

Lot Coding, Product Tracking, Recalls, and Fee Assessments

MAMP Convention
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Overview

- Recall basics and definitions
- Who's involved/gathering information
- Costs
- Lot coding/Trace backs/Recordkeeping
- Recall plan
- Questions



What is a recall?

- Intended to remove food products from commerce when there is a reason to believe the products may be adulterated or misbranded.
- Voluntary action by a manufacturer or distributor to protect the public from products that may cause health problems or possible death.

How are potentially unsafe foods discovered

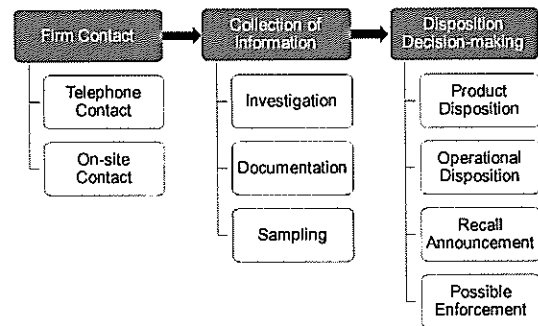
- Human illness – epi investigation with a link to specific product
- Consumer reports – illness or bad product
- Sampling – by firm or government
- Discovery – by firm or government
 - Evaluate the process
 - Evaluate the products - label
 - Record review - HACCP



Who decides to initiate a recall?

- Initiated by the manufacturer or distributor
- Maybe at the 'request' of government (state, FDA, or FSIS)
- Recalls are voluntary, no regulatory requirement
 - w/ refusal – FSIS or FDA can seize products in commerce, seek an injunction against the firm
 - Governments role – to monitor recalls – oversee recall strategy and assess the adequacy of a firm's action, ensure destruction of product, investigate cause

You're in a recall, now what?



Getting to Acceptance

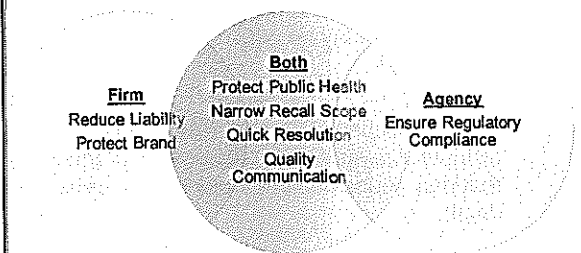
Acceptance is where the action can happen.

THE 5 STAGES OF GRIEF



Image source: <http://locnessdesigns.com/2012/12/01/the-5-stages-of-grief/>

Recall Goals



The Recall

- Working directly with...
 - Inspectors,
 - Compliance officers,
 - RRT personnel → MDH epidemiologist
 - Supervisors/ management
 - Customers



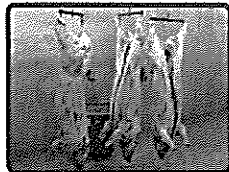
Gathering Information

- Product Information
- Distribution Information
- General Production Information
- Product Production Information



Product Information

- Product Description
- Product Source (Plant, Distributor, Import?)
- Product type (Raw, RTE)
- Affected Codes or Lots
- Affected product scope justification



Product Distribution Information

- Has there been further distribution?
- Mode of distribution
- Distribution list
- Distributors/Purchasers
- Intended End User (Retail food-service/Consumer)
- Have distributors been contacted?

General Production Information

- Production Run/Sanitation Cycles
- HACCP or other production documentation
- Environmental Sampling
- Consumer Complaints on product
- Received Product Notification
 - Reportable Food Registry Reports
 - Ingredient Recall
 - Illness notifications
- Firm Corrective Actions



Product Production Information

- Production Date
- Production Amount
- Ingredients & Sources
- Product Production Flow
- Sampling results related to production of this product
 - During investigation agency may take additional samples

Information Gathered

- Take all information gathered
 - Determine the exact scope of recall
- Issue the official recall
 - May need to expand the scope of recall
 - New/additional information gathered



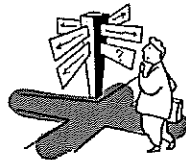
Recall Announcement

- Establishment
- Product recalled
- Production dates/ codes
- Quantity recalled
- Recall classification
- Recall notification level
- Reason for recall
- Nature of Potential Hazard
- How/When Hazard Discovered
- Media/Consumer Contacts & Instructions
- Risk information
- Follow-up activities
- Photos of product codes

Consider need for post-recall press release to let customers know product out in commerce is safe and ready for consumption.

