USDA
United States Department of Agriculture

One Team, One Purpose

Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness

FSIS Recall Overview

Recall Management and Technical Analysis Division

Office of Field Operations

Food Safety and Inspection Service:

What is a recall?

At FSIS, a recall is a firm's voluntary removal of distributed meat, poultry, or egg products from commerce when there is reason to believe those products are adulterated or misbranded under the provisions of the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), or Egg Products Inspection Act (EPIA).

Food Safety and Inspection Service:

Why does FSIS ask firms to recall product?

- Illness outbreaks
- Undeclared allergens
- Products produced without inspection
- Products imported without inspection
- Drug residues
- STECs
- *Listeria monocytogenes* or *Salmonella* in Ready to Eat Foods
- Foreign matter
- Others

When an official establishment believes it has shipped adulterated or misbranded product, it must inform the District Office (DO) of the type, amount, origin, and destination of the product within 24 hours of learning of the problem.

Food Safety and Inspection Service:

What are the classifications for FSIS product recalls?

- Class I: reasonable probability of serious, adverse health consequences or death
- Class II: remote probability of adverse health consequences
- Class III: will not cause adverse health consequences

Food Safety and Inspection Service:

What are the steps involved in the recall process?

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

Note: RMTAD may decide to hold a preliminary call (pre-call) to discuss unique or atypical situations to consolidate information, clarify expectations, and inform decision making. This may include FSIS program areas, partner agencies, or establishments.

Food Safety and Inspection Service:

How does FSIS learn of a potential recall?

Problem Identification

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

- The company
- FSIS sampling results
- Observations or information gathered by FSIS inspection program 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

Food Safety and Inspection Service:

Who conducts the preliminary investigation?

Preliminary Investigation

- Typically, FSIS inspection program personnel (IPP) conduct the initial investigation
- The official establishment should also investigate and gather information
- Depending on distribution of product or whether or not there is associated illness, other participants may include:
  - USDA Agencies (e.g., Food and Nutrition Service, Agricultural Marketing Service)
  - Department of Defense
  - Food and Drug Administration
  - Centers for Disease Control and Prevention
  - Department of Homeland Security

What information should be gathered for a recall?

Contact information for the recalling firm:

Establishment number, name, and address

Company Recall Coordinator, Media Contact, Consumer Contact

Product information:

- Reason for recall;
- Brand names/ Product names
- Packaging (Type & Size (pounds))
- Package codes (Use by/Sell by) and case codes
- Production and Packaging dates
- Amount produced (pounds)
- Amount held at establishment
- Amount distributed (pounds/cases)
- Distribution areas and level
- Photos of label or package
- Count/case
- School lunch (yes/no)
- Department of Defense (yes/no)
- Internet or catalog sales (yes/no)

Food Safety and Inspection Service:

How does FSIS assess the need for a recall?

Recall Deliberations

- 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(s)
  - Firm representatives may ask questions and discuss any concerns
  - Additional information may be considered

Food Safety and Inspection Service:

Who participates on the FSIS Recall Committee?

Recall Deliberations

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

Food Safety and Inspection Service:

How is the recall implemented?

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 issues a Public Health Alert and initiates detention and seizure of product in commerce.

Food Safety and Inspection Service:

What is the Recall (Press) Release?

Notifications & Actions

USDA

Recall Release

CLASS I RECALL
HEALTH RISK: HIGH

Congressional and Public Affairs
Name of Writer (202) 720-9113
Press@fsis.usda.gov
FSIS-RC- ###-201X

COMPANY NAME RECALLS TYPE OF PRODUCTS
DUE TO POSSIBLE FOREIGN MATTER CONTAMINATION

WASHINGTON, MONTH DD, YYYY – Company name, a city, AP state abbrev. establishment, is recalling approximately xxxx pounds of --type of/basic name of-- products that may be contaminated with extraneous materials the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) announced today.

The more specific description items were produced on MONTH DD, YYYY. The following products are subject to recall:

- X-lb. (PLASTIC, TRAY, VACUUM-PACKED, ETC. XXXXXXXXXXX) packages containing XXXX pieces of "COPY WORDING AS PRINTED ON LABEL."
- X-lb. (PLASTIC, TRAY, VACUUM-PACKED, ETC. XXXXXXXXXXX) packages containing XXXX pieces of "COPY WORDING AS PRINTED ON LABEL."
- X-lb. (PLASTIC, TRAY, VACUUM-PACKED, ETC. XXXXXXXXXXX) packages containing XXXX pieces of "COPY WORDING AS PRINTED ON LABEL."
- X-lb. (PLASTIC, TRAY, VACUUM-PACKED, ETC. XXXXXXXXXXX) packages containing XXXX pieces of "COPY WORDING AS PRINTED ON LABEL."

