

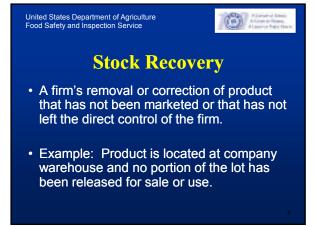




- No violation of FMIA or PPIA
- No Health Hazard

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A Recall is a fast and effective method of removing distributed products, particularly when many lots of product have been widely distributed. A recall may be an alternative to FSIS detention or seizure. United States Department of Agriculture Food Safety and Inspection Service C Alexandra

Who Recalls?

- · Manufacturers and distributors of product
- FSIS does not have mandatory recall authority.
- However, FSIS may initiate the recall process by informing a firm that adulterated product has been identified in commerce .



Recall Process

- Problem Identification:
 - The company discovers the problem
 - FSIS microbiological sampling
 - Information from in-plant inspection program personnel (IPP)
 - Epidemiological or other data gathered by other Federal, State, or local Agencies
 - Consumer complaints

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- Preliminary Investigation
 - FSIS program personnel begin the preliminary inquiry by gathering product and contact information, and any additional relevant information.

Recall Process

- For domestic production, FSIS contacts the plant and works with the firm to complete recall worksheets. The District Recall Officer (DRO) directs these activities and forwards the information to RMS.
- If imported product is involved, Office of International Affairs (OIA) assigns an Import Recall Coordinator (IRC) to direct these activities.

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Preliminary Investigation

- Contact Information for Official Est.
 - Est. number, name, and address
 - Company Recall Coordinator, Media Contact, and Consumer Contact (name, title and phone number)
- Contact Information for Imported Products - Import and Foreign Est. identification and contact information
 - Importer of Record (IOR), IOR Recall Coordinator, IOR Media Contact, IOR Consumer Contact (name, title, and telephone number)

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Preliminary Investigation

- Product Information (for all products)
 - Reason for recall
 - Brand and Product names
 - Packing type/size, dates, codes (Use by/Sell by), Case Codes, Count/Case
 - Production dates, Distribution areas
 - Whether or not the products were part of School Lunch, DoD, or internet/catalog sales

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Preliminary Investigation

- Additional Information (all products)
 - Amount produced/imported (pounds/cases)
 - Amount held at Est./Import Est.
 - Amount distributed (pounds/cases)
 - Distribution level (Depth of Recall, if known)

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FSIS May Also

- > Collect and verify information about suspect product
- > Document chronology of events
- > Contact manufacturer/distributor for additional information
- Interview consumers who allegedly became ill or injured from suspect product
- > Collect/analyze product samples
- > Contact other Federal, State, or local Agencies
- > Analyze any available epidemiological data

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FSIS Recall Committee

- Consist of representatives from various FSIS offices and staffs assembled to respond to potential or real health hazard incidents reported to Recall Management Staff (RMS)
- Recall worksheets and any other information is gathered by RMS, who forwards the relevant materials to the Recall Committee
- RMS makes every effort to ensure the five primary members of the committee are available

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FSIS Recall Committee

- · Chaired by Recall Management Staff
- · Includes personnel from:
- DRO and other district staff as appropriate
- Microbiology/Toxicology/Public Health
- Policy Office
- Media Relations/Communications
- Other (OIA, OPEER, ODIFP)
- Other Federal or States agencies as appropriate (FDA, CDC, FNS)

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FSIS Recall Committee

- Evaluates Hazard, Circumstances, and Statutory basis for recall
- Reviews FSIS and Plant Data
- Reviews Recall Worksheet
- Classifies Hazard
- · Evaluates Scope (product lots involved)
- Recommends Recall
- Evaluates Firm's Recall Strategy



(Health Risk) <u>Class I</u>: Reasonable probability that consumption of product will cause serious,

- adverse health consequences or death
- Examples:
 - Pathogen in ready-to-eat product
 - E. coli O157:H7 in raw ground beef

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Recall Classification

(Health Risk)

