



United States Department of Agriculture

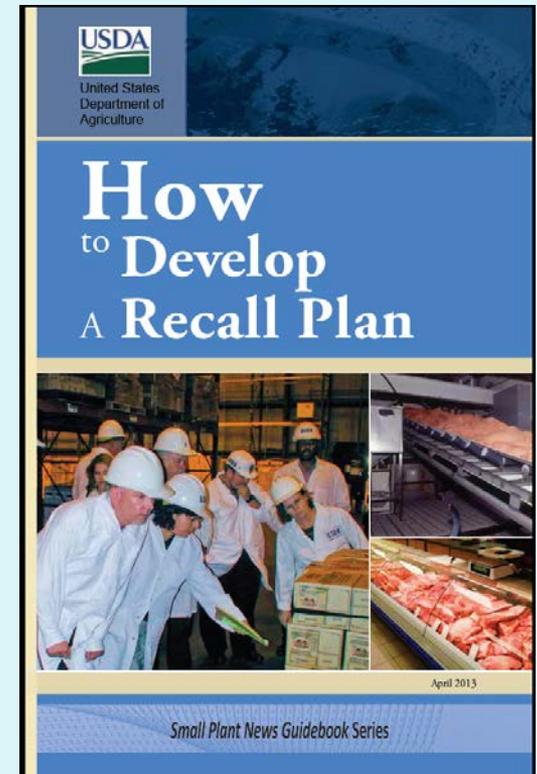
# Developing a Recall Plan: Guidelines for Meeting 9 CFR §418

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## Food Safety Inspection Service

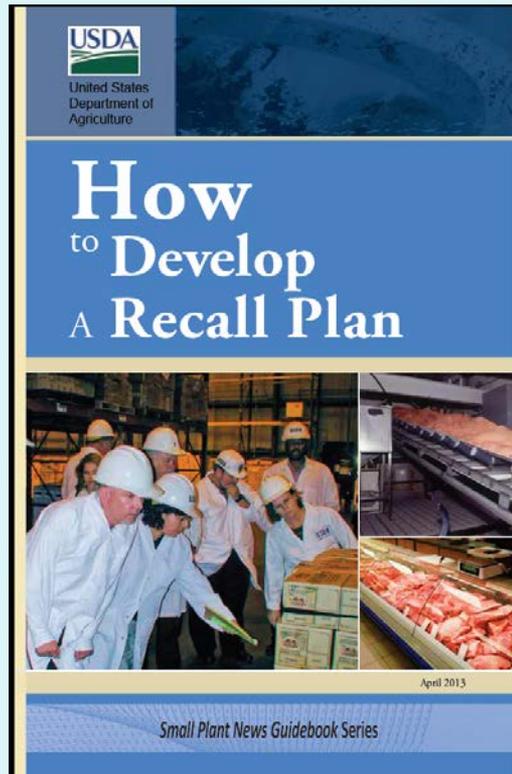
Office of Outreach, Employee Education and Training  
Outreach and Partnership Division



## Recall Plan Video



# Why did FSIS develop the guidebook?





# United States Department of Agriculture 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

Wednesday, April 24, 2013 | TRAFFIC | 43°F

**The Seattle Times**  
Winner of Nine Pulitzer Prizes

Home | News | Business & Tech | Sports | Entertainment | Living | Homes | Travel | Opin

Friday, January 22, 1993 - Page updated at 12:00 AM

E-mail article Print

### Boy Dies From Tainted Meat -- 2-Year-Old Is First Victim Of Food Poisoning

By Greg Heberlein, Warren King, Judith Blake, Margaret Miller

A 2-year-old Tacoma boy died today from an infection linked to contaminated hamburgers from a fast-food restaurant.

It is the first death among more than 100 people sickened by the food-poisoning epidemic that has hit mostly the Puget Sound area this month. The outbreak is linked to Jack in the Box restaurants.

The Tacoma boy died at Children's Hospital Medical Center in Seattle of heart failure stemming from kidney failure caused by the bacteria *E. coli* 0157:H7. He was identified by the King County medical examiner's office as Michael Nole.



