Bovine Spongiform Encephalopathy (BSE): Key Points for the Public Health Veterinarian

OBJECTIVES

- Describe the responsibilities of the PHV when presented with a non-ambulatory disabled bovine on ante-mortem inspection.
- List the tissues that are considered to be specified risk material (SRM).
- Describe the FSIS policies related to specified risk materials (SRMs) and the FSIS responsibilities related to implementing those policies.
- Define the FSIS policies related to mechanically separated (MS) beef.
- Define the FSIS policies related to advanced meat recovery (AMR).
- Explain the reason for the prohibition of air injection stunning.
- Identify the key aspects of the BSE surveillance program.

INTRODUCTION

In this module we will look at the regulatory requirements that were implemented as a result of the positive finding of BSE in the US. In December 2003, a positive case of BSE was confirmed in a cow presented for slaughter at a federally inspected establishment in Washington State. In response to this finding, in January 2004, FSIS issued three interim regulations and a notice in the Federal Register. The purpose of these policy issuances is to minimize human exposure to the BSE agent.

The interim regulations (69 FR 1862-1892) issued in January 2004 include:

- Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle (Docket No. 03-025IF)
- Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems (Docket No. 03-038IF)
- Prohibition of the use of certain stunning devices used to immobilize cattle during slaughter (Docket No. 01-033IF)

On July 13, 2007, FSIS issued Docket 03-025F entitled "*9 CFR Parts 309, 310 and 318 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; Rule*. This document finalized several of the interim regulations that were issued in 2004.

The Federal Register notice (Docket No. 03-048N) issued in 2004 is titled "Bovine Spongiform Encephalopathy Surveillance Program". The following sections provide an overview of each of these policies and the inspection duties associated with them.

Non-ambulatory disabled cattle

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

Non-ambulatory disabled cattle are not allowed to enter the slaughter establishment. They must be humanely handled, killed in a timely manner and removed from the premises to prevent insanitary conditions. Disposal must be in accordance with 9 CFR 309.13. FSIS will record non-ambulatory animals as "condemned" and verify that the carcass is appropriately treated so that it does not enter into the human food chain.

As a result of the policies regarding non-ambulatory disabled cattle, FSIS will also no longer allow the delayed slaughter or emergency slaughter of cattle as prescribed in 9 CFR 311.27.

Specified risk materials

The BSE regulations (9 CFR 310.22) identify specified risk material (SRM) as:

- the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the tail vertebrate, thoracic and lumbar transverse processes, and sacral wings) and dorsal root ganglia (DRG) of <u>cattle 30 months of age and older</u>, and

- the tonsils and distal ileum of the small intestine of <u>all cattle, regardless of age</u>.

These materials were identified as SRMs because scientific studies have shown them to contain the infective agent for BSE. Except for the skull and vertebral column, SRMs have demonstrated infectivity in cattle either naturally or experimentally. The skull and vertebral column are included because they contain the trigeminal ganglia (skull) or the spinal cord and DRG (vertebral column).

Specified risk materials are declared as inedible and cannot be used for human food (9 CFR 310.22 (b)). The interim final rule on SRMs explained , *"Because BSE was recently confirmed in a cow in the United States, FSIS has determined that the SRMs identified in this document are unfit for human food. Thus, the status of most of these materials has changed from edible to inedible. Such a change is likely to affect the underlying hazard analysis that must be conducted as prescribed by 9 CFR 417.4(a)(3). Therefore, in response to this change, FSIS expects that establishments that slaughter cattle and establishments that process the carcasses or parts of cattle will reassess their HACCP plans in accordance with 9 CFR 417.4(a)(3) to address SRM."* Therefore, in accordance with 9 CFR 310.22 (e)(1) establishments must develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs. These procedures must be incorporated into the establishment's HACCP plans, Sanitation SOPs or other prerequisite program.

