A Review of the USDA's Expanded BSE Cattle Surveillance Program

Testimony of The Honorable Phyllis K. Fong

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U.S. Department of Agriculture

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Thank you, Chairman Davis and Chairman Goodlatte, and Ranking Members Waxman and Stenholm, for inviting me to testify on the U.S. Department of Agriculture's (USDA) Bovine Spongiform Encephalopathy (BSE) Expanded Surveillance Plan. It is an honor to be invited to this morning's joint oversight hearing.

The Office of Inspector General (OIG) at USDA fully recognizes that any occurrence of BSE in America's cattle population is a matter of widespread public concern, and can cause deep injury not only to our beef industry, but also to the sense of confidence that both American and foreign consumers have in our beef products. For me personally and for my colleagues and staff at OIG, BSE-related work is a top priority and one of the most difficult challenges we face. I appreciate the oversight and leadership that your Committees bring to this issue, and pledge OIG's assistance in this effort.

I want to thank USDA officials, and APHIS and FSIS employees, for their cooperation with OIG auditors and investigators. I want to especially thank Secretary Veneman for her interest in and support for OIG's efforts to review the Department's plans for its expanded BSE surveillance plan. Our goal is to assist the Department in its development and implementation of an effective BSE surveillance plan.

The Department faces a major undertaking in developing and implementing programs to keep BSE out of the U.S. cattle herd. Preventing BSE from raising concerns about the health of our cattle industry and public perceptions of food safety in the U.S. will require coordinated and cooperative efforts not only within the Department, but among all cattle industry stakeholders.

My testimony today will cover two distinct areas in which we have invested extensive resources over the past 5 months. First, I will summarize the results of the 2 investigations we conducted into allegations of misconduct with respect to the identification of a BSE-infected cow in Washington State in December 2003 and our investigation into the actions of USDA personnel involved in the failure to test a suspect cow in San Angelo, Texas in late April 2004. The second part of my testimony will

cover the findings and recommendations resulting from our audit of the Department's BSE surveillance program.

I. OIG BSE Investigations

A. Investigation of Statements Pertaining to the BSE-Positive Cow in Washington State.

Overview

A cow slaughtered on December 9, 2003 by Vern's Moses Lake Meats (Vern's), a beef processing company in Moses Lake, Washington State, tested positive for BSE on December 23, 2003. Allegations arose in news reports that a person or persons employed by USDA may have provided false or misleading information concerning the ambulatory status of the BSE-positive cow.

On February 3, 2004, an article in *The New York Times* reported that a former employee at Vern's "claimed that the BSE cow was ambulatory (a walker) and not a non-ambulatory (or downer) as recorded on the inspector's report." The former employee "believed the government changed the report on Dec. 23, during the panic at Vern's when a positive test was found."

On March 4, 2004, a UPI article reported further allegations from the same former employee. He alleged that due to duress from USDA management, the Veterinary Medical Officer (VMO) changed his inspection sheet to indicate it was a downer cow *after* it tested positive for BSE. This improper alteration allegedly was done to provide false support for the USDA position that its surveillance program for BSE, focused primarily on downer animals, was effective.

OIG initiated investigations to determine whether any USDA personnel or private parties provided false information or engaged in any intentional misconduct. We also examined whether USDA personnel and employees of the beef processing facility followed proper

procedures during the inspection of the BSE-positive cow, and during their collection, handling, and delivery of tissue samples from the infected cow.

Summary of OIG Findings

Our investigation found no instances where USDA personnel knowingly conveyed false or misleading information, or engaged in intentional misconduct. While some procedural errors led to concerns about whether USDA officials had accurately identified and traced the BSE-positive cow, APHIS and the Canadian Food Inspection Agency (CFIA) concluded that they accurately identified the BSE-positive cow.

OIG discovered no evidence that USDA personnel on site at Vern's on December 9, 2003, falsified any records pertaining to the condition of the BSE cow at the time of its inspection. On December 23, when the FSIS District Manager asked the FSIS VMO at Vern's to provide his inspection records from December 9, the VMO at Vern's did update and annotate the forms filled out during his inspections at the facility the day the BSE-positive cow arrived.

Our investigation did reveal procedural errors and inconsistent descriptions that gave rise to some of the public concerns that the identification of the BSE-positive cow may have been mishandled. For example, the VMO who inspected the BSE-positive cow did not comply with a regulatory requirement to affix an identifying ear tag to the suspect cow.

Our investigation also found that the former employee of Vern's, who alleged that the BSE-positive cow was ambulatory and healthy when it arrived at the facility, described a different animal from the one that arrived in the same trailer and later tested BSE-positive. The former employee's statements pertained to a white Holstein cow that arrived at Vern's on December 9, 2003, while the cow that tested BSE-positive was a black and white cow.

