Recall of Meat and Poultry Products

EIAO Effectiveness Checks

Objectives

1. Learn about the FSIS recall process
2. Understand the EIAO's role in recalls
3. Complete the Recall effectiveness check portion of the Adulterated Product Monitoring (APM) system
4. Describe the methodology and purpose for:
    - collecting distribution and traceback information
    - conducting recall effectiveness checks
    - conducting a product disposition verification

Resources

Directives and guide

- **5000.8** – Verifying Compliance With Requirements For Written Recall Plan Procedures
- **8080.1** – Managing Adulterated or Misbranded Meat, Poultry, and Egg Products
- **8140.1** - Notice of Receipt of Adulterated or Misbranded Product (PHIS)
- **8410.1** – Detention and Seizure
- Recall Plan Booklet - How to Develop a Meat and Poultry Product Recall Plan

During the Food Safety Assessments (FSAs)

Establishment's Responsibilities:

- **9 CFR 418.3** Preparation and maintenance of written recall procedures.
- "Each official establishment **must prepare and maintain written procedures** for the recall of any meat, meat food, poultry, or poultry product produced and shipped by the official establishment. **These written procedures must specify how the official establishment will decide whether to conduct a product recall, and how the establishment will effect the recall, should it decide that one is necessary.**"

- Recall Plan Booklet – How to Develop a Meat and Poultry Product Recall Plan

During the Food Safety Assessments (FSAs) – 1

EIAO's Responsibilities:

- Per **FSIS Directive 5000.8**, EIAOs are to assess whether the establishment has written recall plan procedures in accordance with 9 CFR 418. 3.

- General Tool:
  - Recall Procedure: Does the establishment have a documented recall procedure as required by 9 CFR part 418 to ensure all products could be recalled? Briefly describe any vulnerability or noncompliance (limit 2,000 characters).

During the Food Safety Assessments (FSAs) – 2

EIAO's Responsibilities:

- If EIAOs determine that the establishment did not specify the procedures needed, recommend to the in-plant team perform a **directed Other Inspection Requirements task** in PHIS and document a noncompliance with 9 CFR 418.3.

Terminology:

Recall:

A firm's **voluntary** removal of distributed meat, poultry, or egg products from commerce when there is **reason to believe that such products are adulterated or misbranded** under the provisions of the FMIA, PPIA, or EPIA. and that such product remains available in commerce, free to move to consignees or consumers.

- Announce on FSIS website.
- **A recall is not a market withdrawal or a stock recovery.**

Terminology:

Adulterated or Misbranded:

Federal Meat Inspection Act
- 21 U.S.C. 601 (m) and (n)

Poultry Products Inspection Act
- 21 U.S.C. 453 (g) and (h)

Egg Products Inspection Act
- 21 U.S.C. 1033 (a) and (l)

Terminology: Market Withdrawal

A firm's removal or correction, **on its own initiative**, of product that is in commerce, **for any reason that would not ordinarily lead the Agency to pursue detention and seizure.** This includes deviations from a company quality program or minor regulatory infractions.

- A company can remove product from commerce or have product returned from a customer at any time for any reason. This does not necessarily make that action a recall.

Terminology: Stock Recovery

A firm's **removal or correction of product that has not left the direct control of the firm**.

For example, product is located on the premises owned by the producing firm or stored offsite under its control at a consignee or third-party warehouse.

Terminology: Hazard Classifications

FSIS assesses the public health concern or hazard presented by a product being recalled, or considered for recall, whether firm-initiated or requested by FSIS, and classifies the concern as one of the following:

Class I: Reasonable probability of serious, adverse health consequences or death

Class II: Remote probability of adverse health consequences

Class III: No adverse health consequences

Terminology: Scope

This defines **the amount and type of product in question**.

Several factors are used in determining the scope of product that is potentially adulterated or misbranded (**product scope**), as well as the scope of product meeting that determination and available in commerce (**recall scope**).

Terminology: Disposition

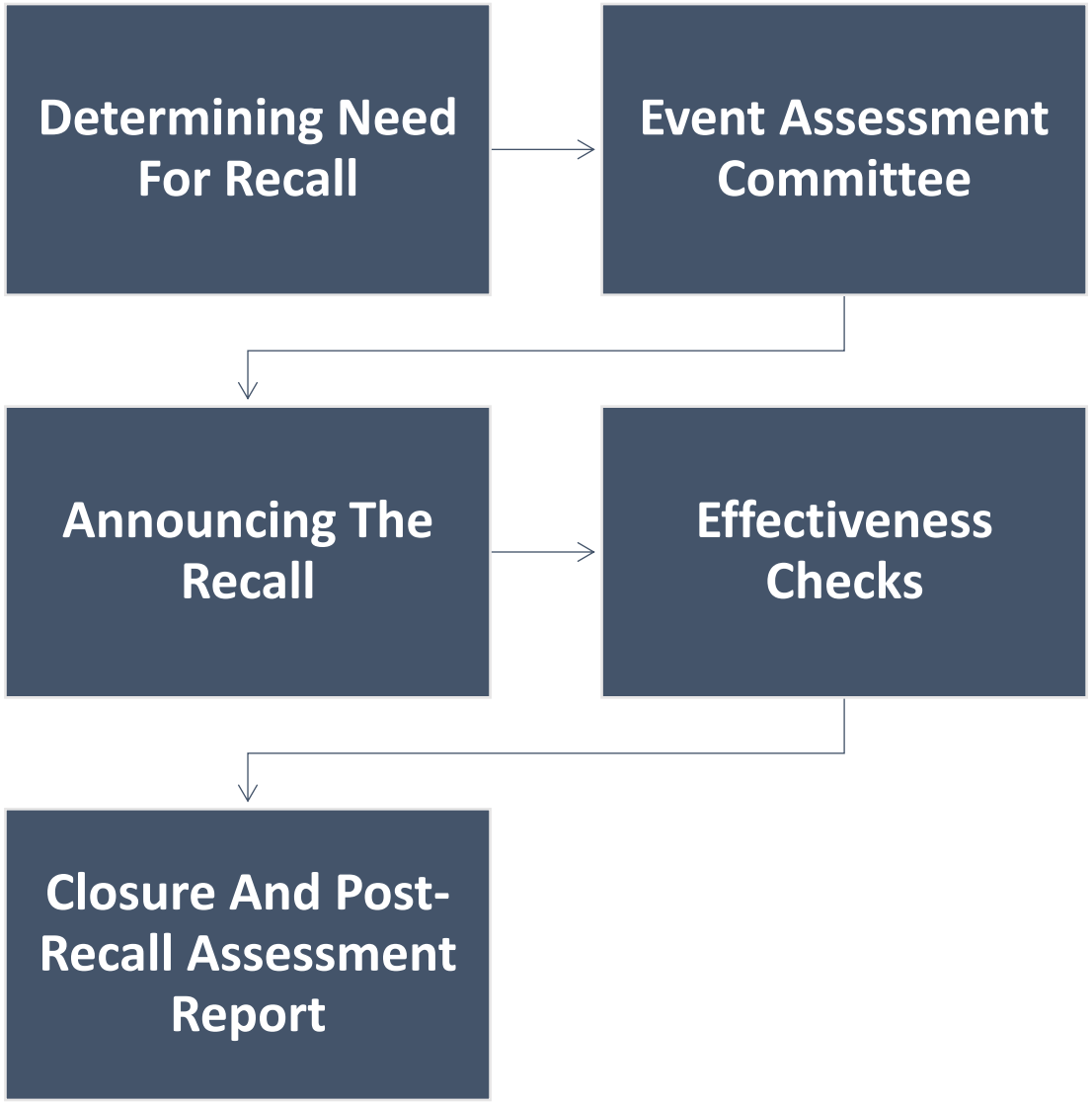
This is the firm's **action** with respect to adulterated or misbranded product **to correct the applicable concern**, such as relabeling, cooking, reworking, or destroying product.

Terminology: Event Assessment Committee

A committee comprised of representatives from various FSIS program areas assembled **to determine the best response to potential health hazard incidents** escalated for analysis to the Recall Management and Technical Analysis Division (RMTAD).

Recall Process Overview

FSIS **Directive 8080.1**: Managing Adulterated Or Misbranded Meat, Poultry, And Egg Products.



Determining Need For Recall

1. Becoming Aware Of Potential Need For A Recall

- When **FSIS official establishments** learn or determine that adulterated or misbranded meat or poultry products have entered commerce, they are required to notify FSIS Office of Field Operation (OFO District Office (DO) personnel within 24 hours (**9 CFR 418.2**).

- If **other firms responsible for products**, such as importers or retailers, determine that adulterated or misbranded product have entered commerce or decide to recover product from commerce on their own initiative, they may notify RMTAD (formtad@usda.gov) or other FSIS personnel.

Determining Need For Recall – 1

Continue…

- FSIS may become aware of adulterated or misbranded product in commerce through its own resources and personnel activities or through other sources outside of FSIS.

- **When there is reason to believe that adulterated or misbranded product is in commerce, FSIS will conduct a preliminary inquiry.**

Determining Need For Recall – 2

2. Preliminary Inquiry

- FSIS OFO District Manager (DM) or Office of Investigations, Enforcement and Audit (OIEA) Regional Director (RD) is to assign personnel to lead this effort.

Determining Need For Recall – 3

2. Preliminary Inquiry

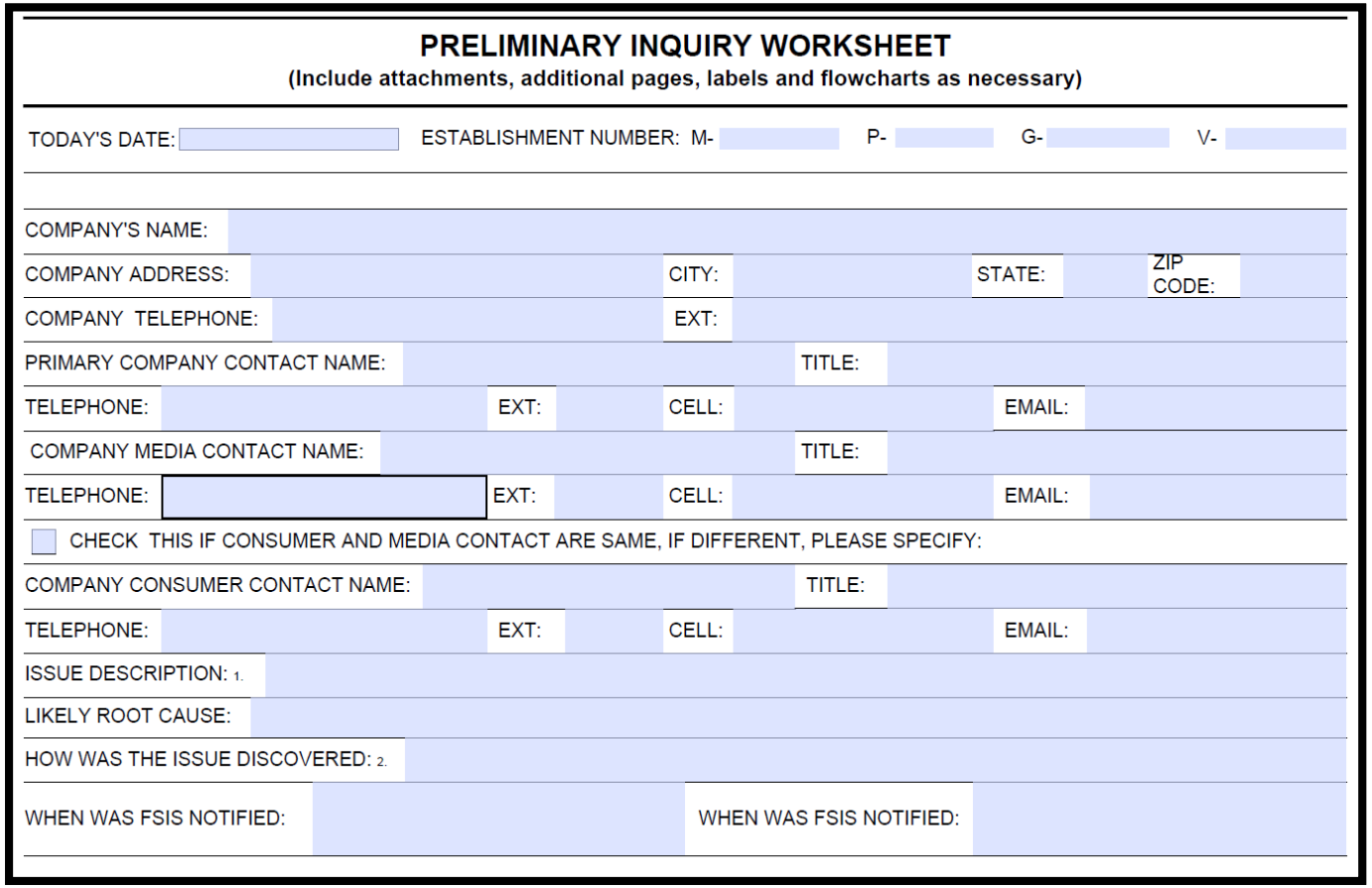
- In the case of OFO is leading the effort, EIAOs and other district personnel is to gather
    - relevant information about the products in question,
    - contact information for the firms involved in production and distribution, and
    - any information that might affect the scope of involved product or mitigate the need for a recall.

