Statement of
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United States Department of Agriculture
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Mr. Chairman and Members of the Committee, 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). As the Secretary announced last week, pending the conclusion of the investigation, we are implementing 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 food-borne 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.

Initial USDA Actions

As soon as we learned of the problems at Hallmark/Westland, USDA 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.

This suspension of inspection will remain in effect, and Hallmark/Westland will be unable to operate, until corrective actions are submitted in writing and verified through a full review by FSIS. This verification process will ensure that all animals will be handled humanely and none will be allowed to proceed to slaughter until Hallmark/Westland complies fully with FSIS regulations.

Evidence from the ongoing investigation demonstrates that, over the past two years, this plant did not always notify the FSIS public health veterinarian when cattle became non-ambulatory after passing ante-mortem (prior to slaughter) inspection, as is required by

FSIS regulations. 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 public health veterinarian 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. 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.

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 we have 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 the available scientific evidence, could be infective in a cow with BSE. FSIS requires that all SRMs, including the brain and spinal cord, 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 ninety-nine 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).

Likewise, another 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. This intensive effort detected only two additional animals with the disease, out of over 759,000 animals tested. 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 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.

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. As I mentioned above, 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. A notice has been issued to all FSIS inspection program personnel to reinforce the work methods for conducting humane handling verification activities at all levels and to ensure the greatest utility of the Humane Activities Tracking System (HATS) program. This began on March 3.

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.

FSIS will continue to collect information in HATS, which provides an accounting of the time spent by FSIS inspection program personnel performing specific tasks and the results of that inspection related to humane handling and slaughter. Starting on March 4, 2008, FSIS inspection program personnel assigned to Federally inspected livestock slaughter establishments increased the amount of time that they spend conducting HATS activities from anywhere between 50-100 percent. This increased HATS inspection will continue for 60 days and will be closely measured during that time.

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 the AMS for nutrition assistance programs, regardless of the type or class of the animal slaughtered, HATS verification time is being doubled. 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 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 to be in compliance will be reported to the in-plant supervisor and the frontline supervisor.

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

FSIS is currently auditing all 19 beef slaughter establishments that participate in AMS's nutrition assistance program. This is the first in a set of audits we will be conducting. We expect to complete that audit by the end of the week, when we will begin to analyze the results.

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 report to the Subcommittee some of the Agency's activities regarding some specific foodborne pathogens. Based on Centers for Disease Control and Prevention's (CDC) annual FoodNet data report, we are making some progress toward meeting the Healthy People 2010 goals regarding the incidence of foodborne illness, though we know we still have work to do to further reduce 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. 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 *Salmonella* strategy.

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.

In July 2007, after an unusual number of *E. coli* O157:H7 positives the month before, FSIS substantially increased the number of raw ground beef samples scheduled for July from 1,100 to 1,943 – an increase greater than 75 percent. After seeing nothing unusual in the positive sample rate in July, FSIS began scheduling samples for every raw ground beef establishment once per month (i.e., approximately 1,350 samples per month).

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 this 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 as early as possible and will be able to prevent contaminated product from entering commerce.

The agency is completing a more in-depth analysis of the data captured in responses to questions, filled out by FSIS inspection program personnel, about reassessment of HACCP plans related to *E. coli* O157:H7. Our preliminary data, completed in November 2007, shows that almost 96 percent of all beef slaughter and processing establishments reassessed their HACCP plans. We are analyzing these responses, and we anticipate that the analysis will lead to new policies, directives, or possibly rules and regulations.

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. Thus, we are planning a public meeting for April 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 will provide updates on FSIS initiatives and build a foundation for establishing solutions to address the challenges posed by this pathogen.

In mid-May, FSIS will hold a meeting with its State and local public health partners, including FDA, CDC, industry and consumer groups, 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, because of new policy implementation and closer oversight and by working with industry, 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. During this time there was also a reduction in illnesses attributed to *E. coli* O157:H7. There was a slight increase in 2006, but several of those illnesses were attributed to food outbreaks that were not related to meat products.

FSIS instructed plants to reassess their food safety plans in 2002. As a result of industry's hard work and commitment to making safer products, we saw the rates of positive samples decrease in 2002, 2003 and 2004, remaining at 0.17 percent for 2005 and 2006. To put that percentage into perspective, out of 12,000 samples taken in 2006, only 20 were positive for *E. coli* O157:H7.

