

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

10,400.1
Revision 1

4/15/20

**SAMPLE COLLECTION FROM CATTLE 12 MONTHS OF AGE OR OLDER THAT DISPLAY
CENTRAL NERVOUS SYSTEM SIGNS UNDER THE BOVINE SPONGIFORM
ENCEPHALOPATHY ONGOING SURVEILLANCE PROGRAM**

I. PURPOSE

This directive provides FSIS inspection program personnel (IPP) with instructions regarding the collection of brain samples for the Animal and Plant Health Inspection Service's (APHIS) Bovine Spongiform Encephalopathy (BSE) ongoing surveillance program. FSIS is reissuing this directive to provide updated instructions on collecting samples only from cattle that are 12 months of age or older that display signs (e.g., head pressing, circling) of a central nervous system (CNS) disorder. This directive includes instructions for the Office of Investigation, Enforcement and Audit (OIEA) Regional Director (RD), when the RD has been notified by the Office of Field Operations (OFO) District Office (DO) of an animal condemned for signs of a CNS disorder. Instructions for obtaining rabies protection are also included for Public Health Veterinarians (PHVs) that collect BSE tissue samples.

KEY POINTS:

- *Provides updated instructions to IPP to collect samples only from cattle that are 12 months of age or older that display signs of a CNS disorder*
- *Sets out definition of collection procedures*
- *Describes FSIS responsibilities related to approved alternative off-site sample collection*

II. CANCELLATION

FSIS Directive 10,400.1, *Sample Collection from Cattle Under the Bovine Spongiform Encephalopathy (BSE) Ongoing Surveillance Program*, 4/11/13

III. DEFINITION OF COLLECTION PROCEDURES

A. At federally-inspected slaughter establishments that have approved alternative off-site sample collection arrangements with APHIS:

1. APHIS will provide for the collection of brain (obex) samples from an allocated number of cattle 30 months and older condemned for any reason on ante-mortem inspection and from cattle 12 months of age or older displaying signs of a CNS disorder.
2. At such establishments, IPP will provide the following to establishment management, to the APHIS Area Veterinarian-in-Charge (AVIC), and to the sample collecting contractors:

DISTRIBUTION: Electronic

OPI: OPPD

- a. Condemn tag (Z-tag) numbers (not the Z-tag itself); and
- b. Disposition information, including history, clinical signs, and the reason for condemnation (as per 9 CFR 309) is to be recorded in the Public Health Information System (PHIS).

B. At federally-inspected establishments that do not have approved alternative off-site sample collection arrangements with APHIS, PHVs are to:

1. Notify the APHIS AVIC when an animal 12 months of age or older has been condemned for CNS reasons and provide the information outlined in paragraph III.A.2.
2. Collect appropriate BSE samples from cattle 12 months of age or older that display CNS signs if the APHIS AVIC cannot arrange for APHIS to collect the sample.

IV. FSIS PERSONNEL RESPONSIBILITIES FOR NOTIFYING THE ESTABLISHMENT OF CHANGES TO SAMPLE COLLECTION

A. Upon receipt of this directive, the PHV is to use the next weekly meeting to advise the beef slaughtering establishment that tissue samples will be collected only from cattle 12 months of age or older that display CNS signs. The PHV is to remind establishment management that they may seek approved alternative off-site sample collection arrangement with APHIS for collecting allocated samples (as per paragraph III.A.).

1. If the establishment does not have such an arrangement (alternative off-site sample collection), then FSIS will follow the directions in paragraphs III.B. and VI.A.
2. The PHV is to document the discussion in a memorandum of interview (MOI). The PHV is to:
 - a. Document the names of establishment management present; how the establishment responded to the question of having an approved offsite collection agreement; the age change for cattle tissue collection and any documents the PHV shared with establishment management.
 - b. Document if the establishment reported that it has submitted a request to APHIS to begin off-site sampling.

V. FSIS RESPONSIBILITIES RELATED TO APPROVED ALTERNATIVE OFF-SITE SAMPLE COLLECTION

A. The FSIS PHV is to complete all of the data entry fields in the PHIS Establishment Reporting Disposition Records and on FSIS Form 6150-1 (Identification Tag – Ante-mortem). The FSIS PHV is to pay special attention to providing a full description of the reason for the condemnation in PHIS, which will appear on FSIS Form 6000-13 (Certification of Ante-mortem or Post-mortem Disposition of Tagged Animals) and verify that all sections of FSIS Form 6150-1 have been completed. Copies of these forms will be provided as instructed in III. A. 2. This information will allow APHIS to triage which condemned animals are sampled for BSE.

