VERMONT AGENCY OF AGRICULTURE, FOOD & MARKETS
FOOD SAFETY CONSUMER PROTECTION DIVISION
Meat Inspection Service
MONTPELIER, VT
Anson Tebbetts, Secretary

# MIS DIRECTIVE **Adopted from FSIS Directive 7160.3 Rev, 2**	7160.3 Rev.2	**10**/1/2017

VERIFICATION ACTIVITIES FOR ADVANCED MEAT RECOVERY USING BEEF VERTEBRAL RAW MATERIALS

I. PURPOSE

This directive significantly updates instructions to inspection program personnel (IPP) in cattle establishments using advanced meat recovery (AMR) systems by incorporating instructions from FSIS Notice 05-15, *Interpreting Results of FSIS Verification Sampling of Domestic Beef Product Derived from Advanced Meat Recovery Systems*. Using the updated instructions, IPP now verify that all beef AMR products from any cattle including veal are free of central nervous system (CNS) tissues (i.e. brain or spinal cord) and CNS-type tissues (i.e. trigeminal ganglia or dorsal root ganglia (DRG)) in accordance with 9 CFR 318.24. Specifically, this directive also updates instructions on how to schedule tasks using the Public Health Information System (PHIS), collect AMR samples, interpret laboratory test results for CNS or CNS-type tissues, and what actions to take when noncompliant product is found.

KEY POINTS:

- *This directive focuses on specific verification activities associated with production of beef AMR from cattle bones*
- *Beef AMR product containing CNS or CNS-type tissues is not "beef" and cannot be used as an ingredient of a "meat food product"*
- *VAAFM will sample only AMR product produced from beef skull or vertebral column bones because these are most likely to contain CNS tissues or CNS-type tissue and therefore eligible for sampling as identified in this directive*
- *Establishments are required to hold or maintain control of AMR product that VAAFM samples and tests for CNS or CNS-type tissues until results are available*

II. CANCELLATION

FSIS Directive 7160.3, Rev. 1, *Advanced Meat Recovery Using Beef Vertebral Raw Materials*, 8/25/03

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. 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.

IV. IPP VERIFICATION

A. Beef AMR establishments must perform a hazard analysis and incorporate their written AMR production procedures into their HACCP system (i.e., HACCP, Sanitation Standard Operating Procedure (Sanitation SOP), or pre-requisite program) as required by 9 CFR 318.24(b). IPP are to verify that Beef AMR establishments address AMR production in their hazard analysis and incorporate their written AMR procedures within their HACCP System per 9 CFR 318.24(b)(2).

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

1. Performing 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; or

2. Verifying the establishment's written control programs for AMR production when performing the applicable HACCP system (i.e., HACCP or Sanitation SOP) verification tasks.

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. 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 5,300.1, *Managing the Establishment Profile in the Public Health Information System (PHIS),* for instructions on how to update the establishment profile in PHIS.

D. 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 HACCP system (i.e., HACCP, Sanitation SOP) verification task that establishment controls exclude the following tissues from in-going components (i.e., source bone materials):

1. Specified-risk-material (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;

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

3. Any trigeminal ganglia or dorsal root ganglia associated with skulls or vertebral column from cattle of any age, [9 CFR 318.24(a)(2) and (b)(1)]; and

4. Recycled, crushed, or "spent" beef skulls and vertebral columns of any cattle 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 per 9 CFR 318.24(c)(3).

E. To ensure the on-going effectiveness of establishment controls, IPP are to verify that the establishment maintains and makes available to IPP 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 per 9 CFR 318.24(b)(2) and (b)(3) including establishment:

1. Monitoring (observing) beef 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)];

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

3. Proper use and labeling of AMR product; and

4. Establishment control and disposal of noncomplying AMR product per 9 CFR 318.24(c).

NOTE: IPP review of establishment records See *FSIS Directive 5000.2, Review of Establishment Testing Data by Inspection Program Personnel*, regarding weekly review of other establishment records

V. VAAFM SAMPLING OF BEEF AMR PRODUCT (AMR01)

A. VAAFM 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 request from the office, 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 a Raw Non-intact HACCP task(s) in PHIS. See VT Notice A-13, *Documenting Laboratory Verification Sampling Tasks in state PHIS;*

3. Verify before sampling that establishment records define or identify what constitutes a "lot" of beef AMR product eligible for sampling; 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 day's production represented by the sample is to be held, controlled, and disposed pending sample results; and

    c. In the event of a positive "unacceptable" result for CNS-type tissue, follow-up sampling 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 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 sample form;

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

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

VI. WHEN BEEF AMR SAMPLES ARE NOT COLLECTED

When AMR product is not available for sampling or not eligible for sampling during the sampling window, IPP are to document the reason for not collecting any AMR samples. IPP are to indicate the reason that the sample was not collected.

