



Conducting Product Recalls

Presented by

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For FSIS “How to” Workshops

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Objectives

- By the end of this workshop, you will be able to
 - Understand agency policies and guidance on recalling products
 - Conduct a recall of product
 - Use practical tools and methods in conducting a recall



Recall of Meat and Poultry Products

- Product recalls are voluntary
- May be initiated by firm or upon request of Food Safety and Inspection Service (FSIS)
- FSIS may detain or seize product if firm refuses to initiate a recall
- FSIS verifies recall activities by firm



Rationale for Recall

- Positive laboratory result for biological hazard
- Consumer complaint
- Epidemiological data from public health agency, Centers for Disease Control and Prevention (CDC), and others



Rationale for Recall (*con't*)

- Information gathered during inspection activities
- Illness outbreaks
- Misbranding of product



Firm is expected to notify FSIS when initiating product recall



Recall Definitions

- 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 provisions of the Federal Meat Inspection Act (FMIA) or the Poultry Products Inspection Act (PPIA)





Recall Definitions (*con't*)

- Market Withdrawal: A firm's removal or correction of product that involves minor infraction that does not cause product to be adulterated or misbranded





Recall Definitions (*con't*)

- Stock Recovery: A firm's removal or correction of product that has not been marketed or has not left control of the firm
- Recall Classification: Designation of recall by FSIS based on public health concern and severity of hazard





Recall Definitions (con't)

Classes of Recall

- Class I: Reasonable probability that eating the food will cause serious adverse health consequences or death



Recall Release

CLASS I RECALL
HEALTH RISK: HIGH

Congressional and Public Affairs
Amanda Esmich (202) 720-0113
FSIS RC 010 2007

██████████ FIRM EXPANDS RECALL OF GROUND BEEF PRODUCTS DUE TO POSSIBLE *E. COLI* O157:H7 CONTAMINATION

WASHINGTON, Sept. 29, 2007 – ██████████, on ██████████ establishment, is voluntarily expanding its Sept. 25 recall to include a total of approximately 21.7 million pounds of frozen ground beef products because they may be contaminated with *E. coli* O157:H7, the U.S. Department of Agriculture's Food Safety and Inspection Service announced today.

The recall is being expanded based on an additional positive product sample reported by the New York Health Department, reported illnesses, and findings from a food safety assessment conducted by FSIS at the establishment.

There are currently 25 illnesses under investigation in Connecticut, Florida, Indiana, Maine, New Jersey, New York, Ohio and Pennsylvania. An investigation carried out by the New York Department of Health in coordination with the Centers for Disease Control and Prevention, preceded the recall of Sept. 25.

Frozen products still in commerce with an unexpired sell-by date are subject to this recall expansion. The company applies a one year sell by date to their frozen products. For best quality, FSIS recommends consumers use any frozen ground beef products within three to four months of the stated sell-by date. It is important that consumers look for the recalled products and return them if found in their freezers.

The frozen ground beef products were produced on various dates between Sept. 25, 2006, and Sept. 25, 2007, and were distributed to food service institutions in the New York metropolitan area and to retail establishments nationwide.

Each package bears the establishment number ██████████ inside the USDA mark of inspection as well as a sell-by date between "SEP 25 07" and "SEP 25 08."

The products subject to the original and expanded recall include:

- 10-pound boxes of ██████████ 100% ALL BEEF PATTIES 75/25, 4 OZ (#-1), 40 PIECES."
- 10-pound boxes of ██████████ 100% ALL BEEF PATTIES 75/25, 6 OZ FLAT, 27 PIECES."

PREPARING GROUND BEEF FOR SAFE CONSUMPTION

USDA Meat and Poultry Hotline
1 800 MPHotline or visit
www.fsis.usda.gov

Although the product(s) being recalled should be returned to the point of purchase, consumers preparing other ground beef products should heed the following advice:

Consumers should only eat ground beef patties that have been cooked to a safe temperature of 160 °F. When a ground beef patty is cooked to 160 °F throughout, it can be safe and juicy, regardless of color.

The only way to be sure a ground beef patty is cooked to a high enough temperature to kill harmful bacteria is to use an accurate food thermometer.

