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

FSIS DIRECTIVE

6100.4 | 9/13/07

DO NOT IMPLEMENT THIS DIRECTIVE UNTIL: 10/1/07

VERIFICATON INSTRUCTIONS RELATED TO SPECIFIED RISK MATERIALS

CHAPTER I -- GENERAL

I. PUPRPOSE

This directive provides instructions to inspection program personnel on how to verify that establishments that slaughter cattle and establishments that process the carcasses or parts of cattle are complying with final regulations that prescribe requirements for the removal, segregation, and disposition of specified risk materials (SRMs). This document consolidates and updates provisions from the FSIS Notices related to SRMs. Instructions on how to verify compliance with the parts of the SRM final rule that are associated with non-ambulatory cattle are in FSIS Directive 6100.1, Ante Mortem Inspection of Livestock.

This directive covers the following topics:

II. CANCELLATIONS

FSIS Notices 4-04, 5-04, 7-04, 9-04, 10-04, 50-04, 58-05, 68-05, 5-06, 5-07, and 10-07

III. RESERVED

IV. REFERENCES

9 CFR 309 and 310.22

V. BACKGROUND

On July 13, 2007, FSIS published a final rule, "Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle; Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter," (72 FR 3870, available on the Internet at http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/03-025F.pdf). See attachment 1 for the regulations pertaining to SRMs.

This final rule (referred to as "the SRM final rule") makes permanent, with certain changes, interim regulations that FSIS issued in January 2004 to prevent potential human exposure to the BSE agent. Like the interim regulations, the SRM final rule prescribes requirements for the handling and disposition of SRMs, requires that all non-ambulatory disabled cattle that are offered for slaughter be condemned, prohibits the use of air-injection stunning devices on cattle, and prohibits Mechanically Separated (beef) for human food. These regulations are effective on October 1, 2007.

VI. TERMINOLOGY

Air-injection Stunning – a type of pneumatic captive bolt stunning that injects compressed air into the cranium/skull at the end of the captive bolt's penetration cycle.

Distal Ileum –The distal ileum describes the last part, or section, of the ileum, and it is this part that attaches to the large intestine at the junction of the cecum and colon (large intestine).

Dorsal Root Ganglia – Nodular enlargements of nervous tissue, connected to the spinal cord, that are located in close proximity to the intervertebral foramina. These enlargements vary in size (see attachment 2).

Specified Risk Materials – Cattle tissues that have been determined to carry the highest risk of infection when harvested from cattle affected with Bovine Spongiform Encephalopathy (BSE). These tissues are defined in 9 CFR 310.22(a).

Trigeminal Ganglia - Clusters of nerve cells connected to the brain stem that lie on the internal surface of the base of the skull near where the trigeminal nerve exits the bone.

Vertebral Column – The articulated series of vertebrae extending from the skull to the tip of the tail that are held together by a series of ligaments and separated by the intervertebral discs.

CHAPTER 2 – SLAUGHTER AND PROCESSING VERIFICATION ACTIVITIES

I. GENERAL VERIFICATION ACTIVITES

9 CFR 310.22(e) requires that establishments that slaughter cattle and establishments that process the carcasses and parts of cattle develop, implement and maintain written procedures for the removal, segregation, and disposition of SRMs, and that they incorporate these procedures into their HAACP plans or Sanitation SOPs or other pre-requisite programs. FSIS inspection program personnel are to conduct the following activities to verify that an establishment's procedures for the removal, segregation, and disposition of SRMs are designed and executed in a manner that complies with 310.22(e):

A. Activities to Verify that an Establishment has Properly Designed its Procedures for the Removal, Segregation, and Disposition of SRMs

1. When verifying the design of an establishment's procedures for the removal, segregation, and disposition of SRMs, inspection program personnel are to verify that the establishment has incorporated these procedures into its HACCP plan or its Sanitation SOPs or other prerequisite program.

a. If an establishment determines that SRMs are a hazard reasonably likely to occur in its process, inspection personnel are to verify that the establishment has designed controls and incorporated them into its HACCP plan in accordance with 9 CFR part 417.

b. If an establishment determines that SRMs are not a hazard reasonably likely to occur because of procedures in its Sanitation SOPs, inspection personnel are to verify that the procedures and documentation supporting the establishment's determination are available for review under 9 CFR 417.5.

c. If an establishment determines that SRMs are not a hazard reasonably likely to occur because of procedures in a prerequisite program, inspection personnel are to verify that the procedures and supporting documentation are available for review under 9 CFR 417.5.

