

FSIS DIRECTIVE

6100.4
Revision 1

10/24/17

VERIFICATION INSTRUCTIONS RELATED TO SPECIFIED RISK MATERIALS IN CATTLE OF ALL AGES

CHAPTER I -- GENERAL

I. PURPOSE

This directive provides updated instructions on how to verify and document that establishments meet 9 CFR 310.22 requirements using food safety system (i.e. HACCP, Sanitation SOP verification, Hazard Analysis) and the dedicated Specified Risk Material (SRM) Control Verification task from FSIS Notice 26-16. Inspection program personnel (IPP) are to also continue verifying that all cattle slaughter and processing establishments that handle SRMs have written procedures describing the removal, segregation, and disposition of SRMs using food safety system and other SRM-related tasks in the Public Health Inspection System (PHIS).

KEY POINTS

- *Tonsils and distal small intestine are SRMs in cattle of all ages, including veal*
- *Cattle over 30 months of age have additional SRMs defined in 9 CFR 310.22(a)*
- *IPP perform hands-on product and records-based verification of the establishment's SRM control programs when performing the SRM Control Verification task*
- *While performing any SRM-related task in PHIS, IPP are to cite all 9 CFR 310.22 regulations that they verify. IPP are to also indicate the specific regulation(s) found not in compliance*

II. CANCELLATIONS

FSIS Directive 6,100.4, *Verification Instructions Related to Specified Risk Materials*, 9/13/07

III. BACKGROUND

A. FSIS published the SRM final rule (72 FR 3870, July 13, 2007, <http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/03-025F.pdf>). The rule designates certain materials from cattle as SRMs and prohibits SRMs for human food. The rule also prohibits the use of certain source materials (i.e., vertebral column from cattle 30 mos. and older) in the production of beef AMR ([9 CFR 318.24](#)); and designates mechanically separated beef (MSB) ([9 CFR 319.5](#)) as inedible. For humane handling reasons, FSIS subsequently updated requirements for the disposition of non-ambulatory cattle including veal ([Docket No. FSIS-2014-0020](#)).

B. As part of a national BSE surveillance program, IPP collect and submit brain tissue samples from cattle condemned on ante-mortem for central nervous system (CNS) conditions ([9 CFR 309.4](#)) [other than when rabies is suspected] using instructions in [FSIS Directive 10,400.1, Sample Collection from Cattle under the Bovine Spongiform Encephalopathy \(BSE\) Ongoing Surveillance Program](#).

C. Prior to development of the SRM Control Verification task in 2013, [9 CFR 310.22](#) regulations could be verified under any one of eleven (11) separate food safety system or Livestock Finished Product Standards tasks in PHIS.

IV. TERMINOLOGY

Specified Risk Material (SRM) –inedible tissues in all cattle depending on age as defined in [9 CFR 310.22\(a\)](#).

Distal Ileum – an SRM in cattle of all ages, the distal ileum describes the terminal or last 80 inches of unstretched small intestine that attaches to the large intestine at the junction of the cecum and colon (large intestine).

Dorsal Root Ganglia (DRG) – an SRM in cattle 30 months of age and older, DRG are nodular enlargements of nerve tissue representing the junction of spinal and peripheral nerves. DRG exit the intervertebral foramina and are usually located anterior and ventral to the transverse vertebral processes in the lumbar region. (See [Attachment 1](#)). Although technically part of the peripheral nervous system, DRG and trigeminal ganglia are described in this directive as “CNS type tissue”

Trigeminal Ganglia – An SRM in cattle 30 months and older, the trigeminal ganglia are nodular enlargements of nerve tissue where cranial nerves exit the base of the skull.

Segregation - For purposes of this directive, segregation of SRMs referenced in [9 CFR 310.22](#) refers to the sorting and identification of cattle, cattle carcasses or parts with particular SRMs before removal and disposal.

Disposition – Disposition of SRMs refers to the disposal (i.e. denaturing, incineration, composting, or rendering) of SRMs as per [9 CFR 314.1 or 314.3](#).

CHAPTER II -- SLAUGHTER AND PROCESSING VERIFICATION ACTIVITIES

I. GENERAL VERIFICATION PROCEDURES

A. IPP are to verify that all establishments that slaughter or process cattle (beef or dairy), including veal, have performed a hazard analysis and have assessed whether SRMs represent a food safety hazard. IPP are to refer to [FSIS Directive 5000.1, Verifying an Establishment's Food Safety System](#), or [FSIS Directive 5000.6, Performance of the Hazard Analysis Verification \(HAV\) Task](#), for instructions on how to verify whether establishment's decisions in their hazard analysis meet regulatory requirements.

