



VETERINARY SERVICES MEMORANDUM NO. 580.16

SUBJECT: Procedures for Conducting the Bovine Spongiform Encephalopathy (BSE) Ongoing Surveillance Program

TO: VS Management Team (VSMT)
Directors, VS

JUL 19 2006

I. PURPOSE

This memorandum clarifies the procedures used to conduct the BSE Ongoing Surveillance Plan.

II. CANCELLATION

VS Memorandum No. 580.16, dated August 19, 2005, is hereby canceled.

III. BACKGROUND

Prevalence of BSE is expected to continue to decline as long as mitigation efforts that maintain low risk for introduction and spread of the BSE agent among U.S. cattle are maintained. This plan details the objectives and methods considered pertinent and necessary for the BSE Ongoing Surveillance Plan. In order to maintain confidence that BSE is exceedingly uncommon among U.S. cattle, sampling methods of ongoing surveillance are designed to detect disease should the prevalence rise above 1 case per 1,000,000 adult cattle.

The principal goals of the BSE Ongoing Surveillance Plan are:

1. To continue to assess and monitor change in the BSE status of U.S. cattle.
2. To provide the mechanisms for early detection of BSE among U.S. cattle.

Detailed instructions and guidelines for the procedures used in the BSE Ongoing Surveillance Program can be found in the VS Procedures Manual for BSE Ongoing Surveillance Plan Implementation.



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IV. INVESTIGATIONS OF CATTLE HIGHLY SUSPICIOUS FOR BSE

Cattle exhibiting clinical signs as described below should be categorized as highly suspicious for BSE and will receive a more detailed examination with collection of the entire brain. Other animals that have abnormal central nervous system (CNS) clinical signs but do not fall into the highly suspicious for BSE category should be sampled within the established framework of the BSE Ongoing Surveillance Plan, and additional information on these animals should be captured in the data collection process.

Animals that are highly suspicious for BSE may only display a few of the signs, and signs may vary significantly in severity. True rabies suspects (i.e., animals in areas where there is a significant level of endemic wildlife rabies and where veterinary practitioners frequently encounter domestic animal exposures) should be treated as such and submitted for rabies testing before BSE testing. If negative for rabies, they should be submitted for BSE testing.

A. Cattle of any age are highly suspicious for BSE if they exhibit the following:

1. Affected by illnesses that are refractory to treatment, including but not limited to, anorexia, loss of condition in spite of a good appetite, pneumonia, and decreased milk yield **and** that are displaying progressive behavioral changes, including but not limited to, apprehension; nervousness; excitability; aggression toward other cattle or humans; head shy with head held low; persistent kicking when milked; high stepping; difficulty in rising; excessive nose scratching; changes in herd hierarchical status; hesitation at doors, gates, and barriers; and reluctance to cross concrete or other "slippery" surfaces.
2. Displaying progressive neurological signs that cannot be attributed to infectious illness and that are not responsive to treatment.

B. Sample collection and submission for cattle that are highly suspicious for BSE:

1. Cattle that show highly suspicious clinical signs should be observed over a period of time (at least 2 weeks) if possible, to determine whether the signs become progressively more severe. If at this time improvement or recovery has not taken place, the suspect animal should be humanely euthanized with an appropriate method and submitted for testing according to the Procedure Manual for Bovine Spongiform Encephalopathy (BSE) Ongoing Surveillance Plan Implementation.

2. Submission of brain specimens for rabies testing will be left to the professional judgment of the Veterinary Medical Officer. Rabies testing should be done at the appropriate State or local public health department. Work with the appropriate public health personnel (laboratory and epidemiology) in your State to discuss:

- (a) collection procedures that will provide acceptable brain specimens for testing for both rabies and BSE;
- (b) procedures for rabies sample submission; and
- (c) if rabies negative, maintenance and submission of appropriate samples for forwarding to the National Veterinary Services Laboratories (NVSL) for BSE testing.

V. SAMPLING TARGETED HIGH-RISK CATTLE FOR SURVEILLANCE

Animals in any of the categories listed below are to be included in the targeted surveillance efforts. Unless otherwise designated, samples should only be obtained from animals 30 months of age or older as evidenced by the eruption of at least one of the second set of permanent incisors.

A. Clinical Presentation of Target Cattle:

- 1. Cattle that cannot rise from a recumbent position (downer) or that cannot walk including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral columns, or metabolic conditions as well as cattle that are severely weakened though they may be able to stand and walk for brief periods of time.
- 2. CNS signs and/or rabies negative – sample animals of any age:
 - (a) Diagnostic laboratories – samples submitted due to evidence of CNS clinical signs.
 - (b) Public health laboratories – rabies negative cases.
 - (c) Slaughter facilities – CNS antemortem condemnments at slaughter, sampled by the Food Safety and Inspection Service (FSIS) or offsite contracted sample collectors.
 - (d) On-the-farm – CNS investigations.

