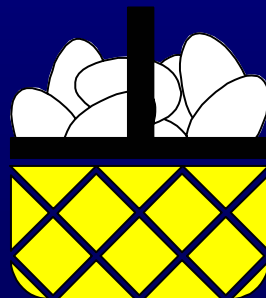


Product Recall Guidelines

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Background

- **Recall is an effective method of removing products from commerce that may represent a health hazard to the consumer.**
- **Processing plants have the responsibility to remove products that are hazardous to the consumer.**
- **Plant operations should prepare and maintain a written recall plan.**

RECALL of Meat Products in the USA

A voluntary procedure initiated by a company in an effort to remove adulterated or misbranded product from trade and or consumer channels. USDA does not have the authority to order a recall, but can initiate its own detention or seizure citations against the products in question. FSIS must oversee all such recall activities.

Recalls and HACCP

- **HACCP plans may help to identify situations where recalls may be necessary.**
 - **HACCP plans identify food borne hazards.**
 - **HACCP records identify the critical limits meet or exceeded and the corrective actions taken.**
- **If product has entered commerce then a recall may be part of a corrective action.**

Recalls in a HACCP System

- Under a HACCP system, the probability of a product recall is reduced
 - When a process failure occurs, the monitoring procedures and the corrective actions should prevent allowing the product into commerce.
- HACCP is not a 100% system
- *E. coli 0157:H7, Salmonella and Listeria monocytogenes* are considered adulterate in foods by US regulations.

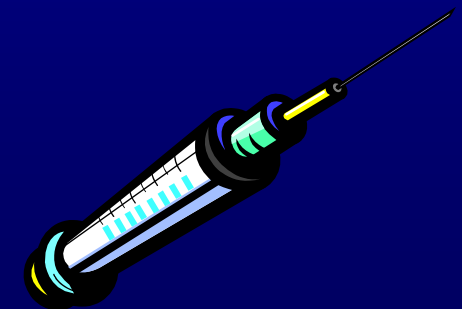
Recalls and HACCP

- Record keeping requirements in HACCP should enhance a company's ability to conduct a product withdrawal or recall.
- Better trace back may facilitate the identification of the source of contamination.



Recall Classes in United States

- **Class I**
 - **Involves a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death.**
 - **Bacteria**
 - **Misbranded**
 - **Proc/Cont Defects**



Recall Classes

- **Class II**
 - **Involves a potential health situation where there is a remote probability of adverse health consequences from the use of the product.**
 - **Extraneous material**
 - **Drug**
 - **Spoilage organisms**
 - **Chemical**
 - **Misbranded**



Recall Classes

- **Class III**
 - **Involves a situation where the use of the product is not likely to cause adverse health consequences.**
 - **Misbranded**



Depth of Recall

- 1. Consumer – This includes household consumers as well as all other levels of distribution.**
- 2. Retail level – The level that includes all retail sales of the recalled product.**
- 3. User level – This level includes hotels, restaurants, and other food service institutional consignees.**
- 4. Wholesale level – The distribution level between the manufacturer and the retailer.**

FSIS Directive 8080.1 Rev. 3

- **Describes the USDA Regulatory Procedures for a Meat Product Recall**



Company Actions

- **Develop a recall team**
- **Develop a recall plan**



Basic elements of a recall plan

- 1. Recall Management Team**
- 2. Complaint File**
- 3. Recall Contact List**
- 4. Tracing the product (coding and records)**
- 5. Production amounts (lot size)**
- 6. Distribution Records**
- 7. Recalled Product Records**
- 8. Recall Procedures**
- 9. Recall Effectiveness Procedures**
- 10. Testing the Recall Plan (Mock Recall)**

1. Recall Management Team

- Identifying personnel will allow your recall plan to work smoothly.
- Recall Coordinator
- Recall team members
 - Members from production, purchasing, marketing, quality assurance, legal, sales, distribution, consumer affairs and public relations.



Responsibilities of the Team

- 1. Decision making**
- 2. Quality assurance/ technical advisory**
- 3. Media and communications**
- 4. Complaint investigation**
- 5. Contacting accounts**
- 6. Contacting regulatory agencies**
- 7. Working with legal counsel**

Identification of the recall team

Name / Position	Alternate Person	Contact information	Responsibilities during a recall
Jim Jones Sales Manager	John Brown / Asst. Sales Manager	Work: Cell: Email: Fax: Home:	Contact all customers that have purchased product from the recalled lots.
Bob Green Production Manager	Joe Green Asst. Production Manager	Work: Cell: Email: Fax: Home:	Identify raw materials, packaging used, amount produced, and anything about the production processes.