Description of Key Events

To address the allegations concerning the BSE-positive cow's condition upon arrival at Vern's, and allegations that USDA personnel engaged in misconduct or falsified reporting documents, OIG investigators performed the following activities: reviewed all pertinent USDA and processing facility records and forms containing information on the BSE-positive cow's handling and identification; reviewed pertinent USDA statutes and regulations, and policy directives; interviewed USDA officials and personnel involved in the case; interviewed managers and former employees of Vern's; interviewed officials at the company which sold the BSE-positive cow to Vern's; and interviewed the independent hauler who actually transported the cow to the facility.

i. Status of the BSE Cow

Several non-USDA employees involved in this matter provided OIG with comments on the condition of the BSE-positive cow on the morning it was delivered to Vern's. The independent hauler who transported the BSE-positive cow to the Vern's facility said in a sworn statement that the cow was ambulatory *at the time of loading*. The hauler did not remember the cow's condition when it arrived at the Vern's facility. The co-owners and foreman of the company that provided the cow to the hauler said the cow walked into the delivery trailer, but it had been seriously injured prior to its shipment to Vern's. One of the owners, who is also a veterinarian, told OIG investigators that while the BSE positive cow did walk into the trailer for delivery, it was very weak and it was possible that it became non-ambulatory by the time it got to the slaughtering site.

OIG investigators interviewed the former employee of Vern's who alleged that the BSE-positive cow arrived at Vern's in a healthy, ambulatory condition, and that the FSIS VMO at the facility later falsified his inspection sheet. He declined to provide a sworn statement. He described the BSE-positive cow as white, ambulatory, and in good condition. The former employee said he had no direct evidence that USDA officials changed their initial reports after the positive BSE test was reported. He said he believed

evidence of alteration would be provided by the fact that only one cow *did not* have its temperature taken, as shown by a handwritten notation of "unable to get temp" on the relevant form. He said that notation proved that the BSE-positive animal was a "walker," not a downer, because, had it been a downer, the VMO would have taken its temperature.

OIG investigators interviewed the Co-Owner of Vern's. He said the cow was lying down at the time the FSIS VMO inspected it, but he did not refer to the BSE-positive cow as a "downer" because he had a policy of not permitting non-ambulatory animals into his facility. The Co-Owner also said the (livestock) haulers understood this policy and that they signed an agreement that they would not mechanically load any animals for transport to Vern's. This was due to his concerns about animal welfare activists having previously protested the forced movement of downer animals in his area. In a written statement provided to a non-governmental organization, the Co-Manager said the cow was lying down in the delivery trailer when it was inspected by FSIS, but "the cow was *capable* of walking off the trailer and therefore was an ambulatory, non-downer cow."

The FSIS VMO who performed the first inspection of the BSE-positive cow at the delivery site (Vern's) provided a sworn statement to OIG investigators. He said the animal arrived at Vern's in a non-ambulatory (downer) condition -- it was lying down in the cattle trailer, along with 10 other animals. Ultimately, 2 of the 11 were able to get up and were deemed ambulatory. Two others were condemned and not allowed to enter the plant, one being dead on arrival. Thus, seven cows remained suspect downers. The cow that ultimately tested positive for BSE was in this group.

The VMO told OIG investigators that there was a <u>white cow standing in the trailer</u>, which he remembered because it was unusual for a Holstein to be almost entirely white. The VMO said this white Holstein <u>was ambulatory</u> during his inspection, and he did not determine it to be a suspect cow for disease. The VMO stated that the ambulatory white Holstein delivered to Vern's that morning was a *different* animal than the <u>non</u>-ambulatory cow, which he subjected to further inspection and which later tested BSE-positive. The

FSIS VMO said he never saw the BSE-positive cow get up and walk that day, and said no one on-site ever advised him that the cow became ambulatory prior to being killed.

The VMO told OIG investigators that he did not affix an ear tag to the BSE-suspect cow nor take its temperature. The VMO explained his actions by saying he did not affix ear tags in that instance in order to prevent the animals from experiencing further stress. He said he did not take the temperature of the cow that eventually tested BSE-positive because its position in the delivery trailer prevented him from doing so, and his professional judgment (based upon visual diagnosis) was that it was unwarranted.

On December 23, 2003, two weeks after his inspection of the suspect cow, the VMO said the District Manager for the FSIS Boulder, Colorado Field Office called him to request information about certain cows slaughtered at Vern's on December 9, without explaining why he wanted the information. (No internal or public announcement had yet been made that a cow from the facility had tested BSE-positive.) The VMO provided verbal information and later faxed copies of various FSIS and plant records to the District Manager, along with an unofficial form he had created and used to record inspection information at Vern's.

