UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE	8080.1, Revision 4	5/24/04

RECALL OF MEAT AND POULTRY PRODUCTS

I. PURPOSE

This directive provides the terminology, responsibilities, and public notification procedures regarding the voluntary recall of FSIS-inspected meat and poultry products.

II. CANCELLATION

FSIS Directive 8080.1, Rev. 3, dated 1/19/00
FSIS, DEO Manual and Training Guidelines, November 1997

III. REASON FOR REISSUANCE

This revision accounts for the 2002 FSIS reorganization and provides updated instructions regarding recall procedures. This directive is reissued in its entirety.

IV. REFERENCES

The Federal Meat Inspection Act and the Poultry Products Inspection Act

V. BACKGROUND

A recall is a firm's voluntary removal of product from trade or consumer channels (e.g., by manufacturers, distributors, or importers) to protect the public from consuming adulterated or misbranded products. A recall may be an alternative to an FSIS detention or seizure of adulterated or misbranded products. Although recalls are voluntary, FSIS verifies all recall activities by official meat and poultry establishments and coordinates any FSIS actions with the recall taken by the firm. For recalls conducted by state-inspected firms or retail establishments, the appropriate state agency verifies the recall in most cases. FSIS will provide the state agencies with any needed assistance and information.

B. The Agency may become aware of misbranded or adulterated product in commerce in several ways. FSIS may be alerted to a potential recall situation by:

1. The company that manufactures or distributes the product,

2. Test results from FSIS sampling programs,

3. Observations or information gathered by FSIS inspection program personnel in the course of their routine duties,

4. Consumer complaints; or

5. Epidemiological or laboratory data submitted by state or local public health departments, other USDA agencies, and other Federal agencies such as the Food and Drug Administration (FDA), Centers for Disease Control and Prevention, and the Department of Defense.

C. When firms recall product on their own initiative, FSIS expects firms to notify the Recall Management Staff (RMS), Office of Field Operations (OFO). However, if other FSIS program personnel in their District are contacted, those program employees should promptly contact RMS through supervisory channels.

VI. TERMINOLOGY

The following are common terms FSIS uses related to recalls:

A. Recall. A firm's voluntary removal of distributed meat or poultry products from commerce when there is reason to believe that such products are adulterated or misbranded under the provisions of the Federal Meat Inspection Act (FMIA) or the Poultry Products Inspection Act (PPIA). "Recall" does not include a market withdrawal or a stock recovery.

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

C. 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. For 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.

D. 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:

1. 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.

2. 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).

3. 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.

E. Depth of Recall. The level of product distribution to which the recall is to extend:

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

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

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

4. Wholesale level - 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.

F. 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). For example, in the absence of additional data, all products produced under a single HACCP plan between performance of complete cleaning and sanitation procedures (clean up to clean up), or all products including any reworked product added to subsequent days' production, may be included in a recall (See Attachment 1 section 2). The findings of epidemiological investigations that link certain lots of product with foodborne illnesses will also affect the scope of a recall.

G. 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.

H. Health Hazard Evaluation Board (HHEB). The Health Hazard Evaluation Board is the primary group in FSIS that reviews the public health significance of any human health hazard about which a regulatory decision needs to be made. If the risk to the public health presented by a given product appears to be unique or in some way

unusual, the Recall Committee may consult the FSIS, Office of Public Health Sciences (OPHS) HHEB. (See FSIS Directive 8091.1, 10/22/01)

I. Recall Committee. A committee of representatives from various FSIS offices and staffs assembled to respond to potential or real health hazard incidents reported to RMS. The primary members of the committee generally are the representatives from the following program areas:

1. Recall Management Staff (RMS),OFO - (chairperson) - calls a committee meeting and distributes information about the recall to committee members. Invites other program areas to assist as necessary.

2. District Recall Officer (DRO), District Office, OFO – clarifies and explains to the committee the information collected during the preliminary inquiry. A Deputy District Manager in the district of the firm will serve as the DRO. The DRO is the responsible official for coordinating field recall activities if a recall should be recommended.

3. Office of Policy, Program, and Employee Development (OPPED) - explains regulatory
codes and policies.

4. Congressional and Public Affairs (Media Relations), Office of Public Affairs, Education and Outreach - Gathers information and generates a press release if necessary. Ensures information contained in the press release is accurate.

NOTE: In addition, the committee may also consist of representatives from the following program areas, at RMS's request:

Human Health Sciences Division, Office of Public Health Sciences (OPHS)
Laboratory Sample Data Management Staff, OPHS
Zoonotic Diseases and Residues Surveillance Division, OPHS
Microbiology Division, OPHS
Labeling and Consumer Protection Staff, OPPED
Compliance and Investigation Division, Office of Program Evaluation, Enforcement and Review (OPEER)
Technical Service Center, OFO
Import-Export Programs Staff, Office of International Affairs (OIA)
Import Inspection Division, OIA
Other Federal or State agencies as appropriate (e.g., Food and Drug Administration (FDA), Food and Nutrition Service, Centers for Disease Control and Prevention (CDC), Office of the General Counsel, state departments of public health, etc.)

VII. PROCEDURE TO DETERMINE THE NEED FOR A RECALL

The following is the general procedure involved to determine the need for a recall. The potential problem can be identified by a firm, the Agency, or other sources outside of the Agency.

A. Preliminary Inquiry. As soon as FSIS learns that product that appears to be adulterated or misbranded may be in commerce, the DRO is assigned to direct the activities of inspection program personnel. The DRO will coordinate a preliminary inquiry to determine whether a recall is necessary.

