

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

FSIS NOTICE

58-05

9/14/05

VERIFICATION INSTRUCTIONS FOR THE SRM AMENDMENT TO 9 CFR 310.22(a)(3) REGARDING BEEF SMALL INTESTINES

NOTE: This Notice is effective on October 7, 2005.

I. PURPOSE

This notice provides instructions to inspection program personnel in beef processing and slaughter establishments on how to verify that an establishment has properly designed and implemented procedures for the removal, segregation, and disposition of the distal ileum of the small intestine of cattle. In addition, this notice provides instructions to inspection program personnel in processing establishments that use beef small intestine in meat food products or for edible rendering, or that use natural casings from beef small intestine as a casing for meat food products on how to verify the establishment has met the amendments to 9 CFR 310.22(a)(3) and provided the appropriate documentation. Finally, this notice instructs import inspection program personnel in import facilities to verify that beef small intestine entering the country meets the requirements of 9 CFR 310.22(a)(3) and the product is accompanied by the appropriate documentation.

Key Points Covered

- *Verification of establishment removal, segregation, and disposition of the distal ileum of the small intestine of cattle in slaughter establishments*
- *Verification of establishment documentation for the removal of the distal ileum of the small intestine of cattle in processing establishments that use beef small intestine in meat food products, for edible rendering, or as natural casings for meat food products*
- *Verification of the documentation for the removal of the distal ileum from beef small intestines entering the country by import inspection program personnel*

II. BACKGROUND

On October 7, 2005, the Food Safety and Inspection Service (FSIS) issued an interim final rule to amend 9 CFR 310.22(a)(3) of its regulations for the removal, segregation, and disposition of specified risk materials (SRMs) to permit, under certain conditions, beef small intestine, excluding the distal ileum, to be used for human food. Under the amendments, the small intestine may be used for human food if:

DISTRIBUTION: Inspection Offices;
T/A Inspectors; Plant Mgt; T/A Plant
Mgt; ABB; PRD; Import Offices

NOTICE EXPIRES: 10/01/06

OPI: OPPED

1. it is derived from cattle that were slaughtered in an official establishment in the United States or in a certified foreign establishment in a foreign country that is eligible to export beef products to the United States; and

2. it was removed by:

a. a procedure that detaches 80 inches of uncoiled and trimmed small intestine starting at the ceco-colic junction and moving proximally towards the jejunum, or

NOTE: The Technical Service Center (TSC) web site (see link below) contains pictures of the ceco-colic junction and approximately 80 inches of small intestine to aid inspection program personnel in performing their verification activities.

<http://www.fsis.usda.gov/ofotsc>

b. by a procedure that the establishment can demonstrate is effective in ensuring complete removal of the distal ileum.

As part of that rulemaking, FSIS also amended 9 CFR 318.6(b)(1) to permit natural casings from cattle to be used as containers of products if the small intestine complies with 9 CFR 310.22(a)(3) as demonstrated through documentation. In addition, FSIS amended 9 CFR 318.6(b)(8) to permit the small intestine from cattle to be used in meat food products or for edible rendering if it complies with 9 CFR 310.22(a)(3).

Because the amendments to the SRM interim final rule do not affect the regulatory authority of either FSIS or FDA, jurisdiction over a product derived from small intestine will continue to depend on whether the product is considered a meat food product as defined in the Federal Meat Inspection Act (FMIA). Thus unprocessed beef small intestine will continue to be regulated by FSIS, and stripped and cleaned natural casing derived from bovine small intestine will continue to be regulated by FDA.

III. AWARENESS MEETING

A. Slaughter Establishments

1. Upon receipt of this notice at the next weekly meeting with establishment management officials, the Inspector-In-Charge (IIC) at all beef slaughter establishments is to have a discussion with establishment management to determine whether the establishment intends to harvest the beef small intestine, excluding the distal ileum, for human food. If the establishment will not be harvesting the small intestine, excluding the distal ileum for human food the IIC should proceed to A 3.

If the establishment will be harvesting the small intestine, excluding the distal ileum, the IIC is to discuss with management:

a. the amendment to the regulations at 9 CFR 310.22(a) that permits, under certain conditions, beef small intestine, excluding the distal ileum, to be used for human food,

b. the procedures that the establishment will use to detach the distal ileum from the intestine,

c. and the procedures that the establishment will use to ensure appropriate segregation and disposal of the distal ileum of the small intestine of all cattle .