The products subject to recall bear establishment number "EST. or P-XXXX" inside the USDA mark of inspection. These items were shipped to a warehouse/distributor/retail locations in add states in alphabetical order.

The problem was discovered (PROVIDE DETAILS--during routine FSIS testing, in-plant verification activities, after the firm received consumer complaints, ETC.).

There have been no confirmed reports of adverse reactions due to consumption of these products. - OR - The company has received reports of minor oral injury associated with consumption of these products. FSIS has received no additional reports of injury or illness from consumption of these products. Anyone concerned about an injury or illness should contact a healthcare provider.

Consumers who have purchased these products are urged not to consume them. These products should be thrown away or returned to the place of purchase.

FSIS routinely conducts recall effectiveness checks to verify recalling firms notify their customers of the recall and that steps are taken to make certain that the product is no longer available to consumers. When available, the retail distribution list(s) will be posted on the FSIS website at www.fsis.usda.gov/recalls.

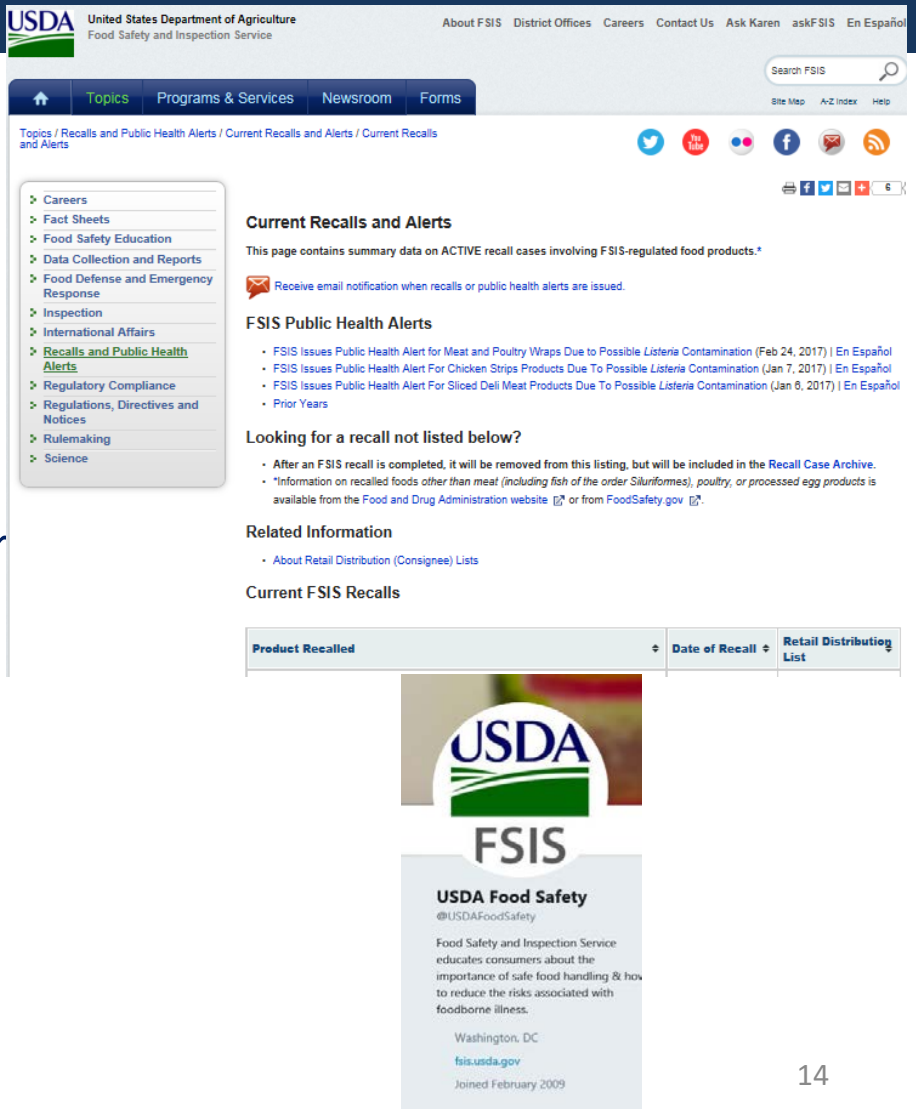
Consumers with questions about the recall can contact person's name, their company title/position, at (xxx) xxx-xxxx. Media with questions about the recall can contact person's name, their company title/position, at (xxx) xxx-xxxx.

