U.S. Department of Agriculture

Office of Inspector General
Great Plains Region

# Audit Report

## Animal and Plant Health Inspection Service
## and
## Food Safety and Inspection Service
## Bovine Spongiform Encephalopathy (BSE) Surveillance Program - Phase I

Report No. 50601-9-KC
August 2004

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington, D.C. 20250

DATE: August 18, 2004

REPLY TO
ATTN OF: 50601-9-KC

SUBJECT: Bovine Spongiform Encephalopathy (BSE) Surveillance Program - Phase I

TO: Dr. Ron DeHaven
Administrator
Animal and Plant Health Inspection Service

Dr. Barbara Masters
Acting Administrator
Food Safety and Inspection Service

ATTN: William J. Hudnall
Deputy Administrator
Marketing Regulatory Program Business Services

Ronald F. Hicks
Assistant Administrator
Office of Program Evaluation, Enforcement, and Review

This report presents the results of our audit of the BSE surveillance program. Your July 30, 2004, written response to the official draft report is included as exhibit E with summaries of the response and the Office of Inspector General's (OIG) position incorporated into the Findings and Recommendations section of the report, where applicable. The response included numerous exhibits that we did not include in the report because of their volume.

We accept the management decisions for all recommendations. Please follow your agency's internal procedures in forwarding documentation for final action to the Office of the Chief Financial Officer (OCFO). We are providing a separate memorandum to the agencies and OCFO that provides specific information on the actions to be completed to achieve final action.

We appreciate the cooperation and assistance provided to our staff during the audit.

ROBERT W. YOUNG
Assistant Inspector General
for Audit

# *Executive Summary*

***Animal and Plant Health Inspection Service and Food Safety and Inspection Service***
***Bovine Spongiform Encephalopathy (BSE) Surveillance Program - Phase I***

**Results in Brief**

Since 1990, the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) has led an interagency effort to monitor Bovine Spongiform Encephalopathy (BSE), widely known as "mad cow disease." 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; under the expanded program, the goal extends to over 200,000 animals to be tested in a 12 to 18 month period.

The objectives of our audit were to determine whether the surveillance program in place at the time of the December 2003 discovery of BSE was adequately implemented and whether the expanded program will accomplish its stated goal—to determine if "…BSE is actually present in the population and if so, at what level."

This is the first in a series of reports we are planning to issue on our evaluation of USDA's BSE surveillance activities. We could not fully evaluate the first objective due to the absence of adequate documentation (see General Comments Section) to support the basis for USDA's BSE surveillance plan prior to the discovery of the BSE-infected cow. Our evaluation of the second objective was limited because the design and implementation of the BSE surveillance program is still in a state of flux. However, where possible, we assessed documents provided to us and interviewed USDA personnel so that we could provide USDA with recommendations on potential concerns and issues as it moves forward with implementation.

USDA's expanded surveillance program is based largely on a broadened plan of sampling. This sampling plan has been announced as scientifically based and representative of the population of U.S. cattle as a whole. However, we concluded that several limitations inherent in the 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.

- Sampling is not truly random because participation in the program is voluntary. The BSE sampling plan, as designed, assumes each animal

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.

- Discovery of BSE cases will result in a statistical projection with either a significantly lower confidence level or a significantly higher maximum BSE prevalence level. By not discussing this, the plan's statistical statements may inadvertently overemphasize the implied "best-case scenario."

- 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.[1]

- 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.

APHIS needs to fully disclose the assumptions that it made in designing its sampling plan, and it needs to clarify the limitations that exist in the data it will collect. Beyond its sampling design, however, lie significant challenges for APHIS in its goal to determine if BSE exists in the United States at a prevalence of at least one case per 10 million adult cattle. These challenges—in identifying and testing the high-risk population of cattle—were inherent in the operations of the surveillance program as it had been conducted prior to June 2004, and still exist under the expanded program.

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

[1] 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).

that condemns cattle at slaughtering plants, the Food Safety and Inspection Service (FSIS). Of the 680 cattle FSIS condemned for CNS symptoms between fiscal years (FY) 2002 and 2004 (through February 2004), we could validate that only 162 were tested for BSE.

USDA needs to increase testing of 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.

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 and the motivation to mischaracterize low-risk carcasses as "high risk" since only the latter may qualify for reimbursement.

The age requirement for BSE testing should be standardized to prevent confusion. 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.

We are recommending that APHIS implement management controls to ensure that all high-risk animals, including those that test negative for rabies, those condemned for CNS symptoms, and those that die on the farm from unknown causes are sampled and tested in accordance with USDA policy and the 2004 Surveillance Plan.

In reviewing APHIS' management of the BSE surveillance program, we also noted some areas of concern in program administration. Most critically, we found that stronger controls were needed over the collection of test samples and the recording of test information. We found cases in which test samplers submitted nonviable samples and provided inaccurate or incomplete information on their submission forms. We found other cases in which some animals that had been tested for such non-high-risk symptoms as diarrhea and inner ear infection were included in APHIS' count of samples for the purpose of meeting surveillance goals. Some information maintained in the

surveillance program's database was the result of misentries. This database was the source of APHIS' reports on surveillance achievements.

We are recommending that APHIS expedite its development of a new management information system to track and report its accomplishments under the expanded surveillance program. We are also recommending that APHIS implement performance measures and a continuous risk assessment to enhance its management of the surveillance program and better assess the program's effectiveness.

Finally, we noted that, 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 and charges from meat plants and contractors who provide sampling services. Use of these entities will increase as the 2004 surveillance program expands. Past arrangements with meat plants and sampling contractors were made on a regional basis, were sometimes informal, and resulted in costs ranging from $0 to $100 per sample taken. We concluded that APHIS should impose a standardized contract specifying the quality of work required and the costs the Government is willing to incur for it.

The problems disclosed during our review, if not corrected, may negatively impact the effectiveness of USDA's overall BSE surveillance program, impair its ability to perform risk assessments and program evaluations, and reduce the credibility of any assertion regarding the prevalence of BSE in the United States. These are complex challenges USDA needs to address as it moves forward with implementation of its expanded BSE surveillance program.

This audit was coordinated with the Office of Inspector General's (OIG) Investigations Division. OIG conducted two investigations to determine whether employees of USDA and/or of the slaughter establishment misled or provided false information concerning the identification of the BSE-positive cow. In addition, OIG verified the procedures used by USDA and the slaughter establishment to maintain the integrity of the brain tissue sample from the slaughter establishment through delivery to the National Veterinary Services Laboratories (NVSL) in Ames, Iowa. OIG also investigated the circumstances surrounding the animal displaying possible CNS symptoms that had not been tested in Texas. The results of these investigations will be reported under separate cover.

## Recommendations In Brief

We are recommending that APHIS fully disclose the assumptions that it made in designing its sampling plan, and that it clarify the limitations that exist in the data it will collect. We are also recommending that APHIS implement management controls to ensure that all high-risk animals,

including those that test negative for rabies, those that are condemned for CNS symptoms, those that die on the farm from unknown causes, and those meeting the age requirement, are sampled and tested in accordance with USDA policy and the 2004 Surveillance Plan.

We are recommending that APHIS expedite its development of a new system to track and report its accomplishments under the expanded surveillance program. We are also recommending that APHIS implement performance measures and a continuous risk assessment to enhance its management of the surveillance program and better assess the program's effectiveness.

Finally, we are recommending that for all State contract laboratories that will perform BSE testing under the new surveillance program and for all meat plants and contractors that will collect test samples, APHIS develop and enter into written agreements that include specific provisions for responsibilities, performance, and reimbursement.

**Agency Response**

In their July 30, 2004, written response to the official draft report, APHIS and FSIS were in agreement with the findings and recommendations presented therein. The response provided specific actions the agencies have taken, or plan to take, as well as timeframes for implementing proposed actions for each recommendation. We have incorporated applicable portions of the response, along with our position, in the Findings and Recommendations section of this report. The APHIS and FSIS joint response is included in its entirety (except for the exhibits provided with the response) as exhibit E.

**OIG Position**

We concur with APHIS' and FSIS' proposed corrective actions and have accepted management decisions for all recommendations.

## *Abbreviations Used in This Report*

| | | |
|---|---|---|
| AMS | - | Agricultural Marketing Service |
| APHIS | - | Animal and Plant Health Inspection Service |
| AVIC | - | Area Veterinarian-in-Charge |
| BSE | - | Bovine Spongiform Encephalopathy |
| CALS | - | Computer Automated Laboratory Systems |
| CFR | - | Code of Federal Regulations |
| CJD | - | Creutzfeldt-Jakob Disease |
| CNS | - | Central Nervous System |
| CD | - | Compact Disk |
| ELISA | - | Enzyme Linked Immune Sorbent Assay |
| FSIS | - | Food Safety and Inspection Service |
| FY | - | Fiscal Year |
| GAO | - | Government Accountability Office (formerly the General Accounting Office) |
| IHC | - | Immunohistochemistry |
| IR Subcommittee | - | International Review Subcommittee |
| NAHMS | - | National Animal Health Monitoring System |
| NASS | - | National Agricultural Statistics Service |
| NVSL | - | National Veterinary Services Laboratories |
| OCFO | - | Office of the Chief Financial Officer |
| OIE | - | Office International des Epizooties |
| OIG | - | Office of Inspector General |
| RA | - | Reference Assistance |
| SOP | - | Standard Operating Procedures |
| TSE | - | Transmissible Spongiform Encephalopathy |
| USDA | - | U.S. Department of Agriculture |
| VS | - | APHIS Veterinary Services |

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# Background and Objectives

## Background

Bovine Spongiform Encephalopathy (BSE), widely known as "mad cow disease," is a chronic, degenerative disease affecting the central nervous system (CNS) of cattle. Worldwide there have been more than 180,000 cases in cattle since the disease was first diagnosed in 1986 in Great Britain. BSE belongs to the family of diseases known as transmissible spongiform encephalopathy (TSE), the causes of which are not fully known. TSE diseases have a prolonged incubation period of months or years and result in a progressive, debilitating neurological illness, which is always fatal. Affected animals may display changes in temperament, such as nervousness or aggression, abnormal posture, decreased milk production, or loss of body weight despite continued appetite. There is no test to detect BSE in a live animal.

The Animal and Plant Health Inspection Service (APHIS) leads an interagency effort to monitor BSE.[2] Its monitoring program includes sampling the brains of selected cattle for traces of BSE. These surveillance samples include field cases of cattle exhibiting signs of neurological disease, cattle condemned at slaughter for neurological reasons, rabies-negative cattle submitted to public health laboratories, cattle that are nonambulatory, and adult cattle that die on farms. As of September 30, 2003, over 57,000 cattle brains had been examined for BSE or other forms of TSE.

The United States has had an active surveillance program for BSE in place since May 1990. More than 250 Federal and State regulatory veterinarians are specially trained to diagnose BSE. The Food Safety and Inspection Service (FSIS) and the Food and Drug Administration are also involved in the surveillance program. Prior to June 1, 2004, FSIS inspectors condemned animals displaying CNS symptoms during ante mortem inspections at slaughterhouses and were required to notify APHIS when testing was warranted.

**APHIS' Surveillance Program, 1990–2003**

The goal of APHIS' pre-2004 surveillance program was to test enough animals to "allow detection if BSE truly exists at a level of one or more cases per million in the adult cattle population." The prevalence of

[2] APHIS surveillance programs operate under the authority of the Animal Health Protection Act that became a part of the Farm Security and Rural Investment Act of 2002 (2002 Farm Bill) effective May 13, 2002. Veterinary Services (VS) is the division within APHIS that is responsible for protecting and improving the health, quality, and marketability of the Nation's animals, animal products, and veterinary biologics. This is accomplished through preventing, controlling, and eliminating animal diseases, and by monitoring and promoting animal health and productivity. In addition, every State has an area veterinarian-in-charge (AVIC) to meet animal health needs on a local level and serve as a liaison between the State and Federal Government.

classical Creutzfeldt-Jakob disease (CJD), a TSE disease occurring in human populations, appears to be approximately one in a million worldwide. It has been hypothesized that other spongiform encephalopathies also might occur in the host populations at the same rate.[3]

Statistical sampling allows data gatherers to collect information from a relatively small group and draw conclusions about the population as a whole. To be scientifically valid, the conclusions must be based on a representative sample of a statistically determined size, such as a random sample. Depending on the size and randomness of the sample, the conclusions (projections) can be expressed in terms of a confidence level. The United States has an adult cattle population of approximately 45 million. To be 95 percent confident of detecting BSE in a random sample of an adult cattle population of 45 million (and in which detectable BSE occurs at a rate of one in a million, for a total of 45 animals), the U.S. Department of Agriculture (USDA) would have to randomly select and test nearly 3 million animals.

However, USDA determined that it could conduct a more efficient survey if it focused on the higher-risk population of cattle—nonambulatory cattle and adult cattle with CNS or other clinical signs not inconsistent with BSE. This segment of the cattle population is the most at risk of having BSE.

Because there is no data on the exact number of nonambulatory cattle in the United States, APHIS estimated 195,000 per year based on a survey conducted by the American Association of Bovine Practitioners.[4] APHIS further assumed that the potential cases of BSE would all be found in the high-risk cattle population. To enable USDA to be 95 percent confident that it would detect at least one case of BSE if 45 animals within the targeted population of 195,000 actually had the disease, APHIS calculated that it needed to test 12,500.

**First Positive Case of BSE Found in the United States, 2003**

On December 23, 2003, the Secretary of Agriculture announced that a dairy cow in the State of Washington had tested presumptive positive for BSE (the test was later confirmed positive). The Department took steps to contain the potential spread of the disease by tracing the positive cow to its herd of origin, depopulating animals of interest from identified herds, recalling meat products derived from the positive cow,

[3] Brown, et al., "Bovine spongiform encephalopathy and variant Creutzfeldt-Jakob disease: background, evolution, and current concerns." Emerging Infectious Diseases, 2001.

[4] Hansen and Bridges, "A survey description of down-cows and cows with progressive or non-progressive neurological signs compatible with a TSE from veterinary-client herds in 38 States." The Bovine Practitioner, 1999.

and issuing a number of regulatory changes related to beef products. In the January 12, 2004, Federal Register, FSIS declared as "specified risk materials"[5] certain beef tissues (the brain, skull, eyes, etc.) and their products and banned these products from the human food supply. Also, in response to the positive BSE test, USDA redesigned its surveillance program to expand testing for BSE.

**USDA's Expanded BSE Surveillance Program, 2004**

On December 30, 2003, the Secretary announced that an international scientific review panel, the International Review Subcommittee (IR Subcommittee) of the Foreign Animal and Poultry Disease Advisory Committee, would review USDA's investigation surrounding the case of BSE. The IR Subcommittee would also consider the scope of policy options and measures being considered to address the BSE situation that existed in the United States and within the broader North American context.

On February 2, 2004, the IR Subcommittee issued a report to the Secretary that concluded, "The epidemiological investigation into the origin of the BSE case conforms to international standards, insofar as it could be conducted in the face of the limitations of cattle identification systems in place in North America." Also, various observations and recommendations were made on the USDA surveillance procedures and policy options being considered. We have incorporated some of the IR subcommittee's comments into this report where relevant to the issues we are reporting.

On March 15, 2004, USDA announced the details of its expanded surveillance effort for BSE in the United States. The primary focus of the enhanced surveillance effort would continue to be to attempt to test the highest-risk cattle, but USDA would greatly increase the number of target animals surveyed and would include a random sample of apparently normal, adult cattle.

In its BSE Surveillance Plan, dated March 15, 2004, 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.[6] With this new estimate, APHIS officials concluded they would need to test about

[5] 9 CFR 310.22(a) defines SRMs as: 1) the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia (DRG) of cattle 30 months of age and older, and 2) the tonsils and distal ileum (for which removal of the distal ileum must be achieved by disposing of the entire small intestine) of all cattle.

[6] 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).

268,500 high-risk animals to be 99 percent confident that at least one of these 268,500 cattle had detectable BSE, assuming that 5 of the estimated 446,000 in the high-risk population had it. 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 prevalence rate was 1 in 10 million. In other words, the goal of the enhanced program was to detect BSE even if there were only five detectable cases in the entire country. 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[7] adult cattle slaughtered 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.

In support of its sampling plan, USDA notes that its pre-2004 plan was in accord with findings by the Office International des Epizooties (OIE), an international animal health organization based in France, and that its new plan has the support of the Harvard Center for Risk Analysis.[8]

USDA planned to test 40,000 animals in fiscal year (FY) 2004 (i.e., by September 30, 2004). USDA began its increased testing on June 1, 2004. Testing will be conducted at USDA's laboratory, the National Veterinary Services Laboratories (NVSL), in Ames, Iowa, and a network of 12 contract laboratories around the country.

APHIS amended the Code of Federal Regulations (CFR)[9] to provide authority for APHIS to collect blood and tissue samples from "listed" slaughter and rendering facilities. The listed facilities must provide space and equipment within their facilities for collection of blood and tissue samples, and allow APHIS, FSIS, or APHIS contractors to take the samples without cost to the Government. However, USDA plans to help defray costs incurred by individuals and entities participating in the surveillance program for such items as transportation, disposal, and storage of carcasses being tested. Moreover, APHIS management asserts that they currently have the regulatory (mandatory) authority necessary to obtain BSE samples at any location the agency determines is essential to the success of the expanded surveillance program. The officials believe that they are currently getting adequate cooperation

[7] In the BSE Surveillance Plan, dated March 15, 2004, APHIS approximates this 6.2 million based on National Agricultural Statistics Service (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 stags).

[8] Comments about USDA's surveillance plan are contained in a March 12, 2004, memorandum to the Deputy Administrator of APHIS' VS from officials from the Harvard Center for Risk Analysis.

[9] 9 CFR 71.21, as amended March 4, 2004. The CFR was silent as to USDA access to collect samples on farms, feedlots, auction barns, etc.

from producers and industry; therefore, the agency has chosen not to invoke its mandatory authority at this time.

## Objectives

Our objectives were to determine 1) whether the BSE surveillance program objectives, policies, procedures, and management controls in place at the time BSE was identified in Washington State were adequate; and 2) whether the expanded BSE surveillance program will accomplish its intended objectives and has been effectively implemented.

# Findings and Recommendations

## Section 1. BSE Surveillance Program – Implementation Plans Not Final and Many Questions and Challenges Remain

On March 15, 2004, APHIS, in cooperation with FSIS and the Food and Drug Administration published a plan outlining its objectives for an intensive national BSE surveillance program. According to the plan, "This is a one-time effort to give a snapshot of the cattle population in the United States and help define whether BSE is actually present in the population and if so, at what level. The goal of this plan is to test as many cattle in the targeted high-risk population as possible in a 12-18 month period." Also, the plan incorporates random sampling of clinically normal aged animals at slaughter. APHIS plans to evaluate the results of this effort over this period and determine if other actions are necessary.

APHIS has targeted the population of "high-risk" cattle (i.e., those showing disorders of the CNS, nonambulatory cattle, cattle that die on the farm from unknown causes) because it has determined that these cattle are the most likely to have BSE. Cattle that are considered clinically normal are least likely to have BSE. Assuming random sampling, tests from a selection of high-risk cattle will allow APHIS to draw conclusions only about that population. APHIS has estimated a total population of 45 million adult cattle and a high-risk population of 446,000. The latter figure was derived partly from APHIS' own National Animal Health Monitoring System (NAHMS).

We reviewed the statistical validity of the BSE sampling and testing program to determine if the plan is designed to enable USDA to achieve the statistical conclusions stated as its desired goals. Our review was limited because implementation plans have not been finalized and APHIS has not yet been able to address some of the questions we have raised. Therefore, our observations and conclusions are based on the March 15, 2004, published BSE surveillance plan, as well as available documents and interviews with various APHIS and FSIS officials. APHIS also provided us with an unpublished, updated BSE surveillance plan as of May 25, 2004, which we considered in finalizing this report.

We recognize that there are many challenges that the Department needs to address in implementing an effective and supportable BSE surveillance program. We offer the following observations and preliminary conclusions for the Department to consider as it moves forward with implementation.

