Food Safety and Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

Recall of Meat and Poultry Products

EIAO Effectiveness Checks

Objectives

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

1. Define recall
2. Define market withdrawal
3. Identify the regulations relevant to recalls
4. State the EIAO's role in recalls
5. 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

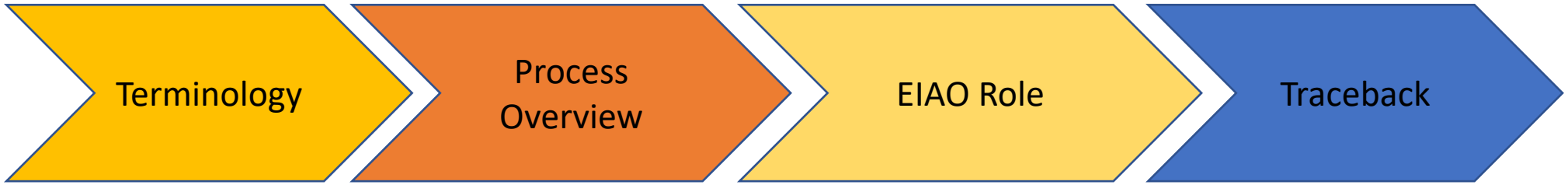
- **8080.1** – Recall of Meat & Poultry Products
- **5000.8** – Verifying Requirements for Recall Procedures
- **10,010.3** – Traceback Methods for *E. coli* 0157:H7

Small Plant Recall Plan Guidebook

Others:

- 8091.1 – Procedures for Health Hazard Evaluation Board
- 8080.3 – Foodborne Illness Investigations
- 8410.1 – Detention and Seizure

Recall of Meat and Poultry Products: Overview



Terminology: Recalls Defined

Terminology

What is a recall?

A firm's removal of distributed meat or poultry products from commerce when there is reason to believe that such products are adulterated or misbranded under the provisions of the FMIA or the PPIA.

- RTE product positive for Listeria Monocytogenes
- Undeclared allergen
- Others??? Link to FSIS Recalls Website

Is it Mandatory???

Terminology: Market Withdrawal

Terminology

Market Withdrawal:

A firm's removal or correction, on its own initiative, of a distributed product that involves a minor company quality program or regulatory program infraction that would not result in the product being adulterated or misbranded.

Terminology: Adulterated or Misbranded

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: Recall Classifications

Terminology

Recall 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: Depth

Terminology

Depth of Recall - The level of product distribution to which the recall extends

1. Wholesale level: The product has been distributed to a warehouse or distribution center where it is not under the direct control of the producing company. This is the distribution level between the manufacturer and the retailer.
2. Retail level: The product has been received by retailers for sale to household consumers.
3. HRI level: The product has been received by hotels, restaurants, and other institutional customers.
4. Consumer level: The product has been sold directly to household consumers.

Terminology: Scope and Disposition

Scope:

This defines the amount and type of product in question.

Disposition:

This is the firm's action with respect to the recalled product to correct the situation leading to the recall, such as relabeling, cooking, reworking, or destroying product.

Terminology: 9 CFR 418

Terminology

Regulations: 9 CFR 418

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

Terminology: Committee and HHEB

Terminology

Recall Committee

A committee of representatives from various FSIS offices and staffs assembled to respond to potential or real health hazard incidents reported to the Recall Management and Technical Analysis Division (RMTAD).

Health Hazard Evaluation Board (HHEB)

The HHEB is the primary group in FSIS that reviews the public health significance of any human health hazard about which a regulatory decision needs to be made. If the risk to the public health presented by a given product appears to be unique or in some way unusual, the Recall Committee may consult the Office of Public Health Science's (OPHS) HHEB.

Terminology: RMTAD and RO

Terminology

Recall Management Technical Analysis Division (RMTAD)

Manages and coordinates FSIS Recalls. The name was recently changed from Staff to Division, which accounts for separate groups that handle Domestic and Import recalls.

