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

FSIS DIRECTIVE

7160.3
Rev. 3

12/4/23

VERIFICATION ACTIVITIES FOR ADVANCED MEAT RECOVERY SYSTEMS

I. PURPOSE

This directive updates instructions to inspection program personnel (IPP) in livestock establishments using advanced meat recovery (AMR) systems by incorporating instructions from FSIS Directive 7160.1, *Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery* Systems and FSIS Directive 7160.2, *"Meat" Prepared Using Advanced Mechanical Meat/Bone Separation Machinery and Meat Recovery* Systems. This directive now includes instructions for IPP to verify that establishments producing AMR from all livestock species develop written procedures describing the ongoing verification activities that will be performed in order to meet regulatory requirements in 9 CFR 318.24 and the definition of meat. Additionally, this directive clarifies that IPP no longer sample livestock species other than beef for AMR analysis. There is no change to the existing verification activities for AMR systems using beef vertebral raw materials. This directive maintains the existing instructions for IPP to sample beef AMR product for central nervous system (CNS) or CNS-type tissue analysis at the frequency specified in the Public Health Information System (PHIS) under the AMR01 and FAMR01 sampling program.

KEY POINTS:

- *Instructs IPP on specific verification activities associated with production of meat derived from AMR systems*
- *Instructs IPP on sampling beef AMR product derived from skull or vertebral column bones in order to verify the absence of CNS and CNS-type tissues including verification of test and hold procedures*
- *Clarifies that beef AMR product containing CNS or CNS-type tissues cannot be used as an ingredient of a meat food product*

II. CANCELLATION

FSIS Directive 7160.1, *Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery Systems*, 9/13/96

FSIS Directive 7160.2, *"Meat" Prepared Using Advanced Mechanical Meat/Bone Separation Machinery and Meat Recovery Systems,* 4/14/97

FSIS Directive 7160.3, Rev. 2, *Verification Activities for Advanced Meat Recovery Using Beef Vertebral Raw Materials*, 9/21/17

III. BACKGROUND

A. On January 12, 2004, the Agency issued an interim final rule *Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems* (69 FR 1874; later affirmed with changes in 72 FR 38700). In the rule, the Agency noted that AMR systems imitate the physical action of hand-held high-speed knives for the removal of skeletal muscle tissue from bone using hydraulic pressure. Furthermore,

AMR systems apply pressure to detach the meat (skeletal muscle) tissue from the bones in a "hard separation" process (e.g., piston driven). This hard separation process is followed by a soft separation process, a desinewing step that typically involves the use of belt pressure against a rotating perforated steel drum to separate meat from connective tissue, sinews (e.g., tendons), and other non-meat components.

B. The definition of "meat" is found in 9 CFR 301.2. AMR product from livestock bones that meet requirements in 9 CFR 318.24 can be used as "meat." Noncompliant beef AMR product as defined in 9 CFR 318.24 that would otherwise qualify as "mechanically separated" product is inedible per 9 CFR 319.5(b).

C. 9 CFR 318.24 requirements apply to all livestock AMR production; however, production of AMR is usually limited to beef and pork establishments. 9 CFR 318.24 has specific additional requirements associated with the use of beef skull and vertebral bones and the production of beef AMR product.

D. Imported AMR product is not subject to AMR01 or FAMR01 sampling referenced in this directive. Sampling of imported beef or veal AMR is conducted under a different sampling program (IMPAMR). Import inspection personnel are to refer to FSIS Directive 9900.6, *Laboratory Sampling Program for Imported Meat, Poultry, and Egg Products.*

IV. IPP VERIFICATION ACTIVITIES IN LIVESTOCK AMR ESTABLISHMENTS

A. IPP are to verify that establishments develop, implement, and maintain procedures to ensure product derived from livestock AMR systems meets the requirements in 9 CFR 318.24. This includes verifying establishment testing of AMR product for bone solids, marrow, spinal cord, and dorsal root ganglia (DRG).

B. IPP are to verify 9 CFR 318.24 requirements for livestock by:

1. Performing the MSS; MSP; PDBFT; PDPFT; PDCB; PDCP; AMRS task as scheduled in PHIS to verify the economic and wholesomeness AMR requirements in 9 CFR 318.24; and

2. Verifying the establishment's written control program for AMR production. Official establishments that produce AMR product from beef are required (9 CFR 318.24(b)(2)) to incorporate AMR production procedures into the Hazard Analysis and Critical Control Point (HACCP) system. Official establishments that produce AMR product from species other than beef may voluntarily include their written control programs within their HACCP system. IPP are to verify the requirements using the appropriate PHIS tasks (i.e., HACCP, Sanitation Standard Operating Procedure (Sanitation SOP)) when these procedures are incorporated into the HACCP system.