Color is not a reliable indicator that ground beef patties have been cooked to a temperature high enough to kill harmful bacteria such as *E. coli* O157:H7.

Eating a pink or red ground beef patty without first verifying that the safe temperature of 160 °F has been reached is a significant risk factor for foodborne illness.

Thermometer use to ensure proper cooking temperature is especially important for those who cook or serve ground beef patties to people most at risk for foodborne illness, because *E. coli* O157:H7 can lead to serious illness or even death. Those most at risk include young children, seniors, and those with compromised immune systems.



Recall Definitions (con't)

Classes of Recall

- Class II: Remote probability that eating the food will cause adverse health consequences
- Class III: Eating the food will not result in adverse health consequences





Recall Definitions (*con't*)

- Depth of Recall: Level of product distribution for recall purposes:
 1. Consumer: Product has been sold to household consumers, although identifiable quantities may remain under control of retailers
 2. Retail: Product has been received by retailers for sale to household consumers but has not yet been sold to consumers





Recall Definitions (*con't*)

- Wholesale: Product has been distributed to a warehouse or distribution center where it is not under direct control of producer; distribution level between manufacturer and retailer
- HRI: Product has been received by hotels, restaurants, and other institutional customers





Recall Definitions (*con't*)

- Scope: Defines amount and kind of product subject to recall. Factors for consideration include
 - plant procedures for sanitation
 - lot definition
 - HACCP plan
 - clean-up to clean-up
 - use of rework, etc.





Recall Definitions (*con't*)

- Disposition: Firm's action with respect to product subject to recall (e.g., recook, rework, destroy, relabel)



FSIS Directive 8080.1

Recall of Meat and Poultry Products



- Revision 5, November 17, 2008
- Attachments
 - Attachment 1—Product Recall Guidelines for Firms
 - Attachment 2—Factors Considered by FSIS Recall Committee
 - Attachment 3—Effectiveness Checks



Recall Plan

- If faced with recall, having a written procedure will make the process more effective
- Recall plan should specify actions the firm will implement when
 - deciding whether a recall is warranted
 - conducting the actual recall



Elements of Recall Plan

- Personnel
- Hazard evaluation
- Determination of scope
- Recordkeeping
- Communications
- Effectiveness checks
- Recall simulations



Recall Personnel



- One individual should be identified as the Recall Coordinator
 - Identity of coordinator will depend on factors, such as size of operation, number of employees, etc.
 - Coordinator should be knowledgeable of all aspects of operation



Recall Personnel (*con't*)

- Identification of recall personnel
 - All personnel involved in recall action, along with telephone contact numbers, e-mail, etc., should be identified
 - If alternates are part of team, identify them
 - Roles and responsibilities of each person should be described



Evaluation of Hazards

- Firm should collect and evaluate all available information regarding extent and nature of health risk(s) associated with situation, such as
 - whether any disease or injuries have occurred from use of product



Evaluation of Hazards (con't)

- Assessment of hazard to various segments of population that may be exposed, especially those who may be at greatest risk
- Assessment of the likelihood of hazard occurring



Evaluation of Hazards (con't)

- Assessment of the relative degree of seriousness of the health hazard to which the population at risk may be exposed
- Assessment of consequences of hazard's occurrence



Scope of Recall

- Plan should outline how firm will assess the amount and kind of product subject to recall
- Scope of recall based on criteria such as contamination, product coding, same source of raw material, clean-up to clean-up, etc.