1. The preliminary inquiry may include some or all of the following steps:

a. Collecting and verifying information about suspect product;

b. Documenting a chronology of events;

c. Contacting the company that manufactures or distributes the product for more information;

d. Discussions with FSIS field inspection and compliance personnel;

e. Interviewing any consumer who allegedly became ill or injured from eating suspect product;

f. Collecting and analyzing product samples; or

g. Contacting state and local health departments, and;

h. Analyzing any available epidemiological data.

2. To determine whether a recall is needed, the following information is necessary: Establishment Number, Name and Address; Company Recall Coordinator (name, title, telephone); Company Media Contact (name, title, telephone); Company Consumer Contact (name, title, telephone); Reason for recall; Brand name; Product name; Package (Type & Size); Package Code (Use by/Sell by); Packaging date; Case Code; Count/Case; Production Date; Amount Produced (lbs./cases); Amount held at establishment; Amount distributed (lbs/cases); distribution level (institutional/retail); Distribution area; Exported (country); School lunch (yes/no); Department of Defense(yes/no) and Internet or catalog sales (yes/no). The DRO will send the information to RMS, who will then forward the appropriate material to the recall committee.

B. Preliminary Recall Evaluation.

1. The Recall Committee will make a preliminary recall evaluation to determine whether a recall should be recommended. RMS will convene a Recall Committee as soon as possible after receiving any relevant information (a copy of the product label) collected during the preliminary inquiry. Firms are encouraged to submit product label information electronically whenever possible to minimize transcription errors if FSIS must issue a press release. Every effort should be made to ensure at least the four primary members of the Recall Committee are available to conduct the recall evaluation. The Committee will use "Factors That Are Considered by the FSIS Recall Committee in Evaluating the Public Health Significance of an Undeclared Allergen or Other Misbranding of a Meat and Poultry Product" (Attachment 2) as guidance when necessary while conducting a preliminary recall evaluation.

2. The Recall Committee will allow the firm to present information about the hazard or concern to clarify its position during the evaluation. It is expected that the firm will provide FSIS with its recall strategy, including how it intends to notify and instruct its consignees and to retrieve or dispose of the recalled product. The Recall Committee will inquire as to whether the firm has a written recall plan. The Committee should inquire about the content of the plan. The Committee will evaluate all information received and determine whether to recommend that a recall be conducted. The Committee will determine if the plant is voluntarily recalling the product.

3. Typically, there are precedents for determining the significance of the health hazard presented by an adulterated product and the classification of the hazard. The Recall Committee will be guided by these precedents in classifying recalls. However, if there are any questions, particularly with hazards that have not previously been encountered by the Agency, the HHEB will be convened to conduct an evaluation of the hazard. The results of the HHEB's deliberations will be submitted to the Assistant Administrator/OFO (AA/OFO) and RMS for consideration. The firm will be provided an opportunity to present to the HHEB any information that it would like for the HHEB to consider during its deliberation. The HHEB's evaluation will include consideration of at least the following factors:

a. the nature of the defect (i.e., what is the problem with the product and what hazards to health does the problem create),

b. the occurrence of any illnesses or injuries,

c. the likelihood that illnesses or injuries may result, and

d. the type of illnesses or injuries that may result.

4. The Recall Committee will seek the answers to the following questions to assist them in making a determination:

a. Does FSIS have reason to believe that the product in question is adulterated or misbranded?

b. Does any of the product in question remain in commerce and available to consumers? (All facts must be verified by a program employee before the recall committee can determine if product in commerce is not available to consumers.)

c. Is FSIS prepared to detain or move to seize the product in question?

5. If the answer to all of the above questions is "yes," a recall should be recommended. If the answer is "no" to any of the above questions, the committee should not recommend a recall. If the committee does not recommend a recall, RMS will document results of the preliminary inquiry and evaluation with a memo to the file. When a recall is recommended, RMS will submit a recall recommendation.

C. Recall Recommendation. When a recall is recommended by the Recall Committee, RMS will submit a recall recommendation in the form of a memo for approval by the AA/OFO.

1. The recommendation will contain:

a. whether the firm is voluntarily recalling the product

b. the reason for the recall, including why there is a reason to believe that the product is adulterated or misbranded;

c. the recall classification (i.e., Class I, Class II, or Class III);

d. the depth;

e. the scope;

f. the ability of distributors, consumers, or users of the product to identify it;

g. the estimated amount of product in distribution (amount of product that was distributed and is still within sell by/used by code at the time of the recall);

NOTE: The estimate of product in distribution is arrived at by the Recall Committee by taking into account the amount of product produced subject to the recall, and its sell by or use by dates or codes. In cases where the estimate of the amount of product in distribution is zero because all products involved is past its sell by or use by date at the time of the recall, this fact will be noted in the RNR and recall press release (See Section IX).

h. the area of distribution.

NOTE: Much of the above information is generally provided to the Recall Committee by the recalling firm through documents, or orally through telephone conference calls. The Recall Committee will allow the firm an opportunity to clarify any information it provided or to supply additional information that may be significant to a recall recommendation. Before deciding on a recommendation, RMS may request that FSIS inspection program personnel verify the information provided by the firm. The Agency strongly encourages firms to use electronic transfer of the information involved in the recall in order to facilitate the speed and accuracy of the information transfer.

If the AA/OFO approves the recall recommendation, RMS will contact the firm to make the formal request for a recall. RMS will follow-up by sending a letter to the firm confirming the evaluation of the hazard, scope of the recall, and the Agency's understanding of the firm's recall strategy. Congressional and Public Affairs (CPA) will also confirm the information for the press release if FSIS issues one. The DRO will begin to coordinate effectiveness checks (see Section X) and will be responsible for directing the activities of inspection program personnel.

VIII. ACTION BY FIRM

A. FSIS outlines in "Product Recall Guidelines for Firms" (Attachment 1) the actions it expects a firm to take to ensure that the maximum amount of product is recovered in the shortest amount of time. The guidance includes model letters that a firm may use to communicate with its consignees (including providing instructions for product retrieval and extending the recall to additional consignees), model press releases, and recordkeeping requirements.

