

Recalls

OBJECTIVES

At the end of this module, you will be able to:

1. Explain why products are recalled.
2. Identify the classes of product recalls.
3. Identify the roles different groups play in product recalls.

RESOURCES

FSIS Directive 8080.1, Revision 4, "Recall of Meat and Poultry Products."

INTRODUCTION

A recall is a firm's voluntary removal of product from trade or consumer channels (e.g., by manufacturers, distributors, or importers) to protect the public from consuming adulterated (injurious to health or unfit for human consumption) or misbranded (false or misleading labeling and/or packaging) products. If a company refuses to recall its product, then FSIS has the legal authority to detain and/or seize meat and poultry product(s) in commerce when there is a reason to believe they are hazardous to public health or if other consumer protection requirements are not met. Although recalls are voluntary, FSIS oversees all recall activities by official meat and poultry establishments, and coordinates any FSIS actions with the recall taken by the firm. For recalls conducted by state-inspected firms or retail establishments, the appropriate state agency oversees the recall in most cases. FSIS will provide the state agencies any needed assistance and information.

Recall Management Division

The Recall Management Division (RMD) is the division that has the primary responsibilities for recall activities (FSIS Directive 8080.1, Revision 4). The RMD is responsible for the following.

- Leads the Recall Committee meeting.
- Reviews and evaluates incoming data (Recall worksheets, charts, labels).
- Formally recommends and closes out recalls.
- Liaison with other programs and Agencies.

Recall Classifications

FSIS assesses the public health concern or hazard presented by a product being recalled, or considered for recall, whether firm-initiated or requested by FSIS, and classifies the recall based on the relative health risk as follows:

- Class I: Reasonable probability serious, adverse health problem or death.
- Class II: Remote probability of adverse health problem

- Class III: No adverse health consequences

Class I and Class II are therefore public health related. Let's look at each of these in more detail.

Class I. This is a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death. For example, the presence of pathogens in ready-to-eat product or the presence of *E. coli* O157:H7 in ground beef.

Class II. This is a health hazard situation where there is a remote probability of adverse health consequences from the use of the product. For example, the presence of undeclared allergens such as milk or soy products.

Class III. This is a health hazard situation where the use of the product will not cause adverse health consequences. For example, the presence of undeclared generally recognized as safe nonallergen substances, such as excess water.

For every recall, FSIS notifies the public through a press release and a Recall Notification Report (RNR). The press release is issued to media outlets in the areas where the product was distributed and to an email listserv. The news release and the RNR are both posted on the Open Federal Cases area of the Web site. All FSIS press releases concerning recalls can be found on the FSIS web site at: http://www.fsis.usda.gov/OA/recalls/rec_pr.htm.

These press releases clearly describe the product being recalled along with any identifying marks or codes, explain the reason for the recall, and describe the risk involved in consuming the product. They also provide instructions to the public on what to do with the product if people identify it and have it in their possession and the name and telephone number of a company contact for consumers to call with any questions. In addition, they provide general information about the product's destination, for example, "The beef burritos were distributed to an airline caterer and restaurants in the States of....." or "Frankfurters were sold to grocery stores, delis, and convenience stores in the States of" Press releases issued by FSIS will not identify the name and address of the recipients of product (e.g., specific grocery stores, restaurants, airlines, etc.) unless the supplier of the information chooses to release it to the public.

In FY 2003, 51% of the recalls were of a Class I type, 12% were of a Class II type, and 14% were of a Class III type.

District Recall Officer (DRO)

Each District has an individual who acts as the Designated Recall Officer, or DRO. This is typically the Deputy District Manager (DDM) where the recalling firm is located. The DRO is responsible for the following activities.

- Coordinates field recall process.
- Assigns CO/EIAO (Enforcement Investigations and Analysis Officer).
- Interacts with recalling firm, other districts, and RMD.
- Develops effectiveness check strategy.
- Interprets results of the effectiveness checks.

Recall process

The process of recalling a product begins with problem identification. A problem with a product can be identified through various sources; the most common sources are:

- A positive result from FSIS sampling (microbiological, species, chemical)
- Information that the plant itself has (e.g., positive microbiological test results, consumer complaint, formulation records)
- Information from in-plant inspectors
- Information from outbreak investigations
- Consumer complaints reported to FSIS (reported in the FSIS Consumer Complaint Monitoring System)

Let's take a closer look at the process when it is initiated based on a positive microbiological sample taken as part of FSIS sampling programs. There are three potential outcomes from FSIS sampling. The sample can be:

- potential positive- when samples are collected and initially screened.
- presumptive positive- reported samples are based on laboratory preliminary results.
- confirmed positive- when sample analysis has been finalized by the laboratory and the pathogen in question has been identified.

