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Statement of
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Mr. Chairman and Members of the Subcommittee, thank you for inviting me to appear before you today to address the ongoing investigation of the Hallmark/Westland Meat Packing Company (Hallmark/Westland) in Chino, California, and other related issues. I want to assure you that I am deeply concerned about the inhumane handling of non-ambulatory disabled cattle in that facility.

I am Dr. Richard Raymond, Under Secretary for Food Safety at USDA. While there are a number of agencies at the Department working together on this matter, the agency for which I have responsibility is the Food Safety and Inspection Service (FSIS). FSIS is the public health regulatory agency responsible for ensuring that meat, poultry, and processed egg products are safe, wholesome, and accurately labeled. FSIS enforces the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, which require Federal inspection and regulation of meat, poultry, and processed egg products prepared for distribution in commerce for use as human food.

FSIS also enforces the Humane Methods of Slaughter Act, which requires that all livestock at federally inspected establishments be handled and slaughtered in a humane way.

As soon as the Humane Society's video was released on January 30, Secretary Schafer called for an investigation into the matter. USDA's Office of the Inspector General (OIG) is leading that investigation, with support from FSIS and the Agricultural Marketing Service (AMS). This investigation is still ongoing, and in the meantime, FSIS has implemented a series of interim actions to verify and thoroughly analyze humane handling activities in federally inspected establishments.

I remain confident in the safety of the U.S. food supply. To help ensure its safety, we take a number of steps to prevent foodborne illness. FSIS employs over 9,000 personnel, including 7,800 full-time in-plant and other front-line personnel protecting the public health in approximately 6,200 federally inspected establishments nationwide. FSIS personnel must be continuously present for slaughter operations and must inspect processing plants at least once per shift per day. Under the FSIS verification sampling program, FSIS samples meat, poultry, and processed egg products and analyzes them for the presence of microbial pathogens. In addition to its targeted sampling for *Listeria monocytogenes* in ready-to-eat products, the agency has paid particular attention to *E. coli* O157:H7 in raw ground beef through the initiative announced last fall and *Salmonella* in raw meat and poultry products through the ongoing *Salmonella* improvement plan. To protect against bovine spongiform encephalopathy (BSE), the

federal government also has an interlocking system of safeguards, which I will describe in more detail later.

FSIS Actions

When we learned of the problems at Hallmark/Westland on January 30, FSIS took immediate steps to determine if the allegations made public by the Humane Society of the United States (HSUS) were accurate.

On February 1, 2008, Hallmark/Westland voluntarily stopped slaughter operations. As a result of FSIS findings, FSIS suspended inspection at the plant on February 4, 2008. This action was based on FSIS findings that the establishment failed to prevent the inhumane handling of animals at the facility, as required by FSIS regulations and the Humane Methods of Slaughter Act. When a plant is suspended, the suspension of inspection remains in effect until corrective actions are submitted in writing and verified through a full review by FSIS.

On February 17, 2008, FSIS amended the suspension to reflect the fact that Hallmark/Westland had allowed cattle that passed FSIS ante-mortem inspection and subsequently became non-ambulatory to be slaughtered without further inspection by FSIS personnel.

On March 18, 2008, FSIS granted the Hallmark/Westland Meat Packing Company's request for a voluntary withdrawal of inspection.

Evidence from the ongoing investigation demonstrates that, over the past two years, this plant did not always notify the FSIS public health veterinarian (PHV) when cattle became non-ambulatory after passing ante-mortem (prior to slaughter) inspection, as is required by FSIS regulations. This failure by Hallmark/Westland led to the company's February 17, 2008, voluntary recall of 143 million pounds of fresh and frozen beef products produced at the establishment since February 1, 2006.

It is important to note that certain cattle, while ambulatory when they pass ante-mortem inspection, may later become non-ambulatory from an acute injury or another circumstance. If such a situation occurs, FSIS regulations require the PHV to inspect the animal again and determine that the animal did indeed suffer from an acute injury before the animal is permitted to go to slaughter. Otherwise, the animal is condemned, does not go to slaughter, and therefore, does not enter the food chain.

While it is extremely unlikely that these meat products pose a risk to human health, the recall action was deemed necessary because the establishment did not comply with FSIS regulations. The recall was designated Class II because the probability is remote that the recalled beef products would cause adverse health effects if consumed. This recall designation is in contrast to a Class I recall, which is a higher-risk health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death.

Safeguards Against BSE

I am aware that this situation has raised questions about the risk of BSE. I would like to take this opportunity to give you a brief summary of the safeguards against BSE that the United States has in place to protect our food supply.

