shipment than has been provided for years under the Talmadge-Aiken program (wherein state inspection personnel enforce federal laws and regulations at state-inspected plants, which allows them to ship products interstate); and (3) that there would be legal issues involved in allowing one state program to ship interstate because current law prohibits it.

Package Dating

A television news in late summer 2002 brought attention to the issue of "sell by," "use by," and "best if used by" dates on packages of meat and poultry in supermarkets. The report alleged that some retailers were misleading consumers and possibly endangering public health by re-labeling packages with a longer sell-by date.

Since 1972, FSIS has required poultry products to include a date of packing, either as a calendar date or a code (9 CFR 381.126). FSIS also has permitted poultry processors to use a sell-by or use-by date instead of a date-of-packing date. There is no regulation requiring red meat products to bear any date label. However, federally inspected meat packing plants may place a packing, sell-by, or use-by date on their products voluntarily. As long as the meat or poultry product remains in the packaging that bears the USDA "inspected and passed" seal, the product is under FSIS jurisdiction, and the retailer may not change the date that was affixed at the plant. If the retailer re-packages the product, then state and local regulations pertain. Some jurisdictions permit retailers to re-label products to move the sell-by or use-by date forward. FSIS documents indicate that more than 20 states may have product-dating requirements.

FSIS officials state that sell-by or use-by dates relate to product quality, not to safety. A date label affixed at the packing plant helps retailers determine how long to display the product for sale, and helps consumers to know the time limit to purchase or use the product at its best quality. If a product has been handled properly and stored at 40 degrees or below, the product could still be safe even after the use-by date, if the consumer determines that the product's feel and odor appear normal. On the other hand, a product that has been mishandled could be unsafe, even though the use-by date has not passed.

LEGISLATION IN THE 107TH CONGRESS

P.L. 107-171, H.R. 2646/S. 1731

Farm Security and Rural Investment Act of 2002. Provides for the continuation of agricultural programs through FY2007. Contains provisions on bioterrorism preparedness, country-of-origin labeling of meats, irradiation labeling, and humane treatment of livestock, among other things. Conference agreement passed by the House on May 2 and by the Senate on May 8, 2002. Signed into law May 13, 2002.

P.L. 107-188, H.R. 3448/S. 1765

Public Health Security and Bioterrorism Preparedness and Response Act. Improves the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies. Introduced December 11, 2001; passed the House on December 12, 2001, under a suspension of the rules. Senate substituted text of S. 1765 as an amendment to H.R. 3448 on December 20, 2001. Conference agreement filed May 21; passed by House on May 22 and by the Senate on May 23, 2002 (H.Rept. 107-481). Signed into law June 12, 2002.

H.R. 1276 (Lowey)

Expands enforcement options under the Federal Meat Inspection Act and Poultry Products Inspection Act to include the imposition of civil money penalties against violators. Introduced March 28, 2001, and referred to the Committee on Agriculture.

H.R. 3127 (Udall)

Unsafe Meat and Poultry Recall Act of 2001. Amends the Federal Meat Inspection Act and the Poultry Products Inspection Act to authorize the Secretary of Agriculture to order the recall of meat and poultry that is adulterated, misbranded, or otherwise unsafe. Introduced October 12, 2001, and referred to the Committee on Agriculture.

H.R. 4834 (Baldacci)

Safe and Fair Enforcement and Recall for Meat and Poultry Act of 2002. Amends the Federal Meat Inspection Act and the Poultry Products Inspection Act to give USDA the authority to recall suspected contaminated meat and poultry if a firm does not comply with a USDA request for a voluntary recall; also gives authority for civil penalties and withdrawal of inspection. Introduced May 23, 2002, and referred to the Committee on Agriculture.

S. 2803/H.R. 5230 (Harkin/Rivers)

Safe and Fair Enforcement and Recall for Meat, Poultry, and Food Act of 2002. Amends the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Federal Food, Drug, and Cosmetic Act to provide for improved public health through enhanced enforcement. S. 2803 was introduced July 26, 2002, and referred to the Committee on Agriculture, Nutrition, and Forestry. H.R. 5230 was introduced August 7, 2002, and referred to the Subcommittee on Livestock and Horticulture of the Agriculture Committee, and to the Subcommittee on Health of the Energy and Commerce Committee.

H.R. 1671 (DeLauro)/ S. 1501 (Durbin)

Safe Food Act of 2001. To consolidate into a single independent agency within the executive branch responsibilities regarding food safety, labeling, and inspection currently

divided among several federal agencies. H.R. 1671 was introduced May 1, 2001; referred to Committee on Agriculture, Subcommittee on Department Operations, Oversight, Nutrition, and Forestry, and Subcommittee on Livestock and Horticulture, May 14, 2001. Referred to Committee on Energy and Commerce, May 1, 2001, and referred to Subcommittee on Health, May 15, 2001. S. 1501 was introduced October 4, 2001; referred to the Committee on Governmental Affairs. Testimony was given on the measure at a hearing held on bioterrorism preparedness on October 10, 2001, before the Subcommittee on Oversight of Government Management, Restructuring, and the District of Columbia.

S. 2013 (Harkin)/H.R. 3956 (Eshoo)

The Meat and Poultry Pathogen Reduction and Enforcement Act of 2002. To clarify the authority of the Secretary to prescribe performance standards for the reduction of pathogens in meat and poultry produced under federal inspection. Introduced March 14, 2002, and referred to the Senate Committee on Agriculture, Forestry and Human Nutrition and the House Committee on Agriculture.

S. 2532 (Schumer)

The Meat and Poultry Products Safety Improvement Act of 2002. To amend the Federal Meat Inspection Act and the Poultry Products Inspection Act to improve the safety of meat and poultry products by establishing microbiological standards and traceback systems, among other things. Introduced May 17, 2002, and referred to the Senate Committee on Agriculture, Forestry, and Human Nutrition.