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

FSIS DIRECTIVE

7020.1

01/26/16

VERIFYING DONATION OF MISBRANDED AND ECONOMICALLY ADULTERATED MEAT AND POULTRY PRODUCTS TO NON-PROFIT ORGANIZATIONS

I. PURPOSE

This directive issues instructions to inspection program personnel (IPP) to verify whether establishments maintain necessary controls and records when donating certain misbranded or economically adulterated meat and poultry products to non-profit organizations. These instructions apply to IPP at official establishments. The Office of Investigation, Enforcement and Audit (OIEA) Investigators are to use the instructions in FSIS Directive 8410.1, Detention and Seizure, to verify that in-commerce facilities maintain necessary controls and records for the donation of certain misbranded or economically adulterated meat or poultry products.

II. BACKGROUND

- A. FSIS is aware that some official establishments are willing to donate economically adulterated or misbranded meat and poultry products to non-profit organizations, but that they have concerns about the time necessary to apply for and receive temporary label approval and about the labor involved in applying a "Not for Sale" statement to each immediate container. The Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) provide that meat and poultry products that are safe, wholesome, and capable of use as human food can be donated to non-profit organizations (e.g., food banks, charitable institutions, child welfare facilities) (see 21 U.S.C. 673(a)(5)(A) and 467b(a)(5)(A)).
- B. An example of wholesome misbranded product that may be donated includes product that is labeled with the incorrect net weight.
- C. An official establishment cannot dispose of adulterated product by donating it to a non-profit organization, except when the product is found to be economically adulterated under section 1(m)(8) of the FMIA or section 4(g)(8) of the PPIA, but otherwise wholesome.
- D. Economically adulterated product is product from which any valuable constituent in whole or in part has been omitted or removed, or in which a less valuable substance has been substituted. Products into which any substance is added or mixed in a way that misrepresents their weight or bulk, or that makes them appear to be of greater value than they actually are, also are considered to be economically adulterated (21 U.S.C. 601(m)(8) and 453 (g)(8)). In most cases of economic adulteration, a substance is added or intentionally substituted for the purpose of increasing the apparent value of the product. For example, a poultry carcass with added water that exceeds the maximum percentage of water that may be retained under 9 CFR Part 441 would be economically adulterated because the added water increases the product's net weight and makes it appear to be of greater value.

DISTRIBUTION: Electronic OPI: OPPD

III. REQUIREMENTS FOR DONATING PRODUCT

A. IPP are to be aware that FSIS will allow products that are found to be misbranded or economically adulterated to be donated by official establishments without those official establishments having to obtain temporary label approval from the FSIS Labeling and Program Delivery Staff (LPDS) (9 CFR 412.1(f)(1)), except when the product is misbranded because it contains unlabeled ingredients of public health concern that are required to be on the ingredients statement. In addition, IPP are to be aware that FSIS will not require the product to be relabeled to include a "Not for Sale" statement on each immediate container.

B. Ingredients of public health concern include the eight most common ("big 8") food allergens. The "big 8" allergens are:

1.	Wheat;
2.	Crustacean shellfish (e.g., shrimp, crab, lobster);
3.	Eggs;
4.	Fish;

- Peanuts;
- 6. Milk;
- 7. Tree nuts (e.g., almonds, pecans, walnuts); and
- 8. Soybeans.

C. Ingredients of public health concern also include ingredients that may cause food intolerance, such as sulfur-based preservatives (sulfites), lactose, Yellow 5 (tartrazine), gluten, and monosodium glutamate (MSG). The adverse reactions to these substances are caused by the ingredient itself or its chemical composition

NOTE: FSIS will <u>not</u> allow misbranded product that contains unlabeled ingredients of public health concern to be donated without temporary label approval and without the "Not for Sale" statement on each immediate container because these unlabeled ingredients are associated with adverse reactions, such as food allergies and intolerances.

- D. IPP are to verify that the bill of lading for the donated product described in paragraph III. A., above, includes the following information:
 - 1. The quantity of the donated product;
 - 2. A description of the donated product;
 - 3. The reason product is diverted for donation (e.g., incorrect net weight); and
 - 4. A statement that the product is "Not for Sale."

NOTE: If the bills of lading do not contain all of this information, the product is not eligible to move in commerce.

- E. Products may be donated to non-profit organizations such as charitable institutions, food banks, and government-supported facilities (e.g., correctional facilities, child welfare facilities, homes for senior populations, institutions for the physically or mentally ill, or similar qualifying institutions) (see 21 U.S.C. 467b (a)(5)(A) and 673(a)(5)(A)).
- F. IPP are to verify that a copy of the bill of lading will accompany the donated product to the non-profit organization.
- G. IPP are to verify that a copy of the bill of lading is maintained by the establishment in accordance with 9 CFR Parts 320 and 381, Subpart Q. Official establishments must make the bills of lading available to IPP for review and copying if necessary (9 CFR 320.4 and 381.178).

IV. VERIFYING COMPLIANCE WHEN A DONATION IS TO BE MADE

- A. When an establishment notifies IPP that it intends to donate misbranded or economically adulterated product to a non-profit organization, IPP are to perform a directed Other Inspection Requirements task in PHIS.
- B. IPP are to review the bills of lading that have been prepared for the shipment of the product intended for donation and verify that they include the information listed in Section III., D of this notice.
- C. IPP are to reinspect the product before shipment to verify that the product is not adulterated (other than economically adulterated), and that all ingredients of public health concern are listed on the label.
- D. IPP are to document in PHIS that the establishment complied with 9 CFR 320.1(b) or 381.175(b)(1), if:
 - 1. The establishment properly documented the donated product in the bills of lading.
 - 2. The product is not adulterated, and
 - 3. All ingredients of public health concern are listed on the label.
- E. If the information listed in Section III., D. is not included on bills of lading, IPP are not to permit the shipment of misbranded or economically adulterated product to a non-profit organization.
- F. If IPP determine that the product intended for donation is adulterated or misbranded because it contains unlabeled ingredients of public health concern that are required to be listed on the ingredients statement, they are to place the product under retention, perform the appropriate HACCP verification task for the product category in PHIS, and document the noncompliance.

V. QUESTIONS

Refer questions regarding this notice through <u>askFSIS</u>. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter Directive 7020.1

Question Field: Enter your question with as much detail as possible.

Product Field: Select General Inspection Policy from the drop-down menu.

Category Field: Select **Regulations/Agency Issuances** from the drop-down menu.

Policy Arena: Select **Domestic (U.S.) Only** or **International (Import/Export)** from the drop-down

menu.

When all fields are complete, press Continue and at the next screen press Finish Submitting Question.

NOTE: Refer to FSIS Directive 5620.1, Using askFSIS, for additional information on submitting questions.

Assistant Administrator

Office of Policy and Program Development