

Bovine Spongiform Encephalopathy (BSE) Surveillance Plan

March 15, 2004

The Animal and Plant Health Inspection Service (APHIS), in cooperation with the Food Safety Inspection Service (FSIS), and the Food and Drug Administration (FDA), has developed an outline for an intensive national BSE surveillance plan. This one-time effort will give a snapshot of the cattle population in the US and help to 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. We will immediately initiate actions to ramp up our system and expect to reach full capacity in a 2-3 month period. We will analyze the results obtained over this period and evaluate future actions based on the results of this effort. This plan also discusses the incorporation of random sampling of clinically normal aged animals at slaughter in addition to the defined targeted surveillance goal.

A. Targeted High-Risk Population Sampling Plan

Surveillance Objective

Experience in the United Kingdom and Europe has shown that testing cattle that are non-ambulatory, dead on the farm, or showing clinical signs consistent with BSE is the method most likely to disclose BSE if it is present in the cattle population. Targeted surveillance efforts in recent years were designed to detect BSE in the adult cattle population at the level of at least one infected animal per million adult cattle with a 95 percent confidence level. The intensive one-time surveillance effort will allow us to determine more accurately whether BSE is present in the US cattle population, and if so, estimate the level of disease. By expanding our surveillance, we will be able to provide consumers, trading partners, and industry increased assurances about the BSE status of the U.S. cattle population.

The objective for this portion of the plan is to collect samples from as many adult cattle from the high-risk population as possible in 12-18 months while ensuring that there is statistically appropriate geographical representation of the adult cattle population in the United States. Assuming all the BSE positive cattle are part of the high risk population, if a total of 201,000 samples is collected, this level of sampling would allow us to 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 is collected, this level of sampling would allow us to detect BSE at the same rate at a 99 percent confidence level.

High-Risk Population Estimates

The segment of the adult cattle population in which one is most likely to detect BSE if it is present is the population that contains animals that are exhibiting clinical signs consistent with BSE. The BSE disease takes years to develop from exposure to clinical signs, so that only older animals are an appropriate population for BSE surveillance testing. Therefore, the high-risk population for testing includes adult cattle showing clinical signs involving the central nervous system (CNS), and dead and non-ambulatory cattle where clinical signs cannot be

adequately evaluated. Based on currently available data, we estimate this population to be approximately 446,000 cattle. This estimate includes adult cattle in the following categories: condemned at slaughter for CNS signs; moribund; dead; injured or emaciated (FSIS data 2002); CNS abnormalities reported for foreign animal disease (FAD) investigations (APHIS data); died on farm for unknown causes; lameness, or injury that resulted in euthanasia; and cattle that died with signs of incoordination or severe depression (National Animal Health Monitoring System (NAHMS) data described below).

NAHMS conducts periodic surveys of livestock and poultry producers across the United States to characterize the health and management of animals. In 1997, NAHMS focused on breeding beef cattle. Overall, producers reported approximately 1.5 percent of adult cattle died annually. These death losses were attributed by producers to a variety of causes including digestive, respiratory, weather, and calving related problems as well as other known causes of death and death from unknown causes. Similarly, in 2002, NAHMS collected data to estimate that 4.8 percent of adult dairy cows die annually. Again, losses were attributed to various categories. Our calculations result in an estimate of 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. Estimates of the other described populations are 194,200 in the FSIS condemnation categories outlined, and a total of 129 reported FAD investigations of CNS abnormalities. These give a total of approximately 446,000 adult cattle estimated in the targeted high-risk population.

To ensure that the samples collected for BSE surveillance were geographically representative, these overall numbers were applied to the total cow population estimates (beef and dairy) of the United States as well as the individual State inventory of beef and dairy cows from the National Agricultural Statistics Service (NASS).

State-level data will be recorded based on the origin of animals from which samples are collected. The State in which a sample is collected is not necessarily the same as the State and premises of origin and other relevant data of the animal. Every effort will be made to accurately record the State of origin of animals in this targeted high-risk surveillance and other data. Assuming that most of these animals will not be moved significant distances (that is, most rendering or salvage facilities collect animals from a limited geographical area), information about the State of origin should be readily available.

Definition – Targeted Cattle Population

Age – Over 30 months as evidenced by the eruption of at least one of the second set of permanent incisors.

Clinical Presentation Criteria

1. Non-ambulatory cattle, to include:
 - a. 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;
and

- b. 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:*
- 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.
 - d. On-the-farm – CNS FAD 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 non-ambulatory conditions.
 4. Dead cattle – Any dead cattle where the specimen is of diagnostic quality and the cause of death and/or clinical signs prior to death, if known, do not preclude it from the targeted population.

