Exhibit 42

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

FSIS DIRECTIVE

6100.1 Revision 1	4/16/09

DO NOT IMPLEMENT THIS DIRECTIVE UNTIL: 4/17/09

ANTE-MORTEM LIVESTOCK INSPECTION

I. PURPOSE

The Agency is reissuing this directive to provide new directions to inspection program personnel (IPP) on condemning cattle that become non-ambulatory disabled after passing ante-mortem inspection. This directive provides instructions to all IPP at livestock slaughter establishments to review this Directive (see section VI). The purpose of this directive is to provide instructions to IPP on how to inspect livestock before slaughter (ante-mortem). Additionally, this directive instructs Public Health Veterinarians (PHVs) on making dispositions of livestock ante-mortem and documenting the findings.

II. CANCELLATIONS

FSIS Directive 6100.1, Ante-mortem Livestock Inspection

III. RESERVED

IV. REFERENCES

Federal Meat Inspection Act (FMIA) 21 U.S.C. 603
Regulations 9 CFR 307.2(a), 309, 310, 311, 320.1(b)(1)(iv), and part 500
FSIS Directive 5000.2, Review of Establishment Data by Inspection Personnel
FSIS Directive 6100.2, Post-mortem Livestock Inspection
FSIS Directive 6240.1, Revision 1, Inspection, Sampling, and Disposition of Animals for Tuberculosis
FSIS Directive 6900.1, Humane Handling of Disabled Livestock
FSIS Directive 6900.2, Humane Handling and Slaughter of Livestock
FSIS Form 6150-1, Identification Tag – Ante-mortem
FSIS Form 6200-14, Daily Disposition Record
FSIS Form 6200-16, Summary of Ante-mortem Examination

V. BACKGROUND

On March 18, 2009, FSIS published a final rule, "Requirements for the Disposition of Cattle that Become Non-Ambulatory Disabled Following Ante-mortem Inspection," (74 FR 1146, available on the Internet at http://www.fsis.usda.gov/regulations_&_policies/2009_Interim_&_Final_Rules_Index/index.asp). See Attachment 1 for the regulations pertaining to the disposition of cattle that become non-ambulatory disabled after passing ante-mortem inspection. The final rule requires that all non-ambulatory disabled cattle, including those that have passed ante-mortem inspection, be condemned and properly disposed of and that establishment personnel notify FSIS IPP when cattle become non-ambulatory disabled after passing ante-mortem inspection.

The final rule on non-ambulatory disabled cattle did not modify 9 CFR 309.13. Under the final rule, all non-ambulatory disabled cattle that are offered for slaughter, including non-ambulatory veal calves, must be condemned and disposed of in accordance with 9 CFR 309.13. Section 309.13 of 9 CFR applies after livestock, including veal calves, have been condemned. 9 CFR 309.13(b) provides that veal calves that are unable to rise from a recumbent position and walk because they are tired or cold, before they are condemned, may be set apart and held for treatment but only under appropriate FSIS supervision.

Under the FMIA, IPP perform an examination and inspect all livestock before slaughter to determine whether the animals are fit for slaughter for human food. There are some animal health conditions that can only be assessed when the livestock are alive. Thus, if an establishment does not present animals for ante-mortem inspection in accordance with 21 U.S.C. 603 and 9 CFR 309.1, IPP [the PHV, Consumer Safety Inspector (CSI), or Food Inspector (FI)] conducting post-mortem inspection are not able to determine that carcasses are not adulterated and, therefore, cannot permit the carcasses to be marked as "inspected and passed."

FSIS will continue to permit custom slaughter operators to slaughter for human food cattle that become non-ambulatory disabled after they are delivered to a custom operation if the custom operator does not observe any other condition that would render the animal unfit for human food.

VI. REVIEWING THIS ANTE-MORTEM LIVESTOCK INSPECTION DIRECTIVE

The IICs at all establishments that slaughter livestock are to provide up to 1 hour of official time during the established tour of duty to each FSIS employee that performs ante-mortem duties at the establishment to review FSIS Directive 6100.1, Revision 1, Ante-mortem Livestock Inspection. IICs are to give IPP that perform ante-mortem duties an opportunity to review this directive as soon after issuance as practical. Alternatively, the IIC may conduct a work unit meeting with inspection personnel that perform ante-mortem duties to discuss this directive. Once all FSIS employees at the establishment complete the review, the IIC is to document on a memo a list of the names of all the FSIS employees that reviewed the directive and the date that the review is complete.

VII. VERIFYING AN ESTABLISHMENT'S VOLUNTARY SEGREGATION PROCEDURES BEFORE ANTE-MORTEM INSPECTION FOR SWINE AND SHEEP

A. When an establishment is slaughtering only market classes of swine or sheep (i.e., market hogs and lambs) and voluntarily segregates animals to facilitate its scheduling of animals for slaughter (i.e., segregating those animals showing signs of abnormalities or diseases from healthy animals), IPP (the PHV, CSI, or FI) are to verify that:

1. market classes of swine or sheep represent the type of livestock slaughtered in the greatest number at the establishment;

NOTE: FSIS does not permit voluntary segregation, as described in this directive, of any class of cattle before FSIS performs ante-mortem inspection. However, to facilitate humane handling, an establishment may move any livestock to the U.S. Suspect pen before the performance of ante-mortem inspection by IPP.

2. animals, except market swine, do not arrive under any Animal and Plant Health Inspection Service (APHIS) Veterinary Services (VS) permit or certificate. Market swine arriving under VS-17-30 (Report of Animals, Poultry, or Eggs Offered for Importation) and 17-33 (Animals Imported for Immediate Slaughter) are eligible for segregation under documented plant segregation procedures;

3. the establishment documents its segregation procedures in its HACCP plan or a prerequisite program;

4. the documents on the prerequisite program, and the records related to the prerequisite program, are available to off-line IPP upon request (see FSIS Directive 5000.2, Review of Establishment Data by Inspection Personnel); and

5. the establishment presents all animals to IPP for inspecting before slaughter.

B. IPP inspecting swine and sheep ante-mortem are to:

1. verify that the segregation procedures are only for market classes of swine and sheep;

2. examine all animals found normal by the establishment while the animals are "at rest" (9 CFR 309.1(a));

3. select 5 to 10 percent of all animals that the establishment presents for ante-mortem inspection from several lots and observe in motion;

4. instruct the establishment to move abnormal animals that the PHV may condemn under 9 CFR part 311 to the designated "U.S. Suspect" pen (9 CFR 307.2(a)) for final disposition; and

5. randomly observe establishment personnel performing segregation procedures (i.e., segregating those animals showing signs of abnormalities or diseases from healthy animals) at least once per month.

C. If an establishment does not have documented segregation procedures or fails to implement its segregation procedures properly, the PHV is to instruct IPP not to consider the establishment's segregation program and to follow the instructions in Section VIII.

NOTE: If the establishment sorts livestock for classes other than market swine and sheep (such as cattle) and moves the livestock for inspection by IPP to the designated "U.S. Suspect" pen for final disposition, then the PHV is to carefully examine and inspect all livestock in the "U.S. Suspect" pen (9 CFR 309.2(a) and (n)).

VIII. ANTE-MORTEM LIVESTOCK INSPECTION

A. Steps IPP Follow for Inspecting Livestock Ante-mortem

1. When IPP (i.e., PHV, CSI, or FI) perform ante-mortem inspection, they are to follow the directions in FSIS Directive 6900.1, Humane Handling of Disabled Livestock and 6900.2, Humane Handling and Slaughter of Livestock, for how to verify that the establishment is meeting humane handling requirements. All animals that are on the premises of the establishment, on vehicles that are on the premises, or animals being handled in connection with slaughter (e.g., livestock on trucks being staged for slaughter) are to be handled humanely. Establishment employees are to handle these animals in accordance with the requirements for the humane handling of livestock (9 CFR 313.2).

2. IPP are to perform ante-mortem inspection on the day of slaughter by observing **all** livestock (except at establishments that have voluntary segregation procedures described in section VI):

a. **at rest**;

b. **in motion.** IPP are to observe livestock from **both** sides when the slaughter class (e.g., cows and bulls) or condition of the animals (e.g., diseased, distressed) at the slaughter establishment supports observing from both sides in order to determine whether they are fit to slaughter for human consumption. At establishments where IPP other than PHVs perform ante-mortem inspection, the PHV is to correlate with the IPP on which animals the IPP are to observe from both sides.

3. When performing ante-mortem inspection, IPP are to observe:

a. the overall condition of each animal, including the head, with attention to the eyes, the legs, and the body of the animal;

b. the degree of alertness, mobility, and breathing; and

c. whether there are any unusual swellings or any other abnormalities.

4. IPP are to pass for slaughter livestock that do not show signs of diseases or abnormalities and that are fit to slaughter for human consumption.

5. When IPP find animals showing signs of abnormalities or diseases on ante-mortem inspection, IPP are to direct the establishment to set all affected animals apart into separate pens (i.e., a suspect pen) for further examination by the PHV (9 CFR 309.2(n)).

6. Non-ambulatory disabled cattle are not eligible for slaughter. IPP (non-PHVs) are to notify the PHV if non-ambulatory, disabled cattle are offered for slaughter. If non-ambulatory disabled cattle are offered for slaughter in an official establishment where the PHV is not located on premises, IPP are to:

a. identify and secure the animal. To execute the holding of an animal and to restrict the animals movement, IPP are to apply an FSIS Form 6502-1, "U.S. Rejected - U.S. Retained" tag (in this directive referred to as "U.S. Retained" tag) to the pen containing the affected animal; and

b. promptly notify the PHV assigned to that establishment.

NOTE: Alternatively, the establishment may elect to condemn and humanely destroy the non-ambulatory disabled cattle before the PHV inspects and makes a disposition.

7. PHVs are to conduct ante-mortem inspection on all non-ambulatory disabled cattle, or other livestock, offered for slaughter.

NOTE: Non-ambulatory disabled livestock are livestock that cannot rise from a recumbent position or that cannot walk. Non-ambulatory livestock may include, but are not limited to, those animals with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions (9 CFR 309.2(b)).

8. The IIC is to contact the Policy Development Division (PDD), through supervisory channels, if he or she has not received a slaughter permit when an establishment presents for ante-mortem inspection animals used in a research investigation involving an experimental biological product, drug, or chemical (9 CFR 309.17). The PDD issues the slaughter permit to the IIC, DO, and the researcher based on information provided by the researcher.

9. If an establishment fails to present animals for ante-mortem inspection (21 U.S.C. 603 and 9 CFR 309.1), the off-line IPP are to:

a. retain the animals. The PHV is to condemn the animals;

b. notify the IIC immediately; and

c. issue a noncompliance record (NR) under the 03J01/2 procedure code.

B. Suspect Livestock

1. PHVs are to examine and take the temperature, as necessary, of abnormal or diseased livestock including those set apart by the establishment or IPP.

2. PHVs are to designate as "U.S. Suspect," by directing that a serially numbered "U.S. Suspect" tag (9 CFR 309.18(a)) be applied to livestock (9 CFR 307.2):

NOTE: PHVs do not have to apply the "U.S. Suspect" tag but are to observe that the "U.S. Suspect" tag is applied by an establishment employee.

a. having any disease condition that may cause the PHV to condemn the carcass when inspected post-mortem; and

b. presented as non-ambulatory disabled livestock, **except** cattle. PHVs are to condemn non-ambulatory disabled cattle (see VIII. D.).

NOTE: When an establishment offers for slaughter recumbent livestock for ante-mortem inspection, the establishment may help an animal that is capable of rising by providing the animal support (e.g., providing a steadying hand). Such support may not be by mechanical means, nor is the establishment permitted to lift the animal in any way. Also, once the animal has risen, it is to ambulate without assistance, so that the PHV can observe it in motion. The establishment must treat the animal humanely when attempting to have it rise or ambulate. FSIS does not consider forcing an animal to stand or ambulate by kicking or prodding (e.g., electrical prodding) to be humane.

3. Under the following circumstances PHVs do not need to apply a serially numbered "U.S. Suspect" tag:

a. cattle that are identified, segregated, and slaughtered as "U.S. Suspect" affected with ocular squamous cell carcinoma (epithelioma of the eye), actinobacillosis, or actinomycosis, readily detected on post-mortem inspection (9 CFR 309.18(a)). The readily detected lesions along with FSIS Form 6150-1 identify the animals as being handled as U.S. Suspects; and

b. Livestock that are known to have reacted to the tuberculin test shall be identified as U.S. Suspects (9 CFR 309.2(d))(see FSIS Directive 6240.1) and bear an official "USDA Reactor" or similar State reactor tag (9 CFR 309.2(d)).

