The Role of the EIAO in Recalls

Objectives

Upon completion of this module the trainee will be able to:

1. Complete FSIS Forms 8400-4A and B related to a given recall scenario.

2. Describe the purpose and methodology of collecting distribution information during a recall.

3. Describe the purpose and methodology for conducting a recall effectiveness check in a given recall scenario.

4. Describe the purpose and methodology for conducting a product disposition verification in a given recall scenario.

Introduction

A food recall is a voluntary action by a manufacturer or distributor to protect the public from products that may cause health problems or possible death. A recall is intended to remove food products from commerce when there is reason to believe the products may be adulterated or misbranded. Recalls are initiated by the manufacturer or distributor of the meat or poultry, sometimes at the request of FSIS. All recalls are voluntary, however, if a company refuses to recall its products, FSIS has the legal authority to detain and seize those products in commerce.

Terminology

You will need to be familiar with the following terms before we begin.

Recall - A firm's voluntary removal of distributed meat and poultry products from commerce when there is reason to believe that such products are adulterated or misbranded under the provisions of the Acts.

Market Withdrawal - A firm's voluntary removal or correction of a distributed product that involves a minor infraction that would not warrant legal action by FSIS and constitutes no health hazard.

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. Example, product is located on premises owned by, or under the control of the firm, and no portion of the lot has been released for sale or use.

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. An example of a Class I recall is the presence of pathogens in ready-to-eat product or the presence of E. coli O157:H7 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 I recall is the presence of undeclared allergens such as very small amounts of potential allergenic substance (soy) or small sized non-sharp edged foreign material (plastic).

- *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.

Depth of Recall –The level of product distribution to which the recall is to extend: (see Appendix 1 in this module)

- *Consumer* - This includes household consumers, as well as all other levels of distribution.

- *Retail level* – This includes all retail sales of the recalled product.

- *User level* - This includes hotels, restaurants, and other food service institutional consignees.

- *Wholesale level* – This is the distribution level between the manufacturer and the retailer. This level may not be encountered in every recall situation; i.e., the recalling firm may sell directly to the retail or consumer level.

Scope - This defines the amount and kind of product in question. There are several factors used in determining the scope, such as the plant's processing and sanitation procedures, the definition of a lot, any finished product reincorporated into fresh product (rework).

Disposition - The firm's action with respect to product to correct a situation leading to the recall, such as relabeling, recooking, reworking, or destroying product.

District Recall Officer (DRO) – This is the Deputy District Manager (DDM) of the DO where the recalling firm is residing. There is only one DRO for each recall.

Recall Management Staff (RMS) – This is the responsible division for recall activities that leads the Recall Committee meeting, reviews and evaluates incoming data (Recall worksheets, charts, labels), formally recommends and closes out recalls, and provides liaison with other programs and Agencies

Adulterated or Misbranded Products

There are *four* primary means by which unsafe or improperly labeled meat and poultry products come to the attention of FSIS:

1. The company that manufactured or distributed the food informs FSIS of the potential hazard;

2. Test results received by FSIS as part of its sampling program indicate that the products are adulterated, or, in some situations, misbranded;

3. FSIS field inspectors and program investigators, in the course of their routine duties, discover unsafe or improperly labeled foods; and

4. Epidemiological data submitted by State or local public health departments, or other Federal agencies, such as the Food and Drug Administration (FDA) or the Centers for Disease Control and Prevention (CDC) reveal unsafe, unwholesome or inaccurately labeled food.

EIAO Pre-Recall Responsibilities

As soon as FSIS learns that a potentially unsafe or mislabeled meat or poultry product is in commerce, the Agency conducts a preliminary investigation to determine whether there is a need for a recall. For example, if a sample of ground beef comes back as a presumptive positive for *E. coli* O157:H7, a preliminary investigation will be conducted to determine the need for a recall if it is confirmed.

The District Recall Officer (DRO) is expected to assume overall responsibility for preparing the Agency for a recall and to assign an EIAO to visit the establishment.

You, as the EIAO, are to:

1. Immediately contact the establishment's Recall Coordinator to discuss findings that may lead the establishment to conduct a recall (e.g., FSIS presumptive lab results or consumer complaint).

2. Contact in-plant inspection personnel to obtain their perspective on the establishment's operations that may be relevant.

3. Update the DRO regarding the outcome of discussions.

4. Verify that the establishment has the applicable worksheets and that the Recall Coordinator is clear on the needed information.

5. Discuss with establishment management that if the laboratory results are confirmed, and the establishment decides to conduct a recall, the Agency will ask the establishment to provide recall data as outlined in the applicable worksheets (see Appendix 2) and relevant product labels (preferably electronically) as soon as possible.

6. Conduct a preliminary assessment of establishment practices (e.g., sanitation, microbiological data, possible cross-contamination potential between the product implicated for the recall action and other products, and production history).

7. Update the DRO on the outcome of these discussions with the establishment and in-plant inspection personnel.

EIAO Recall Committee Responsibilities

If the product confirms positive for a pathogen, or in the case of other (non-pathogen) recall situations, you, as the EIAO, will serve as a member of the Recall Committee. As a member of the Recall Committee, you will:

1. Participate in both the FSIS preliminary meeting and the external conference call held with the plant.

2. Share information in the pre-meeting with the Recall Committee that you learned during preliminary meetings and conversations with establishment management and in-plant inspection team.

3. Share factual information you gathered that will assist the Committee in deciding the classification and the scope (amount and kind of product in question) of the recall.

EIAO Recall Responsibilities

Once an establishment decides to conduct a recall, the Recall Committee decides on the class of the recall. When an establishment initiates a voluntary recall, you, as the EIAO, will obtain distribution information for the DRO, perform recall effectiveness checks, and perform product disposition verifications. Now let's look at each of these activities in more detail.

1. Obtain Distribution Information

Your DDM will provide you with the *recalling firm's* distribution list. When initially contacting firms to obtain distribution information for the DRO, you should:

- Ask to speak with the manager who handles recalls.
- Ask the manager if a recall notice was received from the recalling establishment and if recalled product has been distributed to their customers and if the product has been sold to the public.
- Obtain a distribution list from the establishment (i.e., the specific list of customers who were actually shipped the recalled product).

An effectiveness check should not be conducted at this time, unless you are directed to do so. The focus at this stage is to promptly and accurately obtain subsequent distribution information from the firm to enable development of the overall recall distribution.

Information needed on the distribution list includes following:

- Customer (s) name;
- Address, City and State;
- Contact person and phone number;
- Amount of product distributed to each consignee (cases and pounds);
- Copy of Recall Notice sent to their customers, including product disposition.

You should send the distribution information to the District Office as soon as possible. Once the initial distribution information is provided back to the Recalling District, the DRO will take the distribution information and determine which Districts have received product and the total number of consignees. From the total number of consignees, the DRO will determine the total number of and frequency of the effectiveness checks. They will also determine how many product disposition verifications will be performed. The methodology for determining these things is covered in FSIS Directive 8080.1 Rev. 4, Attachment 3 which is included as Appendix 6 of this module.

2. Conducting Recall Effectiveness Checks

A recall effectiveness check is a process through which FSIS verifies that the recalling firm has been diligent and successful in notifying and advising consignees of the need to retrieve and control recalled product and has ensured that the consignees have responded accordingly. Recall effectiveness checks are conducted at primary and secondary customers that received product from the recalling firm and they may be conducted on-site or via the telephone, as determined by the DRO. For a recall to be effective the number of consignees not notified or found to have product in commerce must be equal to or less than the critical number in the sampling plan as found in Directive 8080.1 Rev. 4.