3. Cattle exhibiting other signs that may be associated with BSE – Cattle that were condemned or euthanized or that died as a result of a moribund condition, tetanus, emaciation, injuries, or nonambulatory conditions.

4. Dead cattle – Dead cattle at rendering, 3D/4D establishments and antemortem cattle condemned moved for sampling from inspected slaughter establishments should be sampled only according to provisions of competitive contracts awarded to operators of those facilities.

B. Cattle condemned on antemortem inspection at slaughter:

Samples shall be collected from cattle 30 months of age or older, condemned on antemortem inspection at both State and federally inspected slaughter plants. Sampling numbers will be determined prior to the commencement of each sampling cycle. All cattle, regardless of age, condemned by FSIS upon antemortem inspection for CNS impairment will be sampled.

Sampling done onsite at the slaughter establishment will be done by FSIS personnel at federally inspected plants and by either Animal and Plant Health Inspection Service (APHIS) or State personnel at State inspected plants. Sampling done through approved offsite arrangements will be done by APHIS personnel or their contractors.

C. Cattle of any age with CNS signs:

Cattle that fit the characteristics of the targeted subpopulation “Cattle of any age with CNS signs” will be sampled for surveillance regardless of whether the site they are presented to has been specifically enlisted for surveillance. It is emphasized that cattle identified with the surveillance criteria of “clinical suspect” will be sampled throughout the surveillance period regardless of the avenue through which they present to surveillance, and regardless of the degree with which sampling goals have been met.

D. Sample Collection sites:

1. On-Farm

These samples may be collected by accredited veterinarians, Federal or State employees (including animal health technicians), or VS-approved dead stock haulers. Under VS Area Office oversight, sample collectors with other qualifications may be enlisted when resources preclude the participation of aforementioned sample collectors in a given area.

2. Veterinary Diagnostic Laboratories

Cattle submitted for necropsy, or fresh whole brainstem submitted for ancillary diagnostics to veterinary diagnostic laboratories, including those not involved in BSE testing, will be sampled by laboratory personnel. Such samples are usually accompanied by significant historical information pertaining to clinical signs, and thus are of high value to surveillance.

3. Public Health Laboratories

All samples from cattle that are rabies suspects and test negative for rabies will be submitted for surveillance by laboratory personnel. All samples derived from this data source can be characterized as clinically suspicious for BSE, and thus are of high value to surveillance.

4. Slaughter (FSIS)

Samples shall be collected from cattle 30 months of age or older, condemned on antemortem inspection at both State and federally inspected slaughter plants. Sampling numbers will be determined prior to the commencement of each sampling cycle. All cattle, regardless of age, condemned by FSIS upon antemortem inspection for CNS impairment will be sampled. Samples will be collected by FSIS employees or designated off-site sample collection facilities. Most of these samples are anticipated to represent cattle belonging to the second most valuable surveillance stream ("casualty slaughter").

5. Facilities contracted to collect samples from cattle condemned at antemortem inspection by FSIS

Samples derived from animals presented to slaughter and condemned at antemortem inspection may be collected by personnel of a contracted rendering or 3D/4D facility, or other APHIS approved facility. Under these circumstances, communication of clinical history and condemnation codes to the contracted facility is imperative.

6. Rendering or 3D/4D facilities

In order to represent the "fallen stock" surveillance stream and a wide variety of data sources, a limited number of samples will be collected from targeted cattle presenting to rendering or 3D/4D facilities.

VI. SAMPLING AND SUBMISSION PROCEDURES FOR TARGETED ONGOING SURVEILLANCE SAMPLES

The brain stem, including the obex, will be collected using a brain tissue spoon or other acceptable device. NVSL will provide sampling spoons and tools to sample collectors. Fresh tissue samples will be submitted to designated laboratories as listed in the attached

table. All samples should be submitted as fresh tissue samples; samples should not be fixed in formalin, with the exception as described in the procedure for collecting the entire brain from cattle that are highly suspicious for BSE as specified in Procedure Manual for Bovine Spongiform Encephalopathy (BSE) Ongoing Surveillance Plan Implementation.

Routine surveillance samples should be sent to the appropriate designated laboratory. Appendix 2 provides the list of designated laboratories and sampling locations from which they should receive submissions.

