

Meat and Poultry Recalls:

Process overview

Relevance



Objectives

Recalls defined

Process Overview

EIAO Role

Traceback

At the end of this module, you will be able to:

1. Identify the regulations relevant to recalls
2. State the EIAO's role in recalls
3. Complete FSIS Form 8400-4
4. Describe the methodology and purpose for:
 - collecting distribution and traceback information
 - conducting recall effectiveness checks given a scenario
 - conducting a product disposition verification given a recall scenario.

Resources

- Directives
 - **8080.1** – Recall of Meat & Poultry Products
 - **5100.2** – EIAO Responsibilities for Recalls/Consumer Complaints
 - **5000.8** – Verifying Requirements for Recall Procedures
 - **10,010.3** – Traceback Methods for *E. coli* 0157:H7
- Small Plant Recall Plan Guidebook
- Others:
 - 8091.1 – Procedures for Health Hazard Evaluation Board
 - 8080.3 – Foodborne Illness Investigations
 - 8410.1 – Detention and Seizure

Recalls
defined

Process
Overview

EIAO
Role

Traceback

TERMINOLOGY

Recalls Defined

- Recalls

- Voluntary removal from commerce
- Adulterated or misbranded product
- Initiated by manufacturer or distributor
 - May be requested by FSIS
- If company does not recall
 - FSIS may detain and seize product in commerce

Question: Adulterated or Misbranded

- Where do you find the legal definition of adulterated or misbranded product?

Answer: Adulterated or Misbranded

- Where do you find the legal definition of adulterated or misbranded product?
- 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)

Recall Classes

- 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

- Recall Depth
 - Consumer
 - Retail
 - HRI
 - Wholesale
- Scope
- Disposition



Terminology

- Recall Committee
- Health Hazard Evaluation Board (HHEB)
- Recall Management Technical Analysis Division (RMTAD)
 - Domestic and Imports
- Recall Officer (RO)

9 CFR 418 Recalls

- 418.2 Notification
 - Establishment must notify FSIS within 24 hours if reason to believe adulterated product entered commerce
- 418.3 Written Recall Procedures
 - Establishment must maintain written procedures specifying how to decide on recall and how it would be carried out
- 418.4 Records
 - Available for review and copying

In-plant Verification

- IPP verify that establishments have a written a recall procedure at least once per year using the “Other Inspection Requirements” task.

The image shows a screenshot of a software interface with two columns, labeled 16 and 17. Column 16 contains the following tasks: 'Operational SSOP Record Review :', 'SPS Verification :', 'Heat Treated-Shelf Stable HACCP :', and 'Food Defense - Shipping and Receiving :'. Column 17 contains: 'Operational SSOP Review and Observation :', 'Pre-Op SSOP Record Review :', 'Review of Establishment Data :', 'Other Inspection Requirements :', and 'Heat Treated-Shelf Stable HACCP :'. The 'Other Inspection Requirements :' task in column 17 is circled in red.

Recalls
defined

Process
Overview

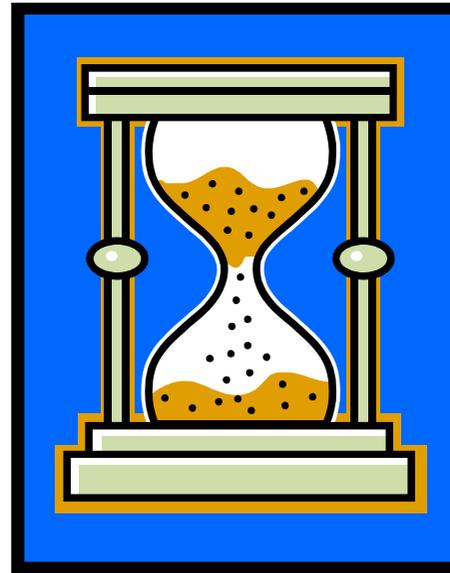
EIAO
Role

Traceback

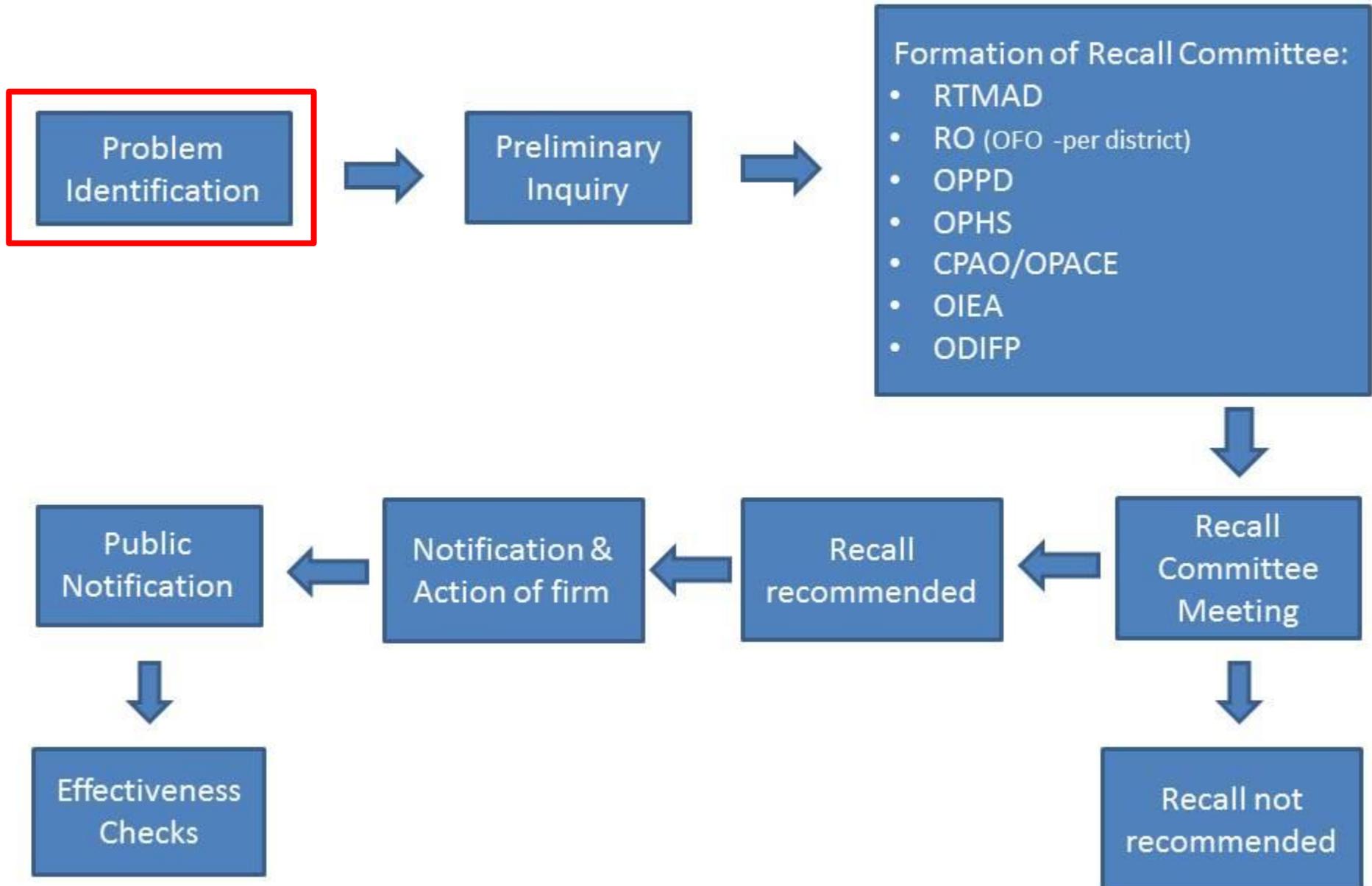
PROCESS OVERVIEW AND EIAO ROLE

Role of the EIAO

- Top priority over other activities
- Protect public health
- Conduct checks ASAP
- Communicate!