Laboratory Capacity and Testing of Samples for BSE from Targeted Cattle

Testing of the targeted high-risk population samples will be conducted at APHIS' National Veterinary Services Laboratories (NVSL) and at participating network laboratories on a fee-for-service basis. High-throughput equipment (such as robotics systems) will be purchased for a limited number of laboratories to support this surveillance effort. As surveillance expands, the number of laboratories approved (if additional laboratories wish to participate) could be significantly larger. It is estimated that between 250,000-400,000 samples could be tested during a one year collection period, which could generate up to 2,000 samples on peak sampling days.

State veterinary diagnostic laboratories will be contacted to determine if they wish to participate in this program. Initially, these laboratories will be contacted based on the following points:

- a. High targeted total sample allocation in their State.
- b. Presence of chronic wasting disease (CWD) in the wildlife of the State (future use of technique and equipment).
- c. Current contract for CWD/scrapie testing.
- d. Geographic distribution.

Depending on the willingness of individual laboratories to participate in this program, a network of laboratories will be established throughout the continental United States.

An appropriate rapid screening test will be used to test time-critical samples. Some can be automated to run between 800-1000 samples per day. Samples that test positive by the rapid

* Test all, regardless of age.

screening test will not be considered presumptive-positives; they will be classified as “suspects.” The rapid screening test suspect samples will be tested by immunohistochemistry (IHC) and/or western blot at NVSL for confirmation.

A certain number of routine samples will be tested at NVSL as to ensure proficiency in conducting all licensed tests. Moreover, the use of network laboratories will allow NVSL to conduct quality assurance check-testing and to conduct confirmatory IHC testing of any suspects in a timely manner. Appropriate geographical distribution of network laboratories will ensure that a consistent and sufficient level of samples will be analyzed to optimize efficiency and competency.

Sample Collection for Targeted Cattle

The following procedures will be followed in sample collection:

1. Sampling – Sampling will be done by authorized State or Federal animal health or public health personnel, accredited veterinarians, or trained State or APHIS contractors.
2. Training – NVSL will train current collectors in the method of sample collection for use in rapid screening tests. APHIS or State personnel that have received training from NVSL will train additional sample collectors. Available training materials, including videos, CDs, and manuals, will be provided.
3. Quality assurance – NVSL will provide feedback to the Veterinary Services (VS) Area Offices regarding sample and data quality. If deficiencies are reported, VS Area Offices will ensure that corrective action is taken regarding sample and record quality.
4. Collection sites – Samples will be collected at any of the following sites as necessary:
 - a. State or Federally inspected slaughter establishments.
 - b. Custom exempt slaughter establishments.
 - c. On-the-farm.
 - d. Rendering facilities.
 - e. Veterinary diagnostic laboratories.
 - f. Animal feed slaughter facilities, i.e. pet food plants.
 - g. Public health laboratories – Rabies negative cases.
 - h. Veterinary clinics or other sites that accredited veterinarians might utilize.
 - i. Sale barns, livestock auctions, etc.
5. Site identification:
 - a. FSIS will supply a list of State or Federally inspected slaughter establishments where sampling may occur.
 - b. FDA will provide APHIS a list of renderers and other FDA regulated facilities receiving intact whole cattle carcasses.
 - c. The Centers for Disease Control and Prevention will provide a list of public health laboratories that conduct rabies testing on cattle.

- d. NVSL will provide a list of veterinary diagnostic laboratories that provide diagnostic services for cattle.
 - e. APHIS will enhance existing educational materials and processes to encourage reporting of suspect cattle identified on farm and for collecting samples from them. See Appendix A for an overview of educational and outreach activities.
 - f. VS Area Offices will work to identify other potential collection sites within their areas such as veterinary clinics, dead stock handlers, and custom exempt slaughter facilities.
6. The VS Area Veterinarian in Charge (AVIC), who will work closely with the State Veterinarian and other officials as appropriate (such as the head of the State meat inspection program, public health veterinarians, and State environmental authorities), will establish a relationship with each site identified in “5” above, in his or her area, to facilitate the submission of samples from high-risk categories of cattle.
 7. Safety – APHIS (and FSIS where needed) will provide the necessary safety equipment such as gloves, protective clothing, face masks, eye protection, etc., to their respective personnel or contractors for use during sample collection.
 8. Sampling supplies – NVSL will provide supplies including scissors, spoons, forceps, screw top plastic tubes (50 ml), shipping boxes/containers, bags, VS Form 10-4 or equivalent submittal forms, cool packs, shipping labels, absorbent materials, and any other necessary items as required.
 9. Data collection – The Sample Data Form and VS Form10-4 must be accurately completed.
 10. Sample – The brain stem, including the obex, will be collected using a brain tissue spoon or other acceptable device. Samples must be appropriately identified and all animal identification devices will be collected from each animal sampled, as described in the next section.
 11. Shipping – Means of shipping will be by overnight contract delivery service or by hand delivery if applicable. Samples will be maintained on cool packs and packaged according to current NVSL protocol.

