Regulatory Requirements & Initiating a Recall

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What is the Purpose of a Recall?

A recall is a firm’s action to remove product from commerce to protect the public from consuming adulterated or misbranded products. Although it is a firm’s decision to recall product, FSIS coordinates with the firm to ensure it has properly identified and removed recalled product from commerce by verifying the effectiveness of the firm’s recall activities. FSIS also notifies the public about product recalls.

Source: FSIS Directive 8080.1, Revision 7
FSIS Directive 8080.1

Recall of Meat and Poultry Products

• Defines key terms (i.e., recall v. market withdrawal v. stock recovery)
• Assigns responsibility – who does what to whom and when do they do it?
• Describes the process from beginning to end (archive)
Key Terms to Know and Love

- **Recall**: A firm’s removal of distributed meat or poultry products from commerce when there is reason to believe that such products are *adulterated or misbranded under the provisions of the FMIA or the PPIA*.

- **Market Withdrawal**: A firm's removal or correction, on its own initiative, of a distributed product that involves a *minor company quality program or regulatory program infraction* that would not result in the product being adulterated or misbranded. For example, product does not meet company quality standards because of discoloration.

- **Stock Recovery**: A firm's removal or correction of product that has not been marketed or that *has not left the direct control of the firm*. For example, product is located on the premises owned by the producing firm or under its control.
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 concern** as one of the following:

- **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. Examples of a Class I recall include the presence of pathogens in ready-to-eat meat or poultry products, or the presence of E. coli O157:H7 or non-O157 Shiga toxin-producing E. coli (STECs) in raw 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. An example of a Class II recall is a recall because of the presence in a product of very small amounts of undeclared allergens typically associated with milder human reactions, e.g., wheat.

- **Class III**: This is a situation where the use of the product will not cause adverse health consequences. An example of a Class III recall is the presence of undeclared, generally recognized as safe, non-allergenic substances, such as excess water in meat or poultry products.
Key Terms to Know and Love

• **Scope:** This defines the *amount and type of product in question.* Several factors are used in determining the scope of a recall, such as the plant’s processing and sanitation procedures, the definition of a lot, or specific grouping, and whether there is any finished product reincorporated into fresh product (rework). The findings of epidemiological investigations that link certain lots of product with known cases of foodborne illnesses may also affect the scope of a recall.

• **Disposition:** This is the *firm's action* with respect to the recalled product to correct the situation leading to the recall, such as relabeling, cooking, reworking, or destroying product.

• **Health Hazard Evaluation Board (HHEB):** The HHEB is the primary group in FSIS 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, the Recall Committee may consult the Office of Public Health Science’s (OPHS) HHEB. (See FSIS Directive 8091.1, Procedures for the FSIS Health Hazard Evaluation Board.)

• **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 Staff (RMTAS).
Who/What is the Recall Committee?

1. Recall Management and Technical Analysis Staff (RMTAS)
2. Field Ops (OFO) – District Office staff at the very least
3. Policy (OPPD)
4. Public Health Science (OPHS)
5. Media Relations
6. Public Affairs

Plus (maybe)...

1. Compliance (OIEA)
2. Data Integration/Food Protection (ODIFP)
3. Other Federal or State Agencies
Who Does What to Whom and When Do They Do It?
## Who Has the Information?

### The Company
- Substantiated customer/consumer complaint
- Supplier notification of issue (FDA or USDA)
- Accidental shipment of hold product

### The USDA (FSIS)
- Positive test results from FSIS sampling programs
- Consumer Complaint Monitoring System (CCMS)
- Other Agencies (e.g., AMS)
- Outbreak investigation (CDC)
- 8140 or 418.2 Notification
Let’s Talk About 418.2 and the 8140 Process

When official establishments **learn or determine** that adulterated or misbranded product has entered commerce, they are required to notify FSIS DO personnel within 24 hours (9 CFR 418.2).

Process for ‘how’ to notify may be contingent upon where the issue was identified

- **B2B** – 1 federally inspected establishment to another
- **B2C** – non-processor customer
You’ve Made the Decision to Recall
So You Know You’re Going to Recall...

Step 1

- Gather and organize your supporting documents
- Complete the Recall Worksheet(s)
  - DO NOT COMPLETE THE WORKSHEET AND HAND TO FSIS UNTIL YOU ARE PREPARED TO RECALL
- Gather product label mock ups
### Step 1 - Complete the Recall Worksheet(s)

| **COUNT/CASE** |  |  |  |
| **PRODUCTION DATE** |  |  |  |
| **USABLE SHELF LIFE OF PRODUCT** |  |  |  |
| **AMOUNT (lbs./cases) PRODUCED** |  |  |  |
| **AMOUNT HELD AT ESTABLISHMENT** |  |  |  |
| **AMOUNT (lbs./cases) DISTRIBUTED** |  |  |  |
| **DISTRIBUTION LEVEL (institutional/retail/etc.)** |  |  |  |
| **DISTRIBUTION AREA** |  |  |  |
| **EXPORTED TO (Country)** |  |  |  |
| **DONATED COMMODITY/USDA FOODS** |  |  |  |
| **DEPT. OF DEFENSE** (DeCA, DLA, AAFES) |  |  |  |
| **INTERNET OR CATALOG SALES** |  |  |  |

(YES) ☐ (NO) ☐ (YES) ☐ (NO) ☐ (YES) ☐ (NO) ☐ (YES) ☐ (NO) ☐
Step 2 – Use Your Words!