As a public health regulatory agency, FSIS is committed to conduct recall effectiveness checks without delay. To ensure that public health is protected, District Recall Officers (DRO), EIAOs, PHVs and Case Specialists may have to work late, weekends and even holidays to accomplish our food safety mission. Normally it is expected that recall activities should take precedence over other EIAO activities. When directed by your District Office to conduct effectiveness checks and/or product disposition verification checks for all recalls, especially those involving illnesses, all of your attention and energy must be focused in gathering information to assure that the affected product is removed from commerce. In the interest of public health, you must maintain a constant level of communication with the District Office to assure recall activities are coordinated and completed in the time frame indicated in Directive 8080.1 Rev. 4. The DDM will provide guidance to you regarding expectations.

Methodology for Recall Effectiveness Checks

When conducting the recall effectiveness check, you should:

- Meet with the contact person identified on the consignee list and identify yourself.

  Example: “I am with the United States Department of Agriculture, Food Safety Inspection Service and I am (your name) from (give name of your

District Office). I am conducting a check of the effectiveness of the recall of (description/brand name of product)."

- Have a copy of the Recall Effectiveness Form (FSIS Form 8400-4A) and pertinent recall information for reference, including a copy of the recalling firm's notice to its customers, or a customer's notice to it's customers.
- Fill out the form while asking questions.

    - Did you receive notification of the recall?
    - When did you receive it? How (email, phone, fax)?
    - What instructions did you receive regarding the recalled product?
    - Did you follow instructions from the recalling establishment. (e.g., product returned to establishment?)
    - Did you sell to persons/businesses that intend to resale the recalled product to someone other than a consumer?
    - If so, have you notified them of this recall?

- Obtain a copy of the recall notice sent to their consignees.
- Obtain distribution information.
- Immediately forward this distribution information to your District Office.

If the consignee states that recalled product was destroyed, ask for details. If the consignee states recalled product was picked up, ask when it was picked up and verify the destination. If the consignee states that the recalled product was not received, advise them FSIS has records indicating they may have received recalled product. Review information about the recall with them to determine if recalled product was received.

3. Conduct Product Disposition Verifications

The purpose of disposition verification is to verify the disposition of the recalled product. Product disposition will be verified at a subset of firms where recall effectiveness checks were conducted. Product disposition verifications track recalled product to the final destination in each district. The final destination would be back to the recalling establishment or destruction of product. The District Office will notify you if you need to conduct specific product disposition verifications. If product was on-site after the recall occurred (as determined during effectiveness checks), these checks should be conducted on-site.

Methodology for Product Disposition Verifications

When conducting the product disposition verifications, you should:

- Have Recall Effectiveness Forms (FSIS Forms 8400-4A) and Product Disposition Verification Forms (FSIS Form 8400-4B) to fill out while asking questions.
- Have pertinent recall information available for reference.

- If it is a retail store - first go to retail case or retail shelf to determine if recalled product is offered for sale to consumer.

    - If recalled product is observed being offered for sale, take a photo of the recalled product.
    - Confirm the establishment number, code dates, lot codes, and package size.

- Locate the contact person identified on your list.
- Identify yourself and show your credentials, and provide a business card.
- Verify if the recalled product is on hold.
- Verify the establishment number, codes, etc.
- If you are informed that no product is on site, check the coolers and freezers.
- If product was returned to the recalling firm, further inquire:

    - Who was it returned to and where?
    - Do you have records to show product was returned? If so, obtain a copy.

- If product is on hold waiting for pickup or instructions for disposition, get answers as to when they expect pickup or delivery.
- When you confirm product has been picked up or returned to the recalling establishment, record this in remarks of FSIS 8400-4B.
- Determine when and how the product was returned?

When conducting product disposition verifications, it is essential that the information is precise and detailed regarding the disposition of the recalled product. For example, if product was destroyed, obtain the records needed to verify destruction (records of destruction, credit memos, or landfill weight tickets, etc.).

If additional product disposition verification checks need to be conducted to verify the final disposition of the recalled product, this should be communicated to the DO. For example, if recalled product has been returned to a distributor, this information is used to determine if a follow-up visit is required to verify the disposition of the product. If additional onsite follow-up checks need to be conducted in other Districts to determine product disposition, communicate this information to your DDM/DRO. The DRO will provide this information to other District (s) for follow-up product disposition verification to verify final destination of recalled product.

Deviations

Deviations are those occurrences where unfavorable results related to the recall are encountered. DDMs in non-originating districts should immediately inform the originating district's DRO when deviations are encountered so that the recalling firm can be informed and corrective action is attained. The DRO will determine if the deviations found follow a pattern or trend.

Documentation of Recall Verification Activities

You should record all recall information obtained on FSIS Form 8400-4A and B. You should fax or e-mail the completed form to the District Office and FedEx the originals, with signature, to your District Office.

Memorandum of Interview (MOI)

If a consignee did not receive notification of the recall and the product is still offered for sale or product is being used (restaurant), you should prepare a Memorandum of Interview (MOI) to capture what occurred and immediately notify the DRO of this prohibited activity. Receiving and shipping records should be collected to document that the consignee received the recalled product. Take a photo of product offered for sale or being used. MOI and supporting documents will be used as evidence.

Ineffective Recall

In the event that the numbers shown in the last columns of Tables 2, 3, 4, and 5 in Directive 8080.1 Rev. 4 are exceeded, it is important that the DRO send the recalling firm a "Notice of Ineffective Recall" letter as soon as possible. The letter will be based upon the collected evidence that demonstrates the recalling firm was not diligent and successful in notifying its consignees of the need to retrieve and control recalled product. The letter should provide the recalling firm the opportunity to respond and describe how it intends to address the situation.

Recall Effectiveness Case File (AER)

The AER system should be used to document and maintain the evidence to support the issuance of a Notice of Ineffective Recall and the plant's response. All District Offices involved in the recall should maintain a recall case file capturing all the information and activities pertinent to the recall. The DRO is responsible for preparing an Administrative Enforcement Report (AER) that contains all pertinent information and which summarizes all recall effectiveness checks conducted, including those conducted by assisting Districts. There should be only one AER prepared to capture OFO's recall effectiveness check activity. It is the responsibility of the DRO to ensure the AER is completed. The AER should include, as applicable, the:

- Recall Notification Report.
- Recall Press Release.
- Letter from Recall Management Staff to the Establishment's Recall Coordinator.
- Recall Worksheet.
- Flow Charts.
- Distribution Lists.
- Product labels and notification letters to customers.
- Letter from DRO requesting assistance in gathering distribution information.
- Letter from DRO requesting assistance in conducting effectiveness checks.
- Recall Effectiveness Reports from assisting districts.
- Recall Effectiveness Check forms 8400-4.
- Company correspondences.
- Lab Results.

- Final Recall Effectiveness Check Report to the Director, RMS.
- Recalling firm close-out letter.
- Tables, calculations and justifications used to determine randomness of consignees.
- Record of any detentions that were taken.
- Prohibited Warning Letters.

District Verification Result Summaries

The DRO will summarize recall activities and provide it to the Recall Management Staff. Items that may be included in the summary are:

- The number of consignees that still have product(s) on sale.
- The reasons for continued sale of the product.
- Other deficiencies that were identified.
- Verification follow-up activities.
- An effectiveness rating to the recalling firm's recall activities.
- A summary of corrective actions taken.