Recall Officer (RO)

FSIS Recall Officer (RO), OFO - Designated FSIS personnel with jurisdiction in the district of the firm that is conducting the recall. The RO is the official responsible for coordinating field recall activities and providing direction to IPP when there is recall.

Recall Process Overview

Process Overview

FSIS Directive 8080.1:

Recall of Meat and Poultry Products provides the terminology, responsibilities, and public notification procedures regarding the voluntary recall of FSIS-regulated products

We will take a brief look into each step of the process and determine the level of EIAO involvement.

Recall Process Overview: Problem Identification

Process Overview

Problem Identification

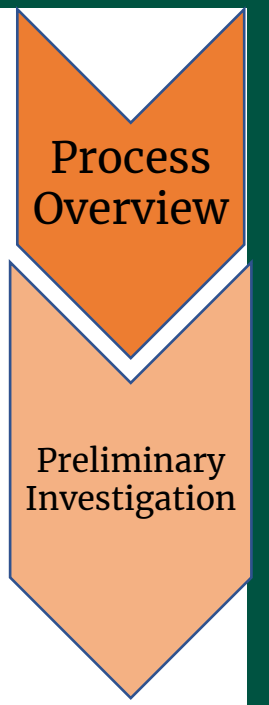
FSIS may become aware of misbranded or adulterated product in commerce through its own resources or through other sources.
Examples:

- The company
- Company competitors
- FSIS sampling results
- Observations or information gathered by FSIS inspection personnel
- Consumer complaints
- Epidemiological or laboratory data submitted by public health departments or other agencies – Other agencies such as the Food and Drug Administration, Department of Homeland Security, USDA agencies, or foreign inspection officials

EIAO Involvement: 

Potential discovery through FSA or involvement with an IVT/RLM

Recall Process Overview: Preliminary Investigation



RO and EIAO typically conduct the initial recall investigation activities.

- Assist Recall Officer:
  - Communicate with establishment
  - Identify if product is under establishment control or in commerce
  - Complete Preliminary Inquiry and other recall worksheets
  - Collect product samples
  - Interview a consumer who became ill (EIAO)
  - Initiate FSA (EIAO) – Analyze epidemiological data, review production or HACCP system records, make FSA recommendation
  - Participate on Recall Committee

EIAO Involvement: ★★★★★

DO Recall Officer will dispatch an EIAO to the Establishment to begin completing Recall Worksheets

Preliminary Inquiry: Inquiry Worksheet

Process Overview

Preliminary Investigation

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:

EIAO Involvement: ★★★★★

DO Recall Officer will dispatch an EIAO to the Establishment to begin completing Recall Worksheets

Preliminary Inquiry

Preliminary Inquiry Worksheet: FSIS Form 5020-3

BRAND NAME			
PRODUCT NAME			
PRODUCT TYPE (e.g., RTE, Canned, Frozen)			
HACCP CATEGORY			
PRODUCTION DATE(S)			
PACKAGING DATE(S)			
LOT CODE(S)			
PACKAGE (type and size)			
PACKAGE CODE(S) (ex: Use by/sell by)			

1. **Please indicate the primary issue. For example: STEC / Listeria Monocytogenes / Salmonella / Residue / Processing Defect / Extraneous (foreign) material/ Undeclared or Allergen or Substance / Other (if other, please describe)**

2. **Notification may include: 3rd Party / Consumer / FDA / IIC / Monitor / Outbreak / Plant / Retail / Other (if other, please describe)**

FSIS 5020-3 (03/31/2021)