B. In a case where a firm decides not to accept the Agency's recommendation and chooses not to conduct a recall, FSIS will detain any product that would have been subject to a recall that it finds in commerce. FSIS, CPA will issue a press release informing the public that product that appears to be adulterated or misbranded has been shipped by the responsible firm, and that the firm has refused to recall it.

IX. PUBLIC NOTIFICATION

A. Press Releases. RMS coordinates with the Congressional and Public Affairs Office to develop a press release.

1. Generally, FSIS will issue a press release for Class I or Class II recalls. FSIS generally will not issue a press release for Class III recalls. However, there may be some Class III recall situations, such as an egregious economic adulteration, where the Agency decides that there are overriding public welfare reasons that warrant issuing a press release. A press release is normally not necessary in cases where FSIS can verify that all products in question were removed from commerce and brought under the firm's control before FSIS requested a recall. However, RMS will develop and issue a

Recall Notification Report (RNR) based on the information provided by the firm (see section B of this part).

2. The press release will:

a. Clearly describe the product being recalled along with any identifying marks or codes, explain the reason for the recall, and describe the risk involved in consuming the product.

b. Provide instructions to the public on what to do with the product if people identify it and have it in their possession and the name and telephone number of a company contact for consumers to call with any questions.

c. Provide general information about the product's destination, for example, "The beef burritos were distributed to an airline caterer and restaurants in the States of….." or "Frankfurters were sold to grocery stores, delis, and convenience stores in the States of …."

d. When possible, and without slowing the public notification of the recall, provide an electronic picture of the product label that can be posted on the FSIS Website and linked to the press release and RNR in order to provide the public with a clear description of the product.

3. When there are extenuating circumstances involving foodborne illnesses and contaminated products, but no legal identification of the source, the Under Secretary for Food Safety and the FSIS Administrator may decide to issue an immediate special "educational" press release. For example, if a foodborne illness outbreak is identified, and a common source is suspected but not confirmed, FSIS may issue an educational press release that provides guidance to consumers and health professionals about the risks of illness associated with the identified pathogen and symptoms.

4. When a recall is conducted by a retail store and is overseen by a state, FSIS will issue press releases announcing intrastate recalls and provide the appropriate factual information, including identification of the State that is verifying the recall.

5. When informed by a foreign government's food inspection agency that it is overseeing a recall, and some of the product may have been distributed in the United States, FSIS will issue a press release announcing the recall to U.S. consumers. The press release will be issued in accordance with current FSIS policy regarding press releases. The press release will provide the appropriate factual information to consumers. This procedure will be followed in cases where FSIS does not have first-hand information that the product is adulterated or misbranded.

B. Recall Notification Report. RMS will notify the appropriate Federal, State, and local public health and food inspection agencies of a product recall by distributing a RNR whenever a recall is necessary.

1. A RNR will be issued for every class of recall, even if FSIS does not issue a press release. RNRs will be posted on the FSIS Recall website.

2. RNRs provide consumers, industry, and the public health community with information related to the product in question. Along with the date and recall case number, RNRs should include the following:

a. The specific products recalled, along with any identifying codes or marks on the packages;

b. The name of the recalling firm, a contact at the firm, and the contact's phone number;

c. The quantity of product recalled;

d. The problem with the product or the reason for the recall and how/when it was discovered;

e. The areas in which the product has been distributed;

f. The classification of the recall and depth or level of the recall;

g. A link to the FSIS press release, if one has been issued;

h. Other agencies involved; and

i. A list of FSIS contacts with phone numbers.

C. FSIS will provide a draft copy of the press release or the RNR, in cases where no press release is issued, by fax to the recalling firm 30 minutes prior to its release. The firm will be provided with this opportunity to review the release or the RNR for accuracy of the telephone numbers, contact names, code numbers, etc. If the firm does not respond within 30 minutes, FSIS will proceed with the planned release. If typographical or other inadvertent errors are noted by the firm, FSIS will correct them before releasing the documents.

X. EFFECTIVENESS CHECKS

A. Effectiveness checks constitute a process by which FSIS inspection 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. Effectiveness checks are risk-based and dependent on the class of the recall (which is based on the hazard and any available epidemiological data) as well as the number of consignees.

B. The recalling firm is responsible for developing and implementing an effective recall strategy used to notify all consignees and successfully removing recalled product from commerce. FSIS will verify that the recall action is being conducted in an effective manner. The DRO is responsible for coordinating the recall activities. If FSIS determines that a firm has not adequately implemented an effective recall strategy, FSIS will take appropriate actions to ensure the health and welfare of the consumer.

C. The DRO will serve as the primary point of contact for the firm conducting the recall. To conduct these checks, the DRO will immediately request upon notice of a recall that the recalling firm provide information regarding product distribution including the names, addresses and phone numbers of its consignees (Attachment 3). The DRO should also review any notice of recall issued by the firm for accuracy of product information, risk and clarity (e.g., no promotional or company information that may obscure the risk).

D. The DRO will coordinate effectiveness checks and direct the activities of inspection program personnel. The DRO will also coordinate with Deputy District Managers in other districts affected by the recall. A sample of consignees will be selected by the DRO based on product distribution information using a statistical sampling plan (Attachment 3). In cases where the recalling firm does not have a recall plan (see Attachment 1), inspection program personnel may conduct more effectiveness checks than if the firm did have a recall plan.

