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

FSIS DIRECTIVE

8140.1
Rev. 1

7/3/17

NOTICE OF RECEIPT OF ADULTERATED OR MISBRANDED PRODUCT

DO NOT IMPLEMENT THIS DIRECTIVE UNTIL AUGUST 3, 2017

I. PURPOSE

This directive instructs inspection program personnel (IPP) when to complete and submit FSIS Form 8140-1, *Notice of Receipt of Adulterated or Misbranded Product*. FSIS is reissuing this directive to update IPP instructions consistent with the requirements of 9 CFR 418.2; replace obsolete inspection system references; and update the distribution instructions to align with current FSIS organizational structure. FSIS is also revising the form to allow electronic completion and distribution to the District Office (DO).

KEY POINTS

- *Instructs IPP on the completion and distribution of FSIS Form 8140-1*
- *Explains notification requirements in 9 CFR 418.2 and when FSIS Form 8140-1 is used in lieu of DO notification*
- *Updates instructions consistent with the current Public Health Information System (PHIS) inspection methodology*

II. BACKGROUND

A. Each inspected establishment is required to produce safe, wholesome, unadulterated, and properly labeled product. When official meat and poultry establishments learn or determine that an adulterated or misbranded product was received or originated from the official establishment, they are required to notify FSIS DO personnel within 24 hours (9 CFR 418.2).

B. Under 9 CFR 418.2, both the receiving and producing establishments are required to report adulterated or misbranded product in commerce. However, when establishments notify IPP in the establishments that receive adulterated or misbranded product, and FSIS completes and distributes FSIS Form 8140-1, the establishment is not required to notify the DO. In this situation, the establishment may either notify the DO or IPP, but is not required to notify both.

C. Product that has been contaminated (e.g., with foreign material) and shipped in commerce or between official establishments meets the regulatory definition of "*adulterated*" in 9 CFR 301.2 and is subject to the procedures outlined in this directive.

III. CANCELLATION

FSIS Directive 8140.1, *Preparation and Submission of FSIS Form 8140-1*, 6/12/95

IV. FSIS RESPONSIBILITIES

A. When an official meat or poultry establishment receives adulterated or misbranded product intended for further processing, IPP are to use FSIS Form 8140-1 to notify IPP at the producing establishment and the applicable District Offices. IPP are NOT to use FSIS Form 8140-1 if:

1. The establishment receiving the adulterated or misbranded product elects to notify the DO directly as required in 9 CFR 418.2;

2. The establishment receives adulterated or misbranded product for further processing under USDA seal and accompanied by FSIS Form 7350-1, *Request and Notice of Shipment of Sealed Meat/Poultry;* or

3. The establishment receives adulterated or misbranded product under other control measures with the intent to treat the product to make it not adulterated or misbranded (e.g., *E. coli* O157:H7 positive product received for cooking under appropriate controls).

B. When IPP become aware that an official meat or poultry establishment receives adulterated or misbranded meat or poultry products for further processing without appropriate controls, IPP are to:

Complete FSIS Form 8140-1 as soon as the establishment provides all applicable information. IPP can locate the form in the "Find a Form" section of InsideFSIS. Users need an E-Authentication account to access this form.

V. PROCEDURES FOR COMPLETING FSIS FORM 8140-1 AT THE RECEIVING ESTABLISHMENT

A. When IPP are notified by an official establishment that adulterated or misbranded meat or poultry products have been received for further processing, IPP are to:

1. Complete Section A (blocks 1-8) on FSIS Form 8140-1 using establishment records such as sales invoices and bills of lading; if the product is imported, use the appropriate blocks in Section A to record the information marked on the containers, such as shipping marks, originating country, import inspection station;

2. Describe in block 9 the observations that support a finding of adulteration or misbranding of the product (e.g., the type of adulteration or misbranding, foreign material such as metal fragments, plastic, rubber, and relevant documentation such as laboratory results);

3. Describe in block 10 the establishment disposition of the product, including whether all or part of the product has been condemned, on hold, reconditioned, or returned to the supplying establishment. If the establishment has not determined how to dispose of the product, IPP are to document the location and control of the affected product (i.e., on QA hold or USDA retain tag number) and update and resubmit the form once the establishment makes a final determination on how to dispose of the product;

4. State in block 11, the likely cause for the adulteration or misbranding (e.g., product mishandling by the carrier, non-official establishment or facility, or producing establishment) as determined by the receiving establishment. If the investigation is ongoing, IPP are to document the preliminary cause for the adulteration or misbranding and update the form once a final determination is made;

NOTE: Non-official establishments or facilities include Identification (ID) warehouses, private uninspected warehouses, and distribution centers.