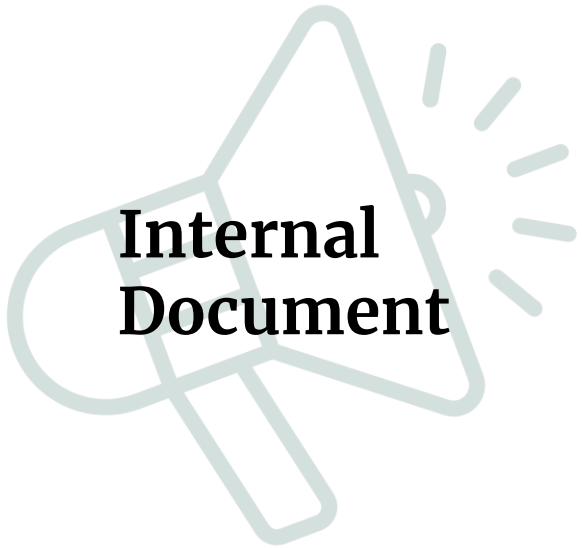
CASE CODE(S) (Identifying)			
UNITS PER CASE			
USABLE SHELF LIFE OF PRODUCT			
AMOUNT PRODUCED (lbs.)			
AMOUNT HELD AT ESTABLISHMENT (lbs.)			
AMOUNT DISTRIBUTED (lbs.)			
DISTRIBUTION LEVEL (Institutional/Retail)			
DISTRIBUTION AREA (states)			
EXPORTED TO (Country)			
DONATED COMMODITY/ USDA FOODS 3	☐ (YES) ☐ (NO)	☐ (YES) ☐ (NO)	☐ (YES) ☐ (NO)
DEPT. OF DEFENSE 4 (DeCA, DLA, AAFES)	☐ (YES) ☐ (NO)	☐ (YES) ☐ (NO)	☐ (YES) ☐ (NO)
INTERNET OR CATALOG SALES	☐ (YES) ☐ (NO)	☐ (YES) ☐ (NO)	☐ (YES) ☐ (NO)

Process Overview

Preliminary Investigation

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:_____

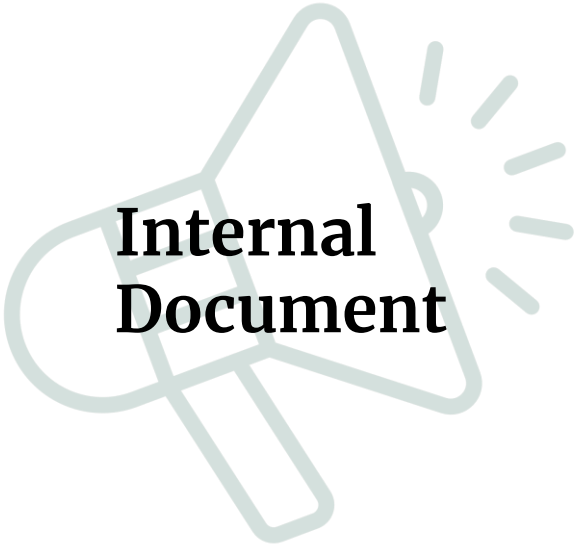
_____

Process Overview

Preliminary Investigation

Recall Worksheet

Recall Worksheet:
E.coli



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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)?_____

