

Specified Risk Material (SRM) Control

Objectives

After completing this section of the training, participants will be able to:

1. Identify Specified Risk Materials (SRMs)
2. State the purpose of the SRM Control Verification task and how to perform it
3. Identify the actions IPP are to take when SRM noncompliance is found while performing the SRM Control Verification task

References

1. 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 (Docket No. 03–025F; Federal Register Volume 72)
2. 9 CFR 310.22
3. FSIS Directive 6100.4, Rev. 1, Verification Instructions Related to Specified Risk Materials in Cattle of All Ages
4. FSIS PHIS Directive 5000.1, Verifying an Establishment's Food Safety System
5. BSE and SRM Guidance Materials and Resources:
<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/specified-risk-material>
6. Using Dentition to Age Cattle: https://www.fsis.usda.gov/wps/portal/frame-redirect?url=https://www.fsis.usda.gov/OFO/TSC/bse_information.htm

Background

Specified risk materials (SRMs) are tissues in cattle that are considered to be of high risk for prion contamination. Prions are thought to be the cause of a group of diseases called transmissible spongiform encephalopathies (TSE) which are diseases of the brain. Mad cow disease or bovine spongiform encephalopathy (BSE) is the brain disease that affects cattle. The human version of BSE is known as variant Creutzfeldt–Jakob disease (vCJD).

The removal of SRMs from all cattle presented for slaughter in accordance with 9 CFR 310.22 is the most important safeguard the United States has against BSE. Establishments that slaughter cattle or process carcasses or parts of cattle must identify, remove, and segregate SRMs from edible materials, and dispose them in accordance with Part 314. SRMs are inedible and cannot be used for human

food (9 CFR 310.22 (b)). All SRMs are prohibited from being used in edible rendering (9 CFR 318.6 (b) (4)). However, SRMs may be used in inedible rendering unless the animal is being tested for BSE.

Note: FDA requires removal of brain and spinal cord SRM from rendered products intended for animal food. To comply with the FDA feed ban final rule, establishments may take additional steps to remove SRM (brain and spinal cord of cattle 30 months and older) to ensure meat and bone meal derived from such rendered product may be used in the manufacture of animal feed. FSIS has no jurisdiction over animal feed and does not verify this requirement.

Specified Risk Materials

SRMs are found in cattle of all ages. The age of cattle determines which SRMs require segregation, removal and disposal. Tonsils and the distal ileum of the small intestine are SRMs from cattle of any age. Several tissues are SRMs only in cattle 30 months of age and older (OTM+). For cattle 30 months of age or older, additional SRMs are the skull, brain, trigeminal ganglia (nerves attached to the brain), eyes, 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 (nerves attached to the spinal cord).

Specified Risk Materials in Cattle

All Ages 310.22(a)(2)	Tonsils and Distal Ileum (80 inches of unstretched small intestine)
30 Months or older 310.22(a)(1)	Skull, Brain, Eyes, Spinal Cord, Trigeminal Ganglia, Dorsal Root Ganglia, Vertebral Column

As indicated previously, tonsils are SRMs, inedible, and not for use in human food. All visible tonsils must be removed under both 9 CFR 310.22(c) and 9 CFR 318.6(b). Beef market heads eligible for the mark of inspection require removal of all identifiable tonsil SRM tissue (i.e., lingual, palatine, and pharyngeal tonsils). Lingual tonsils are located under the skin at the base of the tongue, just behind the last vallate papilla. The vallate papillae are large, circular structures on each side near the back of the tongue. Palatine tonsils are located adjacent to soft palate below the mucosal surface and the opening of sinus of palatine tonsil.

The distal ileum of the small intestine is also designated as an SRM. The distal ileum is defined as 80 inches of uncoiled and trimmed small intestine, measuring from the ceco-colic junction, proximally towards the jejunum. The ceco-colic junction is the anatomic point at which the cecum and the colon join. If conditions

for documentation or removal are not met, the entire small intestine becomes inedible.

Beef small intestines, excluding the distal ileum, can be used for human food or in the manufacture of beef natural casings (9 CFR 318.6(b)(8)). Beef small intestines can be used in meat food products and edible rendering (9 CFR 318.6(b)(1)) provided that the establishment can show that the small intestines comply with 9 CFR 310.22(d).

The dorsal root ganglia represent the junction of spinal and peripheral nerves and are located close to the intervertebral foramina anterior and just ventral to the transverse process of the caudal vertebra. Traditional T-bone or porterhouse steaks and bone-in rib roasts may be derived from domestic cattle less than 30 months of age. A portion of the vertebral column bone defining these cuts of meat from cattle 30 months and older must be removed, resulting in a semi-boneless cut of meat. As long as the cut made by the saw is perpendicular to the blade of the transverse process and far enough out on the transverse processes that neither the dorsal or ventral parts of the articular processes of the vertebrae are transected, the ends of the transverse processes will be oval, there will be no other bone in the roast portion of the product, and the dorsal root ganglia will be removed with the waste bone portion.