## Finding 1

## USDA Needs to Clarify Its Goals of Detecting and Measuring the Maximum Prevalence of BSE in the Adult Cattle Population

### *Critical Assumptions in the Surveillance Plan Will Result in Questionable Estimates of BSE Prevalence*

In its BSE surveillance program, APHIS attempts to focus on the higher-risk population of cattle—cattle with CNS clinical signs or signs not inconsistent with BSE, nonambulatory cattle, and cattle that died on the farm from unknown causes. An objective of the surveillance plan is to collect samples from as many adult cattle from the high-risk population as possible in 12 to 18 months while ensuring there is statistically appropriate geographical representation in the United States. More specifically, APHIS assumes all BSE-detectable cattle are in this high-risk population and states that if a total of 201,000 samples are collected, the level of sampling will detect BSE at the rate of 1 positive in 10 million adult cattle at a 95 percent confidence level. If a total of at least 268,500 samples are collected, this level of sampling will detect BSE at the same rate at a 99 percent confidence limit.

Our review found that APHIS has not clearly communicated the limitations contained in the critical assumptions on which the surveillance plan is based. These critical assumptions have a significant impact on the surveillance program's ability to meet its announced objectives. Full disclosure of these assumptions and their impact on any statistical representations made of the prevalence of BSE in the cattle population is necessary so that the data will not be misinterpreted by the public, industry, or U.S. trading partners.

### *Unstated Limitations in the Sample Selected*

The BSE sampling methodologies are not based on known selection probabilities, even though the plan's statistical projections assume these are known and equal. The more these selection probabilities differ across cattle in the population, the less reliable the statistical projections will become. There are several reasons these selection probabilities are not equal for cattle in the targeted high-risk population, chief among which is the voluntary nature of participation; producers and renderers are not required to participate. Nevertheless, the statistical projections assume each animal has the same non-zero probability of being selected for testing.

APHIS amended the CFR[10] to provide authority for APHIS to collect blood and tissue samples from "listed" slaughter and rendering facilities. A listed facility must provide space and equipment on its premises for collection of blood and tissue samples, and it must allow APHIS, FSIS, or APHIS contractors to take blood and tissue samples from livestock at the facility without cost to the Government.

[10] 9 CFR 71.21, as amended March 4, 2004.

However, because USDA has determined that the surveillance program should be voluntary to encourage participation, it will not enforce this regulation at this time, except for federally-inspected slaughter facilities.

While the voluntary aspect of the program overrides the possibility of a truly random sample of cattle, APHIS recognizes that randomized sampling is not a viable approach for sampling the high-risk population. According to APHIS, the potential for sampling bias exists because the size and distribution of the target population is only approximated. This bias could be reduced if more were known about this population. Consequently, APHIS is conducting a national probability survey to study the distribution of nonambulatory cattle. APHIS officials have also stated that the effect of nonrandom sampling is somewhat negated by the attempt to test all available animals (a process known as a "census"). In written comments provided to us on June 24, 2004, APHIS officials stated that "if no [BSE] cases are detected then the exact confidence we [APHIS] have that the disease is below the design level will have to be based on the assumption that the animals tested are representative of the high-risk population as if they were randomly sampled."

Due to inherent problems with defining, obtaining, and testing either a census or a random sample of high-risk cattle, USDA will face significant challenges when using its anticipated statistical projections. As designed, these assume that the selection probabilities of all truly high-risk cattle are known and equal. If APHIS restricts the high-risk population to those samples voluntarily submitted, whether or not it tests all of them or a random sample of them, there is reduced assurance that BSE will be detected, and any statistical projection regarding the high-risk group may be unreliable.

***Unstated Limitations in the Confidence of Projections***

The expanded surveillance plan emphasizes the confidence level of detecting at least one case of BSE, if it exists at the assumed prevalence level of five cases of BSE. However, the plan does not address the fact that if only one BSE case is detected in the target population, the confidence level of maximum prevalence will be degraded. For example, assuming all other assumptions apply, the 99 percent confidence level will drop to 91.5 percent if one case of BSE cattle is identified. If two cases are detected, the confidence level falls to 68.6 percent; and with three cases, it falls to 34.0 percent. Therefore, if cases of BSE are detected, the test results will indicate either a significantly lower confidence level or a significantly higher maximum BSE prevalence level than those implied in the March 15, 2004, plan.

In written comments provided to us on June 24, 2004, APHIS officials stated that they recognize that if BSE is detected in any of the tests,

USDA will most likely respond immediately with major changes in the surveillance procedures. APHIS officials agree the March 15, 2004, expanded surveillance plan will need to be rewritten if additional BSE cases are detected.

***Unstated Limitations in Obtaining a Geographic Representation of U.S. Cattle***

APHIS has developed sample allocations for each State to provide the appropriate geographic distributions of sample collections. The estimates are based on cattle population data derived from National Agricultural Statistics Service (NASS) surveys and weighted for some assumed differences in death losses between dairy and beef cattle populations. However, APHIS views these allocations as flexible. That is, if the numbers collected from some States are below the allocated amounts, additional samples may be collected from other States. APHIS intends to evaluate this data based on the total number of samples collected and apply the results to the U.S. cattle population. This procedure would bias the sample if APHIS tests more animals from some States to make up for testing too few animals from other States.

The potential for this bias is exacerbated by a subtle conflict between the stated objectives of testing "as many cattle in the targeted population as possible" and "ensuring representation of the adult cattle population." Obtaining as many samples as possible in one area increases the selection probabilities there relative to those in other geographic areas. APHIS has no contingency plans if geographical targets are not obtained.

Challenges in obtaining a geographical distribution of the cattle population can be demonstrated by the allocations established and samples obtained from States in the Northwest Region. Cattle are frequently shipped across regional boundaries for slaughter or rendering in adjoining States. Under procedures in effect prior to June 1, 2004, these cases generally would have been credited to the State or region where the slaughter or rendering plant was located. APHIS and NASS records show that some States, such as Montana and Oregon, were substantially undersampled (a total of three samples in FY 2003) in relation to their estimated target cattle population (3.4 percent of the Nation). However, we could not determine or estimate the number of samples that were incorrectly allocated to individual regions where the cattle did not originate because the origin of the cattle had not always been identified (see Finding 3).

**Figure 1: Distribution of Cattle Tested in the Northwest Region, 2002-2004**

| State | Cattle Population (Beef and Dairy Cows)[1] | Samples FY 2002 | Samples FY 2003 | Samples FY 2004 (through Feb. 2004) | State Goal FY 2004[2] |
|---|---|---|---|---|---|
| Idaho | 900,000 | 143 | 8 | 80 | 8,939 |
| Montana | 1,490,000 | 1 | 1 | 0 | 5,076 |
| Oregon | 720,000 | 26 | 2 | 5 | 4,038 |
| Utah | 440,000 | 162 | 508 | 238 | 2,724 |
| Washington | 510,000 | 1,906 | 264 | 588 | 5,161 |

[1]Source: NASS 2004.
[2]Source: Examples of Geographic Distributions of Sample Collections for the BSE Surveillance Plan. Based on a sample goal of 268,500.

Prior to June 1, we noted the sample collection process was concentrated in a few slaughter establishments and renderers in a few States. During FYs 2002, 2003, and 2004 (through February 2004), four States (Wisconsin, Georgia, Missouri, and Minnesota) collected 36 percent of the Nation's samples, yet these States had only about 17 percent of the adult beef and dairy cows. For example, Georgia had only 1.3 percent of the Nation's adult dairy and beef cows, but during FYs 2002, 2003, and 2004, Georgia collected almost 10 percent of the samples collected for the Nation (see Figure 2). California collected only 8.3 percent of the Nation's samples, but California has over 12 percent of the Nation's adult dairy and beef cows.

**Figure 2: Percentages of Sampling in Four States**

| State | FY 02-04 Sample Percentage | State Goal Percentage | Difference |
|---|---|---|---|
| Wisconsin | 13.5% | 8.6% | 4.9% |
| Georgia | 9.7% | 1.3% | 8.4% |
| Missouri | 6.4% | 3.4% | 3.0% |
| Minnesota | 5.9% | 3.6% | 2.3% |
| **Total** | **35.6%** | **16.9%** | **18.7%** |

During FY 2003, over half of the Nation's samples came from seven entities (six slaughter facilities and one 3D/4D processor (dead, dying, disabled, and diseased)) which submitted from 56 to over 99 percent of the samples from their States. Nationwide, these entities submitted 51 percent of the samples; their resident States had only 34 percent of the adult beef and dairy cows.

The surveillance plan needs to be clarified to explain that the data gathered may not represent an "appropriate statistically geographical representation of the adult cattle population in the United States." Therefore, any references to the prevalence of BSE may need to be qualified.

***Unstated Recognition of Where BSE May Be Found***

The statistical projections assume that all the BSE-positive cattle are part of the high-risk population, even though the Europeans detected about 290 cases (during 2002) in healthy animals taken to slaughter.

OIG and APHIS agree that BSE has been detected in clinically normal, adult cattle but that its prevalence in the population tends to be much less than that for high-risk cattle. However, the number of normal cattle in inventory greatly exceeds the number of high-risk cattle. Combining these relationships, any attempt to extrapolate the high-risk adult cattle test results to the entire adult cattle population yields a significantly higher estimated prevalence rate than if USDA assumes all detectable BSE is limited to the high-risk population. Comments made by the Harvard Center for Risk Analysis refer to Swiss data that suggest that the average detectable prevalence for normal cattle is only one-eighth as much as high-risk cattle. The adult cattle population in the United States (45 million) is about 100 times larger than the targeted high-risk population (446,000). Thus, if the plan's statistical projection (1 in 10 million with 99 percent confidence level) was based on five maximum detectable cases in the 446,000 high-risk population, this can extrapolate to about 67.5 [5 high-risk + 62.5 normal adults ($5 \times 1/8 \times 100$)] maximum detectable cases in the 45 million adult cattle population, or about 15 in 10 million[11].

The plan needs to be clarified to remove the misconception that BSE will appear in only high-risk animals.

***Unstated Limitations in Test Results for Normal Cattle***

The statistical projections implicitly assume that all negative BSE test results are accurate. However, the Harvard Center for Risk Analysis estimated that BSE tests yield a 92-percent false negative rate for "normal adult" cattle because the disease is undetectable in early stages (e.g., for every 8 clinically healthy adult cattle with the disease 92 others have the disease, but it is not yet in a detectable stage).[12] The

[11] Such extrapolations are sensitive to numerous assumptions including (1) the number of high-risk cattle tested, (2) the number of normal adult cattle, and (3) the ratio of BSE prevalence of normal adult to high-risk cattle. The extrapolated maximum detectable BSE cases decreases as (1) increases, but this extrapolated maximum increases as items (2) or (3) above increase. Like the Harvard Center, we use the 1 to 8 normal adult to high-risk prevalence ratio, which is derived from Table 1 of "Trends in prevalence of BSE in Switzerland based on fallen stock and slaughter surveillance" (*The Veterinary Record,* (March 16, 2002, pages 347-348), by Doherr, M. G., A. R. Hett, C. H. Cohen, R. Fatzer, J. Rufenacht, A. Zurbriggen, and D. Heim). While there are multiple sources for deriving normal to high-risk prevalence ratios, we present this example primarily to contrast the March 15, 2004, plan's assumption of no detectable BSE in the normal adult population with a different assumption based on one of the approaches suggested by the Harvard Center for Risk Analysis. Also, NASS officials noted in their comments on APHIS' surveillance plan that it is inappropriate to directly associate a statistical confidence level with such extrapolations. APHIS noted that when using other assumptions (such as non-Swiss European data) in the same formula, the extrapolated maximum BSE prevalence is reduced.

[12] In contrast, it may be reasonable to assume a low, if not zero false negative rate for cattle exhibiting clinical signs of BSE ("Comments on USDA bovine spongiform encephalopathy (BSE) surveillance plan," Harvard Center for Risk Analysis, March 12, 2004, page 4).

statistical projections in the plan significantly understate the maximum prevalence of total BSE, because they are based on only detectable BSE. Extending the previous example and assuming that the estimated maximum prevalence of detectable BSE is roughly 62.5 cases in normal adult cattle, this extrapolates to 781.25 (62.5 ÷ .08) total BSE cases in normal adult cattle.

***Unstated Limitations in Selecting a Small Sample of Normal Cattle***

Under the expanded surveillance program, testing of clinically normal adult cattle (20,000) has little, if any, statistical significance and may inadvertently create a false impression of the actual BSE incidence rate in these animals, due to the deceptively small sample size relative to the extraordinarily low expected prevalence of detectable BSE in this population, which is due to a combination of a low expected prevalence of total BSE and the high expected false negative rate for these cattle.

The IR Subcommittee, in reviewing USDA's BSE Surveillance Plan, recognized that the testing of all cattle slaughtered for human consumption is scientifically unjustified, in terms of protecting both human and animal health. However, they recommended that a random sample of healthy slaughter cattle over 30 months should be strongly considered to support the overall surveillance system and encourage reporting at the farm level.

At the time of our review, details of how APHIS plans to conduct surveillance of clinically normal adult cattle were not available. APHIS officials have advised us in written comments on June 24, 2004, that they are not testing these 20,000 animals to determine if BSE exists nor to statistically project the maximum BSE prevalence rates in normal cattle. Instead, the primary purpose of these tests is "to deter producers who might send potentially infected cattle into the normal slaughter process."

This objective, however, conflicts with published goals, as well as press releases by APHIS stressing the importance of testing adult, aged animals. According to published documents, APHIS officials stated that this population of animals is being tested because the disease has a very long incubation period, and APHIS wants to target its testing of animals born before the feed ban, which went into place in August 1997.

***Unstated Limitations in Estimating the Size of the High-Risk Population***

APHIS may have underestimated the number of adult cattle "dying on farms from unknown causes" or those with symptoms "not inconsistent with BSE." This is because of the lack of specificity in the National Animal Health Monitoring System (NAHMS) reported data on known causes of death (especially regarding beef breeding cattle). This concern is important because USDA may inadvertently overstate the

proportion of the high-risk population tested, and the reliability of any related statistical projection.

***Some Unstated Limitations in the Levels of Risk in Targeted Animals***

In determining the high-risk population, APHIS does not consider a risk-based determination of country of origin of BSE-positive animals. A 2001 Harvard Risk Assessment observed that the United States imports millions of cattle each year from Canada and Mexico. According to the Harvard study, approximately 80 percent of the cattle imported are slaughtered shortly after arrival. We discussed with APHIS officials the possibility of targeting for testing animals from those countries where BSE has been detected. According to an APHIS official, additional surveillance in specific areas of the United States, based on the country of origin, is not warranted, because imported cattle that have not been slaughtered shortly after importation have already been dispersed beyond the geographic areas where they were initially received. These cattle would be available for sampling selection under the expanded surveillance program.

As the surveillance program moves forward and supportable data regarding the cattle population and testing results are gathered, USDA should consider a risk assessment to target limited resources towards an approach that provides increased assurance that BSE can be detected and is not prevalent in the United States (see Finding 6).

APHIS needs to fully disclose the assumptions made in the design of its surveillance program and the limitations in its projections of the prevalence of BSE in the United Sates. Full disclosure is necessary to avoid misrepresenting the data and to minimize the risk of misinterpretation by the public, industry, or U.S. trading partners.

### Recommendation No. 1

Clarify the goals and objectives of the BSE surveillance program. Fully disclose the assumptions made in estimating the prevalence of BSE in the United States and the limitations on using the data.

### Agency Response.

APHIS agreed that additional discussion and clarification of these points would contribute to public understanding of its efforts (see exhibit E for the complete response). Unlike the case with many other animal diseases, APHIS recognized that science has yet to fully understand all aspects of BSE and that reasonable opinions differ in the scientific community. APHIS will prepare a more detailed explanation of the BSE surveillance program objectives and assumptions. This paper will also include some discussions of various options for extrapolating or inferring estimated prevalence rates in broader

populations. APHIS will complete this paper, and post it on the APHIS website by August 31, 2004. The paper will address specific concerns and issues raised by the audit, including:

- that critical assumptions in the surveillance plan could result in questionable estimates of BSE prevalence,
- any limitations in the sample selected,
- any limitations in the confidence of projections,
- any limitations in obtaining a geographic representation of U.S. cattle,
- recognizing that BSE might be found in animals not in the surveillance plan's target population,
- limitations inherent in testing normal cattle, including a small sample size,
- difficulties in estimating the size of the high-risk population, and
- uncertainty in determining the levels of risk in targeted animals.

APHIS will complete final action on this recommendation as described by August 31, 2004.

### OIG Position.

We accept the management decision.

## Recommendation No. 2

Develop contingency plans that address how APHIS will continue to implement the provisions of its expanded BSE surveillance plan if one or more States are unsuccessful in reaching their sampling goals.

### Agency Response.

APHIS agreed with this recommendation and recognized that it must obtain adequate representative samples from all parts of the country. APHIS noted the political boundaries of any given State may be less important than how the cattle in that State move through the surrounding region where practices are common.

APHIS actions included: 1) APHIS field personnel in each State worked with industry and State personnel to estimate the number of samples that it likely could obtain in that State, 2) APHIS created a database to capture data to allow for ongoing analysis throughout the surveillance effort with the capability to analyze data at all levels, and 3) planned to analyze collected data throughout the life of the program with significant deviations to be reported and addressed.

APHIS noted that if the ongoing analysis determines that it will fall short in certain States or regions, it will invoke a variety of outreach mechanisms and will engage in an appropriate action plan depending on the situation. APHIS Legislative and Public Affairs staff has planned a followup outreach campaign using advertisements, radio spots, and other marketing efforts. These will also target any areas in which APHIS may not be obtaining the desired number of samples.

Specific one-time actions as described will be completed by August 31, 2004.

**OIG Position.**

We accept the management decision.

## Finding 2 — USDA Faces Significant Challenges in Estimating a Maximum BSE Prevalence Rate for High-Risk Cattle

***Inherent Problems With Identifying the High-Risk Population and Testing Samples Need To Be Addressed***

Identifying the universe of high-risk cattle and developing detailed procedures for obtaining samples is critical to the success of the BSE surveillance program. As discussed in Finding 1, there are inherent problems with identifying the high-risk cattle population because the program is voluntary. Also, there may be significant uncertainty regarding whether weakened high and low-risk cattle condemned post mortem, restricted,[13] or passed after trim,[14] at FSIS-inspected slaughter facilities should be sampled.[15] This uncertainty is due to the inherent lack of obvious criteria for distinguishing diseases or injuries that cause symptoms not inconsistent with BSE from those diseases or injuries that do not. Such lack of distinction may blur the focus on this portion of the designated high-risk population by potentially excluding truly high-risk cattle or including truly low-risk cattle. This in turn may ultimately distort the projected maximum BSE prevalence rate or reduce the chances of detecting BSE, if it exists.

[13] Any meat or meat food product that has been inspected and passed, but cannot be released for human consumption until it has been subjected to required treatment, such as refrigeration, heating, cooling, or processed into a comminuted (pulverized) or otherwise ground product or processed into small pieces.

[14] After trimming adulterated portions of the carcass, this is the unadulterated portion which passed inspection.

[15] For the purpose of developing the targeted high-risk cattle population, APHIS included about 164,000 injured and 3,000 emaciated adult cattle that were either condemned post mortem or passed after trim by FSIS (in 2002). APHIS has acknowledged that this group would include animals with injuries or emaciation that are not related to BSE (i.e., bruising due to rough handling or a lesion associated with an old injury). APHIS and FSIS believe that since FSIS began condemning all nonambulatory disabled cattle on ante mortem inspection (starting on January 12, 2004) that some of those cattle previously passed after trim or condemned post mortem due to injuries or emaciation would currently be condemned ante mortem or not presented for slaughter. According to APHIS officials, they have no plans to sample cattle condemned on post mortem inspection or passed after trim, at this time.

