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Animal and Plant
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Veterinary Services

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National
Bovine Spongiform Encephalopathy
Surveillance Plan

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National Bovine Spongiform Encephalopathy Surveillance Plan
Updated November 2024
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1. Introduction and Rationale

Bovine Spongiform Encephalopathy (BSE), widely referred to as "mad cow disease," is a progressive and fatal neurologic disease of cattle.[1] It is caused by a prion, an abnormal cellular protein which acts as an unconventional transmissible agent. BSE belongs to a family of diseases known as transmissible spongiform encephalopathies (TSEs) that includes scrapie in sheep and goats, chronic wasting disease (CWD) in deer, elk, and moose, and classic and variant Creutzfeldt-Jakob disease (CJD) in humans, among other syndromes. The prion agent is resistant to enzymatic breakdown by the body and most disinfection treatments. BSE is an animal health threat; cattle can become infected with the disease after consuming feed contaminated with the infectious prion agent, such as meat and bone meal containing protein derived from rendered infected cattle.[2] BSE also presents a public health concern because occurrences of variant CJD in humans have been linked to the consumption of food containing ingredients derived from BSE-infected cattle.

The United States enacts food safety and importation prevention measures to protect animals and the public from BSE. Regulations by the Food and Drug Administration (FDA) have prohibited the inclusion of mammalian protein in feed for cattle and other ruminants since 1997. FDA regulations have also prohibited high-risk tissue materials, including ruminant brains, spinal cords, and whole uninspected or unfit ruminant carcasses in all animal feed since 2009. The mission of the U.S. Department of Agriculture (USDA) national BSE Program is to safeguard American agriculture by protecting the cattle population from BSE and to facilitate trade by demonstrating to our trading partners that the disease does not exist in the United States. Further BSE prevention measures by the USDA include banning non-ambulatory (downer) cattle and those displaying signs of neurological disease from entering the human food supply and upholding safe trade regulations on imported ruminants and ruminant products to keep BSE out of the country.

BSE is a nationally reportable disease; surveillance in U.S. cattle has been in place since 1990. BSE prevention measures and surveillance efforts work together to reassure consumers and international trading partners of the ability to detect the disease should it arise. USDA's BSE Program includes surveillance that targets clinically suspicious animals and disease education and outreach to cattle production stakeholders.

This document outlines USDA's National Bovine Spongiform Encephalopathy Surveillance Plan, a surveillance plan which transitions from the Bovine Spongiform Encephalopathy Ongoing Surveillance Plan (2006) to a plan that aligns with updated World Organisation for Animal Health (WOAH) guidelines for BSE surveillance. It focuses on increasing awareness of the disease while leveraging current diagnostic and surveillance methodologies. Specific and measurable surveillance plan objectives are identified in Section 5, Surveillance System

[1] Used here, cattle refer to species, *Bos taurus* or *Bos indicus.*

[2] As stated in the World Organisation for Animal Health (WOAH) Terrestrial Code (2023), "Other animal species may be naturally and experimentally susceptible to BSE, but they are not regarded as being epidemiologically significant, particularly when feeding ruminants with ruminant-derived protein meal is not practiced." In alignment with WOAH guidelines, this surveillance plan will focus on BSE monitoring in cattle, the epidemiologically significant species of concern.

Overview. These surveillance plan changes will continue to meet or exceed WOAH BSE guidelines and better align U.S. activities with recently adopted WOAH surveillance updates.[3]

The National BSE Surveillance Plan supports the national BSE Program through its four-fold purpose:

1. Demonstrate the effectiveness of national disease prevention measures enacted to stop BSE introduction and spread among U.S. cattle.
2. Facilitate planning for national BSE emergency preparedness and response programs.
3. Support U.S. claims of WOAH negligible risk status for BSE, providing market confidence in the safety of consuming U.S. cattle and cattle products.
4. Inform the design and implementation of current and future BSE surveillance plans.

2. Disease Overview

BSE predominantly affects bovines. It exists in two forms: classical (C-type) and atypical (L- or H-types). Most classical BSE infections occur early in life. The incubation period, from time of infection until the onset of clinical signs, averages 2 to 8 years. The most common source of infection for classical BSE is feed contaminated with the infectious prion agent, such as meat and bone meal containing protein derived from rendered infected cattle. The atypical BSE forms, L-type and H-type, occur spontaneously at very low levels in all cattle populations, and are most commonly observed in cattle 8 years of age or older. Atypical BSE does not appear to be associated with contaminated feed, though this cannot be completely ruled out (WOAH, 2023). Bioassay data support the hypotheses that these strains are biologically distinct from classical BSE. Atypical BSE seems to arise rarely and spontaneously. There is no treatment or vaccine to prevent BSE.

BSE was first detected in 1986 in the United Kingdom, which has had the most cases worldwide. The disease has since been detected in many other countries, including seven cases in the United States from 2003 to 2023. Of the seven U.S. cases, the first was a case of classical BSE in an imported cow, while the remainder were atypical BSE.

3. Animal Populations Affected

Cattle are the primary population of concern for BSE in the United States although the disease can affect other species (Spickler, 2016). No breed or sex differences in susceptibility to BSE exist (Wilesmith et al., 1992). Due to its lengthy incubation period (2 to 8 years), BSE is not likely to occur in animals less than 12 months old. Classical BSE has peak occurrence in cattle ages 4 to 5 years old, as observed during the United Kingdom outbreak of the 1980s and 1990s; atypical BSE is more likely to occur in cattle 8 years old and older.

[3] In 2023, WOAH adopted updated guidelines regarding BSE surveillance, which can be found in Article 11.4.20 of the WOAH Terrestrial Code (2023).

4. Clinical Signs

WOAH states that "BSE causes progressive neurological signs" (WOAH Targeted Surveillance, 2023). Affected cattle may concurrently show non-specific signs of disease, such as anorexia, loss of body condition despite good appetite, or decreased milk yield. They will be unresponsive to treatment, eventually becoming severely uncoordinated and unable to walk or rise. Animals die from BSE within weeks to months of developing clinical signs. Table 1 lists neurological and non-specific changes that may be seen with BSE.