Although we ended 2007 with 21 recalls due to *E. coli* O157:H7, the percentage of *E. coli* O157:H7 positive samples for 2007 – 0.23 – 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 2006 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 49 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, the agency will begin posting on its Web site completed verification test results from establishments performing in Category 2 or 3, beginning with young chicken slaughter establishments. The agency will also offer 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

In conjunction with CDC, FDA, and epidemiologists and public health laboratories in several States, FSIS continues to build upon existing data in the Foodborne Diseases Active Surveillance Network, or FoodNet, which conducts active surveillance of foodborne diseases, case-control studies to identify risk factors for acquiring foodborne illness, and surveys to assess medical and laboratory practices related to foodborne illness diagnoses. 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 collaborative national computer network of public health laboratories that link seemingly sporadic illnesses together and enable public health officials to more quickly identify and respond to multi-State illness outbreaks. In fact, through the use of PulseNet, we 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, 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.

How FSIS Ensures the Safety of Imports

I know another area of interest for the Subcommittee is how the Agency ensures the safety of imports. FSIS uses a comprehensive system to ensure that imported meat, poultry, and processed egg products are safe and secure. The three-part system includes a thorough analysis of each country's food laws and inspection systems to determine initial equivalence; on-site audits of each country's food safety system to verify that the system is implemented in accordance with what is in writing, and then to ensure equivalence is

maintained; and port-of-entry inspection on all FSIS-regulated meat, poultry, and processed egg products coming into the United States, with a few exceptions. The amount of FSIS-regulated meat and poultry imports has remained approximately the same over the past five years, hovering around four billion pounds of meat and poultry from 29 of the now 34 eligible countries, approved through rulemaking.

In addition to the initial re-inspection of product entering the United States, FSIS performs intensive random re-inspection on approximately 10 percent of the shipments of meat and poultry products. These re-inspection tasks include product examinations, microbiological analysis for pathogens, and/or a test for chemical residues.

Approximately five percent of shipments of imported meat and poultry products receive microbiological and chemical verification testing. This system is enhanced by FSIS' Import Surveillance Liaison Officers, who conduct a broad range of surveillance activities at import facilities and in commerce, and serve as liaisons to improve coordination with other agencies like U.S. Customs and Border Protection.

Access to the U.S. Customs and Border Protection's Automated Commercial Environment (ACE) database has provided FSIS a more targeted approach to identifying and controlling ineligible entries of FSIS-regulated product closer to the entry point, rather than after its release into commerce. In FY 2005, prior to FSIS' use of the ACE system, the amount of ineligible product removed from commerce that did not pass through import houses was a little over 36,000 pounds. In FY 2006, this amount

increased to 1.6 million pounds, and in FY 2007, 2.1 million pounds was identified, destroyed, or redirected to FSIS for re-inspection.

Interagency Working Group on Import Safety

Recently, I represented USDA in the Interagency Working Group on Import Safety, helping to determine which aspects of the U.S. food safety system can be strengthened. The President formed this Working Group to conduct an across-the-board review of import safety by U.S. importers, and by Federal, State, and local governments. It was also given the task of providing recommendations to the President that will help to further improve the safety of imported products.

In September 2007, the Working Group issued a strategic framework for doing more to ensure the safety of imported products. This framework outlines a risk-based approach that includes the principles of prevention, intervention, and response. The framework supports USDA's long-standing approach to evaluating and verifying the ability of foreign food safety systems to meet food safety requirements for meat, poultry, and processed egg products exported to the United States.

On November 6, 2007, the Working Group released an implementation action plan containing 14 recommendations and 50 action steps. The Working Group provided specific short- and long-term recommendations for import safety improvements and reflected stakeholder input received through several outreach activities, as well as from a public meeting that was held on October 1, 2007, at USDA headquarters here in

Washington. The Administration is working toward implementation of the Working Group's recommendations. Progress is being measured by each action step.

Continued Evolution of Inspection and Use of Risk

Because of my medical background and passion for public health, I have pursued the issue of how best to use risk in inspection. It has been a healthy debate. I believe this open and frank debate on risk needs to be expanded to include all foods.

We need to continue to pursue these looming questions: Where is the risk greatest and where do inspection and other resources belong? Not all food products are equal from a risk standpoint. I am encouraging all food safety partners to join together and assess all foods and ensure that we are getting the best return for the Federal investment in food safety for the American public.

Higher risk products and processes would appear to warrant a higher level of effort to ensure measures are in place and put into action to control pathogens, lowering the likelihood of foodborne illness. While inspection may be critical for some plants and products, a system of audits may be acceptable for products with less inherent risk, or processes with less risk or hazards, where established methods have proven effective to control pathogens.

We need to develop a uniform, consistent process to determine when and where inspection is warranted, based on the inherent risk of the product and a plant's

demonstrated control of that risk, and when and where audits are sufficient. I hope that we will collectively ask the tough questions and come up with answers for a new approach to inspection based on public health and risk.

Conclusion

FSIS is committed to improving its approach to inspection to focus on public health and risk. As a medical doctor and a public health professional, I believe that what all of us with a stake in food safety must accomplish is protecting 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 am now happy to take your questions.