Corrective actions must be taken by the establishment when either the establishment or FSIS determines that the establishment's SRM removal procedures have failed. This direction is reflected in the 9 CFR 310.22 (e)(2) regulation, which states, "*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 such procedures, have failed to ensure that such materials are adequately and effectively removed from the carcass of cattle, segregated from edible materials, and disposed of in accordance with paragraph (c) of this section."* If SRM removal is included in the HACCP plan, then corrective actions described under 9 CFR 417.3 should be addressed. If it is included in the Sanitation SOP, the corrective actions identified under 9 CFR 416.15 should be addressed.

The establishment must also routinely evaluate the effectiveness of their procedures and revise the procedures as necessary. 9 CFR 310.22 (e)(3) states, "*Establishments that process the carcasses or parts of cattle shall 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 shall revise the procedures as necessary whenever any changes occur that could affect the removal, segregation, and disposition of specified risk materials."* Custom-exempt establishments must comply with the adulteration provisions of the FMIA and SRM must be handled as inedible.

Establishments must maintain daily records sufficient to document the implementation and monitoring of all SRM procedures. The regulations (310.22 (e)(4)(i)) state, "*Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle shall 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."*

Required establishment records may be maintained on computers provided that the establishment implements appropriate controls to ensure the integrity of the electronic data (9 CFR 310.22 (e)(4)(ii)).

Records must be retained for at least one year and must be accessible to FSIS. All such records must also be maintained at the official establishment 48 hours following completion (310.22 (e)(4)(iii)). After 48 hours records may be maintained off-site provided they can be made available to FSIS within 24 hours of request.

The SRMs are considered to be from cattle 30 months of age and older unless the establishment can demonstrate that the materials are from an animal that was younger than 30 months of age at the time of slaughter (9 CFR 310.22 (h)). One of an establishment's first activities should be to identify the age of cattle because SRMs are different for cattle 30 months of age and older. If the establishment does not have records on the age and is not using dentition, it should handle <u>all</u> carcasses and parts as if they were from cattle 30 months of age and older. Documentation (records-based age verification), 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.

In the final regulations issued in July 2007, FSIS added a regulatory requirement for the sanitation of equipment used to cut through SRMs (310.22 (f). The regulations allow the establishment flexibility to choose if they will segregate young cattle (less than 30 months of age) from older cattle in their establishment In establishments that slaughter both young cattle and cattle 30 months and older, FSIS recommends that young cattle be slaughtered first. When cattle 30 months of age and older are slaughtered first, inspection program personnel should verify that equipment is sanitized and cross-contamination of carcasses younger than 30 months does not occur.

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

Vertebral columns / spinal cord

The vertebral column and spinal cord of cattle 30 months of age and older are considered to be SRM. 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. Any spinal cord found on the carcass is considered to be contamination and must be addressed by the establishment. After carcass-splitting, it is acceptable to remove visible spinal cord outside of the spinal canal with knife trimming.

The vertebral column does not have to be removed during the slaughter operation. Establishments are permitted to transport such carcasses or parts to another official establishment for processing. 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. There are four conditions that must be met. The establishment must:

> (1) Maintain control of the carcasses or parts while they are in transit or ensures that the carcasses or parts move under FSIS control;
>
> (2) Ensure 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) Maintain records that identify the official establishment that received the carcasses or parts;
>
> (4) Maintain 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