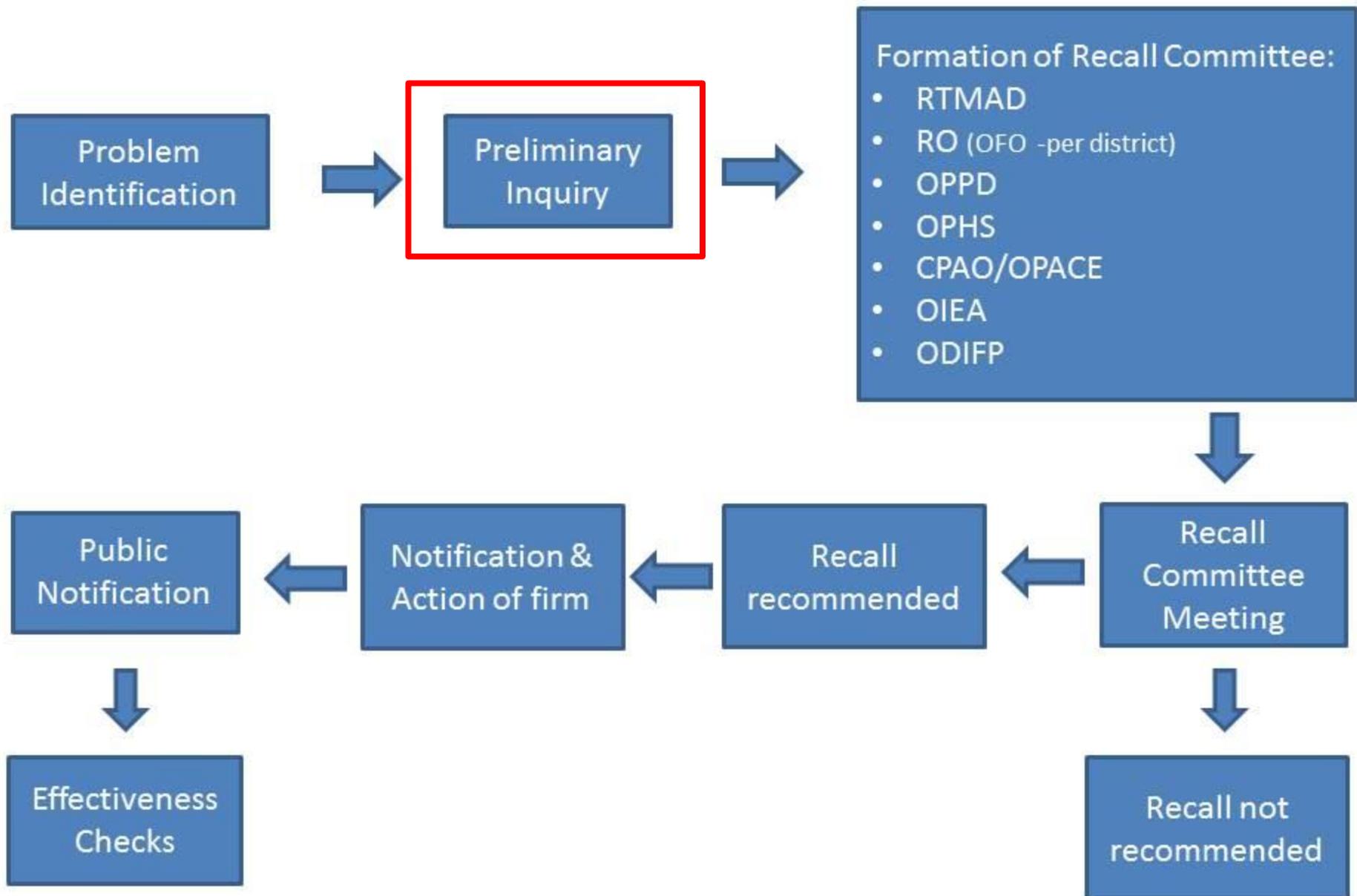
Recall Process: Overview



Recall Process

- Begins with Problem Identification:
 - In-plant inspectors
 - FSIS sampling
 - Establishment information
 - Outbreak investigations and other agencies
 - Consumer complaints (CCMS)

Recall Process: Overview



Recall Process

Preliminary Inquiry

- Recall Officer has overall responsibility for gathering information
 - Establishment Contact Information
 - Product Information
 - Develop a chronology of events
 - Communicate with FSIS personnel
 - Collect and submit samples
 - Contact other agencies

Role of the EIAO

Preliminary Inquiry

- Assist Recall Officer:
 - Identify if product is under controls
 - Recall worksheets
 - Communicate with establishment
 - Interview a consumer who became ill
 - Collect a product sample
 - Start FSA (analyze epidemiological data and review production or HACCP system records)
 - Participate on Recall Committee

RECALL WORKSHEET- FOR INTERNAL FSIS USE ONLY

(Include attachments, additional pages, label copies and flowcharts as necessary)

TODAY'S DATE: August 24, 2015

ESTABLISHMENT NUMBERS: EST. [REDACTED]

ESTABLISHMENT NAME: [REDACTED]

ADDRESS: [REDACTED]

COMPANY RECALL COORDINATOR (name, title, telephone) [REDACTED]

COMPANY MEDIA CONTACT (name, title, telephone) [REDACTED]

COMPANY CONSUMER CONTACT (name, title, telephone) [REDACTED]

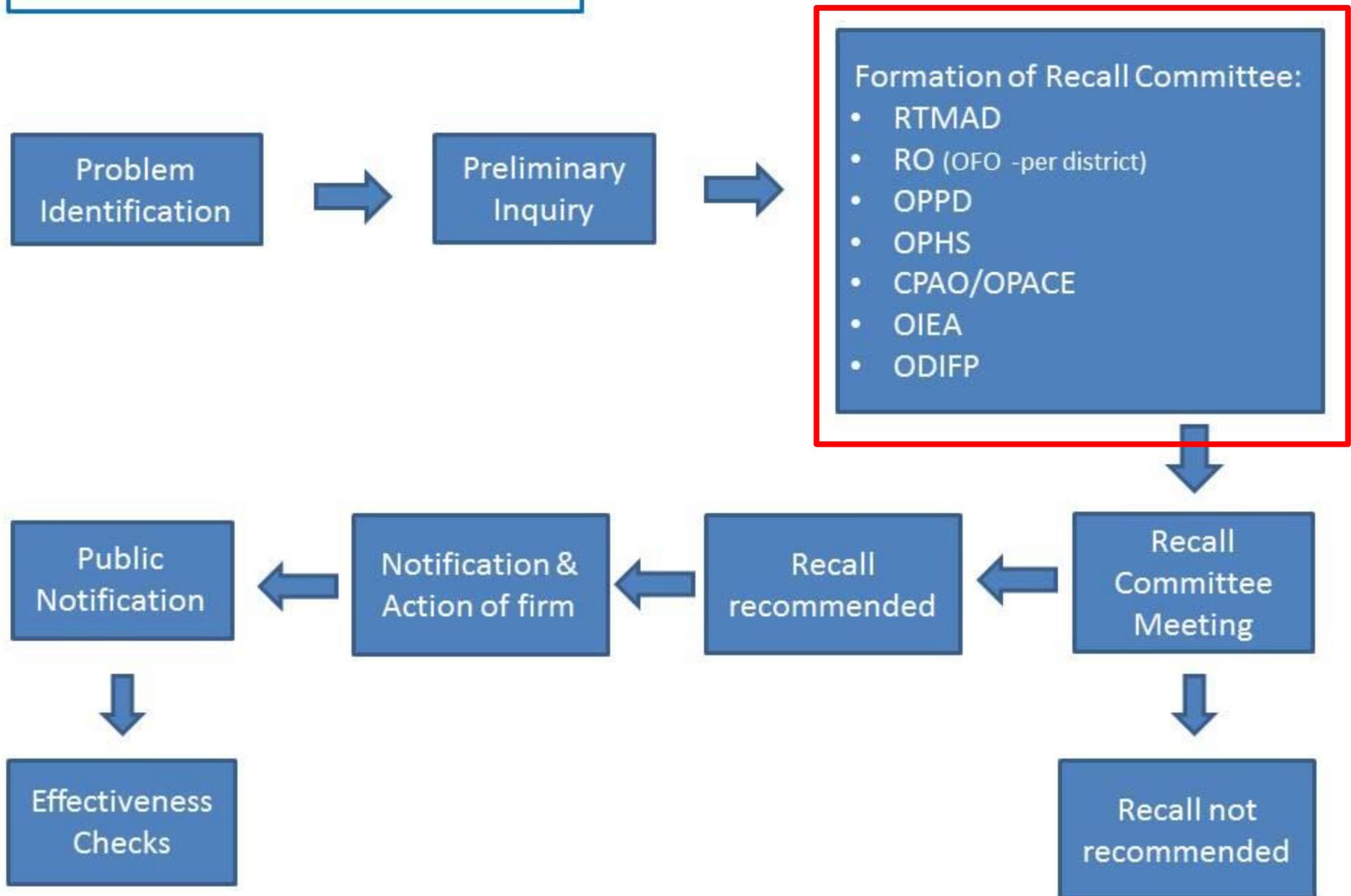
REASON FOR RECALL: Some packages are showing signs of spoilage in advance of the code date. The spoilage is consistent with lactic acid bacteria that are commonly known to affect products of this type, typically after the established shelf life. Although this is not a food safety issue, we decided a recall would be appropriate because we would like to retrieve all distributed product that is still within code.