From the presumptive positive group, 90% of the samples have shown later to be confirmed positive. When the sample is confirmed positive, the product represented by that sample is considered to be adulterated.

Data from the FSIS laboratories about the sample are entered into two systems. One system is the Laboratory Electronic Application for Results Notification (LEARN). LEARN is a computer application that reports sample status and analysis result information of samples submitted to FSIS laboratories for analysis. The other is the Biological Information Transfer E. mail System, or BITES. BITES is an electronic method of quickly reporting sample status and analysis result information of samples submitted to FSIS laboratories for analysis. BITES is generally provided to district level and above.

The District Office reviews the information in BITES and LEARN routinely. For all samples that are identified as presumptive positives, the DRO verifies with inspection personnel in the establishment that the product is in a holding status and notifies the RMD within 2 hours. If the in plant inspection personnel indicate that the affected product is being held by the establishment, no recall action is initiated. However, if in plant inspection personnel indicate that the product has left the control of the establishment and has entered commerce, the DDM assigns a Program Investigator (PI) or an Enforcement Investigations Analysis Officer (EIAO), and the pre-recall process begins.

Stage 1 – Pre-recall (presumptive positive):

During Stage 1, pre-recall, the PI or EIAO will immediately contact the establishment's Recall Coordinator (RC) to discuss presumptive positive findings. They will also ensure that the firm receives copies of FSIS recall worksheets. They will conduct a walk-through of the worksheets with the company RC. They will also gather supplier documentation when the

sample is presumptive positive for *E. coli* O157:H7 per Directive 10,010.1, Revision 1. Note that this Directive is applicable whether the establishment is holding the product or not. They will then coordinate with IIC or CS, and update the DDM on progress.

Stage 2 – Recall Committee (laboratory result is confirmed positive)

If the sample is confirmed positive by the FSIS laboratory, the Recall Committee is convened, and Stage 2 is implemented. The CO/EIAO who was assigned becomes a member of the Recall Committee. The CO/EIAO participates and provides information to the Recall Committee. They also provide information to the establishment. For example, the CO/EIAO will explain the recall effectiveness check process and the expectation of company consignees' notification to the establishment officials.

Stage 3 – After the recall (recall effectiveness checks)

In cases where the company conducts a voluntary recall, the RMD issues a RNR which provides detailed information about the product being recalled. FSIS then issues a press release. This press release is posted on the FSIS website. The CO/EIAO will follow up by verifying that the distribution information is collected. They also provide feedback to the DRO. The DRO directs the CO/EIAO in the DO where the recall originated to conduct recall effectiveness checks.

If the affected product has been distributed in other Districts, the DRO notifies other DDMs that assistance in conducting recall effectiveness checks is needed. Other Districts conduct effectiveness checks and report results back to DRO. If there is an MOU with a state (9 CFR 390.9), the DRO or DDMs notifies state authorities about the recall. When it is appropriate, the DRO recommends closure of the recall to the RMD.

The CO/EIAO will follow the process outline in Directive 8080.1, Revision 4, to perform the effectiveness checks. The effectiveness checks are conducted based on risk to public health. Risk is measured by combining the hazard, as defined by the class of recall, and potential exposure to the product measured by the number of the consignees or exposure. By means of this effectiveness checks FSIS program personnel ensures that the firm makes all reasonable efforts to retrieve the recalled meat, poultry, or egg product. A sufficient number of effectiveness checks are made to verify that the recall is conducted in an effective manner, and that the firm locating, retrieving, controlling, and disposition of the food is acting according to regulatory requirements.

After FSIS has determined that the recalling firm has made all reasonable effort to retrieve and appropriately dispose of the recalled food product, the firm is officially notified by letter that the recall is completed and no further action is expected.

Recall data systems

Some of the data that is generated from the recall process is entered in two systems: STEPS and CCMS. STEPS stand for System Tracking E. coli O157:H7 Positive Suppliers and is a public health surveillance tool. It is a database of plants that supplied production from an agency positive for *E. coli* O157:H7. District personnel enter supplier information into STEPS. The RMD maintains the STEPS database. The TSC conducts analyses of the information contained in STEPS. Data from STEPS is used to generate notification to supplier plants when a recall takes place. For repeat suppliers, FSIS conducts HACCP 02

procedures. These establishments may also receive EIAO assessments or team food safety assessments.