Since the discovery of the first case of BSE in Great Britain in 1986, we have learned a tremendous amount about this disease. That knowledge has greatly informed USDA's regulatory systems and response efforts. It has also given us the opportunity to examine our own cattle herd, which is why we know that the risk of BSE in the United States is extremely low.

As noted earlier, the federal government's interlocking system of controls to protect the food supply from BSE includes a ban on non-ambulatory disabled cattle. But that is simply one of the multiple measures in place.

We have learned that the single most important thing we can do to protect human health regarding BSE is the removal from the food supply of specified risk materials (SRMs) – those tissues that, according to scientific evidence, could be infective in a cow with BSE. FSIS requires that all SRMs are removed from carcasses so that they do not enter the food supply. Slaughter facilities cannot operate their slaughter operations without the continuous presence of FSIS inspection personnel to ensure safe and wholesome product,

including the removal and segregation of SRMs. According to the 2005 Harvard Risk Assessment, SRM removal alone reduces the potential exposure to consumers of BSE by 99 percent. FSIS line inspectors are stationed at key points along the production line where they are able to directly observe certain SRM removal activities. Other off-line inspection personnel verify additional plant SRM removal, segregation and disposal. Moreover, FDA bans SRMs in FDA-regulated human foods and cosmetics.

An additional significant step we have taken to prevent the spread of BSE and bring about its eradication in the animal population is the ruminant feed ban. In 1997, the FDA implemented a mandatory feed ban that prohibits feeding most mammalian protein to ruminants, including cattle. The feed ban is a vital measure to prevent the transmission of BSE to cattle.

Another step is BSE testing, which is best used as a surveillance tool. By testing high-risk animals, including those that show possible clinical signs of the disease, we can document the effectiveness of our security measures.

USDA's Animal and Plant Health Inspection Service (APHIS) has conducted targeted BSE surveillance testing since 1990, including an enhanced surveillance effort that was initiated after a cow tested positive for the disease in December 2003. The goal of the enhanced effort, which began in June 2004, was to test as many animals in the targeted population as possible over a 24-month period. Out of over 759,000 animals tested, this intensive effort detected only two additional animals with the disease. Both of those

animals were born prior to initiation of the FDA feed ban and neither entered the food supply. This testing confirms an extremely low prevalence of the disease in the United States.

The enhanced surveillance program provided sufficient data to allow USDA to more accurately estimate the prevalence or level of BSE within the U.S. cattle population. Based on this analysis, we can definitively say that the incidence of BSE in the United States is extremely low. APHIS continues to conduct an ongoing BSE surveillance program targeted to high-risk animals that samples approximately 40,000 high-risk animals annually. This level of surveillance significantly exceeds the guidelines set forth by the World Animal Health Organization, which has affirmed that U.S. regulatory controls against the disease are effective.

It is because of the strong system that the United States has put in place, and which we continue to work to strengthen, that we can be confident of the safety of our beef supply from BSE and that the spread of BSE has been prevented in this nation.

Regulations Regarding Non-Ambulatory Cattle

On July 12, 2007, FSIS announced a permanent prohibition on the non-ambulatory disabled or "downer" cattle from the food supply, except otherwise normal, healthy animals that become non-ambulatory after passing ante-mortem inspection. The rule, published in the Federal Register on July 13, 2007, made permanent what had been an

interim final rule published in January 2004. The final rule became effective on October 1, 2007.

Further Actions

The investigation led by OIG with support from FSIS and AMS is ongoing. However, we are not waiting for the completion of the investigation to act.

USDA has already taken a number of steps to strengthen our inspection system. Pending the conclusion of the investigation, USDA has implemented a series of interim actions to verify and thoroughly analyze humane handling activities in all federally inspected establishments.

FSIS has increased the amount of time allocated per shift by inspection program personnel to verify humane handling activities and to verify that animals are handled humanely in ante-mortem areas. FSIS is also conducting surveillance activities to observe the handling of animals outside the approved hours of operation from vantage points within and adjacent to the official premises. On March 3, the agency issued a notice to all FSIS inspection program personnel directing them to increase significantly the time they spend conducting humane handling verification activities at all levels and to document those verification activities in the Humane Activities Tracking System (HATS) program. This began on March 10 and will continue until May 6, a total of 60 days.

Surveillance and inspection activities are being prioritized and focused based on existing data such as the category of livestock handled at the facility, humane handling data, observations made at the facility during regular inspection, and a plant's operating schedule.

