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

# FSIS NOTICE	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).