Food Safety and Inspection Service:

How is the recall release distributed?

Notifications & Actions

- Public Health Partners
  - Sent to FSIS, USDA, and other Federal, State, and Local partners
- Public Notification
  - Posted on the FSIS Website
    - Class I: Retail lists posted
  - Sent to targeted media lists for each of the 50 states (unless Class III)
  - Tweeted out through the FSIS Twitter account
- Translation
  - Releases are translated into Spanish for Web posting and distribution



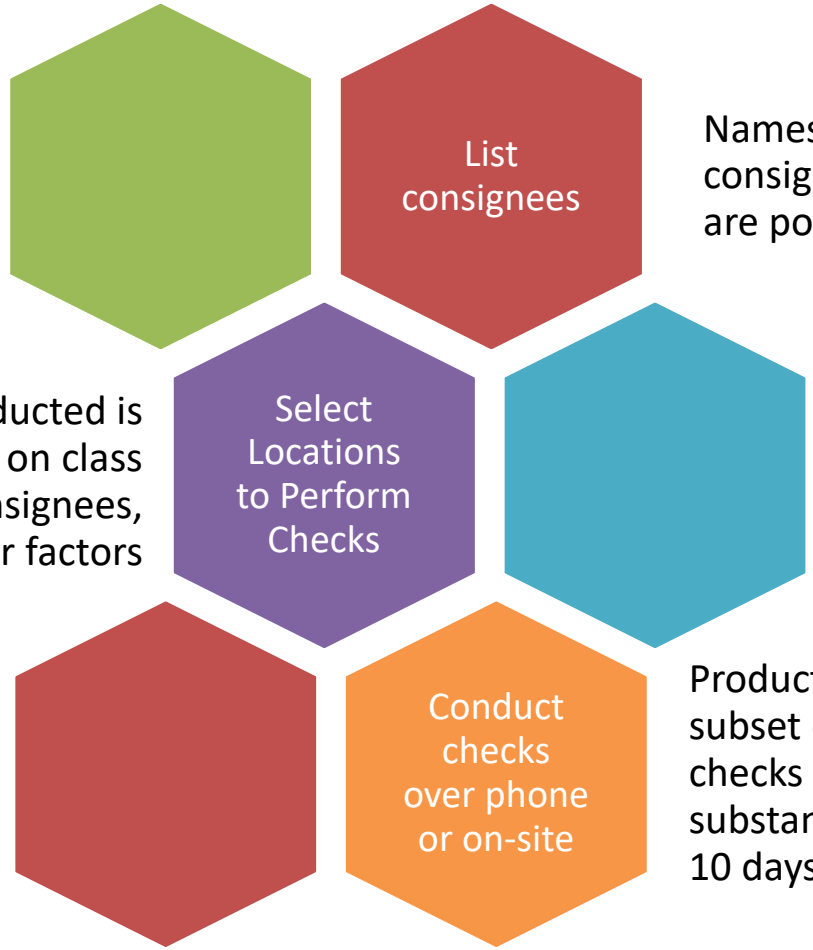
What is a Public Health Alert?

- Press release that may be issued if …
  - Meat, poultry, or egg product may be associated with illnesses but the Agency cannot identify a specific product to recommend be recalled
  - Product presents public health risk but is no longer believed to be in commerce
  - Firm refuses to voluntarily recall product
- Similar to a recall release, alert identifies:
  - Firm that produced product
  - Describes product involved
  - Potential health risk(s)
  - Why product adulterated or misbranded
  - How consumers should handle the product
  - Company contact(s) for consumers and media

Food Safety and Inspection Service:

How does FSIS assess recall effectiveness?

Notifications & Actions



Names and addresses for retail consignees for a Class I recall are posted to the website.

Number of checks conducted is risk-based, dependent on class of recall, number of consignees, and other factors

Product disposition verified at subset of total. For Class I, checks begin within 3 days and substantially complete within 10 days.