4. PHVs are to verify that the establishment identifies any "U.S. Suspect" swine with a tattoo if they are to be mechanically-dehaired. The use of the tattoo is to maintain the identity of the swine as "U.S. Suspect" through the dehairing process (9 CFR 309.18(b)).

5. See section IX for documenting ante-mortem "U.S. Suspect" findings.

C. PHV Disposition of Cattle That Become Non-ambulatory Disabled After Ante-mortem Inspection

1. When notified by the establishment of cattle that become non-ambulatory disabled after passing ante-mortem inspection, PHVs are to condemn the cattle (9 CFR 309.3(e)); and

2. PHVs are to tag the cattle they have condemned as "U.S. Condemned" (9 CFR 309.3(e)).

D. Condemned Livestock

1. In accordance with 9 CFR 309.3(a) – (e), PHVs are to identify as "U.S. Condemned" by directing that a serially numbered metal "U.S. Condemned" ear tag (9 CFR 309.18(c)) be applied to all animals that are condemned on ante-mortem inspection (9 CFR 309.3(a) – (e)):

NOTE: PHVs do not have to apply the "U.S. Condemned" tag but are to observe that the "U.S. Condemned" tag is applied by an establishment employee.

a. livestock that are dead or in a dying condition when offered for slaughter on the premises of the official establishment;

NOTE: Non-PHVs may identify and tag dead animals as "U.S. Condemned." Only PHVs may condemn live animals.

b. livestock that are plainly showing on ante-mortem inspection any disease or condition that, under 9 CFR part 311, would cause the PHV to condemn the carcass when inspecting post-mortem;

c. any swine having a temperature of 106°F or higher, and any cattle, sheep, goats, horses, mules, or other equines having a temperature of 105°F or higher;

NOTE: If there is doubt as to the cause of the high temperature, an establishment may hold an animal for further observation, at the discretion of, and under the supervision of, IPP. The PHV is to re-examine the animal, including taking the temperature when the establishment again offers an animal for ante-mortem inspection. If the temperature is still 106° F or above for swine or 105° F or above for other livestock, the PHV is to condemn the animal. Animals may have high temperatures because of a bacterial infection. Animals may also have increased temperatures for reasons other than disease. For example, in the summer, animals may develop heat stress from elevated environmental temperatures.

d. all animals in a comatose or semicomatose condition;

e. all non-ambulatory disabled cattle that are offered for slaughter; and

f. all animals that have any other condition that would preclude the release of the animal for slaughter, including all livestock exhibiting clinical signs of central nervous system disorders. Clinical signs of nervous system disorders on ante-mortem inspection include, but are not limited to, the following: excitement or depression; deviation or rotation of the head; drooping of the lips, eyelids, cheeks, and

ears; convulsions and tremors; paralysis; sudden onset of fainting; head pressing; aimless walking; ataxia; and blindness. Other diseases may mimic nervous system disorders. For example, lameness may be difficult to differentiate from ataxia or paresis, and shivering from the cold may be difficult to differentiate from tremors. IPP are to retain any animal exhibiting signs of nervous system disorders for veterinary disposition (9 CFR 309.4(a)).

2. If an establishment requests to hold livestock, including veal calves that cannot rise from a recumbent position or that cannot walk because they are tired or cold, for treatment or to treat the livestock set apart (9 CFR 309.13(b)), the PHV is to:

a. verify that the establishment maintains the identity of the animals and holds the animals in an area that bears the documented identification of the animals, or that the establishment has received permission from the appropriate local, State, or Federal livestock sanitary official having jurisdiction to move the animals off premises;

NOTE: For example, if the establishment presented a market steer for slaughter, and the animal suffered an injury after passing ante-mortem inspection (e.g., the market steer broke its leg and became non-ambulatory disabled), then in this example the market steer is condemned. Also, the establishment may not divert and slaughter the market steer having been presented for ante-mortem inspection under custom exempt. The establishment may still set apart and treat the market steer.

b. change the FSIS Form 6150-1, Identification Tag – Ante-mortem Form - by crossing out the word "slaughter" and by writing in the words "held for treatment" in the appropriate space for animals that are treated on premises; and

c. just before the animal is shipped, remove the "U.S. Suspect" or "U.S. Condemned" tag on animals that are to be treated off premise.

3. PHVs are to:

a. verify the disposal of condemned livestock by the establishment (9 CFR 314), and that the establishment maintains the required records (9 CFR 320), or that the animals are set apart and held for further observation or treatment under supervision of a FSIS program employee; and

NOTE: It is the responsibility of the PHV to verify that an animal that is identified as "U.S. Condemned" is either disposed of properly or held for further observation or treatment by the establishment (see 9 CFR 309.13(a)(b)).

b. complete FSIS Form 6150-1, Identification Tag – Ante-mortem, for each animal identified as "U.S. Condemned" on ante-mortem inspection.

NOTE: IPP may record multiple deads (e.g., DOAs) and the associated serial "U.S. Condemned" tag (Z-tag) numbers on a single FSIS Form 6150-1, Identification Tag – Ante-mortem.

D. Delayed Slaughter

Low-volume establishments utilize delayed slaughter when slaughtering animals on a day other than on the day of ante-mortem inspection. A low-volume establishment for this purpose is one that slaughters 1-15 animals per day. To conduct delayed slaughter, establishments need approval by the FLS. Delayed slaughter is not permitted for cattle (9 CFR 309.1(a) and 311.27).

Off-line IPP verify that the establishment:

1. only slaughters livestock that have received ante-mortem inspection within the previous 24 hours;

2. does not slaughter livestock designated as "U.S. Suspect" without the presence of IPP; and

3. does not slaughter and chill in one day more animals than were inspected on ante-mortem inspection.

E. Emergency Slaughter

For livestock species other than cattle, if an establishment informs the PHV that it was necessary for it to slaughter an animal because of a serious injury at a time other than normal inspection hours (9 CFR 309.12), then the PHV is to:

1. determine post-mortem whether there is evidence of an injury present that rendered emergency slaughter necessary. PHVs are to condemn the entire carcass if there is no evidence of a condition that provides a valid reason for the emergency slaughter; and

2. assess the condition of the animal that underwent the emergency slaughter and make a disposition determination. PHVs are to condemn the entire carcass if he/she finds evidence of a lesion to indicate sickness or disease or any other condition requiring such disposition (9 CFR 311.27).

NOTE: FSIS does not permit emergency slaughter of cattle. IPP are to check all cattle before slaughter.

IX. DOCUMENTATION AND ENFORCEMENT

A. Identification System

IPP are to verify that the establishment has an animal identification system that accurately identifies each animal and establishes that IPP have performed ante-mortem inspection on that animal (9 CFR 307.2(a), 310.2(a)(b), and 320.1(b)(1)). An example is the pen card system.

B. Documentation

1. PHVs are to complete FSIS Form 6150-1, Identification Tag – Ante-mortem, for each animal identified as a "U.S. Suspect" or "U.S. Condemned" on ante-mortem inspection and file the form in the inspection office. IPP are to retain the form for one year.

2. Complete Form 6150-1, Identification Tag – Ante-mortem, by recording the following:

a. Slaughter at Est. No. – Indicate the official establishment number where the animal is to be slaughtered;

b. Condemn or Suspect Tag No. – Write in the tag number and cross out the not applicable "U.S. Condemned" or "U.S. Suspect;"

c. Kind of Animal – Species, breed, or class of animal (e.g., Hereford Bull, Hampshire gilt, and mixed breed ewe);

d. Sex;

e. Tagged For – Name of condition causing animal to be a suspect. Additional information may be included on the back of the form, write "see back of form" on the front when the back is used;

f. Temperature – Actual temperature of the animal (TB reactors and animals the PHV suspects may have an abnormal temperature);

g. Weight – Estimate the animal's weight in pounds;

h. Remarks – Brief description of ante-mortem findings that may aid post-mortem disposition. Also, record back tags and any other identifying numbers;

i. PHV Signature – A PHV is to sign the form when an animal is condemned;

j. Date – Current date; and

k. Post-mortem Report – Use of the Post-mortem Report section of the form is optional. The observations documented on the form should support the decision to tag the bovine as "U.S. Suspect," including any re-examinations of cattle. Attach FSIS Form 6150-1 to the associated FSIS Form 6200-14, Daily Disposition Record. Retain FSIS Form 6200-14 and, if attached, FSIS Form 6150-1, for one fiscal year.

3. Additional uses for FSIS Form 6150-1, Identification Tag – Ante-mortem, include:

a. For a TB reactor, use the reactor tag number instead of the "U.S. Suspect" tag number on line 2;

b. For epithelioma, actinobacillosis, and actinomycosis, include the number of animals in the lot on line 2 and state animals are "untagged".

NOTE: A separate FSIS Form 6150-1, Identification Tag – Ante-mortem is not necessary for each bovine with epithelioma of the eye, actinobacillosis, or actinomycosis. However, the PHV is to verify that the establishment segregates affected animals into a separate lot and is to record the condition and number of animals on the form. The establishment determines the size of the lot. PHVs are to record the condition (ocular squamous cell carcinoma, actinobacillosis, or actinomycosis) and the number of animals affected with each condition. PHVs are to use a separate form for each group of animals with a separate condition in a lot. When the animals are slaughtered, the PHV is to identify each animal individually with a multi-sectioned "U.S. Rejected – U. S. Retain" tag and record them as suspects on the Daily Disposition Record, FSIS Form 6200-14 (see FSIS Directive 6100.2, Post-mortem Livestock Inspection, Ch. IV. I. B. 2.). Under these circumstances the FSIS Form 6150-1 serves as the means to identify the group of animals with each condition.

c. PHVs are to complete FSIS Form 6150-1 for each "U.S. Condemned" animal, alive or dead. Mark through suspect and record the condemned tag number.

4. The PHV or designee is to record the appropriate ante-mortem information on the Daily Disposition Record, FSIS Form 6200-14, following the directions in FSIS Directive 6100.2, Post-mortem Livestock Inspection, Chapter IV; and

5. The PHV or designee is to complete Form 6200-16, Summary of Ante-mortem Examination, when directed to do so by the FLS. When the PHV has been directed to complete this form, he/she is to do so only on days of slaughter. IPP are to retain this form for one year. Complete the Summary of Ante-mortem Examination, FSIS Form 6200-16, by recording the following:

a. Date of last report of this species. This refers to the last date this species was slaughtered,

b. Establishment number,

c. Today's date,

d. Name of species inspected (use a separate FSIS Form 6200-16 for each species inspected on this date),

e. Number of animals passed for regular slaughter (does not include suspects),

f. Number of animals that were suspected on the previous day but not slaughtered,

g. Number of animals suspected today (include both tagged and handled as suspects),

h. Total of lines f and g,

i. Number of animals that were suspected today and the previous day but later released and not slaughtered as suspects,

j. Number of animals that died in the pens today and the previous day after being tagged as suspects from today and the previous day,

k. Number of suspect animals slaughtered on this date,

l. Total of lines i, j, and k,

m. Number of suspect animals that are not slaughtered and are being held as suspects from today and the previous day,

n. Number condemned on ante-mortem plus dead animals (do not include suspects that died in pens – they are reported on line j),

o. Write in "dead" or cause for condemnation and the number of animals disposed of in that category,

p. The first condemned tag number and the last condemned tag number used, and

q. The signature of IPP completing the report.

Refer questions regarding this directive to the Policy Development Division through askFSIS at http://askfsis.custhelp.com or by telephone at 1-800-233-3935.

Assistant Administrator
Office of Policy and Program Development

Attachment 1

PART 309--ANTE-MORTEM INSPECTION

1. The authority citation for part 309 is revised to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

2. Section 309.3(e) is revised to read as follows:

§. 309.3 Dead, dying, disabled, or diseased and similar livestock.

* * * * *

(e) Establishment personnel must notify FSIS inspection personnel when cattle become non-ambulatory disabled after passing ante-mortem inspection. Non-ambulatory disabled cattle that are offered for slaughter must be condemned and disposed of in accordance with § 309.13.