VII. RECEIVING LABORATORY RESULTS

A. IPP will be notified of the results by the office.

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).

VIII. PRODUCT DISPOSITION AND LABELING

A. Disposition of the lot of sampled product 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 or DRG Sensory Ganglia (CNS-type tissues)	"…the presence of sensory ganglion (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. Otherwise product would be misbranded. AMR product with foreign matter must be restored to wholesomeness before it can receive the mark of inspection.

IX. DOCUMENTATION

A. When IPP observe or determine that AMR product is misbranded, IPP are to take regulatory control action of the affected product and equipment, document the appropriate MSS; MSP; PDBFT; PDPFT; PDCB; PDCP; AMRS task noncompliance, and cite the appropriate 9 CFR 318.24 regulation. See Table 2.0 below.

B. When IPP observe or determine that AMR product is adulterated (e. g., SRMs), IPP are to take regulatory control action of the affected product and equipment, document the appropriate HACCP system task (i.e. HACCP, Sanitation SOP) noncompliance based on where the establishment's written AMR control procedures are written, and cite the appropriate 9 CFR 318.24 regulation. See 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 SSOP task based on location of written procedures.	Raw Non-Intact HACCP or SSOP 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.

C. After any noncompliance determination, IPP are to verify that the establishment performs and documents all corrective actions and any subsequent changes in written procedures to the establishment's HACCP system (i.e. HACCP, Sanitation SOP, or prerequisite program) by performing the relevant HACCP or Sanitation SOP task where the establishment has documented their written AMR control procedures per 9 CFR 318.24(b)(2).

NOTE: If SRM bones were used to produce AMR product, the AMR product is adulterated and IPP are to document the noncompliance as a HACCP system noncompliance.

D. If noncompliant product enters commerce, IPP are to notify their supervisor. See *VT Directive 8080.1, Recall of Meat and Poultry Products*.

X. FOLLOW-UP SAMPLING AND ENFORCEMENT

A. IPP are to:

1. When VAAFM testing reveals that the establishment has produced noncompliant beef AMR product due to the presence of CNS or CNS-type tissue, IPP will receive and are to schedule eight (8) sampling tasks;

2. IPP are to 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 sampling results are available;

3. After the establishment has implemented corrective actions to reestablish process control and is producing AMR product eligible for sampling per this directive, IPP are to:

    a. Schedule eight (8) samples each consisting of two pounds (2.0 lb.) of AMR product eligible for sampling. Collect one sample for each day of AMR production following the sampling instructions in Section V. B. above;

    b. Ship the chilled sample(s) per instructions on the sample form at the next available opportunity;

    c. Review laboratory results of each sample and verify the establishment takes appropriate action for the product represented by each sample; and

    d. If all eight (8) are “acceptable”, continue verifying the establishment’s AMR system as scheduled in PHIS. Normal sampling resumes;

4. If any of the eight (8) follow-up samples are “not acceptable” (i.e. contains CNS or CNS-type tissue), IPP are to:

    a. Retain product represented by the sample(s);

    b. Reject equipment that produced the sampled product; and

    c. Notify the establishment and document noncompliance; and

B. Upon notification that the follow-up sample results were also “not acceptable”, the office 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 use of the label after:

    a. The establishment has taken immediate and further preventive actions to correct the AMR system, and such actions are verified by IPP;

    b. The establishment has provided 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 VAAFM; and

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

NOTE: Product produced during this period would be held and the mark of inspection would not be applied until acceptable results become available.

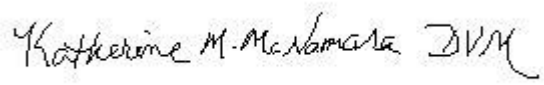
XI. DELAYED FOLLOW-UP SAMPLING

A. In the event IPP are unable to complete a follow-up sampling 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), IPP are to document the reason in an MOI.

B. IPP are to notify or keep the office informed when production of AMR product eligible for sampling resumes so the office can reschedule sample collections.

XII. QUESTIONS

Questions can be referred to the meat inspection office at 802-828-2426.



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