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."
FSIS 8080.1, Rev. 4, Amend. 1 (7/29/04)
FSIS 8080.1, Rev. 4, Amend. 2 (7/26/05)
FSIS 8080.1, Rev. 4, Amend. 3 (3/02/06)

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.

FSIS Directive 8080.1, Rev. 4 (issued in 5/24/04) provides the FSIS program personnel with the terminology, responsibilities, and public notification procedures regarding the voluntary recall of FSIS-inspected meat and poultry products. Revision 4 accounts for the 2002 FSIS reorganization and provides updated instructions regarding recall procedures. On July 29, 4004, Amend. 1was issued where revisions were made to Attachment 3 of this Directive to be consistent with the standards that was set out in the text of the directive. Following, Amend. 2 (7/26/05) was issued where revisions to Section X (*Effectiveness Checks*) and XI (*Closures*) were revised where new instructions are provided to the District Recall Officers (DRO) and the Recall Management Staff (RMS); also, revisions were made to Attachment 3, *Recall Effectiveness Checks*. Recently, on March 2, 2006 FSIS Directive 8080.1, Rev. 4, Amend. 3 was issued where revisions were made on Section IX, *Public Notification*. These changes include when FSIS issues press releases and Recall Notification Reports, specifically the way the Agency communicates information about recalls.

TERMINOLOGY

The following are some of the common terms (pertinent to the discussion of this module) that Directive 8080.1, Rev. 4 uses related to recalls:

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 of 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 very small amounts of potential allergenic substances (milk or soy) or small sized non-sharp edged foreign materials (plastic).

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.

Health Hazard Evaluation Board (HHEB)

This is the primary group in FSIS, Office of Public Health Sciences (OPHS) that reviews the public health significance of any human health hazard about which a regulatory decision needs to be made. If the risk to the public health presented by a given product appears to be unique, or in some way unusual, then the Recall Committee may consult with this group.

Recall Committee

A committee of representatives from various FSIS offices and staffs assembled to respond to potential or real health hazard incidents reported to the Recall Management Staff. The primary members of the committee are representatives of the following program areas:

Recall Management Staff (RMS) OFO-

RMS calls a committee meeting and distributes information about the recall to committee members and has the primary responsibilities for recall activities and is responsible for the following:

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

They invite other program areas to assist as necessary.

District Recall Officer (DRO), District Office, OFO

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 activities if a recall should be recommended.
- Assigns EIAO (Enforcement Investigations and Analysis Officer).
- Interacts with recalling firm, other districts, and RMS.
- Clarifies and explains to the Recall Committee the information collected during the preliminary inquiry.
- Develops effectiveness check strategy.
- Interprets results of the effectiveness checks and disposition of affected product.
- Submit a final recall effectiveness report to RMS.

Congressional and Public Affairs (CPA; Media Relations), Office of Public Affairs, Education and Outreach (OPAEO)

For every recall, FSIS notifies the public through a press release, entitled Recall Release (for Class I or Class II), and/or a Recall Notification Report (RNR; for Class III only). The press release will inform the consumer, industry, and he public health community with information related to the product in question; it 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/Fsis_Recalls/ (Refer to page 8).

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. For FY 2004, there were a total of 48 federal recall cases of which 40 recalls were for Class I, four for Class II, and 4 for Class III. The Class I were due to the presence of pathogenic bacteria (*L. monocytogenes, E. coli* O157:H7, and *Salmonella*), foreign material, or misbranding (allergen).

In FY 2005, there were 52 recall cases; 48 of which were Class I, three were Class II, and 1 was Class III (misbranding). Twenty nine of the Class I recalls were due to *L. monocytogenes* and 5 were due to *E. coli* O157:H7. The remaining of the Class I was due to issues such as under processing of product, foreign material, undeclared allergens, etc.

As of this fiscal year (2006) there has been 31 recalls; 26 which were Class I attributed to undeclared allergens (7), *L. monocytogenes* (5), *E. coli* O157:H7 (8), other pathogenic bacteria (2) as well as other causes (4). Five of the Class II was due to foreign materials (2), mislabeling (1), and other (2).