Food Safety and Inspection Service:

When is a recall considered closed?

Recall Closure

Firm sends FSIS closeout memo with list of customers, amount of product retrieved, actions taken, and disposition of returned product.

FSIS issues closeout letter to firm and moves recall from the Current Recalls and Alerts page on the FSIS website to the Recall Case Archive.

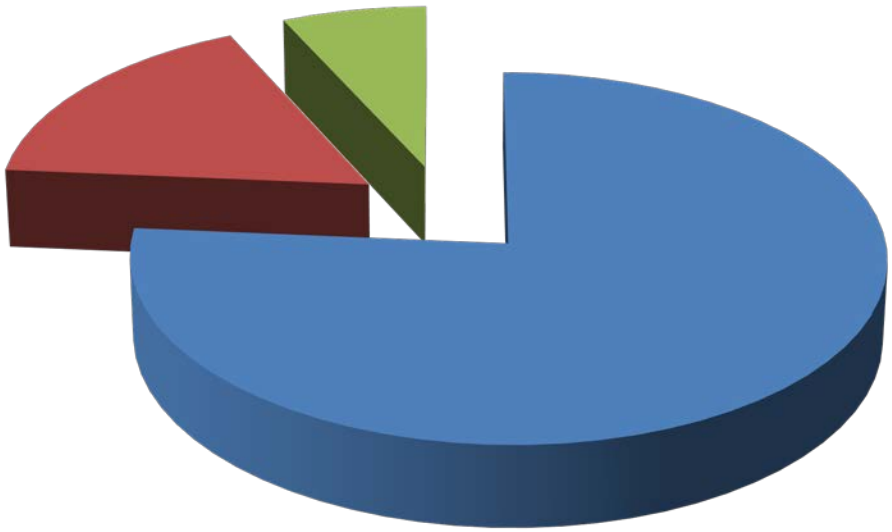
Agency reviews lessons learned for improved decision-making, increased public health protection, and increased consumer confidence.

2017 Recall Statistics

Food Safety and Inspection Service:

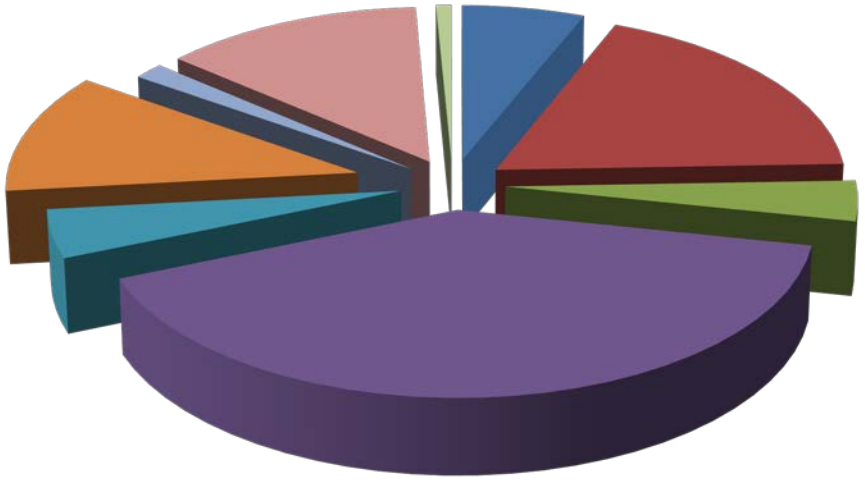
2017 Recall Summary by Classification and Reasons for Recall

Calendar Year 2017 - Recall Classification (N = 131 Recalls)



Class I (100) Class II (22) Class III (9)

Calendar Year 2017 - Reasons for Recall (N = 131 recalls)

