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Meat and Poultry Inspection Issues

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Jean M. Rawson
Resources, Science, and Industry Division

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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.

Since September 11, much of the Congress's and food inspection agencies' attention has focused on assuring that food and the U.S. agricultural production system are adequately protected from bioterrorism. On May 22 and 23, the House and Senate, respectively, passed the conference agreement on H.R. 3448, the Bioterrorism Preparedness Act. The Senate bill authorizes $15 million for enhanced FSIS inspection activities, along with additional funds for USDA and state-level research on bioterrorism detection and response.

Prior to the concern with bioterrorism, Congress 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 has been 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.

Although most consumer advocates, the meat and poultry industries, scientists, and USDA officials state that recent program and policy reforms have improved meat and poultry safety, implementation of HACCP has not quelled congressional debate on how to maintain progress and whether further improvements in meat and poultry safety — through regulatory and/or legislative changes — are needed.

Both before and since September 11, lawmakers have introduced measures intended to consolidate and modernize the inspection of *all* foods, including meat and poultry (S. 1501, Durbin), and to give FSIS stronger enforcement powers (H.R. 1276, H.R. 3127). In addition, two bills have been introduced to establish the Secretary's authority to prescribe performance standards for pathogen reduction (S. 2013, S. 2532). These proposals relate to a federal court ruling in 2000 (which was reaffirmed on December 11, 2001) that held that FSIS does not have the statutory authority to use *Salmonella* bacteria test results as a basis for enforcement decisions under HACCP.

The Bush Administration's homeland security department proposal currently does not address protection of the food supply other than by transferring to the new agency USDA's Animal and Plant Health Inspection Service (APHIS), which, among other things, provides border inspection for agricultural and food imports. The Administration has stated that it might propose consolidation of food safety agencies under one entity shortly.

MOST RECENT DEVELOPMENTS

On June 24, 2002, Representative Dick Armey introduced the Administration's bill to create a Department of Homeland Security (H.R. 5005). Although the measure does not specifically address protecting the Nation's food supply as part of homeland security, Director Tom Ridge testified on June 20 that the Administration is considering an eventual merger of the federal food safety agencies into the proposed department or a separate entity. H.R. 5005 proposes transferring USDA's Animal and Plant Health Inspection Service(APHIS) into the security department along with several other federal agencies with border security responsibilities. FSIS-regulated meat and poultry imports are first inspected by APHIS at U.S. borders and ports of entry to ensure that they do not harbor foreign pests and diseases.

On June 12, 2002, President Bush signed into law the Public Health Security and Bioterrorism Preparedness and Response Act (P.L. 107-188). Title 3, Subtitle C of the Act contains provisions to enhance the biosecurity of U.S. agricultural production and the food supply, including $15 million to expand FSIS's inspection activities.

On May 17, 2002, legislation was introduced in the Senate to give the USDA Secretary authority to set and enforce microbiological performance standards, and for a variety of other purposes, including establishing a traceback mechanism for livestock and poultry and studying how to improve recruitment of meat inspectors (S. 2532).

On May 2, 2002, legislation was introduced in the House and Senate to create a Department of Homeland Security (S. 2452/H.R. 4660). These proposals would transfer APHIS's border inspection function, which provides initial inspection of FSIS-regulated meat and poultry imports, but not its domestic agricultural protection programs.

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 operates 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.

In December 1999, a coalition of eight major meat industry trade associations petitioned FSIS asking the agency to tighten and clarify certain sections of the 1996 HACCP final rule. Two lawsuits, one in 1999 and another in 2000, also have challenged FSIS's authority to carry out HACCP reforms under existing statutes. These events raise the question of whether the original laws sufficiently undergird FSIS's stated intention to move to a science-based 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* prevalences 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(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. Nonetheless, 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). Imports from foreign countries must be processed under equivalent inspection systems and be certified prior to entry into the United States.

