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

# **FSIS DIRECTIVE**

9510.1 Revision <u>4</u>

12/18/20

# IMPORTATION OF UNDENATURED INEDIBLE MEAT, FAT, RENDERED FAT, POULTRY, AND EGG PRODUCTS

# DO NOT IMPLEMENT THIS NOTICE UNTIL DECEMBER 28, 2020.

#### I. PURPOSE

This directive provides instructions to the Recall Management and Technical Analysis Division (RMTAD) of the Office of Field Operations (OFO) and the Compliance and Investigations Division (CID) of the Office of Investigation, Enforcement and Audit (OIEA) on actions to take when verifying that the requirements for imported undenatured inedible meat (which includes Siluriformes fish) and egg products are met. This directive also provides limited instructions to the Office of Policy and Program Development (OPPD) and the Office of International Coordination (OIC). At this time, inedible poultry cannot be imported unless it is denatured regardless of the intended use (9 CFR 381.193). FSIS is reissuing this directive to update regulatory cites for egg products contained in the final rule Egg Products Inspection Regulations (85 FR 68640).

#### **KEY POINTS:**

- How to review and verify the documentation and labeling required for imported undenatured inedible products
- How to verify that shipments of imported undenatured inedible products move from the United States (U.S.) port of entry to the final destination as stated on the shipment documentation

#### II. CANCELLATION

FSIS Directive 9510.1, Revision 1 Importation of Inedible Meat, Poultry and Egg Products, 12/30/19

#### III. BACKGROUND

- A. The Federal Meat Inspection Act (FMIA) (21 U.S.C. 641) states that carcasses or parts of carcasses produced from amenable species that are not intended for human food cannot be offered for sale or transported in commerce unless they are naturally inedible for humans, are denatured, or otherwise identified as required by regulation to deter their use for human food.
- B. FSIS provides for the segregation, handling, and transportation of undenatured inedible livestock products, including fat and rendered fat, that have the physical characteristics of a product fit for human food from official establishments in the U.S. under certain very limited conditions (9 CFR 325.11). FSIS also requires that undenatured inedible Siluriformes fish products must be transported according to 9 CFR 325.11(e) (9 CFR 555.5).

- C. Inedible grease, tallow, or other inedible rendered fat shall not be imported into the U.S. unless it has first been denatured as prescribed in <u>9 CFR 327.25</u>, and marked as prescribed in <u>9 CFR 316.15</u>, or it is identified and handled as prescribed by §325.11 (b) or (c) and (9 CFR 327.20).
- D. Given the treatment of domestic meat products under the FMIA, FSIS will allow undenatured inedible livestock and Siluriformes fish products to be imported into the U.S. provided that the products are labeled, packed, and handled in accordance with the requirements in <u>9 CFR 325.11 (e)</u>,
- E. Section 10 of the Egg Products Inspection Act (21 U.S.C. 1039) prohibits the transporting of inedible eggs in commerce unless they are denatured or otherwise identified as required by the regulations of the Secretary of Agriculture, which may be found in 9 CFR 590.45. 9 CFR 590.45(d) provides that the central competent authority (CCA) of a foreign government may petition FSIS for approval to import undenatured inedible egg products into the U.S. for industrial use or animal food requirements.
- F. FSIS is responsible for verifying that undenatured inedible fat, rendered fat, meat, and egg products that have the appearance of being fit for human consumption, but are intended for the manufacture of articles not for human food, meet the requirements in <u>9 CFR 325.11</u>, <u>9 CFR 327.20</u>, and <u>9 CFR 590.45(d)</u>, respectively. These products must originate from foreign countries eligible to export fat, rendered fat, meat, or egg products to the U.S. Such imported materials must be denatured before movement in U.S. commerce to a manufacturer of articles not for human food unless the materials are covered by a numbered permit and comply with the conditions for exception in 9 CFR 325.11 for inedible fat, rendered fat, and meat, or with conditions for exception in 9 CFR 590.45(d) for inedible egg products.
- G. The Animal and Plant Health Inspection Service (APHIS) restricts certain products from entering the U.S. because of animal health disease conditions in the country of origin. Importers of undenatured inedible products are required to contact APHIS to verify that the product is eligible to enter the U.S. given any animal health disease restriction for the country of origin under 9 CFR parts\_93 and 94.
- H. Shipments of imported undenatured inedible product are not required to be presented to FSIS at an official import inspection establishment and are not subject to reinspection by OFO. With that said, any undenatured inedible fat, rendered fat, meat, or egg products found in commerce are subject to OIEA surveillance.