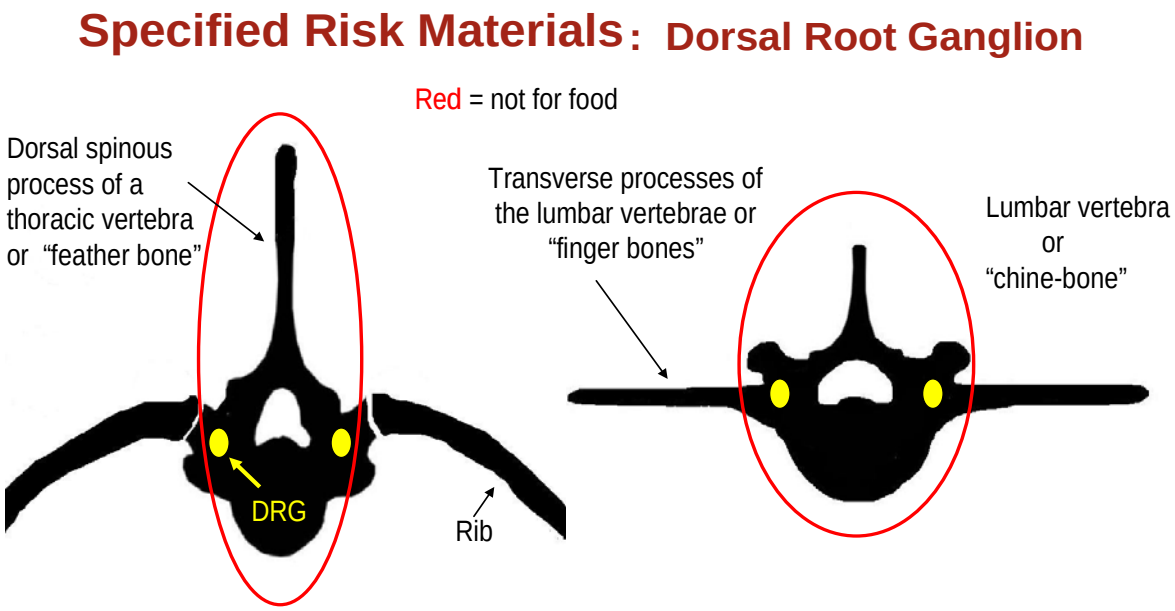
Inspection program personnel are to conduct verification activities to ensure that establishments that ship beef carcasses or parts are complying with 9 CFR 310.22(g). Verification procedures for FSIS inspection program personnel are detailed in FSIS Directive 6100.4. “Verification instruction related to specified risk materials".

Dorsal Root Ganglion (DRG)

The dorsal root ganglia are nodular enlargements of nervous tissue connected to the spinal cord, that are located in close proximity to the intervertebral foramina. Processing establishments that use bone-in carcasses or parts from cattle 30 months of age and older must properly address SRM removal and control.

Traditional T-bone or porterhouse steaks and bone-in rib roasts can no longer come from cattle older than 30 months. A portion of the vertebral column bone defining these cuts of meat must be removed (see the figure below), 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 DRG should be left in the waste bone portion.

Figure 1.



Heads

Since stunning may result in contamination of head surfaces, heads from cattle 30 months of age or older, are to be condemned unless the establishment can ensure that the stunning does not result in brain leakage onto the head.

Tonsillar Material

If the establishment will be harvesting beef tongues or market heads for human food, procedures must be in place to effectively remove tonsillar tissue from each tongue and head. The establishment can use any verifiable method of removing tonsillar tissue. Two methods currently being used are:

- Transverse cut - The edible portion of the tongue can be separated from affected portions of the tongue by making a transverse cut behind the last vallate papilla. (IKE 06-04)
- Skinning - A new technology, using a skinning machine allows the establishment to salvage most of the muscular portion of the tongue typically removed with the transverse cut method. The skinning machine removes a minimum of 5 mm from the surface of the affected part of the tongue, removing the tonsillar material sitting just below the mucosal surface. Guidance to inspection program personnel about verification procedures associated with the removal of tonsillar material using a skinning machine is provided in FSIS Directive 6100.4.

Small Intestines

On September 7, 2005 FSIS amended the regulations to permit, under certain conditions, the use of beef small intestines, excluding the distal ileum, to be used for human food. Initially the use of the entire beef small intestine was prohibited. Under the 2005 amendment, beef small intestine may be used for human food if (1) it is derived from cattle slaughtered from an official establishment in the U.S., or a certified foreign establishment in a foreign country that is eligible to export beef products to the U.S. **and** (2) the distal ileum is removed by a procedure that detaches 80 inches of uncoiled and trimmed small intestine, measuring from the ceco-colic junction, proximally towards the jejunum.

