Best Practices and Recall Management

Roya Galindo
Director, Regulatory Services
Topics

• How and what prompts a recall
• What happens on a recall call
• Recall classifications
• Notifying customers of the recall, some tips and suggestions
What prompts a recall?

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 PPIA.

- Poisonous or deleterious materials
- Pesticide
- Additive
- Filthy, putrid, decomposed substance, unsound, unwholesome, unfit for human food.
- Packed handled and held under insanitary conditions
- Misbranding
- Undeclared Allergens
- Working without the benefit of inspection
How do recalls begin?

• In plant inspection personnel findings during routine inspection
• Findings during a food safety assessment
• Customer Complaint
• FSIS investigation or notification
• The company recognizes that they may have shipped adulterate or misbranded product.
Before the recall call...

• Typically the company will be communicating with a staff member from the District Office and supplying information related to the product in question.
• Recall worksheet are typically used to gather this information.
• Once the district has all the information the information is provided to the recall committee to discuss whether the information provided should prompt a recall.
The recall call...

- Conference call where the company and the recall committee discuss the whether or not a recall should be initiated.
  - Recall Committee: A number of FSIS employees from various sub offices that may be subject matter experts pertaining to the recall situation.
    - Policy staff
    - Office of field operations
    - Public health science
    - Public affairs
    - Compliance
    - Other federal or state agencies if applicable
  - Company representatives
    * Make sure the people who know the facts are on the call
The recall call cont.

• The scenario based on the information provided to them from OFO will be presented to the company. This will include information about what happened, scope, and will also include recall classification.

• The agency will request you to recall product. They can’t force you, its voluntary. But if you refuse the agency has other means to remove product off the market. They can detain the product.

• If you agree to the recall, a member of the committee will explain the next steps. It will include information on the press release. The agency writes up the press release and gives you an opportunity to review it.
What do the recall classifications mean?

- **Class I**: Reasonable probability that the use of the product will cause serious, adverse consequences or death.
  - Example: Pathogens present in finished product.
- **Class II**: Remote possibility of adverse health consequences.
  - Example: Undeclared wheat in very small amounts
  - Plastic
- **Class III**: Use of product will not cause adverse consequences.
  - Excess water not identified on label.
- **Recall Release vs. Recall notification Report**
- **Distribution level**
  - Retail
    - If distributed to retail level a recall a recall release is issued
    - Media is notified, posted on website
  - Wholesale and distribution
    - Generally if products are not in retail a recall notification report will be generated and media outlets wont be notified. Posted on website and email subscribers will be issued an email.
Recall has begun

- Notify customers
  - Phone Call
  - Email
  - Calling and following up with an email is ideal
  - Fax and follow up with a call and document that fax was received.

- FSIS Directive 8080.1 template
Notifying customers

- Adding a picture of where to find the lot code might be helpful.
- Requesting confirmation that notification was received would demonstrate effective notification efforts.

Note: only products ending in 00 are subject to recall. All other products are NOT subject to recall. Lot number is found on the front of package. If there is any confusion please contact customer service.
Recall Effectiveness Checks

- EIAOs will conduct recall effectiveness checks
- FSIS Form 8400-4
• Notify customers that FSIS may be calling or visiting
• Customer service should be part of your recall team
• Recordkeeping is key!
  - SAP system
  - Excel
Thank you!

Links:

• FSIS Directive 8080.1
• 9 CFR 418.2-418.4
• FSIS 8400-4 recall effectiveness form
• How to develop a recall plan