Determining Need For Recall – 4

- If determine the event should be escalated for further RMTAD analysis:
  - the personnel assigned to lead this effort are to work with the firm to complete and forward a copy of **FSIS Form 5020-3, Preliminary Inquiry Worksheet**, to RMTAD for assessment and
  - escalate the event by creating an **Agency Report of Adulteration** (ARA) in PHIS. - **FSIS Directive 8140.1**.
  - gather product label information, including photographs or digital scans of labels, and submit to RMTAD via email whenever possible.

Preliminary Inquiry: Inquiry Worksheet

Preliminary Inquiry Worksheet: FSIS Form 5020-3



PRELIMINARY INQUIRY WORKSHEET

(Include attachments, additional pages, labels and flowcharts as necessary)

TODAY'S DATE: ESTABLISHMENT NUMBER: M- P- G- V-

COMPANY'S NAME:

COMPANY ADDRESS: CITY: STATE: ZIP CODE:

COMPANY TELEPHONE: EXT:

PRIMARY COMPANY CONTACT NAME: TITLE:

TELEPHONE: EXT: CELL: EMAIL:

COMPANY MEDIA CONTACT NAME: TITLE:

TELEPHONE: EXT: CELL: EMAIL:

☐ CHECK THIS IF CONSUMER AND MEDIA CONTACT ARE SAME, IF DIFFERENT, PLEASE SPECIFY:

COMPANY CONSUMER CONTACT NAME: TITLE:

TELEPHONE: EXT: CELL: EMAIL:

ISSUE DESCRIPTION: 1.

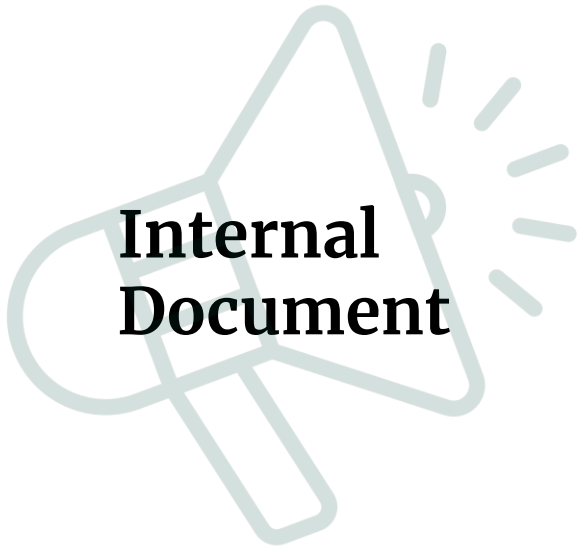
LIKELY ROOT CAUSE:

HOW WAS THE ISSUE DISCOVERED: 2.

WHEN WAS FSIS NOTIFIED: WHEN WAS FSIS NOTIFIED:

Recall Worksheet

Recall Worksheet: Listeria



Internal Document

RECALL WORKSHEET -FOR INTERNAL FSIS USE ONLY

(*Listeria monocytogenes* ATTACHMENT)

(READY-TO-EAT PRODUCT)

DESCRIBE THE PRODUCTION/PROCESSING OPERATION AND/OR ATTACH A PROCESS FLOW DIAGRAM:_____

_____

_____

_____

_____

WHAT WERE THE "CLEAN-UP TO CLEAN-UP" TIMES?_____

WAS CARRYOVER PRODUCT FROM PREVIOUS PRODUCTION PACKED WITH THIS PACKAGING CODE? (YES) (NO)

WAS THERE A COMPLETE LINE CLEANUP AFTER THE CARRYOVER WAS RUN? (YES) (NO)

WHAT DATE WAS THE CARRYOVER PRODUCT CARRIED OVER FROM?_____

WERE THERE ANY PROCESS DEVIATIONS DURING THE PRODUCTION OF THE CARRYOVER PRODUCT? (YES) (NO)

EXPLAIN:_____

WHAT WAS/WERE THE CORRECTIVE ACTION(S)?_____

_____

WERE OTHER PRODUCTS PRODUCED ON THE SAME LINE OR USING SOME OF THE SAME EQUIPMENT DURING THE "CLEAN-UP TO CLEAN-UP" PERIOD? (YES) (NO) EXPLAIN:_____

_____

WHAT INTERNAL COOK TEMPERATURE WAS REACHED?_____

DID THE PRODUCT REACH ANY SPECIFIED Aw OR pH REQUIREMENT? (YES) (NO) SPECIFY:_____

DOES THE FIRM HAVE AN IN-PLANT ENVIRONMENTAL MONITORING PROGRAM FOR *Listeria monocytogenes*? (YES) (NO)

WAS THE SOURCE OF THE CONTAMINATION IDENTIFIED? (YES) (NO)

EXPLAIN:_____

_____

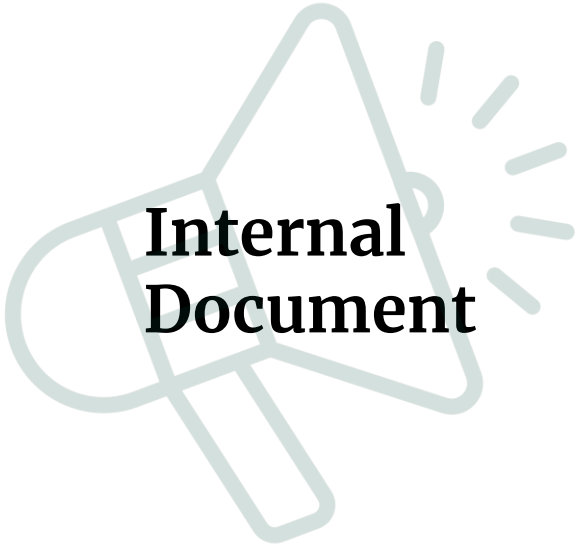
IS THERE DATA THAT COULD LIMIT THE AMOUNT OF PRODUCT AFFECTED? (YES) (NO) EXPLAIN:_____

_____

Recall Worksheet

Recall Worksheet:
STEC

Directive 10,010.3 – Traceback Methodology for Escherichia Coli (E. Coli) O157:H7 in Raw Ground Beef Products and Bench Trim



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RECALL WORKSHEET- FOR INTERNAL FSIS USE ONLY

(*E. coli* O157:H7 ATTACHMENT)

DESCRIBE THE PRODUCTION/PROCESSING OPERATION AND/OR ATTACH A PROCESS FLOW DIAGRAM:_____

_____

_____

_____

DOES THE ESTABLISHMENT CONDUCT *E. coli* O157:H7 TESTING? (YES) (NO) WHAT FREQUENCY?

WHAT WAS/WERE THE SOURCE(S) OF THE MATERIALS YOU PROCESSED? _____

_____

WERE OTHER PRODUCTS PRODUCED FROM THE SOURCE MATERIALS? (YES) (NO)
EXPLAIN:_____

_____

WAS REWORK OR CARRYOVER FROM THIS PRODUCT USED IN FUTURE PRODUCTION? (YES) (NO)

IF YES, ON WHAT DATES WERE THE REWORK OR CARRYOVER USED AND WAS THERE ANY REWORK OR CARRYOVER FROM THAT DAYS PRODUCTION USED IN FUTURE PRODUCTION?

_____

WHAT WERE THE "CLEAN-UP TO CLEAN-UP" TIMES?_____

WERE OTHER PRODUCTS PRODUCED ON THE SAME LINE OR USING SOME OF THE SAME EQUIPMENT DURING THE "CLEAN-UP

TO CLEAN-UP" PERIOD? (YES) (NO) EXPLAIN:_____

_____

WAS ANY MICROBIOLOGICAL TESTING PREFORMED BY THE COMPANY? (YES) (NO) EXPLAIN, INCLUDE RESULTS:_____

_____

IS THERE DATA THAT COULD LIMIT THE AMOUNT OF PRODUCT AFFECTED? (YES) (NO) EXPLAIN:_____

_____

_____

_____

_____

WERE THERE ANY PROCESS DEVIATIONS DURING THE PRODUCTION OF THE AFFECTED PRODUCT? (YES) (NO)

WHAT WAS/WERE THE CORRECTIVE ACTION(S)?_____

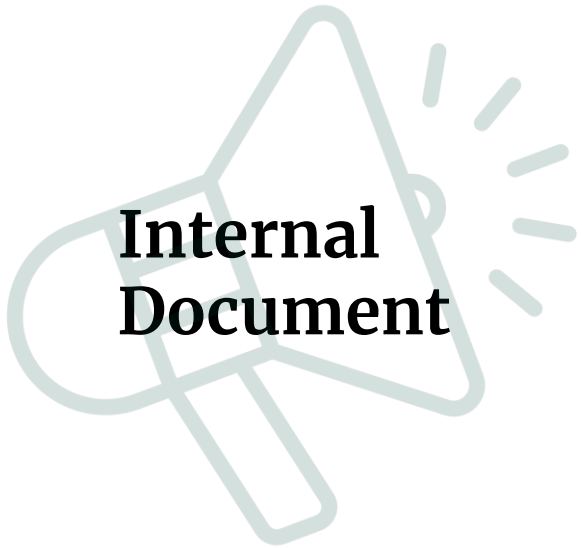
_____

_____

_____

Recall Worksheet

Recall Worksheet: Salmonella



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RECALL WORKSHEET -FOR INTERNAL FSIS USE ONLY

(*Salmonella sp.* ATTACHMENT)

(READY-TO-EAT PRODUCT)

DESCRIBE THE PRODUCTION/PROCESSING OPERATION AND/OR ATTACH A PROCESS FLOW DIAGRAM:_____

_____

_____

_____

WHAT WERE THE "CLEAN-UP TO CLEAN-UP" TIMES?_____

WAS CARRYOVER PRODUCT FROM PREVIOUS PRODUCTION PACKED WITH THIS CODE? (YES) (NO)

WAS THERE A LINE CLEANUP AFTER THE CARRYOVER WAS RUN? (YES) (NO)

WHAT DATE WAS THE CARRYOVER PRODUCT CARRIED OVER FROM?_____

WERE THERE ANY PROCESS DEVIATIONS DURING THE PRODUCTION OF THE CARRYOVER PRODUCT? (YES) (NO)

EXPLAIN:_____

_____

WHAT WAS/WERE THE CORRECTIVE ACTION(S)?_____

_____

WERE OTHER PRODUCTS PRODUCED ON THE SAME LINE OR USING SOME OF THE SAME EQUIPMENT DURING THE "CLEAN-UP TO CLEAN-UP" PERIOD? (YES) (NO) EXPLAIN:_____