2. Inspection personnel are to verify that the establishment has designed its procedures for the removal, segregation, and disposition of SRMs to address monitoring, verification, recordkeeping, and corrective actions, including reassessment as appropriate, to implement its HACCP plan, Sanitation SOPs, and other supporting prerequisite programs. Questions that inspection program personnel may ask to verify that the establishment has properly designed its procedures for the removal, segregation, and disposition of SRMs include:

a. Does the establishment have written procedures designed to identify the cattle to be slaughtered that are 30 months of age and older? If it does not, does the establishment handle all cattle as if they are 30 months of age or older?

b. Are the establishment's written procedures designed to ensure the complete and proper removal of SRMs?

c. Does the establishment have written procedures designed to ensure that SRMs are segregated from edible product?

d. Does the establishment have written procedures designed to ensure that SRMs are removed and disposed of in a manner that will prevent contamination of edible product?

e. Does the establishment have written procedures that address potential contamination with SRMs before, during, and after entry into the establishment?

f. Does the establishment have written control procedures designed to either (1) prohibit the entry into the establishment of bone-in beef from cattle 30 months of age and older, or (2) ensure that such product is handled in an appropriate manner if it is permitted to enter the establishment (e.g., by ensuring that SRMs are removed and disposed of appropriately)?

g. Has the establishment implemented monitoring and verification measures to ensure that the control procedures are followed?

h. Has the establishment maintained daily records sufficient to document the implementation and monitoring of the procedures for the removal, segregation, and disposition of the SRMs? (As required in 9 CFR 310.22 (d) (4)).

B. Activities to Verify the Proper Execution of an Establishment's Procedures for the Removal, Segregation, and Disposition of SRMs

1. Inspection program personnel are to verify the proper execution of an establishment's procedures for the removal, segregation, and disposition of SRMs while conducting HACCP 01 or 02 procedures as set out in FSIS Directive 5000.1, if these procedures have been incorporated into a HACCP plan or a prerequisite program. If these procedures have been incorporated into the Sanitation SOPs, inspection program are to verify the proper execution of the procedures while verifying the effectiveness of Sanitation SOPs under 01B or 01C procedures. Inspection program personnel are to perform the verification activities related to SRM removal in conjunction with the other food safety concerns by:

a. reviewing records (e.g., looking at HACCP monitoring records);

b. observing plant employees performing procedures (e.g., observing plant employee performing a dentition examination); or

c. by conducting hands-on inspection verification procedures (e.g., verifying the adequacy of Sanitation SOP procedures, observing carcasses for SRM).

2. Inspection program personnel should verify that the establishment is conducting monitoring, verification, recordkeeping, and corrective actions, including reassessment as appropriate, to implement its HACCP plan, Sanitation SOPs, and other supporting prerequisite programs.

II. VERIFICATION RESPONSIBILITIES FOR AGE DETERMINATION

Certain materials from cattle are designated as SRMs only if they are from cattle 30 months of age and older. Therefore, to ensure the proper removal, segregation, and disposition of all SRMs, establishments that slaughter cattle must either 1) include procedures for determining the age of cattle that are slaughtered as part of their procedures for the removal, segregation, and disposition of SRMs required under 9 CFR 310.22(e) or 2) handle all carcasses and parts as if they are from cattle that were 30 months of age and older.

Inspection program personnel are to conduct the following activities to verify that establishments that do not handle all carcasses and parts as if they were from cattle that were 30 months of age and older are following their aging procedures, and that they are making appropriate age determinations. Establishments may use dentition or documentation to determine the age of cattle.

A. Verification Activities when Dentition is used to Determine Age

1. Inspection program personnel are to consider cattle to be 30 months and older when the examination of the dentition of the animal shows that at least one of the second set of permanent incisors (I2) has erupted above the gum line. FSIS recognizes that the second set of permanent incisors of cattle erupt from 24 through 30 months of age, but this dentition procedure is to be used because it is most protective of public health. The following web site provides photographs for aging cattle using dentition: http://www.fsis.usda.gov/ofo/tsc/bse_information.htm

2. While performing verification activities related to the age of cattle, inspection program personnel are to verify that, in establishments using dentition, the establishment's determinations are consistent with the results obtained using this procedure. Inspection personnel should not check dentition on each animal but should periodically verify that the establishment is correctly and accurately using this procedure by:

a. reviewing records;

b. observing employees performing dentition examinations, and

c. periodically performing hands-on dentition checks.