_____

_____

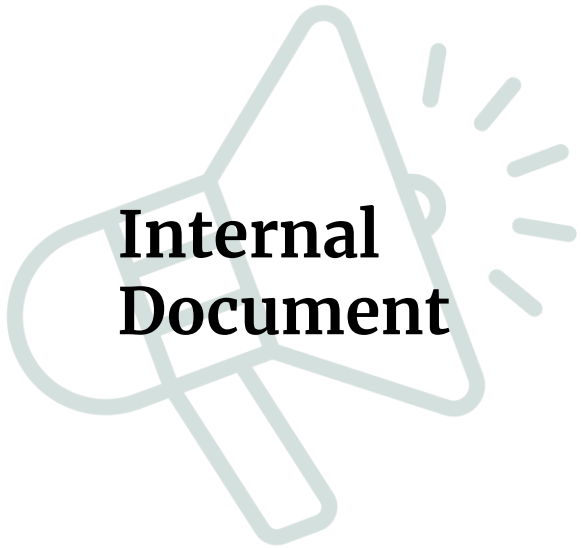
_____

Process Overview

Preliminary Investigation

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:_____

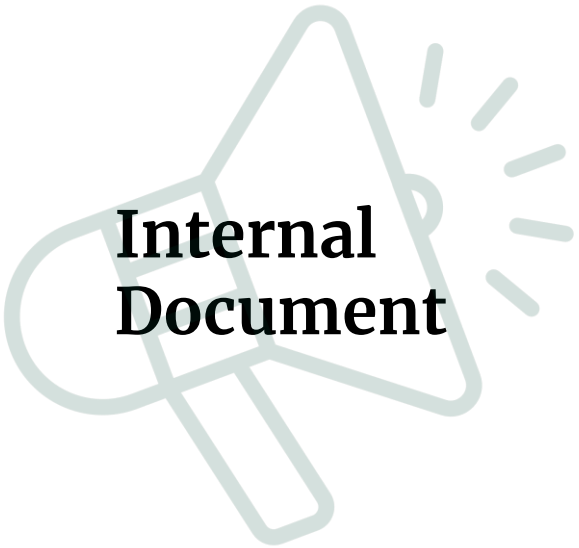
_____

Process Overview

Preliminary Investigation

Recall Worksheet

Recall Worksheet:
Foreign Material



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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:_____

_____

Process Overview

Preliminary Investigation

Recall Process Overview: Committee Deliberations

Process Overview

Recall Deliberations

FSIS Recall Committee

Office of Field Operations
Recall Management and Technical Analysis Division – Chairs committee meetings, analyzes and disseminates information to other members, and invites other program areas to assist as necessary District Office – Clarifies information collected during the preliminary inquiry and coordinates field recall activities in the event of a recall

Office of Policy and Program Development
Provides the statutory basis for each recall and addresses other statutory issues along with any relevant regulations and policies

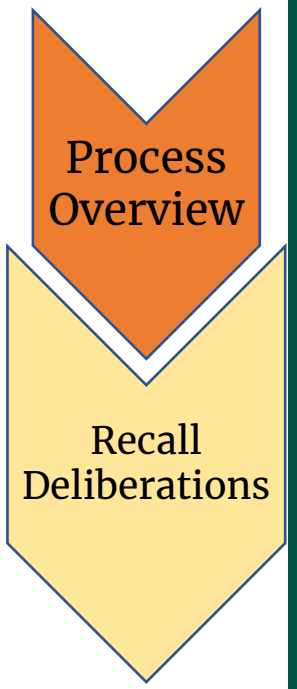
Office of Public Health Science
Addresses microbiological, epidemiological, and other scientific issues associated with a recall

Office of Investigation, Enforcement, and Audit
Provides support for detention and seizure of product, if necessary

Office of Public Affairs and Consumer Education
Generates a Recall Release or Recall Notification Report in the event of a recall or, when appropriate, other notifications such as a Public Health Alert

Office of Data Integration and Food Protection
Coordinates the FSIS Emergency Management Committee, as appropriate

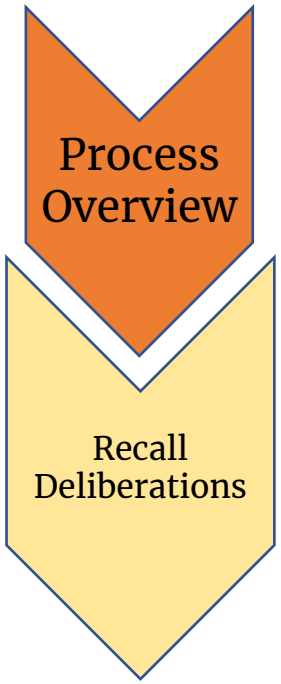
Recall Deliberations: Committee Meeting



FSIS 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

Recall Deliberations: Considerations & Recommendation



- Considerations to determine whether a recall or other action is warranted include:
  - Hazard assessment
  - Regulatory support
  - Whether or not product is available in commerce

- FSIS Recall Committee deliberates to determine recommendation. Outcomes can include:
  - Recall
  - Public Health Alert
  - Regulatory Action
  - No Action

- If analysis supports a recall, the FSIS Recall Committee contacts the firm and requests voluntary recall of the product.
  - Firm representatives may ask questions and discuss any concerns
  - Additional information may be considered

Recall Process Overview: Notifications & Actions

If the firm agrees to a voluntary recall, FSIS issues a recall press release
– Firms should issue recall notice to consignees, notify public if needed, and provide FSIS with a list of retail stores where product was sold

Recall effectiveness checks are implemented

If the firm does not agree to a voluntary recall, FSIS may issue a Public Health Alert and initiates detention and seizure of product in commerce.