B. IPP are to verify that the spinal cord from the carcasses of cattle 30 months and older is removed at the establishment (i.e. not necessarily on the slaughter floor) where the cattle are slaughtered ([9 CFR 310.22\(c\)](#)).

C. When performing the SRM Control Verification, food safety, or other SRM-related task at cattle slaughter establishments or at cattle processing establishments that segregate, remove, and dispose SRMs, IPP are to verify that beef or beef products are free of SRMs, comply with requirements in [9 CFR 310.22](#), and are eligible to enter commerce by:

1. Direct observation of establishment employees performing segregation, removal and disposal procedures;
2. Reinspection of cattle carcasses and parts after removal of SRMs to verify such products are free of SRMs; and
3. Review of records.

D. When reviewing records while performing the SRM Control Verification, food safety, or other SRM-related task, IPP are to verify that establishments have written SRM procedures and maintain daily records ([9 CFR 310.22\(f\)](#)) demonstrating that those establishments effectively segregate, remove, and dispose of SRMs. Specifically, IPP are to:

1. Verify that the establishment's written procedures to segregate, remove, and dispose of SRMs are incorporated within their HACCP, Sanitation SOP, or prerequisite programs or any combination thereof ([9 CFR 310.22\(e\)\(1\)](#));
2. Verify that the establishment sufficiently documents daily the procedures (i.e. segregate, remove, and dispose) performed, establishment monitoring of product, and the results of such monitoring;
3. Verify that records demonstrate carcasses containing SRMs are correctly identified and handled throughout slaughter and fabrication until SRMs are removed and disposed; and
4. Verify that any corrective actions performed meet regulatory requirements (9 CFR Part 417 or 416) and determine if any changes to the food safety system made after noncompliant product with SRMs are found are adequate and effective (See [FSIS Directive 5000.1, Verifying an Establishment's Food Safety System](#)).

E. If the beef processing establishment does not receive or handle beef product with SRMs and does not require or rely on an SRM pre-requisite program and records to support the decision in its hazard analysis, IPP can disable the SRM Control Verification Task in PHIS, and not perform the SRM Control Verification Task using the instructions in [FSIS Directive 13,000.1, Scheduling In-Plant Inspection Tasks in the Public Health Information System \(PHIS\)](#).

F. IPP are to verify that the establishment is not using any captive bolt stunning devices that inject air into the cranium of cattle per [9 CFR 313.15 \(b\) \(2\) \(ii\)](#) and [310.13 \(a\) \(2\) \(iv\) \(C\)](#).

G. When SRM-related tasks are scheduled and not performed, IPP are to document reasons for not performing the task. See instructions in [FSIS Directive 13,000.1, Scheduling In-Plant Inspection Tasks in the Public Health Information System \(PHIS\)](#).

II. SANITATION DURING SLAUGHTER AND PROCESSING

A. While inspecting heads, viscera, and carcasses on-line IPP are to ensure that:

1. Each carcass or part is not contaminated with visibly intact and identifiable SRM tissue displaced from its normal anatomical location (e.g., pieces of brain matter around the knock hole) at the time of inspection; and
2. Visible SRM contamination of head, viscera, or carcass is removed in a satisfactory and sanitary manner (e.g. trimming; vacuuming; washing) before completing the inspection and passing the carcass or part.

B. On-line IPP are to notify off-line IPP as directed by the Inspector-in-Charge (IIC) whenever the establishment fails to consistently present carcass and parts for inspection that are free of visibly intact and identifiable SRM contamination.

NOTE: "Clean and sanitize" ([9 CFR 310.22\(f\)\(1\)\(ii\)](#)) refers to the sanitizing of food contact surfaces (e.g., splitting saws, knives) used to cut through SRMs from cattle 30 months and older before using on cattle less than 30 months of age with 180°F water or chemical equivalent. This requirement applies without the presence of visibly intact or identifiable SRM contamination.

C. During slaughter or processing when equipment is used to cut through SRMs of cattle 30 months and older, IPP are to verify that the establishment:

1. Uses routine sanitary procedures whenever equipment is contaminated with visibly intact or identifiable SRM material to prevent adulteration of edible product;
2. Cleans and sanitizes all equipment used to cut through SRMs from cattle 30 months and older before using on cattle less than 30 months of age per [9 CFR 310.22\(f\)](#); or
3. Handles all cattle as 30 months and older.

