| MSA DIRECTIVE | 8140.1 Rev. 2 | 6/1/2021 |
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# NOTICE OF RECEIPT OF ADULTERATED OR MISBRANDED PRODUCT

## I. PURPOSE

This directive instructs inspection program personnel (IPP) when to complete and submit MSA Form MI-89, *Notice of Receipt of Adulterated or Misbranded Product*.

*KEY POINTS*

- *Instructs IPP on the completion and distribution of MSA Form MI-89*
- *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. Whenever an establishment has produced adulterated or misbranded meat or poultry product, that production may indicate problems with the Hazard Analysis and Critical Control Point (HACCP) system or other establishment control programs. 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 the office 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 within 24 hours. FSIS considers products to have entered commerce when they have left the direct control of the producing establishment and are in distribution. When establishments notify IPP in the establishments that receive adulterated or misbranded product, and IPP completes and distributes MSA Form MI-89, the establishment is not required to notify the office. In this situation, the establishment may either notify the office or IPP, but is not required to notify both.

C. FSIS has expanded PHIS to include Adulterated Product Monitoring (APM) module, and the revisions in this directive are directly related to the use of this module. Currently, the guidance from FSIS to the States is to not use the APM module. Therefore, the revisions in this version of the directive discussing the use of APM module do not apply to the State MPI Programs and are not included.

D. Products that have been contaminated (e.g., with foreign material) meet the regulatory definition of "adulterated" in 9 CFR 301.2 and 381.1 and, when shipped in commerce or between official

establishments, are subject to the procedures outlined in this directive. Although the regulatory requirement to notify FSIS under 9 CFR 418.2 is limited to products that have entered commerce, the instructions in this directive are broader in scope and include procedures to document the receipt of adulterated or misbranded product by an official establishment, even when such product is shipped under the direct control of the producing establishment or between establishments within the same company.

E. For instructions related to identification and segregation of returned or received adulterated or misbranded products, IPP are to refer to VT Directive 5000.3, *Identification and Segregation of Product*. For additional instructions related to establishment responses to adulterated or misbranded products, IPP are to refer to FSIS Directive 7310.5, *Presence of Foreign Material in Meat or Poultry Products* and VT Directive 5000.1, *Verifying an Establishment's Food Safety System*.

## III. CANCELLATION

FSIS Directive 8140.1, *Revision 1, Notice of Receipt of Adulterated or Misbranded Product, 7/3/17*

## IV. IPP RESPONSIBILITIES

A. When an official meat or poultry establishment receives adulterated or misbranded product intended for further processing, IPP are to use MSA Form MI-89 to notify IPP at the producing establishment and the central office. IPP are NOT to use MSA Form MI-89 if:

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

2. The establishment receives adulterated or misbranded product for further processing under MSA seal; 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. IPP are to schedule an Other Inspection Requirements task to verify whether the establishment met the requirements of 9 CFR 418.2 when they become aware that adulterated or misbranded products have entered commerce. IPP are to document compliance when the official establishment notifies MSA as required by 9 CFR 418.2.

IPP are to document noncompliance, cite 9 CFR 418.2 on the noncompliance record (NR), and describe how their findings support a determination of noncompliance when IPP determine an official establishment did not notify MSA as required by 9 CFR 418.2. IPP are to ask their supervisor if they have questions about documenting 9 CFR 418.2 verification and for assistance to determine if products have entered commerce.

C. 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 MSA Form MI-89 as soon as the establishment provides all applicable information.

D. IPP are to be aware that an establishment is required by 9 CFR 320.6 and 381.180 to provide IPP with the information required to be maintained in 9 CFR 320.1 and 381.175 in order for IPP to complete reports. These regulations require an official establishment to maintain records and provide information to the Agency and apply to products that have not entered commerce (e.g., under the direct control of the producing establishment). These requirements are in addition to and separate from the 9 CFR 418.2 requirement to notify the Central Office when adulterated or misbranded products have entered commerce or the 9 CFR 320.7 or 381.181 requirement to provide information when a consignee refuses to accept delivery of allegedly adulterated or misbranded products. IPP are not to require "notification" under 9 CFR 418.2 when the products have not entered commerce but are to gather information by asking questions and reviewing applicable records when they become aware of the adulterated or misbranded products.

## V. PROCEDURES FOR COMPLETING MSA FORM MI-89 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 MSA Form MI-89 using establishment records such as sales invoices and bills of lading;

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 Texas 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.

6. E-mail MSA Form MI-89 to the Central Office and Supervisor.

B. When MSA Form MI-89 is received at the Central Office, the Central Office will:

1. Forward the form to the Inspector-in-Charge (IIC) at the producing or shipping establishment(s);

2. Forward the form to the MSA Compliance and Investigations Manager if the product came from a non-inspected facility or appears to have become adulterated during transportation.

## VI. PROCEDURES FOR COMPLETING MSA FORM MI-89 AT THE SUPPLYING ESTABLISHMENT

A. Upon receiving MSA Form MI-89, 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.

2. Perform the directed HACCP Verification or General Labeling Verification task as set out in MSA Directive 5000.1, *Verifying an Establishment's Food Safety System* for adulterated products 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 MSA Directive 5000.1 or Directive 7000.1.

6. Describe establishment management's corrective actions in Section B of MSA Form MI-89 and provide a copy to the Central Office, 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 MSA Form MI-89 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 Central Office when an official establishment notifies IPP that adulterated or misbranded product has entered commerce beyond the product identified on MSA Form MI-89. The Central Office may implement recall procedures as outlined in MSA 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,* and Title 6 V.S.A Chapter 204. When determining enforcement actions, each receipt of MSA Form MI-89 should be evaluated on a case-by-case basis to determine the cause and nature of the deficiency.

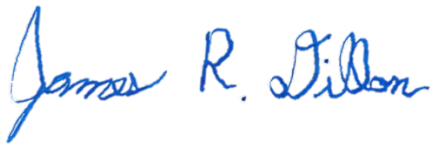
## VII. PROCEDURES FOR MANAGING REPORTS OUTSIDE OF OFFICIAL ESTABLISHMENTS

A. Although the notification requirements in 9 CFR 418.2 only apply to official establishments, there may be scenarios when facilities other than official establishments voluntarily report adulterated or misbranded products.

B. Supervisors are to ensure that the IIC at the producing establishment is notified that adulterated or misbranded products were produced and shipped from that establishment when they receive notification from outside channels (i.e., other State inspection program officials or FSIS).

## VIII. QUESTIONS

Refer questions through supervisory channels.



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