Exhibit 43

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

FSIS DIRECTIVE	6100.2	9/17/07

POST-MORTEM LIVESTOCK INSPECTION

CHAPTER I -- GENERAL

I. PURPOSE

The purpose of this directive is to provide instructions to the Food Safety and Inspection Service (FSIS) personnel on how to inspect livestock after slaughter (post-mortem). In addition, this directive officially cancels the Meat and Poultry Inspection Manual Subparts 9A and 9B (post-mortem livestock section). Inspection program personnel are no longer to use the Meat and Poultry Inspection Manual. This directive updates information from, and cancels, FSIS Directive 6200.1, Preparation and Submission of FSIS 6200 Form Series. Finally, this directive instructs Public Health Veterinarians (PHVs) on how to make dispositions for livestock post-mortem and how to document the findings.

Key Points Covered

- *Inspecting livestock post-mortem*
- *Making dispositions*
- *Documenting post-mortem findings*

II. CANCELLATIONS

Meat and Poultry Inspection Manual Subparts 9A and 9B, post-mortem livestock sections
FSIS Directive 6160.1, Inspection Procedure for Lamb
FSIS Directive 6200.1, Preparation and Submission of FSIS 6200 Form Series
FSIS Notice 41-06, Inspection of Ox Tails

III. RESERVED

IV. REFERENCES

Federal Meat Inspection Act (FMIA) 21 U.S.C. 604

Regulations 9 CFR 310, 311, 325 and 500.2
FSIS Directive 6000.1, Revision 1, Responsibilities Related to Foreign Animal Diseases (FADs) and Reportable Conditions

V. BACKGROUND

Inspection program personnel, under the Federal Meat Inspection Act (FMIA), examine and inspect carcasses post-mortem during the slaughter process. Inspection program personnel inspecting carcasses in establishments determine whether carcasses are wholesome and not adulterated. The FMIA requires that FSIS inspection program personnel inspect the carcasses and parts of carcasses. Product that is wholesome and not adulterated, and passes for human consumption, may bear the mark of inspection as provided by 21 U.S.C. 604 and 9 CFR 310.1(a). Identification and inspection of the carcass includes the head, tail, tongue, thymus gland, and all viscera of each animal slaughtered (9 CFR 310.2(a)).

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CHAPTER II -- POST-MORTEM INSPECTION

Inspection program personnel conduct post-mortem inspection in the following manner.

I. CATTLE

A. Heads

1. For Tongue-in head presentation, inspection program personnel are to:

a. observe the head's surfaces and eyes;

b. incise and observe the mandibular, parotid, medial, and lateral retropharyngeal lymph nodes;

c. incise and observe the lateral and medial masticatory muscles (cheeks) after tongue "dropping"; and

d. observe and palpate the tongue.

2. For Tongue-out – base-up head presentation, inspection program personnel are to:

a. incise the lymph nodes attached to the tongue including the medial and lateral retropharyngeal and the mandibular lymph nodes;

b. observe and palpate the tongue;

c. observe the head's surfaces and eyes; and

d. incise and observe the parotid lymph nodes and the lateral and medial masticatory muscles (cheeks).

3. For Tongue-out – base-down head presentation, inspection program personnel are to:

a. incise the lymph nodes attached to the tongue including the medial and lateral retropharyngeal and the mandibular lymph nodes;

b. observe and palpate the tongue;

c. observe the head's surfaces and eyes; and

d. incise and observe the parotid lymph nodes and the medial and lateral masticatory muscles (cheeks).

4. Inspection program personnel are to look for:

a. inflammation, exudate, swelling, or masses that indicate disease (9 CFR 310.1(a));

b. pathology or abnormal conditions in lymph nodes;

c. cysts or yellow, green, white, or red lesions in muscles;

d. parasites (e.g., cysticercosis, sarcocystosis) (9 CFR 311.21, 311.23, and 311.25);

e. sanitary dressing defects (e.g., hair, hide, ear canals, lips or horns, ingesta, bruises); and

f. identifiable specified risk materials (SRMs) (9 CFR 310.22) on edible portions of the product.

5. When inspection program personnel find heads showing signs of abnormalities or diseases that may affect the disposition of the carcass while performing post-mortem inspection, they are to:

a. retain the head, viscera, and carcass for veterinary disposition if the disease or condition is generalized, or when inspection program personnel have questions regarding disease conditions, abnormalities, or the appropriate disposition of the head (9 CFR 310.3 and 500.2). Inspection program personnel are to attach "retain" tags to carcasses and parts as soon as practical (9 CFR 310.4).

b. condemn abnormal or diseased tissue and verify that the establishment trims the affected tissues if the disease or condition of the head is localized. If inspection program personnel have any doubt or question as to whether the disease or condition is localized, they are to retain the head, viscera, and carcass for veterinary disposition.

6. When inspection program personnel find dressing defects (e.g., hair, hide, ear canals, lips, or horns), they are to verify that the defects are removed in a sanitary manner (9 CFR 310.18).

NOTE: If the establishment does not present heads, viscera, and carcasses that are free of dressing defects, then inspection program personnel are to verify that the establishment makes the product wholesome before passing the head, viscera, or carcass by stopping the line or else must condemn the product.

B. Viscera

When an establishment eviscerates carcasses into a viscera truck, inspection program personnel are to follow the sequence for "hindquarter inspection" to observe the eviscerated carcass, unless a rail inspector is performing rail inspection. If an establishment eviscerates carcasses onto a moving top table, inspection program personnel are to observe the eviscerated carcass.

1. Stomachs, Esophagus, and Spleen

a. Inspection program personnel are to:

i. observe the mesenteric lymph nodes and abdominal viscera;

ii. observe and palpate the rumino-reticular junction; and

iii. observe the esophagus and the spleen.

b. Inspection program personnel are to look for:

i. inflammation, exudate, swelling, or masses that indicate disease (CFR 310.1(a));

ii. pathology or abnormal conditions in lymph nodes;

iii. cysts or yellow, green, white, or red lesions in muscles of the esophagus;

iv. parasites (9 CFR 311.21, 311.23, and 311.25);

v. sanitary dressing defects (e.g., ingesta) (9 CFR 310.18); and

vi. identifiable SRMs (9 CFR 310.22) on edible portions of the product.

2. Pluck (heart and lungs)

a. Inspection program personnel are to:

i. incise and observe the lymph nodes associated with the lungs, including the mediastinal (posterior, middle, and anterior) and bronchial (right and left);

ii. observe and palpate the costal (pertaining to the ribs) surfaces (which appears curved) of the lungs ;

iii. observe the cut and inner surfaces, after incising the heart from base to apex or vice versa, through the interventricular septum; and

iv. turn the lungs over and observe the ventral (front) surfaces (which appears flat) and the heart's outer surface.

b. Inspection program personnel are to look for:

i. inflammation, exudate, swelling, or masses that indicate disease (CFR 310.1(a));

ii. pathology or abnormal conditions in lymph nodes;

iii. cysts or yellow, green, white, or red lesions in muscles;

iv. parasites, cysticercosis, sarcocystosis (9 CFR 311.21, 311.23, and 311.25); and

v. sanitary dressing defects (e.g., ingesta).

3. Liver

a. Inspection program personnel are to:

i. incise and observe the hepatic (portal) lymph nodes of the liver;

ii. open the bile duct in both directions and observe the contents for flukes;

iii. observe and palpate the liver's ventral surface; and

iv. turn the liver over, palpate the renal impression, and observe and palpate the parietal [dorsal (back)] surface.

b. Inspection program personnel are to look for:

i. inflammation, exudate, swelling, or masses that indicate disease (CFR 310.1(a));

ii. pathology or abnormal conditions in lymph nodes;

iii. parasites, especially liver flukes (distoma) (9 CFR 311.21-311.25);

iv. sanitary dressing defects (e.g., ingesta);

v. carotenosis which is a yellow-orange discoloration of the liver;

vi. cirrhosis where the liver degenerates and is replaced by hard, tough fibrous connective tissue;

vii. melanoma;

viii. sawdust, which is a pinkish-white to yellow-gray necrotic lesion seen in the liver; and

ix. telangiectasis where the liver has purple-red to bluish-black lesions.

4. When inspection program personnel find viscera showing signs of abnormalities or diseases while performing post-mortem inspection, they are to:

a. retain the viscera, head, and carcass for veterinary disposition if the disease or condition is generalized and affects the viscera, or when inspection program

personnel have questions regarding disease conditions, abnormalities, or the appropriate disposition of carcasses or parts (9 CFR 310.3). Inspection program personnel are to attach "retain" tags to carcasses and parts as soon as practical.

b. verify that the establishment trims the affected tissues if the disease or condition of the viscera is localized. If inspection program personnel have any doubt or question as to whether the disease or condition is localized, they are to retain the viscera, head, and carcass for veterinary disposition.

5. When inspection program personnel find dressing defects (e.g., ingesta), they are to verify that the defects are removed in a sanitary manner (9 CFR 310.18).

C. Carcasses

1. Hindquarter Inspection – Inspection program personnel use hindquarter inspection when the establishment combines viscera and carcass inspections.

Inspection program personnel are to:

a. observe the back of the skinned carcass during evisceration;

b. palpate the superficial inguinal, or supramammary, and internal iliac lymph nodes;

c. observe the body cavities

2. Forequarter Inspection – Inspection program personnel use forequarter inspection to complete the carcass inspection started under hindquarter inspection.

Inspection program personnel are to:

a. observe the cut surfaces of muscles and bones, the diaphragm's pillars, and the peritoneum;

b. observe and palpate the kidneys and the diaphragm;

c. observe the pleura, neck, and carcass exterior.

3. Complete Carcass Inspection – Inspection program personnel use complete carcass inspection when establishments use moving lines with separate carcass inspection stations.

Inspection program personnel are to:

a. palpate the superficial inguinal, or supramammary, and internal iliac lymph nodes;

b. observe the lumbar region;

c. observe and palpate the kidneys;

d. observe the cut surfaces of muscles and bones, the diaphragm's pillars, and the peritoneum;

e. observe and palpate the diaphragm; and

f. observe the pleura, cut surfaces of muscles, bones, neck, and the carcass exterior.

NOTE: Inspection program personnel are to observe all ox tails. Ox tails may be presented: (1) attached to the carcass before removing the tail at the rail inspection, (2) if previously removed, pinned to the carcass, at the rail inspection, (3) with the viscera on the viscera table, or (4) other means such as a moving tail chain.

4. Inspection program personnel are to look for:

a. inflammation, exudate, swelling, or masses that indicate disease (CFR 310.1(a));

b. pathology or abnormal conditions in lymph nodes;

c. cysts or yellow, green, white, or red lesions in muscles;

d. parasites (9 CFR 311.21, 311.23, and 311.25);

e. sanitary dressing defects (e.g., fecal material, urine, ingesta, bile, dirt, hair, milk, and foreign matter) (9 CFR 310.18); and

f. identifiable SRMs (9 CFR 310.22) on edible portions of the product.

5. When inspection program personnel find carcasses showing signs of abnormalities or diseases while performing post-mortem inspection, they are to:

a. retain the head, viscera, and carcass for veterinary disposition if the disease or condition is generalized and affects the majority of the carcass, or when inspection program personnel have questions regarding disease conditions, abnormalities, or the appropriate disposition of carcasses or parts (9 CFR 310.3). Inspection program personnel will attach "retain tags" to carcasses and parts as soon as practical.

b. condemn abnormal or diseased tissue and verify that the establishment trims the affected tissues, if the disease or condition of the carcass is localized. If inspection program personnel have any doubt or question as to whether the disease or condition is localized, they are to retain the head, viscera, and carcass for veterinary disposition.

6. When inspection program personnel find dressing defects (e.g., fecal material, urine, ingesta, bile, dirt, hair, and foreign matter), they are to verify that the defects are removed in a sanitary manner (9 CFR 310.18).

II. CALVES

Skinned Carcasses

A. Heads

1. Inspection program personnel are to:

a. observe the head's surfaces; and

b. incise and observe the medial retropharyngeal lymph nodes (both left and right).

2. Inspection program personnel are to follow Chapter II, I., A. 4., 5., and 6. for what to look for and the actions to take when inspecting the heads of calves post-mortem.

B. Viscera

1. Inspection program personnel are to:

a. observe and palpate the bronchial and mediastinal lymph nodes of the lungs, the costal (pertaining to the ribs) surfaces of the lungs (which appear curved), and the heart;

b. turn the lungs over and observe the ventral (front) surfaces (which appear flat);

c. observe the spleen;

d. observe and palpate the dorsal surface of the liver;

e. turn the liver over, observe the ventral surface, and palpate the portal lymph nodes; and

f. observe the stomach and intestines.