E. Inspection program personnel will contact or visit the consignees to determine whether they were notified of the recall and have removed the recalled product from commerce. All firms with the recalled products are expected to remove that product from commerce and notify their subsequent consignee of the recall and product disposition actions. The checks will also verify that the firm's consignees are handling the product in accordance with regulatory requirements and the instructions of the recalling firm. For a recall to be deemed effective, the number of consignees checked that are found to have the product available to the public must be equal to or less than the critical number in the sampling plan applied to the effectiveness check (Attachment 3). FSIS inspection program personnel record the results of the checks on FSIS Form 8400-4, Report of Recall Effectiveness (Attachment 4) and document any potential prohibited activities such as putting product for which the Agency has reason to believe is adulterated in commerce. In cases where prohibited activities are noted or suspected, inspection program personnel should contact the DRO, who will contact OPEER, to investigate and take any follow-up compliance or legal actions. In cases where a complete determination cannot be made upon an initial check, inspection program personnel will conduct a follow-up effectiveness check to ensure that the product was handled in accordance with the instructions and regulatory requirements. Inspection program personnel will document this on FSIS Form 8400-4 as a follow-up under "type of effectiveness review."

F. If at any time during the effectiveness checks, FSIS discovers that a firm did not take prompt action to contact the consignees with recall instructions, or that the

consignees are not acting with respect to the product in the manner as requested by the firm, inspection program personnel will detain any product that they find in commerce. Inspection program personnel will immediately notify the DRO when the recalled product remains available to the consumer and when the recalling firm's recall strategy has not been properly implemented.

G. If the DRO determines that the recall action is ineffective, the DRO will notify the recalling firm in writing, with a cc to the RMS Director, detailing the reasons why its recall action was deemed ineffective. The DRO will ask how the recalling firm intends to address the situation. If the recalling firm is unwilling or unable to correct its recall strategy, FSIS will take further action to mitigate the risk to the public. FSIS actions may include public warnings, product detentions and seizures, or other appropriate actions.

NOTE: If the firm's recall strategy includes destroying product on site, the 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. This is to be documented on FSIS Form 8400-4 as follow-up, under "type of effectiveness review."

XI. CLOSURE

When the DRO has completed the recall effectiveness checks and determined that the recalling firm has made all reasonable efforts to recall the product, and that it has either disposed of the product that was in commerce at the time of the recall, or the product is under FSIS control (retention or detention) or has documented control by the firm, he or she will send a recall termination report to the Director of RMS. The termination report must include the amount of recalled product recovered and the method of disposition or if the product is being held under documented control. RMS will then submit a recommendation for terminating the recall to the AA, OFO for review. The recommendation will summarize the recall efforts by the firm that has conducted the product recall and the findings of the effectiveness checks. With the concurrence of the AA, OFO, RMS will notify the recalling firm in writing.

NOTE: If a federally inspected establishment shipped adulterated product, FSIS inspection program personnel will verify that the establishment took the appropriate corrective actions in accordance with 9 CFR 417.3 (See FSIS Directive 5000.1). FSIS may send an Evaluation and Investigative Analysis Officer (EIAO) to conduct a Food Safety Assessment at recalling plants as appropriate.

FDA oversees egg product recalls in accordance with the Egg Products Inspection Act and two Memoranda of Understanding between the Department of Health and Human Services and United States Department of Agriculture (dated June 7, 1983 and February 23, 1999).

/s/ Philip S. Derfler

Assistant Administrator
Office of Policy, Program, and Employee Development

Change Transmittal Sheet - Amendment 3 (Mar 2, 2006)
(http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8080.1Rev4Amend3.pdf

Change Transmittal Sheet - Amendment 2 (Jul 26, 2005)
(http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8080.1Rev4Amend2.pdf)

Change Transmittal Sheet - Amendment 1 (Jul 29, 2004)
(http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8080.1Rev4Amend1.pdf)

PRODUCT RECALL GUIDELINES FOR FIRMS

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1. Background and Objectives

A recall is an effective method of removing from commerce any product that may be adulterated or misbranded. Firms such as a manufacturer, distributor, or importer take these actions as part of their responsibility to protect the public health and welfare.

A recall can be disruptive to a firm's operation and business; however, there are several steps that a firm can take to minimize this disruption. An operator of an inspected establishment should take measures that will ensure rapid and effective response if products that appear to be adulterated have entered commerce. The operator should prepare and maintain a detailed, written recall plan. This plan should describe, step by step, the procedures the firm will follow in case it becomes necessary to recall a product.

Official establishments are required to have HACCP plans that control hazards reasonably likely to occur and that identify in-plant corrective actions when there is a failure to control a critical control point (9 CFR 417.2-417.3). FSIS believes that establishments can identify corrective actions, including a recall if necessary when violative product has entered commerce. There is no regulatory requirement that an establishment includes this recall plan in its HACCP plan or as a prerequisite program; however, FSIS believes that prudent establishments will.

The guidance presented here is intended for all meat and poultry firms that may need to conduct a recall without regard to plant size or the number of people employed. Some of the recommendations may speak in terms of forming teams of employees to conduct certain activities related to recalls, or may seem to imply that sophisticated analyses of potential health hazard situations be conducted. However, the key activities discussed below can be performed by one or two individuals in circumstances where there are limited resources. For example, in a small plant operation, the owner or manager of the establishment may be the recall coordinator as well as the contact for the Agency, the firm’s consignees, and the public. The Agency does not expect smaller establishments to hire

personnel simply to prepare for recalls. On the contrary, the Agency strongly encourages the management of all firms to prepare themselves, and their personnel regularly employed, for the potential of having to conduct a recall.

2. The Recall Plan

One person should be identified as the recall coordinator (firms may use other titles as appropriate) to prepare for and coordinate all activities related to recalls. The recall coordinator should be knowledgeable about every aspect of the firm's operations, including purchasing, processing, quality assurance, distribution, and consumer complaints. The recall coordinator should select people to form a recall team. The recall coordinator should be authorized to make decisions in carrying out a recall and should report to top management at regular, specified intervals.

