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

FSIS DIRECTIVE

9000.2 | 10/27/08

INSPECTION AND EXPORT CERTIFICATION OF LIVESTOCK INTESTINES OR CASINGS

DO NOT IMPLEMENT THIS DIRECTIVE UNTIL NOVEMBER 26, 2008.

I. PURPOSE

This directive instructs inspection program personnel (IPP) how to determine whether intestines or casings from livestock are eligible to receive the mark of inspection and how to certify intestines or casings for export.

Key Points Covered

- explains how to determine whether intestines or casings are eligible to receive the mark of inspection;

- instructs IPP on what is required to certify intestines or casings for export;

- instructs IPP on what is required to certify imported intestines or casings for export;

- provides November 26, 2008, as the implementation date for the instructions provided in this directive; and

- contains Questions and Answers for The Inspection and Export Certification of Livestock Intestines (Attachment 1). The Food Safety and Inspection Service (FSIS) may post additional Questions and Answers on askFSIS.

II. CANCELLATIONS

FSIS Notice 11-07, Continuation of Interim Period for Voluntary Inspection and Certification of Natural Casings, dated 2/15/07

III. [RESERVED]

IV. REFERENCES

9 CFR 310.22
9 CFR Parts 96.3, 322, and 350
FSIS Directive 6100.4, "Verification Instructions Related to Specified Risk Materials"
FSIS Directive 6420.2, "Verification of Procedures for Controlling Fecal Material, Ingesta and Milk in Slaughter Operations"
FSIS Directive 9000.1, "Export Certification"
FSIS Directive 12,600.1, "Voluntary Reimbursable Inspection Services"

V. BACKGROUND

Since June 2006, FSIS has issued a series of notices designed to bring the inspection and certification services that FSIS performs on a fee-for-service basis under 9 CFR Part 350, Special Services Relating to Meat and Other Products, in line with other inspection activities that the Agency performs, particularly those that may result in the application of the mark of inspection.

Products labeled as "(species) intestines" are meat byproducts derived from the intestines of livestock and, as such, are under FSIS jurisdiction. Therefore, products labeled "(species) intestines" are required to be produced under inspection and are eligible to bear the mark of inspection.

Products labeled as "(species) casings" are derived from the intestines of livestock and are used as containers to prepare sausage and other meat food products. Casings are under the jurisdiction of the Food and Drug Administration (FDA) and normally do not bear the mark of inspection. A non-FSIS inspected facility (a casing manufacturer) may request voluntary reimbursable service under 9 CFR 350.3 to prepare casings under FSIS inspection, thus making them eligible to bear the mark of inspection.

NOTE: Beef distal ileum is a specified risk material (SRM) in all ages of cattle and must be disposed according to 9 CFR 310.22(a)(2) and 310.22(c) prior to leaving inspection oversight at the slaughter establishment.

VI. INSPECTION PROGRAM PERSONNEL VERIFICATION ACTIVITIES AT OFFICIAL ESTABLISHMENTS PREPARING INTESTINES OR CASINGS

A. Intestines or casings prepared at official establishments are eligible to bear the mark of inspection and can be certified for export, provided, they are produced under sanitary conditions resulting in clean, wholesome, not adulterated, and properly labeled product.

B. IPP are to consider the intestines or casings clean when they are visibly free of digestive tract contents. Intestines or casings are not subject to a zero tolerance standard for ingesta and fecal material. The zero tolerance standard applies to livestock carcasses and parts only (FSIS Directive 6420.2).

C. IPP are to verify that the intestines or casings are suitable for the intended use of the product. To receive the mark of inspection, the intestines or casings must be in an appropriate condition and suitable for use as an edible product.

D. Intestines or casings prepared at an official establishment are not required to bear the mark of inspection. When requested by establishments, IPP are to allow official establishments to prepare and ship intestines or casings that do not bear the mark of inspection and without denaturing the intestines, provided the process does not cause adulteration of edible product or produce unsanitary conditions, and the product is suitable for its intended purpose. After removal of the distal ileum from bovine intestines, the remaining intestines may leave the establishment undenatured as inspected or uninspected product.