B. Verification Activities when Documentation is used to Determine Age

1. Documentation, rather than dentition, provides the best means for determining the age of cattle. While dentition can be useful in the absence of documentation, it only provides a means of making general determinations about age. Documentation provides the means to specifically age the animals. The characteristics of documentation that are most useful in determining the age of cattle offered for slaughter are documentation that can be related to individual cattle and not just information about an entire lot. Such documentation includes:

a. documentation that provides evidence of age that goes back to the farm/ranch where the cattle were born, including the name and the address of the owner; or

b. documentation that identifies the date that the cattle entered a feedlot and were given individual identification and documentation that the producer provides with the cattle as they enter feedlot that includes on-farm records:

c. documentation that is in the form of:

i. birth certificates or records;

ii. cattle passports, or some other form of identification that is presented with the animal when it arrives for slaughter;

iii. pregnancy check records (checks for individual cows and the results of the check for each one);

iv. breeding records of which cows were in a herd when a bull was put in with the herd, and when the bull was removed from the herd (to determine start of gestation), or when individual cows were artificially inseminated;

v.calving records that document where (i.e., name and address of the producer) and when a calf was born;

vi. identification applied to calves (e.g., records from branding, electronic ear IDs, or ear tags);

vii. medication records or worming records at the feedlot that tie back to when the animal was received by the feedlot and identify the producer. The feedlot could use these records to identify the producer, who then could provide documentation when the cattle were born;

viii. auditable records of the dentition examination of cattle at the feedlot (cattle may be deemed to be under 30 months if accompanied by documentation that demonstrates that the animal's dentition exam upon arrival to the feedlot showed no permanent incisors, and the animal is sent to slaughter within six months of its arrival at the feedlot);

ix. Official health certificates (e.g., Canadian) that certify the ages of cattle.

NOTE: When calving date ranges are provided, the oldest possible age based on the ranges should be assigned to the group of cattle.

2. The use of documentation as the primary method for determining the age of cattle does not preclude the use of dentition if documentation is not available.

NOTE: Hands-on dentition examinations are not to be used to determine the adequacy of the documentation. If inspection program personnel have no basis to question the accuracy and reliability of records, the records are to be accepted as verification of the age of the cattle. Inspection program personnel are to conduct a hands-on dentition examination only if they have significant reason to believe that the documentation

provided by the establishment is inadequate. If a PHV examines the records and finds significant reasons for questioning their validity, they are to verify the age of the cattle through dental examination. PHVs on patrol assignments are to correlate with inspection program personnel at slaughter establishment. If a PHV is unsure as to whether the plant's records or dentition checks are adequate, he or she is to contact the Policy Development Division (formerly the Technical Service Center) for technical assistance at 1-800-233-3935.

3. If the establishment failed to accurately age cattle using dentition or documentation, then inspection program personnel are to issue a non-compliance Record (NR) as set out in FSIS Directive 5000.1, and verify that the establishment takes the proper action to restore regulatory compliance.

III. VERIFICATION OF SANITATION PROCEDURES

9 CFR 310.22(f) prescribes requirements for the sanitation of equipment used to cut through SRMs. FSIS inspection personnel are to conduct the following activities when verifying compliance with 9 CFR 310.22(f):

A**.** If an establishment does not segregate the carcasses and parts from cattle 30 months of age and older from the carcasses and parts from cattle younger than 30 months during processing operations, inspection program personnel are to verify that the establishment uses dedicated equipment to cut through SRMs, or that the establishment cleans and sanitizes equipment before it uses the equipment on the carcasses or parts from cattle younger than 30 months.

B. If an establishment segregates the carcasses and parts of cattle 30 months of age and older from cattle younger than 30 months of age during processing operations, inspection personnel are to verify that the establishment processes the carcasses or parts from the cattle younger than 30 months first or that the establishment cleans and sanitizes equipment before it is uses the equipment on the carcasses or parts from cattle younger than 30 months.

C. If during verification activities inspection program personnel find that the establishment is not appropriately sanitizing equipment, then they are to issue a NR as set out in FSIS Directive 5000.1, and verify that the establishment takes the proper action to restore regulatory compliance.

IV. POST-MORTEM VERIFICATION DUTIES

9 CFR 310.22(e)(1) requires that the procedures establishments adopt for the removal, segregation, and disposition of SRMs address potential contamination of edible materials with SRMs before, during, and after the material enters into the establishment. FSIS inspection program personnel are to conduct the following activities to verify that an establishment's procedures for the removal, segregation, and disposition of SRMs are effective in preventing contamination of edible carcasses and parts with SRMs and that the establishment takes appropriate corrective actions when such contamination occurs:

A. When on-line inspection program personnel perform individual carcass or head inspection and observe visible (readily identifiable) SRMs on edible product, the establishment may recondition the carcass or head by knife trimming. Readily identifiable SRM contamination would include grossly identifiable brain material, spinal cord outside of the spinal canal, or fluid from punctured eyes.

1. Inspection program personnel at head inspection are to have the establishment trim the readily identifiable SRMs before the carcass passes the inspection station. Inspection program personnel are to take a regulatory control action by stopping the line if such action is necessary for the establishment to trim the SRMs.

2. At carcass inspection, inspection program personnel may allow the establishment to rail out the carcass to trim the readily identifiable SRM, or take a regulatory control action by retaining the carcass and then have the establishment rail it out for trimming.

B. On-line inspection program personnel are to notify the PHV or, if unavailable, off-line inspection program personnel when there is evidence that an establishment's SRM control program is ineffective (for example, when repeated presentation of contaminated heads or carcasses for post-mortem inspection at the rail and head inspection station evidences failure to control SRM contamination.)

