
FSIS DIRECTIVE

7160.3

12/2/2002

ADVANCED MEAT RECOVERY USING BEEF VERTEBRAL RAW MATERIALS

I. PURPOSE

This directive provides inspection program personnel with new instructions for Office of Public Health and Science (OPHS) directed sampling of boneless comminuted beef produced from an advanced meat recovery (AMR) system in which vertebral column components are used, and on the actions inspection program personnel will take if such product contains spinal cord. (**NOTE:** This directive only addresses the presence of beef spinal cord in boneless, comminuted beef; other issues, such as calcium levels, and products addressed in FSIS Directive 7160.1 and 7160.2 remain unchanged.)

II. RESERVED

III. RESERVED

IV. REFERENCES

9 CFR 301.2 (the definition of meat)
FSIS Directive 8800.2, revision 1

V. BACKGROUND

A. Boneless comminuted beef product containing spinal cord does not meet the regulatory definition of meat (301.2, *meat*), and, therefore, is misbranded. If boneless, comminuted beef product containing spinal cord enters commerce, FSIS will request a voluntary recall and will take a number of enforcement actions, as outlined in paragraph VI. B.

B. This directive's focus is on beef AMR. Proper processing of pork AMR also is of concern to the Agency, but for now, the new laboratory testing procedures will focus exclusively on beef. FSIS expects to survey pork operations to ascertain whether spinal cord and other bone components (e.g., marrow) are being inappropriately incorporated into this product.

C. The purpose of this AMR sampling program is to determine whether an establishment's AMR system is operating properly and is preventing the presence of spinal cord. The sampling for AMR will be directed by OPHS.

VI. TERMINOLOGY

Sampled Lot - This is the amount of product represented by the sample. A lot consists of the meat derived from advanced meat/bone separation machinery and recovery systems, designated as a lot by the operator of the establishment or his or her agent, from the product produced from a single species of livestock in no more than one continuous shift of up to 12 hours. (See 9 CFR 318.24(b)(1).) The lot size defined by the establishment should be the same used for determining calcium compliance.

VII. INSPECTION PROGRAM PERSONNEL RESPONSIBILITIES

A. What are the sampling procedures?

1. When samples are scheduled to be taken at an establishment, the Inspector-in-Charge (IIC) receives FSIS Form 10,210-3, "Requested Sample Programs," from OPHS. When the forms are sent, certain blocks will be pre-printed on the form with information specific to the samples to be collected. Using the project code in **Block 14** of the forms, follow the corresponding instructions found in Attachment 1 (NOTE: These instructions will be incorporated into FSIS Directive 10,210.1).

2. Before collecting samples, inspection program personnel are to notify the establishment management and recommend that the establishment hold the sampled lot. Inspection program personnel are to provide the establishment management enough notice so that they can hold the sampled lot.

3. As specified on the sample request form, inspection program personnel will collect on the designated day a 2-pound sample of product made up of a composite of sub-samples. Inspection program personnel are to collect at least three sub-samples by:

a. sampling at random times throughout the production of the sampled lot, or

b. sampling from different locations within one or more containers (e.g., sampling at the bottom, middle, and top of the combo bin).

4. Each sample request form is for the collection of a single composite sample (a total of two pounds) of a specific sampled lot of AMR product. For example, if two request forms are received by inspection program personnel with the same designated day of collection, then inspection program personnel will collect one 2-pound composite sample from a sampled lot, and, if available, one 2-pound composite sample from a different sampled lot of AMR product.

5. Inspection program personnel will determine when and how to collect the sub-samples of a composite sample based on available inspection time.

6. Inspection program personnel are to complete all requested information in blocks 19, 20, 22, 28, 29, 30, and 32 of Part II of the FSIS Form 10,210-3. Enter "N/A" if information is unavailable.

B. What are the enforcement actions when an FSIS collected sample of AMR-produced boneless comminuted beef tests positive for spinal cord?