Subsequently, natural casings of beef small intestines, and beef small intestines can be used as containers for meat food products (9 CFR 318.6(b)(8)), and beef small intestines can be used in meat food products and edible rendering (9 CFR 318.6 (b)(1)) provided the establishment can demonstrate, through documentation, that the small intestines comply with 9 CFR 310.22 (d).

Guidance to inspection program personnel about verification procedures associated with beef small intestines is provided in FSIS Directive 6100.4

SRM Non-compliance

When an establishment does not meet the regulatory requirements for controlling SRM, inspection program personnel are to issue a non-compliance record (NR) and cite 9 CFR 310.22 in the *Relevant Regulation* section of the NR. In addition to selecting 9 CFR 310.22, inspection program personnel are to select **all** other regulations with which there has been noncompliance. The IIC is responsible for notifying the appropriate establishment official of the SRM non-compliance and for verifying that the corrective actions implemented by the establishment meet the HACCP requirements of 9 CFR 417.3(a) or Sanitation SOP requirements of 9 CFR 416.15; or pre-requisite program requirements documented under record-keeping requirements in 9 CFR 417.5 before issuing the NR. Refer to FSIS Directive 6100.4 and the Interactive Knowledge Exchange, (IKE) 01-07 "Citing Relevant Regulations When Documenting SRM Noncompliance" for more detailed guidance.

Mechanically separated (MS) beef

Mechanically separated (MS) beef is prohibited from use for human food. This product has a paste-like consistency as a result of forcing beef, pork or chicken bones, with attached edible meat, under high pressure through a sieve or similar device to separate the bone from the edible meat tissue. The MS process usually crushes bones, resulting in a product that contains high levels of calcium, iron and any nervous tissue that may be associated with the bones used.

There are currently no regulatory restrictions on the incorporation of spinal cord and DRG into MS (beef) meat food product and such product may contain concentrated amounts of these high-risk tissues. Therefore FSIS has concluded that MS (beef) is unfit for human food under section 1(m)(3) of the FMIA (21 U.S.C. 601(m)(3)).

Advanced Meat Recovery (AMR)

AMR also removes muscle tissue from the bone of beef carcasses under high pressure. However, in contrast to MS product, this is achieved without incorporating bone material into the product. The AMR process is sometimes referred to as a "soft" extrusion method. A "baader type" machine is an example of a mechanism used for the AMR process.

An AMR product can be labeled as "meat." Regulations define the materials that may go into the process and what may be contained in the recovered product. "Meat" may not include significant portions of bone, including hard bone and related components, such as bone marrow, or any amount of brain, trigeminal ganglia, spinal cord, or dorsal root ganglia (DRG).

Skulls and vertebral column bones of cattle 30 months of age and older are now prohibited from being used in AMR product. 9 CFR 318.24 (a) of the regulations state, "*Meat, as defined in § 301.2 of this subchapter, may be derived by mechanically separating skeletal muscle tissue from the bones of livestock, other than skulls or vertebral column bones of cattle 30 months of age and older as provided in § 310.22 of this sub-chapter, using advances in mechanical meat/bone separation machinery (i.e., AMR systems).*"

Brain, trigeminal ganglia, spinal cord, or dorsal root ganglia (DRG) tissue may not be present in any product prepared using AMR. Any product that contains SRM material from cattle 30 months of age and older is considered adulterated. Meat that contains unlabeled brain, trigeminal ganglia, spinal cord or DRG from cattle less than 30 months of age is considered "misbranded". Therefore, the AMR production process is not in control if skulls entering the AMR system contain any brain or trigeminal ganglia tissue, or if the vertebral column bones entering the AMR system contain any spinal cord.