Table 1. BSE Clinical Signs

Mental Status or Behavior Changes
Apprehension*
Nervousness
Excitability
Aggression toward other cattle or humans when previously even-tempered
Changes in herd hierarchical status
Hesitation at doors, gates, and barriers
Persistent kicking during milking
Reluctance to cross concrete or other "slippery" surfaces
Sensation Changes
Over-reactive to stimuli (touch, light, or sound)*
Head shyness
Excessive nose scratching
Posture and Movement Changes
Ataxia or uncoordinated movement*
Exaggerated movements (hypermetria)
Low head
Wide-based posture and incoordination
Walking or running into objects or walls with eyes appearing normal
Walking aimlessly around in circles or drifting to one side when walking
Non-specific Signs Concurrent with Neurological Changes
Anorexia
Decreased milk yield
Loss of body condition despite good appetite
Difficulty or inability to rise
Difficulty walking or non-ambulatory

*Three of the most common BSE clinical signs noted

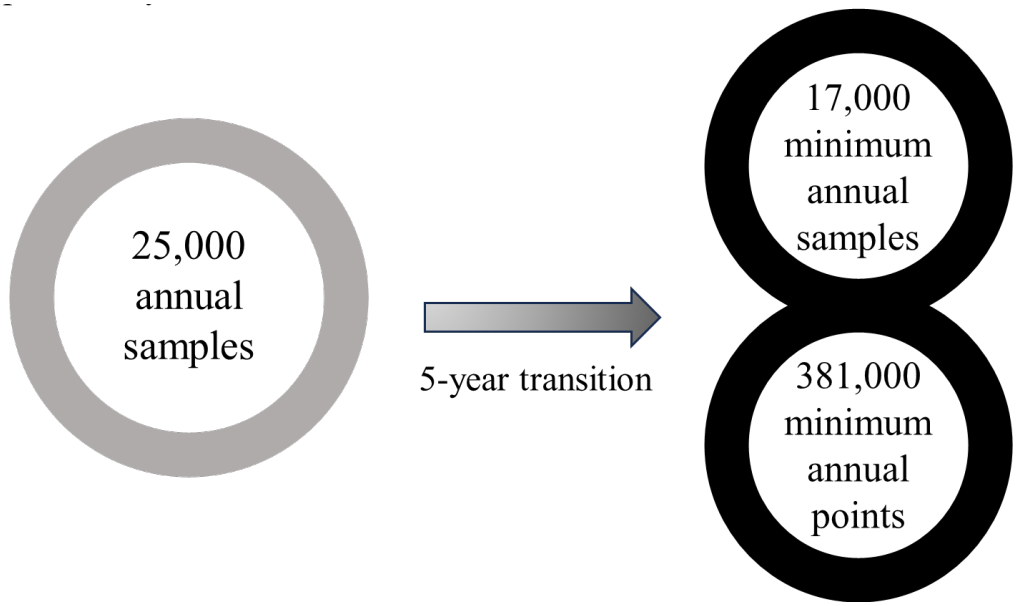
5. Surveillance System Overview

USDA's National BSE Surveillance Plan continues to use a weighted surveillance points system based on the BSurvE model (Wilesmith et al., 2004) as it applies to the U.S. cattle population. The BSurvE model was adopted by the United States in May 2005 and previously used in the 2006 Bovine Spongiform Encephalopathy Ongoing Surveillance Plan. It continues to reflect international scientific consensus that effective and efficient BSE surveillance, particularly in countries with few or no BSE cases, should focus on obtaining high quality samples from targeted subpopulations rather than looking at a country's entire adult cattle population (Al-

Zoughool et al., 2015). The number of points assigned to a sample (hereafter referenced as BSurvE points) are determined by an animal's age and clinical presentation at the time of sampling. The highest point values are assigned to samples from animals with progressive neurological clinical signs. Intensive rearing practices and regular observation of most cattle in the United States allow for stratification of the national cattle herd and targeting of higher risk subpopulations of animals, where the likelihood of finding BSE is highest. Therefore, the BSurvE model continues to be uniquely appropriate for assigning value to each surveillance sample collected in the United States when compared to information that would be gained from a random sample.

The previous BSE surveillance plan[4] established a collection target of 25,000 valid samples per year and did not include a target for BSurvE points.[5] Over a 5-year period, this plan transitions BSE surveillance activities to collecting a minimum of 17,000[6] valid samples *and* 381,000 BSurvE points annually (Diagram 1). The plan will accumulate 3,048,000 BSurvE points or more over an 8-year WOAH assessment period.[7] This level of surveillance can detect one BSE case per 1 million animals in the national herd with 95 percent confidence during the designated timeframe.

Diagram 1. Proposed 5-year transition for annual BSE surveillance sample targets



Primary Surveillance Objective: Detect one BSE case per 1 million animals
Secondary Surveillance Objective: Provide adequate samples for laboratory proficiency

[4] BSE Ongoing Surveillance Plan (2006)

[5] Though not a focus of surveillance efforts during this time, BSurvE annual points were tracked and ranged between 570,345 and 962,010 from 2019 to 2023.

[6] Minimum sample total required by four approved National Animal Health Laboratory Network laboratories and the National Veterinary Services Laboratories to meet annual laboratory proficiency standards.

[7] In 2023, WOAH adopted updated guidelines for their official recognition of BSE risk status. A Member Country's risk status for BSE will now be assessed from information the country provides, including annual surveillance data, covering the preceding 8-year period up to their review. Prior to 2023, WOAH prescribed a 7-year assessment period for official BSE risk status.