NOTE: The key for the abbreviations in this PHIS task name is as follows: MSS (Mechanically Separated Species other than from beef including veal); MSP (Mechanically Separated Pork); PDBFT (Partially Defatted Beef Fatty Tissue); PDPFT (Partially Defatted Pork Fatty Tissue); PDCB (Partially Defatted Chopped Beef); PDCP (Partially Defatted Chopped Pork); AMRS (Advanced Meat Recovery Systems).

C. The AMR regulation (9 CFR 318.24) limits what materials can be used to make AMR product. IPP are to verify using the appropriate economic (i.e., AMR) or, if applicable, food safety system (i.e., HACCP or Sanitation SOP) verification task to verify that establishment controls exclude the following tissues from in-going components (i.e., source bone materials):

1. Any visibly identifiable brain or spinal cord (9 CFR 318.24(a)(2) and (b)(1)); and

2. Any trigeminal ganglia or dorsal root ganglia associated with skulls or vertebral column (9 CFR 318.24(a)(2) and (b)(1)).

D. IPP are to verify that the establishment maintains daily records (9 CFR 318.24(b)(4)) that document that the establishment is routinely implementing their written procedures and verifying their process controls on a regular basis (9 CFR 318.24(b)(2) and (b)(3)), including:

1. Monitoring (observing) bones entering the AMR system for visible brain, trigeminal ganglia and spinal cord at the specified frequency;

2. Testing of AMR product by the establishment to ensure AMR product:

    a. Does not contain CNS or CNS-type tissue (9 CFR 318.24(c)(1)(iv) and 9 CFR 318.24(c)(v)); and

    b. Complies with definition of meat (9 CFR 301.2 and other provisions in 9 CFR 318.24(c)(1));

3. Labeling of AMR product. Product that may not be labeled or used as "meat," but meets the requirements of 9 CFR 319.5, may bear the name "Mechanically Separated (Species)," except for beef. Beef cannot be labeled as "Mechanically Separated," as this product is inedible; and

4. Identifying and controlling noncompliant AMR product (9 CFR 318.24(c)).

E. IPP are to refer to FSIS Directive 5000.2, *Review of Establishment Testing Data by Inspection Program Personnel*, for instructions on weekly review of establishment records.

NOTE: The Agency does not currently sample AMR products derived from species other than beef.

F. IPP are to take regulatory control action when IPP observe or determine that AMR product from livestock other than beef is misbranded, document noncompliance under the MSS; MSP; PDBFT; PDPFT; PDCB; PDCP; AMRS task, and cite the appropriate 9 CFR 318.24 regulation. Instructions for documenting noncompliance in beef AMR are provided in Section X.

V. ADDITIONAL VERIFICATION ACTIVITIES FOR BEEF AMR ESTABLISHMENTS

A. IPP are to verify that beef AMR establishments perform a hazard analysis for AMR and incorporate their written AMR production procedures into their HACCP system (i.e., HACCP, Sanitation SOP, or prerequisite program) as required by 9 CFR 318.24(b)(2).

B. IPP are to perform the MSS; MSP; PDBFT; PDPFT; PDCB; PDCP; AMRS task in PHIS whenever scheduled and prior to sampling AMR product to verify the economic and wholesomeness AMR requirements in 9 CFR 318.24.

C. All AMR sampling requests are based on accurate product and volume information in the PHIS establishment profile. IPP are to verify that the establishment profile of AMR-producing establishments contains accurate information. IPP are to refer to FSIS Directive 5300.1, *Managing the Establishment Profile in the Public Health Information System,* for instructions on how to update the establishment profile in PHIS.

D. IPP are to use the appropriate food safety system (i.e., HACCP or Sanitation SOP) verification task to verify that the establishment controls in beef establishments exclude the following tissues (in addition to those listed in Section IV. C. above) from in-going components (i.e., source bone materials):

1. Specified-risk-materials (SRMs). SRMs include skull and vertebral bones of cattle 30 months and older as described in 9 CFR 310.22(a). SRMs are never permitted as raw materials for AMR product; and

2. Recycled, crushed, or "spent" beef skulls and vertebral columns of any cattle of any age that exit the AMR system.

NOTE: Recycled, crushed, or spent beef skulls and vertebral bones of any cattle are prohibited as an ingredient in any meat food product (9 CFR 318.24(c)(3)).