Prioritization will help to ensure the optimal use of resources to ensure humane handling and food safety. FSIS is focusing surveillance and inspection activities at establishments where older or potentially distressed animals are slaughtered, such as facilities that handle dairy or veal cattle. At these facilities, the time spent performing HATS activities will be doubled. At facilities with contracts from AMS for nutrition assistance programs, HATS verification time is being doubled, regardless of the type or class of the animal slaughtered. At facilities where non-ambulatory livestock are infrequently presented, such as in slaughter facilities that handle young market classes including steers, heifers, market hogs, and lambs, an additional 50 percent of HATS verification time may be required. At least once every two weeks, a District Veterinary Medical Specialist (DVMS) – a subject matter specialist dedicated to providing technical expertise and oversight related to humane handling and slaughter – or a district analyst is verifying that inspection personnel at each official livestock slaughter establishment are conducting the appropriate increase in HATS verification time. Any plant found not in compliance will be reported to the in-plant supervisor and the frontline supervisor.

Meanwhile, FSIS will begin reviewing HATS to determine what, if any, adjustments are needed to maximize its utility as a tracking tool to improve compliance.

FSIS has conducted humane handling verification audits at all 18 federally inspected beef slaughter establishments that are under contract and actively participate in USDA's Federal food assistance programs. Twelve of the establishments slaughter predominantly cull cows or veal calves, and six slaughter predominantly young market cattle.

FSIS' DVMSs visited each of the establishments along with in-plant inspection program personnel to analyze HATS data and review each establishment's systematic approach for humane handling. FSIS also analyzed the frequency of monitoring the HATS categories completed by PHVs and other in-plant inspection program personnel. The DVMS reported their findings to establishment management at the conclusion of each visit and issued recommendations or took enforcement actions, if necessary.

FSIS concluded that 17 establishments audited had acceptable humane handling programs and practices. However, based on observations during the audit, FSIS issued a non-compliance record (NR) at three establishments: one establishment received an NR for overcrowded holding pens; one for excessive use of electric stunning prods; and one for excessive balking at the stunning area. In addition, one establishment received a Letter of Concern for using a high-powered hose to wash cattle before slaughter. Although no inhumane activity was observed, FSIS notified the establishment that, while the use of a high-powered hose to wash cattle is not a violation of FSIS regulations, care should be taken while conducting this activity to avoid undue stress or excitement to the animal.

One establishment's humane handling program was not acceptable. That establishment was issued a Notice of Suspension because of inadequate stunning that did not render the animal insensible on the initial stunning attempt. The establishment took corrective measures and FSIS notified the establishment that the suspension is being held in abeyance to provide the establishment an opportunity to demonstrate that its corrective measures effectively remedied its problems with stunning.

Based on its review of HATS data going back to July 1, 2007, FSIS found that the time spent by FSIS inspection program personnel at the 18 establishments on HATS categories is acceptable. Even so, as a result of the audit, FSIS inspection program personnel made modifications to their HATS procedures for five establishments to improve FSIS protocols even further. Those modifications included: increasing the amount of overall time FSIS inspection program personnel spend on HATS tasks, carrying out observations in a more random manner to confirm humane handling; and increasing the amount of PHV time assessing stunning.

The investigation being led by OIG with support from FSIS and AMS is ongoing. Once the investigation has concluded, we will have additional information that, along with the results of the additional verification activities, will determine the actions for FSIS oversight, inspection and enforcement that may be required.

Efforts to Fight Foodborne Pathogens

In addition to BSE, I wanted to take this opportunity to provide the Subcommittee with an update on some of the agency's activities regarding some specific foodborne pathogens. Based on Centers for Disease Control and Prevention's (CDC) annual FoodNet data reports, we have made some progress toward meeting the Healthy People 2010 goals regarding the incidence of foodborne illness. However, the majority of this progress was made during the beginning of the decade, and has slowed in recent years. Thus, we still have work to do in the fight against foodborne illness.

FSIS' verification sampling is a critical method the agency uses to collect data and is a good example of how we have taken a more risk-based approach. Under the agency's verification sampling program, FSIS samples meat, poultry, and processed egg products and analyzes them for the presence of microbial pathogens. However, the agency has paid particular attention to *E. coli* O157:H7 in raw ground beef and *Salmonella* in raw meat and poultry products through the *E. coli* O157:H7 initiative announced last fall and its ongoing plan to improve establishment controls over *Salmonella*.