2. Complaint File

- **Used to record the details and conduct and investigation of the problem**
- **Three Main parts:**
 - 1. Record the initial complaint information.**
 - 2. Investigate the complaint and record findings.**
 - 3. Take action based on the findings.**

Important Complaint Information

- 1. Details of person, firm or agency making complaint – name, address, phone**
- 2. Details of the problem**
 - 1. Illness**
 - 2. Foreign object in food**
 - 3. Pathogen test results**
- 3. Product details**
 - 1. Package type and size**
 - 2. Product name**
 - 3. Product codes**
 - 4. Do they have a sample**

Important Complaint Information

4. Retail Details

- 1. Name and address of store**
- 2. Date of purchase**

5. How the product was stored and handled

6. Illness and injury details

7. Has the complaint been referred to regulatory agencies

Complaint Investigation

- Investigated by a trained person in your company.
- Review all products that may have been affected by the problem.
- Record all findings in a complaint file
 - Name, date, findings, other products
- Form a decision of action to be taken.
- Inform regulatory agencies and confirm action taken.

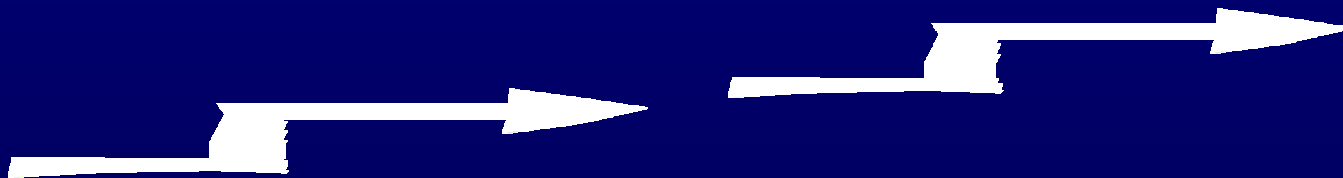
3. Recall Contact List

- Name, address and phone numbers of regulatory personnel.
- Name, address and phone numbers of all company officials not on the recall team.



4. Tracing of Products

- Identification of the finished product will limit the scope of the recall and will assist with removal of the product from distribution.
- Identification of the product may also require identification of the raw material and packaging sources.
- No identification may lead to recalling more product than necessary.



Product records and Coding Recommendations

- 1. Link all raw ingredients to the supplier.**
- 2. Link all raw ingredient lot codes to finished product codes.**
- 3. Code your finished products by lot.**
- 4. Link the ingredients of rework to finished product codes.**
- 5. Link the ingredients in premixes to finished product codes.**
- 6. Link finished product codes to accounts receiving.**

5. Production Amounts

- In a recall your company is responsible to recall as much of the product as possible.**
- Your company needs to know how much has been produced and how much has been sold.**
- These amounts will determine if you have notified all of the customers (accounts) who may have purchased the product.**

6. Distribution Records

- **Accurate distribution records will allow you to limit the recall to specific customers (accounts) that received the product.**
- **Distribution records need to contain specific product and lot codes.**
 - **Name of the account and type of account**
 - **Product name and code**
 - **Who to contact, phone, fax, and email.**
 - **Amount of product shipped**
- **Distribution records need to be kept for a period of time that exceeds the shelf life of the product.**

7. Recalled Product Records

- **Products that are recalled and returned need to be recorded. Records include:**
 - **Description of the product**
 - **The amount of the product recalled**
 - **The date the product was recalled**
 - **Corrective actions taken**
- **Products need to be controlled in the plant to avoid reentry into the marketplace.**
- **Recalled product needs to be corrected or disposed of.**

8. Recall Procedures

- The recall plan should include a step by step list of procedures if recall of a product is necessary.



Procedures

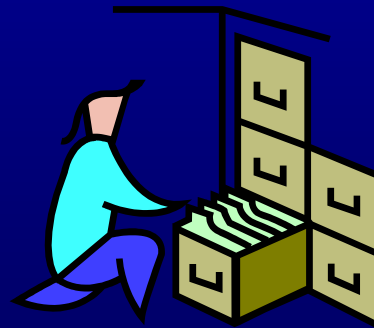
- 1. Assemble Recall Team.**
- 2. Notify Regulatory Agency.**
- 3. Identify all Products.**
- 4. Detain and segregate all products to be recalled that are still in your companies control.**
- 5. Prepare a Press Release**
- 6. Prepare the Distribution List**

Procedures

- 7. Prepare and distribute the Notice of Recall**
- 8. Verify the effectiveness of the recall**
- 9. Control the recalled Product**
- 10. Decide what to do with the recalled products**
- 11. Fix the cause of the problem**

9. Recall Effectiveness Procedures

- An effectiveness plan would determine if all the accounts that you shipped the product to were notified about the recalled product.



10. Testing Your Recall Plan

- **Conduct a mock recall**
- **Allows you identify and correct problems that may occur in your plan.**
- **Test the plan forward from the raw ingredient for a potential problem from raw ingredients.**
- **Test the plan backwards from the finished product for potential problems with products in the marketplace.**
- **Provide a test scenario**

Other Considerations

- **Regulatory requirements may vary.**
- **The Spokesperson that interacts with media is very important.**
- **Recalls can destroy a company.**
- **Recalls can improve the companies image with the public.**



Summary

- **Companies have a responsibility to remove harmful products from the market place.**
- **Government regulations need to be understood.**
- **Recall plans are prerequisites for HACCP plans.**
- **HACCP will enhance your ability to assess a recall situation.**
- **Recall plans should be developed for each production facility.**