RECALL PROCESS

The process of recalling a product begins with problem identification. A problem with a product can be identified through various sources such as the firm, the Agency, or sources outside of the Agency. The most common sources are:

- A positive result from FSIS sampling programs (microbiological, physical, chemical, misbranding)
- The company that manufactured or distributed the food product informs FSIS of the potential hazard (e.g., positive microbiological test results, consumer complaint, formulation records).
- Information from in-plant inspectors and program investigators in the course of their routine duties.
- Information from outbreak investigations, epidemiological or laboratory data submitted by State or local public health department, or other Federal Agencies.
- Consumer complaints reported to FSIS (reported in the FSIS Consumer Complaint Monitoring System)

Let's take a closer look at the recall process when it is initiated based on a *E. coli* O157:H7 positive microbiological sample taken as part of the FSIS sampling programs. There are two potential outcomes from FSIS sampling, the sample can be a:

- 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 Email 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 at the 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 whether the product is in a holding status and notifies the RMS 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 will coordinate a preliminary investigation or inquiry and assigns an Enforcement Investigations Analysis Officer (EIAO); at this point the pre-recall process begins.

Stage 1 – Pre-recall (presumptive positive):

During Stage 1, pre-recall, the EIAO will immediately contact the establishment's Recall Coordinator (RC) to discuss, on-site, the 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 the Inspector-in-charge or Front |Line Supervisor, 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 evaluates all available information giving recommendations to the company about the need for a recall; at this point Stage 2 is implemented. The EIAO who was initially assigned by the DRO becomes a member of the Recall Committee. The EIAO participates and provides information to the Recall Committee as well as the establishment. For example, the 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 RMS issues a RNR which provides detailed information about the product being recalled. FSIS then issues a press release, since the type of hazard in this scenario is classified as Class I. This press release is posted on the FSIS website. The EIAO will follow up by verifying that the distribution information is collected and provide feedback to the DRO. The DRO directs the EIAO in the District Office (DO) where the recall originated to conduct recall effectiveness checks.

Effectiveness checks constitute a process by which FSIS program personnel verify that the recalling firm has been diligent and successful in notifying and advising the consignees of the need to retrieve and control recalled product, and that the consignees have responded accordingly. Subsequent consignees are then expected to notify their customers of the recall. FSIS will conduct these effectiveness checks throughout the distribution chain.

The EAIO 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 any available epidemiological data, 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 product 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.

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 a Memorandum of Understanding (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 RMS.

RECALL DATA SYSTEM

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 RMS maintains the STEPS database. The Technical Service Center (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 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. As mentioned earlier, an EIAO is assigned to the matter for further investigation and should immediately contact the consumer to verify information alleged in the complaint. The 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 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.

The Office of Program Evaluation, Enforcement and Review should be contacted if there are concerns regarding criminal activity. Also, complaint 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 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 EIAO gather information about a consumer complaint concerning 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 you district DRO if you suspect such a problem exists, discuss it with your supervisor first.

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FSIS Recalls

A recall is a voluntary action by a manufacturer or distributor to protect the public from products that may cause health problems. Look here first for current recall news.

Receive Automatic Notification of Recall Updates
Sign up now and get an alert when recall information has been updated.

Recall of Meat and Poultry Products - Revision 4 (May 24, 2004; PDF Only)
FSIS Directive 8080.1 provides the terminology, responsibilities, and public notification procedures regarding the voluntary recall of FSIS-inspected meat and poultry products.

FSIS Food Recalls Fact Sheet | PDF
What is the purpose of a recall? How are unsafe or mislabeled products discovered? How does FSIS ensure that products subject to the recall are returned (Directives)? Find the answers to these questions and more.

Open Federal Cases More

FSIS monitors recalls of meat and poultry products produced by Federally-inspected establishments. This page contains summary data on the FSIS recalls that are still in progress.

Recall Case Archive More

The archive contains press releases and notification reports issued by FSIS in conjunction with recalls of meat and poultry products from 1996 to the present. The quantity of product recovered is available for the most recent recalls (beginning in September 2005).

Open Retail Recall Cases More

State agencies coordinate and monitor recalls of meat and poultry products produced by privately-owned retail outlets. This area serves as a clearinghouse for information on these product recalls.

