



FSIS Notice 25-10

Interpreting Results of FSIS Verification Sampling of Beef Product Derived from Advanced Meat Recovery Systems (AMR01/FAMR01)



FSIS Notice 25-10

I. PURPOSE

- ✓ How to interpret test results obtained from sampling beef product derived from AMR.
- ✓ Update **FSIS Directive 7160.3** *Advanced Meat Recovery Using Beef Vertebral Raw Materials - Revision 1.*
 - CNS-type tissue and other tissues not considered as “meat”



FSIS Notice 25-10

II. BACKGROUND

9 CFR 301.2 Definition “Meat”

Meat. (1) The part of the muscle of any cattle which is skeletal or which is found in the tongue, diaphragm, heart, or esophagus... (ii) Meat may not include significant portions of bone, including hard bone and related components, such as bone marrow, or any amount of brain, trigeminal ganglia, spinal cord, or dorsal root ganglia (DRG).

- comminuted meat may not include any amount of central nervous system (CNS) or CNS-type tissues (i.e., brain, trigeminal ganglia, spinal cord, and dorsal root ganglia (DRG)).



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II. BACKGROUND

- AMR product containing CNS or CNS-type tissues (9 CFR 318.24(a)(2)) is misbranded under Section 1(n) of the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601(n)) if labeled as “meat.”
- The FMIA (21 U.S.C. 607(d)) prohibits the sale of products whose labeling is false or misleading.



FSIS Notice 25-10

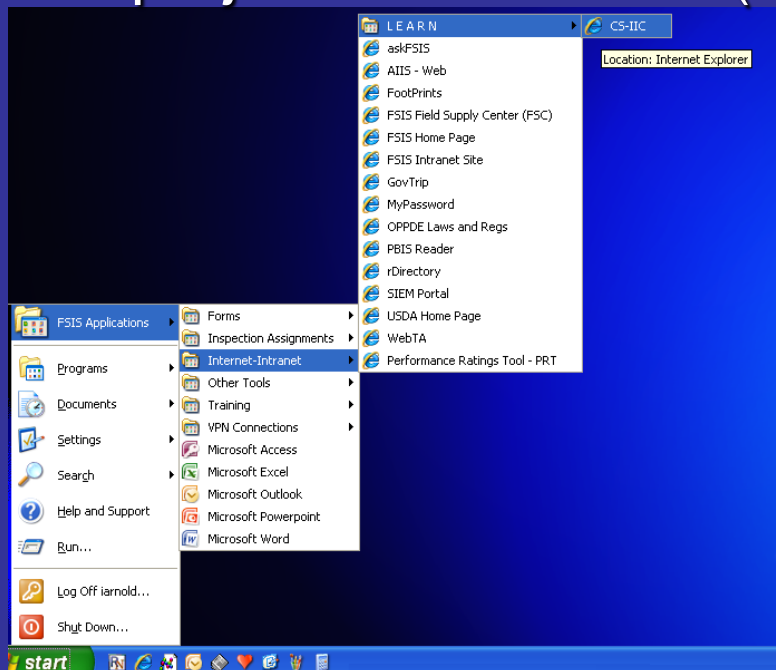
II. BACKGROUND

- Skulls or vertebral column bones of cattle 30 months of age and older are prohibited from being used in an AMR system (9 CFR 318.24(a)) because these components are defined as specified risk material (SRM) in cattle 30 months of age and older (9 CFR 310.22).

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III. IPP SAMPLE VERIFICATION RESPONSIBILITIES

- IPP submit beef AMR samples under the HQ Directed project code AMR01 (or FAMR01).



- Access LEARN for the results
 - instructions in *FSIS Directive 10,200.1 Accessing Laboratory Sample Information via LEARN*



LEARN

FSISnet.gov >> where ideas and information intersect

> lab results for establishment 00086H M

LEARN results for a specific establishment may only be released to the establishment from which they were collected.