- <u>Class II</u>: Remote probability of adverse health consequences from use of the product
- · Examples:
 - Very small amounts of allergens typically associated with milder reactions, such as wheat or soy products
 - Extraneous, non-sharp edged, material such as pieces of plastic

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Recall Classification (Health Risk)

- <u>Class III</u>: Use of product will not cause adverse health consequences
- Example: Undeclared, non-allergenic, Generally Regarded As Safe (G.R.A.S.) ingredient such as excess added water

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Public Health Alerts

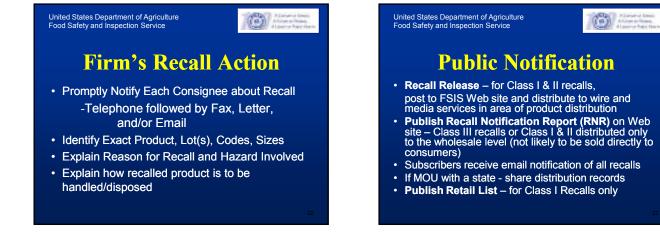
Product presents a public health risk

- Specific class of product implicated, rather than a specific product brand
- Human illness associated with a common, but unidentified source
- · Product is long out of date

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Recall Process

- The plant recall coordinator is contacted by the recall committee and advised of the recommendations
- Questions from both FSIS and the plant are discussed
- Although not required, FSIS expects the firm to provide the Committee its recall strategy, including how it intends to notify and instruct its consignees to retrieve or dispose of recalled product



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Recall Verification Activities

FSIS personnel conduct **Effectiveness Checks** to verify the recalling firm has been diligent and successful in contacting and advising the consignees of the need to retrieve and control the recall product, and that consignees have responded accordingly. United States Department of Agriculture Food Safety and Inspection Service

Recall Verification Activities

- Effectiveness checks are conducted throughout the distribution chain
- Risk Based and dependent on the class of the recall, the number of consignees, and other relevant factors

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DRO/IRC Responsibilities

- · Primary contact for recalling firm
- Request product distribution information • (names, addresses, and phone numbers of consigned
- Coordinate Effectiveness Checks
- Request assistance from other DDMs, Regional Import Field Supervisors, Office of Program Evaluation, Enforcement and Review (OPEER) Regional Managers to conduct effectiveness checks and gather any additional distribution information from consignees
- · Develops sampling plan based on distribution

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Field Recall Responsibilities

- DRO (DDM) coordinates and directs Enforcement Investigations and Analysis Officers (EIAOs) to conduct effectiveness checks
- · IRC coordinates and directs Import Surveillance Liaison Officers (ISLOs) or Compliance and Investigation Division (CID) Investigators to conduct checks if recalling firm is an importer

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EIAO/CID/ISLO Responsibilities

- Randomly conduct effectiveness checks
- Verify consignees are handling product in accordance with regulatory requirements and instructions of recalling firm
- Take action, if necessary, to detain product
- Submit findings to DRO/IRC
 - Identify process or product failures/trends?
 - Determine whether distributor or consignee failed to appropriately address recalled product
 Issue Prohibited Activity Notice as appropriate

 - Consider other enforcement actions, if necessary

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| Ve | Trification Pr | |
| Determine | e the hazard (class of reca | ll) and exposure |
| Recall classification | FSIS verification activities begin as soon as possible within a period of: | 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 |

| | f Effectiveness (| |
|----------------------|--------------------------------------------------------------------------|----------------------------------------------------------|
| Number of Consignees | ess, outbreak, or school Number of Effectiveness Checks to Make | Deviations for Recall to be Considered Ineffective |
| 1 to 200 | 100% | 0 |
| 201 to 10,000 | 200 | 0 |
| 10,001 - 500,000 | 800 | 1 |
| Over 500.001 | 1250 | 2 |

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Verification Process

Class I recalls without illness, outbreak, or school lunch implications.