The CCMS, or Consumer Complaint Monitoring System, is an electronic database used to record, triage, coordinate, and track all consumer complaints reported to the agency. Some examples of complaints associated with consumption of a meat, poultry or egg product are as follows:

- Product caused an illness or injury
- Product contained a foreign object/material
- Product caused an allergic reaction
- RTE product has been under processed
- Product is misbranded/economic adulteration
- Product is of inferior quality

A consumer may report a complaint either locally to a public health official, to FSIS OPHS, or to the Meat & Poultry Hotline. The CO/EIAO can enter consumer information into the CCMS and OPHS triages the information. They may recommend case investigation.

When cases are investigated, the DDM of the complainant district is notified through the CCMS. A CO/EIAO is assigned to the matter for further investigation. The CO/EIAO should immediately contact the consumer to verify information alleged in the complaint.

The CO/EIAO visits the consumer who made the complaint to verify that the information provided by the consumer and entered into the CCMS is accurate. The CO/EIAO will collect the relevant information and evidence needed to identify and document the problem. Based on the findings of the investigation, FSIS may initiate recall proceedings, or take a regulatory or enforcement action. PEER should be contacted if there are concerns regarding criminal activity.

Complaints concerning product tampering or potential food security threats should be referred to the USDA, Office of the Inspector General (OIG).

Role of the Public Health Veterinarian in a recall

The role of the PHV in a recall is to assist the DRO and the PI/EIAO when requested in gathering information about the affected product. For example, you may be asked to provide information about whether the product represented by an FSIS or establishment sample that tested positive for *E. coli* O157:H7 has been held under the establishment's control, or whether it has left the establishment's control and has entered commerce. You might be asked to help the PI/EIAO gather information about a consumer complaint about a product that was produced in the establishment that you cover in your assignment. You might even report product that you believe has a problem to the RMD. If you suspect such a problem exists, discuss it with your supervisor first.



FOOD SAFETY AND INSPECTION SERVICE
U.S. DEPARTMENT OF AGRICULTURE
WASHINGTON, DC 20250-3700

RECALL INFORMATION CENTER

| [Introduction](#) | [Active Recalls](#) | [Recall Case Archive](#) |
| [Recall Database](#) | Press Releases |
[2002](#) | [2001](#) | [2000](#) | [1999](#) | [1998](#) | [1997](#) | [1996](#) |

[Sign up for the FSIS News listserv](#) and automatically receive FSIS **press releases** and **product recall releases** by e-mail.

2004

- [California Firm Recalls Ground Beef Products For Possible *E. coli* O157:H7](#) (February 24, 2004)
- [California Firm Recalls Cooked Turkey Breasts That May Contain Small Pieces Of Blue Plastic Film](#) (February 20, 2004)
- [New York Firm Recalls Frankfurters For Possible *Listeria* Contamination](#) (February 17, 2004)
- [Missouri Firm Recalls Turkey That May Contain Metal](#) (February 6, 2004)
- [Pennsylvania Firm Recalls Meat Products For Possible *Listeria* Contamination](#) (January 28, 2004)
- [California Firm Recalls Chili With Meat That May Contain Foreign Material](#) (January 28, 2004)
- [Illinois Firm Recalls Frozen Beef Brisket Dinners For Possible *Listeria* Contamination](#) (January 11, 2004)

For Further Information, Contact:

- **Consumers:**
 - **Voice:** Meat and Poultry Hotline, 1-888-MPHotline (1-888-674-6854)
 - **TTY:** 1-800-256-7072
- **Media:** (202) 720-9113

Recall Release
FSIS-RC-007-2004
CLASS I RECALL
HEALTH RISK: HIGH

Congressional and Public Affairs
(202) 720-9113; FAX: (202) 690-0460
Steven Cohen

California Firm Recalls Ground Beef Products For Possible *E. coli* O157:H7

WASHINGTON, Feb. 24, 2004 — Richwood Meat Co., Inc., a Merced, Calif., firm, is voluntarily recalling approximately 90,000 pounds of frozen ground beef and beef patties that may be contaminated with *E. coli* O157:H7.

The products were produced on August 11, 2003. They were distributed to U.S. military installations in the Far East and to retail stores and institutions in California, Washington, Oregon and Idaho.

The recall was prompted after testing conducted by a laboratory in Japan determined the presence of *E. coli* O157:H7. Testing was prompted by the reports of several recent illnesses in Japan. No illnesses related to products distributed in the U.S. have been reported.