Recordkeeping

- Firm should use coding system on product to permit positive identification and facilitate effective recall
- Records should be maintained for period of time exceeding shelf life of product and expected use as well as regulation
- Distribution records should be maintained to facilitate identification and location of product subject to recall



Recordkeeping (con't)

- Records should help facilitate both the trace back to the source of materials purchased by the plant AND trace forward to entities that received recalled product



Depth of Recall

- Plan should specify how to determine the depth of recalls for various scenarios
- Depth will depend on distribution levels



Recall Communication

- The recalling firm is responsible for promptly notifying all affected consignees about a recall
- The plan should specify the means of communication that will be used



Recall Communication (*con't*)

- Communication should convey that the product in question is subject to recall and that further distribution of product should cease immediately
- If applicable, consignee should notify its consignees that received the product



Purpose of Recall Communication

- Provide instructions on what to do with the product
- Provide contact information (name and phone number) for questions concerning the recalled product



Format of Recall Communication

- May be in form of telephone, facsimile, e-mail, special delivery letter, or combination of methods
- Keep record of documentation and follow-up of all recall communications



Written Recall Communication

- Should be brief and to the point
- Clearly identify product and any descriptive information to enable accurate identification of product



Information to Include in Recall Communication

- Product/brand name
- Product codes (include UPC code)
- Package size and date code
- Lot number (include expiration date if appropriate)



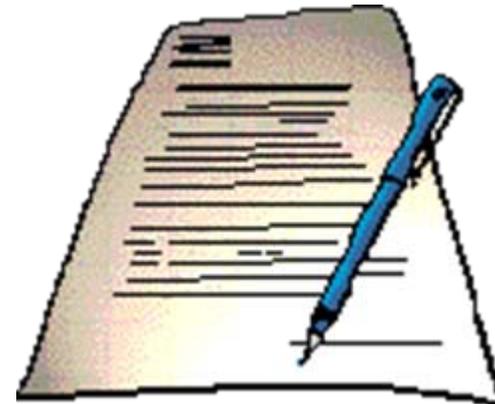
Information to Include in Recall Communication (*con't*)

- Provide explanation of risk involved if product is consumed
- Explain hazard and reason for recall
- Provide specific instructions on what to do with recalled product
- Request written response from consignee



Model Recall Letters

- Include model recall letters as part of the recall plan to assist in providing important information to consignees in consistent manner
- May want to include different models to cover multiple scenarios



Response by Consignee

- Provide means (i.e., toll-free phone number) for consignee to report whether they have any of the recalled product
- Make follow-up contact if consignee does not respond within reasonable time frame



Public Notification

- May want to include contact information for news media in plan
- Regardless of actions by firm, FSIS will issue Recall Release for Class I and II recalls



Discussion Questions

- Do you have a master list of your consignees for contact purposes?
- Do you have contact information for those consignees?



Effectiveness Checks

- Recalling firm is expected to conduct effectiveness checks
- Purpose is to verify that all consignees that received recalled product have also received notification and have taken appropriate action



Effectiveness Checks (con't)

- Firm's methods for conducting effectiveness checks should be specified in written recall plan
- FSIS will verify a firm's effectiveness checks in the event of a product recall



Information Needed to Assess Effectiveness of Recall



- Amount of product implicated in the recall
- Lot markings or other methods of identifying product in recall
- Amount of product shipped from firm
- Amount of product still under firm's control
- Locations to which product was shipped
- Method of communicating product removal to consignees



Questions to Consider

- Was communication documented?
- What actions or dispositions were taken with product?
- If product was destroyed, was destruction witnessed and documented?



Questions to Consider (con't)

- If product is on hold by consignee, is it documented?
- Can recalling firm account for all product shipped that is subject to recall (i.e., amount produced, amount shipped, returned, destroyed, or irretrievable)?



Returned Product

- Returned product control/disposition
- Method of controlling, disposing of, or correcting recalled product should be outlined in plan

Note: FSIS may want to observe destruction of product



Recall Simulations

- Also called “mock” recalls
- Firm should conduct periodic simulated recalls to test the plan
- Simulation should involve selecting hypothetical reason for recall



Recall Simulations (con't)

- Select one lot or run of product to recall
- Follow recall plan to assess effectiveness
- Proceed with simulation to point of communication beyond organizational limits of firm
- Maintain record of details and results



Recall Simulations (con't)

- Simulation records should include all contact information (e.g., lot codes) of product used in simulation
- Assess results to make changes in plan or improvements in recall strategy if needed



Discussion Questions

- What would you do with product that is recalled?
- Do you have suitable facilities for accepting and holding product that may be returned?