Workshop

1. Use the following recall information to prepare the attached FSIS Form 8400-4A & B.

EP 123-2004 Class I
Product recalled – 80/20 fine ground beef. Four - 5 lb. chubs per case. (E-coli)
Codes – Produced 8/30/04 – Shift A
Luke's Meat Market EST 00003
Hwy 231 West
Hamburger, ID 77777

You are conducting a recall effectiveness check and product disposition verification at 1005 on Sept 10, 2004 at Lucy's Diner, RR3, Hampton, OR and meet with Hugh Day, manager, who had been shipped one case of ground beef from XYZ Warehouse, Big Town, OR. He received a faxed Notice of the Recall on Sept 08, 2004 and uses the ground beef in his diner for the end consumer. When he received the Notice he had two 5 pound chubs of the recalled product. This product was picked up on Sept 9, 2004 by XYZ Warehouse and he had a credit invoice (No. 55) for it.

2. EST 20C, Onward Meat and Poultry Co, 2939 Jefferson, New York, NY is recalling Onward Hotdogs, for *Listeria monocytogenes*. The Hotdogs are 16-ounce packages with 12 packages in a case. The packages and the case have a sell by date of 3/13/05. EST 20C sold this product to five distribution warehouses. One of these warehouses, Winn Dixie, Tampa, Florida received 500 cases. You are an EIAO in Florida and are to obtain a distribution list for the Albany District.

a. Why do you have to obtain this list?

b. Explain the steps you would follow to obtain this list and the information you would need to collect for the Albany District.

3. You are conducting a recall effectiveness check by telephone for Fully Cooked Pork Sausage Patties, which are positive for *Listeria monocytogenes*. They are in 10-pound cases, bearing EST 2020, and code date of 10/10/04. The distribution list from the recalling District has Joe's House, 4010 Main, Blue Earth, MN, owner Joe Nelson, receiving 30 cases of recalled Pork Sausage.

a. What is the purpose of the recall effectiveness check?

b. What questions would you ask Mr. Nelson when conducting an effectiveness check?

c. What if Mr. Nelson tells you he has 10 cases of the recalled Sausage?

d. What if Mr. Nelson has transported product to his retail grocery stores?

4. You are conducting a product disposition verification check at Henry's Grocery Stop, 1234 Sunshine St., Abby, AR. The owner is Mr. Albert Henry. The recall information is:

EP 234-2004
Product Recalled - 25 ounce bags of Mary's Chicken Patties (Undeclared Allergen)
Codes - Sell by 1/31/05
Producing EST 91234 – Mary's Chicken House, 23 Heavy Drive, Light, Mass

a. What is the purpose of the product disposition verification?

b. What is the first thing you do when you arrive at Henry's Grocery Stop?

c. There are ten 25-ounce bags of Mary's Chicken Patties in the retail freezer bearing EST 91234 and sell by date of 1/31/05. Now what would you do?

d. Mr. Henry tells you he received the product in the retail freezer today to replace the recalled product in the storage freezer. He tells you he has 12 packages in the storage freezer waiting for pick-up. What would you want to know based on this information?

e. Mr. Henry received his product from a distributor in Missouri. What would you do next?

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0583-0015. The time required to complete this information collection is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

REPORT OF RECALL EFFECTIVENESS:
PART A - Effectiveness Check

1. NAME AND ADDRESS OF CONSIGNEE/CUSTOMER

2. RECALL CASE NO.

3. CLASS

4. NAME OF PRODUCT(S) RECEIVED

5. PRODUCT CODES/LOTS/SELL-BY DATE *(attach separate sheet if needed)*

6. NAME AND TITLE OF PERSON INTERVIEWED

7. DATE OF INTERVIEW

8. TIME OF INTERVIEW

9. INTERVIEW CONDUCTED BY?

☐ TELEPHONE ☐ ON-SITE

10. WAS RECALL NOTIFICATION RECEIVED?

☐ NO

☐ YES *(Date notified):* _____

11. HOW WAS NOTIFICATION RECEIVED?

☐ MAIL ☐ PHONE

☐ FAX ☐ E-MAIL

☐ OTHER *(explain):*

12. AMOUNT OF RECALLED PRODUCT RECEIVED *(in lbs.)*

If amount unknown, explain:

13. HOW MUCH OF THE PRODUCT IN QUESTION 12 IS IDENTIFIED DURING EFFECTIVENESS CHECKS?
(Check all that applies, specifying amounts (in lbs.)

☐ On Hand _____ ☐ Sold _____ ☐ Consumed _____

☐ Destroyed _____ ☐ Returned to recalling firm _____ ☐ Further Distributed _____

☐ Other *(specify):* _____

If further distributed, obtain consignee list and give number of consignees:

14. REMARKS:

SIGNATURE OF FSIS OFFICIAL

DATE:

FSIS FORM 8400-4 (05/20/2005) ALL PREVIOUS EDITIONS OF FSIS 8400-4 ARE OBSOLETE. PART A

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0583-0015. The time required to complete this information collection is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

REPORT OF RECALL EFFECTIVENESS:
PART B - Product Disposition Verification

1. NAME AND ADDRESS OF CONSIGNEE/CUSTOMER

2. RECALL CASE NO.

3. DATE OF VERIFICATION:

4. VERIFIED BY ?
- ☐ TELEPHONE
- ☐ ON-SITE *(obtain records to support)*

5. WAS PRODUCT DETAINED?
- ☐ NO
- ☐ YES

If yes, give date of action and the amount)

6. AMOUNT OF PRODUCT IDENTIFIED DURING PRODUCT DISPOSITION CHECKS:

7. PRODUCT DISPOSITION *(Check appropriate disposition, and give a description)*
- ☐ Product on Voluntary hold
- ☐ Returned to recalling firm*(When)?*
- ☐ Other *(specify):* _____
- ☐ Denatured, decharacterized, destroyed *(Did you observe?)*
- ☐ Cooked

Description:

8. IS FOLLOW-UP NEEDED?
- ☐ NO ☐ YES

Explain:

9. REMARKS:

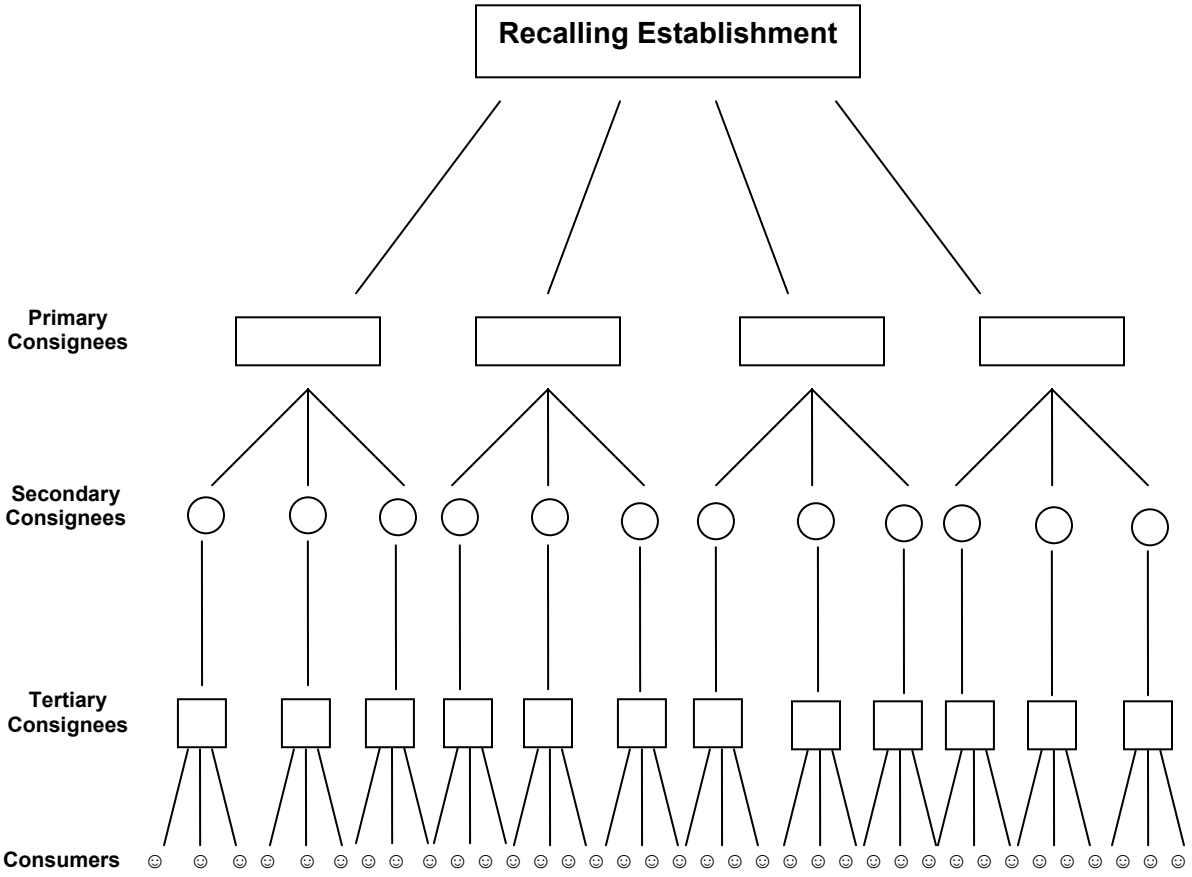
SIGNATURE OF FSIS OFFICIAL

DATE:

FSIS FORM 8400-4 (05/20/2005) PART B

Appendix 1

Levels of Distribution in Commerce



Primary Consignees – Wholesale Level
Examples: Distribution centers, wholesalers

Secondary Consignees – HRI Level
Examples: Intermediate wholesalers, HRI

Tertiary Consignees – Retail level
Examples: Retail markets, HRI

Note: This is an example only. Product flow in commerce can have many different variations. One or more of these levels may not apply in some recalls.

Appendix 2

RECALL WORKSHEET- FOR INTERNAL FSIS USE ONLY

(Include attachments, additional pages, label copies and flowcharts as necessary)

TODAYS DATE:_____

ESTABLISHMENT NUMBERS: EST._____P-_____

ESTABLISHMENT NAME:_____

ADDRESS:_____

COMPANY RECALL COORDINATOR (name, title, telephone)_____

_____

COMPANY MEDIA CONTACT (name, title, telephone)_____

_____

COMPANY CONSUMER CONTACT (name, title, telephone)_____

_____

REASON FOR RECALL:_____

IDENTIFY RECALLED PRODUCTS SEPARATELY BY:

BRAND NAME			
PRODUCT NAME			
PACKAGE (Type & Size)			
PACKAGE CODE (Use By/Sell By)			
PACKAGING DATE			
CASE CODE (Identifying)			
COUNT/CASE			
PRODUCTION DATE			
AMOUNT (lbs./cases) PRODUCED			
AMOUNT HELD AT ESTABLISHMENT			
AMOUNT (lbs./cases) DISTRIBUTED			
DISTRIBUTION LEVEL (institutional/retail/etc)			
DISTRIBUTION AREA			
EXPORTED TO (country)			
SCHOOL LUNCH (CN, AMS Contract)	(YES) (NO)	(YES) (NO)	(YES) (NO)
DEPT. OF DEFENSE (DSCP, Commissary, etc.)	(YES) (NO)	(YES) (NO)	(YES) (NO)
INTERNET OR CATALOG SALES	(YES) (NO)	(YES) (NO)	(YES) (NO)

THE FOLLOWING TO BE COMPLETED BY FSIS HEADQUARTERS STAFF:

CASE NUMBER:_____ DATE INITIATED:_____ CLASS:_____ DEPTH:_____ DO Rep.:_____

RECALL WORKSHEET -FOR INTERNAL FSIS USE ONLY

(*Listeria monocytogenes* ATTACHMENT)

(READY-TO-EAT PRODUCT)

DESCRIBE THE PRODUCTION/PROCESSING OPERATION AND/OR ATTACH A PROCESS FLOW DIAGRAM: _____

_____

_____

_____

_____

WHAT WERE THE "CLEAN-UP TO CLEAN-UP" TIMES? _____

WAS CARRYOVER PRODUCT FROM PREVIOUS PRODUCTION PACKED WITH THIS PACKAGING CODE? (YES) (NO)

WAS THERE A COMPLETE LINE CLEANUP AFTER THE CARRYOVER WAS RUN? (YES) (NO)

WHAT DATE WAS THE CARRYOVER PRODUCT CARRIED OVER FROM? _____

WERE THERE ANY PROCESS DEVIATIONS DURING THE PRODUCTION OF THE CARRYOVER PRODUCT? (YES) (NO)

EXPLAIN: _____

WHAT WAS/WERE THE CORRECTIVE ACTION(S)? _____

_____

WERE OTHER PRODUCTS PRODUCED ON THE SAME LINE OR USING SOME OF THE SAME EQUIPMENT DURING THE "CLEAN-UP TO CLEAN-UP" PERIOD? (YES) (NO) EXPLAIN: _____

_____

WHAT INTERNAL COOK TEMPERATURE WAS REACHED? _____

DID THE PRODUCT REACH ANY SPECIFIED Aw OR pH REQUIREMENT? (YES) (NO) SPECIFY: _____

DOES THE FIRM HAVE AN IN-PLANT ENVIRONMENTAL MONITORING PROGRAM FOR *Listeria monocytogenes*? (YES) (NO)

WAS THE SOURCE OF THE CONTAMINATION IDENTIFIED? (YES) (NO)

EXPLAIN: _____

_____

IS THERE DATA THAT COULD LIMIT THE AMOUNT OF PRODUCT AFFECTED? (YES) (NO) EXPLAIN: _____

RECALL WORKSHEET- FOR INTERNAL FSIS USE ONLY

(*E. coli* O157:H7 ATTACHMENT)

DESCRIBE THE PRODUCTION/PROCESSING OPERATION AND/OR ATTACH A PROCESS FLOW DIAGRAM: _____

_____

_____

_____

DOES THE ESTABLISHMENT CONDUCT DAILY *E. coli* O157:H7 TESTING? (YES) (NO) WHAT FREQUENCY?

WHAT WERE THE "CLEAN-UP TO CLEAN-UP" TIMES? _____

WHAT WAS/WERE THE SOURCE(S) OF THE MATERIALS YOU PROCESSED? _____

_____

POUNDS OF PRODUCT PRODUCED "CLEAN-UP TO CLEAN-UP": _____

WAS REWORK OR CARRYOVER FROM THIS PRODUCT USED IN FUTURE PRODUCTION? (YES) (NO)

ON WHAT DATES WERE THE REWORK OR CARRYOVER USED AND WAS THERE ANY REWORK OR CARRYOVER FROM THAT DAYS PRODUCTION USED IN FUTURE PRODUCTION?

