

## Recalls

### OBJECTIVES

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

1. Identify the regulations and statutes which are relevant to recalls.
2. Discuss recall class types and common examples.
3. Understand the PHV's role in the recall process
4. Walk through the critical thinking process and generate a decision tree used to determine if a recall is recommended.

### RESOURCES

[FSIS Directive 5000.8 "Verifying Compliance with Requirements for Written Recall Procedures"](#)

[FSIS Directive 8080.1 "Recall of Meat and Poultry Products"](#)

[FSIS Directive 8091.1 "Procedures for the FSIS Health Hazard Evaluation Board"](#)

[FSIS Directive 8410.1 "Detention and Seizure"](#)

[How to Develop a Meat and Poultry Product Recall Plan guidebook](#)

### PRE-CLASS ACTIVITY (optional)

Visit FSIS [Recalls and Public Health Alerts](#) Website

Review [Federal Register 77 FR 26929](#)

Review [FSIS Food Recalls Fact Sheet](#)

Review [9 CFR 418.2 – 418.4](#)

Review [FSIS Directive 8080.1 "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. **(21 U.S.C. 601(m),(n); 21 U.S.C. 453(g),(h); 21 U.S.C. 1033 (a),(l))**

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 & 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** "Recall of Meat and Poultry Products" provides the FSIS program personnel with the terminology, responsibilities, and public notification procedures regarding the voluntary recall of FSIS-inspected meat and poultry products.

Federally inspected meat and poultry establishments are required to prepare and maintain written recall procedures. The written procedures must specify how the establishment will decide if they need to conduct a product recall and how they will implement a recall. The written procedures and all records associated with recalls must be available for FSIS review. **(9 CFR 418)**

## TERMINOLOGY

The following are some of the common terms (pertinent to the discussion of this module) that Directive 8080.1 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

Each product recall's classification is unique. Let's look at each of these in more detail, with some common examples.

*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 non-allergenic substances, such as excess water.

### Depth & Scope

Recalls are also classified by the level of product distribution to which the recall is to extend (Wholesale, Retail, HRI, Consumer). This is defined as the depth of the recall.

The scope of a recall is defined by the amount and type of product in question. Multiple factors are used in determining the scope, such as establishment sanitation procedures and process flow.

### OPHS

This group addresses microbiological, epidemiological, and other scientific issues associated with the recall.

### Health Hazard Evaluation Board (HHEB)

This group is convened on an ad hoc basis to address situations involving potential human health hazards when the Agency is uncertain about the nature or severity of the human health risk. If the hazard presented by a given product appears to be unique or in some way unusual, the Recall Committee may consult with the HHEB.

## 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 and Technical Analysis Division. The primary members of the committee are representatives of the following program areas:

### 1. *Recall Management and Technical Analysis Staff (RMTAD) OFO*

RMTAD calls a committee meeting, distributes information about the recall to committee members, 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.
- Acts as a liaison with other programs and Agencies.

They invite other program areas to assist as necessary. This includes:

- Office of Investigation, Enforcement and Audit (OIEA), Compliance and Investigations Division (CID) (conducts investigations of alleged criminal violations),
- Office of Public Health Science (OPHS),
- Office of Policy and Program Development (OPPD),
- Office of Public Affairs and Consumer Education (OPACE), Congressional and Public Affairs Staff (CPA),
- Office of Data Integration and Food Protection (ODIFP), and
- Other Federal or State agencies (such as FDA, Food and Nutrition Service, CDC, Office of General Counsel, State Departments of public health).

### 2. *FSIS Recall Officer (RO), District Office, OFO*

Each District designates an individual who acts as the FSIS Recall Officer, or RO. This is a designated FSIS person with jurisdiction in the district of the firm conducting the recall. This may be a Deputy District Manager (DDM), the District Case Specialist (DCS), or Enforcement, Investigations, and Analysis Officer (EIAO) in the district where the recalling firm is located. The RO is responsible for the following activities:

- Coordinates field recall activities if a recall should be recommended.
- Assigns designee (often an EIAO).
- Interacts with recalling firm, other districts, and RMTAD.
- 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.
- Submits a final recall effectiveness report to RMTAD.