A Recall Plan should address the following elements:

a. Identification of Recall Personnel - All internal and external personnel to be involved in the recall actions, along with their respective telephone and facsimile numbers, e-mail addresses, etc., as appropriate, should be identified. For each identified individual, an alternate to act in his or her absence should be specified. The roles and responsibilities of every person identified should be clearly specified.

b. Recall Procedures – The recall plan should specify, in detail, actions that the firm will take in deciding whether to recall a product and in effecting the recall should it decide to do so.

c. Evaluation of Health Hazards – A firm may collect and evaluate any information it has regarding the nature and extent of the associated health risks. A firm may take into account the following factors if it chooses to submit this information to the FSIS Recall Committee during the preliminary recall evaluation:

- Whether any disease or injuries have already occurred from the use of the product.
- Assessment of the hazard to various segments of the population,(e.g., children, the elderly, immuno-compromised individuals, etc.), who are expected to be exposed to the product being considered for recall, with particular attention paid to the hazard to those individuals who may be at greatest risk.
- Assessment of the relative degree of seriousness of the health hazard to which the population at risk would be exposed.
- Assessment of the likelihood of occurrence of the hazard.
- Assessment of the consequences (immediate or long-range) of the hazard's occurrence.

d. Scope of Recall – The plan should outline how the establishment will assess the amount and kind of product that is implicated in a problem. When the problem involves contamination with microbial pathogens, FSIS generally considers all products produced under a single HACCP plan between performance of complete cleaning and sanitizing procedures (clean-up to clean-up) to be potentially involved. However, sanitation does not necessarily define the scope of all product removal actions.

Some examples of product removal actions where the scope is defined other than by clean-up to clean-up include: the contamination of a vat of product with a foreign object, the use of an incorrect label, or the use of the same source of raw materials in other lots on other days of production. FSIS will consider such factors as the establishment's coding of product; the pathogen of concern; the processing and packaging; the equipment; the establishment's HACCP plan monitoring and verification activities (including microbiological testing); the establishments Sanitation SOP records; and whether some or all of the products controlled by the same or substantially similar HACCP plans have been affected.

If the use of the "clean-up to clean-up" approach does not define the scope of the problem, the firm will have to identify the product involved by defining, for example, when the problem began, and when it ended. The plan should specify how the firm will determine the scope of the implicated product for various scenarios and contingencies.

e. Records - A system of product coding sufficient to permit positive product identification and to facilitate effective recalls should be in use by all firms. Records should be maintained for a period of time that exceeds the shelf life and expected use of the product and at least the length of time specified in FSIS regulations concerning record retention (9 CFR 320; 381.175).

Distribution records should be maintained as are necessary to facilitate identification and location of products that are recalled. These records can be used to quickly provide FSIS with requested information regarding product distribution. Records such as bills of sale, invoices, and shipping papers are required to be kept with respect to each transaction in which any livestock, poultry or poultry food, or meat or meat food product is purchased, sold, shipped, received or otherwise handled by the establishment in connection with any business subject to the FMIA. These records should include names and address of consignees, shipment method, date of shipment, etc. It is also useful to note consignees that are hospitals, chains, restaurants, distributors, independent retailers or sellers to the National School Lunch Program or the Department of Defense.

Production records should be maintained that would facilitate the traceback of product ingredients in order to help determine causes of adulteration and define the scope of recalls. In the event that a recall becomes necessary because of an Agency sample testing positive or an outbreak of foodborne illness, verified records could be used to demonstrate limiting factors that may narrow the scope

of a recall by a particular plant. Moreover, the records would be essential in facilitating the traceback of the contamination to its source.

In practical terms related to *Escherichia coli O157:H7* as detailed in FSIS Directive 10,010.1 establishments are expected to maintain records of their suppliers of ground beef raw materials and to make the records available to Agency personnel upon request in order for them, in the event that a sample of ground beef is reported positive, to notify suppliers that their product may have been the source of the contamination. The information inspection program personnel collect includes the name of the supplying establishment, the supplier's lot number, and production date of the product. This information has proven to be an effective tool for initiating tracebacks in an effort to find the source of contamination.

If a recall of ground beef is necessary because of contamination with *E. coli* O157:H7, a prudent establishment may be able to limit the amount of affected product if it has a detailed recordkeeping system in place. Carefully maintained production records can serve a vital public health purpose by providing an establishment and the Agency with an essential means of pinpointing potential sources of contamination and allow for greater accuracy in deciding which products may be affected. The kinds of records comprising such a system include production or grinding logs showing the times of each grind, the formulation or blend of raw ingredients including amounts, supplier lot identification, the finished product lot and sublot identification, and any test results associated with either the raw materials or finished product. The records should indicate and track which lots or sublots of a grinding establishment's ground beef particular raw materials were used and the amounts of each that were used.

For example, establishment 38 is a beef slaughter/fabricating/grinding establishment. It produces approximately 50,000 pounds of ground beef products per day. The raw materials used in the ground beef include its own in-house generated boneless beef, as well as boneless beef products purchased from other establishments. The establishment tests each lot of raw material it purchases from outside sources as well as those that it generates in-house and does not use any boneless beef that tests positive on the *E. coli O157:H7* screening test. It also tests its finished ground beef by pulling a sample representing every 2000-pound blender batch and combining those four batches into one composite sample representing an 8000-pound sublot of the day's lot. For example, a given day's ground beef production log might (in part) look like this:

Ground Beef Log **Date : November 3, 2003**

Product ID	Sublot #	Blend #	Time of Sample	Product Ground	Amt (lbs)	Sample Result	Date	Initials
Good Grind	1	1	7:50 AM	Est 38 - 103003 Lean trim	1000	Negative	05-Nov	QC
				Est 42 - 102903 80% trim	500			
				Est 38A - 103103 50% trim	300			
				Est 38 - 103003 Head/Cheek meat	100			
				Est Aust. 38B - 90603 Cow Shoulder	100			

Note: [Blend #2, #3, and #4 making up sublot #1 would be recorded in the same way. The sample result represents the entire sublot.]