During our limited fieldwork to determine how BSE surveillance was operating prior to June 1, 2004, we identified several operational weaknesses that can have an adverse impact on the surveillance program, if controls are not in place and if detailed operational procedures are not established. The surveillance program has been designed to target nonambulatory cattle, cattle showing signs of CNS disease (including cattle testing negative for rabies), cattle exhibiting signs not inconsistent with BSE, and dead cattle. We found that cattle condemned at slaughter for exhibiting CNS symptoms were not always tested, and that brain samples from cattle testing negative for rabies were not always submitted for BSE testing. This occurred because of 1) insufficient monitoring of slaughter data to ensure CNS animals were sampled, 2) lack of effective coordination between FSIS and APHIS, and 3) lack of formalized agreements with non-Federal laboratories involved in rabies testing. In addition, we were unable to evaluate how successful APHIS will be in collecting samples from cattle that "died on the farm," because detailed procedures for such sampling did not exist and no testing information was collected to identify this targeted group.

### *Cattle With CNS Symptoms Were Not Always Tested*

Cattle condemned at slaughter plants for CNS symptoms were not always tested for BSE. Cattle in this targeted high-risk population were not always sampled due to confusion in testing requirements and lack of coordination between FSIS and APHIS. This is especially significant because there are only a small number of cattle identified each year with CNS symptoms and it is critical that as many cattle as possible be tested. The cattle were not sampled, in part, due to differing directions in FSIS and APHIS inspection and sampling procedures.

OIE procedures[16] provide that surveillance programs should focus on the subpopulation containing cattle displaying clinical signs compatible with BSE. These clinical signs include those animals displaying progressive neurological abnormalities without signs of infectious illness.

Between FYs 2002 and 2004 (through February 2004), FSIS condemned 680 cattle of all ages due to CNS symptoms. About 357 of these could be classified as adult. We could validate that only 162 were tested for BSE (per APHIS records).

[16] Surveillance and Monitoring Systems for Bovine Spongiform Encephalopathy, Articles 3.8.4.1 and 3.8.4.2.

**Figure 3. Cattle Condemned vs. Cattle Tested**

| Year | Adult Cattle Condemned for CNS Symptoms By FSIS | Total Cattle Condemned for CNS Symptoms By FSIS | *Samples Tested Showing Clinical Sign(s) of CNS per APHIS Database |
|---|---|---|---|
| 2002 | 135 | 285 | 37 |
| 2003 | 133 | 266 | 63 |
| 2004 | 89 | 129 | 62 |
| Total | 357 | 680 | 162 |

* Number shown is the number of samples tested that originated from slaughter facilities (samples from farm locations and rendering companies are not included). FY 2004 statistics are through February 2004.

Our field visits to eight slaughter plants reporting condemnations for CNS and contacts with APHIS area veterinarians-in-charge (AVIC) disclosed that there were weaknesses in reporting CNS animals by FSIS and in obtaining the samples by APHIS. Figure 4 shows the low testing numbers for four of the eight plants visited and the reasons tests were not taken. Noticeably, the age of the animal was most frequently offered as a reason.

**Figure 4: Cattle Condemned Exceeded Cattle Tested, 2003-2004**

| Plant | Cattle Condemned for CNS by FSIS | Cattle Tested for BSE by APHIS | Cattle Not Tested | Reasons Cattle Not Tested |
|---|---|---|---|---|
| A | 9 | 0 | 9 | 1/ |
| B | 61 | 2 | 59 | 2/ |
| D | 48 | 7 | 41 | 3/ |
| E | 2 | 1 | 1 | 4/ |
| Totals | 120 | 10 | 110 | |

1/ FSIS Inspectors did not believe they were required to report cattle to APHIS for testing.
2/ It was APHIS' policy not to sample animals younger than 24 months of age. Records were not available, however, to confirm the age of the animals. In one case, APHIS could not locate transportation for the suspect animal. In another case, APHIS personnel were not available to take a sample. In a third case, the FSIS inspector was not aware of the requirement for notifying APHIS when a cow was condemned for CNS.
3/ It was APHIS' policy not to sample animals younger than 24 months of age. Records were not available, however, to confirm the age of the animals. In one case, APHIS did not have personnel available to take a sample on the day the cow was reported by FSIS.
4/ FSIS records did not explain why this animal was not sampled; there was no record of referral for testing.

We also identified problems with inspection data reported by FSIS. Inspectors at three of the eight plants we visited appeared to overstate CNS condemnations significantly enough to impact national statistics. One facility reported 35 CNS condemned cattle in FY 2003 (13 percent of the national total), but its inspection records did not show that the cattle were condemned for CNS. The inspector told us that the count of 35 may have included some cattle condemned for reasons other than CNS. He said there were only about five cattle condemned for CNS symptoms in FY 2003.

APHIS Veterinary Services (VS) Memorandum No. 580.16, dated June 11, 1997, recognized the disparity in the number of cattle condemned by FSIS for CNS signs and the number of tests for BSE conducted by APHIS. The memorandum also states that "based on information provided by FSIS, the number of adult cattle (2 years of age or greater) condemned at slaughter due to CNS signs is much greater than the number whose brains have been collected for testing. It is essential that brain specimens be collected from adult cattle condemned for CNS signs as part of our national surveillance of BSE."

We could find no further directives from APHIS or FSIS on actions necessary to resolve this disparity until the media disclosure of an untested cow exhibiting possible CNS signs in April 2004. Shortly after that disclosure, APHIS and FSIS issued a joint instruction, FSIS Notice 28-04 (dated May 20, 2004), which stated that all animals condemned for CNS clinical symptoms would be sampled for BSE, regardless of the age of the animal. FSIS will also sample all animals condemned during ante mortem inspection except for veal calves weighing less than 400 pounds.

FSIS and APHIS need to develop sufficient management controls to ensure this policy is followed.

***USDA Needs To Increase Testing of Rabies-Negative Brain Samples***

A high priority population, rabies-negative samples, has not been adequately pursued for BSE testing. This target group is important to USDA's assertions regarding the prevalence of BSE in the United States because rabies cases exhibit clinical signs not inconsistent with BSE, and a negative rabies test means the cause of the signs has not been diagnosed. 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 routinely submit samples for BSE testing. APHIS records showed only limited numbers of rabies-negative cases have been submitted for BSE testing.[17]

The March 15, 2004, expanded BSE Surveillance Plan states that CNS signs and/or rabies-negative cases are part of the target population and those samples will be collected from public health laboratories. There are approximately 35 U.S. laboratories accredited by the American Association of Veterinary Laboratory Diagnosticians and an undetermined number of other State, regional, and local laboratories that perform rabies testing. We identified that APHIS obtained rabies-negative samples from 23 States during FY 2003 and from

[17] For FYs 2002, 2003, and 2004 (through February 2004), NVSL received 170, 133, and 45 rabies-negative samples, respectively. APHIS officials noted for that period they were only interested in testing adult cattle with rabies-negative clinical signs.

10 States during FY 2004 (through February 2004). We also noted that, at the time of our fieldwork, APHIS had generally not executed any formal agreements with these non-Federal laboratories to provide for the routine referral of rabies-negative samples for BSE testing.

A NVSL official said rabies-negative cases are one of the most important sources for BSE testing. He said that APHIS needs to work harder to get rabies-negative samples because BSE and rabies symptoms are so similar. He also said the program is voluntary; APHIS does not have any authority over public health and State veterinary diagnostic laboratories.

We interviewed officials at five laboratories that test for rabies. Those officials confirmed they are not required to submit rabies-negative samples to APHIS for BSE testing. A South Dakota laboratory official said they were not aware they could submit rabies-negative samples to APHIS for BSE testing. A laboratory official in another State said all rabies-negative cases were not submitted to APHIS because BSE was "not on their radar screen." Officials from New York, Wisconsin, Texas, and Iowa advised they would not submit samples from animals they considered too young. Four of the five States contacted defined this age as 24 months; Wisconsin defined it as 30 months. Texas officials also advised that they do not always have sufficient tissue remaining to submit a BSE sample.

The following table shows the proportion of rabies-negative samples that were not sent for BSE testing from the laboratories within the five States we contacted.

**Figure 5: Rabies-Negative Tests Not Sent for BSE Testing**

| State | Time Period | Negative-Rabies Tests | Sent for Testing | Not Sent for Testing |
|---|---|---|---|---|
| Iowa | FY 02-03 | 175 | 2 | 173 |
| Wisconsin | FY 02-04 | 116 | 8 | 108 |
| South Dakota | FY 01-04 | 81 | 0 | 81 |
| Texas | FY 03 | 108 | 29 | 79 |
| New York | FY 03 | 106 | 55 | 51 |
| Total | | 586 | 94 | 492 |

As of June 1, 2004, APHIS has not provided us with any detailed plans on how samples for this targeted high-risk group will be obtained.

***Process for Obtaining Samples From Animals That "Died on the Farm" Has Not Been Developed***

We were unable to determine how APHIS plans to obtain samples from the targeted high-risk population known as "cattle that died on the farm." Identifying this target group and obtaining representative samples will be a significant challenge for USDA because of the inherent problems with obtaining voluntary compliance and transporting the carcasses for testing. Also, we could not determine if samples from this targeted group have been obtained in the past (this category was not included on VS Form 10-4, Specimen Submission).

According to the NVSL database, 2,818, 3,107, and 2,749 samples were shown as "dead" for FYs 2002, 2003, and 2004 (through February 2004), respectively. We noted "died on farm" was sometimes listed in the Additional Data section of the form, but that information was not incorporated into the database. For example, we noted that one submitter in Mississippi had preprinted "died on farm" on his submission forms. Those animals were listed as "dead" in the NVSL database.

Identifying truly high-risk cattle that die on the farm may be complicated by the reluctance of producers to submit them and the motivation to mischaracterize low-risk carcasses as "high risk" since only the latter may qualify for reimbursement. These inherent problems can lead to an understatement of the projected maximum BSE prevalence rate for truly high-risk cattle and a reduced chance of detecting BSE, if it exists. In addition to developing a process for obtaining samples, APHIS will need to collect better information to differentiate between samples taken from livestock "condemned by slaughter plants" and samples taken from high-risk animals that "die on the farm." This information is important because the high-risk animals that die on the farm comprise the largest component of the targeted high-risk population[18] and are the most difficult to define, obtain, and test.

APHIS has accredited[19] over 60,000 veterinarians across the country, including almost all veterinarians that provide care to large animals (this includes cattle). As accredited veterinarians, these individuals are to immediately report to the AVIC or the State Animal Health Official all diagnosed or suspected cases of a foreign or eradicated animal disease for which APHIS has a control or eradication program. This includes BSE. If properly utilized, this network of animal care

[18] The BSE Surveillance Plan, dated March 15, 2004, page 2, states the 446,000 adult cattle APHIS estimated to be high-risk includes an estimated "251,500 adult cattle that die on farm each year due to unknown reasons or reasons that could be consistent with BSE-related clinical signs."

[19] APHIS administers the National Veterinary Accreditation Program, which is a voluntary program that certifies private veterinary practitioners to work cooperatively with Federal veterinarians and State animal health officials.

providers could prove an effective tool in identifying suspected cases of BSE on farms and ranches.

A Government Accountability Office (GAO) audit report issued in January 2002[20] also raised concerns with USDA efforts to sample cattle that die on the farm. GAO reported that with regard to animal testing to detect BSE, the USDA had steadily increased the number of animals it tested, but the agency did not include many animals that died on farms. USDA did not track brain samples from cattle that had died on farms; the few that were taken would have been counted in with the nonambulatory cattle. USDA told GAO that efforts to obtain samples from animals that died on farms had been limited by: a) lack of sufficient staff and time to collect the samples; b) lack of adequate laboratory capacity to conduct the tests; and c) lack of timely intervention (when animals die on farms they may be buried on the farm, taken to landfills, or collected by renderers who recycle animals and other animal tissues into, among other things, animal feed).

As of June 1, 2004, USDA has not developed a plan as to how these challenges will be addressed.

***Proper Identification of "Downers" Is Still Critical To the BSE Surveillance Program***

APHIS and FSIS had differing definitions of the targeted group of "downer" cattle that caused confusion as to when BSE samples were to be taken. Although FSIS and APHIS have recently issued a joint directive to their field inspection and veterinary staffs to provide clarification, additional direction is necessary to ensure that all cattle displaying symptoms not inconsistent with BSE are sampled.

Before the first case of BSE was discovered in the United States, there was no regulatory definition of "downer" by either FSIS or APHIS. However, an FSIS directive[21] defined a "downer" as nonambulatory disabled livestock that cannot rise from a recumbent position or cannot walk. "Downer" livestock were identified as suspect and were either condemned upon ante mortem inspection, condemned upon post mortem inspection, or allowed to enter the food chain if they passed post mortem inspection.

In response to the discovery of BSE, FSIS amended the CFR[22] to define animals that should be prohibited for human food as nonambulatory disabled livestock. The CFR states that such animals shall be condemned and cannot enter the slaughter establishment. FSIS officials stated that this terminology more accurately described the

[20] GAO Audit Report, Mad Cow Disease: Improvements in the Animal Feed Ban and other Regulatory Areas Would Strengthen U.S. Prevention Efforts, GAO-02-183, dated January 25, 2002. (GAO was formerly known as the General Accounting Office.)
[21] FSIS Directive 6900.1 (Revision 1), dated April 29, 1992.
[22] 9 CFR, Part 309.2, dated January 12, 2004.

prohibited cattle rather than using the term "downer" that had not been defined in the regulations.

After an incident in Texas in which a cow displaying possible CNS symptoms was condemned and rendered without BSE testing, FSIS and APHIS issued a notice[23] substantially broadening the sampling process at slaughter plants. The notice stated that FSIS would take samples from all cattle (without regard to age) that show signs of CNS disorders (about 300 annually). In addition, the notice specified that all ante mortem condemned cattle would have a portion of the brain collected, except for cattle that were 400 pounds or less (veal calves).

According to the March 2004 BSE surveillance plan, APHIS considers "downer" cattle to be nonambulatory animals that cannot rise from a recumbent position or cannot walk. This is consistent with the FSIS' definition of a "downer." However, APHIS also defines high-risk cattle as being severely weakened, though they may be able to stand and walk for brief time periods. Since FSIS may not always condemn cattle in a weakened state that are ambulatory at the time of inspection, there is a potential this targeted high-risk group may not be tested for BSE.

The IR Subcommittee considered the merits and the unintended consequences of the ban prohibiting nonambulatory cattle (downers) from entering the food supply. Since downers will no longer be available for BSE surveillance at inspected slaughterhouses, the Subcommittee stated that it is "imperative that the USDA take additional steps to assure that facilitated pathways exist for dead and nonambulatory cattle to allow for the collection of samples and proper disposal of carcasses."

APHIS and FSIS need to provide additional direction to their field staffs as to how cattle in a "severely weakened" state will be identified and tested. Also, USDA needs to develop a plan for identifying and testing "downer" cattle no longer sent to slaughter.

***Age Requirement for BSE Testing Should Be Standardized To Prevent Confusion***

Inspection and BSE testing guidance contain inconsistent age criteria for testing cattle for BSE. This has contributed to the confusion of APHIS and FSIS field staffs as to which cattle should be tested.

APHIS Veterinary Services Memorandum No. 580.16, dated June 11, 1997, states, "All adult cattle (**2 years of age and older**) with CNS signs, including cattle condemned at slaughter, should be investigated as foreign animal disease investigations."

[23] FSIS Notice 28-04, FSIS Sample Collection From Cattle Condemned During Ante Mortem Inspection for the BSE Surveillance Program, dated May 20, 2004.

A 1997 memorandum[24] provides for AVICs to contact State diagnostic laboratories to identify the laboratory's standard operating procedures for examining brains of cattle with CNS signs and to identify the areas of the brain that are routinely examined. The memorandum states, "The medulla must be examined for lesions of BSE.….AVICs are to report quarterly on the number of adult (**20 months of age or greater**) cattle with CNS signs that have been examined histologically from each laboratory." The memorandum also notes that many State diagnostic laboratories were reporting the number of CNS-diseased brains they examined and found negative for lesions of BSE, but that the reports did not specify the age of the animals or the clinical signs reported by the submitter. The memorandum stated that incomplete reports from diagnostic laboratories would no longer be included in surveillance reports.

FSIS procedure[25] issued to meat inspectors at slaughter plants required that cattle **20 months and older** exhibiting CNS symptoms be referred to APHIS for testing. However, a newspaper article, dated May 4, 2004, quoted a USDA spokesman stating that the agency's procedure was to test any and all cows exhibiting CNS disorders. According to the news article, an anonymous USDA veterinarian told the media that APHIS would rarely show up if the CNS animal was less than **30 months old**. Our field visits confirmed that APHIS employees would not take samples unless cattle were either at least **24 or 30 months old**.

20 months and older. NVSL followed the policy of testing all submitted samples; however, only cattle 20 months and older were counted toward meeting sampling goals. (For FYs 2002, 2003, and 2004 (through February 2004), the NVSL received and tested 199 cattle less than 20 months of age and an additional 144 animals between 20 and 23 months of age.) Also, a draft implementation plan being developed by the APHIS AVIC in Nebraska showed sampling would include animals **20 months and older**. The AVIC believed dentition was inexact, so 20 months was specified in the State plan.

24 months and older. APHIS' training procedures show cattle **24 months and older** are to be tested. Before December 2003, APHIS officials advised they were accepting samples only from those cattle more than 24 months of age. In addition, the expanded February 19, 2004, draft Surveillance Plan shows cattle **over 24 months** are to be tested.

[24] Veterinary Services Memorandum No. 580.17, dated August 26, 1997.
[25] FSIS Notice 15-02, Bovine Spongiform Encephalopathy (BSE) Surveillance Program, dated May 10, 2002.

Over 30 months. APHIS officials advised that since January 1, 2004, they will test animals age **30 months or older.** The APHIS Surveillance Plan, dated March 15, 2004, shows cattle **over 30 months** are to be tested.

Our review of sampling information contained in the NVSL database showed that in FY 2003, 9,848 tested animals were categorized as "adult," and in FY 2004 (through February 2004), 6,408 tested animals were recorded as "adult." We could not determine what age classified the cattle as "adult" because age determinations were not documented on the sample submission forms (i.e., over 20, 24, or 30 months) even though instructions on the form specify that the approximate age is to be documented in years, months, weeks, or days.

On May 5, 2004, the APHIS and FSIS National offices issued a joint policy that requires BSE testing of all cattle condemned by FSIS on ante mortem inspection for exhibiting signs compatible with CNS disease, regardless of age.

Because of the confusion regarding the minimum age required for a BSE test, there is a potential that cattle in other segments of the targeted high-risk population may not be subject to BSE testing (i.e., rabies-negative and cattle that die on the farm). Consistent definitions and age requirements are essential to ensure that cattle in the targeted high-risk population are tested. This is especially critical since USDA is expanding its network of cooperating partners, who will need to have clear direction.

### Recommendation No. 3

Develop and implement management controls to ensure USDA policy for sampling cattle condemned at slaughter is consistently implemented by FSIS and APHIS field staff.

### Agency Response.

APHIS and FSIS agreed with this recommendation, and noted their understanding that it applies to cattle condemned ante mortem. APHIS has implemented measures to ensure a cross-check between FSIS condemned cattle statistics and APHIS BSE surveillance statistics.

Both FSIS and APHIS have issued instructions to field personnel that clearly state the policy to sample all cattle condemned on ante mortem inspection (except veal calves condemned for non-CNS reasons). On June 1, 2004, FSIS implemented FSIS Notice 28-04, which provides sample collection, documentation, and shipping procedures to inspection program personnel. Additionally, on May 27, 2004, FSIS

issued FSIS Notice 29-04, which outlines FSIS' expectations regarding APHIS arrangements with establishments for sampling condemned cattle at an alternative central location. In particular, the notice defines what controls FSIS has in place for working with an establishment during the sampling process, and recognizing an APHIS arrangement to have FSIS condemned cattle transported offsite from the establishment to an APHIS central sample collection point. On July 29, 2004, FSIS Notice 40-04, Additional Bovine Spongiform Encephalopathy Surveillance Sampling Questions and Answers, was issued. This notice responded to questions FSIS personnel asked regarding the BSE sampling program.

