



Meat and Poultry Recalls

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Recall

A firm's removal of distributed meat or poultry products from commerce when there is reason to believe they are adulterated or misbranded under the Federal Meat Inspection Act (FMIA) or the Poultry Products Inspection Act (PPIA). Recall does not include a market withdrawal or a stock recovery.



Market Withdrawal

- A firm's removal or correction by its own initiative of a distributed product that involves a minor regulatory infraction that would not cause the product to be adulterated or misbranded.
- No violation of FMIA or PPIA
- No Health Hazard



Stock Recovery

- A firm's removal or correction of product that has not been marketed or that has not left the direct control of the firm.
- Example: Product is located at company warehouse and no portion of the lot has been released for sale or use.



Why Recall?

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.



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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Recall Process

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

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Recall Classification (Health Risk)

- **Class I:** 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)

- **Class II:** 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)

- **Class III:** 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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Firm's Recall Action

- Promptly Notify Each Consignee about Recall
 - Telephone followed by Fax, Letter, and/or Email
- Identify Exact Product, Lot(s), Codes, Sizes
- Explain Reason for Recall and Hazard Involved
- Explain how recalled product is to be handled/disposed

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Public Notification

- **Recall Release** – for Class I & II recalls, post to FSIS Web site and distribute to wire and media services in area of product distribution
- **Publish Recall Notification Report (RNR)** on Web site – Class III recalls or Class I & II distributed only to the wholesale level (not likely to be sold directly to consumers)
- Subscribers receive email notification of all recalls
- If MOU with a state - share distribution records
- **Publish Retail List** – for Class I Recalls only

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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.

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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 consignees)
- 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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Verification Process


Determine the risk

Determine the hazard (class of recall) 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

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Verification Process


Number of Effectiveness Checks

Class I recalls with illness, outbreak, or school lunch implications

Number of Consignees	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

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Verification Process

Class II recalls

Number of Consignees	Number of Effectiveness Checks to Make	Deviations for Recall to be Considered Ineffective
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

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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.

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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.

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Verification Result Summaries (Continued)

- 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

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FSIS Recalls CY 2009 By Class (Total 69)

Class	Count	Percentage
CLASS I	44	64%
CLASS II	21	30%
CLASS III	4	6%

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FSIS Recalls CY 2009 by Problem Type

Problem Type	Count
E. COLI O157:H7	16
L. MONOCYTOGENES	8
SALMONELLA	3
UNDECLARED ALLERGEN	13
EXTRANEOUS MATERIAL	5
ALL OTHER	24

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FSIS Recalls CY 2009 by Source

Source	Count
MONITOR	13
PLANT	19
IIC	12
OUTBREAK	8
COMPLIANCE INV	8
ALL OTHER	9

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Questions ?

- For more information on FSIS recalls, visit our website (www.fsis.usda.gov)

Thank you!

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