IDENTIFY RECALLED PRODUCTS SEPARATELY BY:

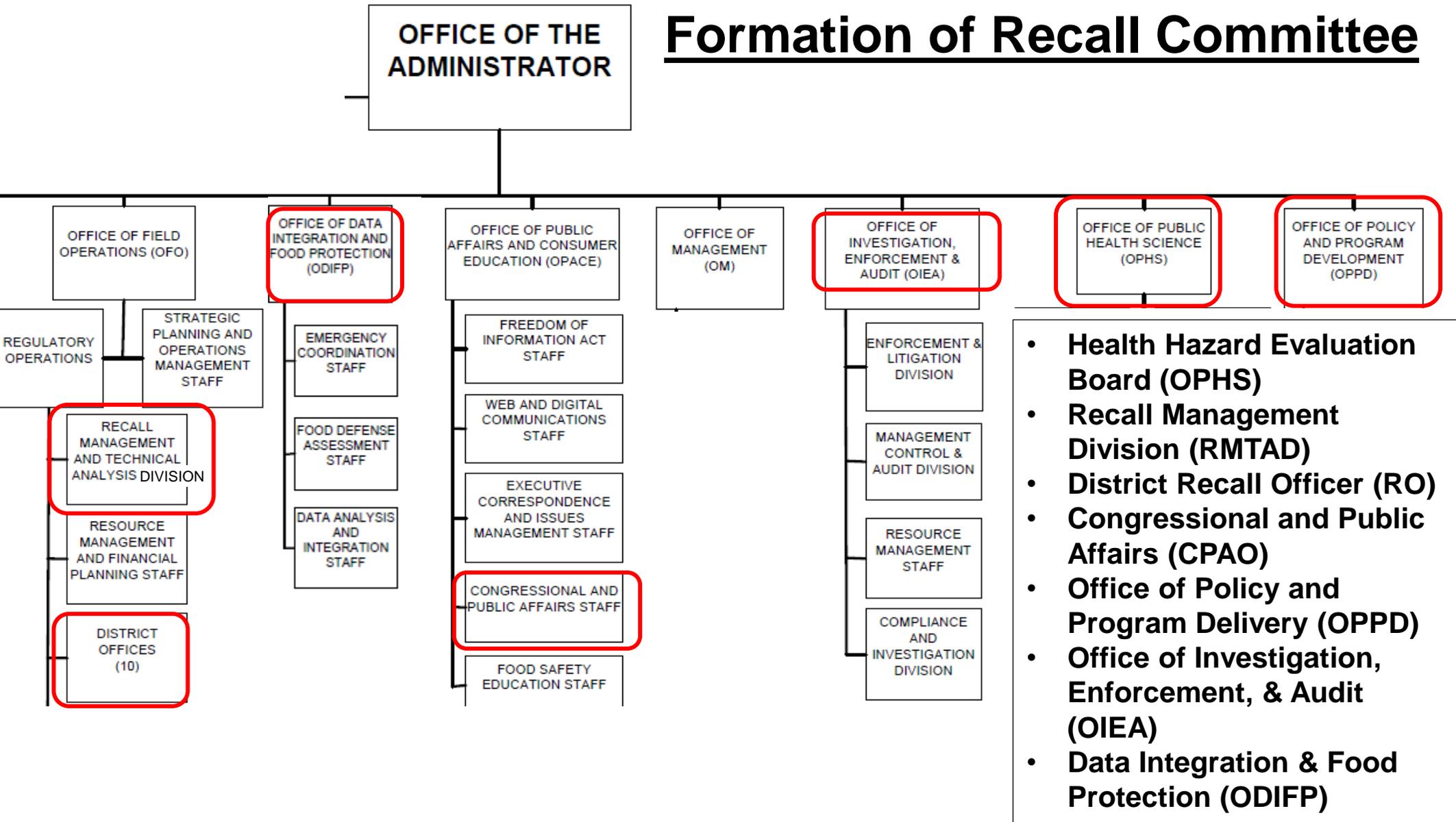
BRAND NAME	[REDACTED]	[REDACTED]	[REDACTED]
PRODUCT NAME	Turkey Bacon (Smoked Cured Turkey Chopped & Formed Smoke Flavor Added Fully Cooked)	Turkey Bacon (Smoked Cured Turkey Chopped & Formed Smoke Flavor Added Fully Cooked)	Uncured Turkey Bacon (Smoked Uncured Turkey Chopped & Formed Smoke Flavor Added)
PACKAGE (Type & Size)	3-12 OZ PKGS (36 OZ) (Individually wrapped vacuum packaged slices in a retail facing carton)	4-12 OZ PKGS (48 OZ) (Individually wrapped vacuum packaged slices in a retail facing carton)	4-14 OZ PKGS Net Wt 56 OZ (3.5 LB) 1.58 KG (Individually wrapped vacuum packaged slices in a retail facing carton)
PACKAGE CODE (Use By/Sell By)	Distributed products with USE BY 28 Aug 2015 through 20 OCT 2015 Product UPC 0 7187154874 8 Plant and line code RS19 (with code date)	Distributed products with USE BY 3 SEP 2015 through 30 OCT 2015 Product UPC 0 7187154879 3 Plant and line code RS19 (with code date)	Distributed products with USE BY 24 Aug 2015 through 26 OCT 2015 Product UPC 0 4470007633 0 Plant and line code RS19 (with code date)
PACKAGING DATE	June 4, 2015 through July 27, 2015	June 10, 2015 through August 6, 2015	May 31, 2015 through August 2, 2015
CASE CODE (Identifying)	00 7187154874 00	00 7187154879 00	00 4470007633 00
COUNT/CASE	10 retail packages per case	8 retail packages per case	8 retail packages per case

