

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

FSIS NOTICE

49-20

9/30/20

IMPLEMENTATION OF THE ADULTERATED PRODUCT MONITORING MODULE OF THE PUBLIC HEALTH INFORMATION SYSTEM

I. PURPOSE

This notice provides instructions to District Office (DO) personnel on the use of the Adulterated Product Monitoring (APM) module of the Public Health Information System (PHIS) to document industry notification that an establishment has shipped or received adulterated product that is in commerce ([9 CFR 418.2](#)) and how to enter FSIS Form 8140-1 reports into the APM module when recall analysis is requested. This notice also provides instructions to DO personnel and Office of Investigation, Enforcement, and Audit (OIEA), Compliance and Investigations Division (CID) Region personnel on the use of the APM module to document incidents where Agency personnel determine that adulterated or misbranded products have entered commerce. The regulatory requirements for notification of adulterated or misbranded products are unchanged and in-plant inspection program personnel (IPP) are to continue to follow the instructions in [FSIS Directive 8140.1](#), *Notice of Receipt of Adulterated or Misbranded Product*; however, the logistics of receiving and reporting the notification at the DO level and documenting Agency assessment have been updated and incorporated into this notice.

II. BACKGROUND

A. Each inspected establishment is required to produce safe, wholesome, unadulterated, and properly labeled products. Whenever an establishment has produced adulterated or misbranded product, that production may indicate problems with the Hazard Analysis and Critical Control Point (HACCP) system or other establishment control programs. In order to streamline the reporting process and prevent redundant reporting, FSIS is in the process of consolidating establishment reporting required by 9 CFR 418.2 and internal FSIS communications to report the receipt or shipping of adulterated or misbranded products into one module in PHIS. When fully implemented, the APM will include the following tools for reporting the receipt or shipping of adulterated or misbranded products:

1. Industry Report of Adulteration (IRA)—This tool will be used by DO designees to document industry notification required by 9 CFR 418.2, to record establishment corrective actions, and District assessment. In the future, this tool will also be available to authorized industry users who have a PHIS account to notify the DO that their establishment has shipped or received adulterated or misbranded products that have entered commerce directly into the system.
2. Industry Report of Adulteration-In Plant (IRA-IP)—When active, this tool will be the digital mechanism to complete FSIS Form 8140-1, *Notice of Receipt of Adulterated or Misbranded Product*, and will be used by IPP at receiving establishments to report incidents of receiving adulterated or misbranded product to IPP at producing establishments and to record establishment corrective actions and District assessment. The IRA-IP will be used as an internal notification tool

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NOTICE EXPIRES: 10/11/21

OPI: OPPD

to capture the information about the movement of adulterated or misbranded products even when the adulterated or misbranded products have not entered commerce and the establishment is not required to notify FSIS by 9 CFR 418.2 (e.g., product received from sister establishments).

3. Agency Report of Adulteration (ARA)—This tool will be used by DO and CID Regional Director (RD) designees to document incidents where Agency personnel determine that adulterated or misbranded products have entered commerce and to document the Agency’s assessment of such incidents. DO personnel will also use this tool to identify IRA and IRA-IP cases for further analysis and document the Agency’s assessment.

NOTE: The IRA-IP report type will not be available in the initial APM release. When events documented on FSIS Form 8140-1 require further inquiry and recall analysis, the DO will create an ARA report using the information gathered during completion of the FSIS Form 8140-1 and follow-up activities.

III. IPP RESPONSIBILITIES

In-plant personnel are not to use APM at this time even if it is visible in PHIS under one of their active roles. IPP are to continue to refer to [FSIS Directive 8140.1](#).

IV. DO RESPONSIBILITIES FOR CREATING ARA CASES FROM AN EXISTING FSIS FORM 8140-1

A. The DO designee is to continue to follow [FSIS Directive 8140.1](#) when in-plant personnel complete and submit FSIS Form 8140-1. The DO designee is to:

1. Forward a PDF of FSIS Form 8140-1 to the FSIS personnel assigned to the shipping establishment when both the notifying and shipping establishments are assigned to the same district; or
2. E-mail FSIS Form 8140-1 to the DO assigned to the identified shipping establishment when the notifying and shipping establishment are in different districts.