Just before faxing the records to the District Manager, the VMO stated he made additional notations on his original, unofficial form, such as "unable to get temp" for one cow under the column for temperature readings for suspect cows, and putting an asterisk and the name of the company that provided the cow. The VMO said he had no idea at that time that the cow for which those annotations were made had tested BSE-positive, and that he added the annotations to clarify the information on the form for the District Manager.

The VMO stated he did not falsify any document before or after the announcement that the cow tested positive for BSE, and that no USDA officials ever urged him to do so. He recorded the condition of the cow as he observed it at the time of inspection on December 9, 2003 -- using the term "sternal" to identify it as a downer animal, lying on its sternum.

An FSIS Consumer Safety Inspector was present when the VMO received the telephone request for information on a particular cow at the Vern's facility on December 23, 2003. The Consumer Safety Inspector said he overheard the District Manager request pertinent records from the VMO, and that he assisted the VMO in retrieving them. The Consumer Safety Inspector witnessed the VMO making the notations described above, and said the VMO described them as clarifications for the District Manager. The Consumer Safety Inspector also told us that the VMO commented to him at that time that the cow in question had likely been positioned against a wall, thereby preventing the VMO from taking its temperature on December 9th.

The FSIS District Manager in the Boulder Field Office who requested the FSIS and plant records from the VMO at the facility provided a sworn statement to OIG. The District Manager said that on December 23, 2003, he called the VMO and requested information on the disposition of all ante-mortem and post-mortem findings, as well as the tag number and trace-back information about one specific cow. He said the VMO had classified the BSE-positive cow as a downer upon inspection at the plant, and declared it a "U.S. Suspect" animal before it entered the plant (triggering requirements, generally, that such livestock be further examined/tested, the inspection be documented, suspect ear tags be affixed, etc.) The FSIS District Manager said that to his knowledge, the VMO was not asked to change or annotate any of the records or documents in question.

OIG took a sworn statement from a retired FSIS District Manager in Oregon who had been asked by Vern's Co-Owner to serve as a consultant to the facility after the public announcement that a BSE-positive cow was identified at his plant. (The retired FSIS official had no prior involvement in the case.) The retired FSIS District Manager said that on approximately December 24, 2003, the Co-Owner told him that the BSE-positive cow was a downer at the time of slaughter, but that if the cow had been prodded with a lot of effort it could "probably" have gotten up. Additionally, a FSIS Consumer Safety Inspector stated to OIG investigators that she observed that the BSE sampling process at the facility was not as well organized as at other plants she had worked at.

ii. The Identity of the BSE Cow.

The trace-back investigation conducted by APHIS and the Canadian Food Inspection Agency in January 2004 successfully identified the original Canadian owner of the BSE-positive cow, which enabled the agencies to locate the cow's hide, and DNA testing was then used to conclusively determine the cow's identity and origin. The cow's identity and origin were substantiated by the concurrence of the cow's Canadian ear tag registration number, photographs of the animal, a written description on its Canadian Health Certificate, inspection of its hide, and DNA testing. The trace-back evidence established by APHIS and Canadian officials shows that the BSE-positive cow had a black and white hide. OIG agents obtained photographs of the hide and verified its color and pattern. The trace-back evidence does not support the allegation that the BSE-positive cow had a white hide, as alleged by a former employee of Vern's.

The OIG investigation found no evidence of falsification of records or other intentional misconduct by USDA personnel. Our investigation found that the FSIS VMO who performed the inspection and oversaw the processing of the suspect cattle at the delivery site, including the BSE-positive cow, did not comply with a requirement to affix a "U.S. Suspect" ear tag to all downer animals. We determined that the VMO's failure to affix an ear tag and decision not to take the BSE-suspect cow's temperature did not have a material effect on the handling, testing, or identification of the cow by USDA.

Our investigation further determined that one brain tissue sample from a suspect cow was mistakenly left at the USDA office in the facility by a Washington State veterinary official on December 10, 2003, when he picked up samples for mailing to the USDA's National Veterinary Services Laboratory (NVSL) in Ames, Iowa. The State veterinary official subsequently gave an erroneous sample number to the sample. However, this improperly handled tissue sample was not from the BSE-positive cow, and did not affect the identification of the infected cow.

