United States Department of Agriculture

Developing a Recall Plan: Guidelines for Meeting 9 CFR §418

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Why did FSIS develop the guidebook?
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Outbreaks

Jack in the Box
- 1992-1993
- 73 Jack in the Box restaurants identified (outbreak and recall)
- *E. coli* O157:H7
- Sickened 700 people in 4 states
  - 171 had to be hospitalized
  - 4 deaths
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Outbreaks

Pilgrim’s Pride

- 2002
- 27.4 million pounds of fresh and frozen ready-to-eat turkey and chicken products recalled
- *Listeria monocytogenes*
- Sickened 120 people
  - 20 deaths

Los Angeles Times

Pilgrim’s Pride Issues Record Recall of Poultry

The company says 27.4 million pounds of ready-to-eat products could be contaminated with listeria bacteria.

October 14, 2002 | From Bloomberg News
Cargill Meat Solutions

- 2011
- 36 million pounds of ground turkey products recalled
- *Salmonella* Heidelberg
- Sickened 136 people in 34 states
  - 37 hospitalized
  - 1 death
United States Department of Agriculture

**Recall Release**

**Arkansas Firm Recalls Breaded Chicken Products Due to Undeclared Allergens and Misbranding.**

WASHINGTON, April 2, 2018 - Tyson Foods Inc., a Springdale, Ark., establishment, is recalling approximately 121,000 lbs. of uncooked breaded chicken tenders and uncooked chicken tenderloin products because of an undeclared allergen and misbranding. The product contains soy, a known allergen not declared on the label.

The following products are subject to recall:

- 20-lb. packages of "SPARE TIME Uncooked Chicken Tenderloin" bearing the establishment number "P-3907" inside the USDA mark of inspection and a case code of "W0897." The products were produced between March 13, 2017 and March 17, 2017 and shipped to food service, convenience stores, and further distribution to restaurants and institutions.
- The chicken has a package code of "0221TLAN," "0301TLAN," "0311TLAN," "0401TLAN," or "0411TLAN" under the product code. The term represents a time stamp.

The problem was discovered by the company and occurred as a result of a label change after formulation of the product. A maternal ingredient that is labeled as an incidental ingredient (concentrations of less than 2%) was not declared on the label. Tyson and the company have received no reports of adverse reactions associated with the consumption of these products.

100%) chicken is included in the recall. Consumers who have questions about the recall should contact Tyson Foods Consumer Relations at 1-800-232-6872. Consumers with questions about the recall should contact Tyson Foods Consumer Relations at 1-800-232-6872.

For more information, consumers can visit the FDA website at www.fda.gov or the USDA website at www.fsis.usda.gov.

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Examples of companies that have declared bankruptcy or gone under due to recalls
United States Department of Agriculture

Costs

Jack in the Box

- Lost approximately $160 million in sales
- Lost approximately 30 percent of its stock market value
- Tens of millions in individual and class-action suits

http://www.howstuffworks.com/10-food-recalls.htm
United States Department of Agriculture

Costs

Westland/Hallmark

- 2008
- 143 million pounds of beef recalled
- Failure of plant to notify FSIS when cattle became non-ambulatory after passing ante-mortem inspection
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Costs (continued)

Westland/Hallmark

- Total cost about $117 million
- $497 million more to settle the civil suit against the plant
  - The settlement is largely symbolic because the company is bankrupt and out of business
- The recall cost taxpayers $150 million

http://www.howstuffworks.com/10-food-recalls.htm
Total Number of Recalls by Year

- 2012: 82
- 2011: 103
- 2010: 70
- 2009: 69
- 2008: 54
- 2007: 58
- 2006: 34
- 2005: 53

Total Recalls by Class 2011

Class I: 62
Class II: 29
Class III: 12
Total Recalls by Class 2012

Class I: 46
Class II: 24
Class III: 12
Total Recalls by Class So Far This Year

- Class I: 17
- Class II: 7
- Class III: 2
What is a Recall?

- A recall is a voluntary action conducted by a firm to remove adulterated or misbranded products from commerce.

- Although it is your company’s decision to recall product, FSIS coordinates with you to ensure....
Levels of Recall

Class I
There is a reasonable probability that eating the product will cause serious, adverse health consequences or death.

Examples include:
- Presence of pathogens (e.g., LM) in RTE meat or poultry products
- Presence of *E. coli* O157:H7 and other STECs in raw ground beef
Levels of Recall

Class II
There is a remote probability of adverse health consequences if the product is eaten.

Examples include:
• Presence of very small amounts of undeclared allergens typically associated with milder human reactions (e.g., wheat, or small-sized, non-sharp-edged foreign material) in a meat or poultry product.
Levels of Recall

Class III
Eating the product will not cause adverse health consequences.