APHIS Veterinary Services Memorandum 580.16 outlines the policy for the entire BSE surveillance program, including the expectations for obtaining samples from all cattle condemned on ante mortem inspection, with the exception of veal calves condemned for non-CNS reasons. Personnel in both APHIS and FSIS have been trained on the sample collection process. Also, APHIS has entered into an agreement with the Agricultural Marketing Service (AMS) to review the BSE surveillance plan. The initial review will be completed by September 15, 2004, with a followup review some time in the next 16-18 months.

APHIS will measure the results of these efforts through ongoing analysis and cross-checking of data with FSIS and through the results of the AMS review process. In addition, FSIS' Office of Program Evaluation, Enforcement, and Review will evaluate the FSIS ante mortem/alternative collection site procedures as well as ensure that there is no diversion of condemned animals into edible channels in accordance with FSIS Notice 33-04.

These actions will be ongoing and continuous throughout the program.

### OIG Position.

We accept the management decision.

## Recommendation No. 4

With assistance from public health and State veterinary diagnostic laboratories, develop and implement a process for testing rabies-negative samples for BSE.

### Agency Response.

APHIS agreed with this recommendation and has already taken several actions. APHIS first engaged in conversations with the leadership of

the American Association of Veterinary Laboratory Diagnosticians to emphasize the importance of testing rabies-negative samples. APHIS followed this with a letter to all State laboratories regularly conducting rabies testing. This letter requests submission of samples that meet the APHIS' target population. Also, APHIS coordinated this request with the national rabies coordination group at the Centers for Disease Control, and they have distributed similar requests.

APHIS also wrote to the laboratories to describe specific sampling and shipping procedures and to emphasize that NVSL will provide shipping boxes and any assistance necessary to receive samples. These standard procedures were distributed to all State animal health diagnostic laboratories and all known public health laboratories throughout the United States.

APHIS directed each AVIC to personally contact the appropriate public health authorities and laboratories conducting rabies testing by August 31, with the AVICs also directed to report the results of these contacts by September 30. APHIS will hold discussions about the appropriate splitting of samples to ensure access to proper tissue for each laboratory (rabies and BSE), with agreed procedures noted for splitting and/or forwarding appropriate samples.

APHIS noted that there are at least 200 laboratories that conduct some level of rabies testing on animal samples and that they believed that cooperation through contact and reminders is the best approach to maintaining access to those samples that fit the targeted population.

APHIS will measure the results of these efforts through the described ongoing analysis, conducted on a regular basis throughout the program. Specific one-time actions as described will be completed by September 30, 2004.

**OIG Position.**

We accept the management decision.

## Recommendation No. 5

Provide outreach and education to accredited veterinarians on BSE issues and develop cooperating relationships that will facilitate the identification, reporting, and testing of suspect "high-risk" animals on the farms, feedlots, etc.

### Agency Response.

APHIS agreed with this recommendation. APHIS noted it had longstanding relationships with accredited veterinarians for all disease reporting purposes and will build on those relationships to encourage their assistance. Accredited veterinarians are obligated to report highly suspicious clinical cases and are generally well aware of this professional responsibility. (Of approximately 79,000 accredited veterinarians, fewer than 10 percent are working in bovine, mixed animal, or large animal practices.)

APHIS actions include: 1) contacting applicable veterinarians, 2) providing information directly to accredited veterinarians during regular liaison activity, 3) using e-mail to distribute information, 4) distributing BSE Surveillance information sheets, and 5) conducting outreach efforts at fairs, clubs, industry meetings, and other agricultural events to inform the public.

APHIS is in regular contact with the American Veterinary Medical Association (which has BSE information prominently displayed on their main web page), the American Association of Bovine Practitioners, and other veterinary and producer groups to ensure education and understanding of BSE clinical signs and symptoms, as well as the targeted sampling program.

APHIS will continue regular contact with the various veterinary associations and send regular mailings to accredited veterinarians as reminders. Also, APHIS will ensure that information is available about its fee-basis offers for sample collectors and cost neutral options for producers.

These actions – maintaining contact and providing information – will be ongoing and continuous throughout the program.

### OIG Position.

We accept the management decision.

## Recommendation No. 6

Develop sampling and reporting procedures that require accurate classification of samples taken from high-risk populations.

### Agency Response.

APHIS agreed with Recommendations Nos. 6 and 9 and provided a consolidated response for the recommendations. APHIS has developed

a database to enable it to track and analyze various data points on samples. The database captures data from an electronic version of the standard laboratory submission form, VS Form 10-4, as well as a supplemental data form. The supplemental form that accompanies each sample requires the submitter to note the age, clinical signs, condemnation code (where applicable), and 'category' (i.e., where collected and reason). Electronic submissions of these forms and business rules in the database ensure consistency.

APHIS has trained sample collectors on use of the electronic forms and instructed them to accurately record the relevant information necessary to classify samples into various aspects of the targeted population. A total of 985 personnel – including personnel from APHIS, FSIS, State animal health agencies, and contractors – have received this training. Compact disk (CD) copies of the entire training sessions for the net casts and satellite seminars have been distributed. Also, sample collectors can find written instructions in the BSE Surveillance Guide. APHIS attached a list of training courses and opportunities provided.

APHIS recognizes that data collection processes over the past 14 years of the surveillance program have varied considerably. In general, NVSL personnel recorded certain data in multiple formats using information noted on the submission form. To address this inconsistency, APHIS has developed a new, single database that allows the laboratories to track sample submissions and report test results, and provides a repository for data gathered at the point of sample collection. These data include information about the sample collector, the origin of the animal, the collection site, and specific animal information. For example, when a sample is collected at a rendering facility, that facility is documented as the site of collection and the location from which the animal carcass originated before arriving at the rendering facility is documented as the owner or source location. Moreover, information pertaining to clinical signs that the animal was exhibiting prior to death is also collected. If the animal is sampled because it is condemned at slaughter, the reason for its condemnation is entered into the database. Other data that are collected include all identification on the animal, and the animal's age, sex, and breed. Finally, the general category of the high-risk population to which the sampled animal belongs (e.g., suspect, dead, nonambulatory, etc.) is recorded.

The primary data entry occurs at either the sample collector or Area Office level; the laboratory also has the capability to enter data when necessary. The system is interlinked, and allows data entry onsite at a collection location with electronic transmission to the designated laboratory or at the laboratory. The system can return reports of results to the submitter and the AVIC.

APHIS is monitoring for data integrity and quality, and has developed data reconciliation protocols. APHIS recognized that all data points may not be known for every animal sampled, but it will seek to maximize the data it can obtain. If a particular submitter or collector does not regularly provide testable samples or adequate and full information, the AVIC in the relevant State will follow up to correct any deficiencies. Additionally, the AMS quality assurance review will evaluate the training of the sample collectors and how well they are completing the Sample Data Form and VS Form 10-4 to verify accuracy.

APHIS recognized that ensuring it identifies and obtains samples from animals dying on the farm is a special challenge. APHIS noted that for purposes of its enhanced surveillance program, the key is obtaining the sample and information about clinical signs prior to death. Whether the animal died on the farm, on the way to the salvage facility, or in the pens at the slaughter facility does not matter because in each of these instances, a sample could be collected and recorded as "dead" or "died of unknown causes" – which fits the targeted population.

APHIS advised that the actions to address this recommendation – data monitoring and reporting – will be ongoing and continuous throughout the program.

**OIG Position**.

We accept the management decision.

## Recommendation No. 7

Clarify sampling and testing requirements for those animals in a weakened state sent to slaughter. Develop a plan for testing "downer" cattle no longer sent to slaughter.

**Agency Response.**

APHIS and FSIS agreed with this recommendation. Although FSIS does not have a specific regulatory definition for severely weakened, APHIS finds that animals encompassed by their use of this term are already covered in the FSIS regulations.

Under the interim final rule published January 12, 2004, (9 CFR 309.2 and 309.3), nonambulatory disabled livestock are defined as animals that "cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or

metabolic conditions." All nonambulatory disabled cattle are condemned and not allowed to enter the food supply. Other animals such as those exhibiting septicemia, toxemia, and those encompassed by the regulatory definition of nonambulatory disabled are condemned on ante mortem. APHIS and FSIS agree that the term severely weakened encompasses several distinct ante mortem conditions already in the FSIS regulations. Animals that are severely weakened at ante mortem would therefore be condemned by FSIS under their regulations and sampled consistent with FSIS Notice 28-04.

APHIS VS Memorandum 580.16 includes animals that are "severely weakened though they may be able to stand and walk for brief periods of time" in the clinical presentation criteria for animals to be sampled as part of the targeted cattle population.

APHIS noted that there are other channels available for nonambulatory animals other than slaughter for human food. These facilities include rendering facilities, 3D/4D or salvage slaughter facilities, and other disposal options, such as deadstock facilities. APHIS provided statistics that they believed demonstrate continued access through channels other than slaughter for human consumption.

APHIS will continue ongoing and routine evaluations to document maintained access to these populations, and the AMS quality assurance review will validate its efforts. Furthermore, if targeted samples are not acquired, contingency plans referenced earlier will address this issue on an as-needed basis. The initial AMS review will be completed by September 15, 2004, and other actions will be continuous and ongoing throughout the program.

### OIG Position.

We accept the management decision.

## Recommendation No. 8

Issue consistent USDA age requirements for testing the various targeted high-risk populations.

### Agency Response.

APHIS agreed with this recommendation. APHIS recognized that the age requirements for sampling have changed at times since 1990 and noted that only samples above the then in place age limit were reported in any official counts of surveillance samples or included in any statistical calculations or analysis.

APHIS noted it had already addressed this recommendation through the provision of APHIS VS Memorandum 580.16 which states that only samples that meet the target population, including the age requirement, will be counted in any data analysis. FSIS Notice 29-04 provides that APHIS sampling of ante mortem condemned slaughter origin cattle is consistent with FSIS Notice 28-04.

### OIG Position.

We accept the management decision.

USDA needs to establish and implement a strong management control structure to provide assurance that the BSE surveillance program has been effectively implemented and operates as represented to the public, industry, and U.S. trading partners. Prior to June 1, 2004, we reviewed the surveillance policies and processes in place and performed fieldwork to determine how BSE sampling and testing was being accomplished. We identified concerns that, if not corrected, will have an adverse impact on the success of the expanded BSE surveillance program. Most of our concerns relate to the way APHIS collects test samples and maintains information about them. Specifically—

- Some sample-submitters frequently submitted nonviable samples.

- Sample submission documents frequently listed the slaughter establishment as the owner of the animal rather than the ranch or dairy it came from. This can affect APHIS' ability to timely trace potentially diseased animals to their herd of origin.

- APHIS did not always exclude nontarget animals from its surveillance statistics. Animals that had been tested for signs of diarrhea, severe pneumonia, and inner ear infection were counted towards the surveillance goals. Therefore, conclusions made about the prevalence of BSE in high-risk cattle may be compromised.

- Some entries in APHIS' database were incomplete, inaccurate, or questionable. Sample submitters did not include critical data (i.e., breed, sex, clinical signs) that are essential to any risk analysis and measurement of the success of surveillance efforts.

Inaccuracies in data occurred because the system APHIS used to maintain the data was not designed for that purpose. We are recommending that APHIS expedite its development of a new system to track and report its accomplishments under the expanded surveillance program. We are also recommending that APHIS implement performance measures and a continuous risk assessment to enhance its management of the surveillance program and better assess the program's effectiveness.

## Finding 3 — APHIS' Sampling and Data Collection Processes Raise Questions About the Integrity of Surveillance Data

APHIS needs to reform its processes for collecting samples and for ensuring the integrity of its BSE test data. The current processes do not

ensure that all samples submitted are properly identified according to the animal's origin, that all animals whose tests are recorded are within the target or nontarget population, and that all samplers retain backup samples of brain tissue for purposes of verification should the sample test positive. APHIS processes led to inconsistent practices and improper data entries because of inadequate training, inadequate instructions, and unclear criteria. These deficiencies can impact APHIS' ability to timely trace potentially diseased animals to the birth cohort and other risk animals, as well as any by-products that may need to be recalled. Also, APHIS' ability to evaluate and assess the effectiveness of its surveillance program can be compromised.

a. Collecting and Submitting Samples

APHIS needs to adequately train the parties responsible for collecting and preparing samples and the accompanying paperwork to support the integrity of its BSE testing program. Before December 2003, APHIS had developed a limited amount of handouts and training materials for APHIS and State personnel. There was no standard training specifically designed for those sample collectors working in the private sector and no requirement that training or reference material of any type be provided to them. As a result, field personnel did not consistently prepare and process samples for submission.

Training needs were manifest in several areas. Field personnel in Nebraska and Missouri did not normally keep excess tissue, while those in Washington State, where the cow tested positive for BSE, did. Some APHIS and State personnel stated that frozen samples of excess tissue may be retained for up to 30 days after a test result is reported, but this guidance is not presented in any official APHIS rules, directives, or notices. Concerning identification of cattle tested, the January 30, 2004, BSE Surveillance Guide Training notes that all identification devices (i.e., ear tags), brands (in digital pictures), and tattoos (in refrigerated tissue) will be collected and maintained by the submitter/APHIS area office until a negative diagnosis is received. However, we observed one instance where cattle ear tags were incorrectly submitted with the BSE samples. Laboratory officials estimated that 2 percent of the time they incorrectly received ear tags along with BSE samples, instead of the tags being retained onsite.

We also found that specimen submission forms (VS Form 10-4) were not properly completed by sample collectors because instructions for the form only explained 2 of the 22 form entries.

For FYs 2002 and 2003, submitters of samples failed to list the breed of the tested animal about 18 percent and 43 percent of the time, respectively. They failed to list the sex of the animal about 8 percent of the time for both years. For FY 2004, through February 2004, submitters failed to list the breed of the animal 36 percent of the time, its sex 10 percent of the time, and its clinical signs, identification, age, and owner less than 1 percent of the time. These data are essential to any risk analysis and measurement made of the success of surveillance efforts.

b. Recognizing Sampled Cattle According To Their Geographic Locations

Data submitted to the NVSL were not sufficient to adequately identify the origin of the tested animal or permit accurate assignment of samples against geographic sampling goals. The BSE specimen submission forms and the NVSL database disclosed that the slaughter (or rendering) plants where the animals were slaughtered were generally shown as the owners rather than the farmer, rancher, dairy, or feed lot that last marketed the animal. APHIS headquarters officials stated that they intended that the farmer, rancher, or dairy where the animals came from should have been documented on the form rather than the slaughter or rendering firm where the sample was collected.

The NVSL assigned geographic locations (origin) to the tested sample that were frequently incorrect. For example, the NVSL database showed that for FY 2003, a Wisconsin slaughter establishment was the owner providing the most samples (2,445) for BSE testing. However, the slaughter establishment actually purchased animals from other States before slaughter. By contrast, we identified one APHIS employee at a Florida slaughter establishment who provided 376 samples showing the owners' locations as the States from which the cattle were trucked. Similar practices were noted for 281 samples from an Oregon slaughter establishment and 20 samples from an Indiana slaughter establishment, both of which recorded owner locations in other States. We concluded that generally the data in the NVSL database could not be relied upon to show the geographic location (origin) of the cattle.

As noted above, the specimen submission form includes instructions for completing the form, but these instructions explain only 2 of the 22 entries needed. Unexplained is the part of the form that asks for the origin of the animals.

c. Distinguishing Nontarget Cattle From the Target Population

APHIS needs to properly classify the clinical signs tested for BSE. We found lack of adequate data and inconsistencies in how test results were reported toward BSE surveillance program accomplishments. Reporting controls are necessary if USDA is to conduct an adequate risk assessment of cattle most at risk for BSE and to assess the effectiveness of its BSE surveillance program.

Reacting to criticism that it allowed a cow with possible CNS symptoms to be rendered without taking a sample for BSE testing, FSIS issued a notice[26] substantially broadening the sampling process at slaughter plants. The notice stressed that FSIS will take samples from all cattle that show signs of CNS disorders (about 300 annually). Based on the wording of the notice, however, FSIS inspectors will be sampling steers, heifers, and calves that are condemned for symptoms, such as pneumonia, that are not related to any BSE symptoms. APHIS officials told us that they would not include tests of nontargeted animals in their statistics showing achievement of goals, but they could not explain how such exclusions will be identified in its database.

We also identified cases in which animals that had been tested for signs unrelated to BSE were included in reported BSE testing statistics. Test results for those animals that suffered from diarrhea, severe pneumonia, high temperature, and inner ear infections were included in the reported BSE testing results. Among the cases that NVSL classifies as counting towards BSE surveillance goals are those cattle that are reported as sick. In FY 2003, the NVSL classified 374 of 20,514 cattle samples received for BSE testing as sick. In FY 2004, the NVSL classified 552 of 11,488 cattle samples received for BSE testing as sick.

Laboratory officials stated that a list does not exist that clearly defines the diseases and clinical signs indicating BSE. However, an NVSL official stated that animals with diarrhea and severe pneumonia should not count towards BSE surveillance goals, because animals with these conditions are not included in APHIS' target population.

All animals tested for BSE should be identified in the BSE testing database with appropriate identifying characteristics, location of

[26] FSIS Notice 28-04, FSIS Sample Collection From Cattle Condemned During Ante Mortem Inspection for the BSE Surveillance Program, dated May 20, 2004.

origin, and clinical signs. This information is essential for risk analysis and for USDA to determine if changes are needed to its surveillance program.

### Recommendation No. 9

Develop written guidance detailing how animals should be classified and recorded in the BSE database, based on the clinical signs of the animal.

#### Agency Response.

See the Agency Response under Recommendation No. 6 and exhibit E.

#### OIG Position.

We accept the management decision.

### Recommendation No. 10

Develop instructions for the specimen submission forms that provide specific instructions on the information to be included, specifically clarify requirements relating to the origin of the animal. Develop a followup process to ensure erroneous or improperly completed forms are corrected.

#### Agency Response.

APHIS agreed with this recommendation and cited steps they had taken to implement it. Actions taken were:

- Instructions on the completion of forms (electronic and/or web-based) were included in the BSE Surveillance Guide sent to field sample collectors.
- All of the sample collectors had multiple training opportunities including Web casts, training CDs, and a satellite seminar.
- All training addressed the completion of electronic forms and emphasized accurate and timely data entry.

The response also stated that with the enhanced BSE surveillance effort, a new module of VS' surveillance information systems has been developed and is being used. This new database (see response to Recommendations Nos. 6 and 9 for details) provides support for the laboratories to track sample submissions and report test results, and a repository for data gathered at the point of sample collection. These data include information about the sample collector, the origin of the animal, the collection site, and specific animal information. For

example, when a sample is collected at a rendering facility, that facility is documented as the site of collection and the location from which the animal carcass originated before arriving at the rendering facility is documented as the owner or source location. Collecting a more complete set of data at the time that samples are obtained will expand APHIS' ability to attribute each sample to the State in which the animal most recently resided. In this way, it will be possible to more accurately assess the geographic representation of samples obtained against the standing adult cattle population.

APHIS reported that sample collectors were trained extensively on the submission forms and instructed how to accurately record the relevant information. APHIS also stated that they were monitoring data being entered into the information system for quality and had developed data reconciliation protocols. APHIS said that all data points might not be known for every animal sampled, however, if a particular submitter or collector did not regularly provide testable samples or adequate and full information, the AVIC in the relevant State would provide followup to correct any deficiencies. Further, APHIS reported that the laboratory would contact the AVIC so that appropriate feedback and supervisory guidance can be provided to sample collectors who do not accurately or completely fill out the sample submission forms.

In addition, APHIS noted that the AMS quality assurance review will validate training, ensure that data are accurately entered in the database, and will include quality control checks of the Sample Data form and VS Form 10-4. Monitoring these actions will be continuous and ongoing throughout the program.

### OIG Position.

We accept the management decision.