NOTE: “Routine” sanitary procedures ([9 CFR 310.22\(f\)\(2\)](#)) are those sanitary procedures required and performed on equipment or food contact surfaces with visibly intact and identifiable SRM tissue.

III. DETERMINING AGE OF CATTLE USING DENTITION

A. Identification of SRMs is dependent on accurate determination of cattle age. IPP are to verify that establishments determine age of cattle, segregate cattle that are 30 months and older from cattle less than 30 months of age and thereby identify, remove, and dispose of the associated SRMs. When establishments make age determinations by examining cattle teeth (dentition), IPP are to ensure that those age determinations are consistent with FSIS guidelines described below.

B. FSIS considers cattle that exhibit eruption of one or both of the second set of permanent incisors (I-2) (i.e. third or fourth permanent incisor) above the gum line to be 30 months or older in age. The following web site provides photographs for aging cattle using dentition:

http://www.fsis.usda.gov/wps/portal/frame-redirect?url=https://www.fsis.usda.gov/OFO/TSC/bse_information.htm

Off-line IPP are to verify in establishments that use dentition to determine age that the establishments are using eruption of the second pair of incisors as the standard or mark of cattle being 30 months or older by:

1. Observing employees performing dentition examinations;
2. Verifying that the employee correctly determines and records the age per their written procedures and identifies the carcass according to establishment procedures;
3. Performing dentition checks and comparing inspection results with establishment’s results;
4. Reviewing establishment records documenting procedures performed as above.

IV. DETERMINING AGE OF CATTLE USING LIVESTOCK PRODUCER RECORDS

A. As an alternative to using dentition, IPP are to be aware that establishments may also determine cattle age using accurate livestock producer records.

B. IPP in establishments that use producer records to determine age of cattle are to verify that producer records accepted by the establishment are sufficient to accurately:

1. Identify the particular cattle (e.g., tags, breed, description, owner); and
2. Indicate the age of cattle based on but not limited to:
 - a. Production dates relating to breeding, gestation, or calving;

- b. Production dates relating to live cattle processing (vaccination, castration, dehorning) of livestock during the first year of life (of a spring or fall calf crop) of a particular year; or
- c. Production dates relative to live animal dentition on official health certificates (e.g., VS-1-27; Canadian) that certify the age of cattle.

C. When the establishment accepts producer records of cattle that:

1. Are clearly not sufficient to accurately determine age of cattle per above; and
2. Show a significant discrepancy between records and dentition exists (i.e., greater than 3-6 months); or
3. Are based on owner affidavits alone,

the PHV, based on his or her professional judgment, has the authority to reject the establishment's determination, verify compliance based on dentition, handle as cattle 30 months and older per [9 CFR 310.22\(h\)](#), and take regulatory control actions when necessary.

V. REMOVAL OF TONSILS

Tonsils are present in cattle of all ages. Tonsils exist in the head and tongue. IPP are to verify that the establishment properly identifies, removes, and disposes of all SRMs including tonsils. Off-line IPP are to verify that the establishment:

1. Identifies, removes, and disposes of the tonsils (i.e., SRM) from the head and tongue of cattle of all ages ([9 CFR 310.22\(a\)](#)) saved as edible.
2. Does not use tonsil in the manufacture of meat food products ([9 CFR 318.6\(b\)\(6\)](#)) or contaminate edible product with SRM tissue;
3. When using a knife to remove lingual tonsils, removes tonsils within the skin layer of the tongue (i.e., mucosa) and submucosal layers of the tongue by first making a transverse cut caudal to (just behind or below) the last vallate papillae.
4. When using a skinning machine to remove lingual tonsils,
 - a. Removes No less than 5 mm (~0.2 inches) from the surface of the tongue down to the muscular layer caudal to the last vallate papillae; and
 - b. Removes tonsillar material in a sanitary manner. Routine sanitary procedures are required to remove any visible tonsillar material (i.e., the SRM) on the blade or food contact surfaces of the skinning machine to prevent adulteration of edible product; and
5. When shipping beef market heads, has removed lingual and palatine tonsils before cattle market heads or tongues enter commerce.