B. Investigation of Handling of CNS-Suspect Cow in San Angelo, Texas

Overview

On May 4, 2004, the FSIS Acting Regional Director in Dallas, Texas reported that a cow identified as having Central Nervous System (CNS) symptoms by an FSIS veterinarian at Lone Star Beef Processors (Lone Star Beef), a beef processing facility in San Angelo, Texas was not tested for BSE after it had been slaughtered. The initial decision by the FSIS Veterinary Medical Officer (VMO) on-site at Lone Star Beef to have the cow tested for BSE was overturned by a senior APHIS official and the cow's carcass was sent to a rendering plant. FSIS regulations at the time of the incident required VMOs to contact the APHIS Assistant Area Veterinarian in Charge (AAVIC) to allow APHIS to collect a BSE surveillance sample from suspect cattle.

OIG initiated an investigation to determine if the AAVIC in Austin, Texas, provided a false statement to USDA FSIS investigators during their inquiry of his decision not to test the animal at Lone Star Beef. To conduct our investigation, OIG reviewed previously obtained statements, various documents and USDA regulations, and interviewed APHIS, FSIS, beef processing facility, and rendering company personnel.

Summary of OIG Findings

The OIG investigation found no substantive evidence that the USDA official(s) responsible for the decision not to take brain tissue samples from the cow for BSE testing, or any other USDA personnel, provided false information or engaged in intentional misconduct. We determined that a misjudgment was made by at least one USDA veterinary official in the handling of the suspect cow. Sworn statements provided by the two responsible USDA veterinary officials involved differ as to whether both concurred in this decision.

The suspect cow's carcass was sent to a rendering plant in San Angelo on April 27, 2004 for processing as inedible by-product. APHIS then utilized its "Indemnity Plan"

procedures to purchase the by-products as a preventative safety measure, and disposed of it at a local landfill in accordance with applicable environmental standards.

Evidence shows that at the time of this incident, communication problems occurred between the APHIS and FSIS employees involved. Taken together, the statements of both APHIS and FSIS personnel and other evidence indicate inconsistencies in their understanding of procedures for BSE tissue sampling of CNS suspect cattle in certain circumstances, and the handling of the carcass pending test results. It is apparent from the sworn statements provided to OIG that APHIS and FSIS personnel and Lone Star Beef officials could not resolve how best to proceed, and that confusion existed about how to properly handle the CNS-suspect carcass.

On May 5, 2004, FSIS and APHIS Veterinary Services announced a new joint policy regarding BSE sampling of condemned cattle at slaughter plants. The policy establishes protocols for the agencies' responsibilities to obtain samples from condemned cattle exhibiting signs of CNS disorders, regardless of age. The policy provides that FSIS will henceforth do all sampling at Federally-inspected slaughter facilities. For any condemned cattle that APHIS samples for BSE at other facilities, the protocols request (though not require) that the carcass not go to inedible rendering until the sample comes back negative.

Description of Key Events

At approximately 8 a.m. on April 27, 2004, the cow that later became the subject of controversy was delivered to Lone Star Beef in San Angelo, Texas. The cow's owner informed OIG investigators that it had injured itself some months earlier and, subsequently, experienced difficulty in walking. Upon its arrival at Lone Star Beef, an FSIS VMO and a Lone Star Beef employee saw the cow stagger, fall, and then get up. The VMO condemned the cow for exhibiting CNS disorder symptoms. The cow was then immediately killed and injected with dye by Lone Star Beef workers, to mark the carcass as unusable for human consumption. These actions by Lone Star Beef

employees were premature because, at that time, APHIS's regional BSE protocol called for CNS-suspect cattle to be transported live to Texas A&M University for observation, tissue sampling, and disposal.

The FSIS VMO notified an APHIS Animal Health Technician that he had condemned a cow at Lone Star Beef for CNS symptoms, and the Technician arrived at the facility to take a brain tissue sample for BSE testing. Before a tissue sample was taken, the FSIS VMO and APHIS Technician spoke to Lone Star Beef officials about what to do with the cow's carcass during the period in which the BSE testing of the tissue would be performed. The USDA personnel and Lone Star Beef officials could not reach agreement on proper retention of the carcass; company officials did not want to keep a decomposing carcass on site, since they believed that a local landfill would refuse to take the carcass.

Seeking a resolution to the dispute, Lone Star Beef's vice president placed a phone call to the AAVIC at the regional office in Austin, Texas. In the sworn statement he provided to OIG investigators, Lone Star Beef's vice president said he informed the AAVIC that, based upon an employee's description of the cow's condition before it was killed, the vice president believed the cow was possibly experiencing wheat poisoning, not CNS disorders. The vice president informed the AAVIC that he rejected the recommendations of the USDA personnel on-site to preserve the carcass at the facility, or transport it to a landfill, for the reasons stated above. The vice president said the AAVIC then told him APHIS would not require a brain tissue sample for BSE testing from the carcass, and that it could be sent to a rendering facility.