_____

WHAT INTERNAL COOK TEMPERATURE WAS REACHED?_____

DID THE PRODUCT REACH ANY SPECIFIED Aw OR pH REQUIREMENT? (YES) (NO) SPECIFY:_____

_____

DOES THE ESTABLISHMENT HAVE POST-PROCESSING CONTROLS? (YES) (NO) SPECIFY (include records):_____

_____

WAS ANY MICROBIOLOGICAL TESTING PERFORMED BY THE COMPANY? (YES) (NO) EXPLAIN, INCLUDE RESULTS:_____

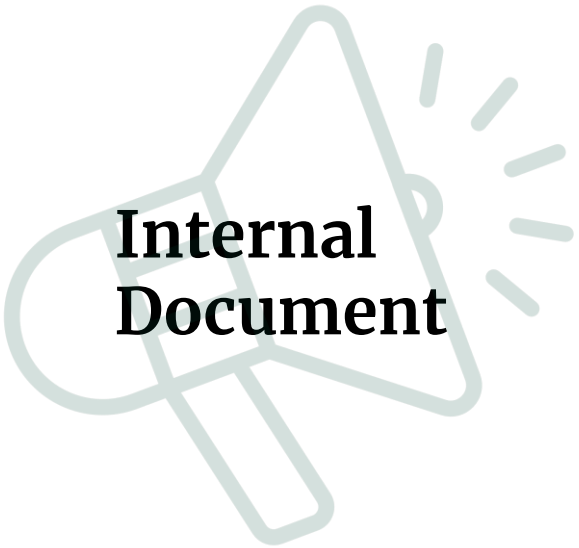
_____

IS THERE DATA THAT COULD LIMIT THE AMOUNT OF PRODUCT AFFECTED? (YES) (NO) EXPLAIN:_____

_____

Recall Worksheet

Recall Worksheet:
Foreign Material



Internal Document

RECALL WORKSHEET- FOR INTERNAL FSIS USE ONLY

(Foreign Material or Non-Microbial Contamination Attachment)

DESCRIBE THE PRODUCTION/PROCESSING OPERATION AND/OR ATTACH A PROCESS FLOW DIAGRAM:_____

_____

_____

_____

WHAT WERE THE "CLEAN-UP TO CLEAN-UP" TIMES (where applicable)?_____

HAVE YOU IDENTIFIED THE SOURCE OF THE CONTAMINATION? EXPLAIN:_____

_____

_____

IS THERE DATA THAT COULD LIMIT THE AMOUNT OF PRODUCT AFFECTED? (YES) (NO)
EXPLAIN:_____

_____

WERE THERE ANY DEVIATIONS REPORTED IN THE MEASURING AND/OR MIXING OF INGREDIENTS? (YES) (NO)

EXPLAIN:_____

_____

DOES THE ESTABLISHMENT ROUTINELY USE METAL DETECTORS OR OTHER VISUAL IMAGING DEVICES? (YES) (NO)
EXPLAIN:_____

_____

_____

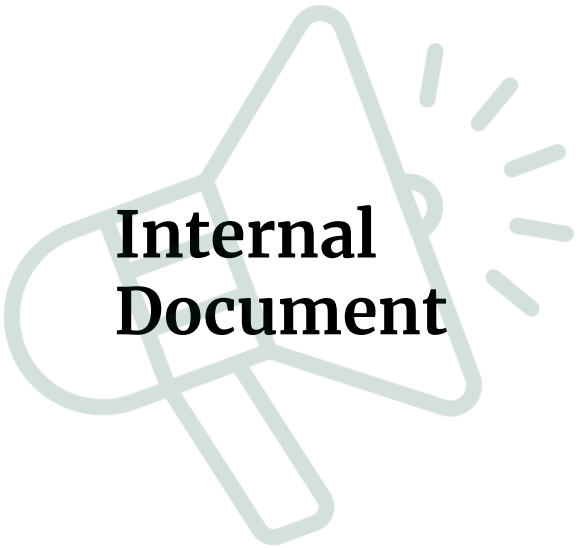
WERE OTHER PRODUCTS PRODUCED ON THE SAME LINE OR USING SOME OF THE SAME EQUIPMENT DURING THE "CLEAN-UP

TO CLEAN-UP" PERIOD? (YES) (NO) EXPLAIN:_____

_____

Traceback

Recall Worksheet:
Foreign Material



Internal Document

RECALL WORKSHEET- FOR INTERNAL FSIS USE ONLY

(Foreign Material or Non-Microbial Contamination Attachment)

DESCRIBE THE PRODUCTION/PROCESSING OPERATION AND/OR ATTACH A PROCESS FLOW DIAGRAM:_____

_____

_____

_____

WHAT WERE THE "CLEAN-UP TO CLEAN-UP" TIMES (where applicable)?_____

HAVE YOU IDENTIFIED THE SOURCE OF THE CONTAMINATION? EXPLAIN:_____

_____

_____

IS THERE DATA THAT COULD LIMIT THE AMOUNT OF PRODUCT AFFECTED? (YES) (NO)
EXPLAIN:_____

_____

WERE THERE ANY DEVIATIONS REPORTED IN THE MEASURING AND/OR MIXING OF INGREDIENTS? (YES) (NO)

EXPLAIN:_____

_____

DOES THE ESTABLISHMENT ROUTINELY USE METAL DETECTORS OR OTHER VISUAL IMAGING DEVICES? (YES) (NO)
EXPLAIN:_____

_____

_____

WERE OTHER PRODUCTS PRODUCED ON THE SAME LINE OR USING SOME OF THE SAME EQUIPMENT DURING THE "CLEAN-UP

TO CLEAN-UP" PERIOD? (YES) (NO) EXPLAIN:_____

_____

Determining Need For Recall – 5

- Per **Directive 8140.1**, when an ARA is created, the DO designee is to:

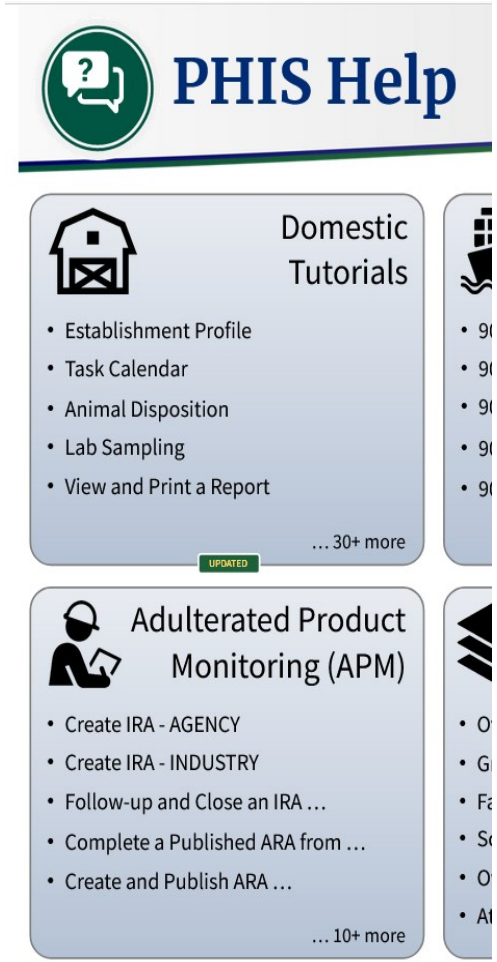
1. Forward the information to the DO in other involved districts, if needed;
2. Notify the involved establishments that they have been identified as an establishment that shipped or received adulterated or misbranded product;
3. Gather any necessary information needed and enter it into the ARA;
4. Identify if the report should be linked to any other ARA or Report of Adulteration (IRA) case reports;

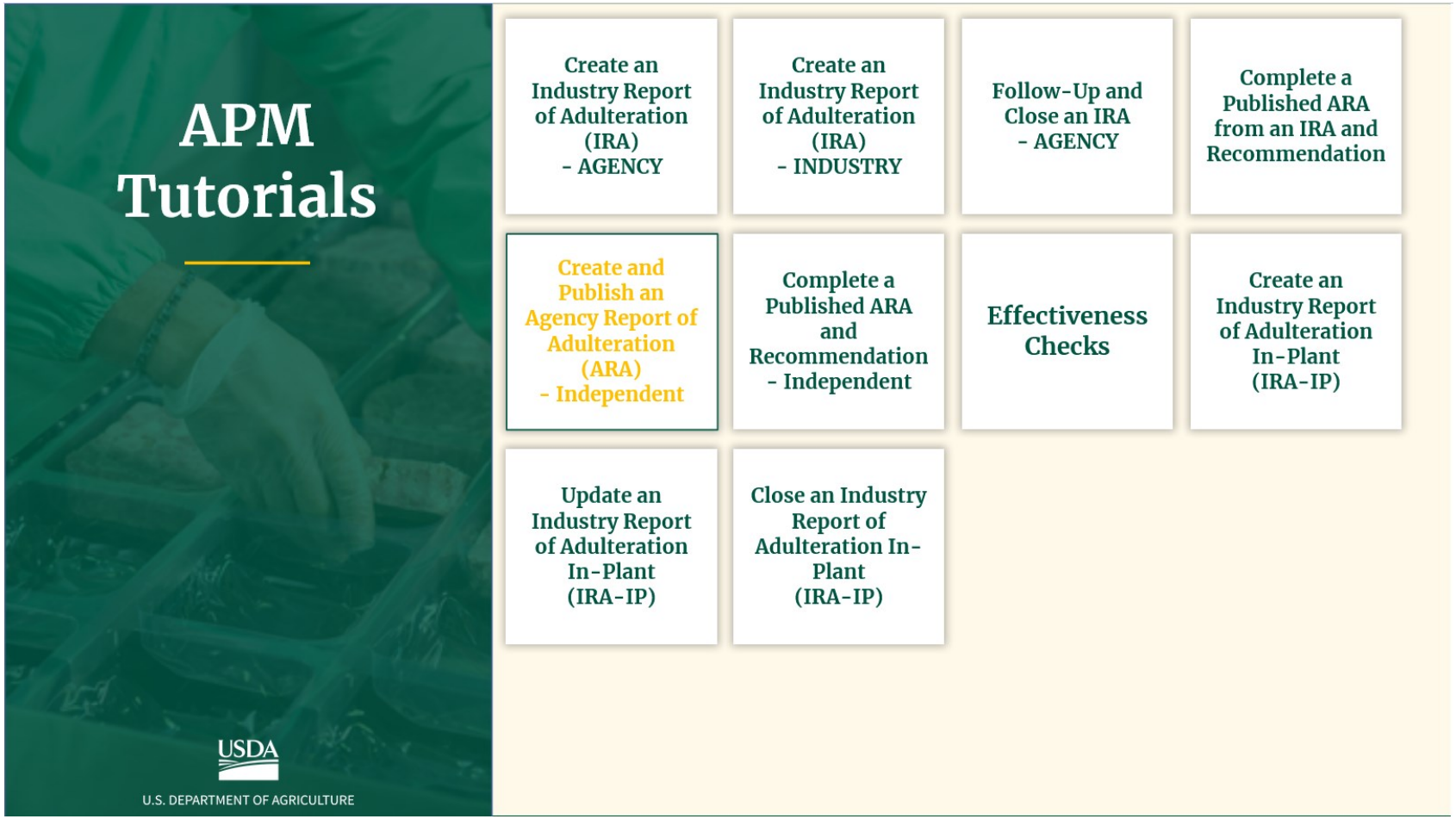
Determining Need For Recall – 6

- Continue…

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.