Designated laboratories will report rapid screening test results to the sample submitter, the Area Veterinarian in Charge (AVIC), and when requested, to plant management of the facility where the sample was collected. Rapid screening test results will be reported as either negative or inconclusive. In accordance with agreed laboratory standard operating procedures, any samples with inconclusive rapid screening test results must be immediately forwarded to NVSL for confirmatory testing.

VII. COST RECOVERY PAYMENTS

Payments for the services listed in Appendix 3: Cost Recovery Methods may be made according to approved cost recovery guidelines and payment procedures. Additional payments may be approved on a case-by-case basis with appropriate justification provided to and approved by the Regional Office. Refer to the Animal Health Protection Act, agreement guidance, or Federal acquisition regulations for further specific payment information.

Payment for sample collection, identification, packing, transportation, and storage and disposal of carcasses at rendering, 3D/4D establishments, and off-site collection points for antemortem condemned cattle from FSIS inspected establishments will be made according to provisions of competitive contracts between APHIS and sample collectors.

VIII. COMMUNICATION AND REPORTING OF TEST RESULTS

It is essential to have secure and reliable communication among individuals responsible for sample collection at collection locations, establishment managements, and NVSL or designated laboratories. The following communication guidelines will be followed:

A. Sample collector – designated laboratory communication:

1. The sample collector will notify the appropriate laboratory of incoming samples via facsimile, telephone, e-mail, or any other approved electronic method.

2. It is the responsibility of the sample collector to verify, via the overnight contract delivery service tracking system, that the submission has been delivered to the designated laboratory.

B. Communication from NVSL or designated laboratory:

1. The day the tests are completed, the designated laboratory will transmit a copy of the test results to the collector, the VS Area Office, and appropriate management at the collection site when requested.
2. If all animals tested in the lot are rapid screening test negative, the designated laboratory will report results to the collector and, when requested, to the collection site. If any of the animals in the lot are screening test inconclusive, the designated laboratory report will be sent to the AVIC and will specify which carcasses tested inconclusive. The AVIC will notify the collection site, at the direction of the Deputy Administrator's office, in accordance with the policy on daily announcements of inconclusive results. A decision to hold or dispose of the carcasses pending confirmatory testing should be made with the concurrence of the AVIC.
3. Samples from all screening test inconclusives must be immediately forwarded to NVSL, with prior notification and confirmation of arrival. All confirmatory test results will be transmitted directly to the VS Area Office so that carcass disposal can be coordinated and verified. The AVIC will contact the sample collector and the facility where the sample was collected.

IX. CARCASS AND OFFAL DISPOSAL

A. Disposal of carcasses and offal from screening test inconclusive or test positive animals

When necessary, disposal of carcasses and offal will be in compliance with Federal, State, and local laws. Acceptable options may include any of the following, among others:

1. Refrigerate or freeze pending test results; then render or otherwise process after negative test results are obtained (could include boning out carcass and holding the meat product for use in pet food or rendering materials and holding finished product).
2. Disposal by rendering at dedicated facilities, if available – rendering for nonanimal feed use, such as biofuel or cement.

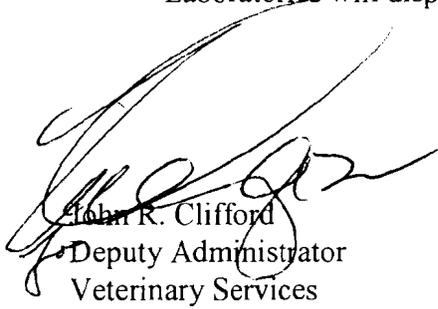
3. Burial in a landfill or on-the-farm.
4. Alkaline digestion.
5. Incineration.

B. Hides

Hides need not be disposed or held pending test results.

C. Sample disposal

Laboratories will dispose of samples using standard operating procedures.



John R. Clifford
Deputy Administrator
Veterinary Services

3 Attachments

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Appendix 1 – Personal safety

If bovine spongiform encephalopathy (BSE) is transmissible to humans in the occupational setting, the most likely routes would be through contact with infective tissues through wounds or open lesions on the skin, contact with mucous membranes (eyes and mouth), or particularly, by swallowing. Transmission by the airborne route (i.e., by the inhalation of infectious airborne particles) is considered to be the least likely route of exposure. In naturally BSE affected cattle, the only tissues that have shown infectivity are the brain, retina, and spinal cord. In experimentally (orally) affected cattle, the distal ileum has also shown infectivity.

