

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

**FSIS NOTICE**

46-05

7/12/05

**VERIFICATION OF AN ESTABLISHMENT'S SEGREGATION PROCEDURES  
PRIOR TO FSIS ANTE-MORTEM INSPECTION**

**NOTE: THIS NOTICE IS NOT TO BE IMPLEMENTED UNTIL: JULY 26, 2005**

With this notice, FSIS is replacing existing memorandum and instructions regarding how inspection program personnel verify an establishment's voluntary segregation of animals prior to FSIS ante-mortem inspection (previously referred to as alternative ante-mortem inspection). FSIS is announcing that an establishment may no longer employ the practice for cattle, but may continue to do so for swine and sheep. This notice provides inspection program personnel new instructions regarding their responsibilities at establishments that voluntarily segregate swine or sheep prior to FSIS ante-mortem inspection.

Inspection program personnel, under the Federal Meat Inspection Act, perform an ante-mortem examination and inspection on all animals prior to slaughter to determine that an animal is fit for slaughter for human food purposes. If an establishment fails to present animals for ante-mortem inspection in accordance with 21 USC 603 and 9 CFR 309.1, inspection program personnel will be unable to determine that carcasses are not adulterated during postmortem inspection, and therefore cannot permit the carcasses to be marked as "inspected and passed."

Provided the establishment properly presents animals for ante-mortem inspection and properly follows the Humane Slaughter Act, FSIS has permitted an establishment to voluntarily segregate animals, to facilitate the establishment's scheduling of animals for slaughter. As of the implementation date of this notice, FSIS will only permit market classes of swine and sheep (i.e., market hogs and lambs), arriving for regular slaughter (i.e., not arriving for slaughter under any APHIS Veterinary Services permit or certificate) to continue to be voluntarily segregated by the establishment prior to FSIS ante-mortem inspection activities provided that:

- A. market classes of animals comprise the predominant class slaughtered at the establishment,
- B. the establishment has documented its segregation procedures in a prerequisite program,
- C. all animals are presented to inspection program personnel for examination and inspection prior to slaughter, and

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D. the procedures in the prerequisite program and related records are available to inspection personnel upon request (See FSIS Directive 5000.2).

**INSPECTION PROGRAM PERSONNEL VERIFICATION OF ESTABLISHMENT SEGREGATION PROCEDURES FOR MARKET SWINE AND LAMBS PRIOR TO FSIS ANTE-MORTEM INSPECTION**

A. Inspection program personnel conducting ante-mortem inspection are to:

1. verify that the segregation procedures are only for market classes of swine and lambs;
2. examine all animals found normal by the establishment while the animals are "at rest," (i.e., by randomly moving around in the pens.) (9 CFR 309.1(a));
3. select 5 to 10 percent of all animals presented for ante-mortem inspection from several lots and observe them on each side in motion;
4. instruct the establishment to move abnormal animals that may be condemned under 9 CFR part 311 to the designated "Suspect" pen under 9 CFR 307.2 for final disposition by the PHV; and
5. randomly observe establishment personnel performing segregation procedures (i.e., segregating those animals showing signs of abnormalities or diseases from healthy animals) at least once per month.

B. If an establishment does not have documented segregation procedures or fails to implement its segregation procedures properly, the PHV is to instruct inspection program personnel to not take into consideration the establishment's segregation program.

**NOTE:** For livestock classes other than market swine and lambs (such as cattle), establishments may presort animals prior to inspection and move the animals that may be designated "U.S. Suspect" or "U.S. Condemn" under 9 CFR part 309 and 311 to the designated "Suspect" pen for final disposition by the PHV. The PHV must conduct a careful examination and inspection on all animals in the "Suspect" pen. Inspection program personnel are to conduct an examination and inspection of all remaining animals by observing them both at rest and in motion.

Refer technical questions to the Technical Service Center at 1-800-233-3935.