_____

_____

_____

WERE THERE ANY PROCESS DEVIATIONS DURING THE PRODUCTION OF THE REWORK/CARRYOVER? (YES) (NO)

WHAT WAS/WERE THE CORRECTIVE ACTION(S)? _____

_____

WERE OTHER PRODUCTS PRODUCED ON THE SAME LINE OR USING SOME OF THE SAME EQUIPMENT DURING THE "CLEAN-UP TO CLEAN-UP" PERIOD? (YES) (NO) EXPLAIN: _____

_____

WERE OTHER PRODUCTS PRODUCED FROM THE SAME MATERIALS? (YES) (NO) EXPLAIN: _____

_____

WAS ANY MICROBIOLOGICAL TESTING PREFORMED BY THE COMPANY? (YES) (NO) EXPLAIN, INCLUDE RESULTS: _____

_____

IS THERE DATA THAT COULD LIMIT THE AMOUNT OF PRODUCT AFFECTED? (YES) (NO) EXPLAIN: _____

_____

RECALL WORKSHEET -FOR INTERNAL FSIS USE ONLY

(*Salmonella sp.* ATTACHMENT)

(READY-TO-EAT PRODUCT)

DESCRIBE THE PRODUCTION/PROCESSING OPERATION AND/OR ATTACH A PROCESS FLOW DIAGRAM:_____

_____

_____

_____

WHAT WERE THE "CLEAN-UP TO CLEAN-UP" TIMES?_____

WAS CARRYOVER PRODUCT FROM PREVIOUS PRODUCTION PACKED WITH THIS CODE? (YES) (NO)

WAS THERE A LINE CLEANUP AFTER THE CARRYOVER WAS RUN? (YES) (NO)

WHAT DATE WAS THE CARRYOVER PRODUCT CARRIED OVER FROM?_____

WERE THERE ANY PROCESS DEVIATIONS DURING THE PRODUCTION OF THE CARRYOVER PRODUCT? (YES) (NO)

EXPLAIN:_____

_____

WHAT WAS/WERE THE CORRECTIVE ACTION(S)?_____

_____

WERE OTHER PRODUCTS PRODUCED ON THE SAME LINE OR USING SOME OF THE SAME EQUIPMENT DURING THE "CLEAN-UP TO CLEAN-UP" PERIOD? (YES) (NO) EXPLAIN:_____

_____

WHAT INTERNAL COOK TEMPERATURE WAS REACHED?_____

DID THE PRODUCT REACH ANY SPECIFIED Aw OR pH REQUIREMENT? (YES) (NO) SPECIFY:_____

_____

DOES THE ESTABLISHMENT HAVE POST-PROCESSING CONTROLS? (YES) (NO) SPECIFY (include records):_____

_____

WAS ANY MICROBIOLOGICAL TESTING PERFORMED BY THE COMPANY? (YES) (NO) EXPLAIN, INCLUDE RESULTS:_____

_____

IS THERE DATA THAT COULD LIMIT THE AMOUNT OF PRODUCT AFFECTED? (YES) (NO) EXPLAIN:_____

_____

United States Department of Agriculture **Food Safety And Inspection** **Office of Field Operations** **District Office Address**

Date

To: Director
Recall Management Staff
Washington, DC

From: Name
Deputy District Manager
District

Re: Final Recall Effectiveness Report: **Recall Number**

Enclosed is the Final Recall Report for the subject recall.

1. **Recalling Establishment Number:** xxxxx M/P

2. **Recalling Firm:**
   Name
   Address
   City, State, Zip Code

3. **Product Description(s):**

4. **Quantity of Recalled Product Distributed (amount recorded on RNR-if expansion, give original amount plus amount from expansion for the total-the amount on the RNR from the expansion is usually the combined total):** Pounds

5. **Date Effectiveness Checks Began:**

6. **States where products were found to be distributed: list**

7. **List of MOU States where product was distributed**

8. **MOU States that conducted recall effectiveness checks:**
9. **Amount of Product on Hand (identified during Effectiveness and product disposition checks):** Pounds

10. **Total Number of Consignees:** all firms that received product.

11. **Table used to Determine Number of Effectiveness Checks:**

12. **Total Number of Effectiveness Checks Conducted:**
    a.) Telephone (how many**)** **b.) Onsite (**how many**)**

13. **Number of DRO Randomly Identified Consignees visited or contacted**

14. **Number of DRO Randomly Identified Consignees not visited or unable to contact (e.g., temporarily closed, out of business, etc)**

15. **Number of other (biased) Consignees visited or contacted. Explain (e.g., non-randomly selected distribution site)**

16. **Total Number of Effectiveness Checks With Identified Problems:** List the number of effectiveness checks that were ineffective and why. For example, non-receipt of notice, firms not issuing prompt notification, did not act in accordance with the notification, problem with destruction or other disposition. Specifically describe whether recalled products still offered for purchase or consumption. State if any identified problems were directly related to the recalling firm.

17. **Number of Product Disposition Verification Checks Conducted: a.) Telephone (**how many**) b.) On site (**how many**)**

    What was done with the product? Be as specific as possible to include pounds verified. Include (a) Number of locations where FSIS (or state) directly verified product destruction, denaturing, or decharacterization. (b) Number of locations where FSIS (or state) verified records of product destruction, denaturing, or decharacterization. (c) Number of locations where FSIS (or state) verified records of product returns to recalling establishment or firm handling product returns. (d) FSIS verification of final product disposition for all product returns to recalling firm or firm handling product returns.

18. **Enforcement Actions:** List all enforcement actions taken by FSIS (or state program), for example detentions, retentions, prohibited activity.

19. **Final Recall Effectiveness Check or Product Disposition Verification Completed On [Date]: [Note to DRO: if there is a protracted delay in performing the final product disposition verification check, please describe e.g. the establishment doesn't want to destroy product right away for legal reasons]**

Conclusion:

Following an evaluation of the entire record related to this recall, we have found this recall to be [effective/ineffective] because the number of locations where recalled product was still offered for sale [did not/did] exceed the critical number in Table [insert] of FSIS Directive 8080.1, rev 4. [Insert if ineffective – However, the actions taken in item 18 above mitigated, to the extent possible, the risk to the public health and welfare at these locations.] This office is maintaining the complete record of the recall effectiveness checks and any associated Administrative Enforcement Reports.

United States Department of Agriculture | **Food Safety And Inspection** | **Office of Field Operations** | **District Office Address**

[DATE]

To: Deputy District Managers
Office of Field Operations
USDA-FSIS

From: Name
Deputy District Manager/District Recall Officer
District Office

Subject: Request for Assistance in Conducting Recall Effectiveness and Product Disposition Verification Checks for Recall
(Enter recall #, Establishment #, and name).

High Priority (include if Class I or II only)

Insert recall information summary from Recall Notification Report (RNR) on web page (Recall class, reason for recall).

Please provide assistance in conducting recall effectiveness checks at consignees in your district. The consignees that received and subsequently distributed or sold products covered by this recall are located in the following states: (list the states [Note to DRO: state list may vary from the initial distribution request list]). In accordance with FSIS Directive 8080.1, Revision 4, we will be conducting recall effectiveness checks using Table (enter applicable Table #) from Attachment 3.

Please promptly review the attached file for firms located in your district. The highlighted locations are ones that we have randomly selected and where recall effectiveness checks must be conducted. If any firms (highlighted or non-highlighted) are distribution centers, please gather the distribution information from each location. Please promptly forward back to the DRO distribution information from any distribution centers in the attached file as soon as possible. Key pieces of information include:

- Name of Consignee or Distribution Center
- Address or Location
- City and State
- Cases or pounds of product distributed or received
- Contact person and phone number.

If we receive additional distribution information, this office will notify your District of any locations where additional random effectiveness checks must be conducted. Unless specifically identified in the attached list as a location to conduct product disposition verification, you will receive a final request for verification of actual product disposition at randomly identified locations in your district.