2. Inspection program personnel are to follow Chapter II, I., B. 1b., 2.b., 3.b., 4., and 5. for what to look for and the actions to take when inspecting the viscera of calves post-mortem.

C. Carcasses

1. Inspection program personnel are to:

a. observe the outer and cut surfaces of the carcass;

b. lift the forelegs and observe the neck and shoulders;

c. observe the body cavities; and

d. observe and palpate the internal iliac lymph nodes and kidneys.

2. Inspection program personnel are to follow Chapter II, I., C. 4., 5., and 6. for what to look for and the actions to take when inspecting the carcasses of calves post-mortem.

D. Hide-On Carcasses

1. Inspection program personnel are to:

a. observe the hide; and

b. palpate the back.

NOTE: After carcasses are cold-skinned in the cooler, inspection program personnel are to examine the carcasses for injection lesions, foreign bodies, parasites, bruises, or other pathology not detectable with the hide still on the carcass.

2. Inspection program personnel are to look for contamination or parasitic conditions (e.g., grubs and other abnormalities).

3. Inspection program personnel are to follow Chapter II, I., C. 4., 5., and 6. for what to look for and the actions to take when inspecting the carcasses of calves post-mortem.

E. Large Calves

Inspection program personnel perform inspection of large calves as described for cattle and are to follow Chapter II, I., A. 4., 5., and 6.; B. 1.b., 2.b., 3.b., 4., and 5.; C. 4., 5., and 6. for what to look for and the actions to take when inspecting calves post-mortem.

III. LAMBS

A. Viscera

The following procedures pertain to lamb carcasses only.

A young sheep or lamb (ovine) carcass meets the following criteria: written documentation that the ovine is less than 14 months of age or the presence of a break joint (epiphysis) of the distal metacarpal bone of either foreleg.

1. Inspection program personnel are to:

a. observe the abdominal viscera, esophagus, mesenteric lymph nodes, and omental fat;

b. observe the bile duct and contents and express the gall bladder;

c. observe and palpate the liver (both sides) and the costal (pertaining to the ribs) surfaces of the lungs (which appear curved);

NOTE: Finding tapeworms in the bile duct may indicate an infestation of tapeworms in the pancreatic gland. The establishment presents the liver with the bile duct incised.

d. palpate the bronchial and mediastinal lymph nodes;

e. observe the ventral surfaces of the lungs;

f. observe and palpate the heart; and

g. examine the pancreatic glands for wholesomeness if the establishment saves the gland for edible purposes.

2. Inspection program personnel are to follow Chapter II, I., B. 1b., 2.b., 3.b., 4., and 5. for what to look for and the actions to take when inspecting the viscera of lambs post-mortem, except for SRMs for BSE, since BSE is not an issue.

B. Carcasses-Heads

1. Inspection program personnel are to:

a. observe the outer surfaces of the carcass;

b. observe the pelvic, abdominal, and thoracic body cavities;

c. observe the spleen and kidneys; and

d. observe the neck, shoulders, and head.

2. Inspection program personnel are to follow Chapter II, I., A. 4., 5., and 6. and C. 4., 5., and 6. for what to look for when inspecting lamb heads-carcasses post-mortem, except for SRMs for BSE, since BSE is not an issue.

3. Inspection program personnel are to selectively palpate observed abnormalities and retain for veterinary disposition carcasses with abnormalities requiring incisions to make disposition determinations.

IV. SHEEP AND GOATS

A. Viscera

1. Inspection program personnel are to:

a. observe the abdominal viscera, esophagus, mesenteric lymph nodes, and omental fat;

b. express the gall bladder and observe the cut bile duct and expressed content for tapeworms;

c. observe and palpate the liver (both sides);

d. observe and palpate the costal (pertaining to the ribs) surfaces of the lungs (which appear curved);

e. palpate the bronchial and mediastinal lymph nodes;

f. observe the ventral surfaces of the lungs;

g. observe and palpate the heart; and

h. examine the pancreatic glands for wholesomeness if the establishment saves them for edible purposes.

NOTE: The establishment should present the liver with the bile duct incised.

2. Inspection program personnel are to follow Chapter II, I., B. 1b., 2.b., 3.b., 4., and 5. for what to look for and the actions to take when inspecting the viscera of sheep and goats post-mortem, except for SRMs for BSE, since BSE is not an issue.

B. Carcasses-Heads

1. Inspection program personnel are to:

a. observe the outer surfaces of the carcass and the body cavities (pelvic, abdominal, and thoracic) and the spleen;

b. observe and palpate the kidneys;

c. observe and palpate the prefemoral, superficial inguinal or supramammary, and popliteal lymph nodes;

d. palpate the back and sides of the carcass;

e. palpate the prescapular lymph nodes and shoulders; and

f. lift the forelegs and observe the neck, shoulders, and head.

2. Inspection program personnel are to follow Chapter II, I., A. 4., 5., and 6. and C. 4., 5., and 6. for what to look for when inspecting sheep and goats heads-carcasses post-mortem, except for SRMs for BSE, since BSE is not an issue.

C. Incising Lymph Nodes

Inspection program personnel are to incise the body lymph nodes whenever palpation is inadequate to determine the absence of abscesses indicating caseous lymphadenitis and are to leave the incised nodes attached to the carcass for final inspection.

V. SWINE

A. Heads

1. Inspection program personnel are to:

a. observe the head and cut surfaces;

b. incise and observe the mandibular lymph nodes; and

c. observe the carcass when required.

2. Inspection program personnel are to follow Chapter II, I., A. 4., 5., and 6. for what to look for and the actions to take when inspecting the heads of swine post-mortem, except for SRMs for BSE, since BSE is not an issue.

B. Viscera

1. Inspection program personnel are to:

a. observe the eviscerated carcass, viscera, and parietal (top) surface of the spleen;

b. observe and palpate the mesenteric lymph nodes;

c. palpate the portal lymph nodes;

d. observe the dorsal surfaces of the lungs and the mediastinal lymph nodes;

e. the bronchial lymph nodes; then,

f. turn the lungs over and observe the ventral surfaces of the lungs;

g. observe the heart and dorsal surface of the liver; and

h. turn the liver over and observe the ventral surface.

NOTE: Inspection program personnel are to observe the nongravid uteri and ovaries when saved for edible use.

2. Inspection program personnel are to follow Chapter II, I., B. 1b., 2.b., 3.b., 4., and 5. for what to look for and the actions to take when inspecting the viscera of swine post-mortem, except for SRMs for BSE, since BSE is not an issue.

C. Carcasses

1. Inspection program personnel are to:

a. observe the back of the carcass by looking in a mirror, or when a mirror is not present, by turning the carcass to observe the back of the carcass; and

b. observe the front parts and inside of the carcass; then grasp, turn, and observe both sides of the kidneys.

2. Inspection program personnel are to follow Chapter II, I., C. 4., 5., and 6. for what to look for when inspecting swine carcasses post-mortem, except for SRMs for BSE, since BSE is not an issue.

CHAPTER III -- MAKING DISPOSITIONS POST-MORTEM

PHVs play a critical role in ensuring that the public health is protected by appropriately identifying and addressing livestock affected with disease conditions and ensuring that there is an appropriate disposition of affected carcasses and parts. PHVs are to conduct a thorough and complete post-mortem examination of carcasses or parts that are held for their final examination. In making dispositions, the PHV should use a consistent, systematic approach for evaluating the carcass. For example, if a PHV starts the examination with the carcass, follows with the viscera, and ends with the head, then he or she should use this same method every time.

PHVs may seek diagnostic assistance from the pathology laboratory. PHVs are to consider the laboratory's report within the context of ante-mortem and post-mortem findings. For residues, PHVs are to make final dispositions based on the regulations (9 CFR 311.39) and whether a tissue is 1) in compliance either as residue not detected or positive but non-violative; or 2) noncompliant as residue detected at a violative level. For information on foreign animal diseases, PHVs are to refer to FSIS Directive 6000.1, Responsibilities Related to Foreign Animal Diseases (FADs) And Reportable Diseases.

I. REGULATORY ACTIONS

When PHVs find diseases and abnormalities, they are to:

1. examine all livestock carcasses showing abnormalities that inspection program personnel retain at post-mortem (9 CFR 310.3); and

2. examine and inspect all "U.S. Suspect" animals identified on ante-mortem inspection.

II. CORRELATING WITH THE TEAM

PHVs are to, during work unit meetings, meet with the inspection team as necessary to review pathology and regulatory requirements for addressing each condition (e.g., show, explain, discuss, and answer questions). PHVs may utilize "The Entry Training for the PHV" modules on Post-Mortem Inspection and Multi-Species Dispositions for correlating.

http://www.fsis.usda.gov/FSIS_Employees/Public_Health_Veterinarian/index.asp.

The following are specific disease conditions and the procedures PHVs are to follow to make carcass and parts dispositions. This section provides disposition information for livestock conditions taken from the discontinued Manual. PHVs may find other post-mortem disposition information in the "Entry Training for the PHV", Multi-Species Disposition and Post-mortem Inspection modules at the link below. PHVs are to use and follow the directions in this directive for dispositions.

http://www.fsis.usda.gov/FSIS_Employees/Public_Health_Veterinarian/index.asp.

III. CYSTICERCOSIS

A. Recognizing Cysticercosis

Cysticercosis is a condition caused by the presence of the larval form of the beef tapeworm, *Taenia saginata*, in the carcass tissues. Beef, pork, or sheep carcasses affected with cysticercosis will contain live, dead, or degenerated cysts in the heart, tongue, esophagus, or muscles. The live cyst will appear as a vesicle or small bladder (balloon) filled with fluid. In most cases, the cyst will be dead and degenerated to some extent and will appear as small foci (small localized bodily infection) of fibrotic (hard, thick) tissue that may or may not be calcified and gritty in texture. In addition to these lesions, the associated muscle tissue may be watery or discolored.

NOTE: Inspection program personnel will find information regarding shipment and control of products containing cysticercosis under 9 CFR 325.7.

B. Steps PHVs Follow for Beef Carcasses Retained for Cysticercosis

1. When a beef carcass is retained for cysticercosis, PHVs are to:

a. incise thoroughly the lateral and medial masticatory (cheek) muscles, heart, diaphragm, and its pillars. The peritoneum is removed before incising the diaphragm;

b. observe and palpate the tongue. If cysts are suspected in the muscular part, the tongue is thoroughly incised and observed; and

c. examine the esophagus and all exposed muscular surfaces.

2. When cysts in a carcass are in two or more of the above sites (Chapter III, III. B.1.), PHVs are to:

a. make one transverse cut in each shoulder (2-3 inches) above the olecranon's point. This cut is to extend to the humerus and expose the triceps brachii;

b. make one cut in each round to expose musculature in cross section; and

c. observe the cut surfaces for cysticercosis lesions.

C. Steps Inspection Program Personnel Follow for Beef Carcasses Infected with Cysticercosis

The presence of even one cyst, whether viable or not, indicates beef cysticercosis. When inspection program personnel find one beef carcass to contain a cyst, the following procedure is to be performed on all carcasses that the establishment receives from the same producer. Inspection program personnel are to verify that the establishment addresses all potentially affected product.

Inspection program personnel are to:

1. make multiple incisions of the interventricular septum of the heart and the external and internal masticatory (cheek) muscles;

2. observe closely the esophagus and cut surfaces of muscles exposed during the dressing operation; and

3. incise, as above, hearts and cheeks from carcasses that passed inspection before the finding of the infected carcass, and identified as part of the potentially affected production.

D. Disposition of Beef Carcasses with Cysticercosis

A carcass is extensively infested if PHVs find lesions in at least two of the usual inspection sites and two of the additional exposed sites.

1. The usual inspection sites are:

a. heart;

b. diaphragm and its pillars;

c. cheeks;

d. esophagus;

e. tongue; and

f. muscles exposed during normal dressing operations.

2. The additional exposed sites are:

a. an incision made into each round exposing the musculature in cross section; and

b. a transverse incision made into each forelimb commencing 2-3 inches above the joint of the olecranon and extending to the humerus exposing the triceps brachii.