The most senior facility official on site, the president of Lone Star Beef, said he was present at the meeting where this phone call to APHIS took place, and that his vice president informed him that the AAVIC said APHIS was not going to take a tissue sample.

The APHIS Technician who had arrived on site intending to perform the tissue sample extraction from the carcass provided a sworn statement to OIG. She stated that in a

phone call subsequent to that between the Lone Star Beef vice president and the AAVIC (described above), she was directed by the AAVIC not to take a brain tissue sample. The FSIS VMO who had condemned the cow told OIG investigators that upon being handed a cell phone by the Technician, he spoke with an unidentified person at APHIS who said, "*We have decided not to take a sample*."[1] The VMO assumed this to mean that APHIS had determined no sample for BSE testing was necessary. However, the VMO told OIG investigators that he never changed his original diagnosis of CNS. This phone conversation between the APHIS AAVIC and the FSIS VMO was the determining action that prevented BSE testing of the CNS suspect carcass.

The AAVIC's sworn statement differs with the FSIS VMO's description of what substantively transpired during the phone call. The AAVIC said that when he received the earlier call from the Lone Star Beef vice president about the problem of handling the carcass, the vice president said the following: the "FSIS" at the facility (namely, the VMO who condemned the cow) had improperly handled the cow; he believed the cow likely had wheat poisoning, not a CNS disorder; and that his facility did not have a place to hold the carcass during any BSE test analysis period. The AAVIC said he then followed up this conversation with a call to the FSIS VMO on site.

The AAVIC states that he and the VMO then discussed the suspect cow's condition before it had been slaughtered. He said the VMO advised that the only problem observed with the cow was that it had fallen and could not get up. The AAVIC said the VMO never said the suspect cow had ever staggered. The AAVIC said that during this conversation, he and the VMO agreed on the following points: many things could have caused the animal to fall and not be able to arise, therefore it need not be sampled for BSE or classified as a CNS condemnation; and due to the lack of CNS symptoms, the carcass could be sent to a rendering facility. At approximately 2:45 p.m., the carcass was picked up by San Angelo Services, and taken to its rendering facility.

[1] The individual was the AAVIC. The AAVIC states in his sworn statement to OIG that he spoke on the phone with the VMO.

At the conclusion of this phone call with the FSIS VMO, the AAVIC said he called Lone Star Beef's vice president to inform him that he (AAVIC) and the VMO agreed the carcass could be sent to the rendering facility. The AAVIC then directed the APHIS Technician on-site not to take any tissue samples from the carcass. When questioned about this decision by OIG investigators, the AAVIC said the decision made on this particular animal was not out of the ordinary, and that as an AAVIC, he made such decisions on a regular basis.

This concludes the summary of OIG's investigations into the conduct of USDA personnel involved in BSE-related incidents in Washington State and San Angelo, Texas. We found no criminal conduct or intentional misconduct by USDA personnel. However, the cases are significant for illustrating some of the difficulties USDA faces in establishing and implementing an effective BSE surveillance plan. Our investigative findings demonstrate the need for the Department to issue clear regulations and policies for BSE inspection and testing, and to provide APHIS and FSIS field personnel with the training and guidance to effectively implement them.

II. OIG's BSE Audit Work

I will now provide an overview of our audit work pertaining to the Department's BSE surveillance efforts.

On July 1, 2004, we provided the Department with a draft audit report containing the results of the first phase of our assessment of USDA's BSE surveillance plan. The focus of our audit was to review the statistical validity of the expanded BSE sampling and testing program, to determine if the plan would enable USDA to achieve its stated statistical objectives. Because the plan's development and implementation were still evolving, we also conducted fieldwork prior to June 1 to provide observations on any issues and inherent challenges USDA will need to address to ensure a successful expanded program as it is implemented.

Customarily, the Department has 30 days to respond to official draft OIG audit reports. I therefore want to emphasize that our report is not final, since the Department has not had sufficient time to fully evaluate and officially respond to our findings and recommendations. Once we receive their response, we will evaluate their comments and make any necessary modifications to the report, including incorporating their response where appropriate.

This audit is the first in a series of reports we are planning to issue on our evaluation of USDA's BSE surveillance activities. We initiated this audit while the Department was in the process of developing its expanded surveillance program, which began on June 1, 2004. Our goal has been to provide impartial observations and recommendations early in the process to assist the Department in meeting its stated objectives. We did field visits (to the NVSL testing lab, slaughter facilities, rendering and 3D/4D plants[2], Federal and State participating agencies) to observe processes in place prior to the June 1, 2004 implementation date, to determine whether there were any issues that the Department needed to consider in designing and implementing effective program and management controls. As a result of our audit work, we identified a number of areas where additional efforts by USDA will improve the success of the expanded BSE surveillance program. I hope my overview this morning of its major elements will be informative.