E. IPP are to verify that the establishment maintains daily HACCP system records (9 CFR 318.24(b)(4)) that document that the establishment is routinely implementing their written procedures and verifying their process controls on a regular basis (9 CFR 318.24(b)(2) and (b)(3)) including control and disposal of noncomplying AMR product (9 CFR 318.24(c)).

VI. FSIS SAMPLING OF BEEF AMR PRODUCT (AMR01)

A. FSIS uses laboratory sampling to verify product exiting the AMR system is free of CNS and CNS-type tissue and compliant with 9 CFR 318.24(c)(1)(iv) and (v). When IPP receive a beef AMR sampling task in PHIS, IPP are to:

1. Verify that the establishment is producing beef AMR product that is eligible for sampling during the sampling frame. AMR product that is eligible to sample is product from bones likely to contain CNS or CNS-type tissue such as vertebral column bones or skulls;

2. Schedule sampling tasks in PHIS as instructed in FSIS Directive 13,000.2, *Performing Sampling Tasks in Official Establishments Using the Public Health Information System;*

3. Verify that establishment records define or identify what constitutes a "lot" of beef AMR product eligible for sampling before collecting the sample; and

4. Notify establishment management that:

    a. A beef AMR sample is to be collected for CNS or CNS-type tissue analysis;

    b. The entire lot of production represented by the sample is to be held, controlled, or disposed pending sample results; and

    c. In the event of a positive "unacceptable" result for CNS-type tissue (AMR01), follow-up sampling (FAMR01) will be scheduled and performed after notification by the establishment that the establishment has implemented corrective actions, documented them in the HACCP system records, and are producing product eligible for sampling. See Section X below for instructions on follow-up sampling.

B. IPP are to submit representative samples of beef AMR product eligible and available for sampling as scheduled. For each (AMR01) sample, IPP are to:

1. Collect a 2-pound composite sample of beef AMR product eligible for sampling. Composite samples are made up of at least four (4) – one-half pound grab sub-samples from the same lot using aseptic techniques:

    a. From different locations within the containers (e.g., sampling near the bottom, middle, and at the top of randomly selected containers); and

    b. From multiple machines if product represents the same lot of product eligible for sampling;

2. Maintain identity and secure the chilled sample using official tags or devices until the sample is shipped;

3. Complete the PHIS sample form including any required data fields and questionnaire in PHIS;

4. Verify that the sample form is printed, signed, and included with the sample to be shipped to the FSIS laboratory specified on the sample form; and

5. Seal and ship samples to the specified laboratory. Instructions for applying seals are provided in FSIS Directive 7355.1, *Use of Sample Seals for Laboratory Samples.*

VII. WHEN BEEF AMR SAMPLES ARE NOT COLLECTED

When beef AMR product is not available for sampling or not eligible for sampling during the sampling window, IPP are to cancel the sampling task and document the reason for not collecting any AMR samples (AMR01 or FAMR01). IPP are not to let the task expire. IPP are to indicate the reason that the sample was not collected from those reasons listed in the drop-down menu in PHIS as instructed in FSIS Directive 13,000.2. IPP are to review the establishment profile when AMR samples are assigned but the establishment does not ever produce beef AMR product.

VIII. VIEWING LABORATORY RESULTS

A. IPP can access beef AMR01 and FAMR01 sample results from:

1. The PHIS homepage under "My Inspections and Samples" tab; and

2. Laboratory Information Management System (LIMS Direct) link in the Lab Result Report in PHIS. Users need an e-authentication account to access LIMS Direct.

NOTE: AMR laboratory results are reported in LIMS as "acceptable" or "not acceptable." A test result that is "Not Acceptable" indicates that the product contains substances other than meat (e.g., CNS tissue or CNS-type tissue).

B. The FSIS Eastern Laboratory e-mails a detailed "Pathology Report" to all recipients listed in the "FSIS - AMR Notification List." See Figure 1.0 as an example of a report for noncomplying AMR product containing CNS-type tissue. IPP are to share the detailed report information and LIMS Direct results with establishment management once detailed laboratory results are received. Positive CNS or CNS-type tissue findings in a beef AMR product generate a follow-up sample request in PHIS under the project code FAMR01.

Figure 1.0 - Example of a Beef AMR Sample Pathology Laboratory Report (not acceptable)

INTERNAL LAB NO.	SERIAL NO.	USDA-FSIS-OPHS EASTERN LABORATORY	EST. NO.	RETAIN TAG NO.
B19333	100222140	**PATHOLOGY REPORT**		

PATHOLOGIST REPORT

Beef AMR product

Skeletal muscle, fibroadipose connective tissue, blood vessels, bone, cartilage, streaming nuclear debris, and dorsal nerve root ganglion are present.