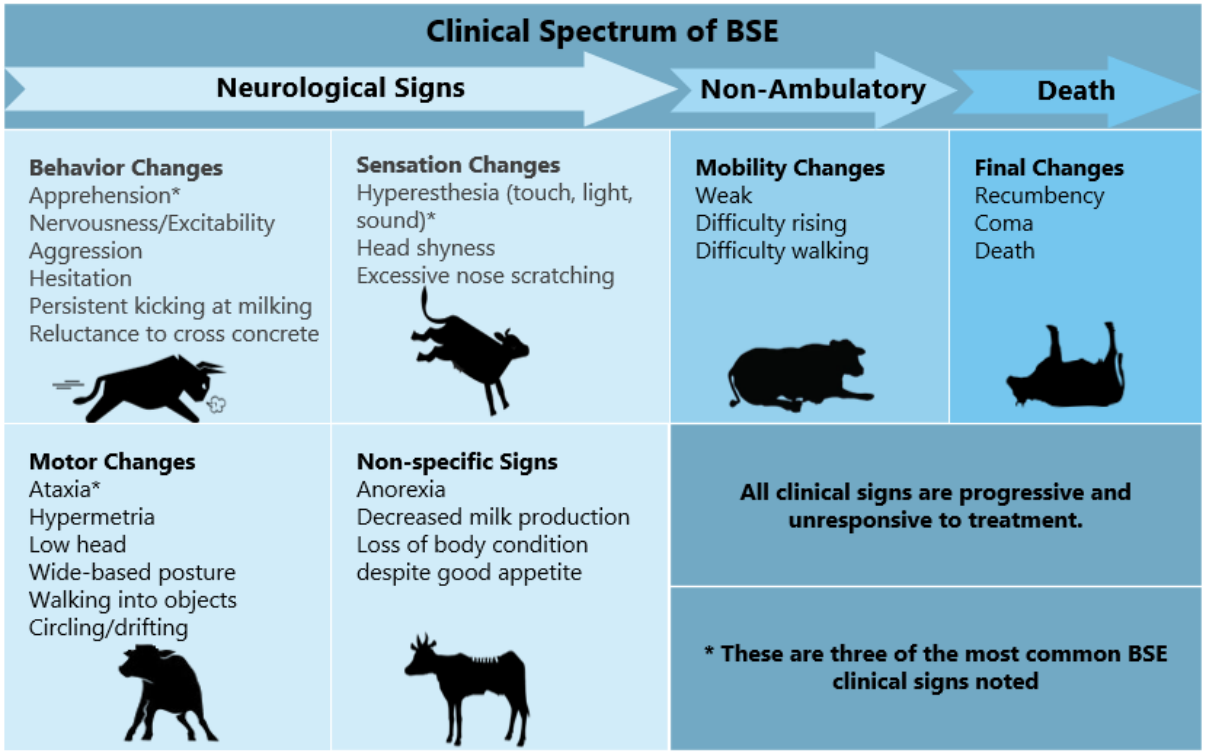
Achieving this high level of surveillance to detect a very low prevalence remains the primary surveillance objective. Renewed energy and funding toward education and outreach about the importance of sampling and recording clinical details for animals that are within the progressive clinical spectrum of BSE will be critical during this program transition. The resulting surveillance aligns U.S. activities with recently adopted WOAH changes to Chapter 11.4 while continuing to meet WOAH BSE surveillance guidelines. The 5-year transition period will commence in fiscal year (FY) 2025. Through FY2024, the national surveillance target continues to be 25,000 valid samples, with each State collecting a target minimum number of samples according to the FY 2024 BSE Sample Collection Plan.

Efforts to identify and sample the highest value animals for BSE surveillance could meet or exceed the annual 381,000 BSurvE points target from fewer than 17,000 valid samples, suggesting the potential to further decrease annual sample targets. However, this plan must also provide sufficient sample quantities (17,000 minimum each year) to approved laboratories to ensure they maintain testing proficiency standards. This surveillance objective, supporting USDA's national BSE emergency preparedness and response programs, cannot be overlooked.

The National BSE Surveillance Plan targets surveillance on three higher risk subpopulations of adult U.S. cattle based upon the progressive clinical spectrum of BSE:

1. Animals displaying neurological or other clinical signs consistent with BSE (Clinical Suspect)
2. Non-ambulatory animals (Disabled)
3. Dead animals with a clinical history suggestive of BSE (Fallen Stock)

Diagram 2. The Progressive Clinical Spectrum of BSE



USDA Animal and Plant Health Inspection Service (APHIS) and Food Safety and Inspection Service (FSIS) along with State and industry partners will monitor the U.S. cattle herd by identifying and testing animals through three surveillance components:

1. Case-compatible sick or dead cattle samples collected within a State[8]
2. Slaughter condemnation samples from case-compatible sick or dead cattle
3. Rendering or salvage facility samples from case-compatible sick or dead cattle

6. Surveillance Components

The surveillance system is comprised of three surveillance sub-systems or components. These components use different data sources and support different aspects of BSE national programs.

a. Surveillance Component 1: Case-compatible cattle samples collected within a State

This surveillance component includes samples from sick and dead cattle from the five sources detailed below (hereafter called data sources). These samples are usually[9] accompanied by significant background information describing an affected animal's neurological or other clinical signs suggestive of BSE. The accompanying animal health history makes these samples high value for surveillance, averaging 472 BSurvE points assigned per animal, depending on age. This surveillance component provides most of the evidence necessary to demonstrate that national disease measures prevent BSE introduction and spread among U.S. cattle. It also provides the strongest risk-based surveillance, increasing the chances for detection of any atypical BSE cases that may sporadically occur within the national herd. The distribution of data sources across States also ensures geographic representation.

APHIS and State personnel are expected to execute ongoing outreach and planning to ensure valid samples and associated animal histories are collected from these data sources. This has always been a high priority but will be given specific attention during the transitional period to reinvigorate efforts in this area as APHIS anticipates a majority of BSurvE points will come from Surveillance Component 1. Achieving the annual point target will require active and concerted efforts from APHIS personnel to understand, revitalize, and expand high-value sampling from data sources in their area.

Data sources for case-compatible sick or dead cattle samples collected within a State

- **Foreign Animal Disease (FAD) Investigations**

  Anyone (including Federal or State personnel, producers, and private veterinarians) who observes cattle 12 months old and older meeting the suspect case classification (see Section 7c. Case Definition), or cattle in which BSE could otherwise reasonably be suspected, must report suspicious cases to State and Federal animal health officials. VS Guidance 12001.4 provides guidance for conducting FAD investigations.

[8] This component excludes Federally inspected slaughter facilities and rendering or salvage facilities as described in components 2 and 3.

[9] Non-ambulatory animals condemned at slaughter without additional historical information suggestive of BSE are still included on the clinical spectrum for BSE and considered valuable samples for testing.

