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Meat and Poultry Inspection Issues

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CONTENTS

SUMMARY

MOST RECENT DEVELOPMENTS

BACKGROUND AND ANALYSIS

Overview

Standard and HACCP Inspection Authority and Requirements

- Coverage

- Plant Sanitation

- Slaughter Inspection

- Processing Inspection

- Enforcement Authority

- Challenges to the HACCP Rule

- HACCP-related Legal Action

Funding Issues

- Pathogen Performance Standards

- E. coli O157:H7

- Listeria monocytogenes

- Recall and Civil Penalty Proposals

- Consolidated Federal Food Safety Agency

- FSIS Bioterrorism Preparedness

- Irradiation

Other Selected Issues

- “Mad Cow” Disease

- State Inspection

LEGISLATION

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, 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). Legislation also was introduced to counter a successful lawsuit by the meat industry challenging pathogen performance standards. S. 2013 would have given FSIS statutory authority to use *Salmonella* bacteria test results as a basis for enforcement actions under HACCP.

The omnibus FY2003 funding bill that the President signed on February 20 contains \$759.8 million for FSIS, which includes \$5 million specifically for the agency to hire at least 50 additional employees to help enforce the Humane Methods of Slaughter Act. The agency's enforcement of the Act came under criticism in 2002. The House bill reflecting the Administration's FY2004 budget request proposes \$797 million for FSIS. Of the \$42 million increase over the FY2003 appropriation, \$25.6 million would support hiring more inspectors and increasing laboratory capacity for analyzing food samples for possible acts of bioterrorism, among other things.

MOST RECENT DEVELOPMENTS

On April 24, 2003, the National Academy of Sciences made available on its website its latest report on food safety. Entitled *Scientific Criteria to Ensure Safe Food*, the report reiterates the Academy's longstanding recommendations for better connections between public health agencies and food safety regulatory agencies, and for a science-based, transparent strategy for developing food safety criteria. The report contains several specific recommendations that NAS believes FSIS should implement as soon as possible to counter the hazard of *E. coli* O157:H7 in ground beef.

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 FY2003 by an annual appropriation of \$759.8 million (P.L. 108-7). In addition, the agency can use for program support the user fees paid by the packing industry for overtime and holiday inspection services (and fees from certifying laboratories that test meat samples) – estimated at \$101 million annually. 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.

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 may be 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*, *Campylobacter*, and *E. coli* O157:H7.

- Both slaughter plants and those that produce raw ground product are expected to 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. 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.

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. Current regulations do 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 [<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 FSIS has experienced difficulties in having sufficient staff to meet the agency's service obligations to the meat and poultry industries. Usually a combination of factors causes these difficulties, including new technologies that increase plant volume, insufficient appropriated funds to hire additional inspectors at times of unexpected increases in demand for inspections, problems in finding 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 included proposals in their annual budget requests to charge the meat packing industry user fees sufficient to cover the entire cost of federal inspection services. Currently (since 1919), FSIS charges user fees for overtime (beyond 3 shifts per day) and holiday inspections, which adds about \$100 million annually to the agency's program level. 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 a one cent per pound. Congressional appropriators

have rejected the user fee proposal every year, arguing that the safety of the food supply is a legitimate responsibility of the government.

The Bush Administration's FY2003 and FY2004 budget requests included proposals to increase the industry's reimbursement for FSIS inspection of second and third shifts, arguing 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 did not adopt the proposal for FY2003. The House bill reflecting the President's FY2004 budget proposal does not assume enactment of such a measure, and calls for a \$42 million in FSIS funding bills have not yet been marked up.

FSIS received \$759.8 million in the omnibus FY2003 appropriations act, P.L. 108-7, an amount that fully funds the President's budget request. Included in that is \$5 million specifically for FSIS to hire 50 additional inspectors to oversee the agency's compliance with the Humane Methods of Slaughter Act. FSIS came under criticism last year for reported lapses in its compliance with this act.

The FY2004 budget request for FSIS is \$797 million. Of the \$41 million increase, which would be provided from the Administration's proposal to raise second and third shift user fees, \$25.6 million would support hiring more inspectors and increasing laboratory capacity to strengthen quick detection and response to potential acts of bioterrorism.