The products subject to recall include:

- Various size cases of CALIFORNIA PACIFIC ASSOCIATES "PURE BEEF PATTIES" and "BEEF/SIRLOIN & BEEF PATTIES." Each case carries a pack date of 8-11-03 and the establishment number "8264" inside the USDA seal of inspection. All of the cases bearing this label were shipped to military installations.
- Various size packages of "GROUND BEEF PATTIES" and "GROUND BEEF BULK" packed for Sysco. The labels for the recalled products contain a pack date of 8-11-03. Each box bears the company name Sysco and is stamped with the establishment number "8264" inside the USDA seal of inspection. These products were sent to institutional establishments.
- Various size packages of Richwood Meat Company "Richwood Meat Company GROUND BEEF," "Richwood Meat Company BEEF PATTIES," "Richwood Meat Company BEEF SIRLION AND BEEF PATTIES" and "Richwood Meat Company GROUND BEEF PATTIES." Each case carries a pack date of 8-11-03 and the establishment number "8264" inside the USDA seal of inspection. These products were shipped to

**PREPARING GROUND
BEEF FOR SAFE
CONSUMPTION**

**USDA Meat and Poultry
Hotline
1-888-MPHotline or
visit
www.fsis.usda.gov**

Although the product being recalled should be returned to the place of purchase, consumers preparing other ground beef products should heed the following advice.

Consumers should only eat ground beef patties that have been cooked to a safe temperature of 160 °F. When a ground beef patty is cooked to 160 °F throughout, it can be safe and juicy, regardless of color.

The only way to be sure a ground beef patty is cooked to a high enough temperature to kill harmful bacteria is to use an accurate digital instant-read thermometer.

Color is not a reliable indicator that ground beef patties have been

institutional and retail establishments.

- Various size packages of "Chef's Pride Brand GROUND BEEF" and "Chef's Pride Brand GROUND BEEF CHUCK." Each case carries a pack date of 8-11-03 and the establishment number "8264" inside the USDA seal of inspection. These products were sent to institutional establishments.
- Ten pound boxes of Golbon "Beef Patties" with a package code of "7320." Each case carries a pack date of 8-11-03 and the establishment number "8264" inside the USDA seal of inspection. These products were sent to institutional establishments.
- Ten pound boxes of DANCO QUALITY FOODS "PURE BEEF PATTIES" with package codes 7067 and 7077 printed on the labels. Each case carries a pack date of 8-11-03 and the establishment number "8264" inside the USDA seal of inspection. These products were sent to institutional establishments.
- Ten pound boxes of "Ritz Food Service GROUND BEEF CHUCK" with package code 4729. Each box carries a pack date of 8-11-03 and the establishment number "8264" inside the USDA seal of inspection. The product was sent to institutional establishments.
- Twenty pound boxes of "GROUND BEEF" packed for COLUMBUS FOODSERVICE. Each box contains two 10-pound chubs of ground beef and carries a pack date of 8-11-03. The establishment number "8264" can be found inside the USDA seal of inspection. The product was sent to institutional establishments.

E. coli O157:H7 is a potentially deadly bacteria that can cause bloody diarrhea and dehydration. The very young, seniors and persons with compromised immune systems are the most susceptible to foodborne illness.

Media and consumers with questions about the recall may contact Company President John C. Wood at 209-722-8171.

Consumers with other food safety questions can phone the toll-free USDA Meat and Poultry Hotline at 1-888-MPHOTLINE. The hotline is available in English and Spanish and can be reached from 10 a.m. to 4 p.m. (Eastern Time), Monday through Friday. Recorded food safety messages are available 24 hours a day.

#

cooked to a temperature high enough to kill harmful bacteria such as *E. coli* O157:H7.

Eating a pink or red ground beef patty without first verifying that the safe temperature of 160 °F has been reached is a significant risk factor for foodborne illness.

Thermometer use to ensure proper cooking temperature is especially important for those who cook or serve ground beef patties to people most at risk for foodborne illness because *E. coli* O157:H7 can lead to serious illness or even death. Those most at risk include young children, the elderly, and those with compromised immune systems.

NOTE: Access news releases and other information at the FSIS Web site at <http://www.fsis.usda.gov>



USDA RECALL CLASSIFICATIONS

Class I This is a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death.

Class II This is a health hazard situation where there is a remote probability of adverse health consequences from the use of the product.

Class III This is a situation where the use of the product will not cause adverse health consequences.