- **On-Farm**

  Properly trained accredited veterinarians, Federal or State employees (including animal health technicians and/or contractors) or cooperating dead stock haulers are encouraged to collect samples from cattle 12 months old and older with case-compatible signs of BSE. Under VS Area Office oversight, sample collectors with other qualifications may be enlisted when the sample collectors in a given area cannot meet the demand.

- **Public Health Laboratories**

  Public health laboratories should submit all valid samples from cattle 12 months old and older that are rabies suspects *and* test negative for rabies to a designated VS contract laboratory for BSE testing. APHIS personnel will contact State public health personnel to identify laboratories used for rabies testing and actively follow up to ensure samples are saved and submitted for testing.

- **Veterinary Diagnostic Laboratories (VDLs)**

  Laboratory personnel at any VDL should collect samples from cattle 12 months old and older that are submitted for necropsy with unexplained conditions, or from fresh whole brainstems of similarly aged cattle submitted for ancillary diagnostics and send to a designated VS contract laboratory for BSE testing. APHIS personnel will identify VDLs used for testing in designated States and actively follow up to ensure samples are saved and submitted for testing.

- **Aggregation Points**

  Producers and other employees interacting with cattle 12 months old and older at various aggregation points, including livestock markets, feedlots, and State-inspected or custom slaughter facilities should contact Federal or State personnel to sample animals showing case-compatible signs of BSE. APHIS personnel will identify and foster ongoing outreach with specific aggregation points in their area to successfully include these data sources in sampling efforts.

b. Surveillance Component 2: Slaughter condemnation samples from case-compatible cattle

BSE sample sources for Surveillance Component 2 are located throughout the United States and service every constituent of the cattle production industry. These data sources contribute moderate to high value samples for surveillance, depending on animal age and clinical signs observed, while providing geographic representation of the national herd and sample quantities to support laboratory proficiency standards.

During the transition period, APHIS will emphasize collecting more samples from higher value animals at these data sources. Sample collectors will target cattle that are condemned for displaying neurological signs and/or with clinical histories suggestive of BSE at the highest volume slaughter facilities in the United States. Focusing on cattle that are on the progressive clinical spectrum of BSE keeps each animal's BSurvE point value greater than one. APHIS recognizes that obtaining animal health histories at high-volume slaughter facilities can be difficult; therefore, sample collection from cattle that are non-ambulatory or condemned for other non-specific clinical signs or conditions suspicious of BSE without further known clinical history will still be encouraged.

APHIS will continue outreach and education to FSIS partners and other facility employees to support this surveillance component.

Data sources for slaughter condemnation samples from case-compatible cattle

- **Slaughter Establishments**

  FSIS personnel or APHIS employees, including contractors, will collect BSE samples from cattle at Federally-inspected slaughter establishments according to FSIS Directive 10400.1. Specifically, cattle 12 months old and older condemned for central nervous system (CNS) signs or as rabies suspects during antemortem inspection are collected for BSE testing.

- **Offsite Sample Collection Facilities contracted by VS**

  APHIS employees, including animal health technicians and/or contractors, may collect samples for BSE testing at an APHIS-approved, offsite collection facility. Cattle 12 months old and older presented for slaughter and condemned on antemortem inspection by FSIS for CNS signs or as rabies suspects may be selected for BSE sample collection. Cattle 30 months old or older that are condemned at antemortem inspection for any other reason suggestive of BSE are also eligible for sample collection at an offsite collection facility. In either situation, communication from slaughter facility personnel to collection facility personnel ***must*** occur with the following information: animal identification information (including FSIS condemnation tag number, i.e., the "Z tag" number), clinical history, and condemnation codes.

c. Surveillance Component 3: Rendering or salvage facility samples from case-compatible cattle

The largest volume of samples comes from Surveillance Component 3, making its data sources instrumental in providing sample quantities to meet laboratory proficiency standards. However, samples from these sources generally hold very low BSurvE value compared to other surveillance components because they predominantly represent fallen stock with little known clinical history. Component 3 data sources can be found nationwide and see cattle that originate from a wide variety of locations, offering geographic representation of the national herd.

Throughout the transitional period, APHIS will work to increase the overall BSurvE points total from Surveillance Component 3 by discouraging and/or limiting the number of samples collected from animals that are found dead with no supporting clinical history consistent with BSE. Sample collector education and training will be critical to success.

Data source for rendering or salvage facility samples from case-compatible cattle

- **Rendering or Salvage Facilities**

  Samples will be collected from cattle 30 months old and older presented to rendering or 3D/4D (diseased, disabled, dying, dead) facilities, also called salvage facilities. Sample collection at these sites should only occur according to provisions of competitive contracts awarded by VS. For cattle sampled at these locations, the collection of any

clinical signs and relevant history is highly desirable and will be emphasized through outreach and education as part of the National BSE Surveillance Plan.

7. Surveillance System Inputs Common to all Components

a. Higher Risk Subpopulation Classifications

The "primary reason for sample submission" and "animal clinical signs" are necessary data pieces for BSE testing and are first captured by sample collectors on VS Form 17-131, "BSE Surveillance Data Collection Form" (USDA, 2014). These data pieces determine best fit for higher risk subpopulation categorization of samples (see Section 5 Surveillance System Overview). The higher risk subpopulation classifications, including any further details about specific signs or condemnation codes, are used in combination with animal age to calculate the number of BSurvE points assigned to each sample. There are seven primary reasons for sample submission for BSE surveillance. The person who determines the animal will be sampled for BSE selects only one of these reasons for submission when providing information about the animal. The seven reasons for submission are:

1. Highly suspicious for BSE
2. Rabies suspect
3. CNS signs
4. FSIS, antemortem condemned cattle with condemnation code
5. Non-ambulatory/Disabled/Downer
6. Other clinical signs that may be associated with BSE
7. Dead

Table 2 lists the higher risk subpopulation classifications for all BSE sample submission reasons.