3. PHVs are to:

a. condemn the carcass and its parts when lesions of cysticercosis are present, and the musculature is edematous or discolored; or if the infestation is extensive (9 CFR 311.23(a));

b. send samples to the FSIS laboratory in Athens, Georgia, to confirm the diagnosis, if necessary;

c. notify the Veterinarian-in-Charge, APHIS, Veterinary Services, of the State of the animal's origin, using VS Form 2-11;

d. notify the health department of the State of the animal's origin;

e. pass for refrigeration, or pass for heating after removal and condemnation of affected parts, any carcass with an infestation that is less than extensive and that does not show edema or discoloration in the musculature;

f. verify that the establishment:

i. holds carcasses for 10 days at not higher than 15° F;

ii. holds boned meat for 20 days at not higher than 15° F; or

iii. heats product to an internal temperature throughout of at least 140° F;

g. verify that the establishment handles edible offal in the same manner as the rest of the carcass. If edible product has lesions of cysticercosis, PHVs are to verify that the offal is condemned (9 CFR 311.23(b)); and

h. identify all products appropriately by "retain" tags. PHVs are to verify removal of "retain" tags only after the product has met the processing restrictions.

E. Steps PHVs Follow for Swine Affected with Cysticercosis (Tapeworm Cysts)

1. When inspection program personnel retain swine carcasses for cysticercosis on post-mortem inspection, PHVs are to:

a. examine the cheeks, heart, and esophagus by sight and numerous incisions;

b. make several deep longitudinal incisions into the tongue;

c. remove the peritoneum from the diaphragm and examine the muscles of the diaphragm by numerous incisions; and

d. carefully examine the cut surfaces of muscles exposed during regular dressing procedures (ventral muscles of the ham).

2. If, after performing the inspections as described in Chapter III, III. E. 1. a-d above, PHVs find:

a. only the initial lesions, they are to make the disposition based on these findings;

b. any additional lesions, they are to:

i. make incisions parallel to cuts as described in Chapter III, III. E. 1.d.; and

ii. remove the peritoneum from the abdominal muscles in the flank and paralumbar regions. Examine visually and then make several incisions to aid in the examination.

3. If PHVs find:

a. no additional lesions on findings through Chapter III, III. E. 2.b., they are to make the disposition based on these findings; or

b. additional lesions, they are to make deep, bold incisions into the heavily-muscled primal parts to determine if various parts of the musculature expose one or more cysts on most of the cut surfaces.

4. PHVs are to:

a. confirm the diagnosis of swine cysticercosis (*Cysticercus cellulosae*) or cases resembling such disease by sending samples to the Pathology Group of the FSIS Eastern Laboratory – Athens, Georgia. PHVs are to retain swine carcasses pending diagnostic results from the laboratory; and

b. follow the directions in FSIS Directive 6000.1, Revision 1, Responsibilities Related to Foreign Animal Diseases (FADs) and Conditions, for reporting diseases.

F. Disposition of Swine Carcasses with Cysticercosis

PHVs are to:

1. condemn the carcass when porcine cysticercosis infestation is excessive (when the lesions are too extensive to be removed by trimming the carcass);

2. pass for cooking, any swine carcass affected with *Cysticercus cellulosae* that is less than excessively affected;

3. verify that the carcass is cooked at 170° F for 30 minutes after removal and condemnation of all affected areas; and

4. verify removal of "retain" tags only after the product has met the processing restrictions in 9 CFR 311.24.

G. When *Cysticercus ovis* Affects Sheep Carcasses, PHVs Are To Perform the Following Procedures

1. When inspection program personnel detect cysticercosis in sheep carcasses during routine post-mortem inspection procedures, PHVs are to:

a. re-examine the heart and esophagus by sight and palpation;

b. palpate the muscles of the diaphragm; and

c. examine carefully the cut surface of muscles exposed during regular dressing procedures (ventral muscles of the neck and brisket and medial muscles of the leg).

2. If PHVs find:

a. only the initial lesions, as described in Chapter III, III. G. 1., they are to make the disposition based on these findings;

b. additional lesions, they are to:

i. make incisions parallel to the cuts as described in Chapter III, III. G. 1.c.; and

ii. remove the peritoneum from the abdominal muscles in the flank and paralumbar regions. PHVs are to examine visually and then make several incisions to aid in the examination;

c. no additional lesions, they are to make the disposition based on the findings as described in Chapter III, III. G. 2.b.; or

d. additional lesions, they are to make deep bold incisions into the heavily-muscled primal parts to determine if various parts of the musculature expose one or more cysts on most of the cut surfaces.

H. Disposition of Sheep Carcasses Affected with *Cysticercus ovis*

PHVs are to:

1. condemn the carcass if complete removal of the infection is impractical because of the extent of the infection;

2. pass the carcass for heating to an internal temperature of 140° F after trimming and condemning affected tissue where:

a. there are more than five cysts in the tissues, excluding the heart; and

b. removing the parasites from the affected tissue is practical; and

3. pass the carcass for human food after trimming and condemning affected tissues when PHVs find five or fewer cysts in the tissues, excluding the heart (9 CFR 311.25).

IV. EOSINOPHILIC MYOSITIS (EM)

A. Recognizing EM

The most common lesions of EM are the irregularly distributed yellowish-green, yellowish-white, and red spindle-shaped lesions found in the heart and tongue. Less common lesions are the large, well-defined, bright green to greenish-gray areas found in the more active muscles (e.g., round, shoulder, esophagus, heart, and brisket). Inspection program personnel may not notice the lesions until the carcass is broken into primal parts. PHVs will most readily detect EM in warm carcasses. Chilling causes muscle to contract and reduces the size and visibility of lesions present. In most cases, EM affects the more active muscles first and affects them more severely than other muscles.

B. Steps PHVs Follow for Carcasses with EM

When inspection program personnel find EM on post-mortem inspection, PHVs are to:

1. thoroughly incise and observe the lateral and medial masticatory muscles and the heart;

2. observe and palpate the esophagus;

3. make several deep longitudinal incisions into the tongue;

4. thoroughly incise and observe the diaphragm and pillars after removal of the peritoneum; and

5. observe the cut surfaces of muscles exposed during dressing operations (ventral muscles of the neck, the brisket, and the medial muscles of round).

6. make several parallel incisions to all such cut surfaces when lesions are in any of the locations as described in Chapter III, IV. B. 5.;

7. incise thoroughly and observe abdominal muscles in the flank and paralumbar region; and

8. slash freely and examine closely the affected primal parts exposed during the above procedures if PHVs find any lesions in those areas.

C. Disposition of Carcasses Affected with EM

PHVs are to:

1. condemn affected parts when localized lesions are present and only certain parts are affected (head, tongue, heart, esophagus, diaphragm, and pillars);

2. follow the disposition requirements in the regulations when carcass muscles other than the diaphragm and pillars are affected;

3. condemn the carcass if lesions in the musculature of the carcass are extensive and impractical to remove; and

4. pass the carcass for comminuted cooked product when lesions are slight, or the establishment personnel cannot remove the lesions easily and completely. This outcome may occur if the lesions are slight or of such character as to be insignificant from a standpoint of wholesomeness. PHVs are to pass the carcass or parts for use in the manufacture of comminuted cooked product after removal and condemnation of the visibly affected portions (9 CFR 311.35).

NOTE: A carcass condemned for EM is eligible for shipment for animal food (pet food) if: (1) the Front-line Supervisor (FLS) grants permission, and (2) the establishment adequately identifies, slashes freely, and denatures (9 CFR 325.11 and 325.13(a)(2)) all parts of the carcass in an inedible area under FSIS supervision.

V. SARCOCYSTOSIS

A. Recognizing Sarcocystosis

Sarcocystosis is caused by specific protozoans not considered pathogenic for humans in the United States. Sarcocystosis is most frequently seen in older sheep. Inspection program personnel may detect the lesions in the esophagus first. Lesions are white, semi-oval, cigar-shaped, or rice grain-shaped lesions. Inspection program personnel may also detect lesions in the diaphragm, skin muscles, internal abdominal

(stomach) muscles, or intracostal (muscles between the ribs) muscles. PHVs may find the lesions in the skeletal muscles, after incision and observation of primal parts.

B. Steps PHVs Follow for Carcasses with Sarcocystosis

1. When inspection program personnel detect sarcocystosis during routine post-mortem inspection procedures, PHVs are to re-examine the esophagus, superficial and cut surfaces of the muscles, diaphragm, and the internal abdominal and intercostal muscles.

2. If PHVs find lesions in locations other than the esophagus, they are to incise the muscles of the shoulder, round, and back to expose the deep muscle tissues.

3. PHVs are to condemn the carcass if the lesions are impractical to remove (9 CFR 311.35).

NOTE: A carcass condemned for sarcocystosis is eligible for shipment for animal food (pet food) by the establishment when: (1) the FLS grants permission, and (2) under FSIS supervision, the establishment identifies, slashes freely, and denatures (9 CFR 325.11 and 325.13(a)(2)) all parts of the carcass in an inedible area.

VI. EPITHELIOMA OF THE EYE

A. Recognizing Epithelioma of the Eye

Epithelioma is a neoplastic (cancerous) lesion involving the eye and surrounding tissues. Metastasis (disease spreads to different parts of the body) may occur to the lymph nodes and lungs. Infection, suppuration (the formation of pus), and necrosis (death or rotting of tissues) of the tissues around the eye may also occur.

B. Disposition of Epithelioma of the Eye

Absence of an eye or associated structure in mature cattle may indicate prior surgical removal of epithelioma. PHVs are to:

1. condemn the head of such carcasses; and

2. condemn the head, viscera, and carcass if they find metastatic lesions, cachexia or evidence of absorption or secondary changes, or involvement of the osseous (bony) structures of the head with extensive infection, suppuration, and necrosis (9 CFR 311.12).

VII. MELANOSIS

A. Recognizing Melanosis

Melanin is a normal black pigment of the body. Melanosis is excessive melanin deposits or deposits in abnormal locations.

B. Disposition of Carcasses with Melanosis

PHVs are to:

1. condemn carcasses with generalized pigmentary deposits of melanin (9 CFR 311.13);

2. condemn affected carcasses, organs, or parts when the establishment cannot remove melanin completely; when its removal is impractical; or, when it makes a carcass, organ, or part unfit for people to eat;

3. remove melanin deposits when they extend into spinal nerve sheaths and meat; however, slight melanin deposits in spinal meninges are insignificant;

4. remove only tumorous or smeary uniform melanin deposits over or in circumscribed skin areas of swine; and

5. record melanin deposits under pigmentary conditions on FSIS Form 6200-14, except record melanin deposits under carcinoma when they are associated with malignant tumor formation.

VIII. XANTHOSIS

A. Recognizing Xanthosis

Xanthosis is the deposition of excessive quantities of cellular waste pigments. The condition is usually seen in older cattle and those suffering from a chronic wasting disease. PHVs will only find Xanthosis during post-mortem inspection. Xanthosis more commonly affects the musculature of the heart and head. Affected muscle has dark brown or coffee-colored discoloration of otherwise normal tissue.

B. Disposition of Carcasses with Xanthosis

PHVs are to:

1. condemn carcasses with generalized pigmentary deposits; or

2. pass for food carcasses with less than generalized distribution of pigmentary deposits after condemnation and removal of the affected areas (9 CFR 311.13).

IX. CAROTENOSIS

A. Recognizing Carotenosis

Carotenoid pigments enter the body with food. Therefore, they are classified with the exogenous pigments. When carotenoid pigments are deposited in the fat tissues and liver to the extent they become grossly visible, the resulting discoloration of tissues is carotenosis. To determine carotenosis, place a white paper towel or napkin on the

cut surface of the liver. A bronze-orange stain indicates carotenoid pigment. Deposition of carotenoid pigments in the fatty tissue does not affect carcass disposition.

B. Disposition of Carcasses with Carotenosis

Inspection program personnel are to condemn livers with carotenosis (9 CFR 311.13).

X. ICTERUS

A. Recognizing Icterus

If, for any reason, the amount of bilirubin (waste product that results from the breakdown of hemoglobin molecules from worn out red blood cells) increases in the blood and therefore in the tissues, a yellowish pigmentation of the tissues arises that is called icterus or jaundice. Look for icterus where the tissues are normally very white or pale, such as (1) the sclera (white part) of the eye, (2) tendons, (3) pleura (lining of the chest cavity), (4) peritoneum (lining of the abdominal cavity), (5) omentum (tissue that extends from the stomach to the adjacent organs in the abdominal cavity), (6) cut surface of abdominal wall fat, (7) joint surfaces, or (8) mesentery (fold of tissue attaching small intestines to the body wall). Fat may be yellow from diet, breed, and age changes that are essentially normal. Yellow fat is normal in some animals.