NOTE: IPP are to be aware that the remaining tonsils in beef market heads are typically discarded with the gullet-larynx and the skull not used for human food. Links to additional information and diagrams on the location of the tonsils in beef market heads and tongues are posted on the FSIS Web with this directive:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/directives/6000-series/6000-series>

VI. SEGREGATING AND MAINTAINING IDENTITY OF CARCASSES WITH SRMS DURING SLAUGHTER AND PROCESSING

As part of the establishment's SRM segregation procedures in [9 CFR 310.22\(e\)](#), off-line IPP are to verify that the establishment segregates cattle 30 months and older from cattle less than 30 months of age during slaughter and processing or handles all cattle as 30 months and older. Off-line IPP are to also verify that the establishment maintains the identity of carcasses 30 months and older or parts with SRMs throughout (i.e., between) slaughter and final processing. This verification activity specifically extends from:

1. Slaughter when age of the cattle is determined;
2. Chilling and storage of carcasses or parts in the cooler before removal of remaining SRMs;
3. Processing until all SRMs are removed and disposed of; or
4. Transport from the slaughter establishment to another official establishment for removal and disposal of vertebral SRMs per Chapter III of this directive below.

VII. REMOVAL OF DISTAL ILEUM

Off-line IPP are to verify that the establishment effectively identifies, removes, and disposes of the distal small intestine or ileum ([9 CFR 310.22\(d\)](#)). Unless supported by alternate establishment procedures, IPP are to verify that the establishment:

1. Effectively identifies, removes, and disposes of no less than 80 inches of uncoiled, unstretched, and trimmed distal end of small intestine (i.e. ileum) as measured from the ceco-colic junction.
2. Is not using the distal small intestine in the manufacture of a meat food product, edible casings, or in edible rendering.
3. That harvests or uses cattle small intestine for casings or in the manufacture of edible products (e.g., tripas; beef chitterlings) complies with the requirements in [9 CFR 310.22\(d\)](#).

NOTE: All imported natural beef casings that enter an FSIS-regulated establishment to be used in the preparation of a meat food product must be accompanied by an "Official Meat-Inspection Certificate for Fresh Meat and Meat Byproducts" ([9 CFR 327.4\(a\)](#)). This certificate attests that the product is in compliance with requirements equivalent to those in the Federal Meat Inspection Act and the regulations adopted thereunder.

VIII. DISPOSAL OF SRMS (9 CFR 310.22(c))

A. IPP are to verify that SRMs removed from the carcasses and parts of cattle are segregated from edible materials, and disposed of in accordance with [9 CFR 314.1 or 314.3](#).

B. IPP are to verify that all SRMs removed from carcasses and parts are handled as condemned product and denatured prior to transport or rendered on site.

NOTE: To meet FDA requirements regarding production of meat and bone meal for animal feed, establishments will separate and segregate brain and spinal cord of cattle 30 months and older from other SRMs and alternatively dispose of such brain and spinal cord material.

CHAPTER III -- TRANSPORTATION OF CARCASSES AND PARTS WITH SRMS TO OTHER OFFICIAL ESTABLISHMENTS

I. VERIFICATION AT SHIPPING ESTABLISHMENTS

A. Carcasses from cattle 30 months of age and older with vertebral column still intact ([9 CFR 310.22\(c\)](#)) are the only beef products containing SRMs that may be transported from one federally-inspected facility to another for further processing and removal of SRMs per [9 CFR 310.22\(g\)](#).

B. IPP at establishments that slaughter and ship cattle carcasses (i.e., sides, quarters) with vertebral SRMs for removal at another official establishment are to verify for each lot that each establishment:

1. Removes the spinal cord from cattle 30 months of age and older when the animal is slaughtered;
2. Maintains control of the carcasses or parts with SRM vertebral column while in transit using company seals or ensures that the carcasses or parts move under FSIS control (e.g., under USDA and accompanied by FSIS Form 7350-1) per [9 CFR 310.22\(g\)\(1\)](#);
3. Clearly identifies on the documentation that accompanies the product that the carcasses or parts are from cattle that were 30 months of age and older at the time of slaughter and contain vertebral SRM per [9 CFR 310.22\(g\)\(2\)](#);
4. Maintains records that identify the official establishment that received the carcasses or parts with vertebral column from cattle 30 months of age per [9 CFR 310.22\(g\)\(3\)](#); and
5. Maintains records that verify that the official establishment that received the carcasses or parts removed and properly disposed of the SRM portions of the vertebral column per [9 CFR 310.22\(g\)\(4\)](#).