Example

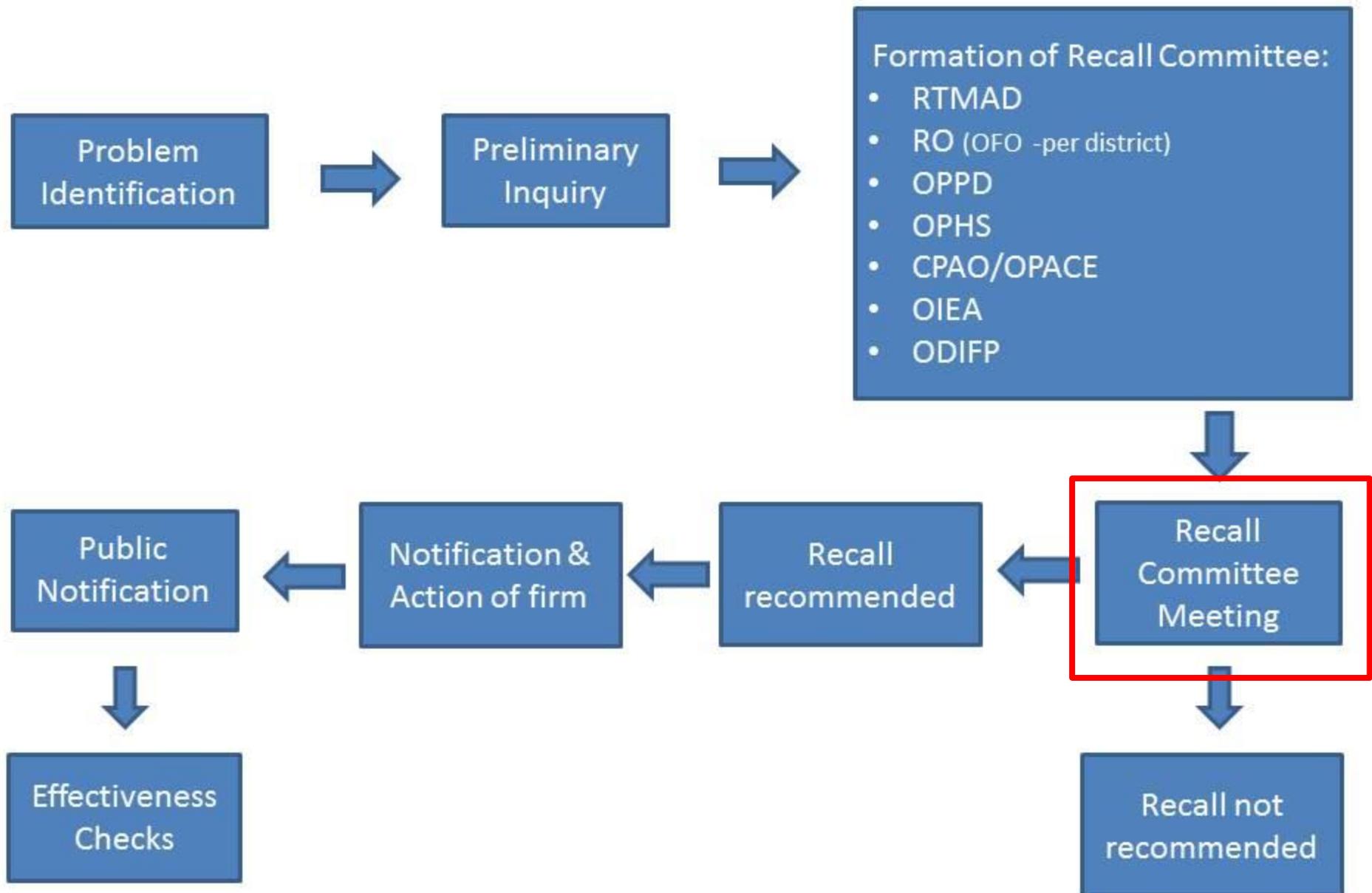
Recall Process: Overview



Formation of Recall Committee



Recall Process: Overview



Recall Process

Recalls defined

EIAO role

Process overview

Traceback

Recall Committee Meeting

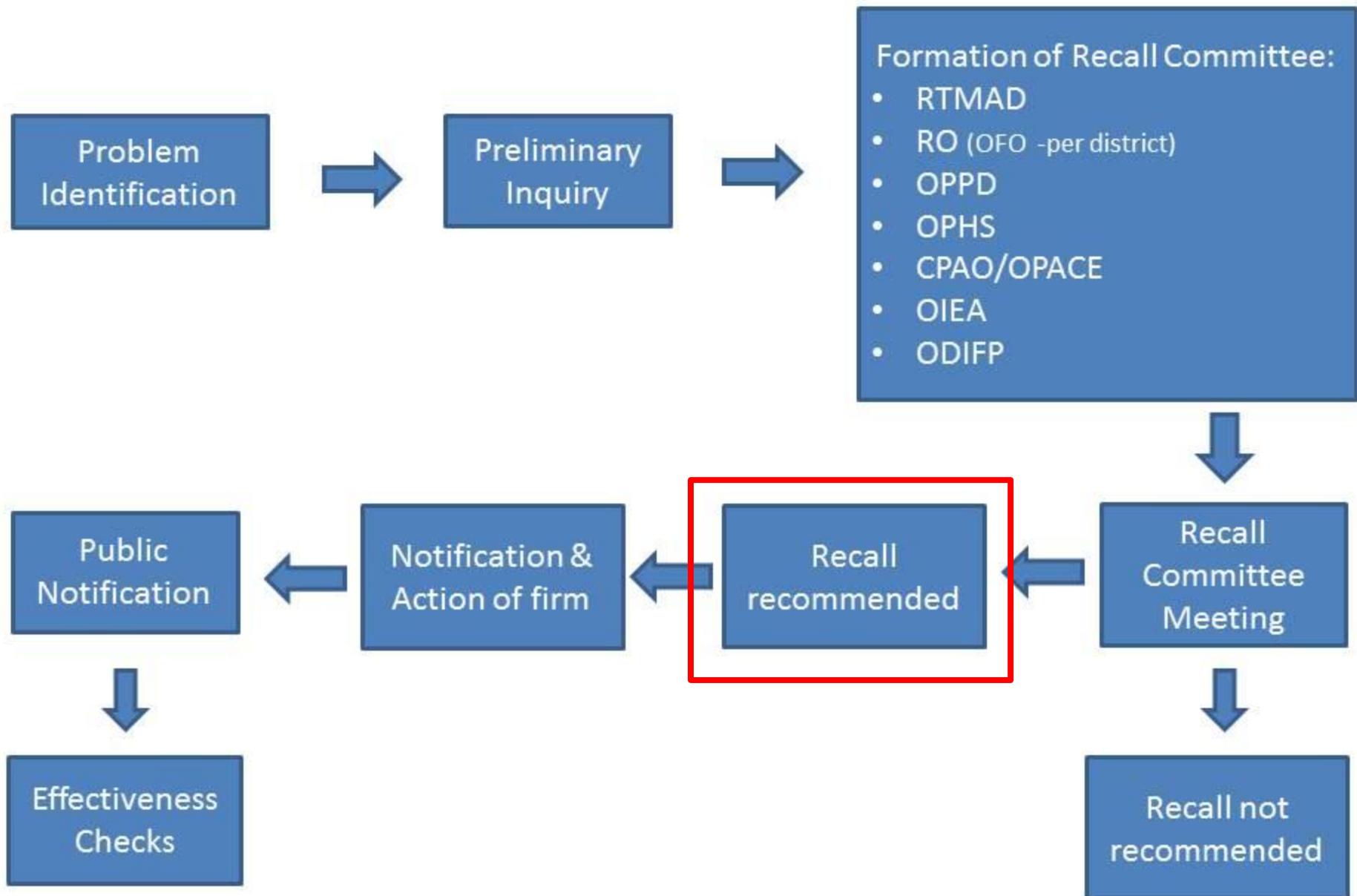
- Committee meets to determine whether to recommend the Agency request a recall
- Recall Officer provides preliminary inquiry data to the recall committee
- Committee considerations:
 - Reason to believe product is adulterated under FMIA, PPIA or EPIA?
 - Is product currently available to consumers?
- EIAO may be a member of the Recall Committee