VII. EXPORT CERTIFICATION OF INTESTINES OR CASINGS AT AN OFFICIAL ESTABLISHMENT

A. When requested, at an official establishment, IPP are to certify intestines or casings for export (see FSIS Directive 9000.1, Revision 1, "Export Certification") as a **non-reimbursable service** in accordance with 9 CFR Part 322.

B. IPP are to provide the certification service and permit the application of approved labels bearing the mark of inspection to intestines or casings prepared from livestock slaughtered, inspected, and passed at that establishment or at another official establishment.

C. When an importing country requires certification of requirements not imposed by FSIS meat and poultry regulations, IPP are to certify intestines and casings for export (when requested) as a **reimbursable service** in accordance with 9 CFR 350.3(b).

VIII. EXPORT CERTIFICATION OF CASINGS AT A CASINGS FACILITY

A. When requested, IPP are to certify casings for export (see FSIS Directive 9000.1, Revision 1, "Export Certification") as a **reimbursable service** in accordance with 9 CFR 350.3.

B. If a casings facility requests FSIS certification service for domestic casings not bearing the mark of inspection, IPP are to sign the Export Certificate, FSIS Form 9060-7 (08/13/2008), "Animal Casings Export Certificate for Countries Requiring Ante-Mortem, Post-Mortem, and Fit for Human Food Statements, "provided IPP are able to certify that all the statements in the certification, including the following statement, are factual based on the documentation accompanying the shipment:

> *I certify that the animal casings specified hereon were derived from animals which received USDA ante-mortem and post-mortem veterinary inspection at the time of slaughter, and that the casings are sound, healthful, wholesome, and otherwise fit for human food. While in establishments subject to USDA inspection, said casings have been handled in a sanitary manner and were not subject to contagion prior to exportation.*

Such casings are not eligible for the mark of inspection. The documentation is to substantiate that the intestines were harvested under sanitary conditions from livestock that passed ante-mortem and post-mortem inspection in the United States (U.S.) and meet the requirements listed in the Export Library for the importing country. Export requirements for destination countries can be found at

http://www.fsis.usda.gov/regulations_&_policies/Export_Information/index.asp.

C. FSIS Form 9060-7 is used for the export of casings derived from livestock slaughtered under inspection in the U.S., regardless of where the casings were further processed. IPP can sign FSIS Form 9060-7 even when the casings do not bear the mark of inspection or were processed outside of the U.S., provided they are presented with evidence that the animals were slaughtered under inspection in the U.S.

NOTE: Casings processed outside of the U.S. must be accompanied by the documentation described in IX.C below.

D. When requested by a casings facility, the application of the mark of inspection will be granted as a reimbursable service, provided the casings were derived from intestines that received the mark of inspection. The casings must not have been processed outside the U.S. Casings processed outside the U.S. are not eligible for the mark of inspection.

IX. EXPORT CERTIFICATION OF IMPORTED CASINGS

Imported casings are regulated by FDA. Therefore, FSIS IPP do not inspect imported casings or permit the application of the USDA mark of inspection to them. However, IPP can certify imported casings for export.

A. When requested, IPP are to certify imported casings for export (see FSIS Directive 9000.1, Revision 1, "Export Certification") as a reimbursable service in accordance with 9 CFR 350.3.