- Engage your District Office staff – they know you and your process!
- Ask for a “Pre-call” with the relevant members of the Recall Committee
- Show and tell to align on scope BEFORE the Recall Committee call
The Booger Bear - Determining Scope

- Be prepared to support your position
  - Lab results
  - Operational records
  - HACCP/SSOP records
  - Complaint data

- The hurdle is not “how do you know x product is affected?”; it’s “how do you know y product is not also affected?”

Not an all-inclusive list!
Step 2a – Climb the Ladder

- If you aren’t aligned with the decision-making, appeal to the next level.
- Ideally, this needs to happen BEFORE the Recall Committee call.
Step 2b – Prepare Your Communications

- Press release?
- Set up a hotline?
- Script/FAQs for Consumer Relations
- Customer letters
  - Affected
  - Not Affected
The Meeting Before the Meeting

“After RMTAS convenes the Recall Committee, the members are to 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 Recall Committee decides to recommend a recall, it is to also determine the appropriate recall classification.”

Source: FSIS Directive 8080.1, Revision 7
Recall Committee Decision-Making

2 Key Questions:

1. Does FSIS have reason to believe that the product in question is adulterated or misbranded under the FMIA or PPIA?

2. Does any of the product in question remain in commerce or available to consumers?
“...there may be situations in which laboratory results are not available or are inconclusive, but, that FSIS believes, on the basis of epidemiological evidence, that a specific meat or poultry product is associated with human illnesses. Under these circumstances, the Recall Committee is to consider the strength of the epidemiological evidence to determine whether there is a basis to conclude that a product contains a pathogen or is otherwise unhealthful and, therefore, adulterated.”

Source: FSIS Directive 8080.1, Revision 7
“If the Recall Committee finds that the establishment has recovered all products from commerce that would have been subject to recall, the Committee should not recommend a recall, as no product should remain available to consumers. Instead, FSIS personnel are to verify that the establishment has recovered all products involved and that it conducted proper disposition of the affected products.”

Source: [FSIS Directive 8080.1, Revision 7](https://www.fsis.usda.gov/wps/portal/fsisMainMenu/?c=lib&cs=0&d=4&l=FEDERAL%20REGULATIONS%20LIBRARY&n=FSIS%20DIRECTIVE%208080.1%2C%20REVISION%207)
Is Product In Commerce?

“...the Recall Committee is to seek responses to the following probing questions:

1. When was the product produced?
2. To whom has the product been distributed?
3. What type of product is involved (e.g., ready-to-eat, fresh packed, canned, frozen)?
4. What is the typical, usable shelf life of the product?
5. What are the typical consumer or user practices concerning handling and storing of the product in question (e.g., is the product typically prepared for immediate consumption and likely is not stored or frozen for later use)?
6. Is the Agency able to verify that the product that was distributed in commerce is no longer available to consumers at retail facilities, restaurants, or other institutions?”

Source: FSIS Directive 8080.1, Revision 7
Moving on to Recall Class

“...The Recall Committee...is to consider the human health hazard presented by the product subject to recall to determine the appropriate recall classification. Typically, there are precedents for determining the significance of the health hazard presented by an adulterated product and the classification of the hazard. The Recall Committee will be guided by these precedents in classifying recalls. However, if the Recall Committee has questions, particularly about hazards or conditions that have not been previously encountered by the Agency, the HHEB will be convened to conduct a hazard evaluation.”

Source: FSIS Directive 8080.1, Revision 7
And Who Is the HHEB Again?

Health Hazard Evaluation Board

“The HHEB’s evaluation will consider, at a minimum, the following factors:

1. The nature of the problem (i.e., what is the problem with the product and what health hazards does the problem create);
2. The occurrence of any illnesses or injuries;
3. The likelihood that illnesses or injuries may result; and
4. The types of illnesses or injuries that may result.”

Source: FSIS Directive 8080.1, Revision 7
Step 3 – The Recall Committee Call

- Purpose is to formalize scope and class of the recall
- FSIS will request your agreement to scope and class
- FSIS media relations will liaise with company media relations for the press release
- Usually 10 minutes or less
Step 4 – Hurry Up and Wait
Step 5 – Finalize Press Release

- Review FSIS press release for factual accuracy only
  - You only get 30 minutes so make them count!
- Adjust your own press release as needed to align with FSIS
Step 6 – Execute External Communications

- Connect with your customers
- Make sure they understand what to do with the recalled products (e.g. return, destroy) AND the documentation requirements
Step 7 – Recall Effectiveness

• Understand that there is a ‘company’ responsibility AND an ‘FSIS’ responsibility
• FSIS will verify that ALL customers were informed AND that the affected product is NOT for sale
• FSIS will request information from the company regarding amount of product recovered
Step 8 – Recall Closure

- FSIS will alert the company once they have completed all effectiveness checks.
- The company will submit a written request to close the recall.
- Prohibited Acts Letters will be issued – to the recalling firm or the customer(s) – if there are failures in execution.
- The recall will be archived on the FSIS website.