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

FSIS DIRECTIVE

7160.3, Revision 1

8/25/03

ADVANCED MEAT RECOVERY USING BEEF VERTEBRAL RAW MATERIALS

I. PURPOSE

Based on the first several months of regulatory (monitoring and follow-up surveillance) sampling, FSIS has determined that some establishments are not adequately addressing the presence of spinal cord tissue in boneless comminuted beef. FSIS is reissuing this directive to define more fully than it did in the initial directive the range of follow-up actions available to the Agency when product from an advanced meat recovery (AMR) system contains spinal cord tissue. This directive continues to provide inspection program personnel with instructions for sampling when a request is received from the Office of Public Health and Science (OPHS).

NOTE: This directive only addresses the presence of spinal cord tissue. Other issues, such as calcium levels and the matters addressed in FSIS Directive 7160.1 and 7160.2, remain unchanged.

II. CANCELLATION

FSIS Directive 7160.3, dated 12/2/2002

III. REASON FOR REISSUANCE

FSIS is reissuing this directive to reiterate that establishments whose AMR system repeatedly fails to produce product that is free of spinal cord will not be allowed to produce AMR meat from beef vertebrae, and that product containing spinal cord tissue will not be allowed to enter commerce labeled as meat. Paragraph VI. B has been entirely rewritten to provide for new enforcement procedures and a flowchart has been added that sets out the enforcement procedures.

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 tissue does not meet the regulatory definition of “meat” (301.2, *meat*) and, therefore, is misbranded. If boneless, comminuted product containing spinal cord tissue enters commerce, FSIS will likely request a recall and may take a number of additional actions, as outlined in this directive.

B. This directive’s focus is on beef AMR product. Proper processing of pork AMR product also is of concern to the Agency, but for now, the Agency will focus on beef. FSIS is completing a survey of pork AMR systems to ascertain whether spinal cord tissues and other bone components (e.g., marrow) are being inappropriately incorporated into this product.

C. The purpose of this AMR system sampling program is to determine whether an establishment’s AMR system is operating properly and not incorporating spinal cord tissue in AMR products. Agency sampling of AMR products will be directed by OPHS.

VI. INSPECTION PROGRAM PERSONNEL RESPONSIBILITIES

A. What are the random sampling procedures?

1. When sample collections are scheduled for 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. Each sample request form is for the collection of a single composite sample (a total of two pounds) of AMR product from a selected AMR system. For the day designated on the form, inspection program personnel are to randomly collect a composite sample for every form received. In establishments with more than one AMR system, inspection program personnel are to randomly select from each of the systems.

2. Before collecting samples, inspection program personnel are to notify the establishment management and provide them the opportunity to hold the AMR products produced on the day of sampling from the AMR system from which the sample will be taken. Inspection program personnel are to provide the establishment management enough notice so that they can hold all products represented by the samples until the test results of the samples are available.

3. As specified on the sample request form, on the designated day inspection program personnel will collect from the selected AMR system a 2-pound sample of product made up of a composite of 4 grab sub-samples. Inspection program personnel are to collect 4 sub-samples to constitute each composite sample by:

a. sampling at random times throughout the production of the designated day, or

b. sampling from different locations within one or more randomly selected, stored (and unfrozen) containers (e.g., sampling near the bottom, middle, and at the top of randomly selected containers) that were produced on the designated day.

4. 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. In the statement "Product of the sample was made from carcasses or carcass parts of some / all / none / cannot determine appearing to be from cattle 30 months of age or older" in Block 28, inspection program personnel are to circle the appropriate choice.

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

1. Inspection program personnel are to inform the establishment management of the positive sample result and issue an FSIS Form 5400-4, Noncompliance Record (NR) using the Inspection System Procedure (ISP) Code 04A03.

2. Inspection program personnel are to take regulatory control:

a. of any product produced by the system tested on the designated day of sampling (i.e., retaining product) in accordance with 9 CFR 500.2(a)(2) because the product is deemed misbranded, and

b. against the AMR system equipment (i.e., reject equipment) in accordance with 9 CFR 500.2(a)(3) because the system is producing misbranded product.