# United States Department of Agriculture

## 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

The screenshot shows the top portion of a news article from the Los Angeles Times. The masthead "Los Angeles Times" is in a large, black, serif font. Below it is a navigation bar with categories: LOCAL, U.S., WORLD, BUSINESS (highlighted), SPORTS, ENTERTAINMENT, HEALTH, LIVING, TRAVEL, OPINION, and SHOP. A secondary navigation bar lists sub-categories: MONEY & CO., TECHNOLOGY, HIGHWAY 1, COMPANY TOWN, PERSONAL FINANCE, JOBS, REAL ESTATE, and CARS. The breadcrumb trail reads "YOU ARE HERE: LAT Home → Collections → Product Recalls". The article title is "Pilgrim's Pride Issues Record Recall of Poultry". The lead paragraph states: "The company says 27.4 million pounds of ready-to-eat products could be contaminated with listeria bacteria." The byline is "October 14, 2002 | From Bloomberg News". The first paragraph of the article text reads: "WASHINGTON — Pilgrim's Pride Corp. is recalling 27.4 million pounds of ready-to-eat chicken and turkey products in what U.S. officials called the largest meat recall in the nation's history." The second paragraph begins: "Pilgrim's Pride, the second-largest U.S. poultry company behind Tyson Foods Inc., suspended



# United States Department of Agriculture Outbreaks

## Cargill Meat Solutions

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

A screenshot of a news article from The New York Times. The page header includes navigation links for "HOME PAGE", "TODAY'S PAPER", "VIDEO", "MOST POPULAR", and "TIMES TOPICS". The main header reads "The New York Times" and "Business Day". Below this are category links: "WORLD", "U.S.", "N.Y. / REGION", "BUSINESS", "TECHNOLOGY", "SCIENCE", "HEALTH", and "SPORTS". A search bar and additional links for "Global", "DealBook", "Markets", and "Economy" are also visible. The article title is "Cargill Recalls Ground Turkey Linked to Outbreak". The byline is "By WILLIAM NEUMAN" and the publication date is "Published: August 3, 2011". The main text states: "Cargill, a major United States meat processor, said Wednesday that it was recalling about 36 million pounds of ground turkey produced at an Arkansas plant after it was [linked to a nationwide outbreak of salmonella sickness](#). It appeared to be one of the largest meat recalls ever." To the right of the text is a sidebar with social media sharing options: "RECOMMEND" (Facebook), "TWITTER", "LINKEDIN", "SIGN IN TO E-MAIL", "PRINT", "REPRINTS", and "SHARE". At the bottom of the article, there is a small image of ground turkey with the text "Enlarge This Image" and a partial caption: "One person in California has died in the outbreak".



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**USDA Food Safety and Inspection Service**

## Recall Release

Congressional and Public Affairs  
Richard J. McInerney (202) 720-9113  
FSIS-RC-024-2013

**CLASS II RECALL**  
**HEALTH RISK: LOW**

**MINNESOTA FIRM RECALLS BONE-IN RIBEYE THAT MAY CONTAIN SPECIFIED RISK MATERIALS**

WASHINGTON, March 25, 2013 – Triple J Family Farms, a Buffalo Lake, Minn. establishment, is recalling approximately 15,270 pounds of bone-in ribeye products because the vertebral column may not have been completely removed, which is not compliant with regulations that require the removal of vertebral column in cattle 30 months of age or older, the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) announced today.

The products subject to recall are:

- Approx. 40-lb boxes of "BEEF B1 RIBE" bearing any of the following case codes: "91-R109H-C," "91-R109H-S," "91-R109H-SE," or "91-R109H-S-SB."

The products subject to recall bear the establishment number "EST 17466" inside the USDA mark of inspection. The products were produced and packaged on various dates between Feb. 8, 2013, and March 21, 2013, and were distributed to an FSIS-inspected establishment in New York for further processing and distribution.