The new, ongoing actions we have undertaken to protect the public against the risk of *E. coli* O157:H7 include expanded testing. By March 2007, FSIS had already begun testing trim, the primary component in ground beef, in addition to ground beef itself. However, as a result of an increase in *E. coli* O157:H7-positive samples, the subsequent increase in

the number of *E. coli* O157:H7-related recalls, and the increase in human illnesses linked to these recalls, FSIS implemented a number of initiatives to combat *E. coli* O157:H7.

On October 26, 2007, FSIS inspection program personnel began testing additional components of ground beef. By testing earlier in the production chain, FSIS minimizes the likelihood that a contaminated source material will be used in ground beef that is available to consumers. FSIS began requiring countries whose beef is imported to the United States to conduct the same trim and beef component sampling or an equivalent measure, and the agency has begun verification sampling of trim at ports of entry to supplement the agency's sampling of ground product at ports of entry. We will be analyzing imported and domestic product test results to determine whether we need to make further changes to FSIS policies and programs.

Other key initiatives targeted to federally-inspected plants that produce raw beef products include verifying control of *E. coli* O157:H7, the creation and use of a new checklist for verifying control, targeted sampling for *E. coli* O157:H7 at slaughter and grinding facilities based on production volume and pathogen controls, follow-up sampling of 16 samples and conducting food safety assessments for plants with a Federal or State positive *E. coli* O157:H7 test result, and refinement of the agency's *E. coli* O157:H7 test method to provide a more sensitive test that will detect *E. coli* O157:H7 at even lower concentrations. All of these policy changes mean that FSIS will be better able to identify an emerging problem earlier in the production chain and will be able to prevent contaminated product from entering commerce.

In the wake of these progressive *E. coli* O157:H7-related policy changes, FSIS determined that steps were also needed to ensure that inspection program personnel and the industry fully understand the nature of the challenge presented by *E. coli* O157:H7. We are developing a strong, ongoing strategy to evaluate the success of our training program. Through the In-Plant Performance System, AssuranceNet management controls, and reports from district analysts, the agency is ensuring that inspection program personnel are doing their jobs correctly, are held accountable, and have appropriate workloads and supervision.

As with any policy or program change, FSIS is making sure that we educate and receive feedback from our public health partners and stakeholders regarding our *E. coli* initiatives. For example, on October 17, 2007, FSIS, FDA, and CDC hosted a public meeting regarding *E. coli* serotypes other than O157:H7 that are related to foodborne illness. In October and November, 2007, FSIS targeted outreach and training sessions around the country for small and very small raw beef processors. On January 23, 2008, FSIS participated in a meeting with the American Meat Institute Foundation and the National Meat Association about *E. coli* O157:H7 surveillance and prevention.

We will continue to work to identify the cause of the recent increase in *E. coli* O157:H7 illnesses and recalls, and to find a permanent, workable solution to the issue. We just held a public meeting, April 9-10, 2008, focused on a discussion with representatives from science, academia, industry, consumer groups and government, about the increase

in illnesses and recalls attributed to *E. coli* O157:H7. This meeting provided updates on FSIS initiatives and helped to continue to build a foundation for establishing solutions to address the challenges posed by this pathogen.

On May 15th and 16th, FSIS will hold a meeting with its State and local public health partners, as well as CDC, industry and consumer groups in St. Louis, MO, about how to improve the effectiveness and efficiency of outbreak investigations and recalls conducted by FSIS in collaboration with these partners. Every *E. coli* O157:H7-related recall last year showed me something that we can improve, and I hope that these meetings will get everyone to start thinking about how to improve the coordination, accuracy, and timeliness of communication and food safety activities, specifically outbreak investigations and recalls.

Another important step in that direction is USDA's announcement on February 5, 2008, that the Department agreed to grant a conditional license to Bioniche for its *E. coli* O157:H7 cattle vaccine. This is the world's first vaccine that may be used as an on-farm intervention to reduce the amount of *E. coli* O157:H7 shed by cattle.

It is important to keep things in perspective. Although last year we observed a rise in *E. coli* O157:H7-positive samples and recalls, USDA has made tremendous progress in controlling *E. coli* O157:H7 overall. In fact, between 2002 and 2006, FSIS testing shows the percentage of samples testing positive for *E. coli* O157:H7 declined by 78.3 percent.