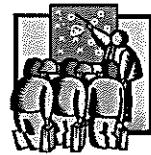
Key to Recall Success

- Demonstrate Control, Not Chaos:
 - Knowledge of your products and process
 - Ability to quickly track and secure product
 - Capability to assess process and determine cause
 - Ability to plan and execute corrective actions



Key to Recall Success

- Showing your firm is in control and can take the necessary steps to mitigate and solve the problem is critical to the regulatory agency working with you.
- Prepared firm = quicker, effective response



COSTS

- Indirect costs of a recall
 - Loss of business/customers
 - Negative name association
- Direct costs
 - Lawsuits
 - Increased insurance premiums
 - *Food Safety Emergency Assessments*



Food Safety Emergency Assessments

- Minnesota Statutes 28A.085(2)
- A food handler that requires re-inspection due to adulteration or misbranded foods that results in food being recalled from commerce.
- Reasonable and direct re-inspection costs
- Re-inspection related to floods, earthquakes, storms, accidental fires, and power outages are excluded.

What situations qualify for a Food Safety Emergency Assessments?

- Product has to be recalled for adulteration or misbranding.
- Product has to have left facilities control.
- Known distribution (typical recall event)
- Unknown distribution (consumer advisory)



Food Safety Emergency Assessments

- Firm is notified a cost assessment might occur when it is apparent there has been/will be a recall
- Statute requires to give cost estimate if the firm requests it

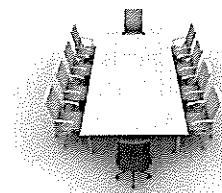


What costs are assessed?

- Personnel costs – total compensation for hours not normally worked (ie. regular inspection hours wouldn't be counted)
 - Planning meetings/Research/Investigation/inspection time
 - Drive time/Overtime/Mileage – for drive time outside your normal inspectional duties/area
 - Laboratory costs – for samples to determine the scope of the recall
 - Supplies – for supplies not normally used
 - Recall effectiveness checks
 - Attorney's costs – if used
- Exclude federal funding (ie. Meat inspector 50%)

Issue Assessment

- Once the recall concludes
- May have Administrative Meeting
 - Discuss corrective actions
 - Preventative controls
 - Solutions



Assessment

- Compliance compiles cost information
- Compliance sends out letter and invoice with cost assessment
- Firm has 30 days to appeal



Over the last few years...

- \$13,000- *Listeria monocytogenes (Lm)*
- \$47,000- *Lm*
- \$6,000- *Salmonella* (RTE product)
- \$5,000- CCP not Met
- \$11,000- *Lm*
- \$12,000- *Salmonella* (RTE product)

Role of Inspectors in a Recall

- Ensure plants follow their Recall Procedures to ensure all affected product is located and recalled.
- Look for recalled product when its been distributed (out of the establishment's control)
- Who: MDA inspectors, delegated agencies, state & local health agencies
- When: During routine inspections or during audit checks at request of FDA/USDA

5 Steps to Recall Management

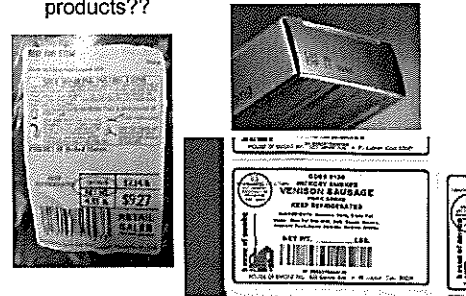
1. Consumer Notification (Press Release)
 - Rapid actions with consistent information and a clear call to action
2. Notification to retailers and vendors:
 - Contact them individually as rapidly as possible
 - Critical in tracking of products
3. Document all communication
4. Affected Products are pulled from commerce in a timely fashion
5. All product retrieval efforts are well documented

Lot Coding & Product Tracking



Lot Coding-What's Out There?

- What are processors currently using to track products??