*Philip S. Derfler /s/*

Assistant Administrator  
Office of Policy, Program, and Employee Development

## 6. 米国における扁桃の取り扱い及び実施状況に関する調査

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

# FSIS NOTICE

4-04

1/09/04

## AWARENESS MEETING REGARDING NEW REGULATIONS THAT PROHIBIT NON-AMBULATORY DISABLED CATTLE AND THE USE OF CERTAIN MATERIALS FROM CATTLE FOR HUMAN FOOD

FSIS will issue three regulations and a notice in the Federal Register on January 12, 2004, in response to the diagnosis by USDA of a positive case of BSE in an adult Holstein cow in the State of Washington. These regulations and the notice will minimize human exposure to materials that scientific studies have demonstrated as containing the BSE agent in cattle infected with the disease.

The regulations prohibit the slaughter of non-ambulatory disabled cattle and identify a list of materials, including Specified Risk Materials (SRMs), that may present a risk for transmitting Bovine Spongiform Encephalopathy (BSE) and are now inedible:

For all cattle:

- The tonsils are an SRM
- The small intestine – the distal ileum is the SRM

For cattle 30 months of age and older:

- The head – skull, eyes, brain, and trigeminal ganglia are the SRMs
- The vertebral column – spinal cord and dorsal root ganglia (DRG) are the

SRMs

Upon receipt of this FSIS notice, at establishments that slaughter cattle or establishments that process bone-in parts of cattle carcasses, inspection program personnel are to inform plant management through an awareness meeting about the new regulations and policies, inform them that the regulations are available on the FSIS website at <http://www.fsis.usda.gov/oa/news/2004/bseregs.htm>, provide them a copy of applicable checklists (see attachments), and inform them that as of Monday January 12, 2004, regulatory requirements will be in effect that prohibit the slaughter of non-

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ambulatory disabled cattle and that require establishments to ensure the removal, segregation, and disposition of SRMs. Inspection program personnel are to inform plant management that if an establishment slaughters non-ambulatory disabled cattle or fails to ensure the removal, segregation, and disposition of SRMs, inspection program personnel will take a regulatory control action as set out in 9 CFR 500.2(a)(3), *conditions preclude FSIS from determining that product is not adulterated.*

At the first weekly scheduled PBIS meeting after receipt of this FSIS notice, inspection program personnel are to review the applicable checklist with the plant management to ensure that the establishment understands what is required under the new regulations. Because the new regulations and policies are for the most part food safety related for beef products, inspection program personnel also are to inform the establishment that it is to reassess its hazard analysis to determine what steps, if any, are necessary to ensure that its products are free of materials that present the risk of transmitting BSE infectivity. Also at this meeting, inspection program personnel are to inform plant management that by the time of the second weekly PBIS-scheduled meeting, inspection program personnel will begin to verify that the establishment has incorporated the appropriate procedures and controls into Hazard Analysis and Critical Control Point (HACCP) plans, Sanitation Standard Operating Procedures (Sanitation SOPs), or prerequisite programs as required by the new regulations. Inspection program personnel also are to inform plant management that if it does not address procedures and controls in its HACCP plans, Sanitation SOPs, or prerequisite programs, a Notice of Intended Enforcement Action will be issued.

In a **memorandum of interview**, inspection program personnel are to document who was present at the initial awareness meeting, the date and time of the meeting, what was discussed, and any documents that were shared with management. Inspection program personnel are to maintain a copy of the memorandum in the official government file and provide a copy to the plant management.

In the interim period prior to the second weekly scheduled PBIS meeting, while the establishment is reassessing the HACCP plan(s), if inspection program personnel identify noncompliance it will be documented as 06D01 using the "product based" trend indicator.

At the second weekly scheduled PBIS meeting, inspection program personnel are to verify that the establishment has addressed, in writing, the necessary procedures and controls within the HACCP plan, Sanitation SOPs, or prerequisite program.

After the second weekly scheduled PBIS meeting, inspection program personnel will verify that the requirements are being met utilizing the HACCP or the Sanitation SOPs procedure and document noncompliance accordingly.