Spent skulls or vertebral column bone materials from cattle younger than 30 months of age that exit the AMR system may not be used as an ingredient of a meat food product. The regulation limits the amount of bone solids or bone marrow as measured by the presence of calcium and iron. AMR product must not contain more than 130 mg of

calcium per 100 grams or more than 3.5 mg of iron per 100 grams (9 CFR 318.24 (c)(1)).

9 CFR 318.24(b) provides that establishments operating AMR systems are required to develop, implement, and maintain procedures that ensure that their production process is in control. The interim final rule (Docket N0. 03-038IF) states*, "The establishment must incorporate its production process procedures in a written program that is designed to ensure the ongoing effectiveness of the process control program. Because of the food safety concerns presented by SRMs, for establishments that process cattle, the written program must be in the establishment's Hazard Analysis and Critical Control Point (HACCP) plan, or in its Sanitation Standard Operating Procedure (Sanitation SOP) or other prerequisite program."* The establishment must document its production process controls in writing. The program must be in its HACCP plan, Sanitation SOP, or other prerequisite program.

The program must describe on-going verification activities including:

- observation of the bones entering the AMR system for brain, trigeminal ganglia, and spinal cord;
- the testing of the product exiting the AMR system for bone solids, bone marrow, spinal cord, and DRG;
- the use of the product and spent bone materials exiting the AMR system; and
- the frequency with which these activities will be performed.

Furthermore, 9 CFR 318.24 (b)(2) of the regulations states, *"The program shall describe the on-going verification activities that will be performed, including the observation of the bones entering the AMR system for brain, trigeminal ganglia, and spinal cord; the testing of the product exiting the AMR system for bone solids, bone marrow, spinal cord, and DRG as prescribed in paragraph (c)(1) of this section; the use of the product and spent bone materials exiting the AMR system; and the frequency with which these activities will be performed."*

The establishments must maintain records on a daily basis sufficient to document the implementation and verification of its production process. These records must be made available to FSIS personnel.

The production process is not in control if:

- the skulls entering the AMR system contain any brain or trigeminal ganglia tissue;
- the vertebral column bones entering the AMR system contain any spinal cord;
- the recovered product contains DRG or spinal cord; or
- the recovered product exceeds calcium or iron levels.

In addition, the production process is not in control if:

- the product is not properly labeled; or
- the spent bone materials are not properly handled.

Prohibition of air injection stunning

Air injection stunning is defined as captive bolt stunners that deliberately inject compressed air into the cranium at the end of the penetration cycle. Studies have

shown that air injection stunning can force visible pieces of brain and other CNS tissues into the circulatory system of cattle.. This can result in brain (SRM) emboli being disseminated into edible tissues. Therefore air injection stunning devices are prohibited. The regulation 9 CFR 313.15 (b)(2)(ii) states, "C*aptive bolt stunners that deliberately inject compressed air into the cranium at the end of the penetration cycle shall not be used to stun cattle."*

BSE surveillance

The USDA has taken aggressive measures to prevent the introduction and potential spread of BSE. Surveillance for this disease has been conducted since 1990, but was expanded in scope and intensity in December 2003 following the confirmation of BSE in a cow imported from Canada. This expanded surveillance effort was designed to estimate the prevalence of disease present in the United States and provide input for designing a long-term surveillance plan.

On July 20, 2006, USDA-APHIS released an updated surveillance plan entitled "Bovine Spongiform Encephalopathy (BSE) Ongoing Surveillance Plan". The plan is intended to inform and educate USDA's partners and stakeholders on approaches to be employed in ongoing BSE surveillance in the U.S. The plan retains the USDA's ability to detect BSE at 1 infected animal per 1,000,000 adult cattle in the population with a high degree of confidence, maintains surveillance at levels that exceed international standards, emphasizes sample collection from cattle subpopulations where BSE is most likely to be detected, and retains sample collections from all important surveillance sources.