It is essential that all Districts involved in this recall maintain a constant level of communication with our Office as we coordinate the recall activities and complete the recall effectiveness process.

Once all effectiveness and product disposition checks have been completed in your District, please promptly provide our District Office with a final summary report. Inclusion of FSIS Form 8400-4, along with copies of any Administrative Enforcement Reports (AER) generated in response to the recall effectiveness checks, should be provided with this summary report. Original copies of AER's or notices of detention should remain at the originating district. If you have any questions or concerns, please contact (enter DRO/designee name and telephone number).

Thank you!

cc: EARO for the recalling district
District Managers of affected states

United States Department of Agriculture | **Food Safety And Inspection** | **Office of Field Operations** | **District Office Address**

[DATE]

To: Deputy District Managers
Office of Field Operations
USDA-FSIS

From: Name
Deputy District Manager/District Recall Officer
District Office

Subject: Request for Assistance in Determining Product Distribution for Recall (Enter recall#, Establishment #, and name).

High Priority (include if Class I or II only)

Insert recall information summary from Recall Notification Report on web page (Recall class, reason for recall).

Please provide assistance in determining product distribution for consignees in your district. The initial consignees provided by the recalling firm are located in the following states: (list the states). [Note to DRO: if the initial distribution list from the recalling firm indicates only terminal distribution, then the DRO would proceed with the random selection of firms and request assistance from the assisting districts at those locations.]

Please promptly review the attached file for firms located in your district. For those firms that are distribution centers or that received and further distributed the recalled product to other firms, please gather the distribution information from each location. You may gather this distribution information using any method (i.e., either on-site or by telephone) that is sufficient to ensure accuracy of the information. You are not required to conduct effectiveness checks at this time. Please promptly forward back to the DRO distribution information from any consignees in the attached file. Key pieces of information include:

- Name of Consignee or Distribution Center
- Address or Location
- City and State
- Cases or pounds of product distributed or received
- Contact person and phone number.

Once we receive this distribution information, this office will subsequently notify your District of the locations where random effectiveness checks and product disposition verification must be conducted in accordance with FSIS Directive 8080.1, rev 4. As the recall proceeds and further distribution information is received, you may therefore

receive an additional request for assistance with effectiveness checks. As the distribution list is completed, you may receive a final request for verification of actual product disposition at randomly identified locations.

It is essential that all Districts involved in this recall maintain a constant level of communication with our Office as we coordinate the recall activities and complete the recall effectiveness process. If you have any questions or concerns, please contact (enter DRO/designee name and telephone number).

Thank you!

cc: EARO for the recalling district
District Managers of affected states

Appendix 6 FSIS Directive 8080.1 Rev. 4, Attachment 3

EFFECTIVENESS CHECKS

I. INTRODUCTION

A. Effectiveness checks constitute a process by which FSIS program personnel verify that the recalling firm has been diligent and successful in notifying and advising the consignees of the need to retrieve and control recalled product and that the consignees have responded accordingly. Subsequent consignees are then expected to notify their consignees or customers of the recall. FSIS will conduct effectiveness checks throughout the distribution chain.

B. FSIS will verify that**:**

i. Adequate notice about the recall has been provided to all consignees by the firm conducting the recall; and

ii. Consignees have located and are controlling products and are following the recalling firm's instructions.

Note: If the firm's recall strategy includes destroying product on site, the District Recall Officer (DRO) must be notified. The DRO may assign FSIS inspection program personnel to witness destruction of the product in accordance with 9 CFR 329 and 381 Subpart U.

C. Roles and Responsibilities:

i. *Industry* - The recalling firm has the responsibility for conducting the recall and for ensuring that its actions have been effective in removing the product from the marketplace.

ii. *FSIS* - FSIS verifies the effectiveness of the recalling firm in conducting its recall. Using a statistical sampling plan, FSIS identifies a sample of consignees to verify the effectiveness of the recall. If FSIS determines that the recalling firm has not been successful in conducting an effective recall, it will take appropriate actions to ensure the health and welfare of the consumer. A DRO is assigned to coordinate effectiveness checks. A Deputy District Manager (DDM) in the district that covers the recalling plant serves as the DRO. The DRO will coordinate recall activities and will be the primary point of contact with the recalling firm. The DRO will prepare the sampling plan and direct the activities of inspection program personnel. Inspection program personnel will assist the DRO in identifying consignees, selecting consignees in accordance with the sampling plan, conducting effectiveness checks, and taking appropriate corrective actions.

iii. *States* - Under 9 CFR 390.9, FSIS may have Memoranda of Understanding (MOU) with one or more states. The specifics of the MOU will vary from State to State. In general, when states and FSIS have MOUs regarding effectiveness checks, the agencies will collaborate in sharing resources and information whenever possible. FSIS will work with states to ensure that effectiveness checks are conducted in a manner consistent with FSIS procedures. FSIS will conduct effectiveness checks based on the number of consignees outside the states with an MOU.

D. Effectiveness checks:

i. Are risk based and dependent on the class of the recall (the hazard and any associated illnesses) and the number of consignees (the exposure). FSIS inspection program personnel will make a statistically-based number of effectiveness checks to verify that the firm is locating, retrieving, and controlling the product, and that product that is recalled does not remain available to consumers. The checks will verify that the firm is handling the product in accordance with regulatory requirements and instructions provided by the recalling firm including those for product destruction or return.

ii. Are performed by on-site verification and by phone. FSIS inspection program personnel will visit the consignees of the firm conducting the recall to verify that they have received appropriate notification of the recall and that they are acting on the basis of that notification. Recall effectiveness checks will be conducted based on resource considerations and knowledge of the recalling firm’s and consignee’s practices.

iii. May disclose that product remains available to consumers and in commerce. FSIS inspection program personnel will immediately notify the DDM in their district for further instructions and may detain product.

II. VERIFICATION PROCESS

A. The number of effectiveness checks inspection program personnel will conduct will be determined according to risk. Risk is characterized by the class of the recall and the exposure of the product to consumers.

i. Determine the class of recall. The class of recall is assigned by the FSIS recall committee based on the hazard the product presents. The discussion of assigning recall classes is presented in FSIS Directive 8080.1 Revision 4.

ii. Determine the exposure based on number of consignees.

a. Upon notice of a recall, the DRO will immediately request information and records in accordance with 9 CFR 320.1 of the recalling firm and subsequent consignees regarding the distribution of recalled product. The information should contain

sufficient details to allow FSIS personnel to understand the distribution patterns and make contacts without further delay.

b. The DRO should sort the information according to geographical regions and by type of consignees. The type of consignee may include retailers, hospitals, chains, independent retailers, restaurants, and food service institutions, as well as distributors. The DRO will coordinate inspection personnel to contact these consignees without further delay.

c. The DRO should attempt to determine the distribution information regarding the recalled product within the timeframe recommended in Table 1.

Table 1 - Recommended timeframes for initiating and reporting verification activities within FSIS

Recall classification	**Following the initiation of a recall, FSIS verification activities should begin as soon as possible within a period of:**	**Following their initiation, FSIS verification activities should be substantially completed within a period of:**
Class I	3 days*	10 days
Class II	5 days	12 days
Class III	10 days	17 days

**W*orking* days: Working days may include Saturday and Sunday, depending upon the risk associated with a recalled product.

iii. The DRO should, in discussion with the recalling firm and as needed (if some of the consignees are distributors) through other FSIS offices, determine the best estimate of the number of consignees (who received the recalled product or who will be notified of the recall).

