

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

FSIS DIRECTIVE

10,400.1

4/11/13

SAMPLE COLLECTION FROM CATTLE UNDER THE BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) 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. Most of the instructions in this directive were last issued in FSIS Notice 13-12. This directive includes new instructions for the Office of Program Evaluation, Enforcement and Review (OPEER) Regional Director, (RD) when he or she has been notified by the Office of Field Operations (OFO) District Office (DO) of a Central Nervous System (CNS) condemned animal.

KEY POINTS:

- *Sets out definition of collection procedures.*
- *Describes FSIS responsibilities related to approved alternative off-site sample collection.*
- *Provides FSIS sample collection for cattle displaying CNS symptoms.*

II. 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 of any age displaying CNS symptoms.
2. At such establishments, FSIS IPP will provide the following to plant management, to the APHIS Area Veterinarian in Charge (AVIC), and to sample collecting contractors:
 - a. Condemn tag (Z-tag) numbers (not the Z-tag itself); and
 - b. Disposition information (i.e., the reason for condemnation under 9 CFR Part 309), including history, clinical signs, and the condemnation code assigned.

DISTRIBUTION: Electronic

OPI: OPPD

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

1. Notify the APHIS AVIC when an animal has been condemned for CNS reasons and provide the information outlined in paragraph II.A.2.
2. If arrangements with the APHIS AVIC cannot be made, collect appropriate BSE samples from cattle of all ages that display CNS symptoms.

NOTE: Certain Alternative Off-Site Agreements that were in place during Enhanced Surveillance may no longer be in effect. Therefore, IPP may need to advise the establishment that they need to establish new agreements with APHIS and potential collectors.

III. FSIS PERSONNEL RESPONSIBILITIES

A. Upon receipt of this directive, the FSIS PHV is to use the next weekly meeting to ask establishment management whether:

1. It has an approved alternative off-site sample collection arrangement with APHIS for collecting allocated samples (as per paragraph II.A.); or
2. It is not an establishment that has an alternative off-site sample collection arrangement with APHIS. If the establishment does not have such an arrangement, then FSIS is to follow the directions in paragraph II.B.

B. If, during the meeting, establishment management states that it has submitted an application to APHIS to begin off-site sampling, until APHIS approves that arrangement, FSIS PHVs are to:

1. Identify all CNS animals condemned on ante-mortem with a "U.S. Condemned" tag;
2. If an animal is condemned for this reason, contact the APHIS AVIC and follow the directions in paragraph II.B.;
3. Ensure that the animals are humanely euthanized, unless APHIS requests that the animal not be euthanized; and
4. Not allow any CNS animal condemned on ante-mortem to move off the premises of the establishment until APHIS collects the sample or APHIS requests otherwise.

C. In a memorandum of interview (MOI), the FSIS PHV is to document who was present at the meeting with establishment management, the date and time of the meeting, how the establishment plans to proceed based on the choices set out in paragraph III.A., and any documents the PHV shared with management.

D. If the establishment states that it has submitted a request to APHIS to begin off-site sampling, the FSIS PHV is to update the MOI as to whether the establishment reached an agreement, and in general, what the agreement was.

E. The FSIS PHV is to maintain a copy of the MOI in the official government file, provide a copy to the plant management, and e-mail a copy to the APHIS AVIC. Any changes in the agreement with APHIS for off-site sample collection are to be reflected in an updated MOI, which is then distributed as above.

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

A. The FSIS PHV is to complete the condemnation form, FSIS Form 6000-13 (Certification of Ante-mortem or Post-mortem Disposition of Tagged Animals), and 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 on FSIS Form 6000-13 and fill out fully FSIS Form 6150-1.

B. Incoming animal identification, except the Z-tag, is to be left on these animals to provide needed identifying information on collection forms at the approved alternative off-site collection location. IPP are, or someone under their supervision is, to remove Z-tags before any carcasses leave the official establishment.

