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

FSIS DIRECTIVE

8140.1
Rev. 2

2/26/21

NOTICE OF RECEIPT OR DISTRIBUTION OF ADULTERATED OR MISBRANDED PRODUCT

DO NOT IMPLEMENT THIS DIRECTIVE UNTIL MARCH 1, 2021

I. PURPOSE

This directive instructs inspection program personnel (IPP) when to enter data into the Public Health Information System (PHIS) Adulterated Product Monitoring (APM) module. FSIS is revising this directive to reflect that the PHIS APM is a digital mechanism to complete FSIS Form 8140-1, *Notice of Receipt of Adulterated or Misbranded Product* and to add information on how the Office of Field Operations (OFO) District Offices (DOs) and Office of Investigation, Enforcement, and Audit (OIEA) personnel are to use the APM to document industry reports required by 9 CFR 418.2. FSIS has added clarification on whether product has entered commerce and new instructions for IPP to verify whether establishments meet the requirements of these regulations. The information from FSIS Notice 49-20, *Implementation of the Adulterated Product Monitoring Module of the Public Health Information System* has been incorporated into this directive with some revisions. The regulatory requirements for establishments to notify FSIS when they have shipped or received adulterated or misbranded products are unchanged; however, the logistics of FSIS receiving and reporting the notification and documenting Agency assessment and establishment corrective actions have been updated and incorporated into this directive.

KEY POINTS:

- *Instructs IPP and DOs on the use of the APM module in PHIS, including data entry in PHIS*
- *Instructs IPP and DOs on actions to take in response to a report of adulterated or misbranded products*

II. CANCELLATION

FSIS Directive 8140.1, Revision 1, *Notice of Receipt of Adulterated or Misbranded Product,* 7/3/17
FSIS Notice 49-20, *Implementation of the Adulterated Product Monitoring Module of the Public Health Information System*, 9/30/20

III. BACKGROUND

A. Each inspected official establishment is required to produce safe, wholesome, unadulterated, and properly labeled products. 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. In order to streamline the reporting process and prevent redundant reporting, FSIS has consolidated reporting required by 9 CFR 418.2 and internal FSIS communications to report the receipt or shipment of adulterated or misbranded products into this module in PHIS. Agency personnel are to continue to use the System Tracking *E. coli* O157:H7-Positive Suppliers (STEPS) as instructed in in FSIS Directive 10,010.1, *Sampling Verification Activities for Shiga Toxin-Producing Escherichia Coli (STEC) in Raw Beef Products*. APM includes the following tools for reporting the receipt or shipping of adulterated or misbranded products:

1. Industry Report of Adulteration (IRA)—This tool is used by DO designees to document industry reports required by 9 CFR 418.2, to record establishment corrective actions, and District assessment of whether a recall analysis is necessary. This tool will also be available to authorized industry users who have a PHIS account to enter reports of adulterated or misbranded products that have entered commerce directly into the system.

2. Industry Report of Adulteration-In Plant (IRA-IP)—This tool is the digital mechanism to complete FSIS Form 8140-1, *Notice of Receipt of Adulterated or Misbranded Product*, and is 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 of whether a recall analysis is necessary. The IRA-IP is used as an internal notification tool 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 shipped between sister establishments).

NOTE: IPP may become aware of adulterated or misbranded products that have not entered commerce through voluntary establishment notifications, record reviews, observing corrective actions and asking questions, or discussions with establishment personnel, including during weekly meetings.

3. Agency Report of Adulteration (ARA)—This tool is used by DO designees and OIEA Compliance and Investigations Division (CID) Regional Director (RD) designees to document their determinations that adulterated or misbranded products have entered commerce, and by the OFO Recall Analysis and Technical Analysis Division (RMTAD) to document the Agency's assessment of such incidents. DO designees also use this tool to identify IRA and IRA-IP cases for further analysis.

B. FSIS regulation 9 CFR 418.2 requires establishments to notify the local FSIS DO within 24 hours of learning or determining that they have received or have shipped adulterated or misbranded products that have entered commerce. FSIS considers products to have entered commerce when they have left the direct control of the producing establishment and are in distribution.

C. 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.

D. For instructions related to identification and segregation of returned or received adulterated or misbranded products, IPP are to refer to FSIS 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 FSIS Directive 5000.1, *Verifying an Establishment's Food Safety System*.