Product ID	Sublot #	Blend #	Sample Time	Product Ground	Amt (lbs)	Sample Result	Date	Initials
Best Grind	2	1	9:20 AM	Est 38 - 103003 Lean trim	1000	Negative	05-Nov	QC
				Est Aust. 38B - 90603 Cow Shoulder	800			
				Est 42 - 102903 80% trim	200			

Note: [The next three blends making up the sublot would be recorded in the same way. The sample result represents the entire sublot.]

Product ID	Sublot #	Blend #	Sample Time	Product Ground	Amt (lbs)	Sample Result	Date	Initials
Meat Loaf Patty Mix	5	1	2:30 PM	Est 38 - 103103 50% trim	700	Negative	05-Nov	QC
				Est 42 – 102703 Boneless Veal	400			
				Est 38 – 103003 Lean Trim	200			
				Est 38 – 103103 Head/Cheek meat	200			
				Est Aust. 38B – 90603 Cow Shoulder	500			

Note: [The next three blends making up the sublot would be recorded in the same way. The sample result represents the entire sublot.]

In the event of a recall, this establishment will be able to identify the more likely sources of contamination from its production records. To illustrate, suppose sublot 5 from the chart above was the only lot that tested positive for *E. coli O157:H7*. The establishment could review their records and identify two sources of raw materials, Est. 42 boneless veal and Est. 38 head/cheeks (103003), that were not used in the other sublots. These two source materials would be more likely than the others to be the vector of contamination in the finished product.

Given this information, the establishment could:

1. Review its dressing procedures and the boning and handling of its head/cheek meat in order to find and eliminate any potential causes of contamination;

2. Confirm the test results for the lot that had the screen test positive;

3. Divert the rest of that lot of head/cheek meat away from ground beef production and into a process with an adequate kill step;

4. Notify its supplier of boneless veal, Est. 42, of its findings regarding that establishment's product; and

5. Inform the Agency of its findings, conclusions, and actions taken.

The establishment may also be able to demonstrate through this type of testing program and thorough recordkeeping that the previous sublots of product were not represented by the positive test from sublot 5. The previous sublots would not need to be removed from commerce if the establishment could adequately demonstrate through additional confirmation testing that they were not adulterated. For production records such as those discussed here to be most useful to an establishment and FSIS, they should be incorporated into an establishment's HACCP plan or be made part of a prerequisite program.

f. Depth of Recall – The plan should specify how the depth of recall will be determined for various scenarios and contingencies. The depth is dependent upon the extent of distribution and the level to which the recalled product was distributed. Levels of recall depth may be:

- Wholesale level, the distribution level between the manufacturer and retail or user level;

- HRI level, which includes hotels, restaurants and other institutional type customers and any intermediate wholesale level to reach those users;

- Retail level, which includes retail sellers and any intermediate wholesale level to reach the retail sellers; or

- Consumer level, which includes household consumers and any prior level distribution.

g. Recall Communications - A recalling firm is responsible for promptly notifying each of its affected consignees about the recall. The plan should specify what means of communication will be used and should include sample communication for various scenarios and contingencies. The format, content,

and extent of a recall communication should be commensurate with the hazard associated with the product being recalled, the strategy developed, and the recall plan. In general terms, the purpose of a recall communication (see attached sample letter) is to convey:

- That the product in question is subject to a recall;
- That further distribution or use of any remaining product should cease immediately;
- Where applicable and required as part of the recall strategy, that the direct consignee should in turn notify its consignees that received the product about the recall;
- Instructions regarding what to do with the product; and
- Contact Information for questions (e.g. a name and toll free number).

i. Recall Communication Implementation - As determined by the recall strategy, developed in conformance with the recall plan, a recall communication can be accomplished by telephone, facsimile transmission, e-mail, or special delivery letters conspicuously marked, preferably in bold red type, on the letter and envelope "URGENT - FOOD RECALL." If firms communicate their recall strategy by telephone calls or other personal contacts, FSIS expects the firms to document and follow-up this communication in some written form (e.g., letter, e-mail message, fax).

ii. Recall Communication Content - A recall communication should be written in accordance with the following guidelines:

- Be brief and to the point;
- Identify clearly the product and any other pertinent descriptive information to enable accurate and immediate definition of the product including, as appropriate;
    - Product/brand name
    - Product code
    - Package/case size
    - Package/case date code
    - Lot number/expiration date
    - UPC code
- Provide an explanation of the risk involved in consuming the product;
- Explain concisely the reason for the recall and the hazard involved;

- Provide specific instructions on what should be done with respect to the recalled products;
- Request an official, written response from the firm;
- Provide a ready means for the recipient of the communication to report to the recalling firm whether it has any of the product, (e.g., by allowing the recipient to place a collect call to the recalling firm);
- The recall communication should not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message; and
- Provide firm contact information (for questions).

Where necessary, follow-up communications should be sent to those who fail to respond to the initial product removal communication within a specified timeframe (e.g., within 24 hours).

The recall plan should specify what means of communication will be used, including sample communications, for various scenarios and contingencies.

iii. Responsibility of Recipient - Consignees that receive a recall communication should immediately carry out all instructions set forth therein and, where necessary, extend the recall to their consignees.

h. Public Notification - The purpose of public notification is to alert the public that a product is being recalled. A firm should consider the need for and means of public notification upon initiating a recall. The recall plan should specify what means of public notification will be used, if appropriate, for various scenarios and contingencies such as:

- General public notification by press release through the general news media, either national or local as appropriate; or
- Public notification through specialized media, (e.g., professional, trade or ethnic press, store placards or notification to specific customers (if known)).