Steps in a Recall

- Notify FSIS
- Implement recall
- Recall assessment
- Close out the recall
- Termination of recall
- Post-action assessment



Notify FSIS of Recall

- Once the decision has been made to initiate a recall, firm should contact FSIS immediately
- Initial contact may be made to the Recall Management Staff (RMS) at FSIS Headquarters or at the District Office having jurisdiction





Basic Information to Provide to FSIS

- Complete and accurate product identity, including labels
- Reason for recall and any details concerning deficiency or defect in product
- An evaluation of the risk associated with consumption of product and how evaluation was made

Note: FSIS will also conduct risk evaluation



Basic Information to Provide to FSIS (con't)

- Amount of product in question and time frame of production
- Estimate of amount of product in distribution, time in distribution, etc.
- Geographical area of distribution, including export if appropriate
- Consignee information
- Name, title, and telephone number of recall coordinator



Basic Information to Provide to FSIS (con't)

- Copies of correspondence with consignees, brokers, etc.
- Copy of proposed press release
- Initial information may be provided to FSIS orally
- Follow-up with worksheets providing information



FSIS Response

- FSIS will usually send a representative from the District Office to the establishment to collect distribution records and confirm information that was provided



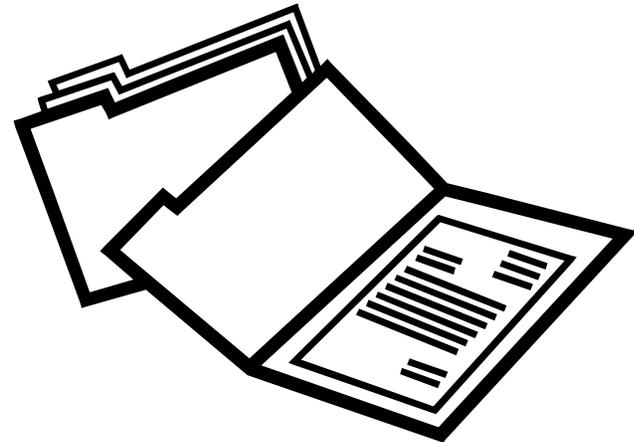
Recall Assessment

- Firm recalling product is expected to provide FSIS with updates on recall effectiveness on a regular basis
- Frequency of updates should be agreed upon by FSIS and firm
- Provide more frequent updates for situations involving high degree of public health concern
- Recalling firm should notify FSIS when it appears that the recall has been completed



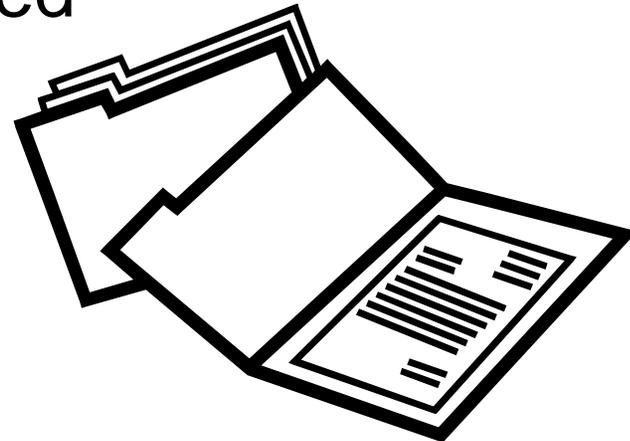
Content of Effectiveness Report

- List number of consignees notified of recall and method of notification
- Number of consignees that responded
- Quantity of product each consignee had on hand, if possible



Content of Effectiveness Report (con't)

- Identity of consignees that did not respond
- Quantity of product returned or placed on hold by each consignee
- If possible, estimated time that recall is expected to be terminated



Closing Out the Recall

- Recalling firm should send a memo closing out the recall to the District Office when it determines that all reasonable efforts to recoup the affected product have been made and the firm has either disposed of the product, has it under control, or corrected it



Close-Out Memo



- Close-out memo should contain lists of customers, amount of product retrieved, and action taken toward product
- If information in close-out memo is not compatible with prior information, rationale for discrepancy may be provided



Termination of Recall



- FSIS will terminate the recall when it has determined that the firm has made all reasonable efforts to recall the product involved and taken whatever measures were deemed necessary (i.e., disposal, control, or in some cases, FSIS control)
- Once the recall has been completed, a firm may want to notify their consignees that it has been completed





Post-action Assessment

- Purpose of post-action assessment is to determine if any part of the recall program needs to be improved or revised



Discussion Questions

- What is the first action to take when deciding to initiate a recall?
- What is the purpose of conducting a post-action assessment?