The vertebral column and spinal cord of cattle 30 months of age and older are considered to be SRM. 9 CFR 310.22(c) indicates that the spinal cord from cattle 30 months of age and older must be removed at the establishment where the animal was slaughtered. Prior to removal, any SRM (e.g., spinal cord found outside the spinal canal) found outside its normal location and not promptly removed is considered to be contamination and must be addressed by the establishment's SRM removal (sanitation) program. After carcass-splitting, it is acceptable to remove visible spinal cord outside of the spinal canal with knife trimming.

Since mechanical stunning of cattle 30 months of age or older may result in contamination of head surfaces with SRM brain material, IPP are to verify effectiveness of establishment procedures to remove SRMs prior to inspection.

Establishments' Specified Risk Material Control Programs

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

Specified Risk Material Control Verification Task

FSIS designed the SRM Control Verification task to verify the implementation of establishments' SRM control programs through review of records and direct observation. The SRM Control Verification task:

- Helps reduce the need for recalls due to SRM distribution in commerce,
- Verifies the establishment's written SRM procedures and records,
- Documents the direct observation of the segregation, removal, and disposal of SRMs,
- Specifies a minimum frequency for SRM compliance verification, and
- Supports the United States' BSE negligible risk status.

Before conducting the SRM Control Verification task, IPP must already be familiar with the written procedures in the establishment's SRM control program. When performing the SRM Control Verification task, IPP are to verify that establishments maintain adequate written SRM procedures and records and, through direct observation, the segregation, removal, and disposal of SRMs by the establishment. IPP are to complete the SRM Control Verification task by performing Review and Observation and Record Keeping activities (components). IPP select the "both" radio button for the task in PHIS.

IPP verify that the establishment is implementing and maintaining adequate written SRM procedures and maintaining records. IPP are to verify that records demonstrate carcasses containing SRMs are correctly identified and handled throughout slaughter and fabrication. IPP verify record keeping requirements according to the regulations that apply (see Diagram 1).

Diagram 1: SRM Regulations to Verify

SRM Written Procedures and Records (Record Keeping)	310.22(d)(2) 310.22(e)(1, 3, 4) 310.22(g)(2, 3, 4) 417 or 416.11-16	Imported Product Written Procedures Shipping Records HACCP or SSOP
SRM Segregation, Removal, and Disposal (Review and Observation)	310.22(c) 310.22(d)(i, ii, iii) 310.22(e)(2) 310.22(f)(1)(i, ii) 310.22(f)(2) 310.22(g)(1) 310.22(h)	SRM Control Small Intestine Corrective Actions Equipment Segregate Shipping Controls Age Determination

IPP also verify that the establishment effectively segregates, removes, and disposes of SRMs for a selected lot of product when performing a routine SRM Control Verification task (see Diagram 1). For example, IPP can observe establishment employees implementing adequate sanitation procedures (e.g., having dedicated equipment for removing or cutting through SRMs, or cleaning and sanitizing equipment used to remove or cut through SRMs before the equipment is used on carcasses or parts from cattle younger than 30 months of age), removing tonsil, distal ileum, any other SRMs, and disposing of the SRMs as inedible product, and corrective actions. IPP may also examine carcasses and carcass parts, e.g., small intestines (if harvested), carcass sides, steaks, and tongues, to verify that SRMs have been removed.

IPP perform a routine SRM Control Verification task approximately once every two weeks on each slaughter or processing shift. The inspection team may increase the number of SRM Control Verification tasks performed by adding inspector generated tasks in PHIS. IPP consider past SRM noncompliance when deciding to perform additional tasks. If warranted, IPP schedule additional **directed instances** of the task and notify their Frontline Supervisor. Examples of situations when it would be appropriate to schedule additional SRM Control Verification tasks include:

- A finding of SRM noncompliance, such as a failure to remove at least 80 inches of the uncoiled and trimmed small intestine as measured from the ceco-colic junction when the small intestine is to be used as human food,
- Modifications to SRM processing, such as changing to knife from vacuum removal of spinal cord from the spinal canal, and
- New establishment personnel are performing SRM procedures.

SRM Noncompliance

When IPP observe SRM noncompliance while performing the SRM Control Verification task, they are to:

- Take a regulatory control action to prevent further contamination of product and retain adulterated product (9 CFR 500.2),
- Notify establishment management of the noncompliance,
- Verify that the establishment takes corrective regarding any edible product adulterated with SRMs (e.g., removal of remaining lingual tonsils on tongues), restores sanitary conditions, and properly disposes of SRMS,

- 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 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.
- Complete the SRM Control Verification task after IPP 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, SSOP) 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 of (9 CFR 310.22(e)(2))

SRM Regulations

§ 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 § 314.1 or § 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 §§ 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 § 314.1 or § 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.