IX. BEEF AMR PRODUCT DISPOSITION AND LABELING

A. Disposition of the lot of sampled product (AMR01 and FAMR01) is based on laboratory results.

Laboratory results limit options for disposition, use, and labeling of product exiting the AMR system. IPP can expect one of three (3) laboratory results with limited options for disposition in Table 1.0 below:

Table 1.0. Possible Beef AMR Laboratory Results and Disposition

Lab Diagnoses (Analysis Result)	Examples of Findings in the Detailed Pathology Report	Disposition and Labeling Restrictions based on Results
Skeletal Muscle & Associated Meat Tissues	"…skeletal muscle, adipose tissue, blood vessels, streaming nuclear debris, bone, and cartilage"	This product meets the definition of "meat" in 9 CFR 301.2 and can be used or labeled as "beef" meat. Compliant AMR product that is free of CNS or CNS-type tissue and identified in the LIMS report as "Acceptable" may be used as meat or "beef" or further processed as "beef" in any multi-ingredient product.
Skeletal Muscle & Associated Meat Tissues with Spinal Cord Tissue, DRG or other CNS-type tissues	"…the presence of DRG or other CNS-type tissue along with skeletal muscle, associated tissues, bone fragments, cartilage, and streaming nuclear debris …"	This noncomplying AMR product containing CNS or CNS-type tissue is identified as "not acceptable" in the LIMS report; does not meet the definition of "meat" as defined in 9 CFR 301.2; and cannot be labeled solely as "beef" meat. AMR product that contains CNS or CNS-type tissue cannot be used as an ingredient in a meat food product (9 CFR 318.24(c)(2)). Beef AMR product that contains CNS or CNS-type tissue and is otherwise compliant with 9 CFR 318.24 (e.g., bone solids and bone marrow criteria based on establishment testing per 9 CFR 318.24(b)) may be descriptively labeled, e.g., "Beef with Spinal Cord" or "Beef with Central Nervous System (type) Tissue." Such meat food products can be used in rendering operations or be used to make broths, extracts or process flavors. See 9 CFR 318.24(c) for additional restrictions or limitations on noncomplying beef product. **NOTE**: Unless skulls or vertebral bones from cattle 30 months of age and older were used, the CNS and CNS-type tissues here are not SRMs.
Organ tissue (i.e., meat byproducts such as kidney, liver, spleen) or foreign matter (e.g., fibrous plant material)	"…organs or tissues other than meat (e.g., kidney; liver) along with skeletal muscle, associated tissues, bone fragments, cartilage, and streaming nuclear debris."	Product containing organ tissue (meat by-product) is not "meat" as defined in 9 CFR 301.2 and cannot be labeled solely as "beef" meat. To enter commerce, this product may be descriptively labeled (e.g., "beef with beef byproducts," or "beef with kidney"). See 9 CFR Part 412. AMR product with foreign matter must be restored to wholesomeness before it can receive the mark of inspection.

X. DOCUMENTATION IN BEEF AMR ESTABLISHMENTS

A. When IPP observe or determine that beef AMR product is adulterated or misbranded, IPP are to take regulatory control action of the affected product and equipment, document the appropriate task noncompliance, and cite the appropriate 9 CFR 318.24 regulation as described in Table 2.0 below.

Table 2.0 - Tasks to Perform and Document Noncompliance with 9 CFR 318.24

Examples indicating a loss of AMR Process Control	Primary Task under which to Verify 9 CFR 318.24 Requirements:	Primary Task to Document Noncompliance with 9 CFR 318.24 Requirements:
1. Prohibited SRM skull and vertebral bones from cattle 30 months and older are likely to enter the AMR process.	Raw Non-Intact HACCP or Sanitation SOP task based on location of written procedures.	Raw Non-Intact HACCP or Sanitation SOP Verification task based on location of written procedures; Product is adulterated.
2. Visible spinal cord (non-SRM) is likely to enter the AMR process; or	MSS; MSP; PDBFT; PDPFT; PDCB; PDCP; AMRS task	MSS; MSP; PDBFT; PDPFT; PDCB; PDCP; AMRS task; Product is misbranded.
3. CNS or CNS-type tissue (non-SRM) is detected by laboratory testing in AMR product; or	MSS; MSP; PDBFT; PDPFT; PDCB; PDCP; AMRS task	MSS; MSP; PDBFT; PDPFT; PDCB; PDCP; AMRS task; Product is misbranded.
4. Product exiting the AMR process meets the standard for "mechanically separated species" in 9 CFR 319.5 and therefore is inedible per 9 CFR 319.5(b); or	MSS; MSP; PDBFT; PDPFT; PDCB; PDCP; AMRS task	MSS; MSP; PDBFT; PDPFT; PDCB; PDCP; AMRS task; Product is misbranded.
5. Establishment process control records indicate noncompliant product per 9 CFR 318.24 is being produced;	MSS; MSP; PDBFT; PDPFT; PDCB; PDCP; AMRS task	MSS; MSP; PDBFT; PDPFT; PDCB; PDCP; AMRS task; Product is misbranded.