Notifications & Actions

Process Overview

Notifications & Actions

Public Notification:

- Link to FSIS Recalls Website
- Recall information is released to the public by OPACE
  - Recall Release – Class I & II
  - Recall Notification Report – Class III (or only wholesale distribution)
  - Public Health Alert- product no longer for sale but could be in consumer's freezer

WASHINGTON, June 28, 2020 –AAA, a (city), (state) establishment, is recalling approximately XXX pounds of fully cooked chicken breast nugget products that may be contaminated with extraneous materials, specifically flexible rubber material, the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) announced today.

The frozen ready-to-eat (RTE) chicken breast nugget items were produced on (date, year). The following products are subject to recall [View Labels (PDF Only)] :

4-lb. plastic bag packages containing "(Product Name) FULLY COOKED CHICKEN BREAST NUGGETS," with a Best-By date of (date, year) and lot code of (###) printed on the retail package. Product cases contain lot codes (00000, 11111, 22222, etc.) printed on the box.

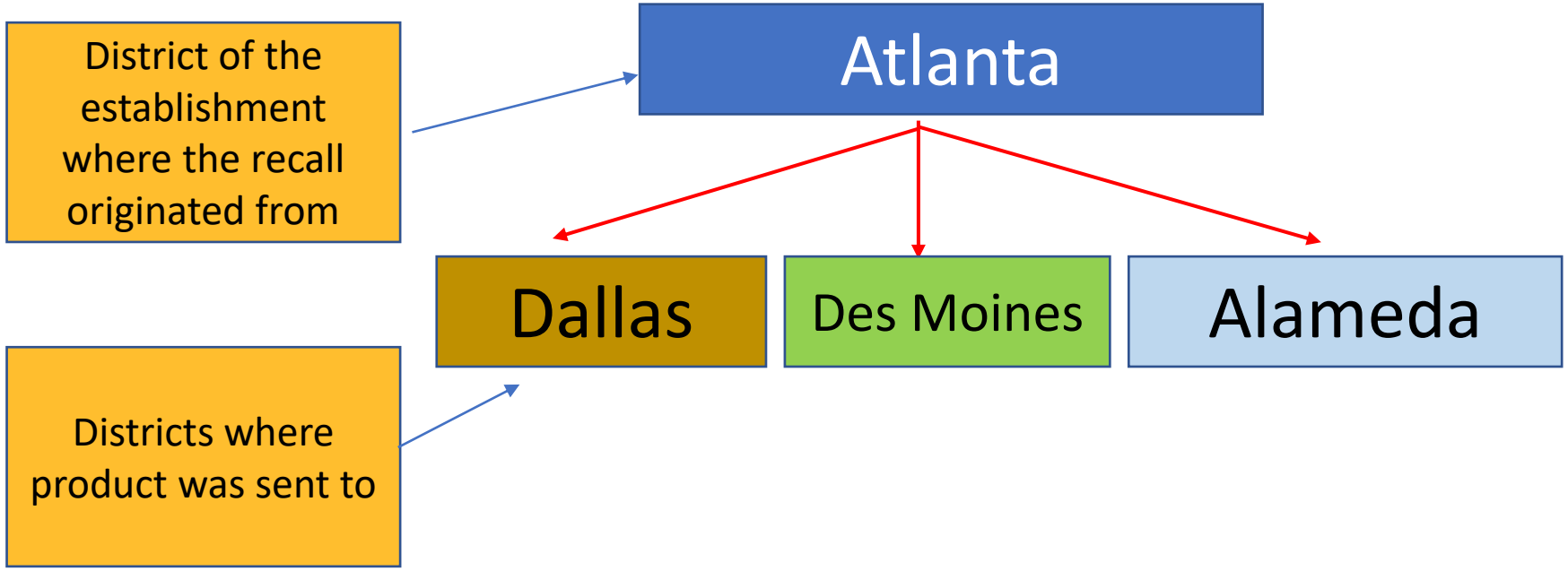
Notifications & Actions: Districts Involved