The problem was discovered by FSIS during a routine specified risk material (SRM) verification and inspection. The products subject to recall bear the establishment number "EST 17466" inside the USDA mark of inspection. The products were produced and packaged on various dates between Feb. 8, 2013, and March 21, 2013, and were distributed to an FSIS-inspected establishment in New York for further processing and distribution.

The problem was discovered by FSIS during a routine specified risk material (SRM) verification and inspection. The products subject to recall bear the establishment number "EST 17466" inside the USDA mark of inspection. The products were produced and packaged on various dates between Feb. 8, 2013, and March 21, 2013, and were distributed to an FSIS-inspected establishment in New York for further processing and distribution.

FSIS routinely conducts recall effectiveness checks to verify recalling firms notify their customers of the recall. Members of the media with questions about the recall should contact Gary Mickelson, Director of Consumer Relations, at (479) 290-6111.

Consumers with questions about the recall should contact Tyson Foods Consumer Relations at (866) 455-6111, or via smartphone at [m.askkaren.gov](http://m.askkaren.gov). "Ask Karen" live chat services are available from 10 a.m. to 4 p.m. ET, the toll-free USDA Meat and Poultry Hotline 1-888-685-6854 is available in English and Spanish and can be reached from 10 a.m. to 4 p.m. ET, Monday through Friday. Recorded food safety messages are available 24 hours a day.

For more information, visit [www.fsis.usda.gov](http://www.fsis.usda.gov) or call 1-888-685-6854.



**USDA Food Safety and Inspection Service**

## Recall Release

Congressional and Public Affairs  
Neil Gatliffy (202) 720-9113  
FSIS-RC-026-2013

**CLASS I RECALL**  
**HEALTH RISK: HIGH**

**ARKANSAS FIRM RECALLS BREADED CHICKEN PRODUCTS DUE TO UNDECLARED ALLERGEN AND MISBRANDING**

WASHINGTON, April 2, 2013 – Tyson Foods Inc., a Russellville, Ark. establishment, is recalling approximately 127,000 lbs. of uncooked breaded chicken tenderloins and uncooked chicken tenderloin fritter 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 Fritters" bearing the establishment number "P-5839" inside the USDA mark of inspection and a case code of "7083861."
- 10-lb. packages of "Tyson UNCOOKED, BREADED CHICKEN TENDERLOINS" bearing the establishment number "P-5839" inside the USDA mark of inspection and a case code of "7083928."

The products were produced between March 1, 2013 and March 27, 2013 and shipped to food service companies nationwide for further distribution to restaurants and institutions. The cartons bear a package code of "0603TYLXXX", "0663TYLXXX", "0733TYLXXX", "0773TYLXXX", "0813TYLXXX", or "0863TYLXXX" under the product code. The XXXX 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 maritime ingredient that included an incorrect sub-ingredient (concentrated soy stem) was not declared on the label. FSIS and the company have received no reports of adverse reactions due to consumption of these products. Anyone concerned about a reaction should contact a health care provider.

FSIS routinely conducts recall effectiveness checks to verify recalling firms notify their customers of the recall to ensure that steps are taken to make certain that the product is no longer available to consumers.

Consumers with questions about the recall should contact Tyson Foods Consumer Relations at (866) 455-6111, or via smartphone at [m.askkaren.gov](http://m.askkaren.gov). "Ask Karen" live chat services are available from 10 a.m. to 4 p.m. ET, the toll-free USDA Meat and Poultry Hotline 1-888-685-6854 is available in English and Spanish and can be reached from 10 a.m. to 4 p.m. ET, Monday through Friday. Recorded food safety messages are available 24 hours a day.

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**USDA Food Safety and Inspection Service**

## Recall Release

Congressional and Public Affairs  
Patricia El-Hemmy (301) 726-4763  
FSIS-RC025-2013

**CLASS I RECALL**  
**HEALTH RISK: HIGH**

**NEW YORK FIRM RECALLS FROZEN MINI QUESADILLA, PIZZA, CHEESE STEAK AND OTHER SNACK PRODUCTS DUE TO POSSIBLE E. COLI O121 CONTAMINATION**

WASHINGTON, March 28, 2013 – Rich Products Corporation, a Buffalo, NY, firm, is recalling approximately 196,222 pounds of frozen chicken quesadilla and various other heat treated, not fully cooked products because they may be contaminated with *E. coli* O121, the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) announced today.