Example: *If the recalling firm has 50 retailers and 5 distributors and the 5 distributors in turn have 400, 200, 300, 100 and 150 retailers, the best estimate of the number of consignees is 1200. The effectiveness checks are done based on 1200 consignees.*

iv. The best estimate is not the “customer” list of a recalling firm. It is rather the estimate of consignees, (e.g., retailers, restaurants and food service institutions), which would have received the recalled product. In order to expedite the verification process, the recalling firm should be able to provide their best estimate to FSIS by phone or E-mail before sending more detailed distribution information. However, care must be taken that the estimate would not significantly differ from the actual distribution information.

v. Where there is concern that the distribution information is not accurate or complete, (i.e., a generic list of chain stores is missing a few known stores), where

necessary, the DRO will prepare a list identifying other potential consignees and/or distributors who may carry the recalled products, but were not included in the distribution information given by the firm.

vi. If States have an MOU with FSIS to conduct their own effectiveness checks, then the number of consignees is based on those consignees outside the states with an MOU.

***Example**: The recalling firm provides information on 1200 consignees who received the product, but 600 of these consignees are in two states that have an MOU with FSIS. The effectiveness checks will be done from the 600 consignees **not** in the two states with an MOU.*

B. Determine the total number of effectiveness checks to be conducted

i. The number of effectiveness checks is based on the risk determined in 2A and is taken from values given in the sampling tables in this document.

ii. FSIS encourages firms to have a recall plan (See Attachment 1). The number of effectiveness checks shown in each table may be increased if the recalling firm does not have a recall plan.

a. Table 2 is used to determine the number of checks for all Class I recalls when there has been an illness or outbreak, or school lunch implications.

Table 2 - **Effectiveness checks to conduct and critical limits for *all* Class I recalls involving an illness or outbreak based on epidemiological evidence or with school lunch implications.**

Number of Consignees	Number of Effectiveness Checks to Make	Recall Considered Ineffective If the Number of Consignees That Were Not Notified Exceeds:
1 to 200	100%	0
201 to 10,000	200	0
10,001 to 35,000	800	1
35,001 to 500,000	800	1
500,001 and over	1,250	2

b. Table 3 is used to determine the number of checks for Class I recalls when there are **no** illnesses, outbreaks, or school lunch implications.

Table 3 - Effectiveness checks to conduct and critical limits for Class I recalls when there are no illnesses, outbreaks, or school lunch implications.

Number of Consignees	Number of Effectiveness Checks to Make	Recall Considered Ineffective If the Number of Consignees That Were Not Notified Exceeds:
1 to 20	100%	0
21 to 150	20	0
151 to 1,200	80	1
1,201 to 2,300	125	2
2,301 to 10,000	200	3
10,001 to 35,000	315	5
35,001 to 150,000	500	8
150,001 to 500,000	800	12
500,001 and over	1250	18

c. Table 4 and Table 5 are used for Class II and Class III recalls, respectively.

Table 4 - Effectiveness checks to conduct and critical limits for Class II recalls or (optionally) for Class III recalls when a firm does not have a Recall Plan.

Number of Consignees	Number of Effectiveness Checks to Make	Recall Considered Ineffective If the Number of Consignees That Were Not Notified Exceeds:
1 to 5	100%	0
6 to 25	5	0
26 to 150	20	1
151 to 280	32	2
281 to 500	50	3
501 to 1,200	80	5
1,201 to 2,300	125	8
2,301 to 10,000	200	12
10,001 and over	315	18

Table 5 - Effectiveness checks to conduct and critical limits for Class III recalls.

Number of Consignees	Number of Effectiveness Checks to Make	Recall Considered Ineffective If the Number of Consignees That Were Not Notified Exceeds:
1 to 8	100%	1
9 to 50	8	1
51 to 90	13	2
91 to 150	20	3
151 to 280	32	5
281 to 500	50	8
501 to 1,200	80	12
1,201 and over	125	18

iii. In special circumstances, to ensure protection of public health, FSIS retains the option to conduct effectiveness checks on a 100% basis. Such as when there is epidemiological evidence that indicates the product may have been implicated in human illnesses.

C. Determine the number of disposition verification checks to be conducted

The purpose of disposition verification checks is to verify the disposition of the recalled product. This is documented on FSIS Form 8400-4.

i. A subset of the total number of effectiveness checks will be selected for on-site visits to verify that consignees have retrieved and controlled recalled product according to the recall notification. All firms with the recalled products are expected to remove that product from commerce.

a. For a Class I recall involving illness, outbreaks, or school lunch implications the DRO will consult with RMS on the number of on-site verification.

b. For recalls other than Class I, the same tables used to determine the total number of recall effectiveness checks will be used to determine the number of effectiveness checks that will be conducted on-site.

Example: *If the number of consignees is estimated to be 600 for a Class II recall, Table 4 shows the total number of effectiveness checks to conduct is 80. Using the same table, this time inserting 80, 20 of those 80 effectiveness checks will be conducted onsite. This is shown in the figure below.*

Table 4. Effectiveness checks to conduct and critical limits for Class II recalls or (optionally) for Class III recalls when a firm does not have a recall plan.

Number of Consignees	Number of Effectiveness Checks to Make	Recall Considered Ineffective If the Number of Consignees That Were Not Notified Exceeds:
1 to 5	100%	0
6 to 25	5	0
26 to 150	20	1
151 to 280	32	2
281 to 500	50	3
501 to 1200	80	5
1201 to 2300	125	8
2301 to 10,000	200	12
10,001 to and over	315	18

Number of on-site disposition verifications

Total number of effectiveness checks

D. Conduct the effectiveness checks within established time frames

i. If the recall spans across multiple districts the DRO that has the jurisdiction over the recalling firm will coordinate activities, in consultation with the appropriate Executive Associate for Regulatory Operations, across the districts. Each of the districts should consider the recall verification activities for public health related recalls to be a high priority. Table 1 describes the recommended timeframes for the initiation of verification activities and for the substantial completion of these activities. However when situations arise that may delay the verification or reporting activities or affect the timeframes presented in this table, it is the responsibility of each district to notify the DRO. The time standards presented in Table 1 are for FSIS verification activities. Recall activities by firms should start immediately upon deciding to do a recall or upon receiving notification of a recall. During this time, the DRO will also have an oversight function to assess whether the recalling firm has in fact initiated the recall activities.

ii. The DRO prepares a sampling plan in consultation with other Districts based on the percentage of distribution.

a. Using the appropriate table, determine the sampling rate.

E*xample*, *for a Class II recall and 600 consignees, the appropriate table is Table 4 and the number of effectiveness checks to conduct is 80.*

b. Alternatively, FSIS may decide to group effectiveness checks by special categories, (e.g., schools, day care centers, hospital cafeterias, and retirement homes). If FSIS decides to separate groups by special categories, then each group of consignees is considered separately and the tables are used to determine the number of effectiveness checks to be conducted for each group.

*If the **example** of 600 consignees represents 3 groups of 200 each, Table 4 shows that each group would have 32 effectiveness checks conducted. Thus, the total sampling number of effectiveness checks for all three groups would be 96.*

c. Grouping consignees into separate categories should always result in an increase in the number of effectiveness checks to be conducted.

d. Determine a sampling interval by dividing the total number of actual or estimated consignees.

*In this **example** divide 600 by the minimum sample size (example 80). In this example, the sampling interval would be 7 (600/80 = 7.5 rounded to the lower whole number)*.

e. Randomly select a number from 1 to the sampling interval to determine the starting point.