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. Contaminated, adulterated, and misbranded products, or parts of them, can be condemned and removed from 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. As mentioned above, a significant portion of the packing industry already was using HACCP-type processes before they became mandatory. Most of these plants already conduct their own pathogen testing, but events since the start of HACCP implementation indicate that although plants for the most part have been staying within the new national *Salmonella* standard, the industry finds the standards problematic. 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.

However, other members of the meat and poultry industry argue that the regulation goes too far beyond HACCP, by establishing what they view as impractical, expensive microbiological testing and unrealistic microbiological standards. 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.

Petition for Changes to the Rule. In December 1999, the American Meat Institute submitted a petition on behalf of eight major meat industry trade associations asking FSIS to tighten and clarify sections of the 1996 HACCP final rule pertaining to: (1) what constitutes a food safety hazard under HACCP; (2) the extent of a plant's responsibility after the product is shipped; and (3) events that signal that a plant's HACCP plan is inadequate. FSIS published the petition in the May 15, 2000 *Federal Register* (65 FR 30952) and asked for responses to six specific questions concerning the scientific and regulatory aspects of the petition; the comment period was re-opened twice and finally closed in late December 2000. At a June 2001 public meeting of the Advisory Committee, FSIS announced it might issue a proposed rule reflecting agreement with certain parts of the petition concerning sanitation, but that further changes in definitions might prove confusing rather than helpful to inspectors.

Recent HACCP-related Legal Actions.

Supreme Beef. 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.

The original ruling in May 2000 applied only to meat processors in the judge's district in Texas. In part because Supreme Beef subsequently went out of business, USDA asked an appeals court in 2001 to overturn the ruling. However, on December 11, 2001 the court upheld the district court's decision. On December 18, 2001, 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 a way to measure the effectiveness of plants' food safety programs.

As evidence in support of its action against Supreme Beef, USDA has stated that only three of 6,400 federally inspected plants have ever failed to meet the standard. Opponents maintained that until scientists could determine what constitutes an unsafe level of *Salmonella* in ground meat, pathogen testing results should not be a basis for enforcement actions. 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 adding microbiological standards to the meat and poultry inspection statutes.

Senator Harkin has made several attempts to amend the meat and poultry inspection statutes to clarify the Secretary's authority to set enforceable performance standards for the reduction of pathogens in meat and poultry. 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 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 complete scientific reviews of the issue in 2002. In March, companion measures containing stronger and more detailed versions of the earlier amendments were introduced as separate legislation. The Meat and Poultry Pathogen Reduction and Enforcement Act (S. 2013, Harkin; H.R. 3956, Eshoo) would require 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 enforce 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.

On May 17, 2002, Senator Schumer introduced related but more comprehensive legislation that would: (1) establish microbiological performance standards; (2) establish livestock and poultry traceback systems; (3) require states to report illnesses from meat and poultry products to the CDC; (4) protect employees at federally inspected meat and poultry plants who report food safety problems from intimidation by their employers; (5) list biological threats to the food supply and enhance preparedness and response plans; and (6) conduct 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.

HACCP-based inspection models project. In 1998, the meat inspectors union charged that a pilot project that FSIS planned to begin in October 1999 would violate language in the meat and poultry inspection statutes that mandates carcass-by-carcass inspection at slaughter operations. The pilot project, called the HACCP-based inspection models project (HIMP), permits FSIS inspectors at approximately 25 chicken, turkey, and swine slaughtering operations to leave the inspection line periodically to conduct increased sampling for microbiological contaminants and to verify the compliance records of plant employees who are now carrying out some of the hands-on inspection and corrective actions that inspectors used to do. Underlying the inspector union's charge is the concern that such a move would threaten inspectors' jobs. In June 2000, a federal appeals court upheld the union's position concerning the statutory language, but did not prohibit FSIS from proceeding with the pilot project. In August 2000 the union asked the court to stop the project; in the meantime, FSIS in September implemented a change in the project to require an inspector to be permanently stationed at the end of the slaughter line. In January 2001 the court ruled that the HIMP project could continue because the changes that FSIS made in September 2000 brought it into compliance with the law. The inspector's union subsequently filed another appeal.