The following products are subject to FSIS recall:

- 7.2-oz. cartons of Farm Rich mini pizza slices with cheese pepperoni and sauce in pizza dough, UPC code 041322376090 with a best by date of May 15 or May 16, 2014.
- 22-oz. cartons of Farm Rich mini pizza slices with cheese pepperoni and sauce in pizza dough, UPC code 041322376037 with a best by date of May 15 or May 16, 2014.
- 18-oz. bags of Farm Rich mini quesadillas with cheese, UPC code 041322376032 with a best by date of May 13 or May 14, 2014.
- 21-oz. bags of Farm Rich Philly cheese steaks with cheese, beef & onions in a crispy crust, UPC code 041322376045 with a best by date of May 13, 2014.
- 22-oz. cartons of Farm Rich mini pizza slices with cheese pepperoni and sauce in pizza dough, UPC code 041322376090 with a best by date of May 15 or May 16, 2014.
- 7-oz. cartons of Farm Rich mozzarella bites in a pizzeria style crust, UPC code 041322376016 with a best by date of May 15, 2014.
- 22-oz. bags of Market Day Mozzarella Dites, UPC code 041322376048 with a best by date of May 12, 2014.

In addition, the following products, which fall under FDA jurisdiction, are also being recalled. FSIS is adulterated and should be properly discarded or destroyed.

Each product package above contains the establishment number "EST: 27232" or "EST: 27233" and the establishment name "Rich Products Corporation".

The products subject to recall were produced between Nov. 1, 2012 and Feb. 28, 2013.

For more information, visit [www.fsis.usda.gov](http://www.fsis.usda.gov) or call 1-888-685-6854.



# Economic Costs of Recall

- Examples of companies that have declared bankruptcy or gone under due to recalls



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## 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



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## 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)**