NOTE: If an FSIS sample tests positive for spinal cord tissue, and the establishment shipped the product produced on the designated day of sampling, FSIS will request a recall of that product (including all products containing the AMR product). The Recall Management Division (RMD) will coordinate a recall as outlined in FSIS Directive 8080.1.

3. Inspection program personnel are to verify that the establishment makes proper disposition of the product.

C. How do inspection program personnel collect follow-up verification composite samples to verify the effectiveness of the establishment's immediate and further preventive actions?

1. To determine the effectiveness of the actions, inspection program will verify the establishment's corrective and preventive (or immediate and further planned) actions have been implemented and are operating as described in the plant's response. Inspection personnel will also collect 10 follow-up composite samples. The samples are needed because spinal cord tissue, if present, is not uniformly distributed through the product. The Agency will make a determination on whether the AMR system is not in control (i.e., the system is producing product that contains spinal cord tissue) based on the results of the 10 composite samples. OPHS will send the IIC sample request forms that will state that they

are for follow-up verification sampling.

2. Upon receipt of the forms, inspection program personnel are to collect 5 follow-up verification composite samples and notify the establishment so that it may hold product represented by the sampling. Each composite sample is to consist of 4 grab sub-samples, for a total of 2 pounds per composite sample. Over a 24-hour production period, inspection program personnel randomly (for collection times) will collect the 5 follow-up verification composite samples. Inspection program personnel may collect the 5 follow-up verification composite samples by a random sampling of stored boxes of chilled (unfrozen) AMR products that represent the production of the day.

3. When the results of analyzing the samples are received:

a. if any of the 5 results are positive, inspection program personnel are to take the actions described in paragraph VI D. below.

b. if the 5 results are negative, inspection program personnel are to:

i. inform the establishment it may ship any product that it held,
ii. collect an additional 5 composite samples as described in paragraph VI C. 2 above:

(A) if any one of the additional 5 results is positive, inspection program personnel take the actions described in paragraph VI D. below, and

(B) if the additional 5 results are negative, then on the basis of 10 negative composite samples, there is no reason to find that product produced by the AMR system is misbranded. Inspection program personnel will continue to verify the AMR system as scheduled by PBIS.

D. What enforcement actions are taken when an FSIS follow-up verification sample of AMR-system-produced boneless comminuted beef tests positive for spinal cord tissue?

1. A positive sample result from the follow-up verification testing provides the evidence that the product represented by the 5 composite samples from the 24-hour production period is misbranded, and that the AMR system is not in control. The product is misbranded in that it does not conform to the regulatory definition of AMR product (9 CFR 301 (*meat*, second paragraph). AMR product only contains meat. The sampled product contains material (spinal cord) that is not meat. Because the system is producing product that is not AMR product, labels representing the product as AMR product are false.

2. Inspection program personnel are to take the control actions as describe in VI B. 2.

3. The DO will advise the establishment that the use of labels representing product produced from the AMR system will be withheld from the product (21 U.S.C. 607(e)).

4. The DO will notify the establishment in writing of:

a. the reason for withholding the use of the labels,

b. the opportunity for the establishment to describe the steps that it will take to modify its process so that the product may be appropriately labeled as AMR product,

c. the opportunity to request a hearing, as described in 9 CFR 500.8(c).

5. The use of the label will be withheld pending a final decision on any appeal by the Secretary, unless the establishment demonstrates that it has corrected its system as described in VI D. 6 below.

6. The DO will 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 inspection program personnel,

b. the establishment has provided to the DO evidence that 10 consecutive composite samples of product from the AMR system were negative for spinal cord 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 additional composite sample and found it negative for spinal cord.

NOTE: Product produced during this period would be held and the mark of inspection would not be applied.

If inspection program personnel find that an establishment has made changes in the AMR system that raise concerns about the possible presence of spinal cord tissue in AMR product, they are to notify the DO through supervisory channels.

Philip S. Derfler /s/

Assistant Administrator
Office of Policy and Program Development

Enforcement Flowchart for 7160.3, Revision 1