

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

### **OBJECTIVES**

- Identify the policies related to non-ambulatory disabled cattle and the FSIS responsibilities related to implementing the policies.
- Identify the policies related to specified risk materials (SRMs) and the FSIS responsibilities related to implementing the 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 new regulatory requirements that were developed and 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)

The Federal Register notice (Docket No. 03-048N) 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 not allowed to enter the slaughter establishment and must be humanely handled and killed by the establishment. FSIS will record such cattle as "condemned" and ensure that the carcass is appropriately treated so that it doesn't

get into the human food chain. The condemned cattle must be disposed of in a timely manner so that an insanitary condition does not arise.

Non-ambulatory disabled cattle are those cattle that cannot rise 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.

Non-ambulatory disabled cattle shall be condemned and disposed of in accordance with 9 CFR 309.13. They must not enter the establishment and must be humanely handled, killed in a timely manner, and removed from the premises to prevent insanitary conditions. As a result of the policies regarding non-ambulatory disabled cattle, FSIS no longer will allow the emergency slaughter of cattle as prescribed in 9 CFR 311.27.

### **Specified risk materials**

The BSE regulations (9 CFR 310.22; FSIS Notice 9-04) has identify specified risk materials (SRM) including the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the tail vertebrae, thoracic and lumbar transverse processes, and sacral wings) and dorsal root ganglia (DRG) of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle. These materials are declared as inedible and cannot be used for human food (section 310.22 (a)). These materials were identified as SRM because scientific studies have shown them to contain the infective agent for BSE. The tonsils and ileum of all cattle are SRM. The other tissues are only SRMs in cattle 30 months and older.

The interim final rule (Docket No. 03-0251F) states, *“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 SRMs.”* Therefore, in accordance with section 310.22 (d)(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 action must be taken when either the establishment or FSIS determines that the establishment’s procedures have failed. This is reflected in the 9 CFR 310.22 (d)(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.”*

Plant must routinely evaluate the effectiveness of their procedures and revise the procedures as necessary. Section 310.22 (d)(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.”*

The plant must maintain daily records sufficient to document the implementation and monitoring of the procedures. The regulations (310.22 (d)(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 records may be maintained on computers provided that the plant implements appropriate controls to ensure the integrity of the electronic data (section 310.22 (d)(4)(ii)).

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

The SRMs are deemed 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. Because the distal ileum is an SRM, the use of casings derived from the entire small intestine is now prohibited.

The interim final rule (Docket 03-0251F) states, *“Casings from cattle may be used as containers of products provided the casings are not derived from the small intestine,”* and *“Detached spinal cords from cattle 30 months of age and older shall not be used as raw materials for edible rendering.”* Also, *“The small intestine of cattle shall not be used in any meat food products or for edible rendering.”*

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.

### **Mechanically separated (MS) beef**

Mechanically separated (MS) beef is now prohibited for human food. Because there are currently no restrictions on the incorporation of spinal cord and DRG into MS (beef) meat food product, such product may contain concentrated amounts of these high-risk tissues. Therefore FSIS has concluded that, like the SRMs described above, MS (beef) is unfit for human food under section 1(m)(3) of the FMIA (21 U.S.C. 601(m)(3)).

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, 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.

### **Advanced Meat Recovery (AMR)**

AMR removes muscle tissue from the bone of beef carcasses under high pressure without incorporating bone material. It can be labeled as “meat.” The 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. Section 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).”*

No brain, trigeminal ganglia, spinal cord, or dorsal root ganglia (DRG) may be present in any product prepared using AMR. The production process is not in control if the 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 (section 318.24 (c)(1)).

Section 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 NO. 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, section 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 plants 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. This type of stunning device shall not be used to stun cattle. It can result in brain (SRM) emboli being disseminated into edible tissues, thus the agency is prohibiting the use of such equipment. The regulation (section 313.15 (b)(2)(ii)) states, *“Captive 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**

In most cases, the animal will have been condemned on ante mortem inspection, but there may be instances in which an animal is tested and it would otherwise pass inspection. That carcass cannot receive the mark of inspection until a negative test result for BSE is confirmed.

FSIS Notice 29-04 provides clarification of FSIS Notice 28-04, “FSIS Sample Collection from Cattle Condemned during Ante-Mortem Inspection for the BSE Surveillance Program.” One of the five issues that FSIS addresses in this notice is the expectations regarding the Animal and Plant Health Inspection (APHIS) arrangements, through the APHIS Veterinarian-in-Charge (AVIC), with the establishments for APHIS to test condemned cattle at a central location. The notice gives questions for the PHV to seek answers to addressing the issues of condemned livestock, carcass identification, transportation, location of the central sampling site and the APHIS person responsible

and how the establishment will provide notification to the PHV that the condemned cattle were delivered to the APHIS central collection point, etc.

FSIS will be collecting brain samples from cattle for BSE testing at official establishments. Specifically trained FSIS PHVs will collect the brain samples. Samples will be shipped to the USDA APHIS National Veterinary Services Laboratory (NVSL) in Ames, Iowa, or another APHIS-designated laboratory. FSIS recognizes arrangements plants have with APHIS to test condemned cattle at a central location when specific controls are in place.

The Food Safety and Inspection Service will no longer pass and apply the mark of inspection to the carcasses and parts from cattle that are selected for testing by USDA-APHIS for BSE until the sample is determined to be negative.

For off-site sample collection FSIS issued Notice 33-04 that depict the protocol for Compliance and Investigation Division (CID) inquiries related to the sample collection of brain samples for BSE testing of bovine animals that were "U.S. Condemned" on ante-mortem inspection at federally-inspected establishments and moved from the federally-inspected establishment to an off-site sample collection location (See FSIS 28-04 and 29-04). The sample collection locations are typically rendering operations, 3D/4D operations, landfills, collection sites, pet food manufacturers, and other non-federally inspected establishments or locations. The APHIS AVIC, APHIS technician or APHIS contractor will collect the brain sample. The purpose of the protocol is to verify that ante-mortem condemned cattle arrive at the locations and APHIS is aware of the cattle's arrival.

## **WORKSHOP**

1. What is the disposition of a non-ambulatory bovine at ante-mortem inspection?
2. What must the plant do with the animal according to the regulations?
3. What are the SRM's?
4. What skeletal materials are not allowed to be used to produce AMR product?
5. Is captive bolt stunning allowed under the new regulations?
6. When will a carcass sampled for BSE testing be marked as "U.S. Inspected and Passed"?