C. The PHV, or off-line inspection personnel, will perform the appropriate HACCP or Sanitation SOP procedures to evaluate the process. If inspection program personnel find that the establishment is not following its program, inspection program personnel are to issue an NR as set out in FSIS Directive 5000.1, and verify that the establishment takes the proper action to restore regulatory compliance.

V. VERIFICATION ACTIVITIES FOR TONSIL REMOVAL, SEGREGATION, AND DISPOSITION

The tonsils from all cattle are among the materials designated as SRMs under 9 CFR 310.22(a). FSIS inspection program personnel are to conduct the following activities to verify that an establishment’s procedures for the removal, segregation, and disposition of SRMs required under 9 CFR 310.22(e) are effective in ensuring that the tonsils do not enter the human food supply:

A. Standard verification activities for tonsil removal

1. Inspection program personnel are to verify that the establishment’s procedures for the removal, segregation, and disposition of tonsils include accepted head dressing procedures, including removal of the tongue and its associated lymph nodes, visible tonsils (palatine and lingual), fatty tissues, and salivary glands.

2. If an establishment harvests the tongue for human food, inspection program personnel are to verify that the establishment’s harvesting is accomplished by making a transverse cut caudal (just behind) to the last vallate papillae.

3. If an establishment does not have such procedures in place, or fails to execute such procedures, then they are to issue a NR as set out in FSIS Directive 5000.1, and verify that the establishment takes the proper action to restore regulatory compliance.

NOTE: Additional information and diagrams on the location of the tonsils are posted on the FSIS Web site at www.fsis.usda.gov/ofo/tsc/

B. Verification activities for tonsil removal when skinning machines are used

1. When an establishment removes tonsils from edible tongue tissue using a skinning machine, PHVs or designated inspection program personnel are to verify that it has appropriately addressed this use in its food safety system, including implementing procedures to ensure that:

a. when the tonsillar material is removed, no less than 5 mm (3/16" equals 4.8 mm and 1/4" equals 6.3 mm) from the surface of the tongue is removed from the affected portions of the tongue; and

b. visible tonsillar material (i.e., the SRM) does not remain on the blade or any part of the skinning machine in a manner that may cross-contaminate product with SRM material.

2. If an establishment does not address the use of skinning machines, or fails to execute such procedures as described in its program, inspection program personnel are to issue a NR as set out in FSIS Directive 5000.1, and verify that the establishment takes the proper action to restore regulatory compliance.
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NOTE: Inspection program personnel can find additional information and diagrams on the location of the tonsillar material on the FSIS Web site under SRM Guidance Material at:

http://www.fsis.usda.gov/About_FSIS/Technical_Service_Center/index.asp.

VI. VERIFICATION ACTIVITIES FOR DISTAL ILEUM REMOVAL, SEGREGATION, AND DISPOSITION

The regulations in 9 CFR 310.22(d) contain requirements for use of the small intestine, excluding the distal ileum, for human food. FSIS inspection personnel are to conduct the following activities to verify that establishments that use beef small intestine for human food are complying with the conditions specified in 9 CFR 310.22(d):

A. Verification Activities for Slaughter Establishments that Harvest the Small Intestine for Human Food

1. PHVs

a. PHVs are to verify into which program (i.e., HACCP plan, Sanitation SOPs, or other prerequisite program) the establishment has incorporated its procedures for removal, segregation, and disposition of the distal ileum.

b. PHVs are to verify that the establishment has appropriately addressed in its food safety system design the effective removal of the distal ileum from the small

intestine by verifying that the procedures:

i. ensure removal of 80 inches of uncoiled and trimmed small intestine as measured from the ceco-colic junction and progressing proximally towards the jejunum, or

ii. are effective in ensuring complete removal of the distal ileum.

2. Off-line inspection personnel

a. Off-line inspection program personnel are to verify the execution of the establishment's food safety system procedures to ensure the removal of the distal ileum from the small intestine.

b. As part of verifying the establishment's monitoring or verification procedures, inspection program personnel may perform a direct observation of the establishment removing the distal ileum. Inspection program personnel may use the ileo-cecal-colic juncture as a verifiable point of reference. In addition, inspection program personnel may identify the distal ileum as having no curve and an irregular thick surface.

B. Verification Activities for Processing Establishments

1. IICs in processing establishments that use small intestines from cattle in meat food products or for edible rendering, or that use casings derived from beef small intestine as containers for meat food products, are to:

a. verify which food safety program (HACCP plan or Sanitation SOP or other pre-requisite program) the establishment has incorporated its procedures for ensuring that beef small intestine for use in a meat food product, for edible rendering, or as a source material for natural casing, complies with 9 CFR 310.22(d), and

b. verify that the establishment can demonstrate, through documentation, that the small intestine complies with 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.