Role of the EIAO

Recall Committee

- Participate in FSIS preliminary meeting and external conference call with the establishment
- Share information from your contacts with the establishment and inspection team
- Share factual information you gathered to aid in deciding the recall classification and the scope

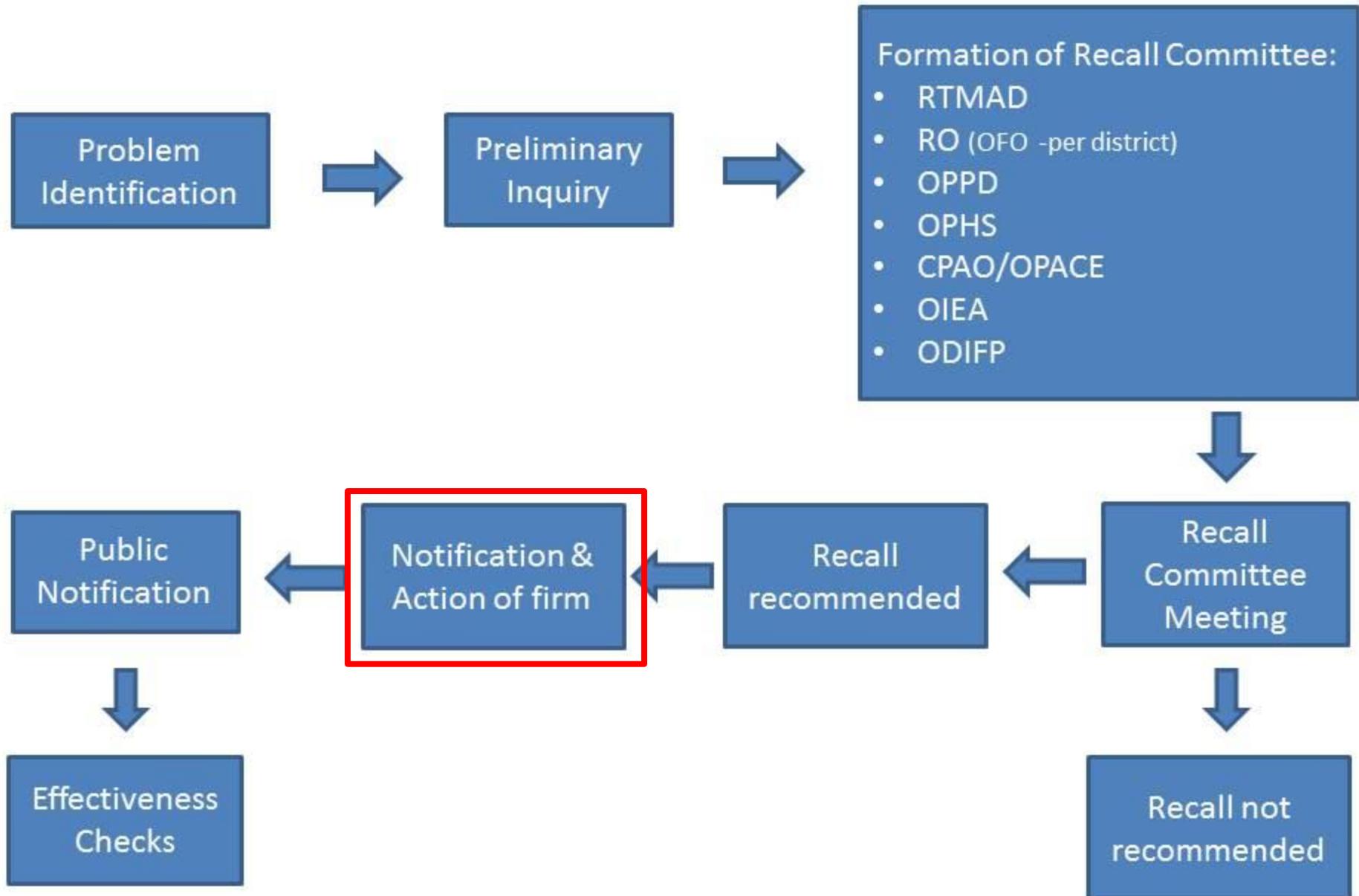
Recall Process: Overview



Recall Process

- If recall is recommended:
 - RMTAD generates a memo which includes the reason for recall and the recall classification.
 - Establishment joins the recall committee discussion.

Recall Process: Overview



Recall Process

Notification & Action of Firm

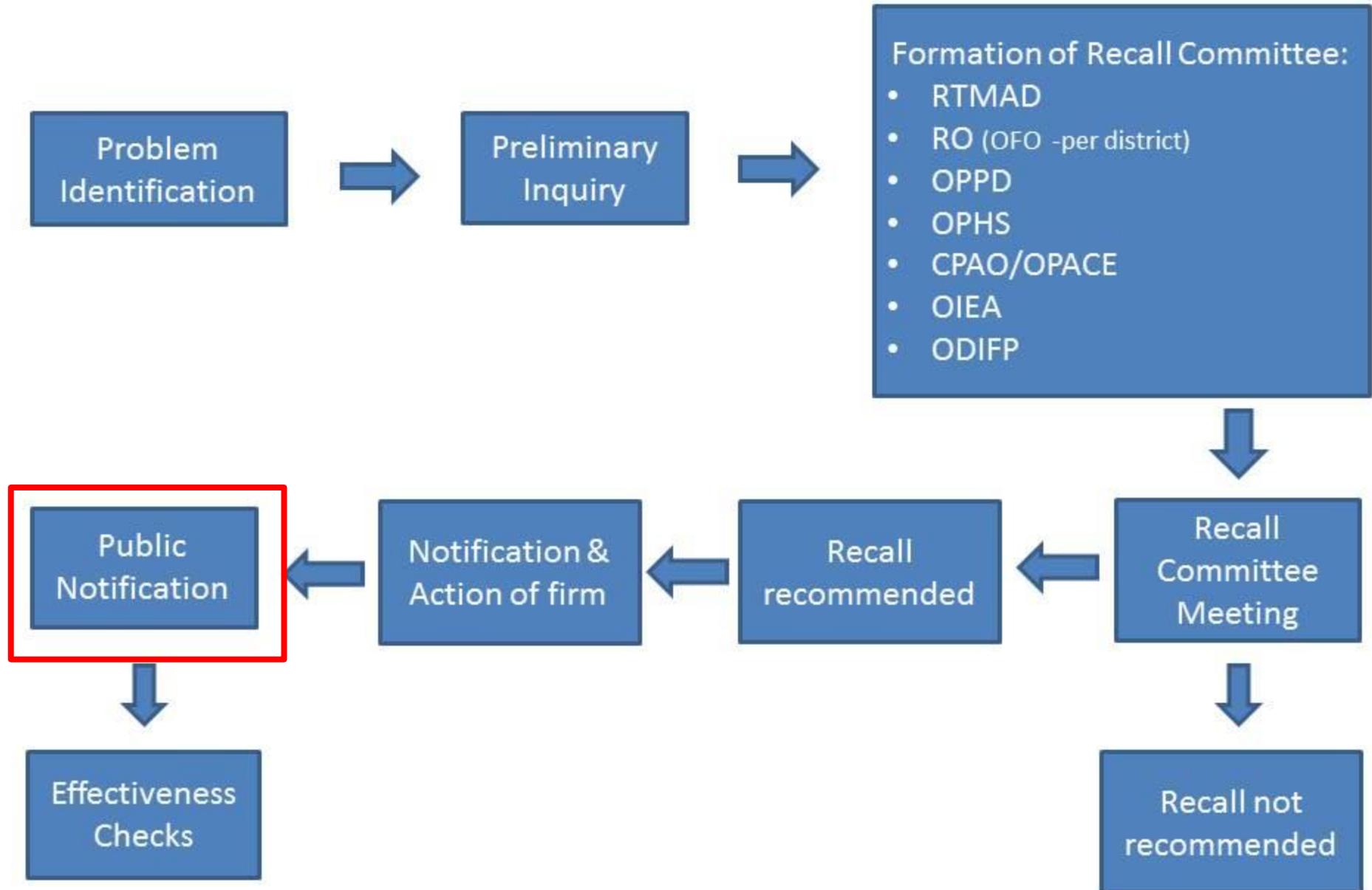
- RMTAD notifies firm
 - Establishment joins the recall committee discussion.
 - Committee asks establishment if they are willing to conduct a voluntary recall.
 - RO will provide ongoing communication between inspectors, establishment and recall committee.
- Firm may conduct a voluntary recall
 - If not, agency may detain/seize product in commerce.