B. Disposition of Carcasses Showing Signs of Icterus

PHVs are to:

1. defer final disposition of carcasses with a slight yellow discoloration and no visible pathological changes in the organs until the establishment has the opportunity to chill the carcasses; then

a. PHVs are to re-examine the carcasses preferably under natural light or a good quality light of at least 50 footcandles and make a disposition; and

b. pass the carcass for food if the discoloration disappears, and there are no other conditions warranting a different disposition.

2. condemn carcasses showing any degree of icterus including either:

a. a parenchymatous degeneration of organs, as the result of infection or intoxication; or

b. showing pronounced yellow or greenish yellow discoloration without evidence of infection or intoxication (9 CFR 311.19).

XI. NEUROFIBROMA (NERVE SHEATH TUMOR)

A. Recognizing Neurofibroma

Neurofibroma is a neoplasia of nerve sheath cells most often seen in cattle. Neurofibromas are found along any nerve trunk of the carcass but are most often found in the intercostals (between the ribs) and paravertebral spaces [beside the spinal (back) bones], heart, brachial plexus (network of nerves located between the shoulder and neck), and celiac plexus (network of nerves located behind the stomach and below the diaphragm). They may be seen as multiple nodular enlargements along any nerve. Neurofibromas are generally regarded as benign but may metastasize to regional lymph nodes. Neurofibromas are often seen in multiple sites because of multicentric origin of neoplasms. The tumors may be firm or soft and often have gelatinous centers and appear as shiny, glistening, white-to-gray, lobulated, firm nodular growths on or within the nerve.

B. Disposition of Carcasses with Neurofibroma

PHVs are to:

1. examine the brachial and celiac plexus for lesions when inspection program personnel find neurofibromas when performing post-mortem inspection;

2. condemn an individual organ or part of a carcass affected with a neoplasm; and

3. condemn the entire carcass if there is evidence of metastasis, or that the general condition of the animal has been adversely affected by the size, position, or nature of the neoplasm (9 CFR 311.11).

XII. ARTHRITIS

Disposition of Carcasses with Arthritis

PHVs are to:

1. condemn joints affected with arthritis;

2. verify removal of lymph nodes corresponding with affected joints;

3. verify that the establishment does not open joint capsules until after they remove affected joints; and

4. condemn the carcass if systemic involvement is present (9 CFR 311.7).

XIII. OTHER DISEASE CONDITIONS

A. Slight Abscesses in Cattle and Swine

When PHVs find slight abscesses in cattle and swine heads, they are to:

1. pass the head for food after removal of the lymph node when a small, well-encapsulated abscess is in a cervical lymph node; and

2. verify removal of all affected lymph nodes, including mandibular and adjacent lymph nodes, when heads with slight abscesses are passed for food (9 CFR 311.14).

B. Chronic Lesions

If PHVs observe chronic lesions that do not create a generalized condition in the carcass when conducting post-mortem dispositions, they are to verify complete removal of all chronic lesions, including adhesions (9 CFR 311.14).

CHAPTER IV -- DOCUMENTING POST- MORTEM INSPECTION FOR LIVESTOCK

PHVs are to document findings in the following manner:

I. COMPLETING THE DAILY DISPOSITION RECORD, FSIS FORM 6200-14

PHVs are to:

A. Provide the date, establishment number, and species.

B. Record the post-mortem carcass disposition by recording:

1. the "U.S. Suspect" tag number for all "U.S. Suspects" identified on ante-mortem inspection;

2. the multi-sectioned "U.S. Rejected - U.S. Retained" tag number across both columns for untagged "U.S. Suspects" on ante-mortem inspection (see FSIS Directive 6100.1, Inspecting Livestock Ante-mortem, VIII B Note); and

3. the name of the disease or condition (diagnosis) and a description of the lesions and their extent in the narrative section. If the exact diagnosis or disposition is not listed, choose the code number that best classifies the diagnosis or use the general miscellaneous classification. The obligation to assign a code number compatible with data processing needs should not influence the Inspector-in-Charge's diagnosis or narrative description. In addition:

a. for tuberculosis or caseous lymphadenitis, use the key at the top of the form to describe the location and extent of lesions in lieu of the word "descriptions;" and

b. for carcasses in which multiple conditions are present, PHVs are to record the following:

i. the code for the primary condition if the conditions are related. For example, for a carcass with ocular squamous cell carcinoma and associated cachexia, describe the eye lesions and the cachexia in the narrative but record only code 169 (carcinoma); and

ii. the code for each condition if the conditions are unrelated. If the carcass was condemned or passed with restriction, enter only the code for the primary condition in the narrative section and tally the other conditions found in the "Unlisted Tags . . ." section. For example, if a carcass that was condemned for extensive ocular squamous cell carcinoma also has a leg fracture, enter code 169 in the narrative section and tally one code 183 (injury) in the "Unlisted Tags . . ." section.

NOTE: PHVs are to report a carcass as condemned only once. PHVs are to only use the residue condemn category for carcasses identified as "U.S. Condemned" for positive residue results. PHVs are not to use the residue condemn category to record collecting a residue sample.

4. for carcasses retained pending laboratory findings, the statement "retained pending laboratory findings" is to be added in the narrative section.

a. PHVs are to write in "see 6-35" for carcasses retained for suspected nonreactor tuberculosis and lesions submitted to the Veterinary Services Laboratory;

b. PHVs are to leave blank the disposition and code number blocks; and

c. On the day PHVs receive the findings from the laboratory, PHVs are to:

i. repeat 2. and 3. above;

ii. mark the appropriate disposition block;

iii. enter the disease code number; and

iv. enter the class code number.

C. Record diseases observed during inspection that are untagged (e.g., abscesses, pneumonia, and arthritis) under the Unlisted Retain Tags, Nonsuspects passed without restriction section, by entering:

1. the tally of each disease or condition entered in the appropriate block in the "Unlisted Tags . . ." section. PHVs are to use the blank blocks in this section on the form not already preprinted with disease conditions, as needed;

2. the class, if the establishment slaughters more than one class within a species on a given day; and

3. the total of each block at the end of the day. PHVs are to include findings of all inspection program personnel.

NOTE: PHVs are to record disease conditions observed by all inspection program personnel, including diseases or conditions from carcasses that inspection program personnel on-line pass without restriction. This information, once entered into the Electronic Animal Disposition Report System (eADRS), gives information about the

prevalence of disease conditions observed in slaughtered livestock. The Agency can use this information to support risk-based inspection decisions and to identify local or national trends in animal diseases.

D. Record the total number of animals condemned on ante-mortem for each cause in the appropriate block.

1. if animals are condemned for reasons not found in this section, write the new condition and its code number in a blank space provided;

2. make only one entry per condemned animal; and

3. record entries in the section "Ante-Mortem Condemned" by class if the establishment slaughters more than one class within a given species on a given day.

E. Complete, as soon as possible after the carcass disposition, FSIS Form 6200-14 to document the disposition actions on retained carcasses and provide the primary information for eADRS. Prepare the form each day for each species.

F. Sign the FSIS Form 6200-14. However, a designated inspector may sign the form in the absence of the PHV. Maintain the form in the inspection file for one fiscal year.

G. Enter the data in the eADRS using the information from the above forms and following the directions in the eADRS User Guide. The eADRS reports most of the information about animals the establishment presents for slaughter, including the number of animals slaughtered daily in each shift and the total animal dispositions in slaughter establishments under Federal or Talmadge-Aiken inspection authority.

II. COMPLETING THE CERTIFICATE OF ANTE-MORTEM OR POST-MORTEM DISPOSITION OF TAGGED ANIMALS, FSIS FORM 6000-13

A. PHVs are to prepare this form for establishment management if requested. FSIS Form 6000-13 is an accountable item. The certificate is void if it contains any erasures or alterations.

B. To complete the form, PHVs are to record:

1. the district number;

2. the establishment name;

3. the establishment number;

4. the date of the disposition;

5. the species;

6. the "U.S. Rejected - U.S. Retained" tag number used on the FSIS Form 6200-14 on the day of condemnation for post-mortem cases;

7. the "U.S. Condemned" tag number from FSIS Form 6150-1, Identification Tag – Ante-Mortem, for ante-mortem cases;

8. any other ear tags, backtags, and other identifying devices affixed to the animal;

9. the diagnosis made on the day of slaughter on the FSIS Form 6200-14, or the diagnosis on the FSIS Form 6150-1 in ante-mortem cases; and

NOTE: If establishments elect to humanely euthanize non-ambulatory disabled cattle, PHVs are to write "non-ambulatory (USDA condemned)" in the "Diagnosis/Condition" column of FSIS Form 6000-13.

10. the word "condemned" for each "U.S. Retained" or "U.S. Condemned" entry.

C. After completing the form, PHVs are to:

1. sign the form and enter the date;

2. make certain that all unused spaces are lined or crossed out;

3. give the original to establishment management; and

4. file the copy in the inspection office.

For technical questions, contact the Policy Development Division (formerly the Technical Service Center) at 1-800-233-3935.

Assistant Administrator
Office of Policy, Program, and Employee Development

Exhibit 44

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

FSIS DIRECTIVE	10,800.1	7/12/07

PROCEDURES FOR RESIDUE SAMPLING, TESTING, AND OTHER RESPONSIBILITIES FOR THE NATIONAL RESIDUE PROGRAM

CHAPTER ONE – GENERAL

I. PURPOSE

This directive instructs inspection program personnel about how to perform residue sampling, testing, and verification procedures in accordance with the National Residue Program (NRP). This directive also:

- emphasizes the important role inspection program personnel have in the initial steps leading to the detection and control of residues in the nation's meat, poultry, and egg products;
- revises and combines instructions from previous FSIS directives;
- focuses on animal identification;
- familiarizes inspection program personnel with the detection of implants; and
- addresses the monitoring and receipt of laboratory results through LEARN.

II. CANCELLATIONS

FSIS Directives 8150.1; 10,001.1; 10,012.1; 10,100.1; 10,110.1; 10,130.1; 10,530.1; 10,600.2; and 10,620.1.

III. RESERVED

IV. REFERENCES

Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), Egg Products Inspection Act (EPIA), 9 CFR 300 to end, 417.3(a) and (b); FSIS Directives 5000.1; 5420.2; 7355.1; 10,200.1;10,210.1; 10,220.1; 10,220.3.

V. BACKGROUND

The Food Safety and Inspection Service (FSIS) works with the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) to accomplish its responsibilities under the National Residue Program. FSIS's primary mission under the NRP is to verify that establishments control animal drug residues, pesticides, environmental contaminants, and any other chemical hazards in and on meat, poultry, and egg products. The NRP also provides for the collection of national data on the occurrence of residues to support risk assessment, enforcement, and educational activities.

CHAPTER TWO – PROGRAM AREAS AND DUTIES

I. SPECIFIC PROGRAM RESPONSIBILITIES

A. Office of Public Health and Science (OPHS)

OPHS is the lead program area in the development and implementation of the FSIS NRP in that it provides scientific guidance in the planning, testing, and data analysis done for the program. OPHS also works in conjunction with the Technical Service Center (TSC), Office of Policy, Program, and Employee Development (OPPED), to respond to the Office of Field Operation's (OFO) questions and requests pertaining to the NRP.

Two components of OPHS play key roles in FSIS' residue program:

1. Residue Branch, Zoonotic Diseases and Residue Surveillance Division (ZDRSD):

a. Receives, evaluates, and provides residue-related information and scientific support to OFO, the Office of International Affairs (OIA), and OPPED regarding procedures and training for residue control activities.

b. Publishes the "FSIS National Residue Program Scheduled Sampling Plans" (Blue Book) and manages the publication and issuance of scheduled sample forms to OFO.

c. Summarizes the residue data published annually in the "FSIS National Residue Program Data" (Red Book).

2. FSIS's three laboratories:

a. Conduct laboratory tests and provide the results of those tests in accordance with Agency objectives and guidelines.

b. Assess and provide necessary modifications to laboratory methodologies in support of scheduled, inspector-generated, and other residue-related sampling.

B. Office of Field Operations (OFO)

1. Public Health Veterinarian/Inspector-in-Charge (PHV/IIC):

a. Identifies animals at ante-mortem inspection as suspect for residue testing.