B. IPP are to verify that all animal identification except the Z-tag is left on these animals to provide needed identifying information on collection forms at the approved alternative off-site collection location. IPP or someone from the establishment under the direction of the IPP are to remove Z-tags before any

carcasses leave the official establishment.

VI. FSIS SAMPLE COLLECTION FOR CATTLE 12 MONTHS OF AGE OR OLDER DISPLAYING SIGNS OF A CNS DISORDER

A. If the establishment does not have an arrangement with APHIS for off-site sampling of cattle 12 months of age or older with signs of a CNS disorder, the PHV is to follow the directions in paragraph III.B. Also:

1. The PHV is to make the final disposition condemning (US Condemn tag) all cattle 12 months of age or older if they have signs of a CNS disorder in accordance with 9 CFR 309.4 (a);
2. The PHV is to advise the establishment to not euthanize the animal until after the PHV has communicated with the APHIS AVIC to determine if euthanasia should be delayed; and
3. The PHV is not to allow the establishment to move cattle 12 months of age or older condemned on ante-mortem for CNS reasons off the establishment's premises until APHIS collects the sample or APHIS requests otherwise.

B. If the responsibility to collect the BSE sample falls to the PHV, the PHV is to direct the establishment to humanely euthanize the animal. Then, the PHV or someone from the establishment under the direction of the PHV is to promptly remove the head to allow the PHV to collect the brain sample.

NOTE: BSE sampling information is provided on the APHIS website in the [Procedure Manual](#) for the BSE ongoing surveillance program.

C. The PHV, being mindful of other potential CNS disease conditions of public health significance that may be present, is to collect the brain sample either in the inedible area of the establishment or in an isolated area set aside for such collection to prevent human exposure or the creation of insanitary conditions (9 CFR 314.7). Establishment personnel and IPP are to take proper sanitary measures before returning to edible areas of the establishment after brain sample collection, in accordance with 9 CFR 416.5.

D. In situations where the PHV has missed the last United Parcel Service (UPS) pick-up for the day, or the PHV collected the sample on a day when UPS does not pick up, the PHV is to refrigerate the samples until the next available UPS pick-up day. The sample is not to pass through or to be stored in areas of the establishment where the establishment produces edible product. The PHV is to maintain the sample's chain-of-custody.

E. The PHV is to verify the collection, documentation, and control of all animal identification associated with cattle condemned during ante-mortem inspection that are to be sampled by FSIS. The PHV is to attach the "U.S. Condemned" tag to cattle condemned during ante-mortem inspection in accordance with 9 CFR 309.13. This documentation will facilitate traceback if the sample result is positive for BSE. The PHV is to include in the documentation all pertinent information to facilitate trace back of the animal in question in accordance with 9 CFR 320.1.

F. PHVs can find forms and order supplies using the following links or address:

1. BSE Surveillance Data Collection Form: [VS 17-131](#);
2. BSE Surveillance Submission Form: [VS 17-146](#);

3. BSE Surveillance Submission Continuation Form: [VS 17-146a](#);

4. BSE Kits and Shipping Containers:

National Veterinary Services Laboratories
1800 Dayton Avenue
Ames, IA 50010
Ph: (515) 663-7530 Fax: (515) 663-7378

5. Kit and Instrument Order Form: [Supply Request Form](#)

G. The FSIS intranet site (e-Authentication is needed to access this site) provides information as well:

1. Go to the FSIS intranet site by selecting the following link: [BSE and SRM Material](#); and
2. Scroll to the needed form or document.

H. The PHV is to verify that the presence of condemned cattle or parts does not create insanitary conditions (9 CFR 416). The establishment is responsible for the disposal of the condemned cattle in accordance with 9 CFR 314. The PHV also is to verify that the establishment maintains records regarding the disposal of the condemned cattle in accordance with 9 CFR 320.1.

I. IPP are to inform the establishment that it may choose to hold the carcass and parts until testing results are available. If the establishment chooses to dispose of any carcass or parts before it receives test results, IPP, after consultation with APHIS ([site list](#)), are to advise the establishment that it must dispose of the carcass in one of the following ways:

1. Render it at a facility for non-animal feed use (e.g., biofuel or cement);
2. Alkaline digestion;
3. Incineration; or
4. Lined landfill.