Legislative and Administrative Actions

Pathogen Performance Standards. In part because of the *Supreme Beef* case, Senator Harkin made several attempts in both the 106th and 107th Congresses to add language to the inspection laws to clarify the Secretary's authority to set enforceable performance standards. Toward the end of the 107th Congress, Senator Harkin introduced The Meat and Poultry Pathogen Reduction and Enforcement Act (S. 2013, Harkin; H.R. 3956, Eshoo). This stronger and more detailed version of the earlier bills 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.

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*, is being conducted by the Institute of Medicine in collaboration with the National Research Council of the National Academy of Sciences. The report is due out in hard copy shortly, but can be read online at [<http://www.nap.edu/books/030908928X/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 56,800 samples since the program began; to date, 232 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, 2002, 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 had 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.

In August 2002, FSIS began investigating a meatpacking plant in Omaha, Nebraska Beef, for repeated violations of inspection regulations. In mid-January 2003, FSIS attempted to close down the plant after discovering *E. coli* O157:H7 in ground beef that the plant had supplied to another company. Nebraska Beef won a temporary restraining order against FSIS on the argument that its meat was safe, and a shut-down would destroy the company’s quality image and cause potentially disastrous economic loss. The U.S. District Court in Omaha was to review the case on January 24, but FSIS and Nebraska Beef came to an agreement before the court hearing. On January 25, 2003, the judge issued a consent order, which will be in effect for 2 years, that commits the company to abiding by certain obligations, such as putting a full-time employee in charge of overseeing the plant’s implementation of sanitary standards and its HACCP plan, and hiring an independent third party to assess the plant’s condition after 60 days.

USDA officials state that this settlement fully reaffirms FSIS's authority to enforce the laws and regulations. Nebraska Beef and other meat industry officials state that the settlement is a straightforward restatement of existing regulations. Consumer groups and some Members state that the case shows that FSIS is steadily losing its power to enforce food safety rules. The case is similar to the Supreme Beef case concerning *Salmonella*, in that, arguably, it shows that the original statutes may be insufficient to support actions that FSIS currently needs to take to assure that meat and poultry products are safe.

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 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 with new and specific instructions for monitoring processing plants that produce hot dogs and deli meats. The guidelines can be found at [<http://www.fsis.usda.gov/OPPDE/rdad/FSISDir7000.htm>]. On February 14, 2003, FSIS released a draft risk assessment on *Listeria* for public comment, saying that it will base its next proposals for controlling the pathogen on the final risk assessment.

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, Members of both Houses introduced bills not only to 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 had been introduced earlier in the 107th Congress that would have given FSIS authority to levy civil penalties on packers that violate inspection laws, and 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.) Another bill 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.

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, 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 Secretary 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 [<http://books.nap.edu/books/0309065593/html/index.html>]. 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 Commission did not receive funding for FY2003, however. The latest NAS report on food safety, *Scientific Criteria to Ensure Safe Food*, (currently only available online), recommends that Congress "...require the development of a comprehensive national plan to harmonize the foodborne disease surveillance conducted by public health agencies with the monitoring of pathogens across the production, processing, and distribution continuum conducted by food safety regulatory agencies."

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).

On June 2002, the President signed into law the Public Health Security and Bioterrorism Preparedness and Response Act (P.L. 107-188). The Act authorized an additional \$15 million in FY2002 and such sums as necessary in subsequent years to strengthen FSIS's inspection force. The 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 such damage. Authorities in the Act to increase the inspection of meat and poultry imports at U.S. ports of entry were shifted to the Department of Homeland Security under the Homeland Security Act of 2002 (P.L. 107-296), which transferred the APHIS border inspection function and personnel to the new department.

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 December 1999, 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. Nonetheless, the newest NAS report on food safety (2003) states that consumers should be notified that even irradiated ground beef should be cooked to 160 degrees to ensure safety from *E. coli* O157:H7. Retailers of meat products, especially ground beef, increasingly are offering irradiated products for sale. Some research studies show potential consumer acceptance of irradiated ground beef could be as high as 50%, but 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. FDA would have to publish proposed regulations to be complying with the law, but it has not done so to date.

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. FSIS also recently announced a new regulatory sampling program to test meat that has been mechanically removed from bones to ensure that no spinal cord tissue is present. This tissue would carry the risk of BSE if the disease were to be detected in U.S. beef herds. (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 (due date unknown).

LEGISLATION

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.

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.