2. IICs are to verify that the establishment has appropriately addressed in its food safety system:

a. the use of small intestine, excluding the distal ileum, in a meat food product or for edible rendering, and

b. the use of natural casings derived from beef small intestine.

3. Inspection program personnel in processing establishments that receive small intestines, excluding the distal ileum, for use in:

a. the production of meat food products, or for edible rendering, or

b. natural beef casings as containers of products,

are to verify the establishment's execution of their food safety system procedures to ensure that the small intestine complies with 9 CFR 310.22(d) by following the directions in FSIS Directive 5000.1.

NOTE: If a processing establishment uses beef small intestines in a meat food product or for edible rendering, or if it uses natural casings derived from beef small intestines, and the establishment cannot demonstrate, through documentation, that the intestines were appropriately harvested and comply with 310.22(d), then inspection program personnel are to take a regulatory control action as set out in 9 CFR 500.2(a)(2) or (3) when product adulteration or misbranding occurs, and inform the District Office so that the District Manager can inform the appropriate Food and Drug Administration (FDA) office (because casings are regulated, at this time, by FDA).

C. Verification Activities for Import Inspection Personnel

1. Import inspection program personnel are to verify that beef small intestines entering the country for use in the production of human food:

a. were harvested in a certified establishment of a country that FSIS has found eligible to import meat and meat products into the United States and is otherwise eligible for importation under 9 CFR 327.1(b); and

b. are accompanied by documentation establishing that the small intestines, excluding the distal ileum, for use as a meat food product meet the requirements of 9 CFR 310.22(d).

NOTE: All imported unprocessed beef small intestine must be accompanied by an "Official Meat-Inspection Certificate for Fresh Meat and Meat Byproducts." (9 CFR 327.4(a)).

2. If these conditions are not met, import inspection program personnel are to follow procedures for refusing entry to the product.

VII. VERIFICAITON ACTIVITIES FOR THE PROHIBITION OF AIR-INJECTION STUNNING DEVICES

9 CFR 313.15 (b) (2) (ii) and 310.13 (a) (2) (iv) (C) prohibit the use of air-injection stunning on cattle. Inspection program personnel are to verify that establishments are not using air-injection captive bolt stunning devices. If an establishment is found to be using air-injection captive bolt stunning device, inspection program personnel are to issue an NR as set out in FSIS Directive 5000.1 and verify that the establishment takes the proper action to restore regulatory compliance.

VIII. VERIFICATION ACTIVITIES FORE THE PROHIBITION OF MECHANICALLY SEPARATED BEEF (MS (beef))

9 CFR 319.5 prohibits MS(beef) for human food. Inspection program personnel are to verify that establishments are not producing MS (beef) for human food. If an establishment is found to be producing MS (beef), inspection program personnel are to issue a NR as set out in FSIS Directive 5000.1 and verify that the establishment takes the proper action to restore regulatory compliance.

CHAPTER 3 – TRANSPORTATION OF CARCASSES/PARTS CONTAINING SRMs

9 CFR 310.22(c) contains requirements that direct that the spinal cord from cattle 30 months of age and older be removed at the establishment where the animal was slaughtered. Thus, the only SRMs that are permitted to be transported from one federally-inspected facility to another are vertebral columns. 9 CFR 310.22(g) prescribes the conditions under which establishments may ship carcasses or parts that contain vertebral columns from cattle 30 months of age and older to another federally-inspected establishment for further processing. Inspection program personnel are to conduct the following activities to verify that establishments that ship beef carcasses or parts are complying with 9 CFR 310.22(g):

I. Verification Activities at Slaughter Establishments

A. Inspection program personnel at an establishment that transports for further processing carcasses or parts of carcasses that contain vertebral columns with SRM portions are to verify that the establishment:

1. removes spinal cord from cattle 30 months of age and older when the animal is slaughtered, and only ships the vertebral column;

2. maintains control of the carcasses or parts while they are in transit (e.g., through company seals) or ensures that the carcasses or parts move under FSIS control (e.g., under USDA seal or accompanied by FSIS Form 7350-1);

3. ensures that the carcasses or parts are accompanied by documentation that clearly identifies that the carcasses or parts are from cattle that were 30 months of age and older at the time of slaughter or that clearly states that the vertebral column must be removed and disposed of as an SRM;

4. maintains records that identify the official establishment that received the carcasses or parts;

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. These records are to show the proper removal and disposition occurred for each carcass or part received; and

6. incorporates the above procedures into its HACCP System (i.e, HACCP plan or Sanitation SOPs or other prerequisite program).

B. If inspection program personnel find that the establishment has failed to develop and implement the procedures described above, they are to issue a NR as set out in FSIS Directive 5000.1, and verify that the establishment takes the proper action to restore regulatory compliance.