A Recall Plan should include contact information for all potential media outlets such as television stations, radio stations, and newspapers and with local, State, and regional coverage areas as well as the national wire services. If the actual contacts are not specified, reference sources of current media contacts for all possible recall scenarios should be specified in the Recall Plan.

NOTE: Regardless of the public notification action taken by the recalling firm, FSIS will generally issue a press release for Class I and Class II recalls. For Class III recalls, generally the Agency will only issue a Recall Notification Report (RNR). The Agency will also post them on the FSIS web site (www.fsis.usda.gov/OA/recalls/rec_actv.htm) for all recalls. In

addition, the RNR will be sent, by means of E-mail or facsimile transmission, to public health officials throughout the country.

i. Firm's Effectiveness Checks - The purpose of effectiveness checks is to verify that all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action. The methods for contacting consignees should be specified, for various scenarios and contingencies, and may be accomplished by personal visits, telephone calls, letters, facsimile transmission, or a combination thereof. This is a means of assessing the progress and efficacy of a recall. The method for determining the number of effectiveness checks to be conducted and the manner for conducting them should be determined for various scenarios and contingencies in the recall plan. FSIS will verify the firm's effectiveness checks.

To assess the effectiveness of a recall, a firm needs the following information:

- How much product is implicated in the recall?
- How is this product identified to a customer/retailer (i.e., lot markings)?
- How much product is within a firm's control?
- How much product has left the firm's control?
- How many locations did the firm ship the product to, and where are those locations?
- How did the firm communicate the product removal action to those who received the product; did the firm document this contact; and did the firm ask for and receive a written response acknowledging receipt of the information?
- What actions were taken with the product and by whom?
- If product was destroyed, was destruction witnessed and documented; were Agency personnel present?
- Is there a written record of when the issue was identified, when customers were notified, and when the firm received notification that product was either placed on hold or was no longer in a customer's control?
- Can the firm account for most of the product? Does the math add up? (The firm produced this amount, shipped this amount, had this amount returned, destroyed or determined to be consumed or irretrievable.)

j. Returned Product Control and Disposition - The means of controlling and disposing of or correcting the defect in the stock returned during a recall should be specified in the recall plan. Remember to check with the Agency before destroying product; FSIS may wish to witness the destruction. (Destroy means

to render inedible for humans and animals, and all labeling is made unusable for trade.)

k. Recall Simulations - In order to evaluate how well its plan will work in the event of an actual recall situation, the establishment should conduct periodic simulations. A simulated recall should involve the selection, without prior notice to personnel involved in the simulated recall, of at least one lot of product that has been distributed in commerce. A hypothetical reason for recalling the product should be specified, and the recall plan should be followed to establish a strategy for recalling the product. Such scenarios may be simple (e.g. one contaminated lot of product) or very complex (e.g. contaminated ingredient used in multiple products and involving rework). A firm may wish to begin with simple scenarios and work up to more complex simulations for their operation. The simulation should proceed at least to the point at which communication is to be made beyond the firm's organizational limits; however, full details of who will be contacted at that point, and how contact will be established, should be specified. Firms, especially those with products distributed by multi-layer distribution systems, may wish to consider conducting at least one simulation in which the product to be recalled has been shipped beyond the firm's initial customer to one or more of the consignee's customers. Taking the simulation beyond the recalling firm's organization could reveal potential problems in the retrieval process that possibly could be addressed before a "live" recall occurs.

A recall simulation file should be maintained to record the details and results of all simulated recalls. The recall simulation file should include the name, address, and telephone number of clients for the test lot, production records, the inventory, and distribution of the test lot. A recall simulation is used to determine whether the recall procedure is capable of identifying and quickly controlling a given lot of potentially affected product and reconciling the quantities produced, quantities in inventory, and quantities distributed. In addition, a recall simulation will identify potential problems and allow personnel to become familiar with recall procedures. If problems are identified during a recall simulation, the recall plan and procedures should be revised to correct the problems.

3. Notifying FSIS of Recalls

FSIS expects that, once it is determined that a recall will be undertaken, the recalling firm will immediately notify FSIS. When doing so, the firm should notify the Recall Management Staff (RMS) or the District Office in the FSIS district where the firm is located. The basic information that should be conveyed to FSIS includes, but is not limited to, the following (see FSIS Directive 8080.1):

- Complete and accurate product identity, including product labels.
- The reason for the recall and details about when and how any defect or deficiency was discovered.

- An evaluation of the risk associated with consumption of the product and how the evaluation was made (although FSIS will make its own determination of risk).
- How much of the product in question was produced and during what period of time.
- An estimate of how much of the product is in distribution and how long it has been in distribution.
- Area of the geographical distribution of the recalled product by State and, if exported, by country.
- Information about which distributors and customers received the product.
- Copies of any firm correspondence with distributors, brokers, or customers relating to the recall strategy or actions, and a copy of any proposed press release.
- The name, title, and telephone number of the recall coordinator for the firm.

This information may initially be provided orally. However, it should be confirmed to the RMS by using the worksheet. For clarity, it is recommended that the worksheet be filled out and submitted via e-mail. Doing so will prevent errors resulting from hard-to-read handwriting or illegibility because of poor fax transmission. Early on in the recall process, FSIS will generally send a program employee designated by the District Office to the establishment to verify distribution records and confirm facts.