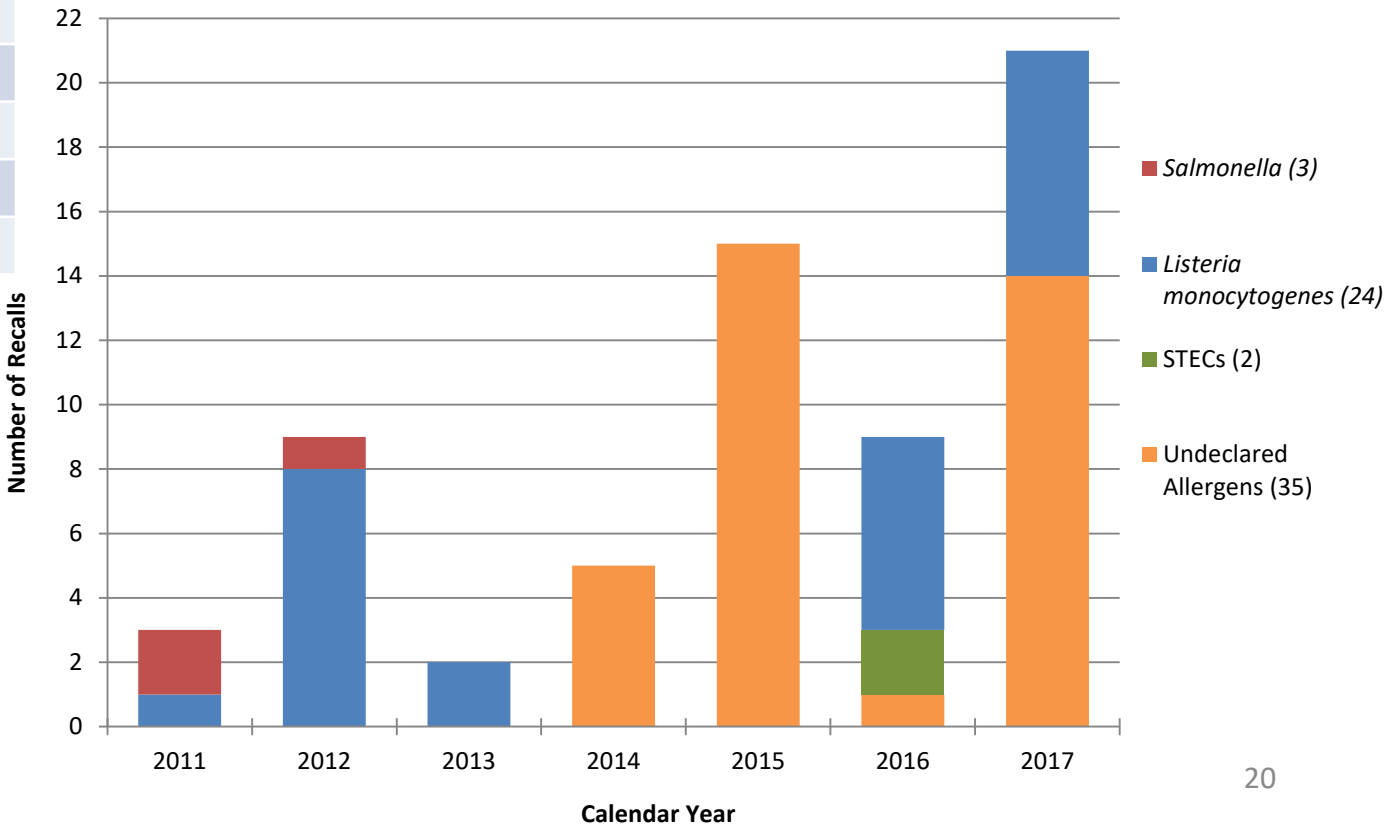


STECs (8)
Extraneous /Foreign Material (24)
Processing Deviation (5)
Undeclared Allergen (53)
Undeclared Substance (6)
Listeria monocytogenes (15)
Residue (2)
Other (17)
Salmonella (1)

Food Safety and Inspection Service:

Calendar Year Recalls associated with recalled FDA ingredient: 2011 -2017

Calendar Year	Pounds Recalled
2011	86,057
2012	99,878
2013	50,733
2014	373,629
2015	242,829
2016	47,470,488
2017	8,497,245
TOTALS	**56,820,859**



Food Safety and Inspection Service:

Additional Information

- FSIS Directive 8080.1 Recall of Meat and Poultry Products
- FSIS Directive 8410.1 Detention and Seizure
- FSIS Current Recalls and Alerts website
- FSIS Directive 9900.1 Imported Product Shipment Presentation
- Directive 9900.2 Import Reinspection of Meat, Poultry, and Egg Products
- How to Develop a Meat and Poultry Product Recall Plan
- AskFSIS
- Small Plant Help Desk or InfoSource@fsis.usda.gov or call 1-877-FSIS-HELP (1-877-374-7435)
- Industry Support and Resources