The plan follows surveillance system design standards and guidelines established by the USDA's Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS), National Surveillance Unit (NSU). This system is based on current World Organization for Animal Health (OIE) guidelines that emphasize obtaining quality samples from high risk subpopulations rather than an arbitrary number of animals. Thus, meaningful surveillance can occur with a fairly low number of animals. For this reason, a major focus of the *Ongoing BSE Surveillance Program* will be to obtain samples from cattle that are "clinical suspects". This subpopulation of cattle, particularly cattle over 30 months of age, has been found to exhibit the highest prevalence of BSE.

Subpopulations of animals targeted for sampling will be those of any age with CNS signs, and cattle 30 months of age or older condemned for any other reason on ante-mortem inspection. Many of these animals will be identified at federally inspected slaughter establishments by FSIS inspection program personnel. How BSE sampling will be handled is dependent on whether or not the establishment has an alternative off-site sample collection agreement with USDA-APHIS.

FSIS responsibilities regarding the collection of brain samples for the APHIS guided BSE Ongoing Surveillance Program are outlined in FSIS Notice 05-10 "Sample collection from cattle under the bovine spongiform encephalopathy (BSE) Ongoing Surveillance Program." The FSIS role in the collection procedures is contingent on whether an establishment has entered into an agreement with APHIS to have brain samples collected at an approved alternative off-site location.

If the establishment is operating under an approved agreement with USDA-APHIS, the USDA-APHIS personnel will provide for the collection of brain samples on these animals at the alternative location. FSIS is responsible for providing establishment management with the “U.S,. Condemn” tag (Z-tag) numbers and disposition information for each animal. In these instances, specific controls must be in-place for FSIS to recognize the arrangements establishments have with USDA-APHIS to test condemned cattle.

If the establishment is not under an approved alternative off site collection agreement with USDA-APHIS, the FSIS PHV will collect the BSE samples from cattle of all ages that display CNS symptoms and ensure final disposition of the condemned cattle are in accordance with 9 CFR 309.

If the establishment plans to work with USDA-APHIS to begin off-site sampling, until USDA-APHIS approves that arrangement, or until FSIS is advised that an off-site agreement will not be forthcoming, FSIS PHVs are to identify all CNS animals with a "U.S. Condemned" tag, contact the USDA-APHIS AVIC so collection of the brain sample can be arranged, and ensure that the animals are humanely euthanized and remain on premise, unless USDA-APHIS requests otherwise.

Samples collected by the FSIS PHV will be shipped to the USDA APHIS National Veterinary Services Laboratory (NVSL) in Ames, Iowa, or another USDA_APHIS designated laboratory. Additional information about BSE sampling can be found through Outlook at: Public Folders/All Public Folders/OFO/Technical Service Center/BSE Training Info

Marks of Inspection

Under the *Ongoing BSE Surveillance Program*, cattle identified for testing at federally inspected establishments is limited those that are condemned on ante-mortem inspection. Therefore marks of inspection would not be applied.

Canadian Cattle

On January 4, 2005, USDA-APHIS published the final rule, Bovine Spongiform Encephalopathy: Minimal-Risk Regions and Importation of Commodities (Docket No. 03–080–8, 70 FR 460 – 553). This final rule amended USDA-APHIS regulations (9 CFR parts 93-96, Attachment 1) to provide for the importation of certain ruminants, and ruminant products and byproducts from regions that pose a minimal risk of introducing bovine spongiform encephalopathy (BSE) into the United States (U.S.), and designated Canada as the first minimal-risk region. The rule was promulgated under the Animal Health Protection Act.

The rule covers the importation of cattle, bison, sheep and goats. Under this rule, only cattle and bison born after March 1, 1999 and sheep and goats that are less than 12 months of age are eligible for importation into the U.S. from Canada and eligible for slaughter. The importation and slaughter of cattle or bison 30 months of age or older or of sheep and goats 12 months of age or older is prohibited. Bison, sheep and goats shipped from Canada have no applicable SRM requirements.