PHVs are to handle animals for slaughter with known violative residue levels in accordance with 9 CFR 309.16.

b. Retains and tests carcasses with all pathologies and conditions listed in Section VI of FSIS Directive 10,220.3. If the in-plant screening test is positive, the PHV is to continue to retain the carcass and parts and submit tissue samples to the appropriate FSIS laboratory.

c. Understands how the establishment addresses residue control in its HACCP system.

d. Manages the duty station to ensure that it has proper equipment needed for the effective collection of samples and performance of in-plant tests and maintains adequate control of supplies, incubators, and other equipment.

e. Verifies that Consumer Safety Inspectors (CSIs) have been trained in residue testing sample submission procedures and in the appropriate identification of carcasses or products suspect for violative residues on post-mortem inspection.

f. Accurately completes FSIS Residue Sample Forms 10,000.2 and 10,210-3 in legible black ink and records the carcass owner's name, address, and other identifying information on the forms. See the Fast Antimicrobial Screen Test (FAST) and Swab Test on Premises (STOP) guidelines at the following link:

http://www.fsis.usda.gov/Science/Chemistry/index.asp

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g. Selects through random animal selection under the NRP surveillance program, carcasses or parts for testing to detect violators, and ensures proper handling, labeling, processing, sealing, and shipping of the samples to avoid discard of any samples.

h. Tracks the status of the sample and determines carcass/part disposition by reviewing LEARN.

i. Documents noncompliance.

2. Frontline Supervisor/Multi In-Plant Performance System Assignment:

a. Evaluates and assesses in-plant residue control performance of PHV or inspection program personnel.

b. Evaluates and assesses in-plant staffing needs, sets priorities to

ensure that an adequate residue control system is in place, and provides feedback to the PHV.

c. Maintains current information on the NRP and apprises inspection program personnel of any program changes in a timely manner.

d. Operates in conjunction with the District Office (DO) to ensure uniform and consistent implementation of the NRP.

3. District Office:

a. Receives notification of residue violations and violators from LEARN and the TSC through the Residue Violator Information System (RVIS).

b. Coordinates residue-related activities and disseminates residue information to field personnel on an as-needed basis and operates in conjunction with the TSC when special sampling situations arise.

c. Cooperates with residue violation investigations that may involve FSIS, FDA, and EPA.

d. Cooperates with and aids the TSC in trace-back activities that may require contacting auction houses, brokers, establishments, or PHVs in order to obtain information that the TSC needs for residue management efforts.

e. Ensures that OFO staff and inspection program personnel enroll in appropriate training necessary to carry out NRP responsibilities.

f. Evaluates the performance of field personnel to ensure uniform and consistent implementation of the NRP.

g. Verifies, through RVIS, the degree and level of application of various residue-related activities conducted at the in-plant level by interpreting and analyzing operational reports, data, and other information to effect corrective actions in situations where the program failed.

h. May receive information from the TSC and OFO Headquarters relating to field residue violations that require increased in-plant testing by the PHV.

C. OPPED, Technical Service Center

The Technical Service Center coordinates residue violator activities and the dissemination of residue-related information among FSIS, FDA, and EPA in accordance with the existing Memorandum of Understanding (MOU). The TSC uses RVIS to manage violation cases. Case management includes communication with FSIS field

personnel, FSIS District Offices, FDA Districts, State officials, and the owners and establishment officials responsible for violations. The TSC also provides correlation as requested by OFO on residue results reported in LEARN, inclusive of carcass or part disposition.

CHAPTER THREE – ANIMAL IDENTIFICATION AND DETECTION OF IMPLANTS

I. ANIMAL IDENTIFICATION VERIFICATION AND ENFORCEMENT ACTIVITIES WHEN ESTABLISHMENTS FAIL TO COLLECT AND MAINTAIN ANIMAL INDENTIFICATION

Inspection program personnel are to verify that all animal identification devices remain associated with the carcass until FSIS completes the post-mortem examination.

A. FSIS verification activities:

1. Inspection program personnel are to verify that the establishment is collecting and maintaining animal identification until the completion of post-mortem inspection in accordance with 9 CFR 310.2.

2. Inspection program personnel are to collect all animal and owner identification from the establishment when they submit a sample for residue testing (e.g., livestock market or sale barn back tags, producer ear tags, feedlot identification tags, Canadian tags, and calf-hood tags [bangs]). (See: 9 CFR 309.16, 309.17, 310.2, 310.3, 310.21, , and 320.1 and FSIS Directive 10,220.3).

B. FSIS enforcement activities:

Inspection program personnel are to prepare a noncompliance record (NR) when the establishment fails to comply with the FSIS's regulations that apply to the identification, holding, and sampling of carcasses and parts for drug residues (9 CFR 309.16, 310.2, 310.3, 310.4, or 310.21, 310.23, and 320.1). NRs are to include a citation of the applicable regulation and the procedure code 06D02, and document "product, facilities" as the trend indicator.

II. VERIFICATION OF IMPLANT USAGE IN PRE-RUMINANT CALVES

A. PHVs are to condemn any pre-ruminant calf presented for slaughter that has an implant or evidence of implant use. PHVs do not need to collect tissue samples when there is an actual implant present.

B. Ante-mortem verification activities in pre-ruminant calves:

1. During ante-mortem inspection of pre-ruminant calves whose meat is to be labeled as "veal," inspection program personnel are to determine whether the animal has an implant.

2. Signs that an implant has been used are:

a. palpable implant;

b. missing ears;

c. ears with incisions indicating recent surgery;

d. mutilated ears;

e. atrophied testicles; or

f. unusually heavy muscle development.

3. If any of the above signs are present in a calf, inspection program personnel are to retain the animal and tag it as "U.S. Suspect." Inspection program personnel are to use their professional judgment to determine when the entire lot (i.e., all calves) from the same producer should be tagged "U.S. Suspect."

C. Post-mortem verification activities in pre-ruminant calves:

1. Inspection program personnel are to palpate the ears of the "U.S. Suspect" carcasses for implants. Inspection program personnel are to consult with their supervisor concerning adjustments in line speed that may be necessary to complete the inspection procedure.

NOTE: If necessary, the establishment may remove ears prior to hide removal, place them in a plastic bag, and attach the bag to the carcass. The establishment can also remove the ears when skinning the head and present them for review in a manner acceptable to the PHV.

2. If an implant is present, inspection program personnel will feel a linear, firm swelling under the skin when palpating the ear. The implant may feel like "beads on a string." The individual pellets that make up the implant are approximately 3 mm in size and about 2 mm apart.

3. Inspection program personnel are to retain the carcass of "U.S. Suspect" calves showing signs of having implants at ante-mortem inspection for the PHV to examine.

4. The PHV is to examine the rumen of the retained carcass to determine whether the rumen was functioning.

a. The PHV may pass the carcass for human food if the animal had a functioning rumen, and the carcass is not subject to condemnation under 9 CFR Part 311 because of the presence of disease.

b. The PHV is to condemn the carcass if the rumen was not functioning (pre-ruminant), and the animal had:

i. an implant; or

ii. missing ears, ears with incisions that indicate recent surgery, or mutilated ears to the extent that the PHV is unable to determine whether an implant was present. In the absence of the ear, the PHV cannot pass the carcass because there is no basis to find that it is not adulterated, and the PHV is to condemn the carcass.

5. If the PHV determines that a calf had an implant and a non-functioning rumen, he or she is to verify, using procedure code 03J, that the establishment takes the appropriate actions under 9 CFR 417.3(a) or 417.3(b).

6. If the establishment fails to take appropriate corrective actions, the PHV is to issue an NR and take the appropriate enforcement action as set out in FSIS Directive 5000.1, Revision 2, Amendment 1.

CHAPTER FOUR - PROCEDURES FOR SAMPLE COLLECTION AND TESTING

I. TISSUE SAMPLE COLLECTION AND TESTING FOR RESIDUES

There are two basic types of residue sampling: Scheduled Sampling on FSIS Form 10,210.3 and Inspector Generated Sampling on FSIS Form 10,000.2.

A. Scheduled Samples (FSIS Form 10,210.3)

1. Inspection program personnel will receive FSIS Form 10,210.3 from OPHS **with** all necessary information needed to collect scheduled samples. The form indicates:

a. when to take the sample;

b. what tissues to collect;

c. what slaughter class to sample; and

d. which FSIS laboratory is to receive the samples. (See FSIS Directive 10,210.1., Amendment 1)

NOTE: When one laboratory cannot conduct all the indicated analyses, inspection program personnel may need to collect split samples (i.e., the collection of extra tissue) and send samples to two or more FSIS laboratories. Inspection program personnel cannot make a disposition until all results from the split samples are in LEARN. For questions on split samples, contact the TSC at: 1-800-233-3935.

2. Inspection program personnel are to notify the appropriate plant official when they collect a sample and are to give the plant official the flyer "Residue Scheduled Sample Information," which the laboratories provide in the sample box.

3. FSIS inspection program personnel should inform the establishment that the Agency recommends that industry hold these scheduled sample carcasses until FSIS reports the results to prevent a recall if the laboratory detects a residue as a violative level.

4. Once the plant makes a decision on whether it will hold the product, inspection program personnel are to document the decision by recording it in action block 22 on FSIS Form 10,210-3.

B. Inspector-Generated Samples

1. Inspection program personnel are to collect tissue samples every time there is reason to suspect that a violative residue is present.

NOTE: There are no exceptions to this direction. Inspection program personnel are to take a sample of any tissue that they believe may contain a violative level of a chemical residue.

2. The PHV is to conduct rapid, in-plant screening tests on any carcass that, based on herd history or ante-mortem or post-mortem inspection findings, there is reason to believe may have an illegal drug residue. The PHV is to retain the carcass while he or she performs the in-plant screening test.

a. The PHV is to perform in-plant screening tests on any animal that he or she suspects of containing an illegal drug residue. The PHV sends the liver, kidney, and muscle tissues, along with FSIS Form 10,000-2, for laboratory analysis when the in-plant screening test is positive.

NOTE: The PHV only needs to collect tissue for submission to the laboratory for confirmation testing. It is not required to collect additional tissue.

b. If the in-plant screening test is negative, the PHV is to determine whether there is reason to suspect that a residue exists that is other than an antimicrobial drug residue. In-plant screening tests are unable to detect anti-inflammatory drugs like flunixin or phenylbutazone, and, therefore, the PHV is to submit liver, kidney, and muscle samples to the appropriate FSIS laboratory for further testing with FSIS Form 10,000-2 if he or she has reason to suspect that an anti-inflammatory drug was used. PHVs are to retain the carcass and parts until the results are available in LEARN.

c. For descriptions of pathologic conditions that may warrant retention and testing of carcasses, see FSIS Directive 10,220.3, "Using the Fast Antimicrobial Screen Test (FAST) to Detect Antimicrobial Drug Residues in Cattle and Swine" in Section VI, "PHV Responsibilities."

i. Unless there is clear evidence of a recent injection, bolus injury, or surgical intervention, the PHV is not to select animals with chronic conditions such as neoplasia, chronic pneumonia, chronic peritonitis, or chronic nephritis for residue testing.

ii. PHVs are to select animals with potential neoplasia or extensive complicated inflammatory conditions (e.g., pneumonias or peritonitis cases) for in-plant screening.

C. Residue Testing of Show Animals

1. When an establishment presents show animals, including steers, heifers, market hogs, mature sheep, and lambs, inspection program personnel are to perform in-plant screening tests for antibiotics (code 200) and sulfonamides (code 800) as follows:

a. On show animals that appear unhealthy or have unusually heavy muscle development. Excessive muscling may indicate Beta-agonist use or abuse. Inspection program personnel are to tag the animal as "U.S. Suspect" and perform inspector-generated testing.

b. When requested by a State health official or Fair Board because of reports of positive beta-agonist results on show animals, such as the Grand Champion. Inspection program personnel are to confirm whether testing is available by reviewing the LEARN web page "laboratory analysis" site or by contacting the TSC at 1-800-233-3935.

c. From the entire lot of show animals, provided the animals appear healthy, and they are from a single fair or livestock show. The PHV is to select animals for testing in the following manner:

i. randomly select and test a minimum of 1 animal if there are 1 to 10 animals in a lot;

ii. randomly select and test a minimum of 2 animals if there are 11 to 50 animals in a lot;

iii. randomly select and test a minimum of 3 animals if there are 51 to 100 animals in a lot; and

iv. randomly select and test a minimum of 4 animals if there are more than 100 animals in a lot.

d. Tissue and sample size requested for beta-agonist testing:

i. collect one pound of liver and one pound of muscle for Ractopamine; and

ii. collect one pound of liver and both eyeballs for Clenbuterol.

e. Required information for show animal lab forms:

i. complete FSIS Form 10,000-2 in the routine manner, including the following specific entries:

(a) Block 10: Project Name – Record "SHOW"

(b) Block 21: Enter Residue Class Code – 560 for Clenbuterol and Ractopamine, 200 for antibiotics, and 800 for sulfonamides. Send samples for Clenbuterol and Ractopamine to the Western Laboratory and send samples for antibiotics and sulfonamides to the Midwestern Laboratory.

