TEXAS DEPARTMENT OF STATE HEALTH SERVICES MEAT SAFETY ASSURANCE AUSTIN, TEXAS

MSA DIRECTIVE

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. 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).

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"

II. CANCELLATION

None

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 <u>9 CFR 301.2</u>. AMR product from livestock

bones that meet requirements in <u>9 CFR 318.24</u> can be used as "meat". Noncompliant beef AMR product as defined in <u>9 CFR 318.24</u> that would otherwise qualify as "mechanically separated" product is inedible per <u>9 CFR 319.5(b)</u>.

C. <u>9 CFR 318.24</u> requirements apply to all livestock AMR production. <u>9 CFR 318.24</u> 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 <u>9 CFR 318.24(b)(2)</u>.

- B. IPP are to verify <u>9 CFR 318.24</u> requirements by:
 - 1. Performing the <u>MSS; MSP; PDBFT; PDPFT; PDCB; PDCP; AMRS task</u> in PHIS whenever scheduled and prior to sampling AMR product to verify the economic and wholesomeness AMR requirements in <u>9 CFR 318.24</u>; 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 (<u>9 CFR 318.24</u>) 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 <u>9 CFR 310.22(a)</u>. 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 <u>9 CFR 318.24(c)(3)</u>.

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 <u>9 CFR</u> <u>318.24(c)</u>.

V. 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 <u>MSS; MSP; PDBFT; PDPFT; PDCB; PDCP; AMRS</u> task noncompliance, and cite the appropriate <u>9 CFR 318.24</u> 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 <u>HACCP system task (i.e. HACCP, Sanitation SOP)</u> <u>noncompliance</u> based on where the establishment's written AMR control procedures are written, and cite the appropriate <u>9 CFR 318.24</u> regulation. See Table 2.0 below.

Table 2.0 - Tasks to Perform and Document Noncompliance with 9 CFR 318.24 Drimony Task under which Drimony Task to Decument		
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:
 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.
 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.
 CNS or CNS-type tissue (non-SRM) is detected by laboratory testing in AMR product; or 	<u>MSS; MSP; PDBFT; PDPFT;</u> <u>PDCB; PDCP; AMRS</u> task	<u>MSS; MSP; PDBFT; PDPFT;</u> <u>PDCB; PDCP; AMRS</u> task; Product is misbranded.
 Product exiting the AMR process meets the standard for "mechanically separated species" in <u>9</u> <u>CFR 319.5</u> and therefore is inedible per <u>9 CFR 319.5(b)</u>; or 	<u>MSS; MSP; PDBFT; PDPFT;</u> <u>PDCB; PDCP; AMRS</u> task	<u>MSS; MSP; PDBFT; PDPFT;</u> <u>PDCB; PDCP; AMRS</u> task; Product is misbranded.
 Establishment process control records indicate noncompliant product per 9 CFR 318.24 is being produced; 	<u>MSS; MSP; PDBFT; PDPFT;</u> <u>PDCB; PDCP; AMRS</u> task	<u>MSS; MSP; PDBFT; PDPFT;</u> <u>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 <u>9 CFR 318.24(b)(2)</u>.

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 *MSA Directive 8080.1, Recall of Meat and Poultry Products*.

VII. QUESTIONS

Refer questions through supervisory channels.

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