## Recommendation No. 11

Issue formal instructions on the policies and procedures to be followed on retaining and preserving excess tissue samples until the test results are reported.

### Agency Response.

APHIS agreed and stated they had issued instructions both to sample collectors and laboratories on maintaining and/or disposing of tissue samples. The instruction to sample collectors was to dispose of excess tissue along with the carcass. Laboratories were instructed, through SOPs, to retain tissue frozen for 5 days if the disease is not detected; if

the result is inconclusive, they are to send all residual tissue and homogenate immediately to NVSL.

APHIS stated these policies and procedures were based on the science behind the various tests used. The immunohistochemistry (IHC) methodology requires tissues to be fixed in formalin rather than fresh. When APHIS exclusively used the IHC test, fresh tissue was preserved separately so other types of tests, like the western blot, could be performed if deemed necessary. Rapid screening tests—now the first line in the program—use fresh tissue. Thus, fresh tissue is available for either western blot methods or to be formalin fixed for IHC. As demonstrated by the two recent inconclusive test results on the initial rapid screening tests, more than sufficient tissue was available to conduct both repeats of the initial screening test and to formalin-fix for immunohistochemistry. Accordingly, it is unnecessary to preserve additional fresh tissue beyond that which is part of the sample itself.

In addition, APHIS noted that the AMS quality assurance review will evaluate how well laboratories are following these procedures.

**OIG Position.**

We accept the management decision.

## Finding 4 — APHIS' Information Technology and Processes Need To Be Upgraded To Perform Adequately Under the New Surveillance Plan

The current information technology system is not adequate for the expanded surveillance program because it does not have sufficient capability and established controls to process and ensure the integrity of the increased number of samples and test results. APHIS needs to implement an integrated system that will track samples from collection to testing to reporting results, as well as integrate with diagnostic testing laboratories. APHIS recognizes this concern and has begun the process of designing a new BSE information system. Our fieldwork disclosed various problems with the current information system and information technology controls that APHIS needs to address as it moves forward with the design and implementation of its new system.

APHIS currently uses two databases for its surveillance program. One database (called the Reference Assistance (RA) database by the person who maintains it) tracks all TSE tests (BSE, chronic wasting disease, scrapie) performed by NVSL or by contract laboratories. The other database (called the Computer Automated Laboratory Systems

(CALS)) is used for reporting test results. Controls over these databases have been such that neither is capable of adequately serving the needs of the expanded surveillance program.

Database accuracy was questionable. We compared information between some of the fields in the CALS and RA systems that should have matched and found they did not. For example, during the 2.5-year reporting period, 2002 through 2004, we found that the purpose for the test (surveillance, foreign animal disease tracking, etc.) as reported in the CALS system did not match the same data in the RA system over 2,000 times.

When asked why the NVSL maintained separate databases with the same data, a NVSL official explained that CALS is not flexible enough to get information or reports out easily. It is easier to get information to Headquarters and the public with the RA database than with CALS.

Data entered into the RA database was not reviewed by a second party for accuracy and consistency. NVSL was inconsistent in how it counted animals with the same clinical signs towards surveillance goals. Dates were also incorrectly entered. Ten samples on one submission form were recorded as collected in 2022. In another instance, the database showed the sample results were reported in 1931.

Establishment/FSIS field data did not always support data in NVSL's database for animals tested. Information in NVSL's database could not always be supported by documentation available from the slaughter/rendering establishment or from FSIS for cattle diagnosed with CNS. Characteristics relating to the CNS animals tested, as shown in establishment records (i.e., owner, origin, age) did not always match information recorded in NVSL records. Also, FSIS condemnation/disposition records did not show the animal's characteristics (FSIS inspection records do not require this type of information to be collected).

NVSL personnel advised us that the CALS system used by the laboratory was outdated but had been reviewed and determined to provide adequate security. Another laboratory official stated that because the RA database was originally used only to track the progress of cases, its subsequent use to report information to Headquarters and the public caused it to be overwhelmed with information.

APHIS needs to expedite development of its new system to accomplish the needs of the expanded surveillance program. APHIS has begun work drafting the requirements of this system, called the National

Animal Health Laboratory Network system. This new information system is being developed to interface with multiple laboratory information management systems in each diagnostic laboratory via a standardized messaging protocol.

Of critical importance, APHIS has not determined how data from the old computer systems will be incorporated with data in the new system. An APHIS official said that although the 'historical data' issue is on their agenda, the group designing the specifications for the National Animal Health Laboratory Network has not yet made a decision about the transfer. The group will need to review such things as data quality, consistency between old and new data, and value of data. The process selected for transferring data will depend on whether or not there is a need to review original submission paperwork.

Requirements and design of the new system are particularly important because sample testing will be contracted out to various laboratories across the country. The test results from contract laboratories will need to be integrated with those maintained by the NVSL.

As APHIS moves forward in designing and implementing its new information system, it needs to address critical functions such as tracking samples, transmitting data, promptly providing negative test results to slaughter establishments and renderers, providing user and management reports, and ensuring system and data security.

### Recommendation No. 12

Establish management controls to ensure the accuracy and integrity of the sample and test database.

#### Agency Response.

APHIS agreed with this recommendation and stated they had already taken steps to implement it. These actions involved instructions on the completion of forms, training efforts, enhanced data, a new database, and feedback to allow correction of deficiencies (see the Agency Response to Recommendations Nos. 6, 9, and 10 for details).

In addition, APHIS noted that the AMS review will validate these efforts and that monitoring these actions will be ongoing throughout the program.

#### OIG Position.

We accept the management decision.

## Recommendation No. 13

Expedite the development of the new BSE information technology system. Ensure appropriate general, logical, and application controls are established.

### Agency Response.

APHIS agreed and reported they were already field testing the BSE system to identify any problems and to improve user access and clarity. As of July 23, 2004, a total of more than 22,500 records were entered into the database. APHIS stated they would have the data entry backlog completed and the database functional for providing reports and analysis by July 30, 2004.

APHIS said that the new system provides secure web-based and pen-tab applications that share BSE surveillance and test result data. The data sharing facilitates proactive collaboration between Federal and State veterinary diagnostic laboratories. It is a component of the national animal health security infrastructure and provides standardization, validation, quality assurance, and secure communications among laboratories and program managers. It is the first online system that integrates animal health laboratory sample information and makes sample data available to help all participants fulfill their roles.

Participants access the system through a secure internet connection that complies with USDA's Office of the Chief Information Officer's requirements. There is a defined permission for data access, based on identification of the user and the user's role. The system uses standardized case data according to the Systemized Nomenclature of Medicine and Veterinary Medicine and Logical Observation Identifiers, Names and Codes. (See the Agency Response to Recommendation No. 10 for additional details.)

The actions to make the database completely functional will be completed by August 20, 2004. Monitoring the data will be ongoing throughout the program.

### OIG Position.

We accept the management decision.

## Finding 5 APHIS Needs to Establish Consistent Terms and Conditions in 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 and charges from meat plants and contractors who provide sampling services. Arrangements with meat plants and sampling contractors were made on a regional basis, frequently with no written agreement and generally with no national guidance.

### Agreements With Non-Federal Laboratories

Agreements with State contract laboratories for performing BSE testing were not written and executed although APHIS had begun to draft various agreements for sample collectors and other cooperators. We believe APHIS needs to formalize all arrangements to include consistent procedures and processes for sample integrity, performance and reporting requirements, as well as reimbursements.

The March 15, 2004, expanded BSE Surveillance Plan states that testing of the targeted high-risk population samples will be conducted at NVSL and at participating network laboratories on a fee-for-service basis. On March 29, 2004, and May 11, 2004, APHIS announced the approval of 12 geographically dispersed State laboratories that would assist in the surveillance program for BSE.

NVSL officials informed us that they did not plan to use a formal written contract with non-Federal laboratories. Instead, APHIS planned to use blanket purchase arrangements similar to those used for chronic wasting disease and scrapie surveillance programs. The blanket purchase arrangements for those surveillance programs covered sample reimbursement, specifications, test methods, and laboratory responsibilities, including receiving and shipping of samples. However, the blanket purchase arrangements did not specifically cover how the laboratories would be monitored for performance and quality control purposes.

### Agreements with Slaughter Establishments, Rendering Firms, and Sampling Contractors

The BSE surveillance program was based on individual arrangements with participants negotiated by each APHIS area office. As of May 2004, APHIS proposed to have both formal and informal

agreements, depending on prior working relationships. There was no National level guidance on the most appropriate approach to take (oral agreement, written contract, purchase order, cooperative agreement, etc.) and no guidelines on amounts that would be considered reasonable for reimbursing costs associated with the program. As a result, the terms, conditions, and payment rates varied.

The APHIS western regional office polled the area offices in the region to identify the types of agreements and payment terms each APHIS office had with the States and private businesses participating in the surveillance program. There were 15 States in the sample and 31 slaughter/renderer facilities. APHIS had written agreements with only 1 of the 15 States and only 4 of the 31 facilities. Two other facilities were paid for samples based on purchase orders, but there was no formal agreement or contract to supply the samples. Details are shown in the table below:

**Figure 6: Agreements and Costs of Testing Samples in 15 States**

| State | Facility[1] | No. | Type of Agreement | Cost Per Sample |
|---|---|---|---|---|
| AZ | Slaughter Plant | 1 | Oral | No Cost |
| AR | Slaughter Plant | 1 | No Agreement | No Cost |
| CO | Slaughter Plant | 1 | Oral | $8/Sample |
| CO | Rendering Plant | 2 | Oral | $8/Sample |
| CO | Pet Food Plant | 1 | Oral | $8/Sample |
| ID | Slaughter Plant | 2 | Oral | No Cost |
| IA | Rendering Plant | 1 | Oral | $25/Sample |
| KS | Rendering Plant | 1 | Written | $615/Week |
| LA | Slaughter Plant | 1 | Oral | $100/Sample |
| MO | 3D/4D Plant | 1 | Written | $10/Sample |
| NE | Slaughter Plant | 1 | Oral | $75/Sample |
| NE | Rendering Plant | 1 | Purchase Order | $50/Sample |
| NM | Slaughter Plant | 1 | Oral | No Cost |
| SD | Rendering Plant | 1 | Oral | $175/Carcass |
| TX | Slaughter Plant | 9 | Oral | No Cost |
| UT | Slaughter Plant | 2 | Oral | No Cost |
| UT | Rendering Plant | 1 | Oral | No Cost |
| WA | Slaughter Plant | 1 | Purchase Order | $10/Sample |
| WI | Slaughter Plant | 1 | Written | $102/Day |
| WI | Rendering Plant | 1 | Written | $400/Month |

[1] The information generally reflects activities during 2003 before December 2003. Surveillance activities were temporarily discontinued in Texas after the discovery of the BSE-infected cow. An additional sample source was added by Nebraska in 2004 that is included in the table.

Many of the sample suppliers have requested increased reimbursement under the new program to cover additional costs for carcass storage and other expenses associated with the increased volume of testing. The BSE expanded Surveillance Plan states that payments for transport, disposal, cold storage, and held product pending negative test results would help cover additional costs incurred by industries participating in BSE surveillance.

We concluded that agreements with private entities that supply samples for BSE testing should be in writing. They should specify procedures for sampling, record retention, and carcass storage and disposal, as well as costs eligible for reimbursement.

After our fieldwork, APHIS advised us that they had developed cost recovery guidelines. The cost recovery arrangements were being finalized in all States and were expected to be completed by June 1, 2004. Templates for contracts and agreements had also been developed and reviewed by Office of the General Counsel. Where formal contracts were required, APHIS reported that the bidding process was underway. As of May 25, 2004, APHIS stated that 225 contracts had been confirmed, and written agreements necessary to begin sampling and testing were projected to be in place by June 1, 2004.

Because APHIS' policies and procedures were not finalized at the time of our review and APHIS officials informed us that they did not intend to establish formal agreements with all cooperating parties, we continue to be concerned and believe that standardized agreements and processes are essential to the success of the BSE surveillance program.

### Recommendation No. 14

For State contract laboratories that will perform BSE testing under the new surveillance program, develop and execute written agreements that include specific provisions for responsibilities, performance, and reimbursement.

#### Agency Response.

APHIS agreed and stated that to ensure that the 12 laboratories designated to perform BSE testing for the program are operating effectively they developed SOPs to address all laboratory responsibilities and performance expectations. There are SOPs for: conducting the specified test procedures; addressing all laboratory responsibilities, performance expectation, and communication or reporting requirements; documenting the chain of custody of forwarded tissues from inconclusive tests; and for proficiency testing. Reimbursement was addressed through a standard purchase order linked to performance and contingent on proper procedures.

APHIS stated that specific issues related to training of laboratory personnel, reporting guidelines, timeliness of reporting, and confidentiality have all been addressed in the SOPs as follows:

- Training was initially conducted by the test kit manufacturer. Competency from this training was demonstrated via the initial proficiency test required prior to participating in this program, and through the ongoing proficiency testing.
- Reporting guidelines and confidentiality issues are addressed in the basic SOP outlining responsibilities.
- The timeliness issue is also specifically addressed in an SOP.

APHIS said they can stop payments if a laboratory is not following the appropriate procedures, since reimbursement is contingent on proper procedures, or they could revoke their approval to participate in the program.

### OIG Position.

We accept the management decision.

## Recommendation No. 15

Require written agreements or contracts with private entities that supply samples for BSE testing. Develop written agreements/contracts that include specific requirements for the responsibilities, sampling procedures, and reimbursement.

### Agency Response.

APHIS agreed and noted that APHIS VS Memorandum 580.16 provides for certain financial reimbursements. When an entity provides samples on a regular basis, APHIS enters into written agreements or contracts. These specify the responsibilities of each party and the agreed amount for the specific financial reimbursement applicable. Where it is feasible to have competition, or there is a special need to protect the Government's interest, APHIS enters into contracts in accordance with federal contracting procedures.

APHIS stated it used agreements where competition was not feasible. A template of this agreement (which has been cleared by the Office of the General Counsel) was provided to AVICs. By August 31, 2004, APHIS plans to amend the template to add a supporting schedule of cost guidelines that includes the responsibilities of the parties, sampling procedures, and reimbursement.

### OIG Position.

We accept the management decision.

## Finding 6 — Performance Measures and Continuous Risk Analysis Is Needed To Better Target and Assess the Effectiveness of USDA's BSE Surveillance Program

As noted in earlier findings of this report, APHIS needs to address some inherent problems with identifying the high-risk cattle population and with ensuring the integrity of its BSE sampling and testing program. A supportable methodology for assessing the effectiveness of the overall BSE surveillance program is essential to provide credibility for any USDA assertion regarding the prevalence of BSE in the United States. Also, a continuous process of risk analysis is critical in targeting limited resources towards an approach that provides increased assurance that BSE can be detected and is not prevalent in the United States.

The IR Subcommittee recommended that policy actions considered by USDA must achieve the objective of establishing the level of effectiveness of measures through surveillance; the success of the prevention and control measures should be monitored. The IR Subcommittee also raised a concern regarding the differing BSE risk assessments presented by the Subcommittee and by the Harvard Center for Risk Analysis. The Subcommittee concluded, "BSE continues to circulate, or even amplify, in the United States and North America"; the Harvard Center for Risk Analysis did not come to this conclusion. The IR Subcommittee emphasized that the best available science and more precise risk assessments are needed to make appropriate regulatory decisions.

In providing a risk analysis, APHIS needs to address the concerns raised earlier in this report relating to the identification of high-risk cattle and sampling integrity. Until these conditions change, they clearly impact APHIS' effectiveness at detecting BSE in cattle in the United States. For example, the IR Subcommittee recommended removal of specific risk materials from animals over 12 months of age, rather than the 30 months specified by USDA. USDA responded to this recommendation by stating that they will reevaluate this issue based on surveillance sampling results. We question whether the current surveillance program will provide USDA with the data it needs to make this reevaluation. A continuous risk analysis, with strong surveillance processes, would assist APHIS in targeting its resources where risk is highest and the need for reform is greatest.

Because USDA is expanding its network of cooperating partners, it is critical for USDA to establish performance standards for its BSE testing program. In reviewing the BSE testing program prior to June 1,

we found that performance standards had not been put in place by APHIS for its internal testing program. In cases where samples were submitted, APHIS had not established adequate controls to provide an efficient, consistent turnaround time for reporting test results and had not established data collection procedures to facilitate timely traceback to a potentially infected animal. Also, there were no management reports to monitor the effectiveness and integrity of sample submission, processing, and reporting of results.

Also impacting USDA's effectiveness is the quality of the samples it receives and the timeliness with which it reports its test analyses. We identified States and submitters who frequently submitted improper samples (animal too young, wrong part of brain, clinical signs not listed, etc.). We found that one State (Indiana) had a consistently higher number of problem submissions in FYs 2003 and 2004 than other States. We also noted a submitter in Mississippi who submitted 48 improper samples (wrong part of brain submitted, not enough brain submitted, etc.) in FY 2003.

Laboratory officials stated that they believed each AVIC was responsible for identifying submission errors in their area and obtaining corrective actions; however, the laboratory did not provide any summary of such errors to the AVICs notifying them of problems encountered.

The timeliness issue should improve with the advent of the Enzyme Linked Immune Sorbent Assay (ELISA) sampling procedure. Before the ELISA procedure, in 2003, it took 5 days, on average, from the time the sample was collected until it was received at the laboratory, and another 12 days, on average, from the time the sample was received until dissemination of the results, for a total of 17 days. During this time, the goal for testing turnaround time, according to a laboratory official, was 8 days for cases in which carcasses were retained (and no goal for cases in which carcasses were not retained). The goal for the ELISA procedure was to report the results within 24 hours of receipt for 95 percent of the samples received by noon. Our analysis of ELISA samples showed that turnaround time was actually 4 days, in about 15 percent of the samples reviewed. However, one laboratory official noted the process was getting better as the laboratory ran more ELISA samples.

The IR Subcommittee also recognized the importance of minimizing the delay between receipt of samples and testing; the speed of confirmation maximizes the ability to trace birth cohort and other risk animals, as well as any by-products that may need to be recalled.

We concluded that APHIS should establish performance measures to monitor the efficiency and integrity of its test analyses and the effectiveness of its surveillance plan. This is especially critical since APHIS has decentralized its testing facilities and will use 12 non-Federal laboratories to conduct tests under the new sampling program.

### Recommendation No. 16

Develop a supportable methodology to evaluate the effectiveness of the BSE surveillance program.

#### Agency Response.

APHIS agreed and stated that analysis of collected data will be an ongoing and evolving effort. An APHIS epidemiologist has been assigned to be responsible for performing the routine analyses. This epidemiologist will work closely with the BSE surveillance program manager and the APHIS TSE Working Group in conducting and reporting these analyses.

APHIS reported that their methodology to evaluate the program's effectiveness is to measure sample results to make certain that they were collecting the number and type of samples appropriate to reach overall targets for achieving statistical validity of the surveillance effort. Using management reports from the database (described in detail in the response to Recommendations 6 and 9), data will be analyzed on a weekly basis over the entire surveillance period. These include:

- Geographic distribution of sample collections,
- Source of sampled animals, and
- Categories or characteristics of sampled animals (clinical presentation - highly suspicious clinical signs, CNS signs, other clinical signs, nonambulatory, dead, etc.; age; other characteristics as necessary).

If the data shows that the samples collected differ significantly in any one of a number of characteristics (e.g., geographic location, source, clinical signs), the cause will be analyzed and the program adjusted as needed. For example, this could include changing or enhancing the focus on certain locations or sources.

The AMS review began on July 15, 2004, and initial results should be reported by September 15, 2004. AMS will conduct additional ongoing reviews throughout the course of the program. Monitoring these actions will be ongoing throughout the program.

### OIG Position.

We accept the management decision.

## Recommendation No. 17

Establish a continuous risk assessment process as progress is made in identifying the universe of and testing high-risk cattle.

### Agency Response.

See the Agency Response under Recommendation No. 16.

### OIG Position.

We accept the management decision.

## Recommendation No. 18

Establish performance measures and develop management reports to monitor the effectiveness and integrity of the submission, processing, and reporting of sample results.