Problems with Food Products More

What do you do if you have a problem with a particular food product? This guide will give you the proper steps to take depending on what type of food it is.

Additional Recall Links More

Find information on recalls of products regulated by the Food and Drug Administration. Connect to recalls, alerts, and warnings provided by selected Federal and State agencies.

Last Modified: November 14, 2006

Iowa Firm Recalls Ground Beef Products for Possible *E. coli* O157:H7 Contamination

Recall Release
FSIS-RC-029-2006
Congressional and Public Affairs
(202) 720-9113
Tara Balsley

CLASS I RECALL
HEALTH RISK: HIGH

WASHINGTON, October 6, 2006 - Jim's Market and Locker, Inc. a Harlan, Iowa, firm, is voluntarily recalling approximately 5,226 pounds of ground beef that may be contaminated with *E. coli* O157:H7, the U.S. Department of Agriculture's Food Safety and Inspection Service announced today.

The products subject to recall include:

- 10-pound boxes of "PACKED FOR: DAVIS MOUNTAIN ORGANIC BEEF, 100% CERTIFIED ORGANIC 3-1 BEEF PATTIES." Each box bears the lot code "G6-540" or "G6-544."
- Five-pound packages of "DAVIS MOUNTAINS 100% ORGANIC BEEF, LEEAN GROUND BEEF 90/10." Each package bears the lot code "G6-544."
- One-pound packages of "MASTER CHOICE 100% ORGANIC ANGUS BEEF, 90/10 GROUND BEEF." Each package bears the lot code "G6-544."
- One-pound packages of "DAVIS MOUNTAINS 100% CERTIFIED ORGANIC GROUND BEEF." Each package bears the lot code "G6-544."
- 10.5-pound boxes of "NEBRASKA, BEEF GROUND BEEF PATTY 6 OZ." Each box bears the lot code "G6-541."
- 60-pound boxes of "SPECIALLY SELECTED FOR: FARNER-BOCKEN FOOD SERVICE BEEF PATTIE MIX 6/10#." Each box bears the lot code "G6-542."
- One-pound packages of "PACKED FOR: IRWIN COUNTRY STORE, BEEF GROUND BEEF 16 OZ." The package bears the lot code "G6-541."
- One-pound blocks of "PACKED FOR: IRWIN COUNTRY STORE, BEEF GROUND BEEF PATTIES 4-1." The product bears the code "G6-541."
- 10-pound boxes of "DISTRIBUTED BY: STUBE RANCH, WAGYU BEEF, BEEF GROUND BEEF PATTIES, 8 OZ. PATTIES." The product bears the lot code "G6-546."

Each package bears the establishment number "Est. 2424" inside the USDA mark of inspection.

The problem was discovered through microbiological testing. FSIS has received no reports of illnesses associated with consumption of this product.

The ground beef products were produced on August 31 and September 1 and distributed to one retail establishment in Iowa and distributors in Georgia, Iowa, Massachusetts, Nebraska, New York, Texas and Wisconsin.

E. coli O157:H7 is a potentially deadly bacterium that can cause bloody diarrhea and dehydration. The very young, seniors and persons with compromised immune

Preparing Ground Beef For Safe Consumption

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

Although the product(s) being recalled should be returned to the point 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 food thermometer.

Color is not a reliable indicator that ground beef patties have been 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, seniors, and those with compromised immune systems.

systems are the most susceptible to foodborne illness.

Media and consumers with questions about the recall should contact company President Jim Goeser at (712) 755-5158.

Consumers with food safety questions can "Ask Karen," the FSIS virtual representative available 24 hours a day at http://www.fsis.usda.gov/Food_Safety_Education/ASK_KAREN/index.asp#Question. The toll-free USDA Meat and Poultry Hotline 1-888-MPHotline (1-888-674-6854) is available in English and Spanish and can be reached from l0 a.m. to 4 p.m. (Eastern Time) Monday through Friday. Recorded food safety messages are available 24 hours a day.

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www.fsis.usda.gov

Food Safety Questions? Ask Karen!
FSIS' automated response system can provide food safety information 24/7

Last Modified: October 6, 2006

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.