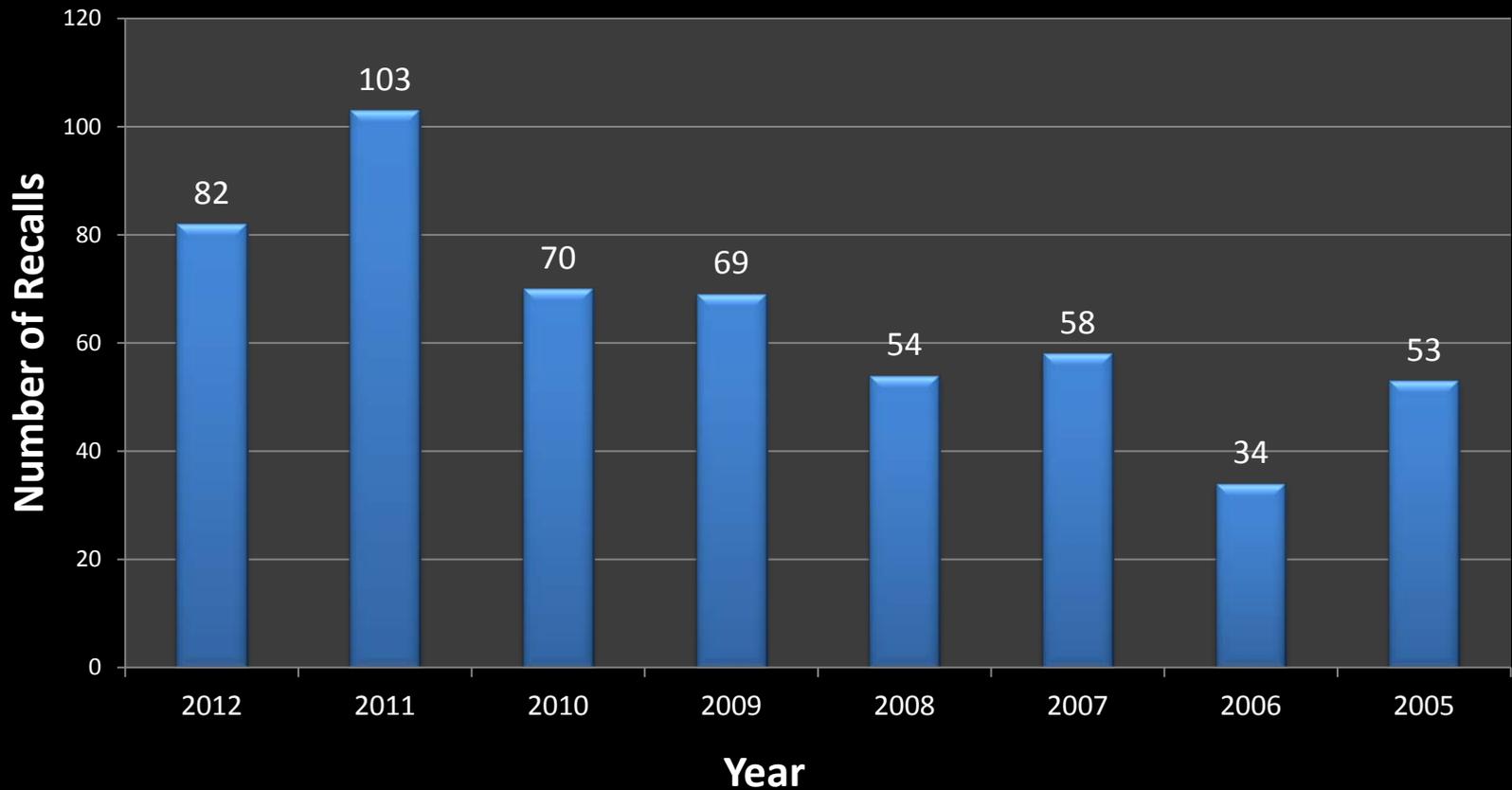
**Westland/Hallmark**

- 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



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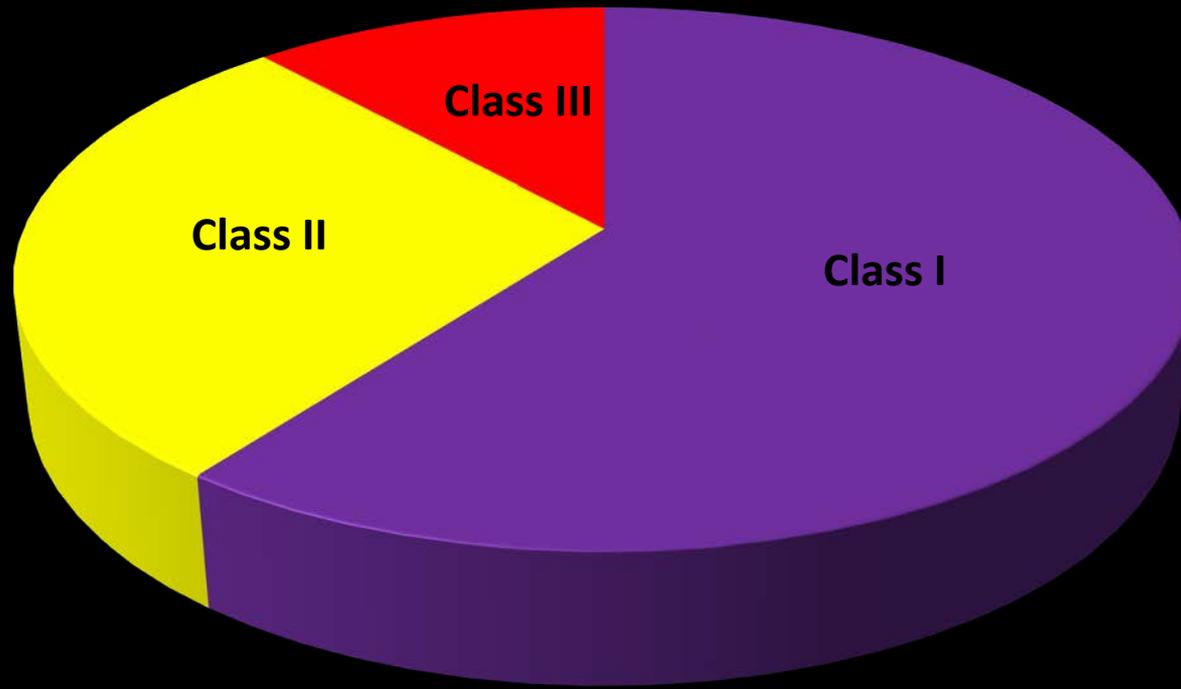
### Total Number of Recalls by Year