Because rabies, listeriosis, and other possible zoonotic diseases must be included in the differential diagnosis, brain and spinal cord collection from cattle with central nervous system clinical signs should be done carefully. The following precautions are generally applicable:

- Adhere to safe working practices and take extra precautions to avoid or minimize the use of tools and equipment likely to cause cuts, abrasions, or puncture wounds.
- Where use of such equipment is unavoidable, wear suitable protective clothing, which includes disposable coveralls, aprons, heavy gloves, and boots.
- Cover existing cuts, abrasions, and skin lesions on exposed skin with waterproof dressings.
- Use face protection such as a facemask and face shield or goggles to protect the mucous membranes of the eye, nose, and mouth from exposure to infective droplets or tissue fragments.
- Take steps to avoid the creation of aerosols and dusts when engaged in activities such as sawing through the skull bones.
- Wash hands and exposed skin before eating, drinking, smoking, taking medication, using the telephone, or going to the toilet.
- Wash and disinfect protective clothing and instruments thoroughly after use.

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Appendix 2 – Designated laboratories

Designated laboratory	State in which sample collected
California Animal Health and Food Safety Lab System University of California, Davis, CA	California, Arizona, Nevada
Colorado State University Veterinary Diagnostic Lab, Ft. Collins, CO	Colorado, Utah, Wyoming, Nebraska, South Dakota, North Dakota, Kansas, Missouri
Texas Veterinary Medical Diagnostic Laboratory, College Station, TX	Texas, Arkansas, Louisiana, New Mexico
Wisconsin Animal Health Laboratory, Madison, WI	Wisconsin
Washington State University Animal Disease Diagnostic Lab, Pullman, WA	Washington, Oregon, Idaho, Montana
Athens Diagnostic Laboratory, College of Veterinary Medicine University of Georgia, Athens, GA	Georgia, Mississippi, Alabama, Tennessee, Virginia, North Carolina, South Carolina, Oklahoma, Florida
NY State College of Veterinary Medicine, Veterinary Diagnostic Laboratory, Cornell University, Ithaca, NY	New York, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, Vermont, Rhode Island, Delaware, Connecticut, Michigan, Pennsylvania
USDA, APHIS, National Veterinary Services Laboratories, Ames, IA	Iowa, Illinois, Indiana, Hawaii, Alaska, Puerto Rico, Minnesota, Kentucky, Ohio, West Virginia

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Appendix 3: Cost Recovery Methods

Fee-basis payments for accredited veterinarians assisting with sample collection can be made in accordance with the intent of VS Memorandum No. 534.2 and these cost recovery guidelines.

Individuals located at collection sites may be contracted with on a per sample basis for collecting appropriate tissue samples from the targeted population. Compensation will only be provided when samples meet the criteria in this memorandum and are counted toward the targeted goal.

Activity	Fees Paid
<i>Identification & Storage</i> – includes identification and storage of carcasses and products	Up to \$100/sample
<i>Transportation</i> of animals/carcasses/heads for BSE sampling	Up to \$2.00/loaded mile
<i>Sample collection*</i> – includes removal of head and collection of obex	Up to \$40/sample
<i>Head removal*</i> – includes head removal and presentation to authorized collectors	Up to \$10/head
<i>Complete sample collection/submission</i> by Accredited Veterinarian – includes travel, collection of the brain stem, data processing, and submission of samples	Up to \$100/sample
<i>Disposal</i> of carcasses	- Up to \$100/carcass (for on-farm burial, composting, or in approved landfill) - Up to \$500/carcass (for incineration)

*Either *sample collection* or *head removal* may be paid, not both.

In addition to the above cost recovery fees, The Animal and Plant Health Inspection Service (APHIS) will purchase any product, derived from a bovine spongiform encephalopathy (BSE) positive (confirmed at the National Veterinary Services Laboratories) animal, that cannot be sold because of an action or request by the Food and Drug Administration. APHIS will pay the fair market value for this product and the disposal costs for the product. These costs will be covered only when the actions taken by the facility involved are in accordance with APHIS policies and procedures. This cost will be determined by the documentation and review of the invoices involving the disposition of the product.

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Any Full Service Fee, other than addressed in the Fee Basis Collection and Carcass Disposal, need to be broken into the costs as described above and be within these parameters for the approval of the payment.

Every effort should be made to pay only the costs associated with the particular transaction and stay within these BSE cost recovery fees guidelines. In situations where the costs are above the cost recovery fees guidelines, provide the Regional Office with a detailed justification of the circumstances involved, efforts taken to find others willing to accept the cost recovery amount, and all relevant information to justify the request. The Regional Office will consider national implications as part of their review of the request to deviate from the cost recovery fees guidelines and then make a determination based on the justification.

If approved, the Regional Director will sign for the authorized amount. The approval will be kept at the Regional Office, the area office, and a copy will be provided along with the related sampling agreement to the MRPBS, FMD, Payments Team, Minneapolis, Minnesota.