Process Overview

Notifications & Actions

District Recall Officer

Determines the Districts involved.



Notifications & Actions: Consignees Involved

District Recall Officer

- Determines the total number of consignees
  - Obtained from distribution lists

Notifications & Actions: Determine Number of Checks

District 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

Notifications & Actions: Table 2

Process Overview

Notifications & Actions

Table 2. Effectiveness checks to conduct and critical limits for ***all*** Class I recalls involving an injury, illness outbreak, or distribution to schools.			
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:**	**Number of On-site Effectiveness Checks**
1 to 200	100% of consignees	0	RO will consult with RMTAD on the number of on-site verifications
201 to 10,000	200	0	
10,001 to 35,000	800	1	
35,001 to 500,000	800	1	
500,001 and over	1,250	2	

Notifications & Actions: Table 3

Process Overview

Notifications & Actions

Table 3. Effectiveness checks to conduct and critical limits for Class I recalls when there are **no** injuries, illnesses, outbreaks, or distribution to schools			
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:**	**Number of On-Site Effectiveness Checks**
1 to 20	100% of consignees	0	100%
21 to 150	20	0	100%
151 to 1,200	80	1	20
1,201 to 2,300	125	2	20
2,301 to 10,000	200	3	80
10,001 to 35,000	315	5	80
35,001 to 150,000	500	8	80
150,001 to 500,000	800	12	80
500,001 and over	1250	18	125

Notifications & Actions: Table 4

Process Overview

Notifications & Actions

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:**	**Number of On-Site Effectiveness Checks**
1 to 5	100% of consignees	0	100%
6 to 25	5	0	100%
26 to 150	13	0	5
151 to 280	15	0	5
281 to 500	32	1	13
501 to 1,200	37	1	13
1,201 to 2,300	42	1	13
2,301 to 10,000	64	2	13
10,001 and over	91	3	13

Notifications & Actions: Assessing Success

District Recall Officer

During the recall, the RO also has an oversight function of assessing whether the recalling firm has in fact initiated and is performing the recall activities necessary for there to be a successful recall.

Table 1. Recommended timeframes for initiating and reporting verification activities within FSIS

Recall classification	Following the initiation of a recall, FSIS verification activities should begin as soon as possible within a period of:	Following their initiation, FSIS verification activities should be substantially completed within a period of:
Class I	3 days*	10 days
Class II	5 days	12 days
Class III	10 days	17 days

* Working days: Working days may include Saturday and Sunday, depending upon the risk associated with a recalled product.

EIAO Role: Recall Effectiveness Checks

EIAO Role

- Communication with consignees to determine if recalling establishment has been diligent and successful in notifying, retrieving, controlling recalled product
- Conducted at primary and secondary consignees
- Onsite (disposition) or telephonic (effectiveness) checks

EIAO Role: Detain and Prohibited Acts

EIAO Role

If consignees are not notified or do not follow instructions and recalled product remains available to the consumer:

- Notify the RO immediately
- Detain product

For suspected prohibited acts such as introducing adulterated product in commerce:

- Document and contact the RO
- RO may issue a prohibited acts letter

EIAO Role : Adulterated Product Monitoring System

EIAO Role

Adulterated Product Monitoring system or APM

APM is a centralized system that FSIS uses to capture information related to all reporting of instances of product adulteration, whether reported by official establishments or identified by FSIS personnel.

The APM is used to document the effectiveness checks that are performed by the EIAOs.

USDA Food Safety and Inspection Service
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Questions?