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## Total Recalls by Class 2011

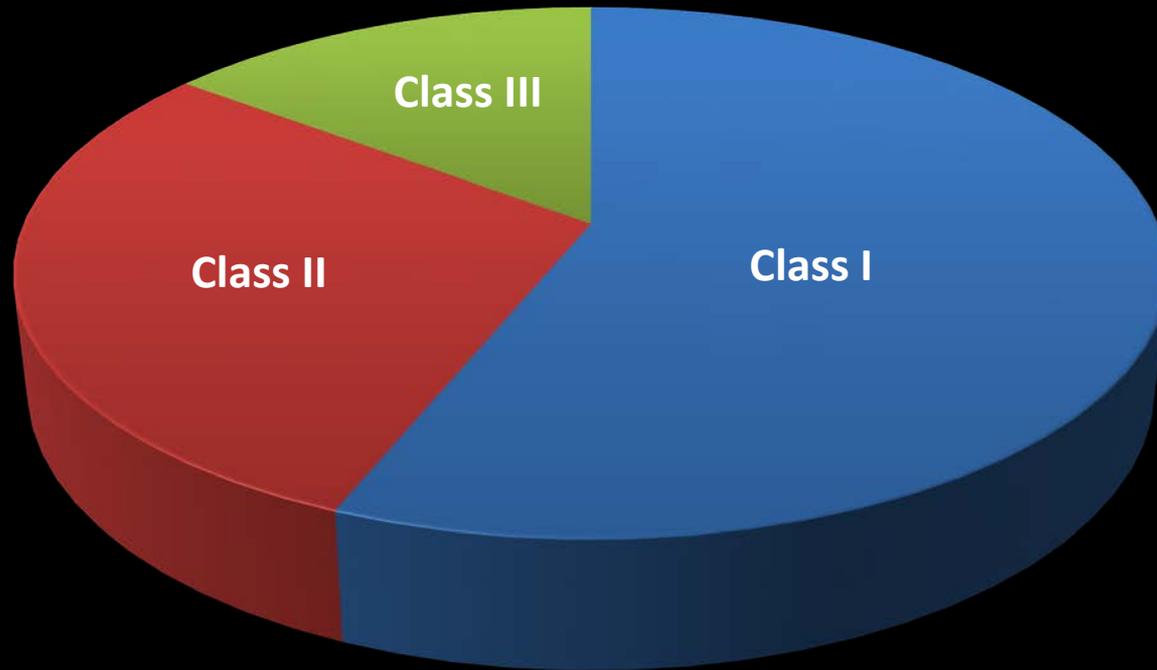


Class I 62 Class II 29 Class III 12



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## Total Recalls by Class 2012