[CHECK FOR PR/HACCP COMPLETED SET RESULTS](#)

HOME
BACK

Establishment: 00000 M

Total Results Found: 28

Collection Date	Form No.	Product Held	Sample Type	Status	Result	Date Posted
05/20/2010	11441806	Yes	Pathology	Analysis Complete	See Diagnosis	05/25/2010
05/19/2010	11431514	Yes	Microbiology	Analysis Complete	Acceptable	05/21/2010
05/18/2010	11429753	Yes	Microbiology	Analysis Complete	Acceptable	05/20/2010

Click on
 "Pathology"



FSIS Notice 25-10

LAB RESULT REPORT-- PATHOLOGY

Date Posted: 11/14/2010	
Establishment: 00038 M	District/Circuit: 0000
Form No: 00076114	ILN: P044XX
Collection Date: 11/09/2009	Date Received At Lab: 11/12/2010
Sample Type: Monitoring Pathology	
Project: AMR01 - Advanced Meat Recovery Monitoring	
Slaughter Class or Product: VERTEBRAE & RIB BONES/TIME COLL=0906	
Producer: MYTFINE MEATS	Producer State: US
Production Date: 11/11/2010	Production Lot No: 1ADUEWA
Product Held: Yes	
Retain Tag No:	
Lab: Eastern Lab - Pathology	
Contact Name: Mr. B. Fine	Contact Phone: (555) 411-1212

IMPORTANT: This result notice is a brief synopsis of the laboratory's findings. A more detailed report will be sent by email, fax or U.S. Postal Service from the FSIS Eastern Lab Pathology Section. No product disposition action is to be taken until the detailed narrative is received.

ANALYSIS RESULT

Tissue	Diagnosis
Comminuted Meat	LIVER

Copy of report sent to establishment management? NO

IPP share the LEARN results and detail report information with the establishment management



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III. IPP SAMPLE VERIFICATION RESPONSIBILITIES

LEARN results

- brief synopsis of the laboratory's findings
- detailed report by email, fax, or U.S. Postal Service.
 - If access to a fax machine, provide the fax number Block 28
“Remarks”
 - “AMR Notification List”
 - RIMD Staff notify the appropriate District Office of the pending noncompliant report prior to the posting on LEARN.



FSIS Notice 25-10

- Detailed Report of histopathology of Beef AMR sample time composition

INTERNAL LAB NO. A913	SERIAL NO. 35	USDA-FSIS-OPHS EASTERN LABORATORY PATHOLOGY	ESI NO. M	RETAIN IAC NO.
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PATHOLOGIST REPORT
Beef AMR product

Skeletal muscle, fibroadipose connective tissue, blood vessels, bone, streaming nuclear debris, and a ganglion fragment are present. The ganglion contains neurons that have morphologic features and immunohistochemical staining that are compatible with those of dorsal root/sensory ganglia.

COMMENT:

DIAGNOSIS:
Sensory ganglion (dorsal nerve root ganglion)
Skeletal muscle, associated tissues, bone fragments, and streaming nuclear debris

PATHOLOGIST'S SIGNATURE DVM, MS	CODE 66	DATE STARTED 6/22/	DATE COMPLETED 6/25/	DATE MAILED
CONDITION ON RECEIPT SATISFACTOR	SRC 51	NO. ISSUES	NO. SLIDES	LAB CODE 1303

FSIS 10,300-4 10/92



FSIS Notice 25-10

IPP will make a product disposition determination and take enforcement action based on the detailed report

There are three possible outcomes:

- Product is labeled “meat” because it is skeletal muscle
- Product not eligible to be labeled “meat” CNS-type tissue identified
- Product not eligible to be labeled “meat” because of organ tissue or other tissues other than meat identified



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Product eligible to be labeled “meat” because it is skeletal muscle:

- LEARN “Diagnosis” field for “ANALYSIS RESULT” displays “Skeletal Muscle & Associated Tissues”
- Detailed report: “skeletal muscle, adipose tissue, blood vessels, streaming nuclear debris, bone, and cartilage.”