Determining Need For Recall - 7





Determining Need For Recall – 8

- While investigating and assessing potential adulteration and misbranding events, OFO personnel may coordinate with other program areas, as necessary, to gain a full understanding of the event:

1. Collecting and verifying information about suspect products and ingredients;
2. Documenting a chronology of events;
3. Contacting the company that manufactures or distributes the product for additional information;
4. Communicating with FSIS field inspection and FSIS enforcement personnel;
5. Interviewing any consumer who allegedly became ill or was injured from eating regulated product;
6. Collecting and submitting product samples for analysis;
7. Contacting other agencies, State and local health departments, or coordinating with the Office of International Coordination (OIC) to contact foreign governments;
8. Coordinating with Office of Public Health Science (OPHS) during the analysis of any available epidemiological data; and
9. Reviewing supporting documentation and evidence (e.g., SSOP , HACCP and production records, risk assessments, etc.).

Determining Need For Recall – 9

- RMTAD is to assess all information gathered during the preliminary inquiry and determines whether
  1. the Event Assessment Committee should be engaged. If so, RMTAD is:
     - to provide the relevant materials to committee members;
     - to facilitate committee deliberations and ensure the appropriate disposition of products;
     - to ensure that firms have an opportunity to submit any mitigating information that the Committee will consider.
  2. **Or** further recall consideration is unnecessary.

Event Assessment Committee – 1

Primary Members

Office of Field Operations
Recall Management and Technical Analysis Division (RMTAD) – Gathers and analyzes information regarding escalated events. Calls a committee meeting, when necessary, and distributes information about the escalated event to committee members. RMTAD invites other FSIS program areas to assist as necessary.

Office of Policy and Program Development (OPPD) Provides the statutory basis for each action recommended by the Committee and addresses any policy questions relevant to the event being assessed.

Office of Public Health Science (OPHS)
Addresses microbiological, epidemiological (including CCMS queries), and other scientific issues associated with the event. OPHS also assesses the public health impact of the event. If the Committee recommends a recall, OPHS proposes the classification.

Office of Investigation, Enforcement, and Audit (OIEA) Assists OFO upon request. May lead preliminary inquiries when products in commerce that did not originate from an official establishment or involves imported products. OIEA also conducts investigations of alleged criminal violations.

Office of Public Affairs and Consumer Education (OPACE) Congressional and Public Affairs Staff (CPAS)
Gathers information and generates a Recall Release (Class I and II) or Recall Notification Report (Class III) if there is a recall. When appropriate, OPACE generates a PHA. OPACE ensures that information contained in the Press Release is accurate.

Reporting Office (OFO or OIEA)
Clarifies and explains to the Committee the information collected during the preliminary inquiry.

May also consist of other **supporting members** at RMTAD's request.

Event Assessment Committee – 2

Deliberations

- The Event Assessment Committee meets **when an adulteration or misbranding event** requires the committee's consideration, including the applicable statutory requirements to determine the Agency's best approach for addressing the event.

Event Assessment Committee – 3

Deliberations

- When determining whether to recommend a product recall, they seek the answers to the following questions:

  - Does FSIS have evidence to demonstrate that the product in question is adulterated or misbranded under the FMIA, PPIA, or EPIA?
  - Does any of the product in question remain in commerce, available for sale or use?

If the answers are both "yes," the Committee should recommend a recall. However, if the Committee is unable to identify the responsible party for the product or cannot readily identify the scope of the issue, the Committee should recommend a PHA

Event Assessment Committee – 4

Deliberations

1. If recall is **not recommended**, RMTAD is to document the results of the preliminary inquiry in a memorandum and upload it to the ARA.

2. If recall is **recommended**, it is they will also determine the appropriate recall classification.

Event Assessment Committee –5

Deliberations

When the committee **recommends a recall**,

- RMTAD – contact the firm and to present the recommendation.
- During the discussion, the Committee provides the recalling firm with an opportunity to present information about the hazard or concern associated with the affected product.
- FSIS expects the firm to have its recall strategy available upon request, including how it intends to notify and instruct its consignees to retrieve or dispose of the recalled product.

Announcing The Recall – 1

Action by Firm:

- Inform the committee whether they accept the recall recommendation or not.

Announcing The Recall - 2

Firm

- Issue recall notice to consignees
- Notify public if needed
- Provide FSIS with distribution list

FSIS

- Recall Recommendation Memo
- Recall Effectiveness Checks

Event Assessment Committee – 6

Recall Recommendation :

- RMTAD is to submit a Recall Recommendation in the form of a memo for approval by the OFO AA or designee, including:

    1. The reason for the recall, including why there is a reason to believe that the product is adulterated or misbranded and the applicable statutory citations;
    2. An explanation of how, when, and by whom the problem was discovered;
    3. The recall classification (i.e., Class I, Class II, or Class III);

Event Assessment Committee – 7

Recall Recommendation :

4. The ability of distributors, consumers, or users of the product to identify the products covered by the recall;
5. How the scope of the recall was determined; and
6. The estimated amount of recalled product in distribution (the amount of product subject to recall that was distributed).

DO is to assign a Recall Officer (RO) to begin coordinating effectiveness checks, consistent with the class of the recall, and is responsible for directing the activities of FSIS field personnel.

Announcing The Recall – 3

Firm

No Recall Initiated

FSIS

Detain products found in commerce

Petition the Department of Justice to seize these products on behalf of FSIS.

Public Health Alert (PHA):

- adulterated or misbranded product has been shipped;
- that the firm has declined to recall the product,
- and that the Agency is detaining product in commerce.

Announcing The Recall – 4

Firm

Adequately recovering adulterated or misbranded product from commerce (e.g., firm proactively notified customers to return, destroy product, etc.)

FSIS

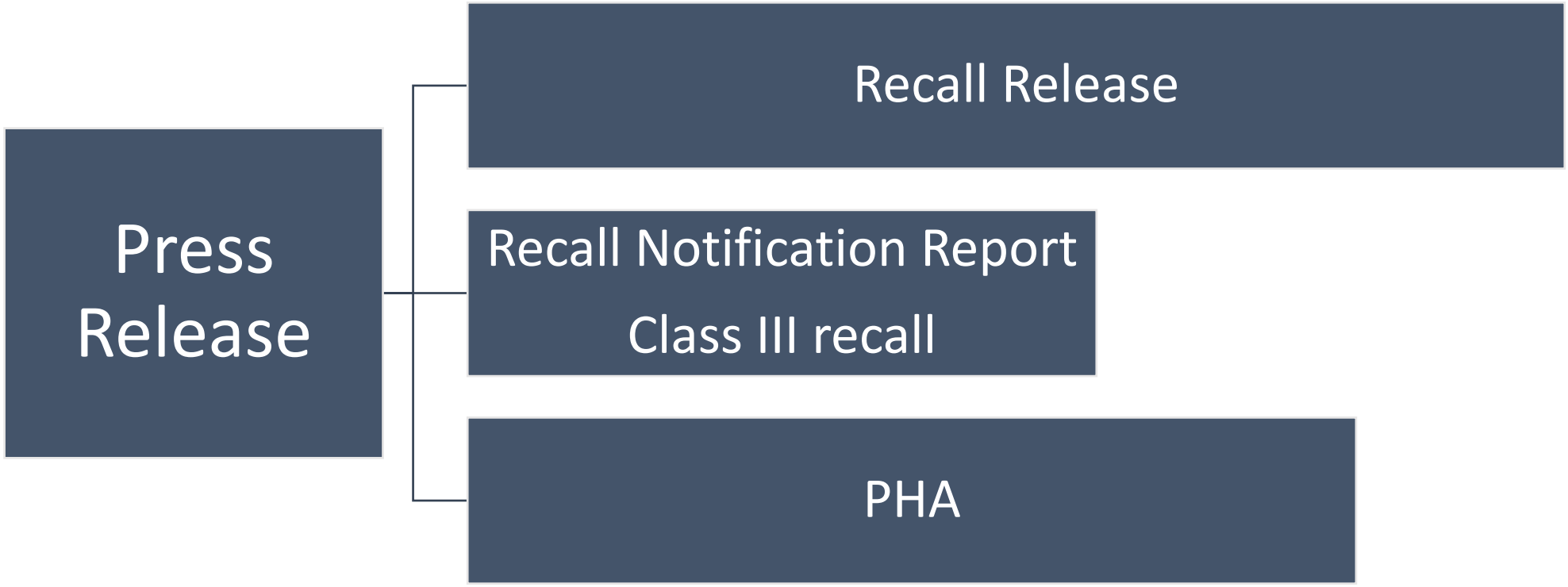
Recall Release

OR

PHA

Case by Case

Announcing The Recall – 5



https://www.fsis.usda.gov/recalls

Announcing The Recall – 6

Recall Release:

1. Identify the firm that produced the product;
2. Clearly describe the product involved, along with any identifying marks or codes;
3. Explain the reason for the recall, including the reason the product is adulterated or misbranded and how the problem was discovered, and describe the risks involved in consuming the product;
4. When possible, and without slowing the public notification of the recall, FSIS will post an electronic picture of the product label that clearly describes the product to the public;

Announcing The Recall – 7

Recall Release:

5. Instruct the public on how to properly handle the product if consumers have it in their possession, including specific recommendations for affected consumers when the product contains an allergen;

6. Provide the name and telephone number of a company contact for consumers and media to call with any questions; and

7. Provide general information about the product's known destination. For example, "Ham and turkey products were distributed to retail stores and institutions in the States of…."

Announcing The Recall – 8

Public Notification of Recalled State- Inspected or Foreign Product:

1. When adulterated or misbranded product produced by an establishment under **a State's Meat and Poultry Inspection (MPI) program** enters intrastate commerce, **FSIS will expect the State's MPI program to take the lead on mitigating these issues and notifying the public**, when necessary, as part of its agreement with FSIS to administer an MPI program at least equal to that of FSIS.

Announcing The Recall – 9

Public Heath Alerts (PHAs):

1. **to inform the public of specific public health risks posed by products** in commerce or in the possession of end consumers
   - when there is no product recall
   - or when available product has already been recovered from commerce and controlled prior to FSIS notification or engagement but may still pose a risk to consumers at their homes
   - or when firms decline to initiate a recall upon FSIS recommendation.
2. The contents of the PHAs are very similar with recall release.

Announcing The Recall – 10

Retail Consignee Lists

1. For every Class I recall, the RO, or designee, use the PHIS-reporting feature to generate the retail consignee list, including the name, street address, city, and state of each retail consignee.
2. Consignees may not be identified all at once. Updated distribution information are to updated in PHIS as it becomes available.
3. FSIS post the list of the retail consignee lists along with the recall release on the FSIS website.

Effectiveness Checks – 1

General:

- Each official establishment is required to develop written procedures in accordance with 9 CFR 418.3.

- FSIS personnel are to conduct effectiveness checks to verify that the recalling firm is implementing their written recall procedures to notify and advise the consignees to retrieve, and control recalled product and that the consignees have responded accordingly.

Effectiveness Checks – 2

General:

- FSIS will conduct effectiveness checks throughout the distribution chain.

- Depending on the availability of Agency personnel and the type of firm conducting the recall,
  - EIAOs or EIAO trained PHV - an official establishment
  - CID Investigators - an importer or otherwise not an FSIS-inspected establishment.

Effectiveness Checks – 3

General:

- Personnel assigned to conduct recall effectiveness checks interview the consignees' representative.

- During the effectiveness checks, if FSIS personnel discover that a consignee is not notified of the recall or properly dispose of recalled products, contact the RO and detain any recalled products available for sale, if necessary.

Effectiveness Checks – 4

Field Recall Responsibilities Upon Notice Of A Recall:

I. The RO is to:
   1. Serve as the primary point of contact for the recalling firm;
   2. Immediately request that the recalling firm provide information regarding product distribution, including the names, addresses, and phone numbers of its consignees;
   3. Obtain a copy of any notice of recall issued by the firm to its consignees or to the public. Upload a copy of the written recall notice to the APM Recall case.