# IV. APPLICATION AND REVIEW PROCESS FOR OBTAINING A PERMIT NUMBER

- A. RMTAD is responsible for deciding whether to issue a numbered permit to an applicant requesting to import an undenatured inedible product.
- B. RMTAD is to verify that any application for an undenatured inedible numbered permit for imported product provides the following information:
  - Applicant name;
  - 2. Applicant address;
  - 3. Applicant telephone number;
  - 4. Applicant facsimile number;

- 5. Applicant e-mail address;
- 6. Description of the type of business operations; and
- 7. Purpose of completing an application requesting a numbered permit.
- C. RMTAD personnel are to:
  - 1. Review each application requesting a numbered permit for completeness; and
  - 2. Assess the non-compliance history of the permit requestor in FSIS databases (e.g., In-Commerce System (ICS)). RMTAD personnel are to contact the OIEA, CID Director or designee for assistance in obtaining necessary enforcement history.
- D. The RMTAD Director or designee (hereafter "the RMTAD Director") is to approve any application for a numbered permit that meets the requirements in 9 CFR 325.11(e) (1). The RMTAD Director is to return incomplete applications to the applicant. A unique numbered permit is to be issued for each approved application. A list of active permit holders is available on the OFO International SharePoint site.

**NOTE:** Although <u>9 CFR 325.11(b)(1)</u> for undenatured inedible rendered animal fats does not list the same requirements as <u>9 CFR 325.11(e)(1)</u>, permits to ship undenatured inedible rendered fats must include the same information.

- E. The RMTAD Director is to notify the permit holder in writing that the numbered permit issued by FSIS is active for three years from the date of issuing the number, unless the permit is suspended or canceled because of a documented violation of the conditions of the permit or the conditions for entry of inedible undenatured product into the U.S. Additionally, the RMTAD Director is to notify the permit holder that:
  - 1. It is the responsibility of the permit holder to renew, update, or request an amendment to the information in his or her application for the numbered permit before it expires;
  - 2. It is the responsibility of the permit holder to notify RMTAD if the company name changes or if the company is sold. The company may then request to use the same permit number, and if FSIS does not agree to this, the company must apply for a new permit number;
  - 3. Numbered permits that are not renewed are considered expired and are no longer valid; and
  - 4. It is the responsibility of the permit holder to submit the completed FSIS Form 9540-4, *Shipper Notification Importation of Undenatured Inedible Product*, in advance of each shipment of undenatured inedible product to the U.S. to RMTAD at: <a href="mailto:ImportInspection@usda.gov">ImportInspection@usda.gov</a>.
- F. Per <u>9 CFR 590.45(d)</u>, when the CCA of the foreign government petitions FSIS for approval to import undenatured inedible egg products into the U.S. for industrial use or animal food:
  - 1. OIC is to forward the petition to OPPD; OPPD will review the request; and
  - 2. OPPD is to prepare notification to the CCA, RMTAD, and CID if the foreign country's petition is approved. If the petition is approved, RMTAD is responsible for processing individual applications in accordance with Section IV. A-E of this directive.

#### V. FSIS FORM 9540-4 PROCEDURES

- A. RMTAD personnel are to receive the FSIS Form 9540-4 and review the form for completeness. When reviewing the FSIS Form 9540-4, RMTAD is to identify any:
  - 1. Incomplete or missing information (e.g., data fields on form not filled out);
  - 2. Inaccurate information (e.g., information that does not match the database for that shipper, questionable data):
  - 3. Ineligible product (e.g., originating from a country not eligible to ship meat or egg products);
  - 4. Shippers that do not have the required permit approval, which can be determined by checking the list of permit holders as per Section IV. D of this directive; or
  - 5. Consignee that <u>is not</u> a pet food manufacturer or manufacturer of articles other than human food (e.g., consigned to a manufacturer in the U.S. of articles other than human food and if the product is for use solely by the consignee for manufacturing articles not for human food).
- B. When RMTAD personnel determine that the FSIS Form 9540-4 is complete and accurate, RMTAD will post the FSIS Form 9540-4 to the OFO International SharePoint site for access by OIEA, CID investigators. If the FSIS form 9540-4 is incomplete or inaccurate, RMTAD personnel are to return the application to the permit requester or holder for correction and resubmission. If RMTAD identifies any information on the FSIS Form 9540-4 that relates to compliance issues/activities, RMTAD is to contact the OIEA, CID Regional Office with those concerns.
- C. RMTAD is to maintain shipment documentation and the FSIS 9540-4 Form for each shipment of undenatured inedible meat, fat, and egg product on the OFO International SharePoint site.