In January 2002, GAO released a new report critical of the HIMP project. The GAO states that (1) the pilot program has design and methodology limitations that compromise the overall validity and reliability of its results; (2) FSIS did not train meat and poultry plant personnel prior to program implementation; (3) the data do not conclusively show that modified inspections are at least equal to traditional inspections; and (4) GAO stands by its long-standing recommendation that legislative changes be made to provide FSIS with clear authority to modify its inspection system [http://www.gao.gov/]. The same month, FSIS issued a statement saying it intended to extend the program to additional plants on a voluntary basis, and that it would publish proposed regulations to address certain of the GAO's criticisms. On March 29, 2002, the federal appeals court ruled that FSIS could continue

HIMP, but stated that any future rulemaking to make permanent changes would likely prompt further judicial review.

In the initial stages of the controversy, officials and industry observers noted that the court's original decision was based on a strict interpretation of the language in the inspection laws and *not* on the efficiency of a change in division of labor or the effectiveness of the HIMP project from a food safety standpoint. FSIS released preliminary data in July 2000 showing that chicken slaughtering plants operating under the HIMP system experienced a 100% decrease in the incidence of diseased carcasses and a 92% decrease in fecal contamination on carcasses, a leading source of potentially illness-causing bacteria. The January 2002 GAO report disputes the validity of these results, but FSIS officials maintain that the data collected accurately demonstrate the project's performance. Nonetheless, the GAO report elicited a strong, negative public reaction to HIMP from at least one major consumer watchdog organization. Prior to this, consumer and food safety groups generally were withholding judgement on HIMP until more performance data could be evaluated.

Funding Issues

USDA for several years has experienced difficulties in meeting its inspection obligations with the annual appropriation it receives from Congress. Among the reasons given are that: (1) technological innovations have increased the amount of product needing inspection; (2) natural attrition in FSIS's sizeable workforce creates steady hiring pressure and it can be difficult to find and retain qualified employees, especially in certain geographical locations; and (3) the addition of HACCP requirements on top of the traditional carcass-by-carcass inspection duties puts additional pressure on adequate inspector staffing.

For almost two decades prior to the current Administration, the President's annual budget request has included a proposal to charge the meat packing industry user fees sufficient to cover the entire cost of federal inspection services – one rationale being that resources would then be adequate to hire new inspectors as necessary. 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.

Separate from a user fee to cover all inspection costs, FSIS has charged user fees for overtime and holiday inspection services since 1919. The agency currently collects approximately $100 million annually from such fees. These funds are available to the agency for supporting its inspection activities.

For FY2003, the Bush Administration is requesting $763 million in FSIS appropriations (+ $47.4 million) and assumes the availability of an additional $101 million in standard user fees collected for overtime and holiday inspection. Although the Bush Administration's FY2002 budget request did not contain the user fee proposal found in previous administrations' budgets, the FY2003 request does propose user fee reform. The Administration proposes to require processing firms to pay a fee to obtain an FSIS license; the collected fees would support FSIS investments in inspection technology. A second proposal would reduce current overtime fee rates and instead charge establishments for inspection services on second and third shifts; such service now is provided without reimbursement.

The FY2002 appropriations act for USDA (P.L. 107-76) provides $715.6 million for FSIS for FY2002, plus an additional $15 million from P.L. 107-117 (the $20 billion Defense supplemental funding measure) for increased inspection and preparedness activities.

Current Legislative and Regulatory Actions

FSIS Bioterrorism Preparedness

Since September 11, 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 on December 20, 2001. The House-passed version (passed on December 12, 2001) did not contain any USDA-related authorities. Conferees were named in February 2002, and the conference report was filed on May 21 and passed by the House on May 22 and the Senate on May 23 (H. Rept. 107-481). The President signed the bill into law on June 12, 2002 (P.L. 107-188, the Public Health Security and Bioterrorism Preparedness and Response Act).