(c) Block 24: Identify any related information

(1) The name and location of the livestock show.

(2) If FSIS receives a report that the animal tested positive for Beta-agonist, inspection program personnel are to collect and report the following information:

Positive "_____" test
Date of test
Name of facility performing the test
Name, title, and address of non-FSIS official reporting the test

II. IN-PLANT SCREENING FOR ANTIMICROBIALS AND SULFANOMIDES IN CALVES PRESENTED AS BOB VEAL CALVES

A. The Calf Antibiotic and Sulfonamide Tests (CAST) is no longer used in federally-inspected establishments for calves and has been replaced with the Fast Antimicrobial Screen Test (FAST). Changes as a result of the implementation of the FAST are:

1. The selection of carcasses for in-plant screening with a FAST test should include carcasses from apparently healthy bob veal calves, as determined by the PHV during ante-mortem inspection. The chart below (taken from 9 CFR 310.21) sets out the testing of healthy calves. For the purposes of this directive, a bob veal is a calf up to 3 weeks of age, or up to 150 pounds. Certified groups (calves) described in 9 CFR 310.21 no longer exist.

Testing of Healthy-Appearing Calves

Testing Level	Number of healthy-appearing animals to sample based on the percent of the day's estimated slaughter
	Healthy-appearing calves
A	100 %
B	50 %
C	30 %
(Start) D	10 %
E	5 %
F	2 %

2. Upon initiation of slaughtering non-ruminating (bob veal) calves at an establishment, the PHV is to begin the testing rate at Level D in the chart above. The PHV is to increase the testing rate to the next higher level on the following business day when three carcasses in 100 or less consecutively tested show a screen test result of presumptive positive for a drug residue. The PHV is to decrease the testing rate to the next lower level when no more than two calves show a screen test result of presumptive positive for a drug residue in 500 calves consecutively tested, or for all calves tested over a 60-working-day period. Tracking of calves tested should be on the back of the FAST sheets.

3. The PHV is to retain all carcasses and parts from the calves selected for in-plant screen testing until all test results are completed. The PHV may reduce inspection line rates when, in his or her judgment, the required testing cannot be adequately performed within the time available because the establishment's compliance history dictates a need for extensive testing.

4. A presumptive positive screen test for a bob veal calf is defined as a FAST zone size of 15 mm or greater. Negative screen test results are defined as zones less than 15 mm. When a screen test is presumptive positive, the PHV is to continue to retain only the carcasses testing positive on the FAST test and submit one-pound samples of the liver, muscle, and kidney to the designated FSIS laboratory for identification and quantification of the specific antibiotic or sulfonamide residue.

a. If the laboratory results do not indicate violative residue levels, the PHV is to release the carcass and parts.

b. If the laboratory results do indicate violative residue levels, the PHV is to condemn the carcass and parts.

III. COLLECTION OF IMPORT SAMPLES FOR RESIDUE ANALYSIS

A. When notified by AIIS to take residue samples, import inspectors are to:

1. Complete FSIS Form 9770-1, "Official Receipt for Samples of Foreign Products Collected for Laboratory Analysis" and provide it to the import establishment personnel.

2. Collect the sample as stated in AIIS and follow the directions in Tables 10 and 11 of the Import Inspection Manual to determine the sample size required and the address of the laboratory for each compound subject to testing.

3. Complete FSIS Form 9770-2, "Import Residue Program," and mail it with the sample to the appropriate laboratory.

B. Laboratory results are posted in AIIS and LEARN.

IV. NATIONAL SECURITY AND OTHER SPECIAL SAMPLES

A. In cases involving national security, severe threat conditions may dictate extra sampling and verification procedures. The DO, OFO Headquarters, or the TSC will contact inspection program personnel with specific instructions in the event of an emergency. (See FSIS Directive 5420.2, Revision 1)

B. The DO, OFO Headquarters, or the TSC will instruct inspection program personnel regarding other special sampling situations on an as-needed basis.

CHAPTER FIVE – ACCESSING LEARN FOR SAMPLE RESULTS

I. TRACKING THE STATUS OF RESIDUE SAMPLES THROUGH THE LABORATORY ELECTRONIC APPLICATION RESULTS NOTIFICATION (LEARN) SYSTEM

A. The Laboratory Electronic Application Results Notification system (LEARN) reports: 1) when the laboratory has received samples; 2) when the laboratory discards them; and 3) when the laboratory has posted the results. FSIS Directive 10,200.1, Accessing Laboratory Sample Information via LEARN, provides complete information on how to access LEARN on the FSIS intranet.

B. The PHV is periodically to check the status of samples.

C. If the laboratory discards the samples, the PHV is to check the reason why as indicated in LEARN and make the necessary adjustments in how he or she collects, seals, and ships the samples to make sure that laboratory does not discard future samples because of improper handling.

1. If the PHV has any tissues from the original submission available, he or she is to send a replacement sample, prepare an FSIS Form 10,000-2 for each individual sample he or she submits, and enter all necessary information on the form. The PHV is to note in the "Remarks" block that the sample is submitted as a replacement.

2. If the PHV discarded all tissues, but the establishment has held the carcass from which he or she collected the original sample, the PHV **may** collect new tissue samples and resubmit them by using Form 10,000-2 and referencing the form number from the original scheduled sample submission. If only muscle is available, then the results from the lab on the muscle will be used to determine the disposition of the carcass and whether there is a violation.

D. PHVs are to print the LEARN screen of the positive residue results after making carcass disposition and maintain it in the office files as supporting documentation.

II. CARCASS AND PARTS DISPOSITIONS BASED ON RESULTS AS REPORTED IN LEARN

A. The PHV is to check LEARN and review the results of laboratory testing of residue samples already submitted. The PHV is to make final dispositions based on the results posted in LEARN. LEARN indicates whether a tissue is "violative;" "detected – non-violative;" or "negative."

B. The PHV is to make the final disposition of the retained carcass and parts, in the following in the following ways:

1. Violation **in muscle** – condemn carcass and parts.

2. Violation **in muscle and parts** – condemn carcass and parts.

3. Violation **in fat** – condemn carcass and parts.

4. Violation **in parts** but not muscle – call the Technical Service Center for disposition of carcass and parts.

5. Flunixin violation – call the Technical Service Center for disposition of carcass and parts.

C. If any test results from the FSIS laboratory show violative levels of antimicrobial residues, the PHV may call the Technical Service Center, Technical Assistance/Correlation Staff, for answers to any questions.

D. When a carcass/part is retained (either by FSIS or the establishment), the PHV is to ensure that the carcass or part is released or condemned in accordance with the LEARN results and in conjunction with the above instructions. In a situation where the establishment did not elect to hold the carcass or part pending test results, the product may be subject to recall if the results are violative.

CHAPTER SIX - COMPLIANCE AND ENFORCEMENT ACTIVITIES

INSPECTION PROGRAM PERSONNEL ACTIONS

After the FSIS laboratories have reported the results for each tissue sample submitted, and the PHV has made the appropriate disposition, the PHV is to take any necessary regulatory enforcement actions.

A. In Compliance: Residue not detected; Positive but non-violative

1. If the PHV retained the product, he or she is to release it.

2. If the establishment held the product, the PHV is to inform the establishment of the "In Compliance" result.

B. Noncompliance: Residue detected at a violative level

1. The PHV is to notify the establishment of the violation and the final disposition of the carcass and parts.

2. The PHV is to verify the disposition of the carcass and parts with the establishment.

3. Noncompliance documentation:

a. The PHV is to review the establishment's residue control program and perform verification of the establishment's residue control program included in its HACCP plan or Sanitation Standard Operating Procedures (Sanitation SOP) or other prerequisite program.

b. If the establishment has not incorporated residue control in its HACCP system, the PHV is to document the noncompliance as an unforeseen hazard, 9 CFR 417.3(b), and use the "verification" trend indicator.

b. If the establishment does address residue control in its HACCP system, the PHV is to perform the O3J02 procedure. If the establishment has failed to follow its residue control program according to its HACCP plan or Sanitation SOP or other

prerequisite program, the PHV is to issue an NR using the appropriate regulation and

trend indicator.

Refer questions to the Technical Service Center at 1-800-233-3935.

Assistant Administrator
Office of Policy, Program, and Employee Development

Exhibit 45

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

# FSIS NOTICE	40-11	8/9/11

NOTE: This notice reissues the content of FSIS Notice 30-10

INSTRUCTIONS FOR CARCASS SELECTION FOR THE NATIONAL RESIDUE PROGRAM SCHEDULED SAMPLES

I. PURPOSE

When IPP are directed to take a scheduled sample for residue surveillance, they are to select from all animals that have passed ante-mortem inspection, without regard to whether the animal may or may not pass post-mortem inspection. Specifically, IPP are to randomly select carcasses at the kill floor stage. This change is necessary to ensure the NRP includes the broadest range of animals. IPP are to continue to follow the procedures for sample collection and testing in FSIS Directive 10,800.1, Chapter 4, "Procedures For Residue Sampling, Testing, And Other Responsibilities For The National Residue Program", http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/10800.1.pdf

II. BACKGROUND

The results of NRP scheduled sampling provides FSIS and other agencies with a means to assess what animal drugs are being used in meat and poultry, and a means to determine whether there are uses of illegal animal drugs. At present, FSIS is aware that the majority of the animals selected for NRP sampling are chosen from healthy-appearing animals that will pass post-mortem inspection. This practice has resulted in limiting the range of animals that are included in the testing program. Also, including the broadest range of animals under NRP scheduled sampling will help FSIS determine whether establishments are properly considering residues in their HACCP plans.

III. FSIS PERSONNEL RESPONSIBILITIES

A. IPP are to include all livestock passing ante-mortem inspection when collecting NRP scheduled samples. Specifically, IPP are to randomly select carcasses at the kill floor stage regardless of post-mortem disposition.

NOTE: IPP are not to select animals condemned on ante-mortem because such animals are not permitted into the slaughter facility.

B. FSIS will take regulatory action on violative results even if the carcass is condemned during post-mortem inspection.

C. To ensure that carcasses are randomly selected, and that IPP are not selecting primarily unhealthy animals, IPP are to check the appropriate box in Block 28 of FSIS Form 10,210-3 to indicate if the carcass is condemned by FSIS, condemned by the establishment or passed inspection.

NOTE: This policy applies only to random selection of carcasses for directed surveillance residue samples. IPP are to continue to perform in-plant residue screening (KIS or FAST) on all carcasses that warrant testing in accordance with existing policies (for certain pathological conditions, injection site lesions, or repetitive violative residues from a supplier). If the same carcass is randomly selected for directed residue testing and also warrants sample submission from positive in-plant screening (KIS or FAST), IPP are to perform both sampling tasks for that carcass and cross reference the form numbers (record FSIS Form 10,000-2 number in block 28 of FSIS Form 10,210-3 and also record FSIS Form 10,210-3 number in block 24 of FSIS Form 10,000-2). Divide available tissue when required to submit with both forms and tissue is limited (e.g. one bob veal kidney or one half bob veal liver with each form).

IV. DATA ANALYSIS

The Chemical Residue Risk Branch (CRRB) within the Office of Public Health Science will monitor data from FSIS Form 10,210-3 Block 28 monthly and report sampling result data to the Office of Field Operations and Office of Policy and Program Development. When the Laboratory Information Management System (LIMS) system is fully operational, CRRB, in conjunction with the Data Analysis and Integration Group (DAIG) within the Office of Data Integration and Food Defense (ODIFP) will analyze Block 28 data on a quarterly basis to determine whether carcasses are randomly selected for scheduled sampling. Data will be reviewed to determine if trends exist by district, establishment, and species.

Refer questions regarding this notice to the Policy Development Division through *askFSIS* at http://askfsis.custhelp.com or by telephone at 1-800-233-3935.

Assistant Administrator
Office of Policy and Program Development