Effectiveness Checks – 5

Field Recall Responsibilities Upon Notice Of A Recall:

I. The RO is to:
4. Upload a copy of the written recall notice to the APM Recall case. If the recall notice is incomplete or inaccurate, the RO is to immediately call the firm and explain the reasons why the notification or instructions are inadequate and follow up the call with a letter to the firm and a courtesy copy to RMTAD;
5. Inquire how the firm plans to control recovered product; and
6. Inquire how the firm plans to handle product disposition.

Effectiveness Checks – 6

RO Responsibilities For Coordinating FSIS Personnel Activities During Effectiveness Checks:

I. The RO is to:
   1. Coordinate effectiveness checks and direct the activities of FSIS personnel;
   2. Determine product distribution and request assistance from Assisting Offices (AOs) in Districts/ Regions where product was distributed.
   3. Eliminate duplicate consignee listings and upload the list of consignees into APM;
   4. Determine and assign the appropriate number and criteria of effectiveness checks in APM that will be performed by on-site verification and by telephone per Directive 8080.1 .

Effectiveness Checks – 7

RO Responsibilities For Coordinating FSIS Personnel Activities During Effectiveness Checks:

- Additional consignees identified after FSIS has started conducting effectiveness checks will be added in the APM
- These consignees will be randomly selected for recall effective checks until the number of checks are reached as defined in Directive 8080.1.

Effectiveness Checks – 8

Consignee List

FSIS 5020-4	FSIS Recall Distribution Information Template:							
(7/27/2021)	Please enter consignee information in the following template. Items with (*) are required. Either a phone number or email for each location is required (**)							
OMB Number: 0583-0135 Expiration Date: 9/30/2024	Establishment number on Product	Product Received by Consignee	Consignee Name*	Street Address Line 1*	Street Address Line 2	City*	State*	Zip Code (5 digit)*

Type of Business* (select from dropdown options)	If Type of Business is "Other", enter description	Distributor product was received from	Amount received in pounds (numerical values only)	Email**	Phone Number**

Comments (4,000 character limit)	Contact Person First Name	Contact Person Last Name	Contact Person Title	Contact Person Phone	Contact Person Email

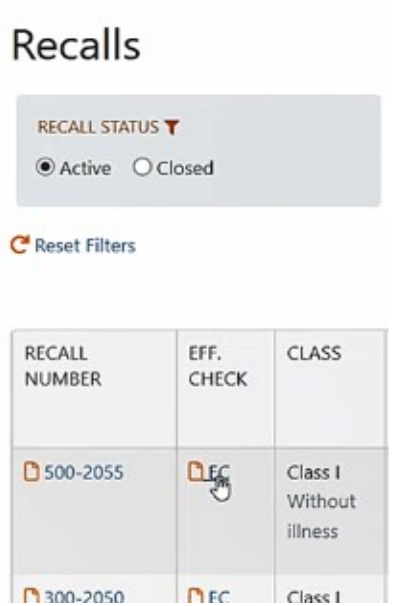
Effectiveness Checks – 9

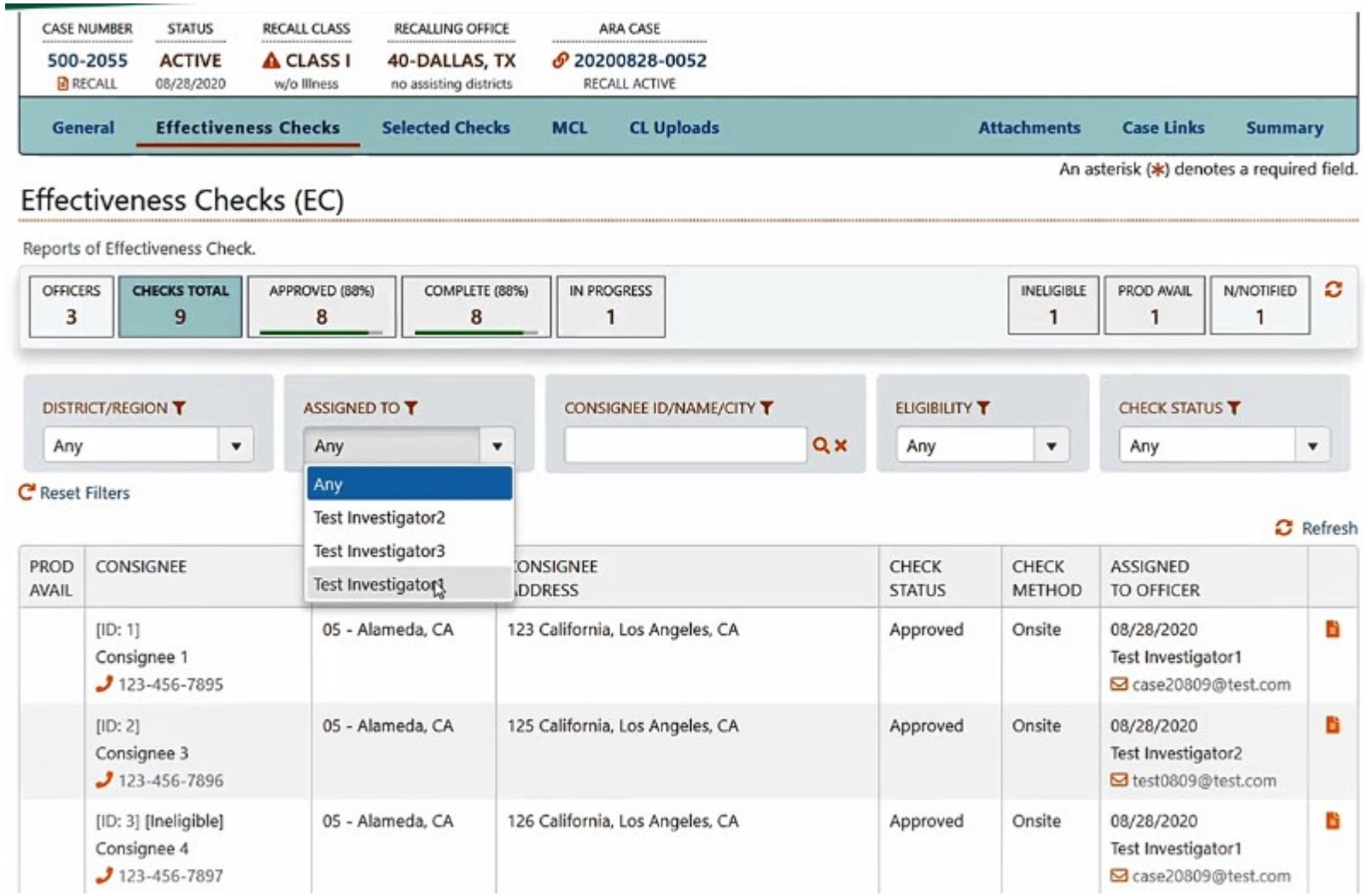
<u>FSIS Personnel Responsibilities For Conducting Effectiveness Checks:</u>

- Prepare to perform your recall effectiveness checks!

Effectiveness Checks – 10

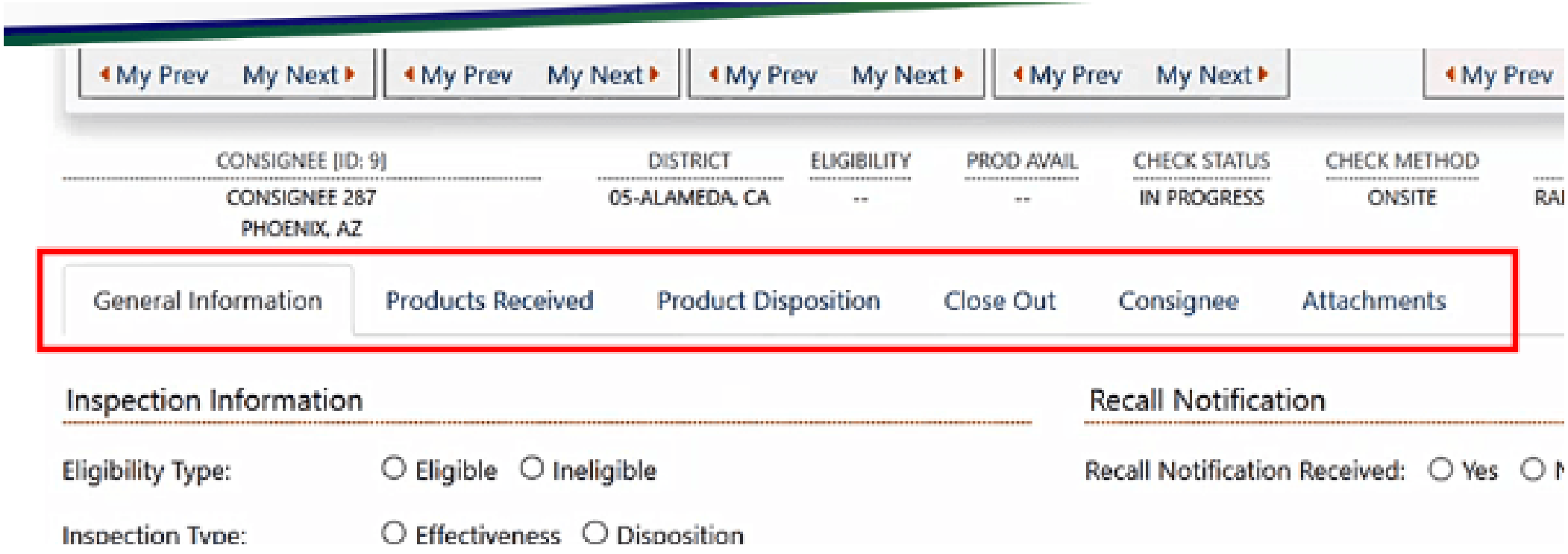
To access recall effectiveness checks assignment on APM





Effectiveness Checks – 11

What information are you gathering during performance of checks?



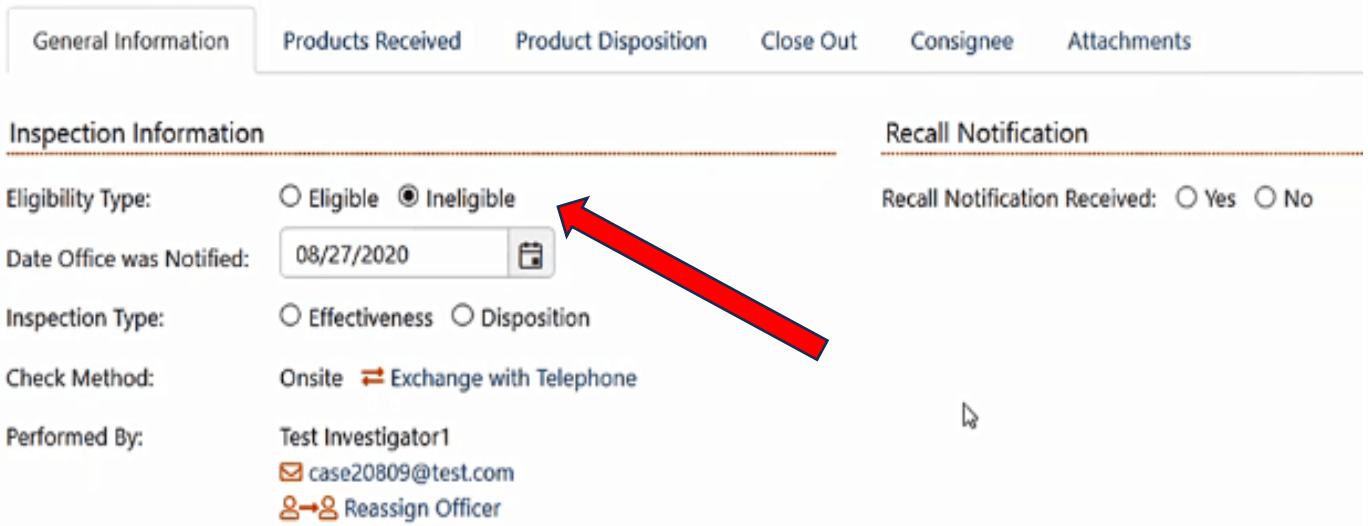
Save your entries often!