B. IPP are to provide export certification to imported casings, provided that the casings in the shipment presented are clean and sound, and the livestock from which the casings were derived were slaughtered in a country that has an equivalent inspection system to that of the U.S. for that species. Information regarding countries and establishments eligible to provide products for importation into the U.S. can be found at:
http://www.fsis.usda.gov/regulations_&_policies/Eligible_Foreign_Establishments/index.asp,

C. IPP need to also verify that:

1. The imported casings must be accompanied by a certificate signed by a government official of the exporting country stating:

> *I hereby certify that the animal casings herein described were derived from healthy animals (cattle, sheep, swine, or goats), which received ante-mortem and post-mortem veterinary inspection at the time of slaughter, are clean and sound, and were prepared and handled only in a sanitary manner and were not subjected to contagion prior to exportation.*

2. There is documentation from an official of the exporting country stating that the casings have not been commingled with casings from other sources, and documentation showing that the casings were released by U.S. Customs and Border Protection.

NOTE: The Animal and Plant Health Inspection Service requires this certificate in accordance with 9 CFR 96.3.

D. IPP are to ensure that the country to which the casings are to be exported does not restrict the importation of casings (i.e., the Export Library does not state "only casings originating from the U.S. are eligible," or similar wording).

E. If requested by an exporter, IPP are to sign FSIS Form 9060-18 (08/13/2008), "Animal Casings Export Certificate for Countries Requiring Ante-mortem, Post-mortem, and Sound and Clean Statement," if, based on all of the documentation accompanying the shipment, they are able to make the following statement,

> *I certify that the animal casings specified hereon were accompanied by documentation showing they were derived from healthy animals which received ante-mortem and post-mortem veterinary inspection at the time of slaughter, and are clean and sound. While in establishments subject to USDA inspection, said casings have been handled in a sanitary manner and were not subject to contagion prior to exportation.*

NOTE: The only imported casings eligible for FSIS certification are ones derived from livestock slaughtered under an inspection system equivalent to the U.S. Facilities may re-pack and re-label imported casings (without the USDA mark of inspection) under voluntary inspection, and FSIS Form 9060-18 may be used for the export of the casings, regardless of where the casings were further processed. FSIS Form 9060-18 can be issued only if all of the casings in a shipment presented for export certification are accounted for in the facility's documentation and meet the conditions described above.

Contact the Policy Development Division at 1-800-233-3935 and follow the auto-attendant menu prompts for questions regarding export of casings. Alternatively, submit technical questions through askFSIS

Assistant Administrator
Office of Policy and Program Development

Attachment

QUESTIONS AND ANSWERS FOR THE INSPECTION AND EXPORT CERTIFICATION OF LIVESTOCK INTESTINES

Q1. The directive states that intestines or casings should be considered clean when they are "visibly free of digestive tract contents", but that some small amount of digestive tract material may still adhere to the intestine or casing. How will inspection program personnel (IPP) be able to determine whether the intestines or casings are clean?

A1. IPP are to verify that the establishment demonstrates good process control in cleaning intestines and makes reasonable efforts to remove contamination during cleaning and other processing of the product. No significant amount of fecal material or other contamination should remain on or in the intestine, although some small amount of digestive tract material may adhere to the intestine (mainly the intestinal mucosal lining) even after a reasonable effort to clean it has been made. The presence of such material should not cause IPP to withhold the mark of inspection. IPP are to make their determinations of the acceptability of product to bear the mark of inspection based on production lots and process controls rather than on individual units of product.

Q2. Does the mucosa (on the inner surface of the intestine) need to be stripped away for the intestine to be "visibly free of digestive tract contents?"

A2. No. The establishment does not have to strip the mucosa from the intestines for them to be given the mark of inspection.

Q3. Are intestines that are intended to be processed into casings required to bear the inspection legend prior to leaving an official establishment?

A3. No. Establishments may prepare and ship in commerce intestines without the mark of inspection.

Q4. Are livestock casings used in preparing meat or poultry food products in federally-inspected establishments required to bear the USDA mark of inspection?

A4. No. The directive does not change any policy regarding the use of casings when preparing other inspected products. Casings used to make meat or poultry food products in federally-inspected establishments are not required to bear the USDA mark of inspection because livestock casings are regulated by FDA as containers. Casings used in preparing meat and poultry in federally-inspected establishments must comply with 9 CFR 318.6 (b) (1), (2), and (3).