### Agency Response.

APHIS agreed and stated that they had already taken steps related to the various critical control points in the process, from the sample collector through the Area Office and the laboratory as necessary.

The sample collectors and submitters are responsible for several things, such as ensuring appropriate quality and tissue location of the sample; packaging and shipping samples correctly; and accurately completing submission and data entry forms. The responsibilities of the sample collector are described in APHIS VS Memorandum 580.16, and in the BSE Surveillance Guide. APHIS stated that sample collectors have received training extensively in these procedures.

APHIS reported that the designated laboratory is the primary control point in this process. Laboratory personnel record samples that are not of sufficient diagnostic quality for testing or from which the tissue location is not identifiable. The laboratory will notify the AVIC of any repeated problems. The AVIC in turn will address problems with the individual sample collector. (It should be noted that there is no requirement for tissue quality evaluation.)

APHIS said the laboratory is also responsible for processing samples appropriately, conducting the test properly, and reporting sample results according to APHIS policy. APHIS has developed SOPs for the designated laboratories and payment to them is contingent on following these guidelines. These SOPs, as described in the response to Recommendations Nos.14 and 19, address all of these responsibilities. APHIS said that perhaps the most important measure to ensure effectiveness and integrity of the testing process is that all inconclusive results reported by the designated laboratories will undergo confirmatory testing by NVSL, the national reference laboratory – using the gold standard test, the IHC.

Further, APHIS stated that one of the SOPs specifically addresses quality assurance at the designated laboratories. This outlines the process of ongoing proficiency testing that will be conducted at NVSL and weekly monitoring of test performance and comparison of this performance to all laboratories involved. These processes will help ensure quality and accuracy of the testing results.

The AMS review would evaluate APHIS' performance in this area and allow correction of any problems. Monitoring these actions will be ongoing throughout the program.

### OIG Position.

We accept the management decision.

## Recommendation No. 19

Ensure all agreements with other laboratories contain requirements that specify the performance measures for processing samples and reporting test results.

### Agency Response.

See the Agency Response under Recommendation No. 14.

### OIG Position.

We accept the management decision.

# General Comments

During this review, two additional items came to our attention that warrant comment and consideration by USDA in finalizing its BSE surveillance and testing program.

### Peer Reviews

The last peer review of the TSE section of the NVSL was conducted in 1995. The long period between reviews occurred in part because there are no specific published requirements for the timeliness of peer reviews. We noted a 2000 procedure[27] that provided some guidance on establishing a peer review process for validation of laboratory services against international standards for high-impact foreign animal disease threats and endemic diseases. However, neither the 2000 document nor the preceding 1998 Standard Operating Procedures (SOP) specified timeframes for conducting peer reviews.

NVSL officials said they thought peer reviews should be conducted every 5 years. The General Requirements for Accreditation of Laboratories, dated January 2003, states the American Association for Laboratory Accreditation conducts a full assessment of all accredited laboratories at least every 2 years.

The 1995 peer review team reported that the laboratory was organized and operating in such a way that it met international standards and that it reported the results of each test clearly and objectively in accordance with the test guidelines. At the time of the BSE-positive test in 2003, the press reported allegations that the laboratory had a history of producing ambiguous and conflicting test results. We concluded that peer reviews at a prescribed and reasonable frequency would help defend the laboratory against such allegations. Also, a recognized peer review process would provide added credibility to the BSE testing program.

### Program Documentation

Our review disclosed an almost complete absence of available documentation supporting the development and evolution of the USDA BSE surveillance program as it existed from its inception in 1990 through 2003. Specifically missing was detailed support for sample size determinations and for critical assumptions made in devising and

[27] The NVSL Validation of Laboratory Activities Through Peer Review SOP, dated October 16, 2000.

revising the sampling plans. When asked for information supporting the USDA surveillance program, we were told by senior department officials responsible for the program that all information and data supporting the surveillance program was contained on the APHIS Internet web site and very little other supporting analyses, decision memoranda, or other documentation was actually provided to us for review. APHIS senior management referred us to the former BSE surveillance program manager, who they said would have documentation supporting the program. However, the former program manager provided us with only limited documentation consisting of various training materials and briefing documents prepared over time for the program.

# Scope and Methodology

We performed our reviews at APHIS and FSIS Headquarters, select APHIS and FSIS field locations, nine slaughter establishments, and one rendering facility and one 3D/4D processor. In addition, we performed reviews at the Boulder, Colorado, FSIS District office, the APHIS Western Regional office in Fort Collins, Colorado, and eight APHIS area offices, as well as the NVSL in Ames, Iowa (see exhibit A for the locations visited). Fieldwork was performed from February 23, 2004, through June 2, 2004.

To accomplish our audit objectives, we performed the following audit procedures:

- We interviewed responsible program officials from APHIS and FSIS, including agency veterinarians.

- We reviewed written policies and procedures relating to the BSE surveillance program, as well as regulatory functions associated with the surveillance program.

- We analyzed available documentation established to evaluate the development of the BSE 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.

- We evaluated the role of the NVSL in Ames, Iowa, and its responsibilities for the BSE surveillance program.

- We verified information in the NVSL database to available FSIS disposition records and ante mortem condemnation records at selected slaughter establishments to validate clinical data recorded for CNS symptoms.

- Using information contained in the NVSL BSE database and utilizing sample submission forms, we created an expanded database for FY 2002, 2003, and 2004.[28] We evaluated this data to determine NVSL sample and testing data accuracy, trends, and anomalies.

- We interviewed plant personnel concerning the surveillance program and actions to address the new food safety initiatives

[28] For purposes of this review, we reviewed the NVSL database as of the end of February 2004 for FY 2004.

announced by the Department immediately after the BSE positive cow was identified.

- We reviewed slaughter plant records and observed operations related to ante mortem inspection and condemnation of cattle.

- We reviewed rendering plant records related to brain samples for BSE testing and observed sample collection at rendering and slaughter establishments.

The audit was performed in accordance with Government Auditing Standards. However, our review was limited due to the lack of information relating to USDA's specific, detailed plans for implementing its BSE surveillance program.

# *Exhibit A – Sites Visited*



APHIS National Office – Riverdale, Maryland
APHIS Regional Office – Fort Collins, Colorado
APHIS National Veterinary Services Laboratories – Ames, Iowa
APHIS Center for Veterinary Biologics – Ames, Iowa
APHIS Area Office – Jefferson City, Missouri
APHIS Area Office – Des Moines, Iowa
APHIS Area Office – Topeka, Kansas
APHIS Area Office – Lincoln, Nebraska
APHIS Area Office – Madison, Wisconsin
APHIS Area Office – Tempe, Arizona
APHIS Area Office – Austin, Texas
APHIS Area Office – Olympia, Washington
Iowa State University Veterinary Diagnostic Laboratory – Ames, Iowa
Agricultural Research Service National Animal Disease Center – Ames, Iowa
FSIS National Office – Washington, DC
FSIS District Office – Boulder, Colorado
FSIS District Office – Madison, Wisconsin
Small Slaughter Plant A – Nebraska
Small Slaughter Plant B – Texas
Small Slaughter Plant C – Texas
Large Slaughter Plant D – Arizona
Very Small Slaughter Plant E – Arizona
Large Slaughter Plant F – Wisconsin
Small Slaughter Plant G – Wisconsin
Small Slaughter Plant H – California
Very Small Slaughter Plant I – Washington
3D/4D Processor[29] – Missouri
Rendering Plant – Wisconsin

[29] Plants that process products from dead, dying, disabled, or diseased animals. USDA does not inspect these facilities because they do not produce meat or poultry products that are intended to enter the human food supply.

# *Exhibit B – Number of Slaughter/Renderers by State Compared to State Sampling Goals*



**Sorted by States with the Lowest Number of Slaughter/Renderer Plants**

| State | Number of Plants that Slaughter Older Cattle | Number of Slaughter Plants | Number of Rendering Plants | Total Slaughter and Rendering Plants | Total FY 2002-2004 BSE Tests Performed | State Goals |
|---|---|---|---|---|---|---|
| WY | 0 | 0 | 0 | 0 | 0 | 2,513 |
| LA | 0 | 0 | 1 | 1 | 127 | 2,312 |
| NH | 1 | 1 | 0 | 1 | 3 | 297 |
| RI | 1 | 1 | 0 | 1 | 0 | 29 |
| NM | 2 | 2 | 0 | 2 | 794 | 7,277 |
| DE | 1 | 1 | 1 | 2 | 1 | 156 |
| AK | 2 | 2 | 0 | 2 | 11 | 38 |
| SC | 1 | 1 | 1 | 2 | 2 | 1,008 |
| NV | 3 | 3 | 0 | 3 | 43 | 1,253 |
| WV | 2 | 3 | 1 | 4 | 3 | 851 |
| CT | 4 | 5 | 0 | 5 | 12 | 395 |
| MA | 4 | 4 | 2 | 6 | 2 | 341 |
| AZ | 4 | 4 | 2 | 6 | 2,559 | 3,335 |
| MS | 2 | 3 | 3 | 6 | 712 | 2,266 |
| SD | 5 | 5 | 1 | 6 | 73 | 6,938 |
| VT | 6 | 6 | 0 | 6 | 173 | 2,638 |
| ME | 6 | 6 | 0 | 6 | 11 | 643 |
| AL | 2 | 2 | 4 | 6 | 112 | 2,686 |
| UT | 5 | 7 | 1 | 8 | 908 | 2,724 |
| OK | 8 | 8 | 2 | 10 | 56 | 7,792 |
| IN | 5 | 6 | 4 | 10 | 1,063 | 3,289 |
| IA | 5 | 6 | 4 | 10 | 1,076 | 6,681 |
| MT | 12 | 12 | 0 | 12 | 2 | 5,076 |
| HI | 8 | 9 | 3 | 12 | 68 | 372 |
| TN | 12 | 12 | 0 | 12 | 1,101 | 4,938 |
| ND | 12 | 12 | 1 | 13 | 17 | 3,616 |
| PR/VI | 11 | 13 | 0 | 13 | 115 | 1,704 |
| AR | 8 | 11 | 2 | 13 | 904 | 3,672 |
| NC | 7 | 10 | 3 | 13 | 2,148 | 2,335 |
| OH | 11 | 12 | 4 | 16 | 1,288 | 5,457 |
| VA | 11 | 11 | 5 | 16 | 578 | 4,121 |
| WI | 11 | 13 | 4 | 17 | 7,059 | 23,040 |
| GA | 11 | 14 | 3 | 17 | 5,074 | 3,491 |
| ID | 13 | 16 | 1 | 17 | 231 | 8,939 |
| WA | 9 | 11 | 6 | 17 | 2,758 | 5,161 |
| NJ | 10 | 15 | 3 | 18 | 729 | 247 |
| OR | 12 | 13 | 5 | 18 | 33 | 4,038 |
| KY | 12 | 14 | 5 | 19 | 73 | 5,645 |
| KS | 10 | 15 | 5 | 20 | 167 | 6,972 |

# *Exhibit B – Number of Slaughter/Renderers by State Compared to State Sampling Goals*



| State | Number of Plants that Slaughter Older Cattle | Number of Slaughter Plants | Number of Rendering Plants | Total Slaughter and Rendering Plants | Total FY 2002-2004 BSE Tests Performed | State Goals |
|---|---|---|---|---|---|---|
| MD | 18 | 19 | 2 | 21 | 20 | 1,512 |
| CO | 18 | 20 | 4 | 24 | 1,421 | 3,728 |
| FL | 15 | 20 | 4 | 24 | 865 | 5,570 |
| IL | 11 | 16 | 9 | 25 | 106 | 3,325 |
| MI | 24 | 27 | 1 | 28 | 747 | 5,636 |
| MN | 19 | 24 | 8 | 32 | 3,073 | 9,586 |
| NE | 27 | 31 | 7 | 38 | 508 | 7,077 |
| CA | 23 | 26 | 12 | 38 | 4,349 | 32,705 |
| MO | 34 | 40 | 5 | 45 | 3,310 | 9,097 |
| NY | 42 | 45 | 8 | 53 | 1,558 | 12,024 |
| TX | 24 | 34 | 16 | 50 | 3,815 | 23,374 |
| PA | 82 | 104 | 3 | 107 | 2,273 | 10,583 |
| Total | [30] 591 | [31] 703 | 156 | [32] 859 | 52,131 | 268,503 |

[30] The column total for plants that slaughter older cattle does not add because we could not identify the plant location (State) for five plants. These plants are in the total, but not included in the individual State numbers.

[31] The column total for the number of slaughter plants does not add because we could not identify the plant location (State) for eight plants. These plants are in the total, but not included in the individual State numbers.

[32] The column total for slaughter and rendering plants does not add because of the additional eight plants where the plant location (State) could not be identified.

# *Exhibit C – Live Cows, Adult Slaughter Statistics, and Number of Slaughter/Renderers by State Compared to State Sampling Goals*



| State | FY 2004 Live Beef Cows | FY 2004 Live Milk Cows | FY 2004 Total Live Cows | FY 2003 Total Bulls and Cows Slaughtered | Number of Plants that Slaughter Older Cattle | Number of Slaughter Plants | Number of Rendering Plants | Total Slaughter and Rendering Plants | Total FY 2002-2004 BSE Tests Performed | State Goals |
|---|---|---|---|---|---|---|---|---|---|---|
| WY | 756,000 | 4,000 | 760,000 | 0 | 0 | 0 | 0 | 0 | 0 | 2,513 |
| LA | 489,000 | 41,000 | 530,000 | 0 | 0 | 0 | 1 | 1 | 127 | 2,312 |
| NH | 3,500 | 16,000 | 19,500 | 123 | 1 | 1 | 0 | 1 | 3 | 297 |
| RI | 1,700 | 1,300 | 3,000 | 1,278 | 1 | 1 | 0 | 1 | 0 | 29 |
| DE | 4,000 | 8,000 | 12,000 | 209 | 1 | 1 | 1 | 2 | 1 | 156 |
| NM | 455,000 | 325,000 | 780,000 | 18,104 | 2 | 2 | 0 | 2 | 794 | 7,277 |
| NV | 244,000 | 26,000 | 270,000 | 110 | 3 | 3 | 0 | 3 | 43 | 1,253 |
| AK | 5,100 | 1,200 | 6,300 | 394 | 2 | 2 | 0 | 2 | 11 | 38 |
| CT | 6,000 | 21,000 | 27,000 | 265 | 4 | 5 | 0 | 5 | 12 | 395 |
| MA | 6,000 | 18,000 | 24,000 | 860 | 4 | 4 | 2 | 6 | 2 | 341 |
| WV | 186,000 | 14,000 | 200,000 | 130 | 2 | 3 | 1 | 4 | 3 | 851 |
| AZ | 175,000 | 155,000 | 330,000 | 135,862 | 4 | 4 | 2 | 6 | 2,559 | 3,335 |
| MS | 541,000 | 29,000 | 570,000 | 33 | 2 | 3 | 3 | 6 | 712 | 2,266 |
| OK | 1,970,000 | 80,000 | 2,050,000 | 8,130 | 8 | 8 | 2 | 10 | 56 | 7,792 |
| SC | 218,000 | 17,000 | 235,000 | 149,766 | 1 | 1 | 1 | 2 | 2 | 1,008 |
| ME | 11,000 | 34,000 | 45,000 | 1,038 | 6 | 6 | 0 | 6 | 11 | 643 |
| SD | 1,711,000 | 79,000 | 1,790,000 | 39,103 | 5 | 5 | 1 | 6 | 73 | 6,938 |
| VT | 9,000 | 146,000 | 155,000 | 8,404 | 6 | 6 | 0 | 6 | 173 | 2,638 |
| IN | 227,000 | 143,000 | 370,000 | 244 | 5 | 6 | 4 | 10 | 1,063 | 3,289 |
| ND | 937,000 | 33,000 | 970,000 | 1,067 | 12 | 12 | 1 | 13 | 17 | 3,616 |
| PR/VI | * | * | * | 39,130 | 11 | 13 | 0 | 13 | 115 | 1,704 |
| UT | 351,000 | 89,000 | 440,000 | 44,144 | 5 | 7 | 1 | 8 | 908 | 2,724 |
| MT | 1,472,000 | 18,000 | 1,490,000 | 2,032 | 12 | 12 | 0 | 12 | 2 | 5,076 |
| AL | 732,000 | 18,000 | 750,000 | 2 | 2 | 2 | 4 | 6 | 112 | 2,686 |
| AR | 982,000 | 28,000 | 1,010,000 | 4,479 | 8 | 11 | 2 | 13 | 904 | 3,672 |
| HI | 82,000 | 6,000 | 88,000 | 6,968 | 8 | 9 | 3 | 12 | 68 | 372 |
| IA | 984,000 | 196,000 | 1,180,000 | 20,160 | 5 | 6 | 4 | 10 | 1,076 | 6,681 |
| TN | 1,103,000 | 77,000 | 1,180,000 | 6,282 | 12 | 12 | 0 | 12 | 1,101 | 4,938 |
| WI | 245,000 | 1,245,000 | 1,490,000 | 1,016,839 | 11 | 13 | 4 | 17 | 7,059 | 23,040 |
| GA | 616,000 | 84,000 | 700,000 | 348,567 | 11 | 14 | 3 | 17 | 5,074 | 3,491 |
| OH | 262,000 | 258,000 | 520,000 | 60,196 | 11 | 12 | 4 | 16 | 1,288 | 5,457 |
| ID | 488,000 | 412,000 | 900,000 | 296,238 | 13 | 16 | 1 | 17 | 231 | 8,939 |
| NC | 402,000 | 58,000 | 460,000 | 228,648 | 7 | 10 | 3 | 13 | 2,148 | 2,335 |
| NJ | 10,000 | 12,000 | 22,000 | 12,365 | 10 | 15 | 3 | 18 | 729 | 247 |
| VA | 695,000 | 105,000 | 800,000 | 1,487 | 11 | 11 | 5 | 16 | 578 | 4,121 |
| WA | 270,000 | 240,000 | 510,000 | 102,887 | 9 | 11 | 6 | 17 | 2,758 | 5,161 |

# *Exhibit C – Live Cows, Adult Slaughter Statistics, and Number of Slaughter/Renderers by State Compared to State Sampling Goals*



| State | FY 2004 Live Beef Cows | FY 2004 Live Milk Cows | FY 2004 Total Live Cows | FY 2003 Total Bulls and Cows Slaughtered | Number of Plants that Slaughter Older Cattle | Number of Slaughter Plants | Number of Rendering Plants | Total Slaughter and Rendering Plants | Total FY 2002-2004 BSE Tests Performed | State Goals |
|---|---|---|---|---|---|---|---|---|---|---|
| OR | 603,000 | 117,000 | 720,000 | 3,565 | 12 | 13 | 5 | 18 | 33 | 4,038 |
| KS | 1,550,000 | 110,000 | 1,660,000 | 4,710 | 10 | 15 | 5 | 20 | 167 | 6,972 |
| KY | 1,128,000 | 112,000 | 1,240,000 | 1,002 | 12 | 14 | 5 | 19 | 73 | 5,645 |
| MD | 42,000 | 77,000 | 119,000 | 3,886 | 18 | 19 | 2 | 21 | 20 | 1,512 |
| CO | 612,000 | 98,000 | 710,000 | 19,712 | 18 | 20 | 4 | 24 | 1,421 | 3,728 |
| FL | 950,000 | 140,000 | 1,090,000 | 9,182 | 15 | 20 | 4 | 24 | 865 | 5,570 |
| IL | 432,000 | 108,000 | 540,000 | 775 | 11 | 16 | 9 | 25 | 106 | 3,325 |
| MI | 85,000 | 300,000 | 385,000 | 86,229 | 24 | 27 | 1 | 28 | 747 | 5,636 |
| MN | 395,000 | 465,000 | 860,000 | 580,078 | 19 | 24 | 8 | 32 | 3,073 | 9,586 |
| NE | 1,848,000 | 62,000 | 1,910,000 | 812,735 | 27 | 31 | 7 | 38 | 508 | 7,077 |
| CA | 720,000 | 1,700,000 | 2,420,000 | 725,845 | 23 | 26 | 12 | 38 | 4,349 | 32,705 |
| MO | 2,125,000 | 125,000 | 2,250,000 | 24,881 | 34 | 40 | 5 | 45 | 3,310 | 9,097 |
| NY | 82,000 | 658,000 | 740,000 | 40,691 | 42 | 45 | 8 | 53 | 1,558 | 12,024 |
| TX | 5,483,000 | 317,000 | 5,800,000 | 928,621 | 24 | 34 | 16 | 50 | 3,815 | 23,374 |
| PA | 156,000 | 564,000 | 720,000 | 521,736 | 82 | 104 | 3 | 107 | 2,273 | 10,583 |
| TOTALS | 32,860,300 | 8,990,500 | 41,850,800[33] | 6,327,198 | 591[34] | 703[35] | 156 | 859[36] | 52,131 | 268,503 |

* - Information not available on the January 30, 2004, NASS data sheet.