5. Sign the form. FSIS Form 8140-1 may be digitally signed by FSIS personnel using a Lincpass by clicking within the signature box (block 12); and

6. E-mail FSIS Form 8140-1 to the DO and Frontline Supervisor (FLS).

B. When products are produced under the Cooperative Interstate Shipment program, state inspection personnel are to include the Office of Field Operations Select Establishment Coordinator (OFO SEC) and appropriate DO, as well as the State Meat and Poultry Inspection program Director, in the electronic distribution of FSIS Form 8140-1.

C. When FSIS Form 8140-1 is received at the DO, the DO will:

1. Forward the form to the DO of the producing establishment. The DO of the producing establishment will then forward the form to the Inspector-in-Charge (IIC) at the producing or shipping establishment(s);

2. Forward the form to the appropriate Office of Investigation, Enforcement, and Audit (OIEA) Regional Compliance and Investigations Division Office (CID) with jurisdiction over that facility if the product came from a non-inspected facility or appears to have become adulterated during transportation: and

NOTE: When OIEA CID receives FSIS Form 8140-1, an Investigator will conduct an investigation and make a determination on the case in accordance with the procedures in FSIS Directive 8010.2, *Investigative Methodology*.

3. Notify the Recall Management and Technical Analysis Division (RMTAD), Import Operations branch via importinspection@usda.fsis.gov when the DO is notified of adulterated product that was shipped from a foreign establishment. RMTAD Import Operations branch will work through internal processes to resolve the situation with the appropriate foreign country officials.

VI. PROCEDURES FOR COMPLETING FSIS FORM 8140-1 AT THE SUPPLYING ESTABLISHMENT

A. Upon receiving FSIS Form 8140-1, IPP at the supplying meat or poultry establishment are to:

1. Notify the establishment management and discuss that the establishment produced and shipped adulterated or misbranded product.

NOTE: When FSIS personnel at the supplying establishment receive notification of the product that has been shipped through the DO, the supplying establishment is not required to provide any additional notification under 9 CFR 418.2.

2. Perform the directed HACCP Verification or General Labeling Verification task as set out in FSIS Directive 5000.1, *Verifying and Establishment's Food Safety System* for adulterated products or Directive 7000.1, *Verification of Non-Food Safety Consumer Protection Regulatory Requirements* for misbranded products to verify that the establishment has accounted for all product involved and in situations involving adulterated product has taken the appropriate corrective actions under 9 CFR 417.3.

3. Follow the instructions in Directive 5000.1 and discuss developing trends with their supervisor when IPP identify a trend of multiple instances of adulterated or misbranded product produced and shipped from the establishment. IPP are to consider that the establishment may not be able to support the decisions in the hazard analysis.

4. Verify the establishment conducts a reassessment if the establishment produced product adulterated with a hazard not addressed in its HACCP plan (9 CFR 417.3(b)(4)) and verify that the establishment can support the decision made as a result of the reassessment. If IPP have questions or concerns about this support they are to contact their supervisor.

5. Document any observed regulatory noncompliance in accordance with FSIS Directive 5000.1 or Directive 7000.1.

6. Describe establishment management's corrective actions in Section B of FSIS Form 8140-1 and provide a copy to the DO, the establishment, and maintain a copy in the inspection files. If an NR is issued by IPP at the supplying establishment and an NR response is provided by establishment management, the NR response may be attached to FSIS Form 8140-1 instead of completing Section B. If the NR response is provided in PHIS then IPP are to note the PHIS NR number in Section B.

7. Contact the DO when an official establishment notifies IPP that adulterated or misbranded product has entered commerce beyond the product identified on FSIS Form 8140-1. The DO may implement recall procedures as outlined in FSIS Directive 8080.1, *Recall of Meat and Poultry Products*.

NOTE: Repetitive instances of an establishment producing adulterated or misbranded product will be justification for considering further enforcement action in accordance with 9 CFR Part 500, *Rules of Practice*. When determining enforcement actions, each receipt of FSIS Form 8140-1 should be evaluated on a case-by-case basis to determine the cause and nature of the deficiency.

VII. QUESTIONS

Refer questions regarding this directive to the Policy Development Staff through askFSIS or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field:	Enter **Directive 8140.1**
Question Field:	Enter 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)"** 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
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