### 3. *Office of Policy and Program Development (OPPD)*

Personnel in this Office provide the statutory basis for each recall; address other statutory issues, the regulations, and any regulatory policies that are relevant to the recall.

#### 4. *Office of Public Health Science (OPHS)*

Personnel in this Office address microbiological, epidemiological, and other scientific issues associated with the recall

#### 5. *Congressional and Public Affairs Office (CPAO; Media Relations), Office of Public Affairs and Consumer Education (OPACE)*

Personnel in this office gather information and generate a Recall Release or a Recall Notification Report if there is a recall. When appropriate, they generate public notification, such as a Public Health Alert or Press Release, in situations where a recall action is not warranted.

### **ROLE OF THE PUBLIC HEALTH VETERINARIAN**

The role of the PHV in a recall is to assist the RO and designee 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 RO designee gather information about a consumer complaint concerning a product that was produced in the establishment that you cover in your assignment.

Establishment personnel may notify you that they learned or determined that adulterated or misbranded product entered commerce. If this happens, you need to contact the District Office, through supervisory channels, as soon as possible. You also need to notify establishment managers that they need to contact the District Office directly within 24 hours. (**9 CFR 418.2**)

If you are an EIAO-trained PHV, you may be asked to investigate a consumer complaint at your duty station or other nearby establishments. You may be asked to complete recall effectiveness checks if product subject to recall was produced or distributed in your local area.

Finally, as you go about your daily in-plant activities, if you suspect that there is a problem with product such that it may need to be recalled, discuss your concerns with your supervisor first. You may then be asked to report your concerns to the district RO.

#### Verifying Written Recall Plans

Part of your responsibilities is to verify that establishments have written recall procedures as required by 9 CFR 418.3. To do this, at least once a year, you or your designee will perform a directed Other Inspection Requirements task. Document your findings in PHIS.

### **RECALL PROCESS**

#### *Problem Identification*

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

- Information from in-plant inspectors and program investigators in the course of their routine duties.
- 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 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 – see *text box below*).
- Information from other agencies such as the Department of Homeland Security, Customs and Border Protection, the Animal and Plant Health Inspection Service, or foreign inspection officials.

### *Preliminary Inquiry*

When FSIS learns there is reason to believe that adulterated or misbranded product is in commerce, FSIS will conduct a preliminary inquiry. A recall officer (RO) contacts in-plant IPP and the establishment's Recall Coordinator (RC) to gather product information, contact information, and any additional relevant information. Information is collected on FSIS Recall Worksheets and provided to RMTAD. The establishment is responsible for providing this information, however as in-plant PHVs with working knowledge of establishment protocols and records, you may be asked to assist with information gathering. It is important that this information is gathered accurately and in a timely manner.

### *Recall Committee Meeting*

Recall Committee members discuss the reason that a particular product may need to be removed from commerce and whether there is a statutory basis to recommend a recall. If the committee decides to recommend a recall, it is also to determine the appropriate recall classification.

When determining whether to recommend a product recall, the Recall Committee is to seek the answers to the following questions:

- Does FSIS have reason to believe that the product in question is adulterated or misbranded under the FMIA or PPIA? For example, if the results of a laboratory analysis show that raw ground beef or beef manufacturing trimmings contains *E. coli* O157:H7, the product is clearly adulterated because it is likely to be injurious to health.
- What is the extent of the hazard to public health? This will assist in determining the recall classification.
- Does any of the product in question remain in commerce or remain available to consumers? If the committee finds that the establishment has recovered all products from commerce that would have been subject to recall, a recall is not recommended as no product is available to consumers.