Recall Process

Notification & Action of Firm

- Establishment is asked to notify consignees of the recall action.
- Disposition of product is discussed between RO, DO, and establishment.

Recall Process: Overview



Recall Process

Public Notification

- Recall information is released to the public by OPACE
 - Recall Release – Class I & II
 - Recall Notification Report – Class III (or only wholesale distribution)
- RO verifies distribution information
 - Product distributed to establishment consignees
 - Product distributed to other districts

Recall Process

Public Notification

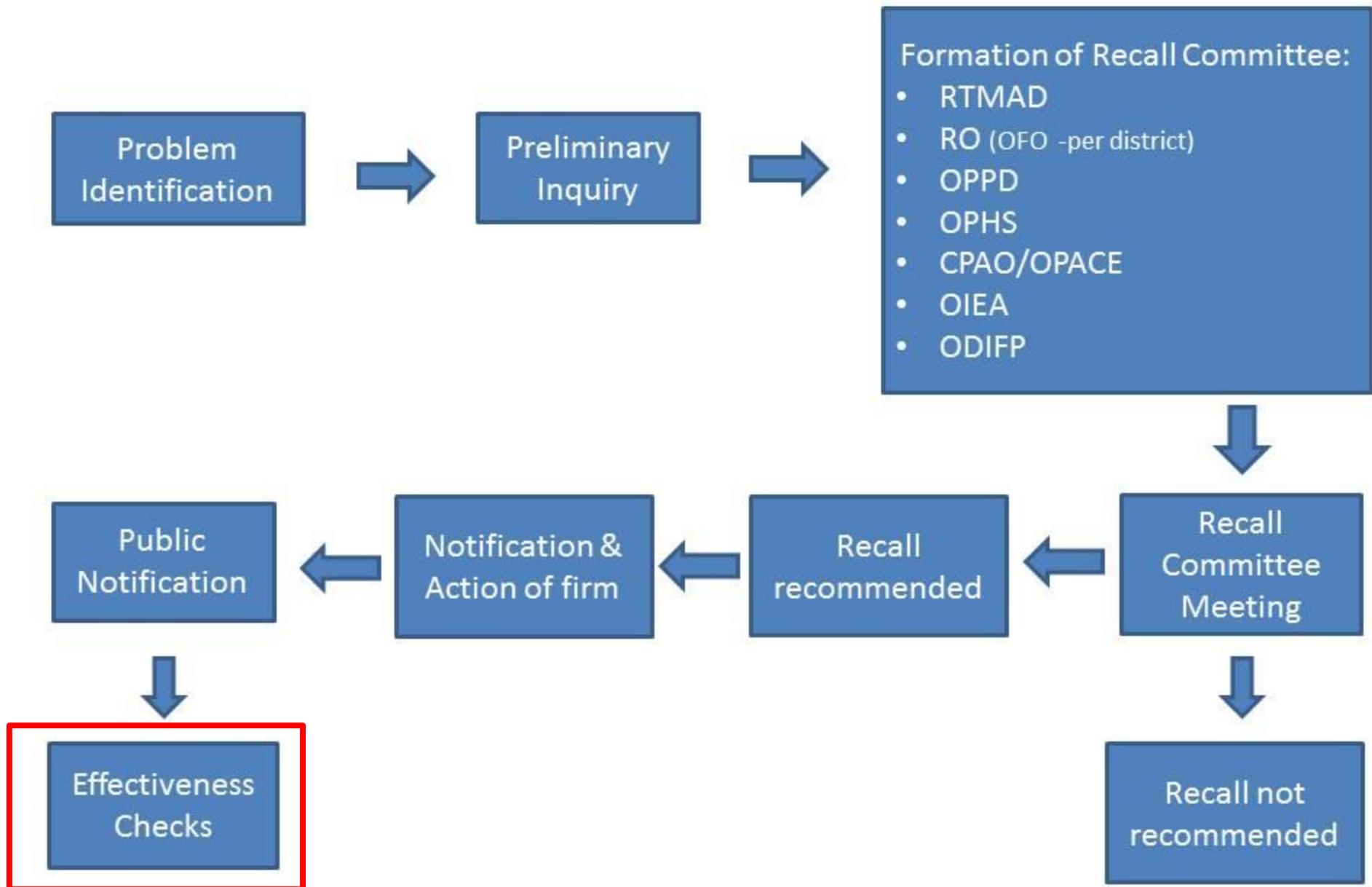
- For Class 1 Recalls
 - List of retail consignees is entered into a database
 - Posted to FSIS website within 3-10 days

Recall Process

Public Notification

- Public Health Alerts - Issued when recall cannot be recommended, but product may present a risk to public
 - Identifies the firm
 - Describes the product
 - Identify any health risks
 - Explanation of adulteration and any risks
 - Instructions on how to handle any product on hand
 - Provide the name and phone number of company

Recall Process: Overview



Recall Process

Recall Effectiveness Checks

- RO assigns effectiveness checks
 - Communication with consignees
 - Verify that firm is locating, retrieving, and controlling the product
- Risk based process dependent on class of recall and number of consignees
 - $\text{Risk} = \text{Hazard} + \text{Exposure}$

Role of the EIAO

During a Recall

- Assist RO as needed
- Obtain distribution information
- Perform recall effectiveness checks
- Perform product disposition verifications



Role of the EIAO

Obtain Distribution Information

- Visit or call primary consignees
- Speak to manager that handles recalls
- Ask if notice was received
- Ask if product has been distributed
- Obtain distribution list



Role of the EIAO

Obtain Distribution Information

- **Do not** perform an effectiveness check at this time, unless directed
- Focus on promptly and accurately obtaining subsequent distribution information from the firm

Role of the EIAO

Distribution List

- Information needed
 - Customer name (s)
 - Customer Address, City and State
 - Customer Contact person and phone number
 - Amount of product distributed to each consignee (cases and pounds)
 - Copy of Recall Notice sent to their customers including product disposition.