[33] The column total for bulls and cows slaughtered does not add because we could not identify the plant location (State) for 582 bulls and stags and 7,424 cows. These animals are in the total, but not included in the individual State numbers.

[34] The column total for plants that slaughter older cattle does not add because we could not identify the plant location (State) for five plants. These plants are in the total, but not included in the individual State numbers.

[35] The column total for the number of slaughter plants does not add because we could not identify the plant location (State) for eight plants. These plants are in the total, but not included in the individual State numbers.

[36] The column total for slaughter and rendering plants does not add because of the additional 8 plants where the plant location (State) could not be identified.

# *Exhibit D – Condemned by Disease for FY 2003*



ANTE MORTEM CONDEMNED

| DISEASE | Total Bulls, Stags, and Cows | Total Steers and Heifers | All Calves | TOTAL |
|---|---|---|---|---|
| DEAD | 20,971 | 2,315 | 8,858 | 32,144 |
| MORIBUND | 6,154 | 168 | 1,403 | 7,725 |
| PYREXIA | 1,070 | 63 | 11 | 1,144 |
| EPITHELIOMA | 600 | 4 | 0 | 604 |
| CENTRAL NERVOUS SYS DISORDR | 133 | 114 | 19 | 266 |
| GEN. MISCELLANEOUS | 23 | 140 | 20 | 183 |
| PNEUMONIA | 65 | 50 | 13 | 128 |
| TOXEMIA | 91 | 5 | 5 | 101 |
| SEPTICEMIA | 50 | 4 | 46 | 100 |
| MALIGNANT LYMPHOMA | 92 | 1 | 0 | 93 |
| MISC. DEGEN. & DROPSIC COND | 52 | 25 | 1 | 78 |
| ABSCESS PYEMIA | 39 | 32 | 6 | 77 |
| ARTHRITIS | 7 | 34 | 24 | 65 |
| MASTITIS | 36 | 0 | 0 | 36 |
| TETANUS | 25 | 0 | 11 | 36 |
| INJURIES | 17 | 11 | 2 | 30 |
| MISC. INFLAMMATORY DISEASES | 4 | 3 | 0 | 7 |
| PERICARDITIS | 2 | 4 | 1 | 7 |
| MISC. INFECTIOUS DISEASES | 3 | 1 | 2 | 6 |
| VESICULAR DISEASES | 6 | 0 | 0 | 6 |
| MISC. NEOPLASMS | 5 | 0 | 0 | 5 |
| RABIES | 2 | 2 | 0 | 4 |
| ACTINOMYCOSIS ACTINOBACIL | 3 | 0 | 0 | 3 |
| METRITIS | 3 | 0 | 0 | 3 |
| RESIDUE | 1 | 0 | 2 | 3 |
| MISC. PARASITIC CONDITIONS | 1 | 0 | 0 | 1 |
| MYIASIS | 0 | 1 | 0 | 1 |
| PIGMENT CONDITIONS | 1 | 0 | 0 | 1 |
| Grand Total | 29,456 | 2,977 | 10,424 | 42,857 |

USDA

**United States Department of Agriculture**

**Marketing and Regulatory Programs**

Animal and Plant Health Inspection Service

Washington, DC 20250

SUBJECT: Bovine Spongiform Encephalopathy (BSE) Surveillance Program – Phase 1, Audit No. 50601-9-KC

JUL 30 2004

TO: Robert W. Young
Assistant Inspector General for Audit
Office of Inspector General

The enclosed information contains our comments for each recommendation identified in OIG's audit 50601-9-KC. The Animal and Plant Health Inspection Service and the Food Safety Inspection Service are committed to keeping both U.S. agriculture and the nation's food supply safe through an aggressive, well managed BSE surveillance program.

Thank you for the opportunity to review the report. We look forward to receiving the final version of your audit pending publication and release.

W. R. DeHaven

W. Ron DeHaven
Administrator
Animal and Plant Health Inspection Service

Barbara Masters

Barbara Masters
Acting Administrator
Food Safety and Inspection Service

Enclosures

APHIS *Safeguarding American Agriculture*
APHIS is an agency of USDA's Marketing and Regulatory Programs
An Equal Opportunity Provider and Employer

**APHIS and FSIS Responses to OIG Report and Recommendations**
**Bovine Spongiform Encephalopathy (BSE) Surveillance Program – Phase I**
**Audit Report No: 50601-9-KC**
**July 30, 2004**

**1. Clarify the goals and objectives of the BSE surveillance program. Fully disclose the assumptions made in estimating the prevalence of BSE in the United States and the limitations on using the data.**

APHIS agrees that additional discussion and clarification of these points would contribute to public understanding of our efforts. Unlike the case with many other animal diseases, we recognize that science has yet to fully understand all aspects of BSE and that reasonable opinions differ in the scientific community. APHIS will prepare a more detailed explanation of the BSE Surveillance program objectives and assumptions. This paper will also include some discussions of various options for extrapolating or inferring estimated prevalence rates in broader populations. APHIS will complete this paper, and post it on the APHIS website by August 31, 2004. The paper will address specific concerns and issues raised by the audit, including:

- that critical assumptions in the surveillance plan could result in questionable estimates of BSE prevalence
- any limitations in the sample selected
- any limitations in the confidence of projections
- any limitations in obtaining a geographic representation of US cattle
- recognizing that BSE might be found in animals not in the surveillance plan's target population
- limitations inherent in testing normal cattle, including a small sample size
- difficulties in estimating the size of the high-risk population
- uncertainty in determining the levels of risk in targeted animals

We will complete final action on this recommendation as described by August 31, 2004.

**2. Develop contingency plans that address how APHIS will continue to implement the provisions of its expanded BSE surveillance plan if one or more States are unsuccessful in reaching their sampling goals.**

APHIS agrees with this recommendation. We recognize that we must obtain adequate representative samples from all parts of the country. In that regard, we note that the political boundaries of any given State may be less important than how the cattle in that State move through the surrounding region where practices are common. By August, 31,

2004, APHIS will determine specific regional boundaries for that purpose and will review program results on both regional and State bases.

We have already taken the following steps to address this recommendation. During the initial implementation and planning phase of the enhanced surveillance program, APHIS field personnel in each State worked with industry and State personnel to estimate the number of samples that we likely could obtain in that State. A complicating factor is that we sometimes are likely to collect the sample in a State other than the one where the animal last resided because typical marketing practices could lead to the animal's movement. Where possible, if a collection site routinely accepted animals from surrounding States, this information and estimates of relative numbers from surrounding states were shared with APHIS personnel in those States respectively. Taking this into account, we determined we could obtain a good geographic distribution.

We created a database to capture data to allow for ongoing analysis throughout this surveillance effort. It gives us the capability to analyze data at all levels – State, regional, and national. It contains specific fields to identify both the location of sample collection and the location of the last place of residence of the animal. (See exhibit 1a). This will allow us to monitor the number of samples we are receiving on a State and regional basis, and provide an early warning signal if we are receiving significantly fewer or more than anticipated for any given State or region.

There will be ongoing analysis of collected data throughout the life of the program. We have designated an epidemiologist with the APHIS-VS National Surveillance Unit at the Centers for Epidemiology and Animal Health to be responsible for performing the routine analyses. This epidemiologist will work closely with the BSE surveillance program manager and the APHIS TSE Working Group in conducting and reporting these analyses. Any significant deviations from expected numbers will be reported and addressed.

If the ongoing analysis determines that we will fall short in certain States or regions, we will invoke a variety of outreach mechanisms and will engage in an appropriate action plan depending on the situation. In many cases, that will be a redoubling of earlier efforts, such as meeting with key industry participants; engaging in an advertising campaign geared towards producers, with media outreach campaigns via newspaper and radio; and consulting with State officials. We will identify the specific reasons for the shortfalls and respond appropriately. For example, if our analysis identifies an issue with a particular concentration point, such as a rendering facility or a 3D-4D facility, we will work directly with the facility in question to resolve the any issues. Issues at these facilities could range from cost recovery, storage, liability, or simply seasonal variation. If, for instance, a change in business practices re-routes targeted animals to another location, we will engage accordingly.

We are acting proactively to ensure maximum participation in all States. APHIS Legislative and Public Affairs staff has planned a follow-up outreach campaign for a second wave of advertisements, radio spots, and other marketing efforts. (See exhibit 2)

These will also target any areas in which we may not be obtaining the desired number of samples.

APHIS will measure the results of these efforts through the described ongoing analysis, conducted on a regular basis throughout the program. Specific one-time actions as described will be completed by August 31, 2004.

**3. Develop and implement management controls to ensure USDA policy for sampling cattle condemned at slaughter is consistently implemented by FSIS and APHIS field staff.**

APHIS and FSIS agree with this recommendation, and note that our understanding is that it applies to cattle condemned ante-mortem. APHIS has implemented measures to ensure a cross-check between FSIS condemned cattle statistics and APHIS BSE surveillance statistics.

We have already taken several steps to address this recommendation. Both FSIS and APHIS have issued instructions to field personnel that clearly state the policy to sample all cattle condemned on ante-mortem inspection (except veal calves condemned for non-CNS reasons).

On June 1, 2004, FSIS implemented FSIS Notice 28-04 (See exhibit 3a), "FSIS Sample Collection from Cattle Condemned During Ante-Mortem Inspection for the Bovine Spongiform Encephalopathy (BSE) Surveillance Program." This Notice provides sample collection, documentation, and shipping procedures to inspection program personnel. It instructs FSIS personnel to collect brain samples from ante-mortem condemned cattle, except for veal calves not exhibiting central nervous symptoms, and to submit the samples to APHIS designated laboratories for analysis.

Additionally, on May 27, 2004, FSIS issued FSIS Notice 29-04, "Questions and Answers for FSIS Notice 28-04 Regarding Ante-Mortem Condemned Cattle." (See exhibit 3b). This Notice outlines FSIS' expectations regarding APHIS arrangements with establishments for sampling condemned cattle at an alternative central location. In particular, the Notice defines what controls FSIS has in place for working with an establishment during the sampling process, and recognizing an APHIS arrangement to have FSIS condemned cattle transported off-site from the establishment to an APHIS central sample collection point. On July 29, 2004, FSIS Notice 40-04, Additional Bovine Spongiform Encephalopathy Surveillance Sampling Questions and Answers, was issued. (see exhibit 3d)

APHIS Veterinary Services Memorandum 580.16 (See exhibit 4) outlines the policy for the entire BSE Surveillance Program, including the expectations for obtaining samples from all cattle condemned on ante-mortem inspection, with the exception of veal calves condemned for non-CNS reasons.

The data collection that accompanies each sample allows for cross-checking as the condemnation code and condemnation numbers are recorded. Personnel in both APHIS and FSIS have been trained on the sample collection process. APHIS personnel assisted in the initial training of FSIS personnel in sample collection (Omaha, May 2004). These FSIS personnel have trained subsequent personnel as necessary, with assistance from local APHIS personnel. APHIS and FSIS management and sample collectors have been jointly trained, and have participated in phone calls led jointly by APHIS and FSIS administrators Drs. Ron DeHaven and Barbara Masters. APHIS employees have

received and studied copies of a CD-ROM that explains sample collection methodology. (See exhibit 5). FSIS employees have reviewed a training presentation on sample collection that is also available through the FSIS Outlook email system. (See exhibit 5)

APHIS has entered into an agreement with the Agricultural Marketing Service (AMS), which has vast experience in establishing and evaluating quality assurance programs, to audit the BSE surveillance plan (See exhibit 6). The initial audit will be completed by September 15, 2004, with a follow-up audit some time in the next 16-18 months. This program contains plans to ensure consistency between the agencies and among sample collectors. Also, it will validate that the program tests the appropriate cattle.

APHIS will measure the results of these efforts through the ongoing continuous analysis and cross-checking of data with FSIS and through the results of the AMS audit process. Specifically, the APHIS database will collect and report numbers of samples collected from animals condemned on ante-mortem inspection. These numbers of samples collected will be compared to the numbers of ante-mortem condemns recorded in FSIS eADRS system. Major differences in these numbers will be investigated and appropriately addressed. In addition, FSIS' PEER will evaluate the FSIS ante-mortem/alternative collection site procedures as well as ensure that there is no diversion of condemned animals into edible channels in accordance with FSIS Notice 33-04.

These actions that will be ongoing and continuous throughout the program.

**4. With assistance from public health and State veterinary diagnostic laboratories, develop and implement a process for testing rabies-negative samples for BSE.**

APHIS agrees with this recommendation and has already taken several actions. APHIS first engaged in conversations with the leadership of the American Association of Veterinary Laboratory Diagnosticians to emphasize the importance of testing rabies-negative samples. We followed this with a letter to all State laboratories regularly conducting rabies testing. This letter requests submission of samples that meet the APHIS' target population. (See exhibit 7a). We coordinated this request with the national rabies coordination group at the Centers for Disease Control, and they have distributed similar requests (See exhibit 7b).

APHIS also wrote to the laboratories to describe specific sampling and shipping procedures and to emphasize that NVSL will provide shipping boxes and any assistance necessary to receive samples. (See exhibit 7c) These standard procedures were distributed to all State animal health diagnostic laboratories and all known public health laboratories throughout the United States.

APHIS will take additional actions. We have directed each AVIC to personally contact the appropriate public health authorities and laboratory conducting rabies testing by August 31, with the AVICs also directed to report the results of these contacts by September 30. This initial contact will be to ensure appropriate communication channels

and understanding of procedures. Discussions about the appropriate splitting of samples to ensure access to proper tissue for each laboratory (rabies and BSE) will also be held, with agreed procedures noted for splitting and/or forwarding appropriate samples.

There are at least 200 laboratories that conduct some level of rabies testing on animal samples. Implementing or maintaining some type of formal agreement with each individual laboratory is logistically difficult and inefficient. Cooperation through contact and reminders is the best approach to maintaining access to those samples that fit our targeted population.

APHIS will measure the results of these efforts through the described ongoing analysis, conducted on a regular basis throughout the program. Specific one-time actions as described will be completed by September 30, 2004.

**5. Provide outreach and education to accredited veterinarians on BSE issues and develop cooperating relationships that will facilitate the identification, reporting, and testing of suspect "high-risk" animals on the farms, feedlots, etc…**

APHIS agrees with this recommendation. APHIS has had long-standing relationships with accredited veterinarians for all disease reporting purposes and will build on those relationships to encourage their assistance. Accredited veterinarians are obligated to report highly suspicious clinical cases and are generally well aware of this professional responsibility. (See exhibit 8a) There are approximately 79,000 accredited veterinarians on file, but fewer than 10 percent are working in bovine, mixed animal, or large animal practices. Most accredited veterinarians are in small animal practice, do not work routinely with livestock producers, and are not well positioned to assist in identifying the target population.

We have already taken several steps to use this valuable asset. APHIS Area Offices are personally contacting those veterinarians who do work with cattle as part of, State's local plan to support submission of samples and have invited them to participate in sample collection training. APHIS personnel have provided information directly to accredited veterinarians during their regular liaison activity. We have used e-mail to distribute information as well. We have distributed BSE Surveillance information sheets (See exhibit 8b) as well as conducted outreach efforts at fairs, clubs, industry meetings, and other agricultural events to inform the public.

APHIS is in regular contact with the American Veterinary Medical Association (which has BSE information prominently displayed on their main web page) (See exhibit 8c), the American Association of Bovine Practitioners, and other veterinary and producer groups to ensure education and understanding of BSE clinical signs and symptoms as well as our targeted sampling program.

APHIS will continue regular contact with the various veterinary associations and send regular mailings to accredited veterinarians as reminders. Also, we will ensure that

information is available about our fee-basis offers for sample collectors and cost neutral options for producers.

These actions – maintaining contact and providing information - will be ongoing and continuous throughout the program.

**6. Develop sampling and reporting procedures that require accurate classification of samples taken from high-risk populations.**

**9. Develop written guidance detailing how animals should be classified and recorded in the BSE database, based on the clinical signs of the animal.**

APHIS agrees with these recommendations. Because Recommendations 6 and 9 are closely related and many of our current and planned actions apply to both, we have consolidated the response here.

APHIS has developed a database to enable us to track and analyze various data points on samples. The database captures data from an electronic version of the standard laboratory submission form, VS Form 10-4 (See exhibit 1a), as well as a supplemental data form. The supplemental form that accompanies each sample requires the submitter to note the age, clinical signs, condemnation code (where applicable), and 'category' (i.e., where collected and reason). Electronic submissions of these forms and business rules in the database ensure consistency (e.g.., if the submitter selects the category for ante-mortem condemn, he or she also must select a condemnation code) and reduce the opportunity for data-entry errors.

We have trained sample collectors on use of the electronic forms and instructed them to accurately record the relevant information necessary to classify samples into various aspects of the targeted population. A total of 985 personnel – including personnel from APHIS, FSIS, State animal health agencies, and contractors – have received this training. CD copies of the entire training sessions for the net casts and satellite seminars have been distributed. Also, sample collectors can find written instructions in the BSE Surveillance Guide (See exhibit 12). We have attached a list of training courses and opportunities provided. (See exhibit 5a).

APHIS recognizes that data collection processes over the past 14 years of the surveillance program have varied considerably. In general, NVSL personnel recorded certain data in multiple formats using information noted on the submission form. To address this inconsistency, APHIS has developed a new, single database that allows the laboratories to track sample submissions and report test results, and provides a repository for data gathered at the point of sample collection. These data include information about the sample collector, the origin of the animal, the collection site, and specific animal information. For example, when a sample is collected at a rendering facility, that facility is documented as the site of collection and the location from which the animal carcass

originated before arriving at the rendering facility is documented as the owner or source location. Moreover, information pertaining to clinical signs that the animal was exhibiting prior to death is also collected. If the animal is sampled because it is condemned at slaughter, the reason for its condemnation is entered into the database. Other data that is collected include all identification on the animal, and the animal's age, sex, and breed. Finally, the general category of the high risk population to which the sampled animal belongs (e.g., suspect, dead, non-ambulatory, etc.) is recorded.

The primary data entry occurs at either the sample collector or Area Office level; the laboratory also has the capability to enter data when necessary. The system is interlinked, and allows data entry on site at a collection location with electronic transmission to the designated laboratory or at the laboratory. The system can return reports of results to the submitter and the AVIC.

APHIS is monitoring for data integrity and quality, and has developed data reconciliation protocols. (See exhibit 1b). We recognize that all data points may not be known for every animal sampled, but will seek to maximize the data we can obtain. If a particular submitter or collector does not regularly provide testable samples or adequate and full information, the AVIC in the relevant State will follow-up to correct any deficiencies. Additionally, the AMS quality assurance audit will evaluate the training of the sample collectors and how well they are completing the Sample Data Form and VS Form 10-4 to verify accuracy.