To determine if product remains available to consumers, the committee seeks answers to questions such as:

- When was the product produced?

*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. An 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. 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 Investigation, Enforcement, and Audit (OIEA) should be contacted if there are concerns regarding criminal activity. In addition, complaints concerning product tampering or potential food security threats should be referred to the USDA, Office of the Inspector General (OIG).*

- To whom has the product been distributed?
- What type of product is involved?
- How much product is involved and how was this determined?
- What is the typical, useable shelf life of the product?

#### *Recall Recommended*

If a recall is recommended, RMTAD generates a memo which includes the reason for the recall and the recall classification (Class I, II, or III).

#### *Notification and Action of Firm*

FSIS outlines in “*Product Recall Guidelines for Firms*” the actions a firm can take to ensure that it recovers the maximum amount of product in the shortest amount of time. If the firm decides not to accept the Agency’s recommendation and chooses not to conduct a recall, FSIS personnel may detain any product found in commerce that would have been subject to recall as set out in FSIS **Directive 8410.1**.

#### *Public Notification*

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 other stakeholders of information related to the product in question. It is issued to media outlets in the areas where the product was distributed and to an e-mail listserv. All FSIS press releases concerning recalls can be found on the FSIS web site at the [Recalls and Public Health Alerts](#) page.

These press releases clearly describe the product 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.). However, for Class I recalls, FSIS posts a retail distribution list, which identifies the retail establishments that may have received the recalled products.

There may be situations in which the Recall Committee determines that a specific product may present a risk to human health, but the committee cannot recommend a recall. In these circumstances, a Public Health Alert may be issued. Public Health Alerts include information on the product involved, identify whether the product presents any health risk, and instructs consumers on how to properly handle the product if they have it in their possession.

#### *Effectiveness Checks*

The RO or designee will follow up on the recalling firm’s actions by verifying that the distribution information is collected and provide feedback to the RO. The RO directs FSIS personnel in the District Office (DO) where the recall originated to conduct recall effectiveness checks.