FSIS Role in Recall Actions

- During recall actions, FSIS provides firm with information and oversight
- FSIS assesses possible health hazards when it has information on a potential problem with a product produced by a firm



FSIS Groups Associated with Recall Activities

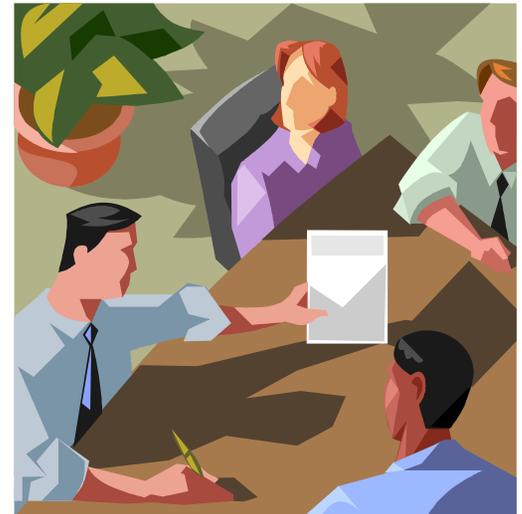


- Health Hazard Evaluation Board (HHEB)
 - Primary group in FSIS that reviews public health significance of hazards to assist in making regulatory decisions
- Recall Committee
 - Comprises representatives from various FSIS offices that respond to potential or real incidents reported to the Recall Management Staff (RMS)



FSIS Groups Associated with Recall Activities (*con't*)

- RMS chairs committee and invites other program areas to assist
- Office of Policy, Program, and Employee Development explains regulatory codes and policies



FSIS Groups Associated with Recall Activities (*con't*)



- District Recall Officer (DRO), Deputy District Manager (DDM): Clarifies and explains to committee information collected during preliminary inquiry; responsible for coordinating recall activities at field level if recall takes place
- Office of Public Health Science (OPHS): Addresses microbiological, epidemiological, and other scientific issues associated with recall



FSIS Groups Associated with Recall Activities (*con't*)



- Congressional and Public Affairs Office (CPAO), Office of Public Affairs and Consumer Education (OPACE):
 - Gathers information and generates Recall Release or Recall Notification (RNR) if there is a Recall. If recall is not warranted, may issue Public Health Alert.
 - Ensures that information in Recall Release or RNR is accurate



FSIS Groups Associated with Recall Activities (*con't*)



- Other program areas that may be represented:
 - Office of International Affairs (OIA)
 - Import Recall Coordinator (IRC)
 - Import-Export Program staff
 - Office of Program Evaluation, Enforcement, and Review (OPEER)
 - Office of Data Integration & Food Protection (ODIFP): Invited to all Recall Committee meetings as non-voting member



FSIS Procedures for Determining Need for Recall



- Preliminary Inquiry: When FSIS learns that adulterated product may be in commerce, DRO is assigned to direct inspection activities to help determine if a recall is necessary
- Preliminary steps may include
 - collecting and verifying information about suspect product
 - documenting chronology of events
 - contacting the manufacturing or distributing firm



FSIS Procedures for Determining Need for Recall (*con't*)



- contacting FSIS personnel at field level
- interviewing consumers who allegedly became ill or injured from use of product
- collecting samples for analysis
- contacting state and local health departments
- analyzing epidemiological data if available
- DRO will forward information gathered to RMS to assist the recall committee