Effectiveness Checks – 12

FSIS Personnel Responsibilities For Conducting Effectiveness Checks:

- **Purpose: to determine whether they were notified of the recall** and **have removed the recalled product from commerce** (e.g., located, segregated, and appropriately controlled affected product pending disposition);

Effectiveness Checks – 13

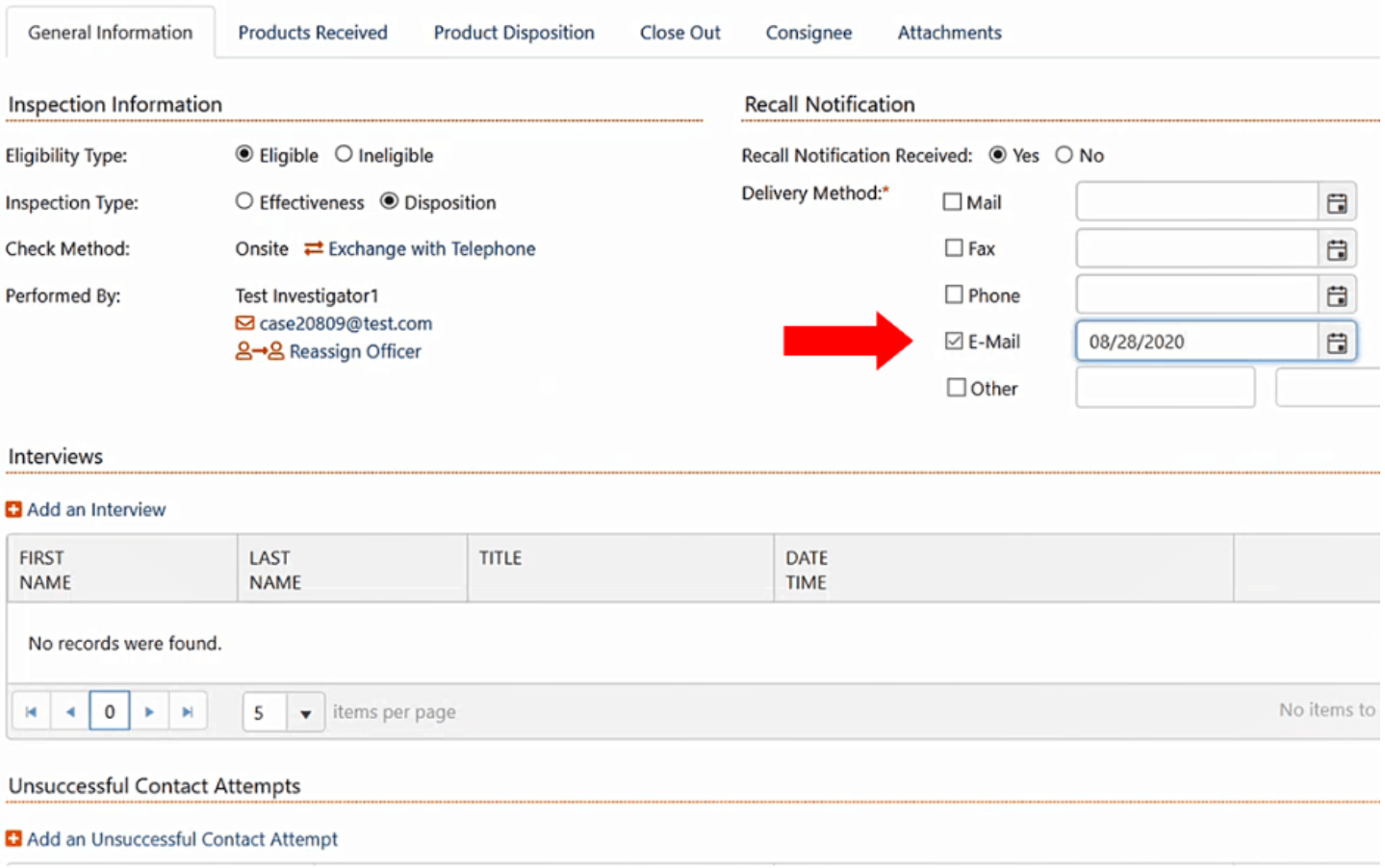


Ineligible Check is when FSIS personnel are **unable to perform an effectiveness check** (e.g., a consignee selected for an effectiveness check did not receive the recalled product or is no longer in business).

- contact the RO or AO as soon as possible so that a replacement effectiveness check can be selected and assigned.
- **Date** of the DO was notified about ineligible check

The RO will use APM to select a replacement effectiveness check random selection or a biased replacement consignee. After making this substitution, APM will designate this effectiveness check to the applicable AO for assignment.

Effectiveness Checks -14



Eligible checks:

- **Date of recall notification received**
- **Inspection Type**:
  - Effectiveness: Phone
  - Disposition: On-site
- Check Method: what was assigned
- **Recall Notification:** was the location notified of the recall? If so, How and when was notified?
- **Obtain a copy of the notification**
- **Interview:**
  - Date and Time
  - Name
  - Title

Effectiveness Checks – 15

- **Unsuccessful contact attempts:**
  - Contact number
  - Date and time
  - Comments

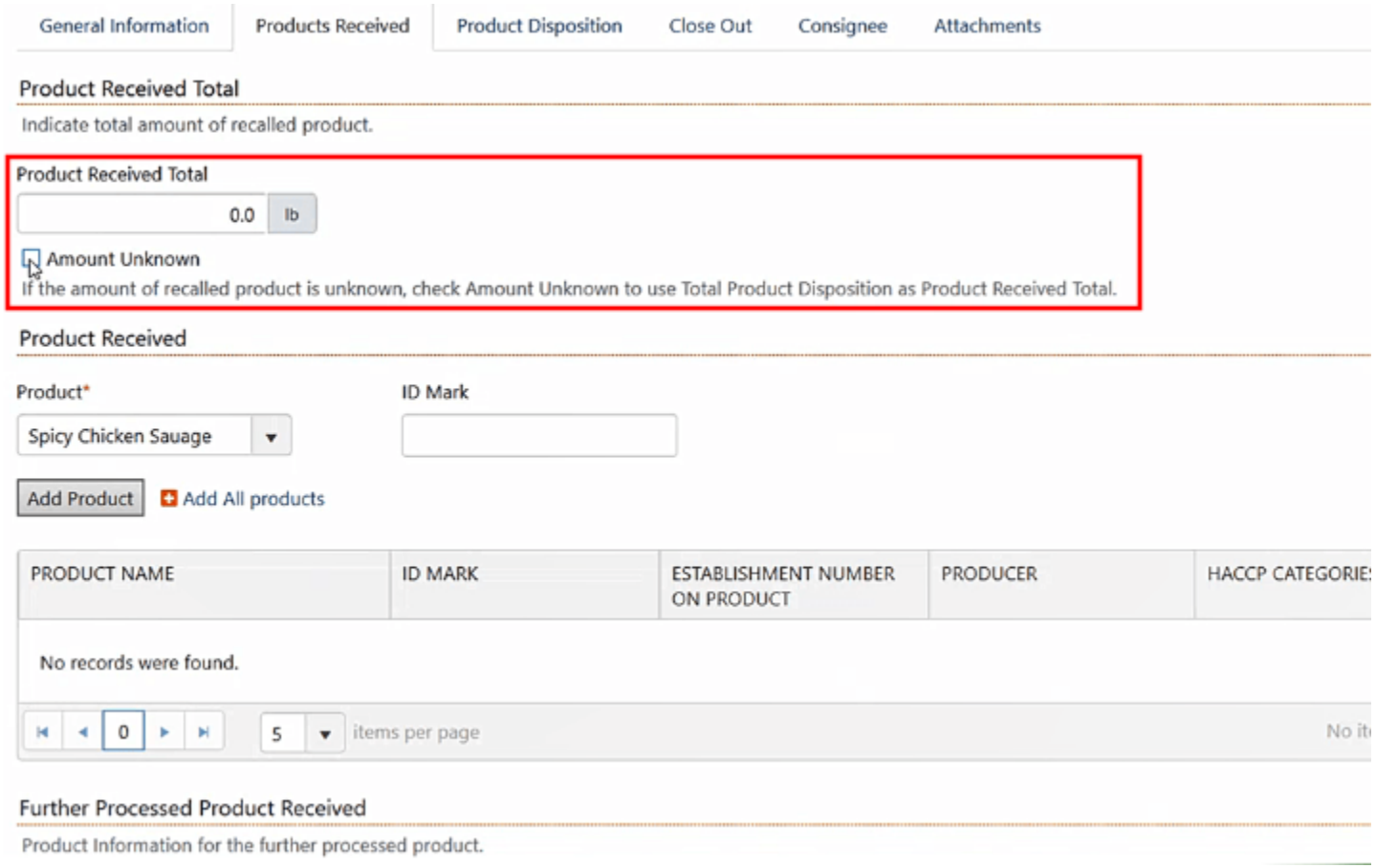
Unsuccessful Contact Attempts

Add an Unsuccessful Contact Attempt

CONSIGNEE PHONE NUMBER	DATE TIME	COMMENTS	
888-888-8888	08/31/2020 08:00 AM	Unable to leave message	

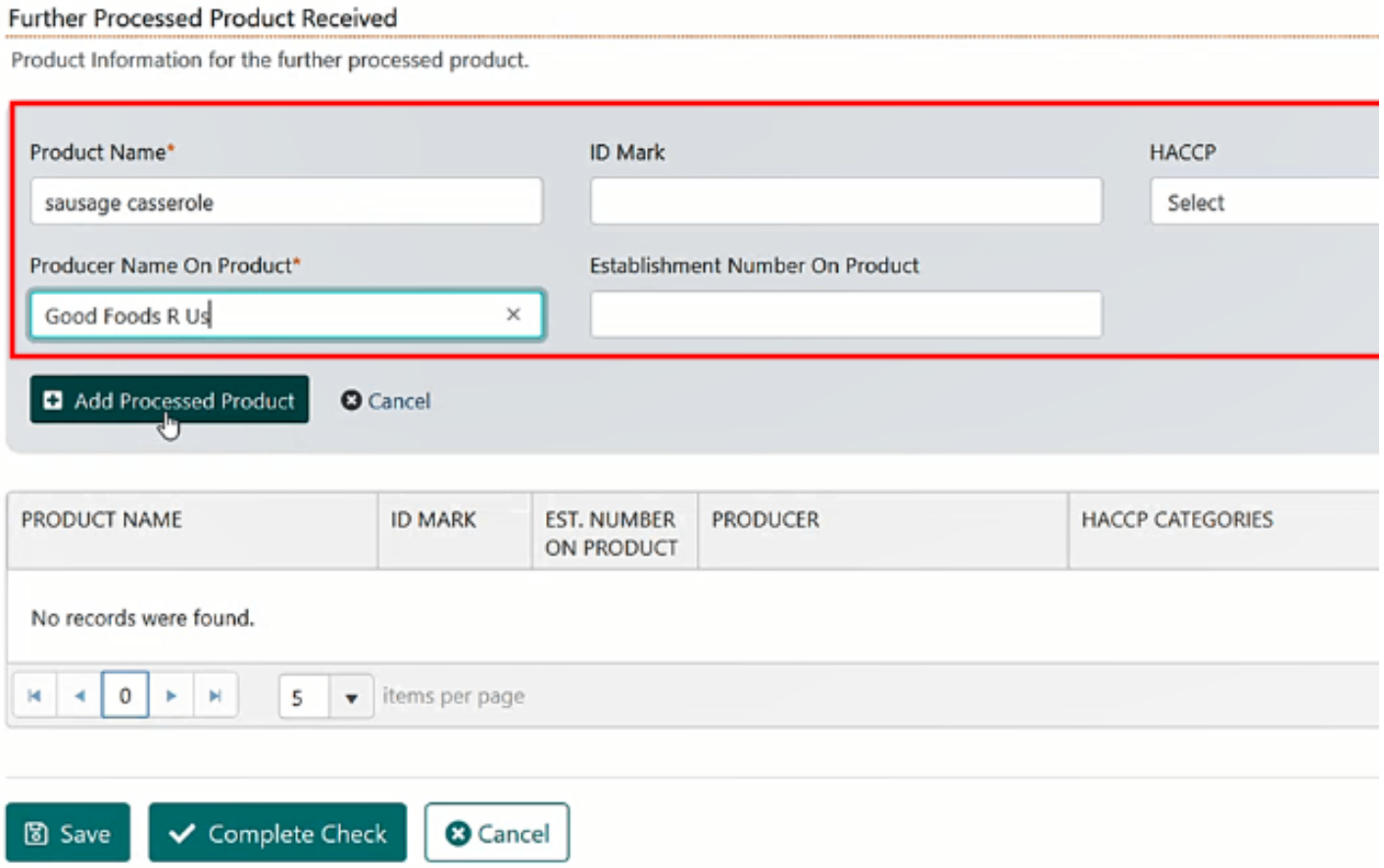
1 5 items per page 1 -

Effectiveness Checks – 16



- **Amount of recalled product received**
- **Name of products received**

Effectiveness Checks – 17



- **Further Processed Product Received : i**f the location received further processed product, or product that was included in additional products not listed in the recall scope
- Contact RO immediately
- Gather product information

Effectiveness Checks – 18

Product disposition total quantities and their verification procedures.