*/s/ Philip S. Derfler*

Assistant Administrator  
Office Policy and Program Development

## **Checklist for New Regulations Regarding Non-Ambulatory Disabled Cattle and Stunning**

### **Is the establishment aware:**

that non-ambulatory disabled livestock, including cattle, are now defined in 9 CFR 309.2(b) as livestock 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?

that the new regulations state that non-ambulatory disabled cattle are to be condemned and disposed of in accordance with 9 CFR 309.13?

that cattle, regardless of whether they are non-ambulatory disabled, can no longer be slaughtered under the emergency slaughter provisions of the regulations, in modified 9 CFR 311.27?

that captive bolt stunners that deliberately inject compressed air (air injection stunning) into the cranium at the end of the penetration cycle shall not be used to stun cattle (see 9 CFR 3313.15(b)(2)(ii))?

that the 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?

that cattle selected by APHIS for BSE Surveillance testing that are not non-ambulatory disabled are slaughtered but will be held and are not "inspected and passed" until the results of the test are received and are negative?

### **Has the establishment addressed:**

o What is being done to ensure that these cattle do not enter the establishment?

o What is being done to ensure that these cattle are humanely handled and killed in a timely fashion, and removed from the premises to prevent insanitary conditions?

## **Checklist for New Regulations Regarding Specified Risk Materials (SRMs) in Slaughter Operations**

### **Is the establishment aware:**

that the regulations at 9 CFR 310.22(a) designate the following materials as SRMs and prohibit their use for human food:

(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 (DRG) of cattle 30 months of age and older, and

(2) the tonsils and the distal ileum (distal ileum is a SRM, but to ensure effective removal of the distal ileum, the establishment is required to remove the entire small intestine from all cattle)?

that if it does not segregate cattle 30 months of age and older from younger cattle it is to handle all cattle as if they were 30 months of age and older?

that it is recommended if old and young cattle are slaughtered and intended to be segregated, that the young cattle are slaughtered before old cattle or that the equipment used on the cattle 30 months of age and older is sanitized and there is no cross-contamination of carcasses less than 30 months of age.

### **Has the establishment addressed:**

o How it will ensure appropriate segregation and disposal of the small intestine and tonsils of all cattle?

o How it will determine age of cattle, such as by records or dentition?

o How it will segregate cattle 30 months of age and older from cattle younger than 30 months.

o How it is removing, segregating, and disposing of SRMs to ensure that there is no cross-contamination with edible product? (NOTE: For example, the vertebral columns from cattle 30 months of age and older do not have to be removed during the slaughter operation. However, if they are not removed in the slaughter operation, procedures must be put in place to ensure that the vertebral columns are adequately identified as being from cattle 30 months of age and older and the documentation transfers with the vertebral columns until they are appropriately disposed of as inedible.)

**Checklist for New Regulations Affecting Boning Operations for Bone-in Parts,  
Including Bones, of Cattle Carcasses**

**Is the establishment aware:**

that the new regulations (9 CFR 310.22) prohibit the use of the skulls and vertebral columns from cattle 30 months of age and older (except for the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum)? (NOTE: Parts of carcasses 30 months of age and older can enter the boning operation, post-slaughter and post-chill, for the removal of the SRMs).

that if it does not have documentation about the age of the cattle from which vertebral columns are derived, it is to handle all skulls and vertebral columns as if they were from cattle 30 months of age and older?

that the traditional T-bone or porterhouse steaks and bone-in rib roasts can no longer come from cattle 30 months of age and older (i.e., a portion of the vertebral column bone defining these cuts of meat must now be removed, resulting in a semi-boneless cut of meat)?

**Has the establishment addressed:**

- o How it receives documentation from the slaughter operation regarding the age of cattle from which the skulls and vertebral columns are derived?
- o How it will segregate the skull and prohibited sections of the vertebral column from cattle 30 months of age and older (i.e., the bones that contain central nervous system-type tissues) from all other bones?



**Checklist for New Regulations Affecting Beef Used in Advanced Meat Recovery (AMR) Systems**

**Is the establishment aware:**

that the new regulations (9 CFR 318.24) prohibit the use of the skulls or vertebral columns (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum bones) of cattle 30 months of age or older from use in an AMR system?

that the new regulations (9 CFR 318.24) prohibit product derived from AMR systems from the bones of cattle of any age from containing any central nervous system-type tissues (i.e., brain and trigeminal ganglia from the skull, or spinal cord and DRG from the vertebral column)?

that the new regulations (9 CFR 319.5) prohibit the use of Mechanically Separated (Beef) and that these labels will be rescinded?

that there are additional new non-food safety related regulatory requirements (9 CFR 318.24) related to the production of AMR for bone solids (calcium) and bone marrow (iron)?