Role of the EIAO

Distribution Information

- Send to RO
- RO will then determine
 - Districts that will be involved
 - Total number of consignees
 - Number and frequency of effectiveness checks
 - Number of disposition verifications
 - Appropriate timeframes

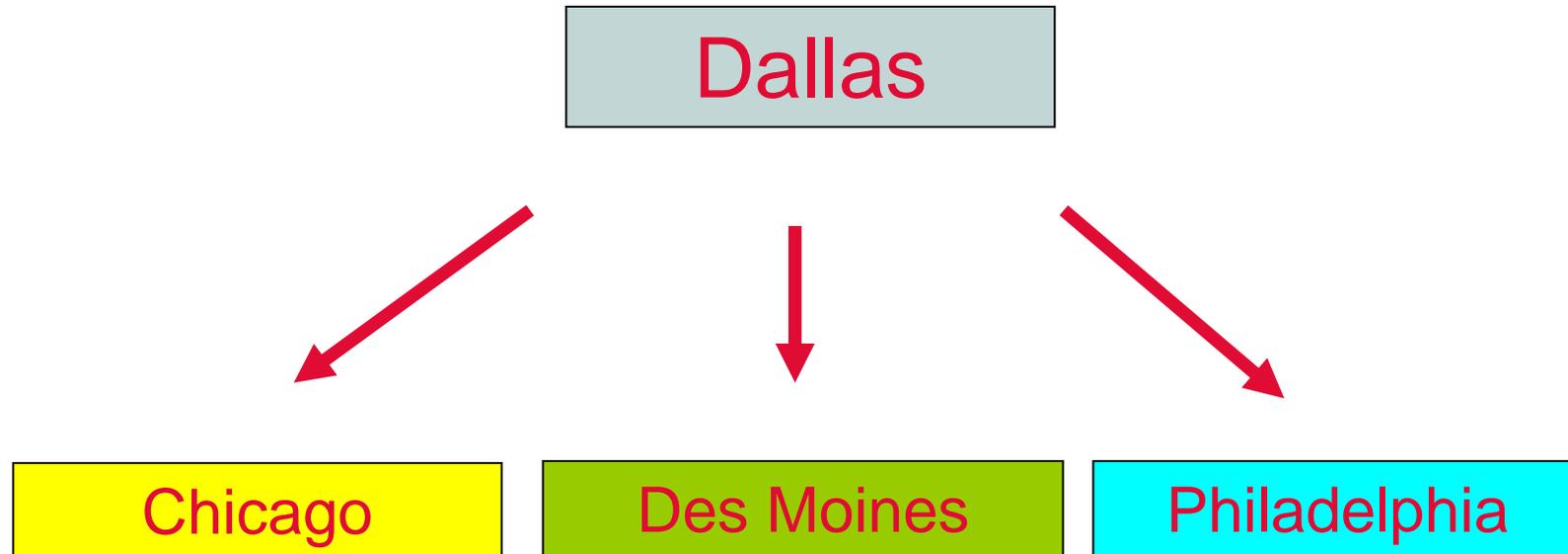
Role of the Recall Officer

- We will briefly cover RO responsibilities as background information



Role of the Recall Officer

Determine districts involved



Role of the Recall Officer

- Determine total number of consignees
 - Obtained from distribution lists



Role of the Recall Officer

- Determine number of effectiveness checks
 - Based on the risk determined (recall class)
 - Taken from values given in the sampling tables 2, 3, 4, and 5 found in FSIS Directive 8080.1
 - May need to estimate initial total distribution

Role of the Recall Officer

- Example from Table 4 - Class II Recall
 - 600 consignees
 - 37 effectiveness checks

Number of Consignees	Number of Effectiveness Checks to Make	Recall Considered Ineffective If the Number of Consignees That Were Not Notified Exceeds:
1 to 5	100%	0
6 to 25	5	0
26 to 150	13	0
151 to 280	15	0
281 to 500	32	1
501 to 1,200	37	1
1,201 to 2,300	42	1
2,301 to 10,000	64	2
10,001 and over	91	3

Role of the Recall Officer

Determine Sampling Interval

- This is done by dividing the total number of consignees by the number of effectiveness checks and this will give you the frequency
 - Example: $600 \div 37 = 16$
- Determine starting number by randomly selecting a number from 1 to the sampling interval
 - Example - 3

Role of the Recall Officer

In our example

- 600 consignees
- 37 recall effectiveness checks
- Sample interval = 16
- Start number = 3
- On the list of consignees, begin with #3, then #19, #35, #51, etc.

Role of the Recall Officer

Determine number of disposition checks

Table 4. Effectiveness checks to conduct and critical limits for Class II recalls.

Number of Consignees	Number of Effectiveness Checks to Make	Recall Considered Ineffective if the Number of Consignees at which Product was Available to Consumers Exceeds:
1 to 5	100%	0
6 to 25	5	
26 to 150	13	
151 to 280	15	
281 to 500	32	1
501 to 1200	37	
1201 to 2300	42	
2301 to 10,000	64	2
10,001 to and over	91	3

Number of on-site disposition verifications

Total number of effectiveness checks

Role of the Recall Officer

Determine number of disposition checks

- For class I involving illness consult RMTAD
- For all others
 - Use tables and the number of effectiveness checks
 - Example: 37 effectiveness checks in Table 4 equals 13 disposition checks
 - 13 of the 37 effectiveness checks will include product disposition verification checks

Role of the Recall Officer

Establish Timeframes

Recall classification	FSIS verification activities begin as soon as possible but in no case later than:	FSIS verification activities should be substantially completed within:
Class I	3 Days	10 Days
Class II	5 Days	12 Days
Class III	10 Days	17 Days

Role of the EIAO

Recall effectiveness checks

- Determines if recalling establishment has been diligent and successful in notifying, retrieving, controlling recalled product
- Conducted at primary and secondary consignees
- Onsite or by phone

Role of the EIAO

Recall Effectiveness Checks

- Meet with the contact person identified on the consignee list and identify yourself
- Have Recall Effectiveness Form (FSIS Form 8400-4) and pertinent recall information for reference



Role of the EIAO

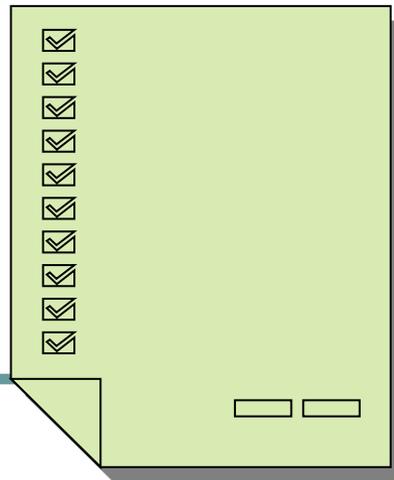
Recall Effectiveness Check Questions

- Did you receive notification of the recall?
- When did you receive it? How (email, phone, fax)?
- What instructions did you receive regarding the recalled product?
- Did you follow instructions from the recalling establishment (e.g., product returned to establishment?)
- Did you sell to persons/businesses that intend to resell the recalled product ?
- If so, have you notified them of this recall?

Role of the EIAO

Recall Effectiveness Check

- Obtain a copy of the recall notice sent to their consignees
- Obtain distribution information
- Immediately forward to your District Office



Role of the EIAO

Recall Effectiveness Check

- If recalled product was destroyed, ask for details
- If recalled product was picked up, ask when it was picked up and verify the destination.
- If consignee states recalled product was not received, advise them FSIS has records indicating they may have received recalled product.
- Review information with them to determine if recalled product was received.

Role of the EIAO

Recall Effectiveness Check

- If consignees are not notified or do not follow instructions and recalled product remains available to the consumer:
 - Detain any product in commerce
 - Notify the RO immediately
- For suspected prohibited acts such as introducing adulterated product in commerce:
 - Document and contact the RO
 - RO may issue a prohibited acts letter

Pop Quiz

- What is the purpose of doing these effectiveness checks?



Role of the EIAO

Product Disposition Verification

- Verifies product disposition
- Performed at a subset of firms where effectiveness checks are done
 - Example: 37 effectiveness checks
 - 13 disposition verifications
- Track product to final destination

Role of the EIAO

Product Disposition Verification

- Have FSIS Form 8400-4
- Have pertinent recall information
- If retail – go to retail case or shelf first
 - If recalled product is observed for sale
 - Take a photo
 - Confirm Est. no, lot codes, etc.