Product available for Sale

○ Yes ◉ No

Total Amount of Product Identified

The amount of product identified during this check that should be included in the total amount of product identified for the entire recall. Consider whether the same product may be counted for other locations, such as a distributor or consignee of this location.

Total Amount of Product Identified

10.0 lb

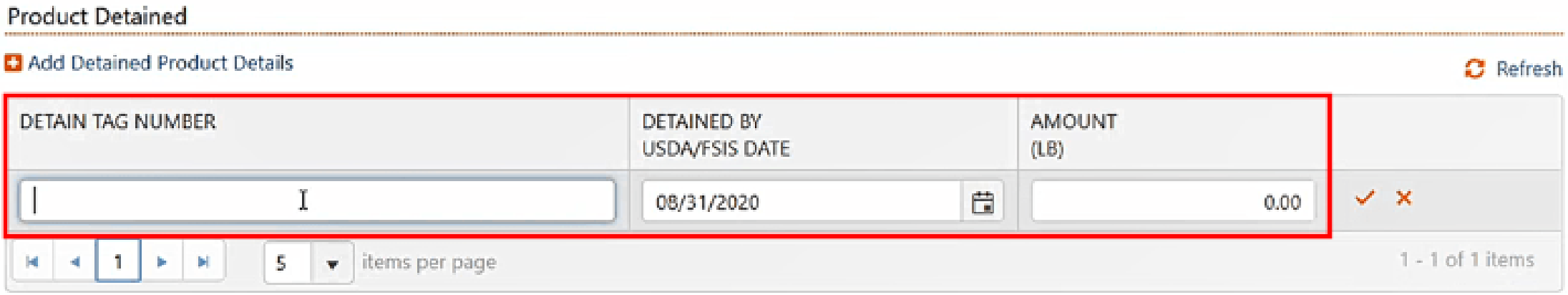
PRODUCT DISPOSITION	AMOUNT	VERIFICATION PROCEDURES
☐ Sold Amount	lb	
☐ Consumed Amount	lb	
☐ Further Distributed Amount	lb	
☐ On Hand Amount	lb	
☑ Denatured/Destroyed/Characterized Amount	10.0 lb	☐ Observation ☑ Records ☐ Statements
☐ Returned to Recalling Firm Amount	lb	
TOTAL:	10.0 lb	

- **Product available for sale:** verify during your on-site check.
- Upon recall notification, did the consignee find any recalled products?
  - If so, how much?
  - What did they do with the products? Were disposition instructions followed?
  - **Obtain a copy of disposition record, if possible.**
- Verification procedures

Effectiveness Checks – 19

On-site check, detained product info, if any:

- Detain tag number
- Date
- Detained amount

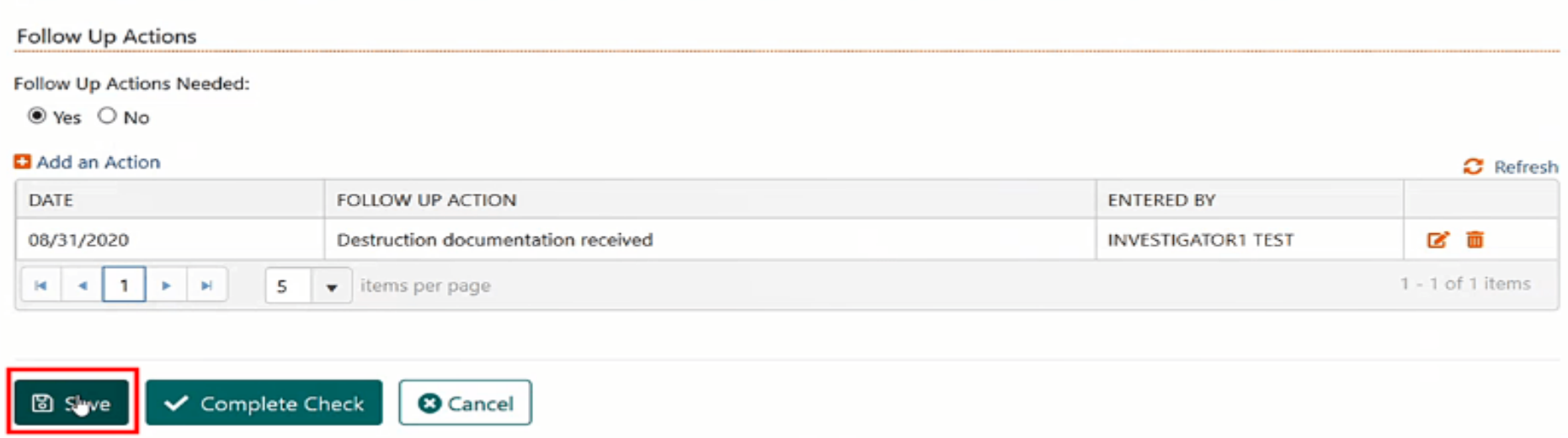


Effectiveness Checks -20

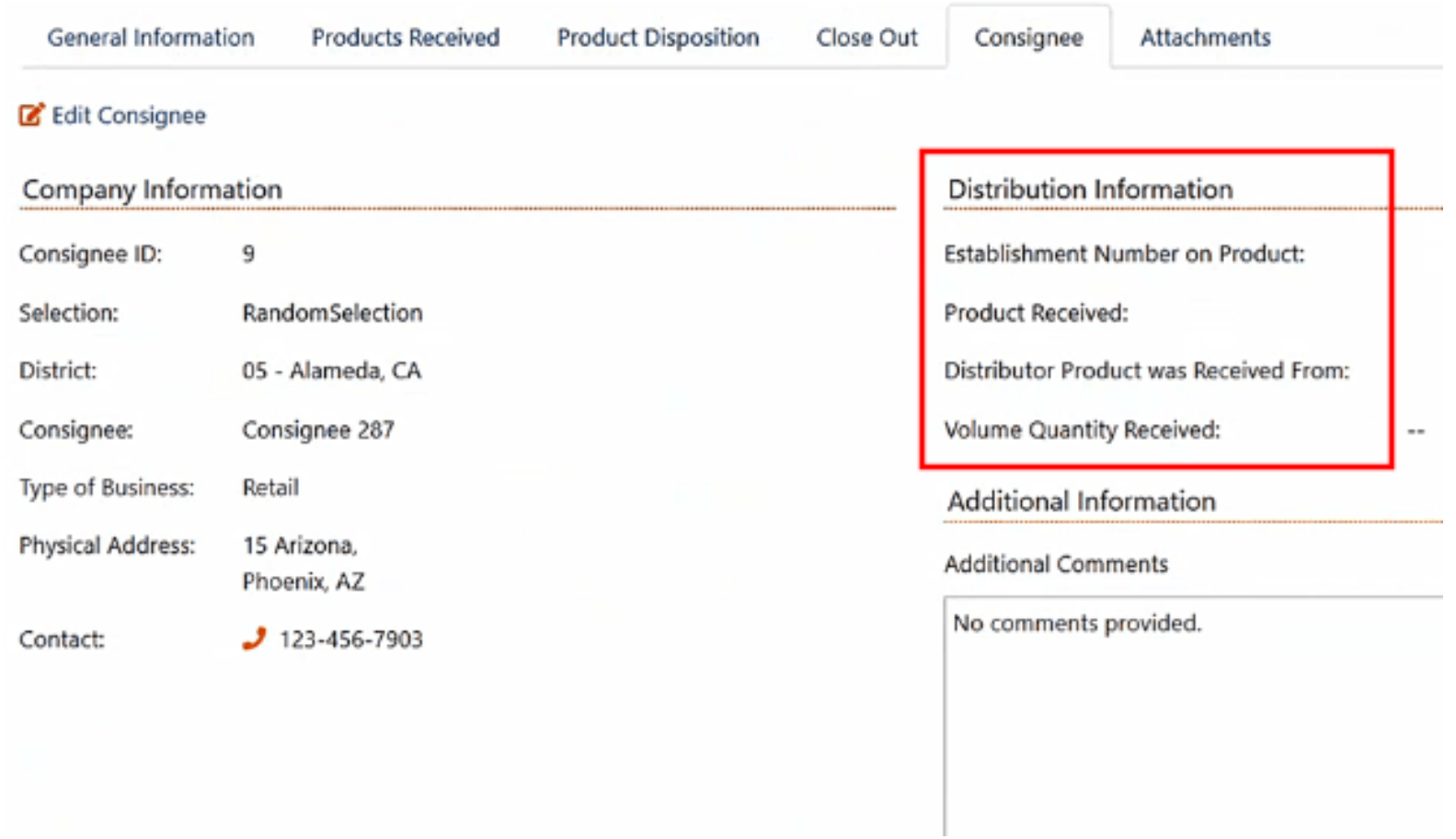
In cases where product disposition is still pending, request that the location provide documentation, when it becomes available, document this on the Report of Effectiveness Check in APM as a follow-up.