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. The Act also authorizes an additional $180 million for upgrading security and biocontainment at ARS labs, and $190 million for increased state and ARS research on bioterrorism detection and response. Finally, the Act contains a provision that originally was in the House-passed 2002 farm bill (H.R. 2646). Title 3, Subtitle C, Section 336 of P.L. 107-188 makes it a federal criminal offense intentionally to damage the property or employees of public or private animal enterprises (e.g., an animal research laboratory or livestock or poultry slaughtering operation) and authorizes restitution for economic loss resulting from the damage.

On March 14, 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. The Protection of the Food Supply and Agriculture Production subcouncil coordinates FSIS/APHIS preparedness and response activities. In the event of a food-related biosecurity event, the Food Emergency Rapid Response and Evaluation Team (FERRET) authorized by the Agricultural Research, Extension and Education Reform Act of 1998 (P.L. 105-185) would join forces with the subcouncil. 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, has conducted mock exercises to improve response time and communication in emergency situations, and is working with slaughtering and processing operations to improve the security of both the physical plant and the workforce. The Food Threat Preparedness Network (PrepNet) is a joint FSIS/FDA group that works on threat prevention and emergency response.

Consolidated Federal Food Safety Agency

The question of bioterrorism preparedness has 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. Senator Durbin, a long-standing proponent of the single agency concept, reintroduced consolidation legislation shortly after the September 11 attacks, stating that such reform was necessary to protecting the food supply from terrorist threats (S. 1501, the Safe Food Act of 2001/H.R. 1671 (DeLauro)). A Senate Government Affairs Subcommittee hearing on October 10, 2001, on food safety preparedness included testimony on the single entity concept proposed in S. 1501. In a speech at a major food industry conference in March 2002, Homeland Security Director Tom Ridge stated that the Bush Administration is considering reorganizing or consolidating federal food safety agencies.

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.

The GAO restated its long-standing criticism of the current fragmented food inspection system at the October 10 hearing on S. 1501, 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. At a June 20,2002, hearing on the President's proposal for a Department of Homeland Security, Director Ridge testified that the Administration is considering consolidating federal agencies with food safety responsibilities into the new department or into a separate entity some time in the future. In the recently enacted 2002 farm act (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. (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).

Enforcement

Two bills have been introduced that address FSIS's enforcement powers separately from the anti-bioterrorism initiatives. Representative Lowey introduced a bill early in the 107th Congress that would give FSIS authority to levy civil penalties for packers that violate inspection laws (H.R. 1276). Shortly after September 11, Representative Udall introduced legislation that would amend the meat and poultry inspection acts to authorize FSIS to recall suspected contaminated products directly (H.R. 3127). Currently, the Secretary must go to the courts in order to recall potentially unsafe products if a firm refuses to issue a recall voluntarily. An August 2000 GAO study on FSIS and FDA recalls (*Food Safety – Actions Needed by USDA and FDA to Ensure that Companies Promptly Carry Out Recalls)* criticized 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 compile 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. Proponents 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 cases where a plant has refused to comply with USDA's recommendation to recall a suspected contaminated product have been extremely rare. Industry representatives have testified also 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.

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 November 30, 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. Senator Durbin has stated his intent to introduce legislation to require greater restrictions on the use of animal tissues carrying a high risk of BSE, and to enhance detection and response plans. (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. 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. Because most of these plants are small, most cannot afford the capital improvements needed to convert to federal inspection, which, they have contended, are not needed for food safety reasons.

Senators Daschle and Hatch introduced USDA-drafted legislation to lift the interstate shipping ban late in 1999. S. 1988 (the New Markets for State-Inspected Meat Act) would have amended the Federal Meat Inspection Act and the Poultry Products Inspection Act to allow state-inspected products to bear the official USDA inspection mark if the state program had entered into a cooperative agreement with USDA to enforce the same federal requirements enforced by FSIS. State programs that chose not to make the transition would be taken over by USDA. At an April 2000 hearing on the proposal, 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 testified in support of S. 1988. Testifying in opposition to the bill was the American Meat Institute (AMI), which represents the manufacturers of about 70% of U.S.

meat products. AMI stated 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. Congress took no further action on the bill after the hearing.

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.

Package Dating

A television news show recently 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

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. 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.

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.