**Has the establishment addressed:**

○ how it segregates skulls and vertebral columns from cattle 30 months of age and older from skulls and vertebral columns from cattle younger than 30 months?

○ how it will prevent product derived from AMR systems from containing brain, trigeminal ganglia, spinal cord, or DRG?

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<b>FSIS NOTICE</b>	9-04	1-23-04
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**VERIFICATION INSTRUCTIONS FOR THE INTERIM FINAL RULE REGARDING  
SPECIFIED RISK MATERIALS (SRMs) IN CATTLE**

**I. PURPOSE**

This notice provides Veterinary Medical Officers (VMOs) with the methodology to use when verifying that an establishment has properly designed procedures to meet the requirements of 9 CFR 310.22 for the removal, segregation, and disposition of specified risk materials (SRMs). Also, this notice provides inspection program personnel with instructions for verifying that an establishment is executing its programs so that there is proper removal, segregation, and disposal of SRMs.

**NOTE:** At some establishments that do not slaughter but that process bone-in parts of cattle carcasses, an Enforcement Investigation Analysis Officer may be called upon to perform the verification of the design of the procedures in the absence of an available VMO.

**II. REGULATORY REQUIREMENTS**

**A. What are the regulatory requirements related to SRMs?**

9 CFR 310.22(a) defines SRMs as:

(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 (DRG) of cattle 30 months of age and older, and

(2) the tonsils and the distal ileum (for which removal of the distal ileum must be achieved by disposing of the entire small intestine) of all cattle.

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9 CFR 310.22(b) and (c) state that SRMs are inedible and shall not be used for human food and shall be disposed of in accordance with 9 CFR 314.1 and 314.3.

**B. What are establishments required to do in regard to SRMs?**

9 CFR 310.22 states that establishments that slaughter cattle and establishments that process the carcasses or parts of cattle shall develop, implement, and maintain written procedures that are incorporated into their HACCP plan, or in their Sanitation SOP or other prerequisite program for the removal, segregation, and disposal of SRMs.

**III. VERIFICATION FOR THE DESIGN OF PROCEDURES FOR SRMs**

A. As described in FSIS Notice 4-04, VMOs are to verify that an establishment has reassessed its hazard analysis to determine what steps, if any, are necessary to ensure that its products are free of materials that present a risk of transmitting BSE.

B. VMOs are to verify into which programs (i.e., HACCP plans, Sanitation SOPs, or prerequisite programs) the establishment incorporated any procedures adopted as a result of its reassessment. All establishments may include their procedures in one or more of these programs.

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

2. If an establishment determines that SRMs are not a hazard reasonably likely to occur because of procedures in its Sanitation SOPs, VMOs are to verify that the procedures and documentation supporting the establishment's determination are available for review under 9 CFR 416.14 and 417.5.

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

C. VMOs should verify that the establishment has designed its monitoring, verification, recordkeeping, and corrective actions, including reassessment as appropriate, to effectuate its HACCP plans, Sanitation SOPs, and other supporting prerequisite programs.

D. Examples of questions that may be asked to verify the design of the establishment's procedures to remove, segregate, and dispose of SRMs include:

1. Has the establishment adopted procedures designed to identify the cattle to be slaughtered that are 30 months of age and older?

**NOTE:** If the establishment identifies in its hazard analysis that all cattle will be considered 30 months of age and older, it is not necessary for the establishment to have evidence about the proof of the age of the cattle.

2. Has the establishment adopted procedures designed to ensure the complete and proper removal of SRMs?

3. Has the establishment adopted procedures designed to ensure that SRMs are segregated from edible product?

4. Has the establishment adopted procedures designed to ensure that SRMs are disposed of in a manner that will prevent cross-contamination with edible product?

**NOTE:** The vertebral columns from cattle 30 months of age and older do not have to be removed during the slaughter operation. However, if they are not removed in the slaughter operation, procedures should be put in place to ensure that the vertebral columns are adequately identified as being from cattle 30 months of age and older, and that the means of identification transfers with the vertebral columns until they are appropriately disposed of as inedible.

