8140.1
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PREPARATION AND SUBMISSION OF FSIS FORM 8140-1

PREPARATION AND SUBMISSION OF FSIS FORM 8140-1

I. PURPOSE

The purpose of this directive is twofold, as follows:

A. Provides instructions for completing and submitting the revised FSIS Form 8140-1, Notice of Receipt of Adulterated or Misbranded Product.

B. Describes the Agency's policy and procedures to be followed when adulterated or misbranded product arrives at inspected facilities.

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

MPI Regulations, Parts 320.1, 325, 381.175, or 381.190.
FSIS Directive 8830.1, dated 3/1/91.

V. ABBREVIATIONS

FMIA	Federal Meat Inspection Act
IIC	Inspector-In-Charge
IID	Import Inspection Division
OIC	Officer-In-Charge
PEA	Progressive Enforcement Action
PBIS	Performance Based Inspection System
PPIA	Poultry Products Inspection Act

VI. POLICY

A. Establishment management is responsible for producing wholesome, unadulterated, and properly labeled product and for ensuring that transportation vehicles are clean and adequate to maintain product wholesomeness.

B. The Agency will undertake appropriate enforcement actions against operators of inspected or non-inspected facilities which place adulterated or misbranded product into commerce.

C. Repetitive instances of establishment management placing adulterated or misbranded product into commerce will be justification for considering initiation or escalation of Progressive Enforcement Action. 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. FSIS RESPONSIBILITIES AND PROCEDURES

A. Inspection Personnel

1. At the Receiving Establishment:

   a. Upon determination that an adulterated or misbranded product has been received, complete Section A of the FSIS Form 8140-1. (This form is basically self explanatory with the exception of a few areas noted in this directive. See Attachment.)

   b. Complete Blocks 3, 4, 6, and 7 using records such as sales invoices, bills of lading, etc. (For information: a non-inspected facility is defined as a facility that does not have an official establishment number. This can be determined by using the shipping records and the MPI Directory.) (Note: If the product is imported, use the appropriate blocks to record the information marked on the containers, such as shipping marks, originating country, import inspection station, etc.)

   c. Record the establishment number on the product in Block 5; this is the producing establishment.

   d. Record the deficiencies in Block 9.

   e. Briefly describe product disposition in Block 10.

   f. Evaluate available evidence and indicative factors such as torn containers, blood soaked boxes, or similar features consistent with temperature/product abuse or container tampering. Determine the most likely cause of the product adulteration/misbranding; i.e. product mishandling

by the producing establishment, carrier, or non-inspected facility, etc. Record your determination and explain the factors in Block 11.

g. Under PBIS, monitor compliance with inspection requirements using Task 05A01a1/2 of the Inspection System Guide.

h. Distribution of FSIS Form 8140-1.

(1). When the evidence indicates that product adulteration or misbranding was caused by the non-inspected facility listed in Block 4, send the original and Copy 1 to the OIC, Compliance Program, that has jurisdiction over that non-inspected facility. OIC addresses and area of jurisdiction are listed in the MPI Directory under Regulatory Programs, Compliance Field Offices. Send Copy 2 to the IIC of the producing establishment.

(2). When the evidence indicates that product adulteration or misbranding was caused by the producing establishment or carrier, send the original and Copy 1 to the Area Supervisor of the producing establishment. Send Copy 2 to the OIC, Compliance Program, that has jurisdiction over that facility.

(3). When the evidence indicates that product adulteration or misbranding was caused by the producing establishment in a foreign country, send the original and Copies 1 and 2 to Import Inspection Division, Washington, D.C.

(4). Maintain Copy 3 in the inspector files.

2. At the Producing Establishment:

a. Upon receiving the original and Copy 1 of FSIS Form 8140-1, perform the following:

(1). Review the deficiencies reported in Block 9. Discuss those deficiencies with establishment management and request that establishment management respond with actions to prevent the reoccurrence of reported deficiencies. Record establishment management's preventive actions in **Block 13.**

(2). If the carrier is suspected to have caused the product to become adulterated, require establishment management to address corrective and preventive actions. Record actions taken by establishment management in Block 13.

(3). Return the completed original copy of FSIS Form 8140-1 to the Area Supervisor. Keep Copy 1 in the inspector files.

(4). Verify establishment management's corrective and preventive actions using appropriate inspection tasks. If results fail to meet compliance standards initiate appropriate action.

b. Upon receiving Copy 2 of FSIS Form 8140-1, which indicates that product adulteration or misbranding was caused by the non-inspected facility listed in Block 4, perform the following:

(1). Inform establishment management of the deficiencies reported in Block 9. In this case, do not request that establishment management respond with preventive actions.

(2). Document establishment management notification in Block 13 and place Copy 2 in inspector files.

B. Area Supervisor of the Producing Establishment

1. Upon receipt of FSIS Form 8140-1, review the inspector's description of product deficiencies in Block 9.

2. Send the original and Copy 1 of the form to the IIC of the producing establishment listed in Block 5.

3. Instruct the IIC to follow the instructions given in Paragraph VII.A.2. of this directive.

4. Make a facsimile copy of the FSIS Form 8140-1 and place in the Area Office's pending file.

5. Upon return of the original of FSIS Form 8140.1 from the IIC, review IIC's evaluation and establishment management's preventive actions in Block 13. If Agency requirements are not being met, ensure that appropriate action is taken.

6. Place the original of FSIS Form 8140.1 in establishment file. Remove and discard the facsimile copy in the pending file.

C. Compliance Program

1. The OIC, Compliance Program, may initiate enforcement action against any person, firm, or corporation when an investigation results in reason to believe that:

   a. Any person, firm, or corporation has violated one or more provisions of the FMIA or PPIA.

   b. Any person, firm, or corporation has placed, or caused to be placed, adulterated or misbranded carcasses, parts of carcasses, meat, meat food products, poultry, or poultry products into human food channels.

   c. Any person, firm, or corporation is engaged in an activity that lends itself to the placement of adulterated or misbranded carcasses, parts of carcasses, meat, meat food products, poultry, or poultry products into human food channels.

2. The receipt of FSIS Form 8140-1 by the OIC, Compliance Program, does not necessarily result in the issuance a Report of Apparent Violation, FSIS Form 8050-1. The OIC, Compliance Program, has the discretion to use a modified report of investigation, when deemed necessary.

D. Import Inspection Division

1. IID will notify the foreign government of the reported deficiencies and request that they investigate the foreign establishment which was determined to have caused the adulteration or misbranding of product.

2. IID will ask the foreign government to respond with a report as to what actions will be taken to correct and prevent occurrence of the reported discrepancies.

3. IID may take immediate action, as appropriate, to intensify import inspection of subsequent shipments from the foreign establishment determined to have shipped misbranded or adulterated product.

Craig A. Reed
Deputy Administrator

Inspection Operations

Attachment
 (Reference hard copy FSIS Directive 8140.1)
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