## VI. VERIFICATION PROCEDURES FOR ENTRY INTO THE U.S.

- A. CID investigators, when conducting in-commerce surveillance activities either at the port of entry or at destination, are to randomly verify that the paperwork, seals, and labels on designated shipments of undenatured, inedible meat, fat, or egg product are in compliance with the regulations (9 CFR 325.11(b) and (e), 9 CFR 327.20, 9 CFR 590.45(d)), or 9 CFR 590.935(b) and the procedures referenced in Section VI. D. of this directive.
- B. An OIEA CID investigator may also target shipments of undenatured, inedible meat, fat, and egg product for verification based on:
  - 1. A determination that the permit holder has had previous violations, or the fact that there are trends of non-compliance documented in the ICS (e.g., product mislabeled); or
  - 2. A review of import entry data obtained from the Automated Commercial Environment (ACE) Portal that identifies shipments entering the U.S. without prior notification (e.g., without FSIS form 9540-4).
- C. When conducting a shipment review, the OIEA CID investigator is to verify that undenatured inedible shipments entering the U.S. are accompanied by a completed FSIS Form 9540-4 and labeled sealed, and transported properly as follows:

- 1. The ends of the outside containers of undenatured inedible rendered fat are labeled with the words "technical animal fat not intended for human food" in letters not less than two inches high in the case of containers such as drums, tierces, barrels, and half barrels and not less than four inches high in the case of tank cars and trucks. All shipping containers must have both ends painted with a durable paint, if necessary, to provide a contrasting background for the required marking, as per 9 CFR 325.11(b)(3);
- 2. The outside container (or wrap) of undenatured inedible meat and fat products is labeled with the words "Inedible Not Intended for Human Food" in letters not less than two inches high in the case of containers such as cartons, drums, tierces, barrels, and half barrels and not less than four inches high in the case of tank cars and trucks used to transport such product not in other containers, as per 9 CFR 325.11(e)(3);
- 3. The conveyance (e.g., railroad cars, trucks, or containers) bears an unofficial seal applied by the shipper that identifies the unique inedible permit number as well as an individual seal serial number assigned by the shipper, and the product is accompanied by an invoice or bill of lading specifying the permit holder's permit number as per 9 CFR 325.11(b)(4) and (e)(4);
- 4. All undenatured inedible, unwholesome, or adulterated egg products are identified with the name and address of the processor, as well as the words "Inedible Egg Products-Not to Be Used as Human Food", as per 9 CFR 590.840 and must be shipped under government seal as per 9 CFR 590.935(b); and/or
- 5. Not transported in commerce to a consignee or storage location other than the one listed on the FSIS Form 9540-4 received by FSIS. Diversion to any other consignee or storage location requires that an updated FSIS Form 9540-4 be submitted to RMTAD before the product is moved in commerce.
- D. OIEA CID Investigators are to follow the procedures outlined in <u>FSIS Directive 8010.1</u>, *Methodology for Conducting In-Commerce Surveillance Activities,* for prioritization of surveillance (verification) activities regarding the end-use of the imported undenatured inedible product.

## VII. VIOLATIONS

- A. When a shipment of undenatured inedible meat, fat, or processed egg product does not meet all required conditions, the OIEA CID investigator is to initiate an investigation and control any undenatured inedible product that has been identified. OIEA CID investigators are to:
  - 1. Document any violations in the ICS in accordance with:
    - a. <u>FSIS Directive 8010.1</u>; Methodology for Conducting In-Commerce Surveillance Activities
    - b. FSIS Directive 8410.1, Detentions and Seizures;
    - c. FSIS Directive 8010.2, Investigative Methodology;
    - d. FSIS Directive 8010.3, Procedures for Evidence Collection, Safeguarding and Disposal; and
    - e. FSIS Directive 8010.4, Report of Investigation.

- 2. Request through RMTAD a redelivery with U.S. Customs and Border Protection (CBP) of any shipment identified in violation of FSIS requirements and request that CBP have the product re-exported;
- 3. Conduct follow-up with the permit holder when compliance verification findings identify deficiencies in a shipment's documentation, storage, or usage; and
- 4. Notify RMTAD of any issues that may require follow-up with the CCA in the country of origin.
- B. RMTAD is to notify OIC, and OIC will notify the CCA in the country of origin when violations are identified that implicate a foreign entity as the permit holder. RMTAD is to request, through OIC, that the foreign country conduct follow-up activities and verify that corrective actions have been implemented when a violation is identified regarding a foreign supplier. RMTAD is to inform the CCA, through OIC, if FSIS plans to take action against the foreign permit holder (supplier), including cancellation of a permit number and prohibition from shipping product into the U.S.

## VIII. QUESTIONS

Refer questions regarding this directive to the OPPD IEPDS through <u>askFSIS</u> or by telephone at 202-690-4354.

Assistant Administrator
Office of Policy and Program Development