IV. IPP RESPONSIBILITIES

A. IPP are to provide the establishment this link: USDA FSIS PHIS Inquiries User Guide for Industry Users and are to share the information in Attachment 1 during the next weekly meeting following issuance of this directive and anytime thereafter when information is requested by the establishment about how to use PHIS to directly report that the establishment has received or shipped adulterated or misbranded products.

B. IPP are to be aware that the official establishment is not required to provide multiple notifications to FSIS for the same adulterated or misbranded products in commerce. IPP are to be aware that the receiving establishment may either notify the DO or IPP but is not required by 9 CFR 418.2 to notify both. No additional notification is required:

1. When establishments that have received adulterated or misbranded products in commerce notify IPP, as agents of the DO, and IPP complete the IRA-IP in PHIS;

2. When shipping or receiving establishments use the IRA self-reporting feature in PHIS to notify the DO;

3. When shipping or receiving establishments notify the DO by e-mail or phone call and the DO completes the IRA in PHIS; or

4. When FSIS personnel notify the shipping or receiving establishments that the establishment has been identified as involved in an APM case and no products beyond what is already identified in the case have entered commerce.

C. 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 FSIS 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 FSIS as required by 9 CFR 418.2. IPP are to perform a search in APM before documenting noncompliance if they suspect notification did not occur to verify that the District Office was not notified directly. 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.

NOTE: APM includes an "Alerts" feature that sends an e-mail alert to Agency personnel when a case is published in APM; however, there are no active APM "alerts" sent to IPP at this time. Until further notice, any data entry performed by Agency personnel that requires action by another person in FSIS must be followed by an e-mail or phone call so that person can act unless otherwise specified below.

D. IPP are to verify that the industry notification of an adulteration or misbranding event is captured by a single IRA or IRA-IP when they are aware of an adulteration or misbranding event. IPP are to notify their supervisor when they observe duplicate entries.

E. IPP are to be aware that FSIS personnel cannot view an establishment's self-reported IRA while the report is in "Draft" status. IPP are to be aware that if the establishment is using PHIS to report adulterated or misbranded products, the establishment has not satisfied the regulatory requirement of notification as per 9 CFR 418.2 until the establishment-generated IRA is successfully submitted. In order to provide notification through an IRA, the establishment must "Submit" the report as described in the Industry User Guide for the PHIS APM. Draft IRA reports created by establishments are automatically deleted by the PHIS APM if they are not submitted within two calendar days. IPP are to refer the establishment to the Industry User Guide for information on how to submit or delete the case record.

F. 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 FSIS 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 DO 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. IPP are to discuss the appropriate actions with their supervisor if an establishment declines to provide access to the records needed to complete the case in the PHIS APM.

G. FSIS Form 8140-1 is only available when downloaded from PHIS through IRA-IP. IPP are not to use the paper/PDF FSIS Form 8140-1 previously available on insideFSIS unless PHIS is not available and they are instructed by their supervisor to do so. IPP are to be aware that there is no requirement to print the FSIS Form 8140-1 for FSIS files. The form and signature history are maintained within the system.

1. The PHIS generated FSIS Form 8140-1 can be downloaded for viewing when:

   a. Section A has been signed for the first time; or

   b. Section A and B are both signed.

NOTE: Once Section A and B are both signed, if a signature is removed from either section, a PDF Form 8140-1 cannot be generated until both sections again have been signed.

2. Only the most recent signed version of FSIS Form 8140-1 will be available in the IRA-IP for view and download.

3. The IRA-IP "Forms" page maintains a signature history.

V. PROCEDURES FOR COMPLETING THE PHIS APM IRA-IP "SECTION A" AT THE RECEIVING ESTABLISHMENT

A. IPP at the receiving establishment are to ask the establishment for the necessary data to complete an IRA-IP when IPP become aware that an establishment has received adulterated or misbranded product and have determined that the Inspector-in-Charge (IIC) at the producing establishment must be notified that adulterated or misbranded products were produced and shipped. IPP are to refer to the PHIS APM Agency User Guide and PHIS Help Tutorials for screen shots and instructions on how to use APM. IPP are not to create an IRA-IP if the following circumstances apply:

1. There is an existing IRA in the system because the receiving establishment has notified the DO directly, either by completing an IRA in the APM themselves or by notifying the DO by e-mail or phone call and the DO completed the IRA; (see section IX on creating an IRA)

2. The establishment receives adulterated or misbranded products for further processing under USDA seal and accompanied by FSIS Form 7350-1, *Request and Notice of Shipment of Sealed Meat/Poultry* that was completed by the shipping establishment and signed by FSIS personnel at the shipping establishment. Users need a USDA e-authentication account to access this form;

3. There is an existing IRA-IP in PHIS for the same event or shipment; or

4. The establishment receives adulterated or misbranded product under control measures with the intent to treat the product to make it not adulterated or misbranded (e.g., misbranded products received for relabeling under appropriate controls).

B. IPP at the receiving establishment are to enter information corresponding to "Section A" of the IRA-IP, then "Publish" the report. IPP are to gather and enter the following information required by APM:

1. Shipping establishment;

2. Date products were received;

3. Description of the misbranding or adulteration;

4. Each product name and description;

5. Establishment numbers on products; and

6. Quantity adulterated or misbranded and quantity in commerce (if any).

C. IPP at the receiving establishment are to navigate to the "Forms" section of the IRA-IP report and take the following steps:

1. IPP are to apply an electronic signature to "Section A" by clicking on "Sign" in the "Section A Signature" area;

2. IPP are not to download the form and use their LincPass or other methods to apply a digital signature to FSIS Form 8140-1. The APM will not recognize any signatures on FSIS Form 8140-1 that have been applied other than by selecting the "Sign" button in the module; and

NOTE: IPP are to be aware that any edits made to "Section A" or "Section B" after they are signed will revoke the signature for that section, and IPP are to apply a new signature to the edited section when they have access to that section. IPP are to sign only the section that applies to the establishment where they are assigned.

3. IPP are to save the IRA-IP by selecting the "Save" button.

D. A PHIS system e-mail alert with the IRA-IP case number and establishment number will be sent to the Frontline Supervisor (FLS) and DO designee when IPP publish the IRA-IP case.

VI. DISTRICT OFFICE RESPONSIBILITIES FOR IRA-IP CASE FLOW

A. The DO designee is to routinely review the IRA-IPs created by IPP to verify that the IPP determination to complete an IRA-IP is in accordance with instructions in this directive. If the District Manager (DM) or designee does not concur with the IPP decision to complete an IRA-IP, the DM, or designee, is to provide appropriate feedback to the supervisor of the IPP.

B. The DO designee is to return any paper/printed FSIS Form 8140-1 to IPP so the data can be entered into PHIS, unless there was supervisory instruction to use the PDF version of the form.

C. When the DO designee in the district assigned to the receiving establishment receives an alert that an IRA-IP case has been published, they are to:

1. Forward the case number to the FSIS personnel assigned to the shipping establishment when both the notifying and shipping establishments are assigned to the same district; or

2. Forward the case number to the DO assigned to the identified shipping establishment when the notifying and shipping establishment are in different districts.

D. The DO designee in the district assigned to the shipping establishment is to forward the case number to the applicable IIC and FLS so IPP can complete the procedures in Section VII. below. The DO designee is to review each IRA-IP and identify whether the report should be linked to any other IRA or IRA-IP case reports in PHIS because they involve the same or related source materials. The DO

designee is also to determine if the case should be referred to the 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 from the associated IRA-IP. The DO designee is able to identify the IRA-IP case for further analysis at any point after the IRA-IP has been "Published" by IPP and is in the open status.

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 PHIS.

VII. PROCEDURES FOR COMPLETING THE PHIS APM IRA-IP "SECTION B" AT THE SHIPPING ESTABLISHMENT

A. When IPP at the shipping establishment receive e-mail notification from the DO designee that there is an APM case for their review, they are to navigate to the PHIS APM and locate the IRA-IP case report number identified in the e-mail. IPP are to search by either case number or establishment number to locate the report. IPP at the shipping establishment are to:

1. Review the information in the IRA-IP as submitted by IPP at the receiving (notifying) establishment;

2. Notify the shipping establishment that it has been identified as an establishment that has produced and shipped adulterated or misbranded products and that IPP will perform additional verification activities related to the affected products as described in B below;