2. IICs are to inform the establishment that if they decide to harvest the small intestine, excluding the distal ileum, for human food, including as a casing for a meat food product, the establishment will need to reassess its food safety system as set out in 9 CFR 417.4(a)(3). The reassessment is necessary because the removal of the distal ileum from the small intestine represents a change in the establishment's slaughter or processing methods that could affect the hazard analysis or alter the HACCP plan. Removal of only the distal ileum instead of the entire small intestine is also a change that affects the establishment's procedures for the removal, segregation, and disposition of SRMs (see 9 CFR 310.22(d)(3)). Any change to these procedures will need to be properly incorporated into the establishment's food safety system (see 9 CFR 310.22(d)(1)).

3. In a memorandum of interview, the IIC is to document who was present at the awareness meeting, the date and time of the meeting, what was discussed, and any documents that were shared with establishment management. Inspection program personnel are to maintain a copy of the memorandum in the official government file and provide a copy to the establishment management.

B. Processing Establishments

1. Upon receipt of this notice at the next weekly meeting with establishment management officials, the IIC at all beef processing establishments is to have a discussion with establishment management to determine whether the establishment intends to use beef small intestine , excluding the distal ileum:

a. in a meat food product or for edible rendering, or

b. as a beef casing, such as a meat sausage casing. If the establishment will not be using the small intestine, excluding the distal ileum, in the above listed products the IIC should proceed to B4.

2. If the establishment will be using the small intestine, excluding the distal ileum, in the above listed products, the IIC is to discuss with management:

a. how the establishment will ensure that beef small intestine for use in a meat food product or for edible rendering, complies with 9 CFR 310.22(a)(3), and

b. how the establishment will ensure that natural beef casings were derived from small intestine that complies with 9 CFR 310.22(a)(3) as demonstrated through documentation.

3. IICs are to inform the establishment that if it decides to use the small intestine, excluding the distal ileum, in a meat food product, for edible rendering, or as a casing for product, the establishment will need to reassess its food safety system as set out in 9 CFR 417.4(a)(3). The reassessment is necessary because the use of beef small intestine or casings derived from beef small intestine represents a change in raw materials that could affect the hazard analysis or alter the HACCP plan.

4. In a memorandum of interview, the IIC is to document who was present at the awareness meeting, the date and time of the meeting, what was discussed, and any documents that were shared with establishment management. Inspection program personnel are to maintain a copy of the memorandum in the official government file and provide a copy to the establishment management.

IV. VERIFICATION OF PROCEDURES FOR REMOVAL OF DISTAL ILEUM IN SLAUGHTER ESTABLISHMENTS

A. After the establishment has performed its reassessment:

1. Public Health Veterinarians (PHVs) are to verify into which program (i.e., HACCP plan, Sanitation SOPs, or prerequisite program) the establishment incorporated any procedures adopted as a result of its reassessment.

2. PHVs are to verify that the establishment has appropriately addressed in its food safety system design the effective removal of the distal ileum from the small intestine by verifying the establishment has procedures that:

a. ensure removal of 80 inches of uncoiled and trimmed small intestine as measured from the ceco-colic junction and progressing proximally towards the jejunum,

or

b. are effective in ensuring complete removal of the distal ileum.

If PHVs have technical questions regarding the procedures establishments have for removal of the distal ileum of the small intestine, contact the TSC.

B. Off-line inspection program personnel are to verify the execution of the establishment's food safety system procedures to ensure the removal of the distal ileum from the small intestine.

1. As part of verifying the establishment's monitoring or verification procedures, inspection program personnel may perform a direct observation of the establishment removing the distal ileum. Inspection program personnel may use the ileo-cecal-colic juncture as a verifiable point of reference. In addition, inspection program personnel may identify the distal ileum as having no curve and an irregular thick surface.

V. VERIFICATION OF PROCEDURES FOR REMOVAL OF DISTAL ILEUM FOR SRMs IN PROCESSING ESTABLISHMENTS

A. After the establishment has performed its reassessment, IICs are to

1. verify the establishment can demonstrate, through documentation, that the small intestine complies with 9 CFR 310.22(a)(3), and

NOTE: All imported natural beef casings that enter an FSIS-regulated establishment to be used in the preparation of a meat food product must be accompanied by an “Official Meat-Inspection Certificate for Fresh Meat and Meat Byproducts.” (9 CFR 327.4(a)). This certificate attests that the product is in compliance with requirements equivalent to those in the Federal Meat Inspection Act and said regulations.

2. verify into which food safety system the establishment incorporated any procedures adopted as a result of its reassessment. IICs are to verify that the establishment has appropriately addressed in its food safety system:

a. the use of small intestine, excluding the distal ileum, in a meat food product or for edible rendering, and

b. the use of natural casings derived from beef small intestine.