Table 2. Overview of higher risk subpopulation classifications based on primary reason for BSE testing submission

Reason for Submission	Additional Conditions	Higher Risk Subpopulation
Central nervous system disorders	None	Clinical Suspect
BSE suspect	None	Clinical Suspect
Rabies suspect	None	Clinical Suspect
Non-ambulatory	At least one BSE-compatible sign with a condition that is progressive and non-responsive to treatment	Clinical Suspect
	At least one BSE-compatible sign *without* a condition that is progressive and non-responsive to treatment	Disabled
	None	Disabled

Dead cattle	At least one BSE-compatible sign with a condition that is progressive and non-responsive to treatment	Clinical Suspect
	At least one BSE-compatible sign *without* a condition that is progressive and non-responsive to treatment	Fallen Stock
	None of the above	Fallen Stock
Slaughter-condemned during antemortem inspection	Condemnation reason: CNS or Rabies	Clinical Suspect
	Condemnation reason: Non-ambulatory	Disabled
	Condemnation reason: Dead	Fallen Stock
	Condemnation reason: Any other reason not listed above, but suggestive of BSE	Clinical Suspect
Other	At least one BSE-compatible sign with a condition that is progressive and non-responsive to treatment	Clinical Suspect
	At least one BSE compatible sign *without* a condition that is progressive and non-responsive to treatment	Fallen Stock
	None of the above	Fallen Stock

b. Sampling and Laboratory Considerations

Fresh obex samples (from the brainstem) should be collected for BSE testing. The appropriate sample must be submitted with little contamination or postmortem decomposition. Samples that are taken from the wrong tissue location or that are significantly autolyzed are not suitable for testing and should not be submitted in most cases. However, samples should still be collected and submitted, regardless of apparent tissue quality, from all cattle condemned by FSIS on antemortem inspection for CNS signs or rabies, and all cattle that are highly suspicious for BSE. Laboratory personnel will decide whether these samples are suitable to test. Proper sampling techniques, animal identification guide, packaging and shipping procedures, and laboratory submission protocols can be found in the Procedures Manual: Bovine Spongiform Encephalopathy (BSE) Ongoing Surveillance Program.
Valid surveillance samples as defined for the National BSE Surveillance Plan are those samples: 1) collected from animals with a primary reason for submission as specified on VS Form 17-131; *and* 2) with a valid test result reported. “Not detected/Not obex” or “Not tested” do not constitute valid test results for this surveillance plan.

BSE test samples are screened with an enzyme-linked immunosorbent assay (ELISA) test at the National Veterinary Services Laboratories (NVSL) or an approved National Animal Health Laboratory Network (NAHLN) laboratory. Any test samples with inconclusive results are sent to NVSL for confirmation. Confirmed positive cases (see Section 7c. Case Definition) at NVSL generate an epidemiological traceback investigation.

c. Case Definition

The BSE Case Definition (https://www.aphis.usda.gov/sites/default/files/bse-case-definition.pdf) provides standardized case classification (suspect, presumptive positive, and confirmed positive) information and disease reporting parameters. It is a living document, subject to periodic review and modification as additional information becomes available.

d. Minimum Data Elements Required for Sample Submission

To use information from surveillance to best support the national BSE Program, APHIS is working to improve consistent reporting of animal-related BSE surveillance data (i.e., the data associated with sampled animals that is critical to assess targeted surveillance effectiveness). Samples from animals with documented (recorded) risk profiles[10] are more valuable than random surveillance samples lacking documentation of known risk factors. Additionally, the surveillance sampling framework should encompass a wide range of cattle operations within which the defined higher risk subpopulations exist. To document desired risk profiles, this program must gather the following minimum data elements for every sample collected:

- BSE Referral Number
- Age of sampled animal
- Animal IDs (i.e., *all* types of animal identification devices/tags, brands, and tattoos associated with the sampled animal)
- Date(s) of sample collection, receipt at laboratory, and test resulting (+/- shipping date)
- Primary reason for submission (including FSIS condemnation codes, when applicable)
- Animal clinical signs and history (if any), especially those compatible with BSE
- Laboratory performing testing
- State of production site, slaughter plant, or market (if a premises identification number (PIN) or latitude-longitude is available, all available data must be included)
- Beef or dairy breed
- Collection site type (e.g., slaughter plant, on-farm, public health lab)
- Sample collector (i.e., individual determining primary reason for collection, such as APHIS veterinary medical officer (VMO), FSIS VMO, producer/owner, or renderer)
- Sample type (e.g., obex)
- Slaughter plant code (e.g., FSIS number), when applicable
- Test result and interpretation

[10] Used here, risk profile means the combination of an animal's higher risk subpopulation classification, clinical signs, and age.

e. Data Platforms for Inputs

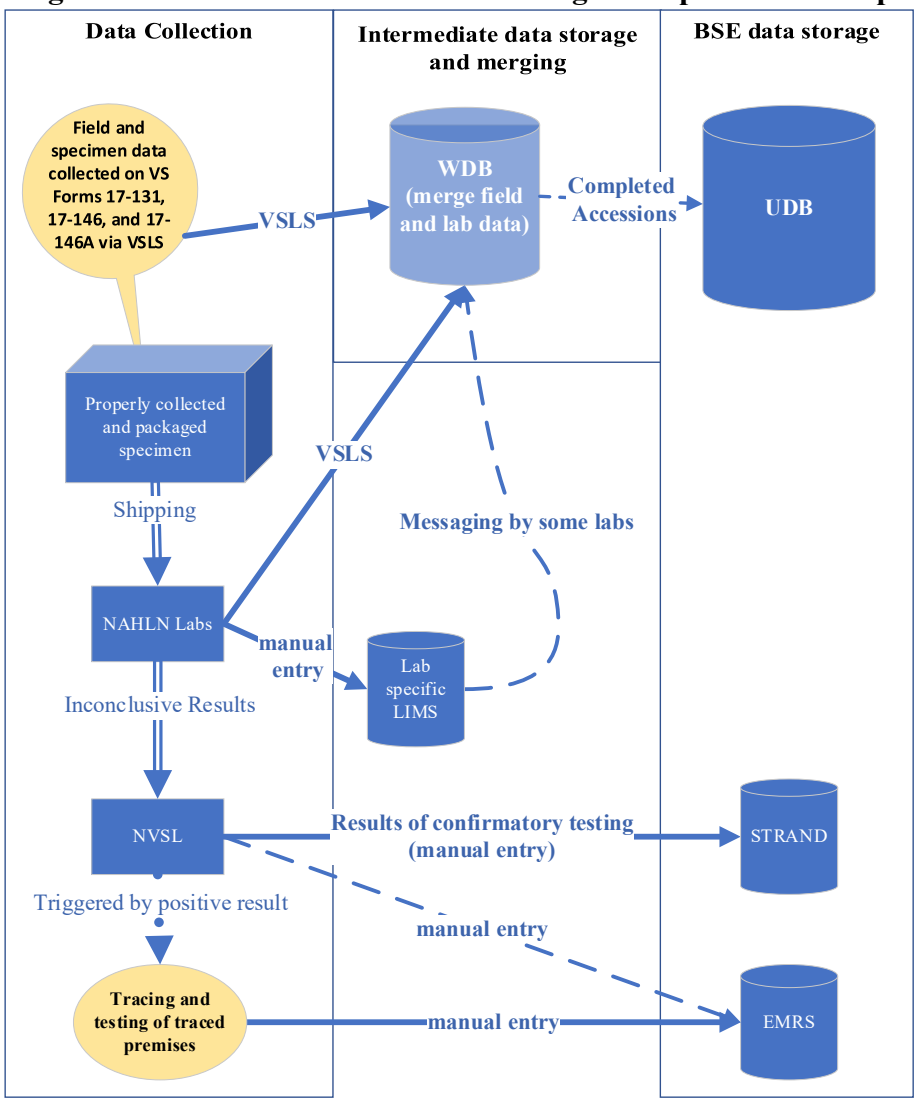
Platforms for data collection and storage include the following:

- VS Form 17-146 (BSE Surveillance Submission Form)
- VS Form 17-146A (BSE Surveillance Submission Form Continuation Sheet)
- VS Form 17-131 (BSE Surveillance Data Collection Form)
- Veterinary Services Laboratory Submission System (VSLS)
- Web Data Base (WDB)
- Unified Database (UDB)
- Emergency Management Response System 2 (EMRS) (for confirmed positive case epidemiological investigations only)
- Searchable Test Results Application for NVSL Diagnostics (STRAND) database

f. Data Collection and Management Processes

BSE data is recorded by sample collectors on VS Form(s) 17-146 and VS Form 17-131, then entered through VSLS for intermediate storage in the WDB. VSLS is the user interface for electronically capturing BSE surveillance data from both field collection and laboratories. Concurrent with field data entry, specimens are sent to an approved NAHLN laboratory for testing. Laboratory personnel then enter corresponding test results into the WDB using VSLS. Some laboratory information management systems (LIMS) are capable of messaging BSE test results without manual entry through the VSLS system.

Diagram 3. BSE data collection and management processes of inputs



As shown in Diagram 3, data collected in the field are held in the WDB until all test results for an accession are complete and entered into the system. The completed BSE surveillance records, including sample submission information and test results, are finally transmitted into the UDB for storage. The UDB is the system of record for storing BSE surveillance data.

All inconclusive results from a NAHLN lab are forwarded to NVSL for confirmation. NVSL test results are captured in STRAND. Confirmed positive cases of BSE are manually entered into EMRS for epidemiological investigation. Information about premises traced from positive cases, including any test results, are also entered into EMRS.

g. Education and Outreach

Increasing higher value sampling from all surveillance components is closely tied to BSE education and outreach efforts. All cattle production stakeholders must understand the clinical spectrum of BSE, recognize the progressive neurological and non-specific changes in cattle they observe, and take appropriate action to select these animals for BSE testing. Updates to WOAH BSE guidelines now emphasize this importance of awareness and training for all cattle production stakeholders, with additional required reporting about outreach activities to meet WOAH official recognition of BSE risk status.[11] Federal and State personnel should conduct awareness and training activities reaching all cattle production stakeholders in their area to meet or exceed national BSE Program goals. To further demonstrate how training and awareness have always been a priority for USDA BSE surveillance, the National BSE Surveillance Plan, in conjunction with State and Federal partners, will support re-energized national BSE Program awareness and training initiatives that aim to:

- Create and refresh BSE resource materials for all cattle production stakeholders
- Improve BSE sampling quality (animal targeting, specimen collection, and other data collection)
- Share strategies for building or revitalizing relationships with laboratories, slaughter facilities, accredited veterinarians, and others who can increase higher value sample collection
- Develop a long-term education program to ensure sustainable awareness and understanding of the rationale and needs of national BSE prevention strategies
- Capture outreach and education metrics which align with updated WOAH BSE guidelines

8. Surveillance System Outputs Common to all Components

a. Data Platforms for Outputs

Platforms for data analysis and reporting include the following:

- Data Integration Services (DIS)
- VS-contracted data visualization platform

b. Data Analysis

BSE surveillance data stored in the UDB are pulled into the DIS for data analysis. Data analysis includes the following:

- Assignment of BSurvE points to valid samples
- Allocation of samples to States (based upon the State where sample was collected)