II. VERIFICATION AT RECEIVING ESTABLISHMENTS

IPP at official establishments that receive carcasses or parts of carcasses of cattle with SRM vertebral column for further processing are to verify for each lot that the receiving establishment has:

1. Implemented controls to identify carcasses or parts that contain vertebral columns with SRM portions until all SRMs are removed;
2. Implemented controls to ensure that the SRM portions of the vertebral column are removed, segregated from edible materials, and properly disposed of as inedible;
3. Maintains records that verify that the SRM portions of the vertebral column were removed and disposed of as inedible.
4. Reported to the shipping establishment that such carcasses were received and SRMs were removed and disposed before products entered commerce.

CHAPTER IV – DOCUMENTATING NONCOMPLIANCE AND ENFORCEMENT

I. NONCOMPLIANCE DOCUMENTATION AND ENFORCEMENT

A. IPP can verify compliance with [9 CFR 310.22](#) while performing the *SRM Control Verification or other food safety tasks (e.g., HACCP, Sanitation SOP)* that includes verification of requirements in [9 CFR 310.22](#). IPP can document noncompliance while performing any SRM related task.

EXAMPLES: Common examples where the establishment has not complied with requirements in [9 CFR 310.22](#) include: 1) failure to implement written SRM control procedures; 2) contamination of product with displaced visibly identifiable SRMs at slaughter; 3) failure to remove visibly identifiable SRMs during processing; 4) production or packaging of processed product with visibly identifiable SRM; or 5) failure to document implementation or monitoring of SRM control procedures.

B. When off-line IPP determine there is noncompliance with requirements in [9 CFR 310.22](#), IPP are to:

1. Take a regulatory control action to prevent further contamination of product and retain adulterated product ([9 CFR 500.2](#));
2. Notify the establishment of the noncompliance;
3. Verify that the establishment takes corrective actions regarding any edible product adulterated with SRMs (e.g., removal of remaining lingual tonsils on tongues), restores sanitary conditions, and properly disposes of SRMs; and
4. Document the noncompliance using any SRM related task citing all the appropriate [9 CFR 310.22](#) regulations verified and found noncompliant. IPP are to include in the noncompliance report (NR) a complete description of the noncompliance, including the type of SRM, adulteration, or insanitary condition resulting from the failure to follow the establishment's written procedures.

C. When noncompliance is documented while performing the SRM Control Verification task, IPP are to verify any *remaining* regulatory requirements, corrective actions, or resulting changes to the food safety system using the appropriate food safety system task (e.g. HACCP, Sanitation SOP) to ensure procedures are complete and effective; products eligible to enter commerce are free of SRMs; sanitary conditions are restored; and SRMs are properly disposed per requirements in [9 CFR 310.22\(e\)\(2\)](#). IPP are to follow instructions in [FSIS Directive 5000.1, Verifying an Establishment's Food Safety System](#).

NOTE: Establishment written procedures to segregate, remove, and dispose SRMs are to be incorporated within the HACCP, Sanitation SOP, or prerequisite program (9 CFR 310.22(e)(1)). When a prerequisite program identified in the hazard analysis (other than a Sanitation SOP) fails to prevent a food safety hazard, it is handled as an unforeseen hazard that requires HACCP corrective actions ([9 CFR 310.22\(e\)\(2\)](#) and [9 CFR 417.3\(b\)](#)).

D. Prior to documenting verification results in PHIS, IPP are to review the information and instructions associated with enforcement actions outlined in Chapter V, in [FSIS Directive 5000.1, Verifying an Establishment's Food Safety System](#).

E. If adulterated product has shipped into commerce IPP are to immediately notify their District Office and Frontline Supervisor. Refer to instructions in [FSIS Directive 8080.1, Recall of Meat and Poultry Products](#).

CHAPTER V – DATA ANALYSIS AND QUESTIONS

I. DATA ANALYSIS

The Office of Policy and Program Development and the Office of Data Integration and Food Protection will analyze the results from PHIS regarding verification and associated noncompliance quarterly, annually, or longer as trends warrant and time permits. Data will be reviewed to determine what trends if any exist.

II. QUESTIONS

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

Subject Field: Enter **Directive 6100.4**
Question Field: Enter question with as much detail as possible.
Product Field: Select "**General Inspection Policy**" from the drop-down menu.
Category Field: Select "**Regulations\Agency Issuances**" from the drop-down menu.
Policy Arena: Select "**Domestic**" from the drop-down menu.

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

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



Assistant Administrator
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Schematic Cross-section of SRM Vertebrae.