II. Verification Activities at Receiving Establishments

A. Inspection program personnel at an establishment that receives for further processing carcasses or parts of carcasses of cattle that contain vertebral columns with SRM portions are to verify that the establishment:

1. has implemented controls to identify carcasses or parts that contain vertebral columns with SRM portions;

2. has 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. has incorporated these controls into its HACCP System (i.e., HACCP plan, or Sanitation SOPs or other prerequisite program); and

4. maintains records that verify that the SRM portions of the vertebral column were removed and disposed of as inedible.

B. Other specific verification procedures will depend on how establishments that receive carcasses or parts of carcasses from cattle for further processing choose to address removal of the SRM portion of the vertebral column.

1. If an establishment only receives carcasses or parts of carcasses from cattle that were 30 months of age and older at the time of slaughter, or processes all carcasses or parts as if they were from cattle 30 months of age and older, inspection program personnel are to verify that the establishment:

a. documents the receipt of the carcasses or parts, including the official establishment from which the carcasses or parts were received;

b. ensures that the SRM portion is removed and disposed of as inedible; and

c. ensures that the SRM portion of the vertebral columns is removed in a manner that does not contaminate edible product.

2. If an establishment receives for further processing mixed carcasses or parts (i.e., carcasses or parts from cattle that were both 30 months of age and older, and younger than 30 months, at the time of slaughter), inspection program personnel are to verify that the establishment:

a. identifies through documentation from the supplier which carcasses or parts are from cattle that were 30 months of age and older at the time of slaughter, and which carcasses or parts were from cattle that were younger than 30 months at the time of slaughter;

b. ensures that carcasses or parts that are from cattle that were 30 months of age and older at the time of slaughter are segregated from the carcasses or parts of cattle that were younger than 30 months at the time of slaughter;

c. ensures that the SRM portion is removed and disposed of as inedible, and

d. ensures that the SRM portion of the vertebral columns is removed in a manner that does not contaminate edible product.

REMINDER: If an establishment that receives carcasses or parts from cattle both under and over 30 months of age, or that receives only carcasses or parts from cattle that were younger than 30 months at the time of slaughter, cannot demonstrate through documentation from the supplier that the carcasses or parts are from cattle that were under 30 months at the time of slaughter, 9 CFR 310.22(e) requires that the establishment handle all carcasses and parts for which such documentation is not provided as if they were from cattle 30 months of age and older at the time of slaughter.

C. If inspection program personnel find that the establishment has failed to develop and implement the procedures described above (where applicable), they are to issue an NR as set forth in FSIS Directive 5000.1, and verify that the establishment takes the proper action to restore regulatory compliance.

CHAPTER 4: FSIS DOCUMENTATION AND ENFORCEMENT

I. DOCUMENTATION

A. For every NR that inspection program personnel issue, it is important that they cite all relevant regulations. These citations provide data that are the basis for critical, risk-based decisions that FSIS makes when working to ensure that meat and poultry products are safe. Thus, it is not appropriate for inspection program personnel to cite only one regulation if other regulations are also violated by the noncompliance that is the subject of the NR.

B. Inspection program personnel are to cite the appropriate subsections of 9 CFR 310.22 in the *Relevant Regulation* section of **every** NR for an establishment that does not meet the regulatory requirements for controlling SRMs. In addition to selecting 9 CFR 310.22, inspection program personnel are to select **all** other regulations with which there has been noncompliance.

C. Inspection program personnel are to describe the noncompliances in the *Narrative Section*, block 10, of the NR. The narrative should include a complete description of the SRM noncompliance, including the type of SRM and any other information relevant to the noncompliance. The narrative should also address each of the other regulations that inspection program personnel cite in the *Relevant Regulations* section on the NR screen. The statements in block 10 of the NR are to support completely and adequately the regulatory noncompliances cited.

II. ENFORCEMENT

A. If inspection program personnel find that an establishment has failed to develop and implement the procedures (e.g., recordkeeping; removal, segregation and disposition of SRMs) to comply with 9 CFR 310.22 or determine that the process failed to prevent SRMs from adulterating product, inspection program personnel are to issue a NR under the appropriate procedure code and mark the appropriate trend indicator as described in FSIS Directive 5000.1, Chapters I (Sanitation), II (HACCP), and IV (Enforcement). Inspection program personnel should verify that the establishment takes the corrective actions required by 9 CFR 417.3(a) or (b) or 416.15. If the procedures are under a prerequisite program, inspection program personnel are to verify that the establishment reassesses its HACCP plan to determine whether the prerequisite program continues to support the decisions made in the hazard analysis.

B. For those establishments failing to prevent SRM contamination of product, FSIS will take a regulatory control action as set out in 9 CFR 500.2(a)(2) or (3) when product adulteration or misbranding occurs.