5. Has the establishment adopted control procedures designed either (1) to not allow bone-in beef from cattle 30 months of age and older into the establishment, or (2) to ensure that such product (e.g., vertebral columns for AMR) is handled in an appropriate manner (e.g., by ensuring that SRMs are removed and disposed of appropriately)? Has the establishment implemented verification measures to ensure that the control procedures are followed?

E. If an establishment has failed to reassess its hazard analysis, the VMOs should document in a decision memorandum to the District Office (DO) the evidence to support the issuance of a Notice of Intended Enforcement Action (NOIE).

#### **IV. VERIFICATION PROCEDURES FOR INSPECTION PROGRAM PERSONNEL**

A. Inspection program personnel are to verify the proper execution of the HACCP plans or the prerequisite programs, while conducting HACCP 01 or 02 procedures as set out in FSIS Directive 5000.1, Revision 1, or 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 reviewing records (e.g., looking at HACCP monitoring records), observing plant employees performing procedures (e.g., observing plant employee performing a dentition examination), or by conducting hands-on inspection verification procedures (e.g., verify adequacy of Sanitation SOP procedures).

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

### **C. Post-mortem on-line verification duties**

#### **Head and Carcass inspection:**

1. When on-line inspection program personnel perform individual carcass or head inspection and observe visible (readily identifiable) SRMs on edible portions of the product, the establishment may recondition the entire carcass or head by knife trimming.

2. On-line inspection program personnel are to notify the VMO or, if unavailable, other 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 indicates failure to control SRM contamination).

3. The VMO or other off-line personnel will perform the appropriate HACCP or Sanitation SOP procedures to evaluate the process.

### **V. ENFORCEMENT**

What enforcement actions do inspection program personnel take when finding noncompliance?

If VMOs or off-line personnel determine the process failed to prevent SRMs from adulterating product, they are to issue a NR under the appropriate procedure code and mark the appropriate trend indicator as described in FSIS Directive 5000.1, Revision 1, Chapters I (Sanitation) II (HACCP) and IV (Enforcement) and 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 the HACCP plan to determine whether the decisions made in the hazard analysis continue to support the use of the prerequisite program.

If the establishment does not properly implement procedures (e.g., recordkeeping), 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, Revision 1, Chapters I (Sanitation) II (HACCP) and IV (Enforcement) and verify that the establishment takes the immediate and further planned actions to correct the noncompliance.

Refer questions to the Technical Service Center.

*/s/ Philip S. Derfler*

Assistant Administrator  
Office of Policy and Program Development

Types of questions inspection program personnel may seek answers to while verifying that an establishment is properly executing its procedures to remove, segregate, and dispose of SRMs.

1. Is the establishment properly implementing its procedures to segregate animals 30 months of age and older?

**NOTE:** If the establishment identifies in its hazard analysis that all cattle will be considered 30 months of age and older, it is not necessary for the establishment to have evidence about the proof of the age of the cattle.

2. Is the establishment properly implementing its written procedures to remove, segregate, and dispose of SRMs?

3. Is the establishment cleaning and sanitizing equipment, (e.g., cleaning and sanitizing the splitting saw prior to use on cattle younger than 30 months if used after slaughtering cattle 30 months of age and older)?

4. Is the establishment maintaining daily records sufficient to document the implementation and monitoring of the procedures for the removal, segregation, and disposition of SRMs?

5. Is the establishment including documentation with the shipped products identifying them as from cattle 30 months and older? Has it considered this step in its hazard analysis? Does it have procedures to ensure that the SRMs are removed at the receiving establishment?

6. Is the establishment routinely evaluating the effectiveness of their procedures for the removal, segregation, and disposition of SRMs in preventing the use of these materials for human food?

7. If an establishment determines that its process failed to remove SRMs, inspection program personnel are to verify that the establishment implements corrective actions in accordance with 9 CFR 417.3(a) or (b) (under HACCP), 9 CFR 416.15 (under Sanitation SOPs). If the procedures are under a prerequisite program, inspection program personnel are to verify that the establishment reassesses the HACCP plan to determine whether the decisions made in the hazard analysis continue to support the use of the prerequisite program.

8. Is the establishment taking appropriate immediate and further planned action when it identifies that it failed to properly implement its procedures (e.g., recordkeeping).