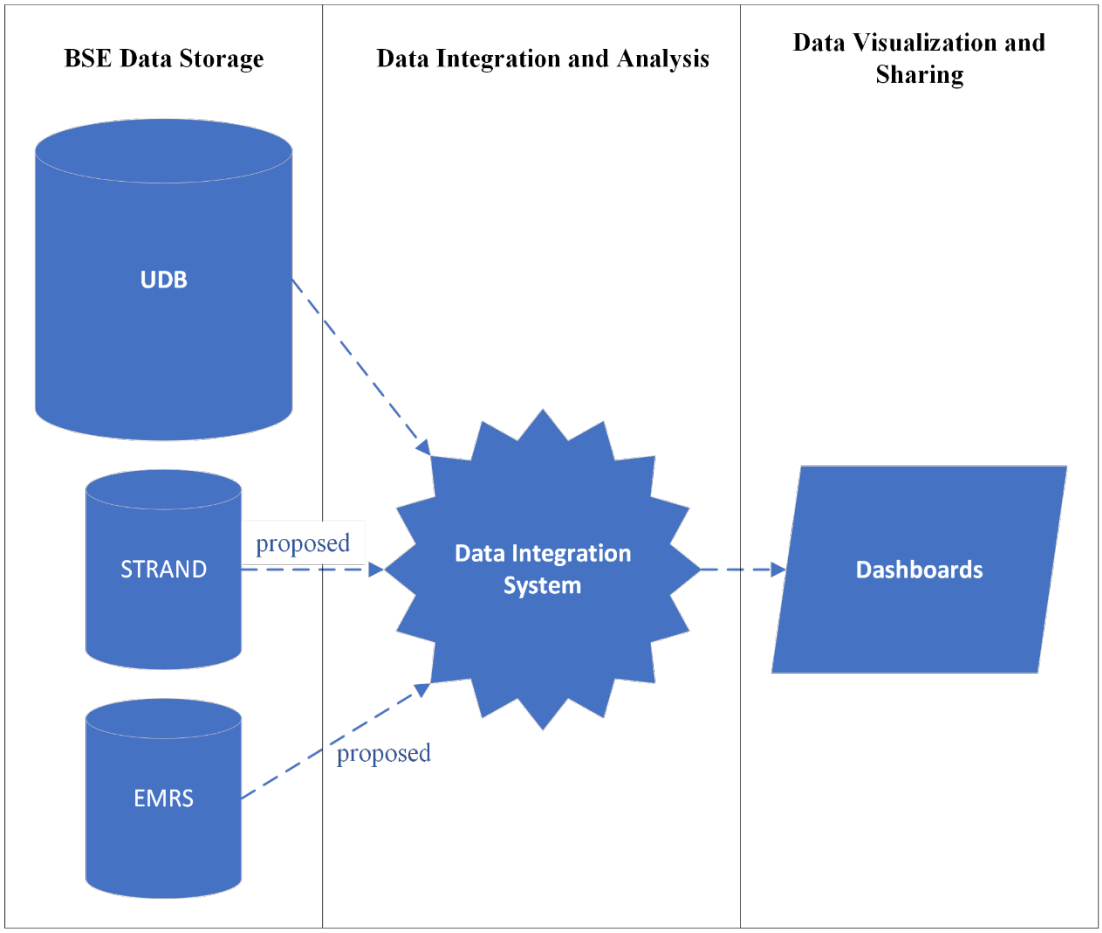
[11] Since 2023, updated WOAH BSE surveillance reporting requirements can be found in Article 1.8.5, "Application for Official Recognition by WOAH of Risk Status for Bovine Spongiform Encephalopathy – Surveillance" of the WOAH Terrestrial Code (2023)

- Calculation of performance metrics measurements
- Calculation of summary statistics for reporting

Summary data for surveillance reporting and reviews are displayed in dashboards for visualization and sharing. Other relevant BSE data from STRAND and EMRS may also be pulled into DIS at a future time but are currently captured qualitatively in some reports.

Diagram 4 illustrates the data analysis and management processes of outputs for BSE surveillance.

Diagram 4. BSE data analysis and management processes of outputs



c. Surveillance System Metrics

APHIS will evaluate the National BSE Surveillance Plan using the following performance metrics. One set of metrics relates to surveillance system activities and a second set of metrics has been included for outreach and education.

Surveillance Metrics

- Representativeness
    - Geographic: The geographic distribution of surveillance samples should generally reflect the population distribution of the U.S. cattle herd. This analysis includes the availability and reliability of animal identification information demonstrating the geographic source.
    - Production type/age: Samples collected should include both dairy and beef cattle at ages representing the higher risk subpopulations of cattle where the likelihood of BSE detection is highest.
    - Temporal: While seasonal fluctuations are expected, cattle highly suspicious for BSE should be continuously pursued throughout the year.
- Probability of Detection and Detection Capability

  The current APHIS surveillance objective is to meet a prevalence detection threshold of one BSE case in one million adult cattle with a 95-percent probability of detection over each 8-year WOAH assessment period. Annual and 8-year detection capabilities (i.e., prevalence detection thresholds possible with current surveillance efforts) will be estimated and the surveillance objective standard revisited.

  The United States has historically exceeded the surveillance objective standard for a prevalence detection threshold of one BSE case in one million adult cattle with a 95-percent probability of detection over previous 7-year WOAH assessment periods. Metrics related to probability of detection may be adjusted in the future to ensure surveillance sustainability and efficient use of resources.
- Sample Characteristics
    - Sample Quality: Analyses will be conducted on samples with invalid test results, such as those that do not include the obex section of brainstem, as well as analyses of samples submitted with official ID and with clinical history.
    - Sample Numbers: A sufficient number of valid samples (17,000 minimum each year) must be tested at approved laboratories to maintain proficiency standards.
- Consistency of Clinical Signs with Case Definition
    - The behavioral and clinical signs reported and reason for submission should be distributed among consistent behavioral and clinical signs, antemortem findings, and higher risk subpopulations. Analyses will also include how completely these signs are captured and reported.
    - Weighted surveillance points will demonstrate the collection of higher point value submissions, indicating consistency with signs of BSE and highest risk ages of cattle.

- Slaughter Condemnations

  Numbers of cattle displaying CNS signs or other conditions suggestive of BSE and condemned at Federally inspected slaughter establishments should closely match BSE sample numbers submitted from Surveillance Component 2. Analyses will include comparing FSIS condemnation reports with BSE sample submission data to monitor program uptake.

- Timeliness
  - Collectors should submit samples as quickly as possible, but no later than 48 hours after collection, with proper sample storage, packaging, and shipping.
  - Laboratories should test samples as quickly as possible and should not hold or delay testing for any longer than one week.

Education and Outreach Metrics

- Stakeholder Group Representation

  Stakeholder groups targeted for BSE education and outreach should include all stakeholders involved in the rearing and production of cattle, such as U.S. cattle producers, veterinarians, industry groups, laboratorians, transporters, slaughter, salvage and rendering facility personnel, and sample collection contractors.

- Type of Programs

  Programs should initially focus on preparing APHIS personnel to succeed in collecting high value samples from Surveillance Component 1, ensuring testing of all appropriate condemnations from Surveillance Component 2, and reducing the volume of samples that do not meet criteria of higher risk subpopulation characteristics from Surveillance Component 3.
  - Awareness Programs: Suggested topics include disease characteristics, the progressive clinical spectrum of BSE, and the rationale behind disease prevention measures and ongoing surveillance efforts.
  - Training Programs: Suggested topics include sample collection procedures, strategies for improved on-farm sampling, and relationship-building practices for increased slaughter and laboratory sampling.