If follow up actions are needed:

- Date
- Actions
- Who



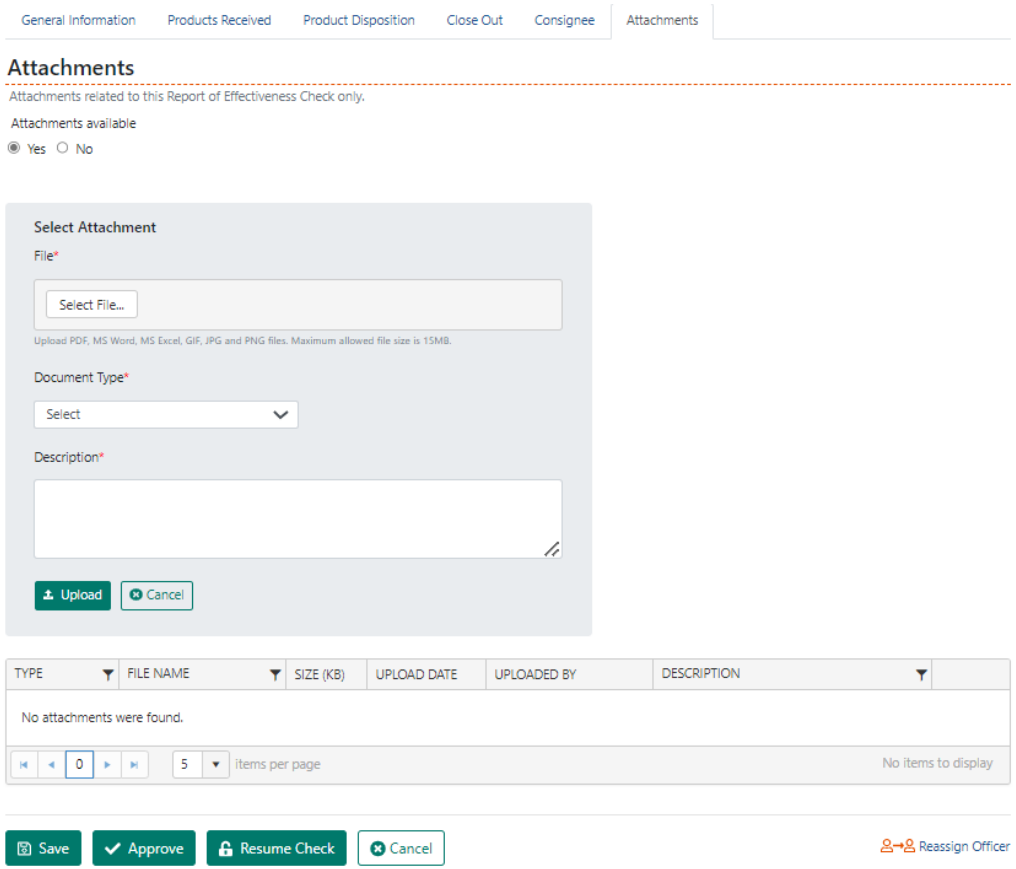
Effectiveness Checks – 21

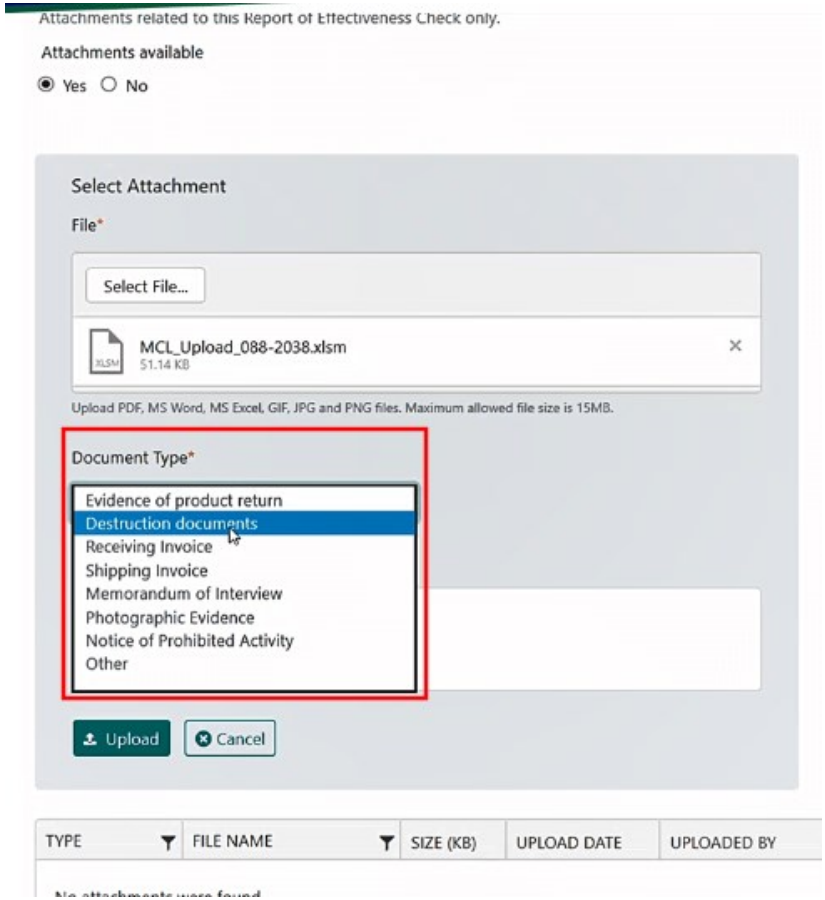


Consignee info

Effectiveness Checks -22

Obtain useful records





Effectiveness Checks - 23

Useful items to take for On-site recall effectiveness checks:

- Consignee information
- Copy of recall press release including attachment
- Items to take notes for your interview
- Identification : business card, badge
- Work phone
- Slip resistant shoes
- Flashlight
- Freezer jacket
- And more…

Effectiveness Checks – 24

General process:

- Check product shelf
- Introduce yourself
- Ask to speak with recall contact personnel
- Inform the purpose of the check
- Interview regarding recall and obtain records
- Thank them
- Check storage

Effectiveness Checks – 25

FSIS Personnel Responsibilities For Conducting Effectiveness Checks:

- FSIS **finds recalled product offered for sale or use in commerce:**
    - E.g., by checking store shelves, storage areas, or freezers during on-site visits.
    - Photo evidences
    - **detain** any recalled product found available for sale or use in accordance with FSIS Directive 8410.1; and
    - **Inquire** how the firm plans to control recovered product; and handle product disposition.
    - Report to the RO.

Effectiveness Checks – 26

Continue…

- The Agency will also consider whether the recalling establishment clearly communicated the recall notification to its consignees and whether those consignees adequately relayed the notification down through the distribution chain.
- When a trend is identified, the RO may assign additional effectiveness checks by biased selection.
- When FSIS determines that an establishment has not taken responsibility to remove or control adulterated, misbranded, or other unsafe product in commerce or to advise its consignees of product that is subject to recall, it **may issue prohibited activity notices to the establishment or firm –** FSIS Directive 8410.1.

Effectiveness Checks – 27

Continue…

- Prohibited Activity:
  - the violating firm may be **a recalling firm** or **their consignee** that failed to adequately notify downstream consignees, request information on how the firm will ensure all consignees are notified of the recall;
  - or it may be a consignee that received adequate notification but failed to follow the recalling firm's instructions to remove product from sale or use.
  - If necessary, the RO is to refer all instances of prohibited activity to OIEA/CID for investigation and enforcement.

Effectiveness Checks – 28

Continued…

- Prohibited Activity Notice describes:
  - the circumstances of any prohibited acts and
  - the potential enforcement or criminal action the Agency may pursue.

- **When you observe any instances involving recalled product found available for sale or use, notify the recalling firm immediately through RO.**

Effectiveness Checks – 29

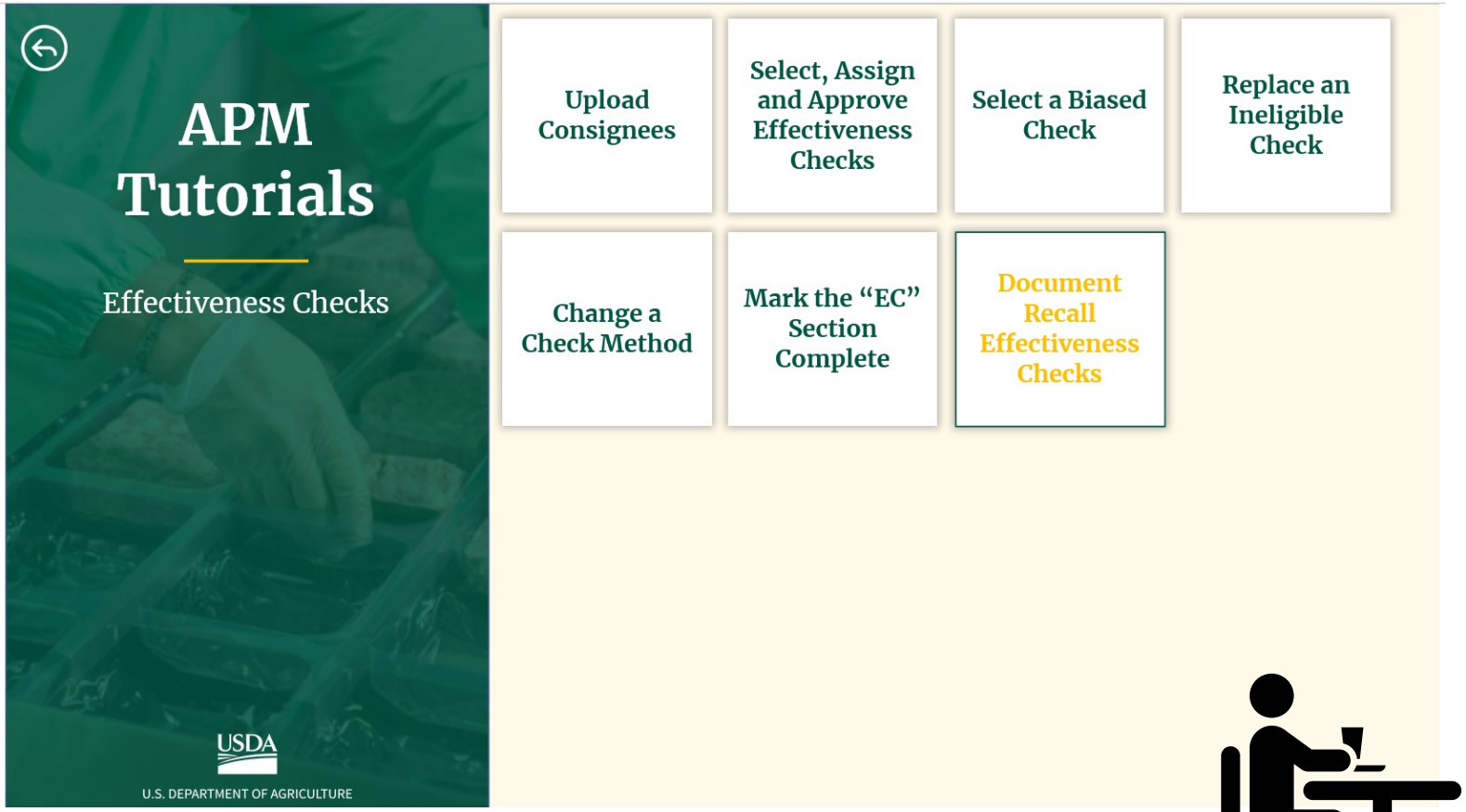
Continue…

- Record the effectiveness checks on the Report of Effectiveness Check in APM and submit the completed reports.

- Supervisors are to review and approve the completed checks, including determining whether any follow-up actions are needed for ineligible checks or locations that did not receive a recall notification.

Record recall effectiveness checks on APM

Please take the next 10 minutes to watch the “Document Recall Effectiveness Checks” tutorial video in PHIS Help



Effectiveness Checks – 30

RO Responsibilities For Reviewing Effectiveness Checks And Confirming The Firm's Control And Disposition Of The Product:

- The RO is to continually monitor recall effectiveness reports in APM.
- Analyze the information.
- If there is any pattern or trend that may suggest certain consignees were not contacted or any other issues that may result in an ineffective recall, contact the recalling firm and RMTAD.

Effectiveness Checks – 31

Continue…

- Maintain contact with the recalling firm
  a. Completed execution of the recall as planned;
  b. Controlled, recovered, or confirmed disposition of the product as planned; and
  c. Considers the recall closed.

- Obtain the recalling firm's request to close the recall either verbally or in writing

Effectiveness Checks – 32

The RO Determination On The Effectiveness Of The Recall:

- The outcome of the recall is deemed effective or ineffective based on the number of locations where products were found to be available for sale.

- Outcome of the recall might be determined prior to all the assigned recall effectiveness checks being completed; FSIS is to continue with all assigned checks even though a recall has been determined ineffective.

Closure and Post- Recall Assessment Report

Closure:

- The RO is to provide a memo to RMTAD with a request to close the recall and include the amount of product recovered, if any, and disposition.
- If the amount of product recovery or disposition is unknown, the memo is to include any available known product recovery or disposition information.
- The RO is to upload the memo to the APM Recall case.

Questions