FSIS Notice 25-10

Product is not eligible to be labeled “meat” w/ CNS-type tissue:

- LEARN “Diagnosis” field for “ANALYSIS RESULT” displays CNS-type tissue (e.g., spinal cord tissue, dorsal root ganglia-sensory ganglia) with “Skeletal Muscle & Associated Tissues;”
- Detailed report describes sensory ganglion (DRG) or CNS-type tissue along with skeletal muscle, associated tissues, bone fragments, cartilage, and streaming nuclear debris



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Product is not eligible to be labeled “meat” because of CNS-type tissue:

9 CFR 318.24(c)(2)(iii) provides that AMR product derived from cattle younger than 30 months that contain spinal cord or DRG may bear a common or usual name that is not false or misleading, except that the product may not bear the name “MS(beef).”



FSIS Notice 25-10

Product is not eligible to be labeled “meat” because of organ tissue or other tissues other than meat:

- LEARN “Diagnosis” field for “ANALYSIS RESULT” displays “organs or other tissues other than meat”(e.g., kidney, liver, spleen, fibrous plant material);
- Detailed report describes organs (i.e., kidney or liver) or tissues other than meat along with skeletal muscle, associated tissues, bone fragments, cartilage, and streaming nuclear debris.



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Product is not eligible to be labeled “meat” because of organ tissue or other tissues other than meat:

To enter commerce, this product will need to be descriptively labeled, as meat with organ tissue and the label will need sketch approval from OPPD LPPD for this non-standardized product (9 CFR 317.4(a)).



FSIS Notice 25-10

IV. ENFORCEMENT ACTIONS

IPP are to continue to follow FSIS Directive 7160.3 *Advanced Meat Recovery Using Beef Vertebral Raw Materials - Revision 1* incorporating the disposition results for CNS and CNS-type tissue or other tissue not considered “meat” when a random AMR01 or follow-up FAMR01 result is noncompliant.



FSIS Notice 25-10

IV. ENFORCEMENT ACTIONS

IPP issue a NR for the production of misbranded product using the ISP procedure code 04A03 based on the detailed pathology report from the FSIS Eastern Laboratory.



FSIS Notice 25-10

IV. ENFORCEMENT ACTIONS

IPP are to take regulatory control action on 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 result is an indication that the process may be out of control and the product produced may be adulterated or misbranded.



FSIS Notice 25-10

IV. ENFORCEMENT ACTIONS

IPP are to take regulatory control action 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.



FSIS Notice 25-10

IV. ENFORCEMENT ACTIONS

If an FSIS sample tests positive for CNS-type tissue, and the establishment shipped the product produced on the designated day of sampling, or if IPP determine that product ineligible for the mark of inspection has been shipped, IPP are to contact the District Recall Officer to alert him/her of the situation.



FSIS Notice 25-10

IV. ENFORCEMENT ACTIONS

Prior to closing out the NR and lifting the regulatory control action, IPP are to verify that the corrective actions proffered by the establishment to ensure that it takes the appropriate actions or measures to bring the AMR process back under control, and that the establishment makes the proper disposition on the product before IPP release the regulatory control action.



FSIS Notice 25-10

IV. ENFORCEMENT ACTIONS

IPP are to follow FSIS Directive 7160.3 *Advanced Meat Recovery Using Beef Vertebral Raw Materials - Revision 1* to determine the effectiveness of the establishment's actions and verify the implementation of the establishment's corrective and preventive (or immediate and further planned) actions are operating as described in the plant's response.