Role of the EIAO

Product Disposition Verification

- Locate contact person
- Identify yourself
- Verify recalled product is on hold
- If contact says no product on site
 - Check the coolers, freezers
- If product was returned
 - Ask questions

Role of the EIAO

Deviations

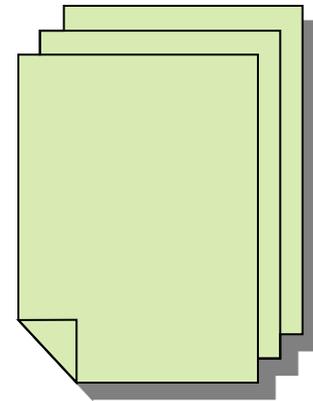
- Unfavorable results
- Inform the DDM/RO
- RO will determine if a trend exists



Role of the EIAO

Documentation

- FSIS Forms 8400-4
- Memorandum of Interview (MOI)
 - If consignee did not receive notification
 - Notify RO
 - Collect evidence



Recall Process

Recall closure

- RO determines effectiveness of recall
 - Compiles effectiveness reports
 - Confirms with firm that product was controlled and disposed of
 - Recommends closure to RMTAD
- RMTAD recommends closure

Recall Process

Determine Recall Effectiveness

- 3rd column in Tables 2-5 is used

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151 to 280	15	0
281 to 500	32	1
501 to 1,200	37	1
1,201 to 2,300	42	1
2,301 to 10,000	64	2
10,001 and over	91	3

Recall Process

Ineffective Recall

- If recall is determined ineffective
 - RO will send “Notice of Ineffective Recall”
 - Based upon evidence demonstrating failure to retrieve and control product
 - Give opportunity to respond
 - If unwilling or unable, recommend further action

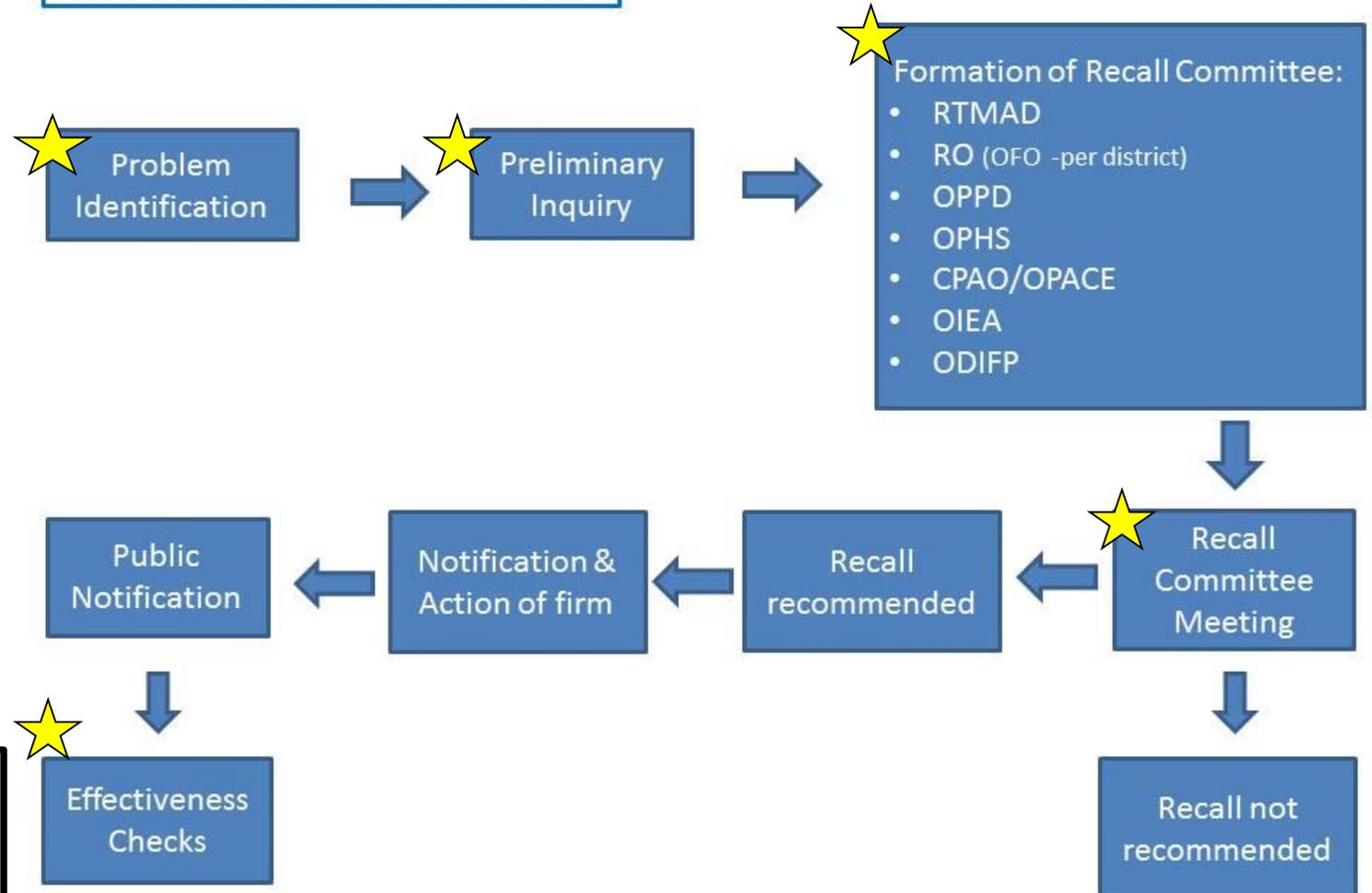
Recall Process

AER Case File

- AER is used to document ineffective recall cases
- One AER per case
- RO has responsibility to prepare and maintain AER
- Include all appropriate supporting documents

Recall Process: Summary

Recall Process: Overview



EIAO has or may have a role

Pop Quiz

- The District informs you that Establishment ABC will be recalling product, which was sent to five distribution centers.
- You are to obtain a distribution list. What do you do?



Traceback

Recalls defined

Goal of traceback activities

- Identify source materials and potential suppliers

Process Overview

Considerations when evaluating the scenario

- Slaughter process
- Sanitary dressing
- Fabrication process
- Sampling results
- Cross-contamination of product or FCS
- Co-mingling of product

EIAO Role

Traceback

Traceback

More traceback considerations

- Review slaughter test results and determine if the establishment had a High Event Period (HEP) – What action did the establishment take during the HEP?
- Microbiological independence- How does the establishment define the sampled lot?
- Were there systematic failures in the establishment's sanitary dressing and process controls?
- Were there any changes in the process or procedure for the production periods in question?

Summary

Recalls defined

Process Overview

EIAO Role

Traceback

At the end of this module, you will be able to:

1. Identify the regulations relevant to recalls
2. State the EIAO's role in recalls
3. Complete FSIS Form 8400-4
4. Describe the methodology and purpose for:
 - collecting distribution and traceback information
 - conducting recall effectiveness checks given a scenario
 - conducting a product disposition verification given a recall scenario.

Questions



What questions do you have?

Workshop



Scenario 1

- You received an e-mail from the District Office about a potential recall situation. A federally inspected establishment received three complaints from customers who stated they had plastic pieces in their FC, NSS, RTE bologna. The customers did not report any injuries associated with eating the bologna. A search in CCMS did not reveal any similar complaints. The establishment provided photographs of two of the plastic pieces measured against a ruler, and the plastic pieces varied in length.

Scenario 2

- During a food safety assessment (FSA), you discover an establishment's finished Chorizo product contained lactose and isolated soy protein as ingredients; however, these ingredients were not declared on the finished product label.