We recognize that ensuring we identify and obtain samples from animals dying on the farm is a special challenge. Animals that die on the farm, or are close to death, move through various processing channels. In some instances, they may remain on the farm and be buried or otherwise disposed of. Many of these animals, however, are sent to salvage facilities, rendering facilities, or are removed by a deadstock hauler. Each of these facilities presents an opportunity for sample collection. For purposes of our enhanced surveillance program, the key is obtaining the sample and information about clinical signs prior to death. Whether the animal died on the farm, on the way to the salvage facility, or in the pens at the slaughter facility does not matter because in each of these instances, a sample could be collected and recorded as "dead" or "died of unknown causes" – which fits our targeted population.

The actions to address this recommendation – data monitoring and reporting – will be ongoing and continuous throughout the program.

**7. Clarify sampling and testing requirements for those animals in a weakened state sent to slaughter. Develop a plan for testing "downer" cattle no longer sent to slaughter.**

APHIS and FSIS agree with this recommendation. Although FSIS does not have a specific regulatory definition for severely weakened, APHIS finds that animals encompassed by their use of this term are already covered in the FSIS regulations.

Under the interim final rule published January 12, 2004 (9 CFR 309.2, 309.3), non-ambulatory disabled livestock are defined as animals that "cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions." All non-ambulatory disabled cattle are condemned and not allowed to enter the food supply. Other animals such as those exhibiting septicemia, toxemia, and those encompassed by the regulatory definition of non-ambulatory disabled are condemned on antemortem. APHIS and FSIS agree that the term severely weakened encompasses several distinct antemortem conditions already in the FSIS regulations. Animals that are severely weakened at antemortem would therefore be condemned by FSIS under their regulations and sampled consistent with FSIS notice 28-04.

APHIS-VS Memorandum 580.16 (see exhibit 4) includes animals that are "severely weakened though they may be able to stand and walk for brief periods of time" in the clinical presentation criteria for animals to sampled as part of the targeted cattle population.

As mentioned previously, there are other channels available for non-ambulatory animals other than slaughter for human food. These facilities include rendering facilities, 3D/4D or salvage slaughter facilities, and other disposal options, such as deadstock facilities. APHIS has worked with these industries since our surveillance efforts began in 1990. This long-standing relationship with such facilities has encouraged continued participation and allowed access to not only non-ambulatory animals, but all other categories in our targeted population.

Surveillance numbers prior to the start of our enhanced program demonstrate the continued access to both non-ambulatory animals as well as deadstock in these facilities. For example, in the first quarter of fiscal year 2004 (Oct-Dec 2003), a total of 8,160 samples were tested. Of this total, 1,266 were from deadstock (15%), and 6,360 (77%) were from non-ambulatory animals. In the second quarter of FY04 – after the condemnation of non-ambulatory animals policy took effect – a total of 5,496 samples were tested. Of this total, 2,776 (50%) were from deadstock, and 2,031 (37%) were from non-ambulatory animals. These collections from non-ambulatory animals demonstrate continued access through channels other than slaughter for human consumption.

Throughout our enhanced surveillance program begun on June 1, the majority of samples collected will be at these types of facilities. In some regions, we estimate that more than 80 percent of our samples will be collected through these animal disposal channels. The initial rough numbers for the month of June 2004 indicate similar actions, with more than 70% of total sample collections from rendering or 3D/4D salvage slaughter facilities.

APHIS will continue ongoing and routine evaluations to document maintained access to these populations, and the AMS quality assurance will validate our efforts. Furthermore, if targeted samples are not acquired, contingency plans referenced earlier will address this issue on an as-needed basis. The initial AMS audit will be completed by September 15, 2004, and other actions will be continuous and ongoing throughout the program.

**8. Issue consistent USDA age requirements for testing the various targeted high-risk populations.**

APHIS agrees with this recommendation. We recognize that the age requirements for sampling have changed at times since 1990. These changes reflected new scientific information about possible incubation periods and appropriate age sampling. While APHIS always tested any submitted tissue of diagnostic quality, only samples above the then in place age limit were reported in any official counts of surveillance samples or included in any statistical calculations or analysis.

We have already addressed this recommendation through the following provision of VS Memo 580.16 (see exhibit 4) : "Age – Unless otherwise designated, samples should only be obtained from animals over 30 months as evidenced by the eruption of at least one of the second set of permanent incisors." The designated exceptions to this definition include sampling animals with CNS signs of any age, and sampling ante-mortem condemned animals (certain veal calves excepted) of any age. Although FSIS Notice 28-04 directs FSIS personnel at slaughter facilities to collect samples from all ante-mortem condemned animals regardless of age (see exhibit 3a)—to ensure that no target animal goes untested. VS Memo 580.16 clearly states that only samples that meet the target population, including the age requirement, will be counted in any data analysis. FSIS Notice 29-04 provides that APHIS sampling of antemortem condemned slaughter origin cattle is consistent with FSIS Notice 28-04.

**10. Develop instructions for the specimen submission forms that provide specific instructions on the information to be included, specifically clarify requirements relating to the origin of the animal. Develop a follow-up process to ensure erroneous or improperly completed forms are corrected.**

APHIS agrees with this recommendation and has already taken steps to implement it. Instructions on the completion of forms (electronic and/or web-based) are included in the BSE Surveillance Guide sent to field sample collectors. All of the sample collectors have had multiple training opportunities including Web casts, training CDs, and a satellite seminar which will be repeated several times throughout the program. All training addressed the completion of electronic forms and emphasized accurate and timely data entry.

Previous BSE surveillance efforts included regional targets for numbers of samples collected from a grouping of states. These regions were designed around movements of adult animals to slaughter establishments. At that time, many of the samples were collected from cattle presented at slaughter facilities, and individual animal identification was often inadequate to determine an animal's state of origin. The data obtained in these efforts were managed at NVSL, generally in a spreadsheet application. With the

enhanced BSE surveillance effort, a new module of VS' surveillance information systems has been developed and is being used.

This new database, described in detail in our response to Recommendations 6 and 9, provides support for the laboratories to track sample submissions and report test results, and a repository for data gathered at the point of sample collection. These data include information about the sample collector, the origin of the animal, the collection site, and specific animal information. For example, when a sample is collected at a rendering facility, that facility is documented as the site of collection and the location from which the animal carcass originated before arriving at the rendering facility is documented as the owner or source location.

Collecting a more complete set of data at the time that samples are obtained will expand our ability to attribute each sample to the state in which the animal most recently resided. In this way, it will be possible to more accurately assess the geographic representation of samples obtained against the standing adult cattle population.

Sample collectors have been trained extensively on the submission forms and instructed how to accurately record the relevant information. A total of 985 personnel – including personnel from APHIS, FSIS, State animal health agencies, and contractors – have received this training. The attached table lists training courses and opportunities by which personnel have received this information. (See exhibit 5a)

APHIS is monitoring data being entered into the information system for quality and has developed data reconciliation protocols. (See exhibit 1b) APHIS recognizes that all data points may not be known for every animal sampled. However, if a particular submitter or collector does not regularly provide testable samples or adequate and full information, the Area Veterinarian in Charge (AVIC) in the relevant State will provide follow-up to correct any deficiencies.

In addition to the monitoring as outlined in the data reconciliation protocol, specific critical control points can be more rapidly addressed. If a sample collector does not accurately or completely fill out the sample submission forms, the laboratory will contact the AVIC who will provide appropriate feedback and supervisory guidance. This is a real-time check or validation on data entry.

The AMS quality assurance review will validate training and will ensure that data is accurately entered in the database. This effort will include quality control checks of the Sample Data form and VS Form 10-4.

Monitoring these actions will be continuous and ongoing throughout the program.

**11. Issue formal instructions on the policies and procedures to be followed on retaining and preserving excess tissue samples until the test results are reported.**

APHIS agrees with this recommendation and has already issued instructions both to sample collectors and laboratories since each has a different role to play in maintaining and/or disposing of tissue samples. The instruction to sample collectors is to dispose of excess tissue along with the carcass. We covered this topic in training and in the BSE Field Surveillance Guide. (See exhibit 12).

We instructed laboratories, through Standard Operating Procedures (SOPs), to retain tissue frozen for five days if the disease is not detected; if the result is inconclusive, they are to send all residual tissue and homogenate immediately to NVSL. (See exhibit 9a)

We developed these policies and procedures based on the science behind the various tests we use. The immunohistochemistry (IHC) methodology requires tissues to be fixed in formalin rather than fresh. When we were exclusively using the IHC test, we preserved fresh tissue separately so we could run other types of tests, like the western blot, if deemed necessary. Rapid screening tests—now the first line in the program—use fresh tissue. Thus, fresh tissue is available for either western blot methods or to be formalin fixed for IHC. As demonstrated by the 2 recent inconclusive test results on the initial rapid screening tests, more than sufficient tissue was available to conduct both repeats of the initial screening test and to formalin-fix for immunohistochemistry. Accordingly, it is unnecessary to preserve additional fresh tissue beyond that which is part of the sample itself.

As with other aspects of the program, the AMS quality assurance review will evaluate how well laboratories are following these procedures.

**12. Establish management controls, to ensure the accuracy and integrity of the sample and test database.**

APHIS agrees with this recommendation and has already taken steps to implement it. Instructions on the completion of forms (electronic and/or web-based) are included in the BSE Surveillance Guide sent to field sample collectors. All of the sample collectors have had multiple training opportunities including Web casts, training CDs, and a satellite seminar which will be repeated several times throughout the program. All training addressed the completion of electronic forms and emphasized accurate and timely data entry.

Previous BSE surveillance efforts included regional targets for numbers of samples collected from a grouping of states. These regions were designed around movements of adult animals to slaughter establishments. At that time, many of the samples were collected from cattle presented at slaughter facilities, and individual animal identification was often inadequate to determine an animal's state of origin. The data obtained in these efforts were managed at NVSL, generally in a spreadsheet application. With the

enhanced BSE surveillance effort, a new module of VS' surveillance information systems has been developed and is being used.

This new database, described in detail in our response to Recommendations 6 and 9, provides support for the laboratories to track sample submissions and report test results, and a repository for data gathered at the point of sample collection. These data include information about the sample collector, the origin of the animal, the collection site, and specific animal information.

Sample collectors have been trained extensively on the submission forms and instructed how to accurately record the relevant information. A total of 985 personnel – including personnel from APHIS, FSIS, State animal health agencies, and contractors – have received this training. The attached table lists training courses and opportunities by which personnel have received this information. (See exhibit 5a) CD copies of the entire training sessions for the net casts and satellite seminars have been provided and additional copies are attached.

APHIS is monitoring data being entered into the information system for quality and has developed data reconciliation protocols.(See exhibit 1b) APHIS recognizes that all data points may not be known for every animal sampled. However, if a particular submitter or collector does not regularly provide testable samples or adequate and full information, the Area Veterinarian in charge in the relevant State will provide follow-up to correct any deficiencies.

In addition to the monitoring as outlined in the data reconciliation protocol, specific critical control points can be more rapidly addressed. If a sample collector does not accurately or completely fill out the sample submission forms, the laboratory will contact the Area Veterinarian in Charge who will provide appropriate feedback and supervisory guidance. This is a real-time check or validation on data entry.

The AMS quality assurance review will validate training and will ensure that data is accurately entered in the database. This effort will include quality control checks of the Sample Data form and VS Form 10-4.

Monitoring these actions will be continuous and ongoing throughout the program.

**13. Expedite the development of the new BSE information technology system. Ensure appropriate general, logical, and application controls are established.**

APHIS agrees with this recommendation and has aggressively moved to implement it. We are field testing the BSE system to identify any problems and to improve user access and clarity. As of July 23, 2004, a total of more than 22,500 records have entered into the database. APHIS will have the data entry backlog completed and the database functional for providing reports and analysis by July 30, 2004. The database will be completely functional, including electronic reporting of laboratory results, by August 20.

Sample collectors are trained in how to enter data, feedback will be provided when mistakes are made on the form, and the AMS quality assurance review will evaluate our performance.

The system provides secure web-based and pen-tab applications that share BSE surveillance and test result data. The data sharing facilitates proactive collaboration between Federal and State veterinary diagnostic laboratories. It is a component of the national animal health security infrastructure and provides standardization, validation, quality assurance, and secure communications among laboratories and program managers. It is the first online system that integrates animal health laboratory sample information and makes sample data available to help all participants fulfill their roles.

Participants access the system through a secure internet connection that complies with USDA's Office of the Chief Information Officer's requirements. There is a defined permission for data access, based on identification of the user and the user's role. The system uses standardized case data according to the Systemized Nomenclature of Medicine and Veterinary Medicine (SNOMED) and Logical Observation Identifiers, Names and Codes (LOINC).

APHIS is monitoring data the system for quality and has developed data reconciliation protocols. (See exhibit 1b) APHIS recognizes that all data points may not be known for every animal sampled. However, if a particular submitter or collector does not regularly provide testable samples or adequate and full information, the Area Veterinarian in charge in the relevant State will provide follow-up to correct any deficiencies.

In addition to the monitoring as outlined in the data reconciliation protocol, we can rapidly address specific critical control points. For example, if a sample collector does not accurately or completely fill out the sample submission forms, the laboratory will contact the Area Veterinarian in Charge who will provide appropriate feedback and supervisory guidance. This is a real-time check or validation on data entry.

The actions to make the database completely functional will be completed by August 20, 2004. Monitoring the data will be continuous and ongoing throughout the program.

**14. For State contract laboratories that will perform BSE testing under the new surveillance program, develop and execute written agreements that include specific provisions for responsibilities, performance, and reimbursement.**

**19. Ensure all agreements with other laboratories contain requirements that specify the performance measures for processing samples and reporting test results.**

APHIS agrees with these recommendations. Because Recommendations 14 and 19 are closely related and many of our current and planned actions apply to both, we have consolidated the response here. We have already taken steps to address the

recommendations and ensure that the 12 laboratories designated to perform BSE testing for the program are operating effectively.

We developed Standard Operating Procedures (SOP's) to address all laboratory responsibilities and performance expectations. There are SOPs for: conducting the specified test procedures (see exhibit 9b); addressing all laboratory responsibilities, performance expectation, and communication or reporting requirements (see exhibit 9a); documenting the chain of custody of forwarded tissues from inconclusive tests (see exhibit 9c); and for proficiency testing (see exhibit 9d). Reimbursement is addressed through a standard purchase order, which is linked to performance and contingent on proper procedures. (See exhibit 9e)

Specific issues have been raised about training of laboratory personnel, reporting guidelines, timeliness of reporting, and confidentiality. These are all addressed in the SOPs as follows. Training was initially conducted by the test kit manufacturer. Competency from this training was demonstrated via the initial proficiency test required prior to participating in this program, and through the ongoing proficiency testing. This is addressed in GPPISOP0033.01. The reporting guidelines and confidentiality issues are addressed in the basic SOP outlining responsibilities – GPPISOP0032.01. Finally, the timeliness issue is also specifically addressed in GPPISOP0032.01.

If a laboratory is not following the appropriate procedures, APHIS can stop payments since reimbursement is contingent on proper procedures, or revoke their approval to participate in the program.

**15. Require written agreements or contracts with private entities that supply samples for BSE testing. Develop written agreements/contracts that include specific requirements for the responsibilities, sampling procedures, and reimbursement.**

APHIS agrees with this recommendation and has already taken steps to implement it. As documented in APHIS-VS Memorandum 580.16, the program provides certain financial reimbursements. When an entity provides samples on a regular basis, we enter into written agreements or contracts. These specify the responsibilities of each party and the agreed amount for the specific financial reimbursement applicable. Where it is feasible to have competition, or there is a special need to protect the Government's interest, we enter into contracts in accordance with federal contracting procedures (see exhibit 10).

We use agreements where competition is not feasible. We have provided a template of this agreement (which has been cleared by the Office of General Counsel) to AVICs. By August 31, 2004, we will amend the template to add a supporting schedule of cost guidelines. It includes the responsibilities of the parties, sampling procedures and reimbursement (see exhibit 11a). Copies of representative agreements signed to date are also provided – additional examples are available for review upon request. (See exhibit 11b).

**16. Develop a supportable methodology to evaluate the effectiveness of the BSE surveillance program.**

**17. Establish a continuous risk assessment process as progress is made in identifying the universe of and testing high-risk cattle.**

APHIS agrees with these recommendations. Because Recommendations 16 and 17 are closely related and many of our current and planned actions apply to both, we have consolidated the response here. APHIS understand Recommendation 17 to mean that we should establish a process to analyze results of the surveillance program, conduct ongoing assessments, and have a process to do mid-course corrections as necessary.

Over the entire period of the enhanced BSE Surveillance Plan, analysis of collected data will be an ongoing and evolving effort. An epidemiologist from the APHIS-VS National Surveillance Unit at the Centers for Epidemiology and Animal Health has been assigned to be responsible for performing the routine analyses. This epidemiologist will work closely with the BSE surveillance program manager and the APHIS TSE Working Group in conducting and reporting these analyses.

Our methodology to evaluate the program's effectiveness is to measure sample results to make certain that we are collecting the number and type of samples appropriate to reach overall targets for achieving statistical validity of the surveillance effort. Using management reports from the database (described in detail in our response to Recommendations 6 and 9), we will analyze data on a weekly basis over the entire surveillance period. These include:

- Geographic distribution of sample collections
- Source of sampled animals
- Categories or characteristics of sampled animals (clinical presentation - highly suspicious clinical signs, CNS signs, other clinical signs, non-ambulatory, dead, etc..; age; other characteristics as necessary)

If our data shows that the samples we are collecting differ significantly in any one of a number of characteristics (e.g., geographic location, source, clinical signs), we will analyze the cause and adjust the program. For example, this could include changing or enhancing our focus on certain locations or sources.

APHIS has worked with AMS to develop an audit to ensure quality assurance of the program. (See exhibit 6) This audit began on July 15, 2004, and we expect initial results by September 15, 2004. AMS will conduct additional ongoing audits throughout the course of the program. Monitoring these actions will be continuous and ongoing throughout the program.

**18. Establish performance measures and develop management reports to monitor the effectiveness and integrity of the submission, processing, and reporting of sample results.**

APHIS agrees with this recommendation and has already taken steps related to the various critical control points in the process, from the sample collector through the Area Office and the laboratory as necessary.

The sample collectors and submitters are responsible for several things, such as ensuring appropriate quality and tissue location of the sample; packaging and shipping samples correctly; and accurately completing submission and data entry forms. The responsibilities of the sample collector are described in VS Memo 580.16, and in the BSE Surveillance Guide (See exhibit 12). Sample collectors have received training extensively in these procedures (See exhibit 5a).

The designated laboratory is the primary control point in this process. Laboratory personnel will record samples which are not of sufficient diagnostic quality for testing or from which the tissue location is not identifiable. The laboratory will notify the AVIC of any repeated problems. The AVIC in turn will address problems with the individual sample collector. It must be noted that there is no requirement for tissue quality evaluation.

The laboratory is responsible for processing samples appropriately, conducting the test properly, and reporting sample results according to APHIS policy. We have developed Standard Operating Procedures (SOP's) for the designated laboratories and payment to them is contingent on following these guidelines. These SOP's, as described in our response to Recommendations 14 and 19, address all of these responsibilities. Of course perhaps the most important measure to ensure effectiveness and integrity of the testing process is that all inconclusive results reported by the designated laboratories will undergo confirmatory testing by NVSL, the national reference laboratory - using the gold standard test, the IHC.

One of the SOP's (see exhibit 9d) specifically addresses quality assurance at the designated laboratories. This outlines the process of ongoing proficiency testing that will be conducted at NVSL, and weekly monitoring of test performance and comparison of this performance to all laboratories involved. These processes will help ensure quality and accuracy of the testing results.

As with other aspects of the program, the AMS quality assurance audit will evaluate our performance in this area and provide ongoing feedback to guide our actions to correct any problems. Monitoring these actions will be continuous and ongoing throughout the program.

Informational copies of this report have been distributed to:

Administrator, FSIS
    Attn: Assistant Administrator for Office of Program Evaluation, Enforcement, and Review (20)
Administrator, APHIS
    Attn: Deputy Administrator for Marketing Regulatory Program Business Services (9)
Government Accountability Office (1)
Office of Management and Budget (2)
Office of the Chief Financial Officer
    Director, Planning and Accountability Division (1)