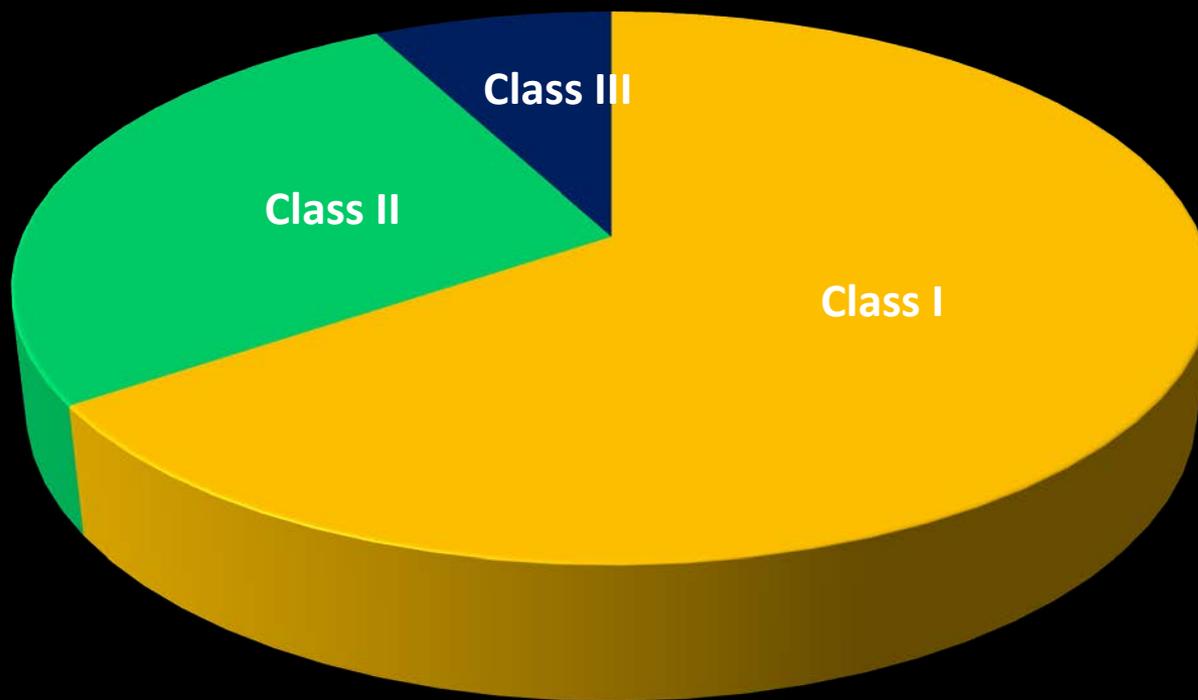


Class I 46 Class II 24 Class III 12



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## 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....



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# 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



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# 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.



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# 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.



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## 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



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## Notification

A firm should notify FSIS within **24 hours** if they have determined that adulterated product has been shipped into commerce.



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# 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



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# 9 CFR §418.3 Effective Dates

Large Establishments  
November 5, 2012

Small and Very Small  
Establishments  
May 8, 2013

November 2012 Calendar

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30				

www.printablehub.com

May 2013 Calendar

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

www.printablehub.com



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# 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



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## 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



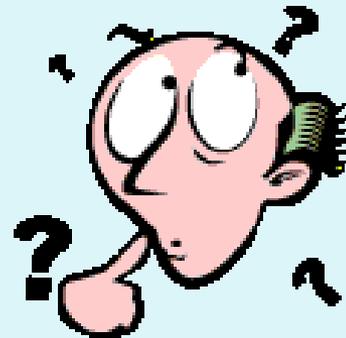


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# Is a Recall Necessary?

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?





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# 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.



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# Factors that May Affect The Scope of Recall

- Microbial Pathogens
- Foreign Material
- Undeclared Allergen
- Misbranding





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## Records

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).





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# 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





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# 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](mailto:jj@goodfoodsrus.com)

Thank you for your cooperation



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# 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.



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# 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.





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# **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.



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# 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



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## **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/re-labeled) and poundage

# Any Questions?

Please contact these the resources below for additional assistance.

- Small Plant Help Desk

1-877-374-7435

[Infosource@fsis.usda.gov](mailto:Infosource@fsis.usda.gov)

- [askFSIS](#)

1-800-233-3935



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**ANY QUESTIONS?**

*[http://www.fsis.usda.gov/Fsis\\_Recalls/index.asp](http://www.fsis.usda.gov/Fsis_Recalls/index.asp)*