USDA's Initial BSE Surveillance Program (1990-2003)

Since 1990, APHIS has led an interagency effort to monitor the potential existence of BSE in the U.S. cattle industry. Central to this effort was the testing of cattle in a high-risk category – those that exhibited a disorder in their central nervous systems (CNS), such as difficulty standing, walking, etc., and cattle that died on the farm from unclear causes. With the discovery of a BSE-infected animal in December 2003, APHIS determined to expand its surveillance program to test a larger number of high-risk animals. The goal of the program before 2004 had been to test 12,500 animals per year;

[2] Designation refers to dead, dying, disabled, or diseased animals.

under the expanded program, the goal extends to over 200,000 animals to be tested in a 12 to 18 month period.

USDA's Expanded BSE Surveillance Program, 2004

After the discovery of a BSE-infected cow in Washington State in December 2003, the Department took multiple administrative steps, including tracing the cow back to its herd of origin, depopulating animals of interest from identified herds, recalling meat products derived from the cow, and issuing a number of regulatory changes related to beef products. In January 2004, FSIS banned "specified risk materials" (*brain, skull, eyes, spinal cord, vertebral column, tonsils, etc*.[3]) from the human food supply in the U.S. Additionally, the USDA redesigned its surveillance program to expand testing for BSE.

On March 15, 2004, USDA announced the details of its expanded surveillance effort for BSE in the U.S. APHIS's fundamental objective is to determine if BSE is actually present in the U.S. cattle population, and if so, to determine at what level. The primary focus of the enhanced surveillance effort would continue to be testing of high-risk cattle. However, USDA plans to greatly increase the number of target animals tested. The new plan would include a random sample of apparently normal, adult cattle. The precise elements of the plan will continue to evolve.

In its expanded BSE surveillance plan, APHIS re-estimated the number of high-risk cattle in the United States as closer to 446,000, or more than double its original estimate.[4] APHIS officials concluded they would need to test about 268,500 high-risk animals to be 99 percent confident that it would detect at least 1 of these 268,500 cattle with BSE. This conclusion was reached upon APHIS's assumption that 5 of the estimated 446,000 in the high-risk population had the disease. By assuming BSE was limited to these high-risk cattle, APHIS concluded it would be 99 percent confident that it could detect BSE if its

[3] See 9 CFR 310.22(a).
[4] The 446,000 figure comes from three sources: FSIS 2002 data for animals partly or wholly condemned at slaughter by FSIS, APHIS 2002 data for animal disease investigations conducted by APHIS, and data collected by APHIS through the National Animal Health Monitoring System on the number and causes of deaths on farms (1996 data for beef breeding; 2001 data for dairy).

prevalence rate was 1 in 10 million. The sampling of an additional 20,000 apparently normal animals would come from 40 federally inspected plants that handle about 86 percent of the 6.2 million[5] adult cattle slaughtered at federally inspected facilities each year. The carcasses from these animals would be held and not allowed to enter the human food chain until test results showed the samples were negative for BSE.

The goal of the program before 2004 had been to test 12,500 animals per year. The expanded program's goal extends to over 200,000[6] animals to be tested in a 12 to 18 month period. USDA planned to test 40,000 animals by September 30, 2004. (These numbers are subject to adjustment by the Department.) In support of its expanded sampling plan, USDA advises that it has the support of the Harvard Center for Risk Analysis.

OIG's Audit of the USDA's BSE Surveillance Plan

The Department's BSE surveillance program has been of continuing interest to OIG. We planned to initiate an audit for FY 2004 to review the Department's BSE surveillance program, and were beginning to define its objectives when the Department announced the discovery of the BSE-positive cow. In light of that development, we focused this audit on the following objectives:

1) Determine whether the surveillance program in place at the time of the December 2003 discovery of BSE had been adequately implemented; and

2) Determine whether the expanded program will accomplish its stated goal of determining if "…BSE is actually present in the population and if so, at what level."

[5] In the BSE Surveillance Plan, dated March 15, 2004, APHIS approximates this 6.2 million based on NASS data (pages 10-11). It is consistent with the 6,256,000 slaughtered under Federal inspection in 2002 per Table 7-13 of NASS publication Agricultural Statistics 2003 (equals 2,607,000 dairy cows plus 3,051,000 other cows plus 598,000 bulls and stages).

[6] Total will depend on the confidence level desired. A 95% confidence level would require 201,000 cattle to be tested. A 99% confidence level would require 268,500.