Data collection and sample identification

All animal identification devices, brands (via digital picture or drawing), and tattoos (refrigerate tissue containing tattoo) will be collected from each animal sampled. These identification items will be bagged, labeled with the sample number, and then attached to a copy of the VS Form 10-4 and saved by the sample collector until negative results are received. In certain instances, samples from other disease programs (tuberculosis, for example) may be obtained from the same animal. Animal identification will be recorded appropriately on all submission forms in these instances, with appropriate notification as to where the identification items are stored.

The Sample Data Form and the VS Form 10-4 must be accurately completed and accompany the sample. Samples that are not accompanied by the appropriate submission forms with all necessary information will not be tested. NVSL or the network laboratory will notify the VS Area Office if there are problems with sample and/or data quality. VS Area Offices will ensure that corrective action is taken regarding sample and data quality if deficiencies are reported.

Cost Recovery and Participation

Payments for the following services would help cover additional costs incurred by industries participating in our surveillance; other payments would help encourage reporting and collection of targeted samples. All of these will be required to some degree in the attempt to collect samples from all of the targeted high-risk population.

1. Transport, including the transport of an animal or carcass to the collection site from a farm, slaughter establishment, etc., and transport from the collection site to a storage, disposal, or rendering site. Payment would be based on per loaded mile fee (for dead or live animal). In addition, contracts with renderers or deadstock haulers could be established when routine transport requirements could be predicted.
2. Disposal for all screening test suspect (non-negative) cattle and for other sampled cattle when rendering is not an option or when the cost of transport and storage at the renderer exceeds disposal costs. This may include the cost of disposal in a landfill, equipment for on-farm burial, incineration, or alkaline digestion.
3. Cold storage will be needed to maintain carcasses in acceptable condition for rendering pending test results. Storage costs may be paid per day at any facility that does not have pre-existing cold storage facilities or that has limited storage where sampled cattle carcasses or parts are held pending test results or disposal (36-48 hours in most cases).
4. Allow rendering to occur and require final products to be held pending negative test results. In the event of a positive diagnosis, the batch and an appropriate amount of “flush” material will be purchased and disposed of rather than paying for storage of raw materials. This option could be offered to facilities that have adequate storage capacity or allow storage facilities to be built, but would require a prorated price for the product.

Collection Methods and Sites

Samples can be collected most efficiently and cost-effectively at concentration points. These are facilities where multiple animals or carcasses are collected, such as a rendering facility, a landfill, or a salvage (3D/4D) slaughter facility. Focusing efforts on these facilities will allow the highest number of samples to be collected within a defined time frame. Although samples will be collected on farms and from individual animals, additional samples will be necessary for this surveillance program.

If Federal or State employees collect samples, no fee will be paid to the collection site owner for collection of the sample. If another entity (such as a contractor, diagnostic laboratory, accredited veterinarian, or plant employee) collects samples, a fee may be paid per sample. Compensation would only be provided when sampling criteria have been met for the targeted cattle population

Collection sites: Samples may be collected at any of the following sites:

Location	Animal Presentation	Personnel who may collect samples
State or Federally inspected slaughter establishments	Ante-mortem condemnns (includes non-ambulatory and CNS signs)	Federal or State employee, contractor, or accredited veterinarian
Custom exempt slaughter	Antemortem condemnns (includes non-ambulatory and CNS signs)	Federal or State employee, contractor, or accredited veterinarian
On farm	Non-ambulatory and deadstock	Federal or State employee, accredited veterinarian, non-accredited veterinarian
On farm	CNS signs/suspect cases	Federal or State employee or accredited veterinarian
Rendering facilities (includes 3D/4D)	Non-ambulatory	Federal or State employee, accredited veterinarian, contractor, or plant employee
Rendering facilities (includes 3D/4D)	Dead stock	Federal or State employee, accredited veterinarian, contractor, or plant employee
Veterinary diagnostic laboratories	CNS signs/ non-ambulatory/ dead stock	Federal or State employee, diagnostic lab employee, or accredited veterinarian
Public health laboratories	Rabies-negative cases	Sample forwarded directly from laboratory
Veterinary clinics or other sites that accredited vets may use	CNS signs/ non-ambulatory/ dead stock	Federal or State employee or accredited veterinarian

BSE Sampling Communication Plan

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

1. For those infrequent sample collections at slaughter plants or for those animals condemned at slaughter, the FSIS Inspector in Charge and the sample collector will establish a working

relationship with the plant manager to facilitate sample collection and/or the required data collection and animal identification needed to allow collection at another site.