B. Inspection program personnel in processing establishments that receive small intestines, excluding the distal ileum for use in:

1. the production of meat food products, or for edible rendering, or

2. natural beef casings as containers of products

are to verify the establishment’s execution of their food safety system procedures to ensure that the small intestine complies with 9 CFR 310.22(a) by following the directions in FSIS Directive 5000.1, Revision 1.

VI. DOCUMENTATION AND ENFORCEMENT

A. In slaughter establishments, if off-line inspection program personnel determine that the establishment is not effectively removing the distal ileum from the small intestine then inspection program personnel are to:

1. take a regulatory control action as set out in 9 CFR 500.2(a)(2) when product adulteration or misbranding occurs,

2. document the noncompliance on a noncompliance record (NR), and

3. take an enforcement action following the methodology in FSIS Directive 5000.1, Revision 1.

B. If a processing establishment uses beef small intestines in a meat food product or for edible rendering, or for natural casings derived from beef small intestines, cannot demonstrate, through documentation, that the intestines were appropriately harvested and comply with 310.22(a)(3), then inspection program personnel are to:

1. take a regulatory control action as set out in 9 CFR 500.2(a)(2) when product adulteration or misbranding occurs, and inform the District Office so that the District Manager can inform the appropriate FDA office (because casings are regulated, at this time, by FDA);

2. document the noncompliance on an NR, and

3. take an enforcement action following the methodology in FSIS Directive 5000.1, Revision 1.

VII. VERIFICATION OF FOREIGN ESTABLISHMENT REQUIREMENTS BY IMPORT INSPECTION PROGRAM PERSONNEL

A. Import inspection program personnel are to verify that beef small intestines entering the country for use in the production of human food:

1. were harvested in a certified establishment of a country that FSIS considers eligible to import meat and meat products into the United States and is otherwise eligible for importation under 9 CFR 327.1(b); and

2. are accompanied by documentation establishing that the small intestines, excluding the distal ileum, for use as a meat food product meet the requirements of 9 CFR 310.22(a)(3).

NOTE: All imported unprocessed beef small intestine must be accompanied by an "Official Meat-Inspection Certificate for Fresh Meat and Meat Byproducts." (9 CFR 327.4(a)).

B. If these conditions are not met, import inspection program personnel are to follow Part 4, Section 11 of the Import Manual of Procedures for refused entry procedures.

Refer technical questions to the Technical Service Center at 1-800-233-3935.



Assistant Administrator
Office of Policy, Program, and Employee Development

Updated Regulation Text

Part 310 – Post-mortem Inspection

1. The authority citation for part 310 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53

2. Paragraph (a)(3) of §310.22 is amended by removing the second sentence and adding the following sentence and paragraphs (a)(3)(i) and (ii) in its place:

§310.22 Specified risk materials from cattle and their handling and disposition.

(a) * * *

(3) * * * The small intestine may be used for human food if:

(i) It is derived from cattle that were inspected and passed in an official establishment in the United States or in a certified foreign establishment in a country listed in 9 CFR 327.2(b) as eligible to export meat and meat products to the United States and it is otherwise eligible for importation under 9 CFR 327.1(b), and

(ii) The distal ileum is removed by a procedure that removes at least 80 inches of the uncoiled and trimmed small intestine as measured from the ceco-colic junction and progressing proximally towards the jejunum or by a procedure that the establishment demonstrates is effective in ensuring complete removal of the distal ileum.

Part 318 – Entry Into Official Establishment; Reinspection and Preparation of Products

3. The authority citation for part 318 continues to read as follows:

Authority: 7 U.S.C. 38F, 450, 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

4. Section 318.6 is amended to revise paragraphs (b)(1) and (b)(8) to read as follows:

§318.6 Requirements concerning ingredients and other articles used in preparation of products.

(b)(1) The only animal casings that may be used as containers of product are those from sheep, swine, or goats. Casings from cattle may be used as containers of products. However, if casings from cattle are derived from the small intestine, the small intestine must comply with the requirements in 9 CFR 310.22(a)(3). Establishments that use casings derived from the small intestine of cattle as containers for products must demonstrate, through documentation, that the small intestine from which the casing was derived complies with the requirements in 9 CFR 310.22(a)(3).

(8) Intestines shall not be used as ingredients in any meat food product for which a standard is prescribed in part 319 of this subchapter and shall not be used in other products unless the products are labeled in accordance with §317.8(b)(3) of this subchapter. When small intestine from cattle is used in a meat food product or for edible rendering, it must comply with the requirements in 9 CFR 310.22(a)(3).