Q5. Does the directive apply to any portion of the livestock digestive tract used to produce casings?

A5. Yes. The directive applies to any part of the digestive tract of livestock, including stomachs (maws), small intestines (rounds), anterior and distal ceacum (bung/cap),

large intestine (middles), rectum (bung/straight casing), or bladder, provided they meet the conditions set forth in this directive.

Q6. Are non-official establishments able to process intestines (for preparation into casings) and casings for export as an FDA product?

A6. Yes, as FDA products.

Q7. If a casings processing firm leases a non-inspected room in a federally-inspected establishment, could it process the intestines produced in that establishment, or another federally-inspected establishment, into casings for export certification under voluntary reimbursable inspection in that room?

A7. Yes. The firm may request voluntary reimbursable service to provide inspection for casings processing under 9 CFR 350.3, in order to apply the USDA mark of inspection to the casings. As mentioned above, FDA regulates casings. Therefore, when firms request the USDA mark of inspection for export certification of casings, the inspection of the processing and preparation is a reimbursable service under 9 CFR Part 350. The firm requesting this voluntary reimbursable service must apply to the District Manager (DM) using FSIS Form 5200-6, "Application Approval for Voluntary Reimbursable Inspection Service," (see FSIS Directive 12,600.1, Revision 1, "Voluntary Reimbursable Inspection Services.") The DM may assign a separate number for the voluntary service, or the firm may use the same number as the establishment in which it operates.

Q8. If a U.S. slaughter establishment harvests intestines from livestock that have passed ante-mortem and post-mortem inspection at the establishment, can the establishment ship the partially-cleaned intestines, without the mark of inspection, to a second establishment for further processing into casings that will be certified later for export?

A8. Yes. A slaughter establishment can harvest intestines from livestock that have passed ante-mortem and post-mortem inspection and ship those intestines only partially cleaned to another facility or establishment for further preparation into casings. Copies of the records are to accompany the shipment of the product in order to maintain its identity. Establishments may use company seals or have the product move under FSIS control (e.g., USDA seal, accompanied by FSIS Form 7350-1, "Request and Notice of Shipment of Sealed Meat/Poultry") while it is in transit. Labels for these intestines should bear a statement of limited use designating what is being done to them and their destination for further processing.

Q9. Can the distal ileum of a beef intestine be removed at another establishment when the intestine is further cleaned?

A9. No. As provided in 9 CFR 310.22(c), SRMs must be removed and disposed of under inspection oversight at the slaughter establishment.

Q10. Who is responsible for costs involved in export certification of casings and intestines?

A10. The firm requesting the export certification is responsible for the expenses

associated with export certification.

Q11. Are HACCP plans required for preparing casings as food articles under 9 CFR Part 350?

A11. No. Preparing casings under Part 350 is a voluntary reimbursable service, which does not require a HACCP plan. IPP are responsible for verifying that the product produced is not adulterated, and that the facilities meet the sanitary performance standards outlined in 9 CFR 416.1-6. For additional information on voluntary reimbursable services, see FSIS Directive 12,600.1, Revision 1. In contrast, intestines labeled as "(species) intestines" are meat byproducts. Therefore, if an establishment prepares and labels "(species) intestines," that process needs to be considered in the establishment's hazard analysis, and any hazards reasonably likely to occur are to be addressed in its HACCP plan.

Q12. Do labels for "(species) casings" prepared under voluntary reimbursable service (9 CFR Part 350) and intended for export need to be approved by FSIS, i.e., the Labeling and Program Delivery Division (LPDD)?

A12. Yes. Companies need to submit labels for "(species) casings" prepared under 9 CFR Part 350 for export to LPDD for approval. Deviations from domestic labeling rules are permitted in accordance with 9 CFR 317.7. The label application should contain documentation that supports the receiving country's acceptance of the deviation. However, labeling for casings that do not bear the mark of inspection or statements of limited use is not required to be submitted to the LPDD for approval.