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

Assistant Administrator
Office of Policy, Program, and Development

PART 310--POST-MORTEM INSPECTION

4. The authority citation for part 310 continues to read as follows:

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

5. Section 310.22 is revised to read as follows:

Sec. 310.22 Specified risk materials from cattle and their handling and disposition.

(a) The following materials from cattle are specified risk materials, except when they are from cattle from a country that can demonstrate that its bovine spongiform encephalopathy (BSE) risk status can reasonable be expected to provide the same level of protection from human exposure to the BSE agent as prohibiting specified risk materials for use as human food does in the United States:

(1) The brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia from cattle 30 months of age and older
and

(2) The distal ileum of the small intestine and the tonsils from all cattle.

(b) Specified risk materials are inedible and prohibited for use as human food.

(c) Specified risk materials must be removed from the carcasses of cattle, segregated from edible materials, and disposed of in accordance with Sec. 314.1 or Sec. 314.3 of this subchapter. The spinal cord from cattle 30 months of age and older must be removed from the carcass at the establishment where the animal was slaughtered.

(d) Requirements for use of the small intestine for human food. (1)

The small intestine from all cattle may be used for human food if:

(i) It is derived from cattle that were inspected and passed in an official establishment in the United States or in a certified foreign establishment in a country listed in 9 CFR 327.2(b) as eligible to export meat and meat products to the United States and it is otherwise eligible for importation under 9 CFR 327.1(b), and

(ii) The distal ileum is removed by a procedure that removes at least 80 inches of the uncoiled and trimmed small intestine as measured from the ceco-colic junction and progressing proximally towards the jejunum or by a procedure that the establishment demonstrates is effective in ensuring complete removal of the distal ileum.

(iii) If the conditions in paragraphs (d)(1)(i) or (ii) of this section are not met, the entire small intestine must be removed from the carcass, segregated from edible materials, and disposed of in accordance with Sec. Sec. 314.1 or 314.3 of this subchapter.

(2) The requirements in paragraph (d)(1) of this section do not apply to materials from cattle from countries that can demonstrate that their BSE risk status can reasonably be expected to provide the same level of protection from human exposure to the BSE agent as prohibiting specified risk materials for use as human food does in the United States.

(e) Procedures for the removal, segregation, and disposition of specified risk materials. (1) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle must develop, implement, and maintain written procedures for the removal, segregation, and disposition of specified risk materials. These procedures must address potential contamination of edible materials with specified risk materials before, during, and after entry into the establishment. Establishments must incorporate their procedures for the removal, segregation, and disposition of specified risk materials into their HACCP plans or Sanitation SOPs or other prerequisite programs.

(2) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle must take appropriate corrective action when either the establishment or FSIS determines that the establishment's procedures for the removal, segregation, and disposition of specified risk materials, or the implementation or maintenance of these procedures, have failed to ensure that specified risk materials are adequately and effectively removed from the carcasses of cattle, segregated from edible materials, and disposed of in accordance with paragraph (c) of this section.

(3) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle must routinely evaluate the effectiveness of their procedures for the removal, segregation, and disposition of specified risk materials in preventing the use of these materials for human food and must revise the procedures as necessary whenever any changes occur that could affect the removal, segregation, and disposition of specified risk materials.

(4) Recordkeeping requirements. (i) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle must maintain daily records sufficient to document the implementation and monitoring of the procedures for the removal, segregation, and disposition of the materials listed in paragraph (a) of this section, and any corrective actions taken.

(ii) Records required by this section may be maintained on computers provided that the establishment implements appropriate controls to ensure the integrity of the electronic data.

(iii) Records required by this section must be retained for at least one year and must be accessible to FSIS. All such records must be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

(f) Sanitation of equipment used to cut through specified risk materials. (1) If an establishment that slaughters cattle, or that processes the carcasses or parts from cattle, does not segregate the carcasses and parts from cattle 30 months of age and older from the carcasses and parts from cattle younger than 30 months during processing operations it must:

(i) Use dedicated equipment to cut through specified risk materials; or

(ii) Clean and sanitize equipment used to cut through specified risk materials before the equipment is used on carcasses or parts from cattle younger than 30 months of age.

(2) If an establishments that slaughters cattle, or that process the carcasses or parts from cattle, segregates the carcasses and parts of cattle 30 months of age and older from cattle younger than 30 months of age during processing operations, and processes the carcasses or parts from the cattle younger than 30 months first, it may use routine operational sanitation procedures on equipment used to cut through specified risk materials.