*For this **example**, select number 3*.

f. Provide the sampling plan to inspection program personnel. The plan should contain the sampling interval and the random starting point, the recommended timeframes for completion, the related recall number and any other details which may help conduct the verification activities more effectively. Also, attached to the plan should be copies of the lists, product/carton labels, notice of recall, and copies of corrected labels and the news release (if applicable).

iii. Inspection program personnel conduct the effectiveness checks.

a. Using the predetermined sampling interval and the random starting point, select the consignees for verification.

b. List consignees in any order; count from the top until reaching the starting point. Then choose consignees according to the predetermined sampling interval.

*In the **example** above select the 3rd consignee. Then select the 10th, 17th, 24th ... and so on until enough consignees are identified for the effectiveness checks.*

c. Ensure that copies of the recalling firm letter to its consignees informing them of the recalling action, Recall Notification Report (RNR), and as applicable, copies of the

news release and labels are on hand when conducting verification activities; these documents can then be referenced or left with consignees if required.

d. Conduct checks to determine if consignees have received the recalling firm notification of the recall action and have taken the prescribed action regarding product such as returning it to the recalling firm, or identifying and holding it for pick-up. Conduct checks by on-site visits or phone based on resources and knowledge of the recalling firm and consignee practices. Determine if any recalled product remains available to consumers.

e. Conduct checks to determine if the recalling firm or consignees have disposed of the recalled product according to the prescribed action. Conduct checks by on-site observation, records review, or phone, based on resources and knowledge of the recalling firm and consignees practices.

f. Request the consignee immediately follow the instructions if the recalled product is being held for sale or used against directions provided in the recalling firm notification of the recall action.

g. In cases where consignees were not notified of the recall, ensure that the appropriate associated firm including distributor, chain store head office, or individual store, are notified and take action if necessary to detain product that is recalled.

h. Continue with all the assigned checks.

i. Submit verification results including findings of product in commerce and consignees that were not properly notified by the recalling firm to the DRO via the fastest possible means (E-mail, fax, phone) as soon as possible.

E. “Findings of Product in Commerce” is defined as those occurrences where recalled product remains available to the consumer

i. When the DDMs are notified by inspection program personnel in their district of findings of product in commerce, he or she will immediately inform the DRO.

ii. Also, the DRO is to determine whether the findings follow a pattern or trend. During the evaluation, it is important to distinguish between isolated reasons (i.e., the product was removed in a store but was re-shelved by mistake), and widespread systemic reasons (i.e. breakdown in the notification process or delay caused by the schedule of sales personnel). This is important to do even if the recall itself is effective because there may be subgroups of consignees that have product available to consumers. As deemed appropriate and necessary, the DRO will notify the Director of Compliance and Investigation Division, OPEER or take other enforcement in accordance with the FMIA or PPIA.

F. DRO determines the effectiveness of the recall

i. The objectives of verification activities are to evaluate:

a. The overall effectiveness of the recall

1) For a recall to be deemed effective, the number of consignees found to have product in commerce must be equal to or less than the critical number in the sampling plan.

2) The DRO should review the results of the recalling firm's effectiveness checks to ensure completeness. This activity is likely to include a review of documentation such as confirmed recall notices, receipts of returned product, telephone call reports, and E-mail confirmations.

b. The recalling firm's process – When a firm's recalling strategy is not adequate to remove product from commerce that is recalled, FSIS will take the appropriate measures, including detaining product to protect consumers.

c. The actions taken by the consignees when advised of the recall – When consignees (e.g., retailers, restaurants, food service institutions, and wholesalers) along the distribution chain were properly advised of the recall but have not taken the requested action to remove product, FSIS may detain product or take other appropriate measures to ensure the product is not in commerce.

ii. Examples of Effective and Ineffective Recalls: The DRO makes the determination of whether a recall is effective or ineffective in consultation with RMS. Inspection personnel conducting checks would need to continue with all the assigned checks even though a recall may appear ineffective. Depending upon the actual sampling calculations, the final sample count would likely differ (generally be higher) from the count listed in tables. Therefore, caution should be used in the interpretation of the critical numbers. The recall activities should be classified as effective or ineffective, after considering both the number and the amount of product available in commerce.

iii. Using the **example** from II. C.ii.a of 600 consignees on a list for a Class II recall, with verification done at 80 randomly selected consignees, Table 4 shows the critical number to be 5.

a. All consignees checked have received the Notice of Recall from the recalling firm and have removed the product from sale.

Action: none, recall is effective.

b. Nine consignees checked have not received the Notice of Recall from the recalling firm, or its subsequent consignees, but were notified of the recall through the media. Six of the nine consignees have removed the product from sale. The remaining three consignees have identified and segregated the product awaiting shipment to the recalling firm. No product is available to the consumer.

1) Action: recall is deemed ineffective. Nine consignees have not received a notice from the firm, exceeding the critical number.
2) Notify the DRO. (See section iv. of this part)

c. Inspection program personnel find that four consignees have not received the recall notice and are still offering the product for sale. Five more consignees received the notice but have not taken the requested product action. Therefore, the product remains available to the consumer at a total of 9 locations, exceeding the critical number.

1) Action: Recall is deemed ineffective.
2) Whenever recalled product is found in commerce during an on-site verification at a consignee (or sub-consignee), the EIAO will detain any of the products on hand.
3) The EIAO will ascertain whether the business received a recall notification and instructions from the recalling firm or one of its consignees.
4) The EIAO will notify the DRO of his/her findings at the business regarding the detained product, and whether or not adequate recall instructions were received.

a. If a recall notification and product instructions were not received, the DRO will proceed as discussed below in section iv.

b. If a recall notification was received, but the consignees did not respond appropriately to the instructions of the recalling firm, the consignee may have committed an act prohibited by the FMIA or PPIA. In such cases, the DRO will immediately notify the Compliance and Investigations Division, OPEER, and the OPEER Regional Office to investigate and for follow-up legal actions in accordance with the Acts.

5) The DRO will also notify any state or local food or health authority with jurisdiction over the business involved for its appropriate follow-up action in conjunction with the FSIS, OPEER.

iv. Responding to an ineffective recall

a. If at any time during the verification of the recall, the DRO determines that the recall effort is ineffective, the DRO will notify the Director of RMS.

b. The DRO will write a letter to the recalling firm detailing the reasons why the recall has been found to be ineffective. The DRO should ask whether the recalling firm intends to act to address the situation.

c. If, after having been formally notified by FSIS of the ineffectiveness of its recall, the recalling firm is unwilling or unable to extend or modify its recall strategy, FSIS will act to mitigate the risk to the public including issuing public warnings, product seizures, or other appropriate legal or compliance actions in accordance with the FMIA and PPIA.

G. Verification result summaries

i. The DRO will prepare a summary of recall activities and provide it to the RMS.

The focus of the summary should be to:

a. Declare the amount of product recovered, relative to the amount of product recalled, both in absolute (pounds) and relative (%) terms.

b. State, in specific terms, how the defect in the product was corrected or how the product was disposed of.

c. State the total number of effectiveness checks and disposition verification checks performed and the numbers conducted both on-site and by telephone.

d. Assign an overall effectiveness rating to the recalling firm's recall activities (effective or ineffective).

e. Determine how many consignees may still have product on sale.

f. Identify reasons for continued sale.

g. Identify other deficiencies in the firms recall process (if applicable).

h. Summarize actions taken by FSIS in the case.

ii. The summary should include a description of the corrective actions taken to correct each identified deficiency, i.e. the product removed and segregated in shipping area, re-notification was issued for all convenience stores including names of affected distributors, as applicable. The DRO will send the memo to the Director of the Recall Management Staff.