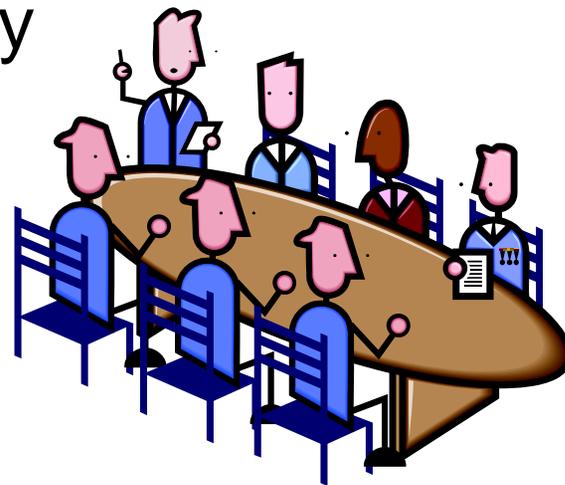
FSIS Recall Committee

- RMS will convene a recall committee as soon as possible after receiving relevant information
- Recall committee will contact firm to discuss concerns and allow firm to present a recall strategy and clarify its position
- Committee may ask if firm has a written recall program



FSIS Recall Committee (con't)

- Committee will evaluate all information available in determining whether to recommend a recall
- Committee will determine if the firm is recalling the product voluntarily



Precedents for Making Recall Determination Include

- Nature of the defect and health implications
- Reports of illness or injuries from use of the product
- Likelihood that illness or injury may result from use
- The type of illness or injury that may result from use of the product



Recall Committee Questions

- Does FSIS have reason to believe that the product in question is adulterated or misbranded?
- Is any of the product in commerce?
- Is FSIS able to verify whether any product is still in commerce?



Recall Committee Questions (con't)

- Has firm recovered all product from commerce that would be subject to recall?
 - If answer is yes and product is no longer available to consumers, recall will not normally be recommended
- Is FSIS prepared to detain or seize the product if the firm refuses to recall it?



Response of Recall Committee

- After evaluating all information, the committee will make a recommendation on whether product should be recalled
 - If a recall is recommended, RMS will submit a recall recommendation
 - If a recall is not recommended, RMS will document inquiry results and file
 - Based on evaluation, FSIS may issue a Public Health Alert



Recall Recommendation

- If RMS decides to recommend a recall, it will submit recommendation memo to Assistant Administrator, Office of Field Operations (AA/OFO) for approval
- RMS will contact the firm and allow representatives to present information about hazard or concerns associated with the product, and committee will clarify its position based on evaluation of information



Recall Recommendation (*con't*)

- If a recall is recommended, RMS will ask firm to provide a recall strategy for notifying consignees for product retrieval and disposition of product



Recall Recommendation Memo



The recommendation memo contains

- Reason that a recall is recommended
- Classification of the recall
- Ability of consumers or consignees to identify the product
- Estimated amount of product in distribution



Approved Recall Recommendation

- If the AA/OFO approves the recall recommendation, RMS will contact the firm and make a formal request for recall
- RMS will follow up with a confirmation letter to the firm
- FSIS will develop a Recall Release if needed and contact the firm to clarify information in the release



Discussion Question

- Do you know what pathogens may be associated with your products or processes that may warrant a recall if they are found in your product outside of your control?



Recall Release



- Recall Releases inform interested parties, such as consumers, industry, and public health officials, with information on product that is being recalled
- Generally issued for Class I and Class II recalls
- Recall Releases are not generally issued for Class III recalls, which usually result in a Recall Notification Report (RNR) posted on FSIS's Web site



Information in Recall Release

- Describes the product being recalled along with any product codes or identifying marks, explains the reason for the recall, and describes the risk involved
- Provides instructions on what to do with the recalled product
- Provides general information on product distribution





Information in Recall Release (*con't*)

- Provides electronic pictures of product labels if available
- Provides name and telephone number of company contact for media and customers
- FSIS will provide a draft copy of the Recall Release to the recalling firm 30 minutes prior to release for review
- Firm may provide corrections for contact information, code numbers, etc.