The Agency's *E. coli* O157:H7 initiatives and the industry's collective response helped drive down the rate of *E. coli* O157:H7-positive samples in 2002, 2003 and 2004, and these rates remained at 0.17 percent for 2005 and 2006. The percentage of *E. coli* O157:H7 positive samples for 2007 increased to 0.23 percent. However, to put that percentage into perspective, out of 12,000 samples taken in 2007, only 27 were positive for *E. coli* O157:H7. Moreover, this rate was still well below the percentage of positives during the 2000-2003 timeframe

As another part of the agency's verification sampling program, FSIS collects and analyzes samples of raw meat and poultry product for *Salmonella*. In response to this continued foodborne threat, in February 2006, FSIS announced an 11-point, risk-based strategy for *Salmonella* reduction in raw products. The initiative included targeting resources at establishments with higher levels of *Salmonella* and changed the reporting and utilization of FSIS' *Salmonella* verification data test results.

We can easily see the positive results of this risk-based strategy. If we compare the plant categories based on broiler carcasses analyzed for *Salmonella* in 2005 to 2007, we see that the percentage of plants in Category 1, or those with sampling results amounting to half or less than half of the current standards, increased dramatically, from 35 percent to 74 percent. Likewise, the percentage of plants in Category 3 decreased significantly from 10 percent to two percent. Essentially, the percentage of young broiler carcasses that tested positive for *Salmonella* decreased by 50 percent – from 16 percent to 8 percent.

Earlier this year, FSIS announced further changes in its *Salmonella* policy to continue driving down the incidence of *Salmonella* in poultry. On March 28, 2008, FSIS began posting on its Web site results of completed sample sets from its Salmonella Verification Program for young chicken (broiler) slaughter establishments in performance Category 2 and Category 3. *Salmonella* performance results will be posted once per month (on or about the 15th). This information will include results received through the end of the previous month.

At this time, FSIS is not listing establishments in Category 1 and other establishments that do not have enough sets completed as required for Category 1. FSIS is looking at establishing a category for these establishments in the future.

The agency is also offering specific waivers to Category 1 establishments. With these waivers, those establishments with the lowest *Salmonella* rates will be able to test new procedures, equipment, or processing techniques that will facilitate improvements in the ongoing control of *Salmonella*.

Coordination with Public Health Partners

USDA participates in CDC's Foodborne Diseases Active Surveillance Network (FoodNet). This network is a collaboration among ten State health departments, CDC, USDA, and FDA that closely monitors the human health burden of foodborne diseases in the United States. It produces reliable estimates of the burden and trends over time for foodborne infections of public health importance. In the participating sites, FoodNet

conducts active surveillance for foodborne diseases and also conducts related epidemiologic studies that look at sporadic and outbreak foodborne infections to help public health officials better understand the epidemiology of foodborne diseases in the United States and how to target prevention strategies. FoodNet data are also used to evaluate progress toward meeting CDC's Healthy People 2010 national objectives for foodborne infections.

A sister system of FoodNet is PulseNet, a national network for molecular subtyping of foodborne bacteria, which was developed in collaboration with the Association of Public Health Laboratories (APHL) and is coordinated by CDC's PulseNet, links seemingly sporadic illnesses together and enables public health officials to more quickly identify and respond to multi-State illness outbreaks. In fact, through the use of PulseNet, State and Federal public health agencies are able to identify seemingly unrelated foodborne illnesses as actual outbreaks more quickly. Prior to PulseNet, many of these outbreaks would not have been recognized as outbreaks. These two systems allow agencies to collaborate and bring their specialized knowledge together to better protect public health.

FSIS also takes every opportunity to diversify and improve the data submitted to CDC's PulseNet. On August 30, 2007, FSIS and the Agricultural Research Service (ARS) signed a memorandum of agreement in order to share data on *Salmonella*. Specifically, the cooperative agreement served to set requirements related to the submission of *Salmonella* strains and carcasses from the FSIS/Pathogen Reduction, Hazard Analysis and Critical Control Point (HACCP) Verification, Baseline, and other programs to ARS

for testing. ARS tests include Pulsed-Field Gel Electrophoresis, which helps to determine the so-called DNA fingerprint of a pathogen; antimicrobial susceptibility tests; and other laboratory sub-typing procedures.

We are committed to working with all of our food safety and public health partners to use the data that is available and seek more data to be able to attribute illnesses to specific foods. To cite one important example, we held a public meeting in April 2007 with our stakeholders and partners and engaged them in a discussion about the importance of foodborne illness attribution data, how this data is being developed, and how it is being used. Because we believe attribution is important in public health decision making, we are pioneering the use of attribution data in our evolving public heath risk-based approach to inspection.

Conclusion

FSIS is committed to improving its approach to inspection to better focus on public health and risk. All of us with a stake in food safety must work to protect people, especially those most vulnerable to a foodborne illness – the very young, the elderly, the immune-compromised, and pregnant women.

Again, thank you for the opportunity to appear before you today. I would be happy to take your questions at this time.