B. The DO designee in the district assigned to the shipping establishment is to review the information and forward FSIS Form 8140-1 to the applicable Inspector-in-Charge and Frontline Supervisor so IPP can complete Section B as instructed in [FSIS Directive 8140.1](#).

C. The DO designee in the district assigned to the shipping establishment is to review each FSIS Form 8140-1 and identify if the event has already been reported by the shipping establishment and documented by the DO as an IRA. If an IRA already exists, the DO designee is to upload FSIS Form 8140-1 into the IRA case and follow the instructions in Section V. C. below to submit a recommendation. If an IRA does not already exist because the establishment did not notify either DO directly, the DO designee is not to create an IRA and is to continue to follow the instructions in [FSIS Directive 8140.1](#) for managing the form logistics.

D. The DO designee in the district assigned to the shipping establishment is to determine if the case should be referred to the Recall Management and Technical Analysis Division (RMTAD) based on the criteria in [FSIS Directive 8080.1](#), *Recall of Meat and Poultry Products*. If so, the DO designee is to identify the case for further analysis by creating an ARA case and uploading FSIS Form 8140-1 generated by IPP into the ARA case.

NOTE: [9 CFR Part 500.3](#) authorizes FSIS to take a withholding action or impose a suspension without prior notification because the establishment produced and shipped adulterated or misbranded products as described in [FSIS Directive 5100.3](#), *Administrative Enforcement Action Decision-Making and Methodology*.

E. The DO designee is to consider if the case also needs to be referred to OIEA as described in [FSIS Directive 8010.5](#), *Case Referral and Disposition* for criminal or administrative action outside of the PHIS system.

V. DO RESPONSIBILITIES FOR IRA

A. The DO designee is to complete an IRA when the DO is notified by an establishment verbally, by phone, or e-mail that the establishment has received or shipped adulterated or misbranded products that are in commerce. The DO designee is not to create an IRA when:

1. There is an existing IRA in PHIS for the same event or shipment because the other involved establishment notified the DO. For example, the receiving establishment is notifying the DO, but there is an existing IRA for notification from the shipping establishment already entered in the PHIS APM; or
2. There is an existing FSIS Form 8140-1 for the same event or shipment.

B. When an IRA is created, the DO designee is to:

1. Forward the information to the DO assigned to the other involved establishment when the notifying establishment and other involved establishment are in different districts;
2. Notify the other involved establishment that they have been identified as an establishment that shipped or received adulterated or misbranded product, when both establishments are assigned to the same district or when the DO is notified that an establishment in their jurisdiction was identified in an IRA;
3. Gather any necessary information needed and enter it into the existing IRA;
4. Identify if the report should be linked to any other IRA case reports or existing FSIS Form 8140-1; and
5. Determine if the case should be referred to RMTAD for recall analysis based on the criteria in [FSIS Directive 8080.1](#). The DO designee is to identify the case for further analysis after the IRA has been published by creating an ARA case from the associated IRA.

C. The District Manager (DM), or designee, is to complete the “Analysis” tab in the IRA and complete the system-generated ARA case when the DM, or designee, determines that escalation to assessment for a recall should be considered. The DM or designee is to:

1. Select “Recall Analysis Recommended;”
2. Select “Make Recommendation;” and

3. Review and complete the ARA case report created in the APM, including the Initial Assessment on the ARA Assessment tab and send the ARA case number to RMTAD via e-mail to request analysis. The IRA case report is partially locked by the system when the DM or designee indicates further analysis is recommended and only the corrective actions and product disposition fields can be edited. The DM/Deputy District Manager (DDM) and Case Specialist (CS)/Supervisory Enforcement Investigations and Analysis Officer (SEIAO) PHIS roles can unlock a locked IRA case if additional information becomes available after the associated ARA case is created. The DM or designee is to reset the lock on the IRA case after editing.