- Activity Characteristics

  Federal and State personnel should report the following characteristics about awareness and training activities conducted in their area to meet or exceed national BSE Program goals and support updated WOAH BSE guidelines. National-level data will be summarized and reported annually:
  - Activity descriptions
  - Targeted stakeholder group/s
  - Number of participants
  - Activity locations

- Effectiveness of Programs

  Programs will administer an appropriate survey to participants to evaluate the effectiveness of activities.

d. Surveillance Reporting

VS will generate surveillance reports monthly and annually, utilizing a BSE dashboard and webpage (BSE Monthly Surveillance). Reporting BSE surveillance results supports the U.S. WOAH negligible risk status and provides market confidence in the safety of consuming U.S. cattle and cattle products. To this end, both national and international stakeholders, including APHIS leadership, partners, the NAHLN Coordination Team, and WOAH,[12] will receive focused reports of annual summary statistics.

e. Decisions and Actions

APHIS will use results and information from the National BSE Surveillance Plan evaluations and reports to support national BSE prevention measures, emergency preparedness and response programs, and U.S. claims of WOAH negligible risk status for BSE. Any major change in the introduction threat of BSE to the United States, in diagnostic capabilities, or in the cattle industry, will lead APHIS to review and potentially modify the plan.

9. Surveillance System Reviews and Evaluations

VS will review BSE surveillance plans annually and conduct a comprehensive evaluation every 5 years. These assessments will be based on the surveillance system metrics (see Section 8i Surveillance System Metrics).

- Focused Review

  At the end of each fiscal year within the transitional period (FY 2025 through FY 2029), APHIS will estimate annual and 8-year surveillance and educational metrics to monitor any effects from changes made to the plan. Based on results from these interim reviews, APHIS may adjust the surveillance approach.

- Comprehensive Evaluation

  Every 5 years, APHIS will comprehensively review the National BSE Surveillance Plan to ensure it continues to adequately support national BSE management strategies.

- Review and Evaluation Reports

  VS will generate reports from focused and comprehensive reviews appropriate to the scale and findings of the investigation. Reports on annual reviews will be shared with partners to communicate findings and changes to the system. Evaluation reports will be shared with a wider range of stakeholders.

[12] Due to WOAH's shift away from requiring countries to use a points-based surveillance system for official BSE recognition status, APHIS will no longer calculate WOAH (formerly OIE) BSE points. Surveillance reporting for annual reconfirmation of WOAH BSE risk status will, instead, focus on animals that were tested as part of higher risk subpopulations, as defined in the WOAH Terrestrial Code Chapter 11.4.

10. Stakeholders and Responsible Parties

Table 3. Stakeholders, responsible parties and their interests or responsibilities

Stakeholder	Interest/Responsibility
USDA–APHIS–VS Field Operations (FiOPS)	• Field implementation of BSE surveillance activities, including sample collection, data collection, education and outreach, and compliance auditing of sample collection/submission process • Situational assessment and implementation of disease response • Reporting of BSE education and outreach metrics • Cooperative data sharing
USDA–APHIS–VS Strategy and Policy (S&P)	• Development, evaluation, reporting, and revision of the BSE surveillance plan and associated documents • Comprehensive risk-based assessments • Policy and budget • Import, export, and international health status management • Surveillance data management, analysis, and reporting • Coordination of disease response • Development and implementation of the BSE education and outreach campaign • Cooperative data sharing
USDA–APHIS–VS Diagnostics and Biologics (D&B)	• Diagnostic laboratory support, reference laboratory services, sample testing and data reporting, diagnostic test development and validations • Initiation of internal response communication for BSE-confirmed positive cases according to BSE Response Plan. • Cooperative data sharing
National Animal Health Laboratory Network (NAHLN)	• Sample testing and electronic submission of test information • Immediate reporting of "inconclusive" results to NVSL
USDA APHIS Marketing and Regulatory Programs Information Technology	• Development, modification, and maintenance of a data management framework infrastructure
State animal health officials and staff	• Jointly responsible with VS Area Veterinarian-in-Charge (AVIC) for field implementation, sample collection, data collection, identification of epidemiological changes related to disease, and coordination of disease response
Veterinary Diagnostic and Public Health Laboratories	• Sample referral from case-compatible necropsy submissions of cattle and/or rabies test-negative specimens
USDA Food Safety and Inspection Service (FSIS)	• Condemnation code information sharing • Sample collection or referral for collection from case-compatible cattle condemned at antemortem inspection
Veterinarians, industry field representatives, and individual producers	• Animal health and production monitoring, rapid disease detection and reporting, sample collection and submission, biosecurity plans, animal traceability measures, and support for business continuity
Academia	• Support with diagnostic validations, disease transmission, agent inactivation, introduction pathways, and risk assessments

USDA Agricultural Research Service (ARS)	• Support with diagnostic validations, molecular epidemiology studies, and development of new diagnostic capabilities
Industry producer groups	• Industry outreach and programming, scientific issues, and surveillance data
USDA APHIS International Services and Foreign Agricultural Service, trading partners	• Trade issues and international disease status report updates
Commercial diagnostic and reagent companies	• Manufacture and sales of commercial reagents and assays
Tag manufacturers	• Manufacture and record distribution of official cattle identification for traceability
Rendering and salvage (3D/4D) facilities, other sample collection contractors	• Sample collection and submission, data collection, and carcass control throughout the sampling process

11. References

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12. Policy and Operational Documents

VS BSE policy and operational documents and the date each became effective:

1. BSE Procedures Manual: BSE ongoing surveillance program (November 2020)
2. BSE Response Plan (June 2023)
3. VS Guidance 7800.1, BSE Ongoing Surveillance Program VS Guidance (October 23, 2020)
4. VS Form 17-131, "BSE Surveillance data collection form" (February 2014)
5. VS Form 17-146 and 17-146A, "BSE surveillance submission form" and "BSE surveillance submission form continuation sheet" (February 2014)
6. BSE Surveillance Dashboard: https://www.aphis.usda.gov/veterinary-services/bse-ongoing-monthly-surveillance-program (Ongoing 2006)