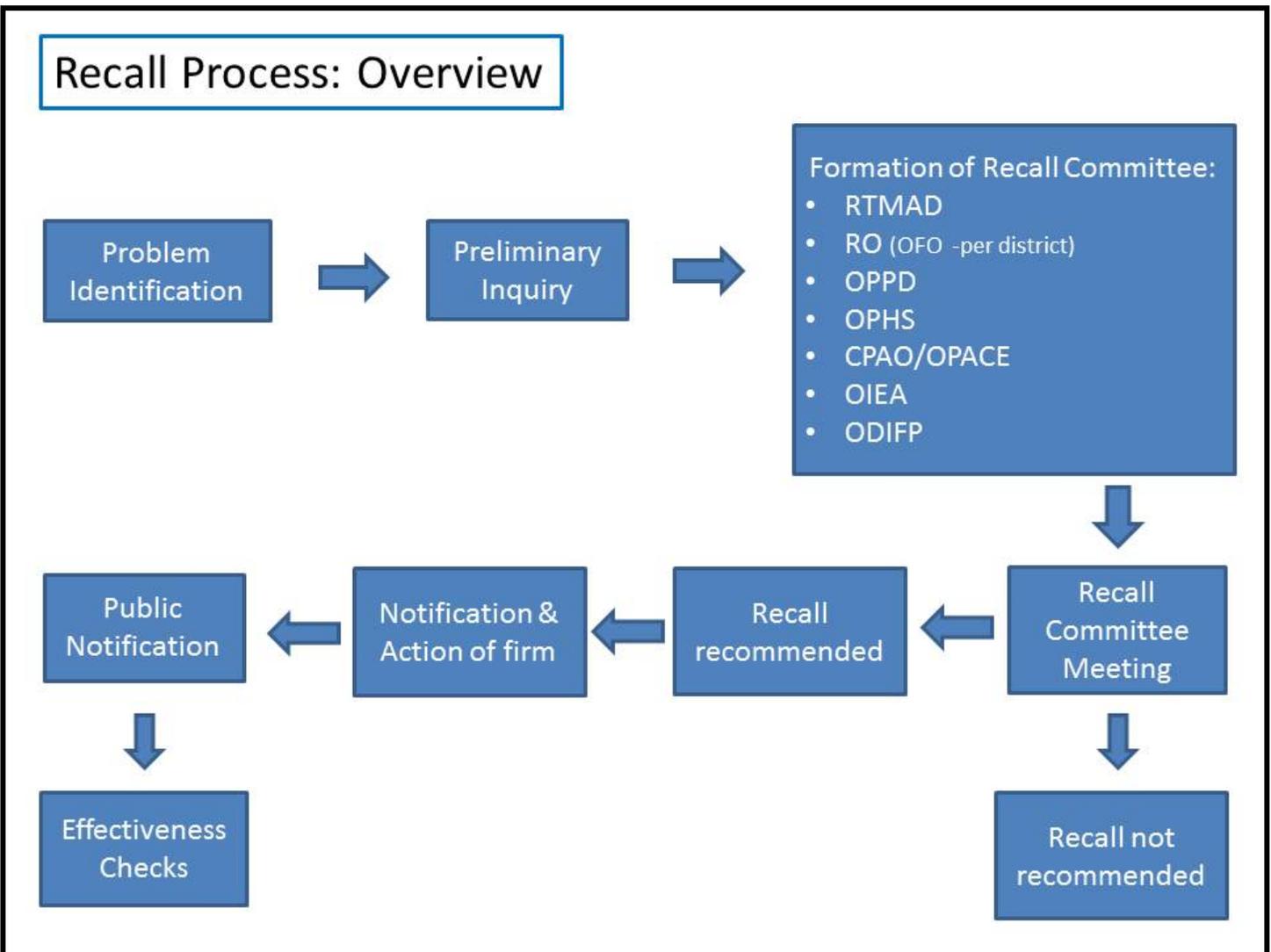
Effectiveness checks are a process by which FSIS program personnel verify that the recalling firm has been diligent and successful in notifying and advising the consignees of the need to retrieve and control recalled product, and that the consignees have responded accordingly. Subsequent consignees are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

The RO or designee will perform effectiveness checks using the process outlined in Directive 8080.1. 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. Recall effectiveness checks allow FSIS program personnel to ensure 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.

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

*Recall Closure*

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.



### *Decision Tree*

RMTAD organizes and supports its thought process for determining if a recall is warranted by using a decision tree. As the committee asks questions, the answers form the tree.

The committee decision process is not standardized. It is unique to each recall and can vary greatly. In other words, there is no one “correct” version of a decision tree/process. The tree develops as more information about a recall and involved products is discovered.

### WORKSHOP

Instructions: Work in small groups and as a class to generate decision trees to assess if a recall may be recommended.

Scenario 1: The District Office has provided you with an electronic mail message regarding a potential recall situation. A Federally inspected establishment received three complaints from customers regarding the presence of plastic pieces in their fully cooked, not shelf stable, ready-to-eat Bologna. The complaints did not indicate the plastic in the bologna injured the consumers. A search in the FSIS Consumer Complaint Monitoring System (CCMS) did not reveal any additional complaints against the establishment or associated with their bologna products. The establishment provided photographs of two of the plastic pieces measured against a ruler, and the plastic pieces varied in length.

Scenario 2: The District Office has provided you with an electronic mail message regarding a potential recall situation associated with an allergen and sensitive ingredient. During a food safety assessment (FSA), an Enforcement, Investigations, and Analysis Officer (EIAO) discovered the Chorizo used as an ingredient in the establishment’s finished product contained lactose and isolated soy protein as ingredients; however, these ingredients were not declared on the finished product label.

**Scenario 1 –  
Example decision tree**

