

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

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# FSIS DIRECTIVE

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7160.3  
Rev. 2

9/21/17

## 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”*
- *FSIS 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 FSIS 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.

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**DISTRIBUTION:** Electronic

**OPI:** OPPD

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.

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 (IMPAMRBEEF). Import inspection personnel are to refer to [FSIS Directive 9900.6](#), *Laboratory Sampling Program for Imported Meat, Poultry, and Egg Products*.

#### 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. 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 task(s) in PHIS. See [FSIS Directive 13.000.2, Performing Sampling Tasks in Official Establishments Using the Public Health Information System](#);
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 (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 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 (AMR01 or FAMR01) by cancelling the sampling task and not letting 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. See [FSIS Directive 13,000.2](#).

## **VII. 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.

B. The result recorded in LIMS Direct provides a brief summary of the laboratory’s findings. To view the summary sample results window, IPP are to:

1. Log into [LIMS Direct](#);
2. Enter either the establishment number or the form number;
3. Click “submit;” and
4. Select the “Form No.” or AMR01 (or FAMR01) in the “Project No.” column.

**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).

C. The FSIS Eastern Laboratory e-mails a detailed “Pathology Report” to all recipients listed in the “FSIS - AMR Notification List.” See Fig. 1.0. 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

INTERNAL LAB NO. B19333	SERIAL NO. 100222140	USDA-FSIS-OPHS EASTERN LABORATORY <b>PATHOLOGY REPORT</b>	EST. NO.	RETAIN TAG NO.
PATHOLOGIST REPORT				
Beef AMR product				
Skeletal muscle, fibroadipose connective tissue, blood vessels, bone, cartilage, streaming nuclear debris, and dorsal nerve root ganglion are present.				

**NOTE:** IPP may advise establishments they can receive lab results by electronic mail. See [FSIS Directive 5300.1](#), and [FSIS Directive 13,000.2](#).

### VIII. 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:

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 <a href="#">9 CFR 301.2</a> 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	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 <a href="#">9 CFR 301.2</a> ; 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 [ <a href="#">9 CFR 318.24(c)(2)</a> ].

	debris ...”	<p>Beef AMR product that contains CNS or CNS-type tissue and is otherwise compliant with <a href="#">9 CFR 318.24</a> (e.g. bone solids and bone marrow criteria based on establishment testing per <a href="#">9 CFR 318.24(b)</a>) 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 <a href="#">9 CFR 318.24(c)</a> for additional restrictions or limitations on noncomplying beef product.</p> <p>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.</p>
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.”	<p>Product containing organ tissue (meat by-product) is not “meat” as defined in <a href="#">9 CFR 301.2</a> 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 <a href="#">9 CFR Part 412</a>. Otherwise product would be misbranded.</p> <p>AMR product with foreign matter must be restored to wholesomeness before it can receive the mark of inspection.</p>

## 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.

<b>Table 2.0 - Tasks to Perform and Document Noncompliance with 9 CFR 318.24</b>		
<b>Examples indicating a loss of AMR Process Control</b>	<b>Primary Task under which to Verify 9 CFR 318.24 Requirements:</b>	<b>Primary Task to Document Noncompliance with 9 CFR 318.24 Requirements:</b>
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	<u>MSS; MSP; PDBFT; PDPFT; PDCB; PDCP; AMRS</u> task	<u>MSS; MSP; PDBFT; PDPFT; PDCB; PDCP; AMRS</u> task; Product is misbranded.
3. CNS or CNS-type tissue (non-SRM) is detected by laboratory testing in AMR product; or	<u>MSS; MSP; PDBFT; PDPFT; PDCB; PDCP; AMRS</u> task	<u>MSS; MSP; PDBFT; PDPFT; PDCB; PDCP; AMRS</u> task; Product is misbranded.
4. Product exiting the AMR process meets the standard for “mechanically separated species” in <a href="#">9 CFR 319.5</a> and therefore is inedible per <a href="#">9 CFR 319.5(b)</a> ; or	<u>MSS; MSP; PDBFT; PDPFT; PDCB; PDCP; AMRS</u> task	<u>MSS; MSP; PDBFT; PDPFT; PDCB; PDCP; AMRS</u> task; Product is misbranded.
5. Establishment process control records indicate noncompliant product per 9 CFR 318.24 is being produced;	<u>MSS; MSP; PDBFT; PDPFT; PDCB; PDCP; AMRS</u> task	<u>MSS; MSP; PDBFT; PDPFT; PDCB; PDCP; AMRS</u> 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 the district office (DO) through supervisory channels. See [FSIS Directive 8080.1, Recall of Meat and Poultry Products](#).

**X. FOLLOW-UP SAMPLING (FAMR01) AND ENFORCEMENT**

A. IPP are to:

1. When FSIS AMR01 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) FAMR01 sampling tasks via PHIS;

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 FAMR01 sampling results are available;
  3. If FAMR01 sampling tasks are not received in three (3) business days of being notified of unacceptable AMR01 sampling results, IPP are to send an email requesting forms and include detailed establishment information to the "FSIS - AMR Notification List" in the Outlook address book. IPP are to enter on the subject line: "FAMR01 forms Not Received";
  4. 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 in PHIS 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. AMR01 sampling resumes;
  5. If any of the eight (8) FAMR01 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
  6. If any of the eight (8) FAMR01 samples are "not acceptable", the Inspector-In-Charge (IIC) is to notify the District Office (DO) by notifying the Front-line Supervisor (FLS).
- B. Upon notification by the IIC or FLS that the follow-up sample results were also "not acceptable", the DO 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 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 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 (FAMR01)**

A. 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), IPP are to cancel the scheduled sampling task and select the correct cancellation reason.

B. IPP are to submit a new request using [askFSIS](#), reschedule sample collections, and complete an FAMR01 sampling task when production of AMR product eligible for sampling resumes.

C. If the sampling window for the FAMR01 sampling set has expired before resumption of beef AMR production eligible for sampling as per this directive or completion of the sample set, IPP are to request through askFSIS per instructions in this directive for additional FAMR01 sampling tasks when AMR product eligible for sampling is available and needed to complete the FAMR01 sample set.

## **XII. DATA ANALYSIS**

The Office of Policy and Program Development (OPPD) and The Office of Data Integration and Food Protection analyze beef AMR01 and FAMR01 sampling and associated noncompliance data on an annual basis. OPPD will use this data to assess the effectiveness of this revised directive.

## **XIII. QUESTIONS**

Refer questions regarding this directive to the Policy Development Staff through [askFSIS](#) or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

- Subject Field: Enter **Directive 7160.3**
- Question Field: Enter your question with as much detail as possible.
- Product Field: Select **General Inspection Policy** from the drop-down menu.
- Category Field: Select **Public Health Information System – General Information** from the drop-down menu.
- Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question**.

**NOTE:** Refer to [FSIS Directive 5620.1, Using askFSIS](#), for additional information on submitting questions.



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