Lot Coding & Product Tracking

- Trace back – using product labels/lot codes to track products back through the production process (in plant documentation/records)
- Trace forward – where did the products get sold?
- Wholesale distributors – Farmer's Market Customers, Roundy's, Reinhart Food Service, Sysco
- Retail stores and restaurants
- Consumers – public notification- press release, media response

USDA FSIS-FINAL RULE ISSUED

- May 8, 2013
- Requirements for Official Establishments to:
 - Notify FSIS of adulterated or misbranded product
 - Prepare and maintain written recall procedures
 - Document HACCP plan reassessments
- What are "Official Establishments"?
- What is required in YOUR plant?
 - USDA
 - State Equal To
 - Retail

Notification

- Notify USDA (or if state Equal-To, the MDA) when adulterated product has entered commerce
- This means you need to contact your inspector directly whenever you recognize that product originating (or even just passing through) your establishment is adulterated
 - ***This includes product that may NOT have originated in your plant!***
- Notification must occur within **24 hours** of learning/determining that adulterated or misbranded product has or may have entered commerce

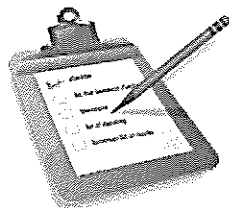
Notification

- Notification needs to be done at any hour of the day, any day of the week
- If you find it on Sunday, don't wait until Monday!



Notification must include:

- Type of product
- Amount of product
- Origin of product
- Destination of product

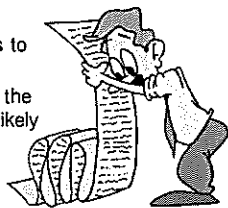


Recall Procedures

- All USDA and State "Equal-To" establishments must maintain Recall procedures as of May 8, 2013
- Is it required for Retail-Exempt plants?
 - *No, but it's a good idea!!*
- Recall procedures must contain:
 - **How the establishment will decide whether to conduct a recall**
 - **How the establishment will implement the recall**

Recall Procedures

- Develop a useful recall plan:
 - Helps prevent last minute scrambling to pull things together
 - Stressful time
 - Familiarize staff with actions to be taken
 - MDA can help you navigate the process, but ultimately it is likely to be your recall unless it is mandated.



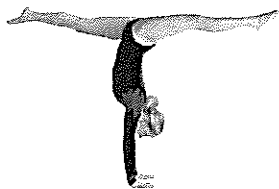
When is this useful or needed?

- Positive product result is obtained from MDA (or USDA) sampling
- Product sourced from another plant is linked to a significant contamination event and must be recalled
- Illness reported to MDH and linked back to product you produced or sold
- Scenarios are wide...*it could happen to you!*

WHY ME?

Mock Recall

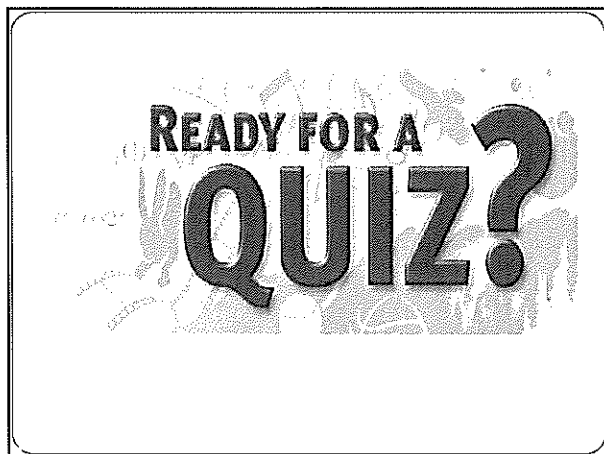
- Testing your Recall Plan-
 - What will you need to do?
- Practice Makes perfect!



Enforcement




- Inspection personnel will be looking to see if the new requirements are met
- Noncompliance records will be documented if recall plans are not available for review
- Not required in Retail or Custom Exempt plants, but highly recommended!
- Be proactive and responsible-*don't wait until it happens to you!*



Question 1


True or False: Recalls are mandatory for any food/meat establishment?

True False



Well Done! Let's move onto the next question.

Oops, that's incorrect.
Try again?



Question 2

What situations qualify for a Food Safety Emergency Assessments?

- A. Product has to be recalled for adulteration or misbranding.
- B. Product has to have left facilities control.
- C. Known distribution (typical recall event)
- D. Unknown distribution (consumer advisory)
- E. All of the above

Well Done! Let's move onto the next question...



Sorry, that's incorrect.
Try again?



Question 3

Notification of a recall must include: Type of product, Origin of product, Destination of product , and _____?

Amount of product

Which employee(s) handled the product

Ingredients contained in the product being recalled

Great job! You are correct!



Close, but that's incorrect.
Please try again...



What's In It For Me??

THESE ARE FINE,
BUT WHAT'S IN
IT FOR ME?



Questions??