2. Sample collector – designated laboratory communication:

- The sample collector will notify the appropriate laboratory of incoming samples via facsimile, telephone, e-mail, or any other approved electronic method. A toll-free telephone number, with voicemail capability, will be established at each laboratory to facilitate this communication. The facsimile number should also be toll-free. The information to be communicated will include the overnight contract delivery service tracking number as applicable, the collection site name and address, the unique submission reference number, and the number of samples. There is currently a dedicated e-mail box for notifying NVSL of incoming samples.
- The sample collector will include the original VS Form 10-4 and a Sample Data Form for each animal sampled with the samples sent to the designated laboratory. The collector will also make and distribute four copies of the VS Form 10-4 (one for the collector, one for the collection site, one for the VS Area Office, and one to be maintained with the identification devices).
- The VS Form 10-4 has space to indicate the identification number for 10 animals. If additional animals are sampled, the sample collector should submit a supplemental form listing the unique identification numbers for each animal. (Use VS Form 10-4A).
- 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. If the sample does not arrive as expected, it is the responsibility of the sample collector to work with the delivery service to determine the location and delivery status of the sample. Samples not acceptable for testing will not be eligible for payment.

3. Communication from NVSL or designated laboratory:

- 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 the management at the collection site when requested. It is the responsibility of the collector to provide all necessary contact information on the VS Form 10-4.
- If all animals tested in the lot are rapid screening test negative, the designated laboratory will report back to the collector and, when requested, to the management at the collection site that all animals in the specific lot are screening test negative. If any of the animals in the lot are screening test suspect, then the designated laboratory report will specify which carcasses tested suspect to the VS Area Office and the management at the collection site.
- Screening test suspects will be tested using IHC or western blot for confirmation through NVSL facilities. Samples from all screening test suspects must be immediately forwarded to NVSL, with prior notification and confirmed arrival. All confirmatory test results will be transmitted 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.
- Presumptive positives will be handled in accordance with the BSE response plan.

Disposal

1. Disposal of carcasses and offal – Disposal of carcasses and offal will be in compliance with Federal, State, and local laws. Acceptable options may include:
 - Refrigerate or freeze pending test results, then render or otherwise process after negative test results obtained (could include boning out carcass and holding the meat product for use in pet food or rendering materials and holding finished product).
 - Disposal by rendering at dedicated facilities, if available – rendering for non-animal feed use, such as biofuel or cement.
 - Burial in a landfill or on-the-farm.
 - Alkaline digestion.
 - Incineration.
2. Hides – Hides need not be disposed or held pending test results.
3. Sample disposal – Laboratories will dispose of samples using standard operating procedures.

Education and Outreach

Significant efforts in education and outreach will be necessary to achieve the goals of this surveillance plan. APHIS will enhance existing educational materials and processes and work with other Federal and State agencies as outlined in Appendix A. These outreach efforts will inform producers and affiliated industries of our surveillance goals, and will encourage reporting of suspect or targeted cattle on farm and elsewhere.

B. Additional Sampling Plan for Clinically Normal Aged Cattle

Surveillance Objective

In addition to sampling the high-risk population, it has been determined that a sampling of clinically normal, aged slaughter cattle be included in the U.S. BSE surveillance plan. This is based on the scientific knowledge that BSE is primarily a disease of older animals, and thus it will focus on clinically normal aged animals presented for slaughter.

Population Estimates and Distribution of Clinically Normal Adult Slaughter Cattle

According to the NASS Livestock Slaughter 2002 Summary, U.S. commercial cattle slaughter during 2002 totaled 35.7 million head, with Federal inspection comprising 98.3 percent of the total. The target population of clinically normal adult cattle (bulls, dairy cows, and other cows) comprised 17.8 percent of cattle slaughtered under Federal inspection. This is equal to

approximately 6.2 million adult cattle. Out of this population, a total of 20,000 samples will be obtained from aged animals.