D. The DM or designee is to complete the “Analysis” tab in the IRA if the DM, or designee, determines analysis for recall should NOT be considered. The DM, or designee, is to:

1. Select “Recall Analysis Not Recommended” and indicate a brief explanation of why no further analysis is required (e.g., “All affected products are under control”); and
2. Select “Make Recommendation.”

VI. CLOSING IRA REPORTS IN THE APM

A. The IRA case report is closed by the APM when the DM or designee indicates no analysis is recommended. No additional action is required.

B. The DM, or designee, is to close the IRA case when further analysis has been recommended and all required information has been entered. The DM, or designee, cannot close the IRA case until all the required fields have been completed, including corrective actions and product disposition. The PHIS APM will allow an IRA to be closed when an associated ARA is open.

C. The DM/DDM and CS/SEIAO PHIS roles can re-open a closed IRA case if additional information becomes available after the case is closed.

VII. DISTRICT (OFO) AND REGIONAL (OIEA) OFFICE RESPONSIBILITIES FOR ARA

A. The DO or RD designee is to create an independent ARA when Agency personnel identify an event of adulteration or misbranding that has not been reported by industry and determine that the adulterated or misbranded products have entered commerce. Independent ARAs are created as new cases and are not an escalation of an existing IRA. Examples of situations where a new ARA is created include, but are not limited to:

1. FSIS IPP at a shipping establishment determine based on observation that the establishment shipped adulterated or misbranded products into commerce, when the establishment did not notify inspection personnel or the DO;
2. Illness outbreaks attributed to a specific establishment and specific product;
3. DO or RD designee assessment and verification that adulterated or misbranded product is in commerce in response to consumer complaints reported to the Agency through the Consumer Complaint Monitoring System (CCMS);

4. DO or RD designee assessment and verification that adulterated or misbranded product is in commerce in response to notifications received by the Agency from public health partners;
5. Failure to Present (FTP) imported product for FSIS reinspection; and
6. CID Investigator findings in commerce that warrant a recall or recall consideration.

B. The DO or RD designee is not to create an independent ARA when there is an existing IRA in PHIS for the same event or shipment because an involved establishment notified the DO.

EXAMPLE: A receiving establishment identifies misbranded product that has entered commerce and notifies the DO directly, a new independent ARA should not be created if an IRA already exists in PHIS for the same shipment (i.e., the DO was already notified by the shipping establishment and previously created an IRA). The ARA would be created as an escalation of the IRA, as described in section V.C. above.

C. When an ARA is created, the DO or RD designee is to:

1. Forward the information to the DO or OIEA Region assigned to the involved establishments or firms when other involved establishments or firms are in different districts;
2. Notify the involved establishments or firms that they have been identified as an establishment or firm that shipped or received adulterated or misbranded product, when both establishments or firms are assigned to the same DO or Region or when the DO or Region is notified that a firm in their jurisdiction was identified in an ARA;
3. Gather any necessary information needed and enter it into the ARA;
4. Identify if the report should be linked to any other ARA or IRA case reports; and
5. Determine if the case should be referred to RMTAD for recall analysis based on the criteria in [FSIS Directive 8080.1](#). The DO or RD designee is to identify the case for further analysis after the ARA has been published.

D. The DO or RD designee is to complete the “Initial Assessment” tab in the ARA when the DM or RD, or designee, determines that assessment for a recall should be considered. The DO or RD designee is to:

1. Select “Further Recall Analysis Recommended;”
2. Select “Make Recommendation;” and
3. Send the ARA case number to RMTAD via e-mail to request analysis.

E. The DO or RD designee is to complete the “Initial Assessment” tab in the ARA when the DM or RD designee, determines that assessment for a recall should be not considered. The DO or RD designee is to:

1. Select “No Further Analysis Required;”
2. Enter the basis of the recommendation in the “Recommendation Rationale” field;

3. Select "Make Recommendation;" and
4. Close the case when all required information has been entered, including the ARA scope and disposition information.

VIII. QUESTIONS

Refer questions regarding this notice to the Office of Policy and Program Development 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 Notice 49-20 .
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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