(g) Slaughter establishments may ship beef carcasses or parts that contain vertebral columns from cattle 30 months of age and older to another federally-inspected establishment for further processing if the establishment shipping these materials:

(1) Maintains control of the carcasses or parts while they are in transit or ensures that the carcasses or parts move under FSIS control;

(2) Ensures that the carcasses or parts are accompanied by documentation that clearly states that the carcasses or parts contain vertebral columns from cattle that were 30 months of age and older at the time of slaughter;

(3) Maintains records that identify the official establishment that received the carcasses or parts;

(4) Maintains records that verify that the official establishment that received the carcasses or parts removed the portions of the vertebral column designated as specified risk materials in paragraph (a)(1) of this section and disposed of them in accordance with Sec. 314.1 or Sec. 314.3 of this subchapter.

(h) The materials listed in paragraph (a)(1) of this section will be deemed to be from cattle 30 months of age and older unless the establishment can demonstrate through documentation that the materials are from an animal that was younger than 30 months of age at the time of slaughter.

PART 318--ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

6. The authority citation for part 318 continues to read as follows:

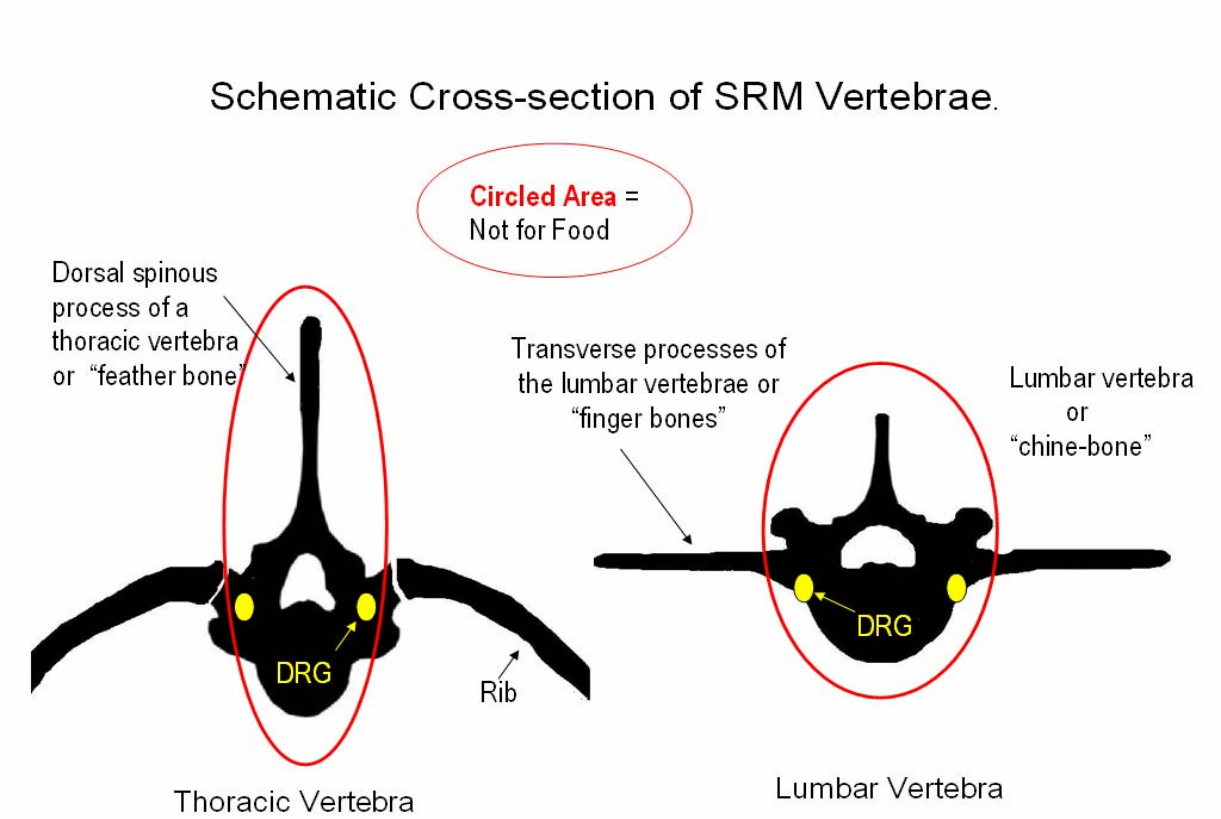
Authority: 7 U.S.C. 38f, 450, 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

Sec. 318.6 [Amended]

7. Section 318.6 is amended as follows:

a. In the third and fourth sentences of paragraph (b)(1) remove “9 CFR 310.22(a)(3)" and add ``9 CFR 310.22(d)" in its place.

b. In the second sentence in paragraph (b)(8) remove “9 CFR 310.22(a)(3)" and add ”9 CFR 310.22(d)" in its place.


Schematic Cross-section of SRM Vertebrae.
Circled Area =
Not for Food
Dorsal spinous process of a thoracic vertebra or "feather bone"
DRG
Rib
Thoracic Vertebra
Transverse processes of the lumbar vertebrae or "finger bones"
Lumbar vertebra or "chine-bone"
DRG
Lumbar Vertebra