With respect to the first objective, we found that we could not fully evaluate the Department's surveillance program as implemented prior to the discovery of the BSE-positive cow, due to the lack of adequate documentation for the basis of the plan. We did, however, perform field tests to determine how the program was operating prior to June 1, 2004, the date that the new plan would be fully implemented. Our purpose was to provide input to the Department on issues they may need to address as implementation of the expanded program moves forward. Our evaluation of the second objective -- assessing if the plan can determine the level of potential BSE infection in the U.S. -- is unavoidably limited, to some degree, because the design and implementation of the Department's BSE surveillance program is still evolving.

I want to emphasize that my testimony and our audit are based on our review of the Department's plan as it was published on March 15, 2004, as well as our review of all other documents provided to us and interviews with Department personnel. (We have received new data and information from the Department as recently as this week.) To provide a basis for our findings and recommendations, we reviewed the Department's plan utilizing the following extensive audit procedures, among others:

- Interviews of responsible program officials from APHIS and FSIS, including agency veterinarians, and interviews of plant personnel concerning the surveillance program and other BSE-related food safety initiatives;

- Review of slaughter plant records and observations of operations related to the inspection and condemnation of cattle, and written policies, procedures, and regulatory functions relating to the BSE surveillance program;

- Analysis of available documentation pertaining to the Department's development of the BSE expanded surveillance program, as well as the records, regulations, and management controls developed for cattle slaughter operations resulting from the discovery of the BSE-infected cow;

- Evaluation of the role of the NVSL in Ames, Iowa, and its responsibilities for the BSE surveillance program. Additionally, we are validating the NVSL's CNS testing data by tracing it back to FSIS and individual slaughter facility records that are their source;

- Creation of an expanded database for FY 2002, 2003, and 2004 (through February 2004), using information contained in the NVSL BSE database and utilizing sample submission forms. We evaluated this data to determine NVSL sample and testing data accuracy, trends, and anomalies; and

- Review of rendering plant records related to brain samples for BSE testing and observation of sample collection at rendering and slaughter establishments.

The Results of OIG's Audit

USDA's expanded surveillance program is based largely on a broadened plan of sampling, based upon the Department effort to more accurately determine the population of high-risk cattle (via use of NASS studies and FSIS condemnation records, etc.) This sampling plan has been announced as scientifically based and representative of the population of U.S. cattle as a whole. However, we believe that several limitations inherent in the expanded sampling plan need to be clarified so that industry, the public, and U.S. trading partners understand what the results of the testing actually imply.

The sampling is not truly random because participation in the program is voluntary. The BSE sampling plan, as designed, assumes each animal in the target population has the same chance of being selected for BSE testing, which will not be true if testing is voluntary. APHIS has the authority to collect samples, but it has chosen not to exercise this authority, except at federally - inspected slaughter facilities. Our audit, currently in draft form and recently provided to USDA for official review, provides the following observations regarding the BSE surveillance plan:

- The expanded plan emphasizes the confidence level of detecting at least one case of BSE in the adult U.S. cattle population, if it exists. Because of the plan's design, discovery of any BSE cases should cause the confidence level of its estimate of the maximum prevalence of BSE to drop dramatically. Therefore, any statistical projection of the maximum prevalence of BSE may give the appearance of being more reliable than it is; in other words, the conclusions reached as to the prevalence of BSE may be less reliable than as projected by APHIS.

- As the plan is currently designed, APHIS cannot obtain a statistically appropriate geographical representation of the U.S. cattle population. Because the program is voluntary and the universe of high-risk cattle is difficult to identify, obtain, and test, the surveillance plan needs to be clarified and its conclusions relating to the prevalence of BSE may need to be qualified.

- APHIS' sampling plan assumes BSE is confined to the high-risk cattle population; other studies show that healthy-looking animals may also have BSE.

- APHIS' plan to test 20,000 clinically normal cattle may give the incorrect impression that these few tests will suggest a level of assurance higher than warranted about the 45 million adult cattle in the United States.[7]

- APHIS cannot easily identify, obtain, or test cattle in its high-risk population; therefore, the chances of detecting BSE, if it exists, may be reduced and the projected maximum BSE prevalence rate may be unreliable.

Identifying the universe of high-risk cattle and developing detailed operational procedures for all BSE surveillance requirements are critical to the success of the expanded program. Because of inherent problems with identifying this universe, the

[7] National Agricultural Statistics Service, Agricultural Statistics 2003, per Table 7-2 for 2002, 44,474,000 (equals 33,118,000 beef cows plus 9,112,000 milk cows plus 2,244,000 bulls).