1. If an FSIS-sample tests positive for spinal cord and the establishment shipped the sampled lot, FSIS will request a recall of that sampled lot. The Recall Management Division (RMD) will coordinate a recall as outlined in FSIS Directive 8080.1. FSIS will also withhold the marks of inspection from product containing product produced from the AMR system as set out in 9 CFR 500.3(a) because the establishment produced and shipped misbranded product. Inspection program personnel will also officially control the AMR equipment as set out in 9 CFR part 500.2(a)(2). The withholding action and the official control will remain in place until the establishment offers the appropriate corrective actions to remedy the situation.

2. If an FSIS-sample tests positive for spinal cord and the establishment did not ship the product, inspection program personnel will verify that the establishment takes the appropriate corrective action to ensure that the AMR system is operating properly. If an establishment fails to do so, inspection program personnel will officially control the AMR equipment as set out in 9 CFR part 500.2(a)(2). The official control will remain in place until the establishment offers the appropriate corrective actions to remedy the situation. Also, inspection program personnel will verify that the establishment management makes the proper product disposition for the lot, by re-labeling the product as Mechanically Separated (Species) if the requirements in 9 CFR 319.5 are met, by rendering, or by condemnation.

3. After corrective actions are complete, inspection program personnel will collect follow-up verification samples. These samples will be collected in the same way as in paragraph VI. A. OPHS will send the IIC sample request forms that will indicate that they are for follow-up sampling.

4. Because conditions exist that preclude FSIS from determining that product is not misbranded (9 CFR 500.2(a)(3)), inspection program personnel will officially control each lot for the collected follow-up verification sample and verify that the lot is held until the sample result is received and is negative.

5. If there are no positives from the follow-up verification samples, the establishment can begin regular operations. If there are positive results, FSIS may initiate additional enforcement actions in accordance with the rules of practice.

Direct questions regarding this directive through supervisory channels.

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**Product Sampling – Pathology
Advanced Meat Recovery Product**

Project Number	AMR01 (initial sample), FAMR01 (follow-ups to positive samples)
Program Title	Advanced Meat Recovery (AMR) Product Monitoring – Raw Product
Program Dates	Ongoing
Analyzed for	Spinal Cord
Product to Sample	Raw beef product derived from vertebral materials as it exits the AMR system (after the desinewer)
Collection Instructions	On the designated day, randomly select one composite sample for each form provided by OPHS, approximately two pounds from throughout a single lot of product. Place sample in an appropriately sized zipper-lock plastic bag. Identify the bag with the Sample Identification Label (FSIS 7355-2B) from an FSIS 7355-2A/B seal packet as outlined in FSIS Directive 7355.1 Rev 2. Refrigerate the sample until shipped.
Sample Request Form	Fill out the form according to the instructions in Block 18. Make sure all information requested in Block 28 is filled out. If product requested is unavailable for sampling, complete Block 33 and mail the form to the Eastern Laboratory. Place a small bar-coded label from same seal packet indicated above as shown in FSIS Directive 7355.1 Rev. 2. Check to insure that the number on the identification label matches the barcode number on the sticker placed on the form. Place the sample request form in a plastic bag and place the plastic bag into the shipping container with the sample. Seal the shipping container as outlined in FSIS Directive 7355.1, Rev.2.
Establishment Management Notification	Notify establishment management prior to sampling. Recommend establishment management to hold the sampled lot.
Shipment	Refrigerated. Ship same day as collected or within 24-hours of collection to the Eastern Laboratory address listed in Block 9 of the sample request form and on the PRE-ADDRESSED LABEL. Use sufficient frozen coolant to keep samples cold during transit. Samples collected and shipped on a Friday must have a SATURDAY DELIVERY sticker on it and Saturday Delivery marked on the shipping label to avoid delivery delays and discarded samples. DO NOT ship samples on Saturdays, Sundays, or the day before a Federal Holiday.
Availability of Test Results	Test results for the presence of spinal cord will be reported by e-mail to the IIC as soon as possible (i.e., typically within 48 hours of receipt of sample at the Eastern Laboratory). A final pathology report will be mailed to the IIC.
References	FSIS Directive 10,210.2 FSIS Directive 7355.1, Rev.2 FSIS Directive 7160.3