Animals imported from Canada will go through specific ports of entry. An USDA-APHIS veterinarian reviews documents and inspects the shipment at the port of entry to ensure

that it is being imported in compliance with the regulations. Animals will either be shipped directly to slaughter, or may be shipped to a feedlot prior to being shipped to slaughter. Animals shipped from Canada directly to slaughter will arrive at slaughter establishments under seal.

Only an authorized USDA representative can break the seal on the truck containing Canadian animals upon arrival at an official establishment. Under a Federal Register Notice issued 11/28/2005, the definition of "authorized USDA representative was broadened to include an USDA-APHIS Veterinary Services employee, USDA FSIS inspection program personnel, a State representative, an accredited veterinarian, or an employee of an accredited veterinarian, slaughtering establishment, or feedlot who is designated by the accredited veterinarian or management of the slaughtering establishment or feedlot to perform the function involved.

If an establishment chooses for a establishment employee to qualify as an authorized USDA representative, the slaughtering establishment must enter into an agreement with USDA-APHIS. Contact the Policy Development Division for details and additional information about these arrangements.

For Animals shipped directly for slaughter

- go to official establishments in sealed trucks,
- will bear a Canadian ear tag,
- will be accompanied by VS Form 17-33 and a Canadian Health Certificate,
- are to be slaughtered or euthanized within two weeks of entry into the U. S.
- are not to leave the official premises.

Sheep and goats that are shipped to a feedlot and then to an official establishment for slaughter

- will bear a Canadian ear tag (or other official identification if the animal lost its eartag at the feedlot and required re-tagging),
- will be accompanied by VS Form 1-27 and a copy of the Canadian Health Certificate

In certain circumstances, if FSIS personnel find that animals that have been delivered for slaughter do not comply with USDA-APHIS regulations, inspection program personnel are delegated the authority to hold the animals under the Animal Health Protection Act (AHPA). FSIS Notice 80-09 provides verification activities and instructions for inspection program personnel regarding the receipt, slaughter, and inspection of cattle, sheep, goats and bison imported from Canada.

REFERENCE DOCUMENTS

Docket No. 03-025F " 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 " (FR 72 No.1347, July 13, 2007).

Docket No. 03-038IF "Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems" (FR 69 No. 7, Jan 12, 2004).

Docket No. 03-048N "Bovine Spongiform Encephalopathy Surveillance Program" (FR 69 No. 7, Jan 12, 2004).

Docket No. 03–080–8 "Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities; Unsealing of Means of Conveyance and Transloading of Products" (FR 70 No.227, November 28, 2005).

Docket No. FSIS-2010-0017 “Notice of Request for Revision of a Currently Approved Information Collection (Specified Risk Materials)” (FR 75 No. 141, July 23, 2010)

9 CFR Parts 309.2; 309.13; 310.22; 311.27; 313; 318.6; 318.24; 417.3; 417.4

FSIS Directive 9530.1 “Importation of Live Canadian Cattle, Sheep, and Goats into the United States:

IKE 06-04 "Illustration of FSIS Notice 50-04 Concerning Tonsils"

IKE 01-07 "Citing Relevant Regulations When Documenting SRM Noncompliance"

WORKSHOP

1. What is the disposition of a non-ambulatory bovine at ante-mortem inspection?

2. What must the establishment do with a non-ambulatory bovine according to the regulations?

3. What tissues are considered as SRM?

4. What skeletal materials are not allowed to be used to produce AMR product?

5. Which captive bolt stunning method is not allowed under the regulations? What is the rationale for focusing on this method of stunning?

6. When will a carcass sampled for BSE testing be marked as “U.S. Inspected and Passed”?

APPENDIX 1: 9 CFR 310.22 From Docket 03-0125F, July 13, 2007)

DEPARTMENT OF AGRICULTURE
Food Safety and Inspection Service
9 CFR Parts 309, 310, and 318
[Docket No. 03–025F]
RIN 0583–AC88
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
AGENCY: Food Safety and Inspection Service, USDA.
ACTION: Affirmation of interim final rules with amendments.

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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:

§ 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.