3. Discuss the information provided by the receiving establishment with the shipping establishment;

4. Navigate to the Corrective Actions tab ("Section B") and enter a description of the establishment's actions to address the adulteration or misbranding. If a NR is issued by IPP at the shipping establishment, IPP are to note the PHIS NR number in the text data box on the "Corrective Actions" tab of the IRA-IP along with the description of the establishment's actions to address the adulteration or misbranding. If the establishment responds to the NR in writing, IPP can follow the instructions in Attachment 2 to upload the NR and written NR response into the IRA-IP but are not required to do so. IPP are not to upload establishment records or copies of establishment records into the IRA-IP Section B;

5. Navigate to the "Forms" tab of the IRA-IP and apply their electronic signature to "Section B" by clicking on "Sign" in the "Section B Signature" area. IPP are not to download the form and use their LincPass or other methods to apply a digital signature to FSIS Form 8140-1. The APM will not recognize any signatures on FSIS Form 8140-1 that have been applied other than by selecting the "Sign" button in the module;

NOTE: IPP are to be aware that any edits made to "Section A" or "Section B" after they are signed will revoke the signature for that section and IPP are to apply a new signature to the edited section.

6. Select "Save" and exit the case; and

7. Notify the DO by e-mail that "Section B" is completed.

NOTE: When FSIS personnel at the shipping establishment receive e-mail notification from the DO designee of products that have been shipped in commerce and discuss the report with the shipping establishment, the shipping establishment is not required to provide any additional notification under 9 CFR 418.2 even if the products have entered commerce.

B. IPP at the shipping establishment are to:

1. Perform the directed HACCP Verification or appropriate Sanitation SOP task as set out in FSIS Directive 5000.1 for adulterated products or General Labeling Verification task as described in FSIS Directive 7221.1, *Prior Labeling Approval* for misbranded products to verify that the establishment has accounted for all products involved, corrected any misbranding, and in situations involving adulterated products, taken the appropriate corrective actions when required by FSIS regulations (9 CFR 417.3 or 9 CFR 416.15);

2. Follow the instructions in FSIS Directive 5000.1 and discuss developing trends with their supervisor when IPP identify a trend of multiple instances of adulterated or misbranded products 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;

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

4. Document any observed regulatory noncompliance in accordance with FSIS Directive 5000.1 or FSIS Directive 7221.1.

VIII. DO RESPONSIBILITIES FOR CLOSING THE IRA-IP

A. The DO designee is to review the IRA-IP when notified by IPP via e-mail that sections A and B are complete and signed. The DM, or designee, is to close the IRA-IP case once all required information has been entered.

B. The DO cannot close the IRA-IP case until all the required fields have been completed, including signatures for both "Section A" and "Section B", and the "Analysis" section. If IPP need to modify the IRA-IP data after the corresponding "Section A" or "Section B" has been signed, IPP are to make the necessary updates and apply new signatures.

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*.

C. The DM, or designee is to complete the "Analysis" tab in the IRA-IP and create an ARA case if the DM, or designee, determines the case should be identified for further analysis because an assessment for recall should be considered. To create an ARA case the DM, or designee, is to:

1. Select "Recall Analysis Recommended"; and

2. Select "Make Recommendation".

D. When further analysis for recall is recommended, most of the data fields in the IRA-IP are locked. A justification can be entered by the DM, or other supervisory designees, to unlock the data for editing if necessary. The most recent FSIS Form 8140-1 can be viewed without unlocking.

E. The PHIS APM will prompt the DM, or designee, to begin the creation of the ARA case report used to notify RMTAD. The DM, or designee, is to review and complete the ARA case report and then send the ARA case number to RMTAD via e-mail to request a review.

F. The DM, or designee is to complete the "Analysis" tab in the IRA-IP if the DM, or designee, determines analysis for recall should NOT be considered. The DM, or designee, is to select "Recall Analysis Not

Recommended" and include a brief explanation of why no further analysis is required. For example, for "All affected products are under establishment control." The DM, or designee, is then to select "Make Recommendation" and be aware of the following:

1. The IRA-IP case report is closed when the DM, or designee, indicates no analysis is recommended; and

2. The PHIS APM will not allow an IRA-IP to be closed if all required fields have not been completed.

G. The DM/Deputy District Manager (DDM), Case Specialist (CS)/Supervisory Enforcement Investigation and Analysis Officer (SEIAO), and FLS PHIS roles can re-open a closed IRA-IP case if additional information becomes available after the case is closed.