To obtain a sampling distribution for 20,000 BSE slaughter samples from healthy adult bulls and cows, USDA-FSIS fiscal year 2003 data were utilized. The total number of bulls and cows slaughtered in 40 plants was 5,382,313 cattle (4,885,855 cows and 496,458 bulls), accounting for approximately 86 percent of annual totals for Federally inspected plants. Sampling efforts can be concentrated in these 40 plants to achieve the most efficient sampling schedule while maintaining access to a significant proportion (86 percent) of the population. A sampling distribution was determined by generating plant-level percentage contributions to the total cattle slaughtered in these 40 plants, which ranged from 20,033 to 368,482 cattle per year. The 40 plants identified are located in 17 States. Some of these States only have one plant identified (Arizona, Georgia, Idaho, Michigan, Montana, South Carolina, South Dakota, and Utah), and some States have more than one (California, Minnesota, Ohio, North Carolina, Nebraska, Pennsylvania, Texas, Washington, and Wisconsin).

Sample Collection for Clinically Normal Aged Slaughter Cattle

Sample collection would be conducted by FSIS employees who would target, via visual inspection, cattle that appear to be the oldest. As necessary, APHIS employees or contractors could assist with sample collection in identified slaughter facilities. All of the previously described points on sample collection, training, and communication are applicable in this portion of the sampling plan.

Appendix A: Education and Outreach

BSE Education, Training, and Outreach Matrix

Audience	Key Messages/Objectives	Outreach Products	Training/Education
Accredited Veterinarians	<p>Outreach: BSE surveillance BSE disease information USDA actions on BSE</p> <p>Education: Sample collection and handling Risk communication</p>	Outreach kit Web site Video PSA	BSE sampling training materials CD-ROM
Federal Veterinarians/Animal Health Technicians	<p>Outreach: BSE surveillance BSE disease information USDA actions on BSE</p> <p>Education: Certification of slaughter plants and renderers Animal traceback process Recognition and diagnosis of TSEs Surveillance sampling Risk communication</p>	Outreach kit Video PSA	BSE sampling training materials CD-ROM Foreign Animal Disease Diagnostician (FADD) schools Foreign Animal Disease (FAD) web-based training Satellite seminars on animal traceback
State Veterinarians	<p>Outreach: BSE surveillance BSE disease information USDA actions on BSE</p> <p>Education: Sample collection and handling Recognition and diagnosis of TSEs Risk communication</p>	Outreach kit Video PSA	FADD schools FAD web-based training Satellite seminars on animal traceback

Audience	Key Messages/Objectives	Outreach Product	Training/Education
FSIS Inspectors	<p>Outreach:</p> <p>BSE surveillance BSE disease information USDA actions on BSE</p> <p>Education:</p> <p>Certification of slaughter plants and renderers Surveillance sampling</p>	Outreach kit	BSE sampling training materials CD-ROM
Industry & Producer Organizations	<p>BSE surveillance BSE disease information USDA actions on BSE</p>	<p>Outreach kit Web site Video PSA</p>	Materials provided in outreach kit contain educational information appropriate for this audience.
National Association of State Departments of Agriculture	<p>BSE surveillance BSE disease information USDA actions on BSE</p>	<p>Outreach kit Video PSA</p>	Materials provided in outreach kit contain educational information appropriate for this audience.
Foreign Agricultural Service, APHIS International Services	<p>BSE surveillance BSE disease information USDA actions on BSE</p>	<p>Outreach kit Powerpoint presentation</p>	Materials provided in outreach kit contain educational information appropriate for this audience.
Producers	<p>Outreach:</p> <p>BSE surveillance BSE disease information USDA actions on BSE</p> <p>Education:</p> <p>Handling of downer animals Contact information for testing</p>	<p>Outreach kit Web site</p>	Materials provided in outreach kit contain educational information appropriate for this audience.

Audience	Key Messages/Objectives	Outreach Product	Training/Education
Livestock Markets	Outreach: BSE surveillance BSE disease information USDA actions on BSE Education: Handling of downer animals Contact information for testing	Outreach kit Web site	Materials provided in outreach kit contain educational information appropriate for this audience.
USDA extension, 4-H, FFA, FSA, Ag Colleges, VoAg Teachers, Farm Bureau	BSE surveillance BSE disease information USDA actions on BSE	Outreach kit Powerpoint presentation	Materials provided in outreach kit contain educational information appropriate for this audience.
Veterinary Schools	Outreach: BSE surveillance BSE disease information USDA actions on BSE Education: Recognition and diagnosis of TSEs	Outreach kit Powerpoint presentation	FAD web-based training
Ag Media	BSE disease information USDA actions on BSE	Press kit Press releases Editorials	
General Public	BSE disease information USDA actions on BSE	Outreach kit Radio PSA Advertising	