J. Documentation for Cattle 12 Months of age or older Showing Signs of CNS Signs:

1. For locations without high-speed internet connections, the PHV is to forward the completed BSE Veterinary Services Laboratory Submissions (BSE-VSLS) sample collection sheets to the corresponding APHIS VS district office by FAX. The following link lists the VS district office FAX numbers and e-mail where available: [site list](#)

NOTE: The PHV can get copies of BSE-VSLS forms by contacting the local APHIS office. The APHIS AVIC may assist with sample delivery verification and troubleshooting.

2. For locations with high-speed connections, the PHV is to enter the relevant information into the BSE-VSLS.

NOTE: PHVs can refer to the BSE-VSLS training for assistance getting access to BSE-VSLS and inputting information. Instructions for completing the sample collection sheets may also be found in the

Procedure Manual ([Procedure Manual](#)). The PHV may contact the DO if he or she needs a copy of the training CD.

VII. TEST RESULTS FOR FSIS SAMPLING FROM CATTLE 12 MONTHS OF AGE OR OLDER SHOWING CNS SIGNS

- A. The PHV will receive, by e-mail, a report from the APHIS AVIC on the BSE test results. The AVIC will also send copies of the results to the DO.
- B. If the test on the carcass condemned for CNS conditions is negative (reported as “not detected”), then any carcasses and parts the establishment has held may be released for rendering or other disposal in accordance with 9 CFR 314.
- C. If the test is inconclusive, the PHV, after consultation with their supervisor and APHIS ([site list](#)), will release any carcasses and parts the establishment has held for rendering or other disposal in accordance with 9 CFR 314 and as set out in paragraph VI. I.
- D. For any sample confirmed positive for BSE, the PHV is to verify that the establishment disposes of the carcasses and parts in the proper manner as set out in paragraph VI.I.

VIII. PHIS PROCEDURES FOR BSE SAMPLING FROM CATTLE SHOWING CNS SIGNS

- A. PHVs are to enter disposition information into PHIS in Animal Disposition Reporting (ADR) following instructions in [FSIS Directive 6100.2](#), “*Post-Mortem Livestock Inspection*.”
- B. PHVs are to enter BSE sampling information into the ADR APHIS Lab Sampling page in ADR. (Refer to [FSIS Directive 13,000.2](#), “*Performing Sampling Tasks in Official Establishments Using the Public Health Information System*” under “BSE Testing.”)

IX. OFFICE OF INVESTIGATION, ENFORCEMENT AND AUDIT RESPONSIBILITIES

- A. When an OIEA RD has been notified by the OFO DO of a CNS condemned bovine 12 months of age or older, they are to verify by onsite visit and record review once per quarter that:
 - 1. The heads or carcasses were received at the off-site location, and
 - 2. That a brain sample for BSE testing was collected by APHIS.
- B. The RD is to perform this verification for off-site location collection only and to document this activity in the In-Commerce System.

X. CATTLE SUSPECTED OF RABIES INFECTION

When a bovine 12 months of age or older is condemned by the PHV on ante-mortem for suspicion of infection with rabies, the PHV is to contact the DO, which will advise APHIS. In these cases, APHIS is responsible for the animal being tested for rabies. APHIS will work with the laboratory to get appropriate samples forwarded for BSE surveillance from rabies-negative animals.

XI. RABIES PROTECTION FOR A PHV COLLECTING BSE SAMPLES

A. PHVs collecting BSE samples are to protect themselves from rabies. PHVs may have their rabies titer checked by arranging with their private physician for testing and contacting their Frontline Supervisor (FLS) for approval of reimbursement before the test. If the test demonstrates that the PHV is not protected, the PHV is to arrange a rabies booster vaccination.

B. PHVs are to arrange with their private physician for the booster vaccine or vaccine series. PHVs are to contact their FLS for approval of reimbursement before receiving the booster vaccine or vaccine series.

NOTE: Only PHVs involved with BSE sample collection will be eligible for reimbursement for rabies protection.

XII. QUESTIONS

Refer questions regarding this directive to the Office of Policy and Program Development through [askFSIS](#) or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter **Directive 10,400.1**.
Question Field: Enter question with as much detail as possible.
Product Field: Select **General Inspection** from the drop-down menu.
Category Field: Select **Slaughter-Livestock** from the drop-down menu.
Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question**.

NOTE: Refer to [FSIS Directive 5620.1](#), *Using askFSIS*, for additional information on submitting questions.



Acting Assistant Administrator
Office of Policy and Program Development