IX. 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. 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 IRA-IP in PHIS for the same event or shipment.

B. The DO designee is to routinely review IRAs that were created by establishments within their jurisdiction to verify that the IRA is complete and the establishment provided necessary information to satisfy the regulatory requirement of notification as per 9 CFR 418.2. The DO is to follow-up with the establishment as necessary when additional information is required and "Publish" the IRA in the PHIS APM.

C. When an IRA is created, either by the DO or by establishment self-reporting, the DO designee is to:

1. Notify the other involved establishments 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;

NOTE: A PHIS system e-mail alert will be sent to management personnel in the DO assigned to other involved establishments when the notifying establishment and other involved establishments are in different districts when the IRA is published.

2. Gather any necessary information needed and enter it into the existing IRA;

3. Identify whether the report should be linked to any other IRA or IRA-IP case reports; and

4. 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.

D. The 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 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 and send the ARA case number to RMTAD via e-mail to request analysis;

    a. 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.

    b. The DM/DDM and CS/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.

E. 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. For example, “All affected products are under establishment control”; and

2. Select “Make Recommendation.”

X. 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 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.

XI. PROCEDURES FOR MANAGING REPORTS OUTSIDE OF OFFICIAL ESTABLISHMENTS

A. Although the notification requirements in 9 CFR 418.2 only apply to official establishments (and not import establishments), there may be scenarios when facilities other than official establishments voluntarily report adulterated or misbranded products. IPP are to create an IRA-IP for these situations only when instructed to do so by their supervisor.

B. DO personnel 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., State inspection program officials or FSIS program area other than OFO).

XII. 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 and determine that the adulterated or misbranded products have entered commerce. Independent ARAs are created as new cases and are not an extension of an existing IRA.

Examples of situations when there is adulterated or misbranded product in commerce and where a new ARA is created include, but are not limited to:

1. FSIS in-plant IPP observations made at a shipping establishment that result in a determination that the establishment shipped adulterated or misbranded products into commerce, when the establishment did not notify inspection personnel or the DO;

2. FSIS sampling result that supports a determination of adulterated product (other than STEC);

3. Illness outbreaks attributed to a specific establishment;

4. Consumer complaints reported to the Agency through the Consumer Complaint Monitoring System (CCMS);

5. Notification from public health partners;

6. Failure to Present (FTP) imported product for FSIS reinspection; and

7. CID Investigator findings in commerce.

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

1. Forward the information to the DO or region assigned to the involved establishments or firms when other involved establishments or firms are in different districts or regions;

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;

5. Refer the case to RMTAD for recall analysis based on the criteria in FSIS Directive 8080.1 after the ARA has been published;

6. Enter available product disposition information in the case;

7. Submit the ARA case number to RMTAD via e-mail to request analysis;

8. Notify RMTAD via e-mail when the case is complete; and

9. Provide any additional information RMTAD requests to close the case.

C. RMTAD personnel are to document the ARA assessment based on the outcome of the case and close the ARA when RMTAD has gathered, entered, and determined the case is complete.

XIII. QUESTIONS

Refer questions regarding this directive to the Office of Policy and Program Development through askFSIS or by telephone at 1-800-233-3935.

Assistant Administrator
Office of Policy and Program Development

Attachment 1:
Information for IPP to facilitate industry use of the PHIS APM

In order to facilitate industry use of the PHIS APM, if requested by the establishment for assistance on using the APM, IPP are to provide the establishment this link: USDA FSIS PHIS Inquiries User Guide for Industry Users and the following information:

To provide notification or awareness to the DO of adulterated or misbranded products that have entered commerce through the PHIS APM, an e-authentication (e-auth) enabled establishment PHIS user must login to PHIS as the Plant Manager or Corporate Administrator, navigate to the APM module, and select "Create a Case" for the IRA case report option.

1. The establishment is to follow the IRA case creation wizard to create the Draft IRA.

2. After the establishment has entered all required information, as indicated by the PHIS APM user screen, the establishment is then able to submit the notification to the DO for review.

3. The notifying establishment is able to continue to login to PHIS and view the status of the IRA case and Case Summary fields as the IRA is addressed by FSIS.