NOTE: Information supplied to plant management to take to the approved alternative off-site collection locations needs to be complete and accurate. FSIS PHVs need to provide a full description of the reason for the condemnation on FSIS Form 6000-13. APHIS will use this information to triage which condemned animals are sampled.

V. FSIS SAMPLE COLLECTION FOR CATTLE DISPLAYING CNS SYMPTOMS

A. If the establishment does not have an arrangement with APHIS for off-site sampling of cattle with CNS symptoms, the FSIS PHV is to follow the directions in paragraph II.B. The FSIS PHV is to make all final disposition decisions regarding whether to condemn cattle in accordance with 9 CFR part 309.

NOTE: FSIS PHVs can find information regarding BSE sampling (e.g., forms, sampling supply information) on the FSIS intranet under Public Folders, OPPD, PDD, BSE, at: [BSE sampling](#).

Additional BSE sampling information is provided on the APHIS website at: [Procedure Manual](#).

B. If the responsibility to collect the BSE sample falls to the FSIS PHV, the FSIS PHV or the establishment under the supervision of the FSIS PHV is to promptly remove the head in order to collect the brain sample. If the establishment does not arrange to remove the head, the FSIS PHV may need to collect the brain sample as a priority over other ante-mortem or post-mortem procedures.

C. The FSIS 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. Establishment personnel and FSIS 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 FSIS PHV has missed the last UPS pick-up for the day, or the FSIS 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. Remember, the sample is not to pass through or to be stored in areas of the establishment where the establishment produces edible product. The FSIS PHV is to maintain the sample's chain-of-custody.

E. The FSIS 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 FSIS 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 in the event that the sample result is positive for BSE. The FSIS 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. The FSIS PHV is to verify that the presence of condemned cattle or parts does not create insanitary conditions (9 CFR Part 416). The establishment is responsible for the disposal of the condemned cattle in accordance with 9 CFR part 314. The FSIS PHV also is to verify that the establishment maintains records regarding the disposal of the condemned cattle in accordance with 9 CFR 320.1.

G. IPP may 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 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. A lined landfill.

H. Documentation for Cattle Showing Signs of CNS Symptoms

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

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

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

NOTE: FSIS PHVs can refer to the BSE-VSLS training for assistance getting access to BSE-VSLS and inputting information. The FSIS PHV may contact the DO if he or she needs a copy of the training CD.

VI. TEST RESULTS FOR FSIS SAMPLING FROM CATTLE SHOWING CNS SYMPTOMS

- A. The FSIS PHV will receive, by e-mail, a report from the 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 FSIS PHV will receive supervisory instruction on further actions.
- D. For any sample confirmed positive for BSE, the FSIS PHV is to verify that the establishment disposes of the carcasses and parts in the proper manner as set out in paragraph V.G.

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

- A. Enter disposition information into PHIS in ADR.
- B. Enter BSE sampling information into the ADR APHIS Lab Sampling page in ADR.

VIII. OFFICE OF PROGRAM EVALUATION, ENFORCEMENT AND REVIEW RESPONSIBILITIES

- A. When an OPEER RD has been notified by the OFO DO of a CNS condemned animal, he or she is 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 document this activity in the In-Commerce System.

IX. RABIES

- A. When an animal is condemned by the FSIS PHV on ante-mortem for rabies, the FSIS PHV is to contact the DO, which will advise APHIS. In these cases, APHIS will see that the animal is tested for rabies. APHIS will work with the laboratory to get appropriate samples forwarded for BSE surveillance from rabies-negative animals.
- B. Rabies booster vaccination for PHVs collecting BSE samples is still highly recommended. PHVs can be reimbursed for rabies vaccinations or boosters. Rabies vaccinations are voluntary. Only PHVs who are actually involved with BSE sample collection will be eligible for reimbursement on the vaccination series. PHVs are to make arrangements for the vaccinations with their private physician. PHVs are to contact their Front-line supervisor for approval of reimbursement before beginning the three-shot vaccination series.

X. QUESTIONS

Refer questions regarding this directive to the Risk, Innovations, and Management Division 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**.



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