Department faces significant challenges in estimating a maximum BSE prevalence rate for high-risk cattle. Our fieldwork, completed prior to June 1, 2004, identified some of the challenges in identifying, obtaining, and testing cattle in the high-risk population. Examples of these challenges are:

Cattle condemned at slaughter plants for CNS symptoms were not always tested for BSE. This occurred because of confusion in testing requirements and lack of coordination between APHIS and the agency that condemns cattle at slaughtering plants, the Food Safety and Inspection Service (FSIS). Of the 680 cattle FSIS condemned for CNS symptoms between FYs 2002 and 2004, we could validate that only 162 were tested for BSE. This was graphically illustrated in our investigation in San Angelo, Texas in late April 2004. On May 20, 2004, the Department issued a directive to its field staffs to clarify the requirements for testing all animals condemned for CNS, regardless of the age of the animal. FSIS and APHIS now need to develop sufficient management controls to ensure this policy is followed.

Additional testing is warranted for rabies-negative brain samples. Rabies cases exhibit clinical signs not inconsistent with BSE, and a negative rabies test means the cause of the cow's disorder has not been diagnosed. Nevertheless, this high priority population has not been adequately pursued for BSE testing. Public health and State veterinary diagnostic laboratories did not always submit rabies-negative samples for BSE testing because there was no formal mechanism in place to ensure the submissions. We suggested that APHIS develop formal processes, in coordination with public health and State veterinary diagnostic laboratories, for testing rabies negative samples for BSE.

A process for obtaining samples from animals that "died on the farm" has not been developed. These samples are important because the high-risk animals that die on the farm comprise the largest component of the targeted high-risk population and the most difficult to identify, obtain, and test. Identifying truly

high-risk cattle that die on the farm may be complicated by the reluctance of producers to submit them for testing or the motivation to mischaracterize low risk carcasses as "high risk" since only the latter may qualify for reimbursement. The Department has initiated outreach efforts to inform producers of the need for testing these animals.

Confusion may arise regarding non-standardized age requirements for BSE testing. Current testing guidance contains inconsistent age criteria for testing cattle for BSE. Some documents emphasize testing of livestock at 20 months of age, some at 24 months of age, and at least one—the APHIS Surveillance Plan of March 2004—over 30 months of age. This confusion has created and will continue to create a potential that some cattle may not be subject to BSE testing.

The second primary focus of our audit was to review the Department's existing program management and administration capabilities with respect to implementation of the BSE surveillance program. The program can only be effectively implemented if USDA establishes a strong management control structure, one that will provide assurance to American consumers, industry, and U.S. trading partners. Our audit reviewed the Department's surveillance processes that were in place up until June 1, 2004. Our goal was to identify concerns about agency management processes that could be improved if the Department's surveillance program is to meet its objectives. Some of our audit's primary findings regarding management and administrative procedures pertaining to the BSE surveillance programs are described below:

APHIS' sampling and data collection processes could be improved to protect the integrity of surveillance data. Current APHIS processes do not ensure that all samples submitted are properly identified as to the animal's origin; that all animals whose tests are recorded are within the target or non-target population; and that all samplers retain backup samples of brain tissue for purposes of verifying any positive tests.

APHIS needs to establish consistent terms and conditions in its agreements with non-Federal entities participating in the surveillance program. Prior to June 1, 2004, APHIS did not have standard written agreements in place to ensure consistent performance from non-Federal laboratories and reasonable arrangements/charges from meat plants and contractors who provide sampling services. Generally, arrangements with such entities contain no written agreement and have no national guidance. (*Ex: In one sample region, APHIS offices had written agreements with only 4 of the 31 slaughter/rendering facilities participating in the surveillance program. Also, our survey of arrangements with meat plants and sampling contractors showed that some were informal, and resulted in costs ranging from $0 to $100 per sample taken.)*

Most importantly, the Department needs to have a supportable methodology for assessing the effectiveness of its overall surveillance program. A supportable methodology is essential to provide credibility for any USDA assertion regarding the prevalence of BSE in the United States. Also, performance measures and continuous risk analysis are needed to better target limited resources and assess whether all program participants are fulfilling their respective roles and responsibilities.

When finalized, our audit will contain a series of recommendations for USDA to improve its BSE surveillance plan, and to strengthen USDA's administrative actions to prevent and mitigate BSE exposure in the U.S. cattle industry. We will also recommend that the Department fully disclose any assumptions that it made in designing its sampling plan, and clarify any limitations that exist in the assumptions made, and that exist in the data it will collect.

Mr. Chairmen and Ranking Members, Members of the Committees, I again thank you for inviting me to testify before your Committees and hope this information is helpful to you in your oversight efforts. We will provide our final audit directly to you upon completion. We offer our findings and recommendations to the Secretary and the Congress in the spirit of improving and refining our nation's BSE prevention and

detection activities so they are as effective as possible. We look forward to working with you in this important effort.