| Number of Consignees | Number of Effectiveness Checks to Make | Deviations for Recall to be Considered Ineffective |
|----------------------|----------------------------------------------|-------------------------------------------------------------|
| 1 to 20 | 100% | 0 |
| 21 to 150 | 20 | 0 |
| 151 to 1,200 | 80 | 1 |
| 1,201 to 2,300 | 125 | 2 |
| 2,301 to 10,000 | 200 | 3 |

| Verification Process Class II recalls | | | | |
|------------------------------------------|------|---|--|--|
| | | | | |
| 1 to 5 | 100% | 0 | | |
| 6 to 25 | 5 | 0 | | |
| 26 to 150 | 20 | 1 | | |
| 151 to 280 | 32 | 2 | | |
| 281 to 500 | 50 | 3 | | |

| Verification Process | | | | |
|-------------------------|-------------------------------------------------|-------------------------------------------------------|--|--|
| Class III recalls | | | | |
| Number of Consignees | Number of Effectiveness Checks to Make | Deviations for Recall to be Considered Ineffective | | |
| 1 to 8 | 100% | 1 | | |
| 9 to 50 | 8 | 1 | | |
| 51 to 90 | 13 | 2 | | |
| 91 to 150 | 20 | 3 | | |
| 151 to 280 | 32 | 5 | | |

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Findings of Product in Commerce

- 1. Findings of product in commerce are those occurrences where recalled product remains available to the consumer
- 2. DDMs should immediately inform DRO when recalled products are encountered in commerce, so that the recalling firm can be informed
- 3. DRO determines if the findings follow a pattern or trend.

United States Department of Agriculture Food Safety and Inspection Service 6 Effectiveness Determinations The objectives of verification activities are to evaluate: 1. The overall effectiveness of the recall 2. The recalling firm's process If the recall is ineffective, FSIS will take further appropriate action to mitigate the risk to the

public, including detention, seizure, or other action within the rules of practice.

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Verification Follow-up

- · The objective of verification follow-up is to determine that product has undergone proper disposition in accordance with regulations.
- Is conducted on a subset of consignees. The same tables used to determine the number of recall effectiveness checks are also used to determine the number of verification follow-ups.
- Disposition includes return to recalling firm, destruction, lethality treatment, relabeling. Verification is on-site by FSIS personnel, independent verification, or may be a records review.

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Verification Result Summaries

The DRO summarizes recall activities and provides Final Recall Effectiveness Report to RMS which includes:

- A summary of findings of the recall effectiveness and product disposition verification checks, and
 Any supporting documentation voluntarily provided by the firm, including information about the amount of recalled product recovered.

Verification Result Summaries (Continued)

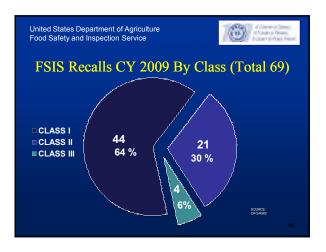
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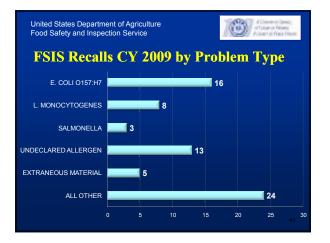
- State the total number of effectiveness checks and disposition verification checks performed and the numbers conducted both on-site and by telephone
- Assign an overall effectiveness rating to the recalling firm's recall activities (effective or ineffective)
- Determine how many consignees may still have product on sale
- Identify other deficiencies in the firm's recall process (if applicable)
- Summarize actions taken by FSIS in the case
- Description of corrective actions for each deficiency found

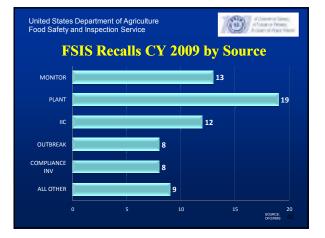
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Recall Termination

- When the establishment completes the recall, it notifies the DRO of amount recovered and disposition of product
- FSIS verification: recall effectiveness checks
- Recommend close-out following reasonable efforts to recover product









Thank you!