Attachment 2:
How to upload attachments in the Adulterated Product Monitoring (APM) module of PHIS

When adding a document to the APM, FSIS personnel are to save the file to the government issued computer using a recognizable file name and note where the file is saved. If the file to be uploaded is a paper form, FSIS personnel are to scan and save the file to the government issued computer as a PDF file.

1. To attach the file to the APM case in PHIS, navigate to the "Attachments" screen.

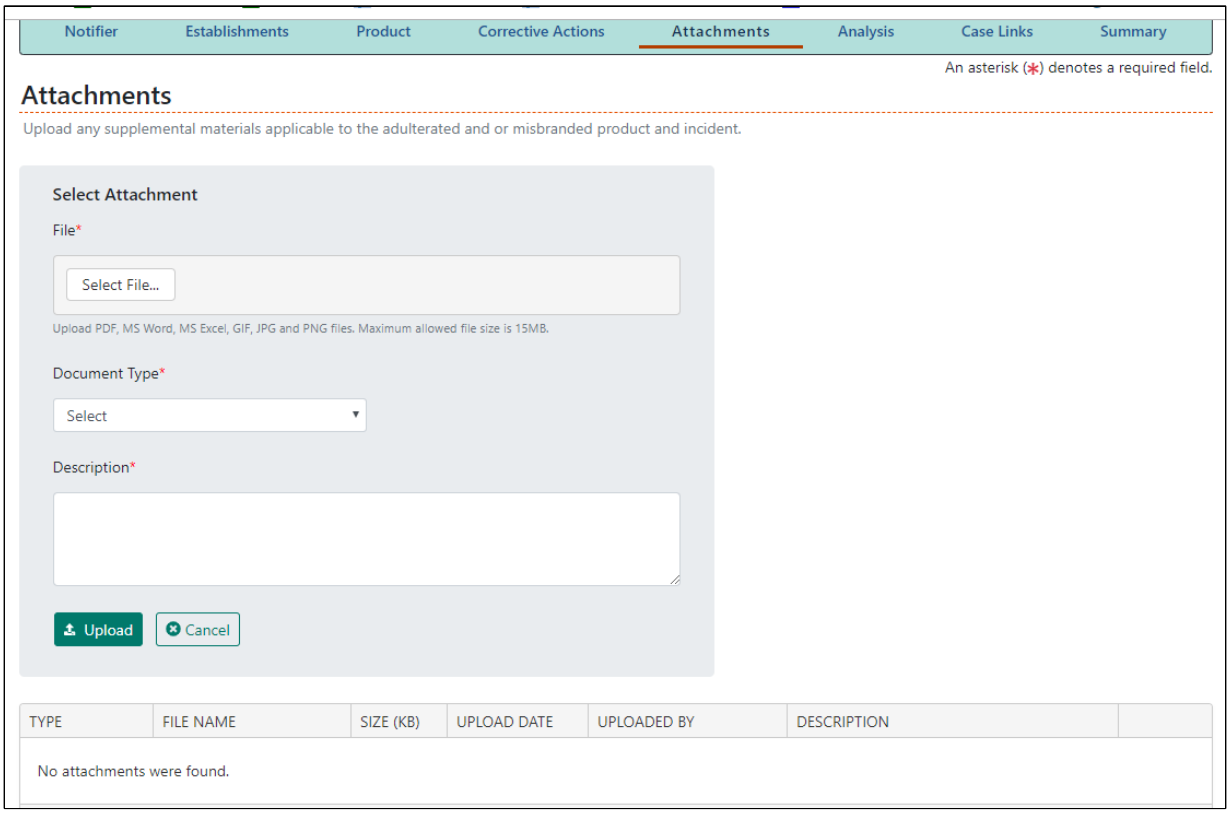

Figure 1: The PHIS APM Attachments screen

2. To upload the attachment:

    a. Click on "Upload an Attachment" and the Attachments table will expand to Figure 1, then "Select File", browse the computer to identify the file and click on the file;

    b. Use the "Document Type" drop-down menu to select the type of document;

    c. Include a brief description of the file in the "Description" text box; and

    d. Select "Upload".

3. When the upload is complete, the file name will appear in the table.

    The file type and description can be edited by selecting the pencil icon in the last column, then the check mark after edits are made. The attachment can be deleted by selecting the trash can icon.