FSIS Notice 25-10

IV. ENFORCEMENT ACTIONS

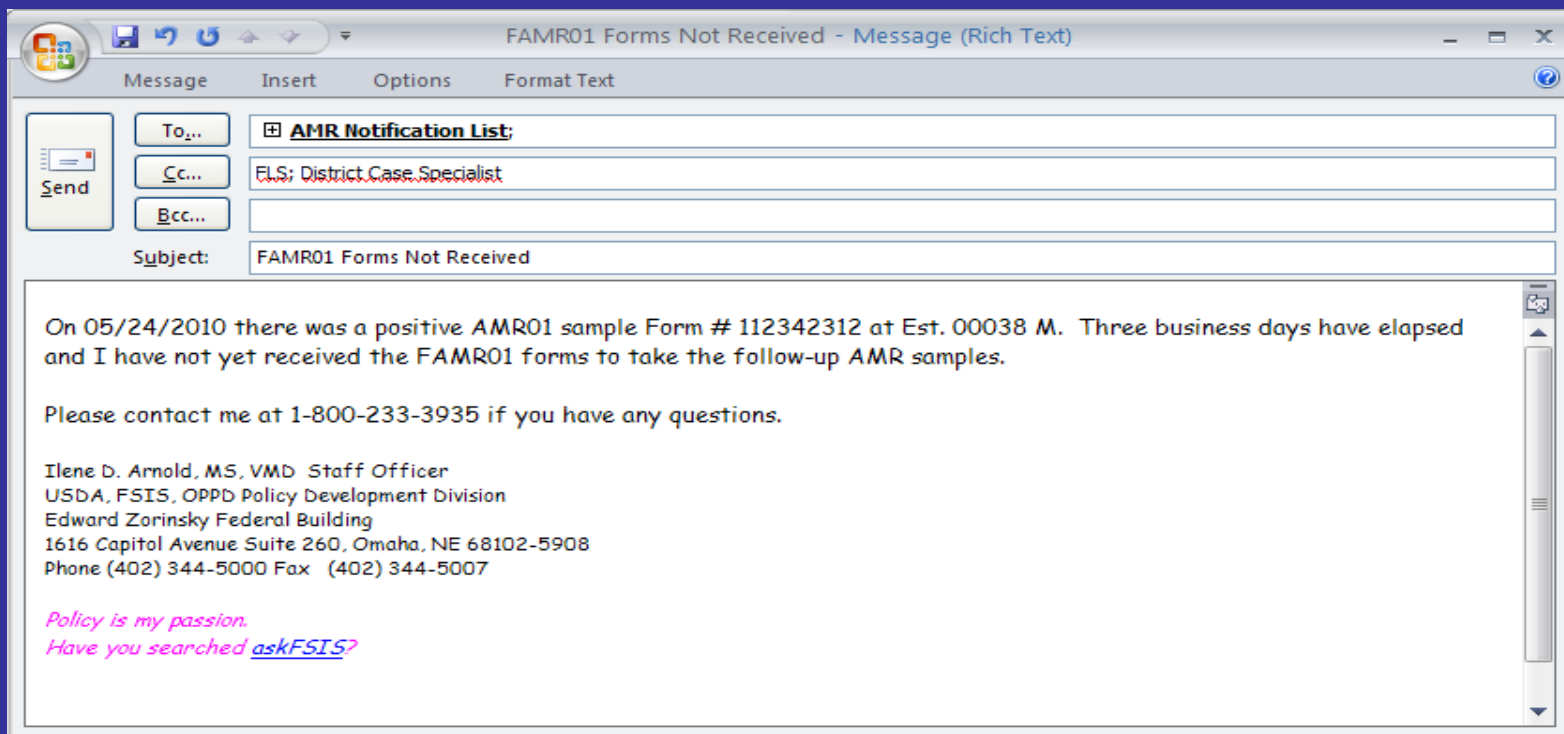
- 11 follow-up (FAMR01) forms HQ LITB.
- Use 10 forms to collect follow-up composite samples
- If there is a positive finding, the IPP use the last form to collect a sample after the establishment demonstrates process control.
- If all 10 composite samples are negative, IPP will mail the last form to the laboratory.



F SIS Notice 25-10

FAMR01 forms should be received in three business days following the positive notification

- If not, IPP will need to send an email:





FSIS Notice 25-10

IV. HOW TO SUBMIT QUESTIONS

- askFSIS <http://askfsis.custhelp.com>
- call 1-800-233-3935
 - For labeling questions press 1, then press 3 (LPDD)
 - For sampling questions press 1, then press 4 (RIMD)
 - For technical questions press 1, then press 5 (PDD).
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