B. IPP are to verify that the establishment performs and documents all applicable corrective actions and any subsequent changes in written procedures by performing the relevant food safety system (i.e., HACCP or Sanitation SOP) task based on where the establishment has documented their written AMR control procedures per 9 CFR 318.24(b)(2).

C. IPP are to notify the District Office (DO) through supervisory channels if adulterated or misbranded product has entered commerce as instructed in FSIS Directive 8140.1, *Notice of Receipt of Adulterated or Misbranded Product*.

XI. FOLLOW-UP SAMPLING (FAMR01) OF NONCOMPLIANT BEEF AMR AND ENFORCEMENT

A. IPP are to:

1. Schedule eight (8) assigned FAMR01 sampling tasks via PHIS after FSIS AMR01 testing reveals that the establishment has produced noncompliant beef AMR product due to the presence of CNS or CNS-type tissue and after the establishment has implemented corrective actions to reestablish process control and is producing AMR product eligible for sampling;

2. Inform establishment management that they are in a test and hold situation and must maintain identity and control of the product represented by each sample until FAMR01 sampling results are available;

3. Send an e-mail requesting the sampling task to the "FSIS – AMR Notification List" if FAMR01 sampling tasks are not assigned in three (3) business days of being notified of unacceptable AMR01 sampling results. IPP are to enter on the subject line: "FAMR01 tasks Not Received" and include the establishment name and establishment number in the e-mail requesting the sampling task assignment;

B. For each FAMR01 task, IPP are to follow the same sampling instructions in Section VI. B. above and ship the chilled sample at the next available opportunity.

C. IPP are to resume routine verification of the establishment's AMR system as scheduled in PHIS if all eight (8) follow-up samples are "acceptable."

D. IPP are to take a regulatory control action to retain product represented by the sample if any of the eight (8) FAMR01 samples are "not acceptable" (i.e., contains CNS or CNS-type tissue). IPP are to notify the Frontline Supervisor (FLS) of the follow-up sample results. Upon notification by the Inspector-in-Charge or FLS that the follow-up sample results were also "not acceptable," the DO designee is to:

1. Advise the establishment that the marks and use of labels representing product produced from the AMR system will be withheld (9 CFR 500.8); and

2. Stop withholding the marks and use of the label after:

   a. IPP have verified that the establishment has taken appropriate corrective actions according to their written AMR control procedures (9 CFR 318.24(b)(2)) to correct the AMR system. IPP are to refer to FSIS Directive 5000.1, *Verifying an Establishment's Food Safety System*, to verify the establishment's corrective actions depending on how the establishment has incorporated their AMR control procedures into their HACCP system;

   b. The establishment has provided to the DO evidence that 10 consecutive composite samples of product eligible for sampling from the AMR system by the establishment were "acceptable" (i.e., free of CNS or CNS-type tissue). It is the establishment's obligation to have the samples analyzed in a qualified laboratory using an analytical method equivalent to that employed by FSIS; and

   c. FSIS has verified the establishment's results by taking 1 or more additional composite samples (AMR01) and results are "acceptable" for beef AMR (i.e., free of CNS and CNS-type tissue).

XII. DELAYED FOLLOW-UP SAMPLING (FAMR01)

A. IPP are to cancel the scheduled sampling task and select the applicable cancellation reason from the drop-down list in the event IPP are unable to complete an FAMR01 sampling task during the sampling window (e.g., establishment fails to resume beef AMR production or produce AMR product eligible for sampling for several weeks or months).

B. IPP are to submit a new request using askFSIS, "Sampling" for the inquiry type, then reschedule sample collections when they are assigned, and complete an FAMR01 sampling task when production of AMR product eligible for sampling resumes.

XIII. QUESTIONS

Refer questions regarding this directive to your supervisor or if needed to the Office of Policy and Program Development through askFSIS or by telephone at 1-800-233-3935. When submitting a question, complete the web form and select General Inspection Policy inquiry type for general questions.

NOTE: Refer to FSIS Directive 5620.1, *Using askFSIS*, for additional information on submitting questions.

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