Examples include:
• Presence of undeclared ingredients, such as excess water in a meat or poultry product.
Background

On May 8, 2012, FSIS published a final rule requiring official establishments to:

1) promptly notify the appropriate District Office that an adulterated or misbranded meat or poultry product has entered commerce, and

2) prepare and maintain written procedures for the recall of meat and poultry products
A firm should notify FSIS within 24 hours if they have determined that adulterated product has been shipped into commerce.
Preparation and maintenance of written recall procedures

Each official establishment must prepare and maintain **written procedures** that **must specify**:

1) How the official establishment will decide whether to conduct a product recall

2) How the establishment will effect the recall
United States Department of Agriculture

9 CFR §418.3 Effective Dates

Large Establishments
November 5, 2012

Small and Very Small Establishments
May 8, 2013
Recall Plans

Factors to consider when developing a Recall Plan:

• Identify the Recall Team
• State the procedures for determining whether a recall is necessary
• Scope of the Recall
• Records
• Recall Communications
• Public Notification
• Effectiveness Checks
• Returned Product Control and Disposition
• Recall Simulations
• Final Actions
Identify the Recall Team

- Identify the Recall Coordinator
- Clearly define member roles and responsibilities
- Team must be knowledgeable about firm’s operations
- Contact information
- Back-up team members as needed
Is a Recall Necessary?

Procedures to determine if a recall is necessary:

• Has adulterated or misbranded product been produced?
• Has adulterated or misbranded product been shipped?
• Where has the product been shipped?
• Is the product in commerce?
• Is the product available to consumers?
What is the Scope of the Recall?

• How will the firm assess the amount and kind of product implicated?
• Accurate, detailed records are essential.
• Factors to consider:
  – When did the problem begin?
  – When was it resolved?
  – What product(s) were affected?

***It is important to note that “clean-up to clean-up” may not be sufficient to determine the scope of recall.
Factors that May Affect The Scope of Recall

- Microbial Pathogens
- Foreign Material
- Undeclared Allergen
- Misbranding
All records, including records documenting procedures required by this part, must be available for official review and copying.

Note: Records should be maintained for a period of time that exceeds the shelf life and expected use of the products (a minimum of that required by 9CFR § 320 and § 381.175).
Records

Records are **vital** in tracing product forward to consignees and back to suppliers, and to facilitating an effective recall.

Information drawn from records includes:

- Product identification
- Production records
- Microbial data
- Distribution information
Recall Communications

Notice of the recall can be disseminated to consignees via e-mail, telephone, letter, or fax.

Written notices should contain:

- Prominent heading
- Reason for recall
- Description of product
- Explanation of risk involved
- Request for official, written response
- Ready means for consignee to report whether it has any implicated product on hand
- Instructions for handling recalled product
- Recalling Firm contact information

URGENT FOOD RECALL
Good Foods R Us

ATTN: Mr. Smith, Market Manager
Re: Recall of Good Ground Beef

Dear Sir:

This letter is to confirm our telephone conversation that Good Foods R Us is recalling the following product because it may be contaminated with E. coli O157:H7.

10 lb chubs of Good Ground Beef, Lot Code 12345, Sell by date 01/01/13. Each box bears a label with the UPC code 33333333 as well as the establishment number "EST. 00000" inside the USDA mark of inspection.

We request you review your inventory records and segregate and destroy the above product. Please send us a receipt of pounds destroyed so we can credit your account. If you have shipped any of this product, we request that you contact your customers and ask them destroy the product and provide you with a receipt of destruction.

Your prompt action will greatly assist Good Foods R Us in this action. If you have any questions please do not hesitate to contact me, John Johnson, Company Recall Coordinator at (555) 555-5555 or via email at jj@goodfoodsrus.com.

Thank you for your cooperation.
Public Notification

FSIS Recall Release

• Class I and Class II recalls
• Class I recalls include a list of retail stores where implicated product was distributed.
• Class III recalls have a Recall Notification Report published on the FSIS website ([www.fsis.usda.gov/Fsis_Recalls/index.asp](http://www.fsis.usda.gov/Fsis_Recalls/index.asp)).

Firms may also issue their own media release.
Firm’s Effectiveness Checks

Firm should verify and record that all consignees have received notification about the recall and have taken appropriate action.

FSIS will also conduct Effectiveness Checks independent of the firm to verify the effectiveness of the recall.
Returned Product Control and Disposition

Specify how the recovered product will be handled and how it will be controlled pending final disposition.

FSIS personnel should be notified prior to disposition actions (e.g. destruction or relabeling) of product returned to the firm.
Recall Simulations

Mock recalls:

- Identify potential problems
- Familiarize personnel with recall procedures
- Smooth the recall process
- Keep recall team prepared
- Instill confidence in the recall team

Should involve:

- One lot of product that has been distributed in commerce
- Hypothetical reason for recalling the product
- No prior notice to personnel involved
- Should proceed at least to the point of communication with primary consignees
Final Actions

Recall Plan should include procedures for notifying FSIS once all reasonable efforts to recover and determine the disposition of recalled products have been made.

Examples of relevant information:
  • Amount (poundage) of product retrieved
  • Final disposition of product (destroyed/relabeled) and poundage
Please contact these the resources below for additional assistance.

- Small Plant Help Desk
  1-877-374-7435
  Infosource@fsis.usda.gov

- askFSIS
  1-800-233-3935
United States Department of Agriculture

ANY QUESTIONS?