Recall Notification Report (RNR)

- May be issued for Class III recalls
- May be issued for Class I and Class II recalls if product subject to recall has not been distributed beyond wholesale level and has only been sent to warehouse or distribution center and is not likely to be sold directly to consumers



Recall Notification Report (RNR) (con't)



- Contents of RNR:
 - Clearly describes product the firm is recalling, including identifying marks or codes, and explains reason for recall
 - Provides name and telephone number of company contact for consumers and media
 - Provides general information about product destination



Recall Notification Report (RNR) (con't)

- FSIS will post electronic picture of product label on FSIS Web site, if available
- FSIS will provide draft copy of RNR to recalling firm for verification of information prior to posting
- Firm has 30 minutes to respond with any corrections



Public Health Alert

- Issued when Recall Committee determines that product may present risk to human health but recall cannot be recommended because product is long past reasonable time that it would likely be in marketplace



Information Provided in Public Health Alert



- Identifies firm that produced product
- Describes product along with identifying codes or marks
- Identifies whether product presents health risk
- Explains why product is adulterated or misbranded and describes risks involved with consumption of product



Information Provided in Public Health Alert (*con't*)



- Provides picture of product label, if available
- Includes instructions for consumers on handling product
- Provides name and telephone number of company contact



FSIS District Office Responsibilities

- Serve as primary point of contact for firm conducting the recall
- Review recall instructions provided by firm to consignees for accuracy
- Oversee recalled product disposition if deemed necessary



FSIS District Office Responsibilities (con't)

- Oversee program personnel effectiveness checks and product disposal verification activities
- Determine product distribution and request assistance from DROs in other districts where product was distributed



Verifying Recall Effectiveness



- FSIS uses a sampling plan to determine the effectiveness of a recall action
- FSIS selects a sample of consignees based on product distribution information using a statistical sampling plan



Verifying Recall Effectiveness (con't)

- FSIS may increase sampling if recalling firm does not have a recall plan
- Effectiveness is based on comparing actions of consignees to critical number in sampling plan



Steps by FSIS when Conducting Effectiveness Checks



- Contact or visit consignees to determine whether they received notification of the recall from firm and have removed recalled product from commerce
- If recalled product is found, initiate action to detain it
- Determine amount of product received by consignee, if possible



Steps by FSIS when Conducting Effectiveness Checks (*con't*)

- Verify that consignees are handling product in accordance with instructions from firm and regulatory requirements
- Conduct record review or observe product disposition



Steps by FSIS when Conducting Effectiveness Checks (*con't*)

- Record effectiveness check results and submit to the District Recall Officer (DRO)
- If product disposition cannot be verified, conduct a follow-up check
- If consignee is suspected of putting adulterated product into commerce, contact the DRO



DRO Response

- DRO will analyze the information provided
- DRO will contact the firm to verify whether the recall is considered closed and whether the firm controlled or disposed of the product as planned
- If DRO determines the recall was effective, a final recall effectiveness report is sent to RMS



DRO Response (*con't*)

- If DRO determines the recall was ineffective, it contacts the firm and asks them to address the situation
- If the firm is unable or unwilling to take corrective action, the DRO will recommend further action by FSIS, such as detention, seizure, or other actions, as deemed appropriate



FSIS Closure of Recall



- RMS is responsible for submitting a recommendation of termination of the recall to AA/OFO
- RMS will review the reports from the DRO and other associated reports, such as illness complaints



FSIS Closure of Recall (*con't*)

- If available data indicate no further complications or illness has occurred and there is no evidence that the product remains in commerce, RMS may proceed with a recommendation to close the recall
- If AA/OFO agrees with the recommendation, RMS will notify the recalling firm in writing that the recall is closed



Discussion Question

- How would you make a determination for checking with consignees for the purpose of conducting effectiveness checks during a recall? In other words, how would you decide how many consignees to contact?



FSIS Resources

- FSIS Directive 8080, Attachment A:
<http://www.fsis.usda.gov/oppde/rdad/fsisdirectives/8080.1rev5.pdf>
- Podcasts on Recalls:
http://www.fsis.usda.gov/News_&_Events/Food_Safety_Inspection_Podcasts/index.asp
- *Small Plant News*, Recalls addressed in May 2008 and March 2008 issues:
http://www.fsis.usda.gov/News_&_Events/Small_Plant_News/index.asp