4. Recall Assessment

The firm is expected to regularly, and in a timely manner, report the results of checks of the effectiveness of its efforts to retrieve the product to FSIS in order to keep the Agency apprised of the status of recalls in progress. The reporting frequency will be agreed upon by the recalling firm and FSIS. FSIS believes that the higher the degree of public health hazard, the more frequently the firm should report. FSIS will conduct its own effectiveness checks as specified in FSIS Directive 8080.1, Rev. 4. In addition, FSIS expects that the firm will notify the agency when it appears that the recall has been completed.

Unless otherwise specified, the recall status report should contain the following information:

- The number of consignees notified of the recall, the dates notifications were made, and the method of notification that the firm used for each consignee.
- The number of consignees responding to the recall communication.

- The quantity of product each consignee had on hand at the time the communication was received.
- The number and identity of consignees that did not respond.
- The quantity of product returned or held by each consignee.
- An estimated time for completion of the recall.

5. Recall Termination

A recall will be terminated when FSIS has completed the recall effectiveness checks and determined that the recalling firm has made all reasonable efforts to recall the product, and that it has either disposed of the recovered product, or the product is under FSIS control (retention or detention) or has documented control by the firm. To effect a timely termination of the recall, the firm should provide all relevant information to the Agency once the firm has determined that it has retrieved all possible product. The firm should send to the relevant District Office, a "closeout memo" containing a list of customers, the amount of product retrieved, and the actions taken. Once the Agency determines that the firm has made all reasonable efforts to recall the product, the RMS will notify the firm in writing.

6. Recall Follow-up

Once a recall action has been completed, the establishment should notify its customers that the recall action has been completed, thank them for their assistance, and provide assurances that the problem has been corrected. The Recall Team should evaluate how the recall action was conducted to determine whether things should have been handled differently, and what, if any, changes should be made to the plan.

MODEL RECALL NOTIFICATION LETTER

DATE

CUSTOMER FIRM NAME & ADDRESS

ATTN: ***CONTACT PERSON NAME & TITLE***

Re: RECALL OF ***TYPE OF PRODUCT***

Dear Sir or Madam:

This letter is to confirm our telephone conversation that ***Company Name*** is recalling the following product because ***Specify Recall Reason.***

Describe the product, including name, brand, code, package size and type, establishment number, etc.

We request that you review your inventory records and segregate and hold the above product. If you have shipped any of this product, we request that you contact your customers and ask them to retrieve the product and return it to you. Once you have retrieved all of the product, please contact us. We will arrange to have the product shipped to our facility. Please do not destroy the product. We will credit your account for product returned.

We are undertaking this action in cooperation with the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture. FSIS officials may contact you to confirm that you have received this notice and are cooperating in this action.

Your prompt action will greatly assist ***Company Name*** in this action. If you have any questions, please do not hesitate to contact ***Company Recall Coordinator*** at ***Phone Number***.

Thank you for your cooperation.

Sincerely,

Company Official Name and Title

MODEL PRESS RELEASE – FOREIGN OBJECT

[State] Company Recalls [Product] That May Contain Glass

[City], [Date]—[Company], a [City, State], establishment, is voluntarily recalling approximately [number of pounds] of [product] because the product may contain [hazardous material, e.g., glass]. Consumption could cause [lacerations].

Specific information on how to identify the product (e.g., the type of container [plastic/metal/glass], size or appearance of the product, product brand name, establishment number and location on package, flavors, codes and expiration dates, etc.).

Product was distributed [Listing of the states and areas where the product was distributed and how it reached consumers (e.g., through retail stores, mail order, direct delivery)].

Status of the number of and types of related illnesses that have been confirmed to date (e.g., "No illnesses have been reported to date").

Brief explanation about what is known about the problems, such as how it was revealed, and what is known about its source. An example of such a description: "The recall was the result of the plant finding several pieces of glass on routine examination of the product. The company immediately contacted FSIS and has ceased distribution of the product as FSIS and the company continue their investigation as to what caused the problem."

Because of the potential hazard, [name of company] urges consumers who have purchased these products not to eat them but to return them to the place of purchase.

Information on what consumers should do with the product and where they can get additional information (e.g., "Consumers who have purchased Brand X are urged not to eat the product but to return it to the place of purchase for a full refund).

Consumers with questions about the recall may contact [name and position or company division], at [phone number], or the consumer hotline at [toll free number]. Media with questions may contact [name and position] at [phone number].

####

MODEL PRESS RELEASE – ALLERGEN

[State] Company Recalls [Product] Because Of Undeclared Allergen

FOR IMMEDIATE RELEASE
DATE

COMPANY CONTACT AND PHONE NUMBER

FOOD CO. ISSUES ALLERGY ALERT ON UNDECLARED ALLERGEN IN PRODUCT

[Company Name] of [City, State] is recalling [Quantity and Type of Product], because it may contain undeclared [specific type of allergen, e.g., egg, milk, etc]. People who have an allergy or severe sensitivity to [specific type of allergen run the risk of serious or life-threatening allergic reaction if they consume these products.

Specific information on how the product can be identified (e.g., the type of container [plastic/metal/glass], size or appearance of the product, product brand name, establishment number and location on package, flavors, codes, expiration dates, etc.).

Product was distributed [Listing of the states and areas where the product was distributed and how it reached consumers (e.g., through retail stores, mail order, direct delivery)].

Status of the number of and types of related illnesses that have been confirmed to date (e.g., “The company has received two reports from consumers allergic to [specific allergen] of mild adverse reactions.”).

Brief explanation about what is known about the problem, such as how it was revealed, and what is known about its source. An example of such a description: “The recall was initiated after it was discovered that product containing (the allergen) was distributed in packaging that did not reveal the presence of (the allergen).”

Information on what consumers should do with the product and where they can get additional information (e.g., “Consumers who have purchased Brand X are urged to return it to the place of purchase for a full refund. Consumers with questions may contact the company at 1-800-XXX-XXXX”).

# # # #

MODEL PRESS RELEASE – *L. monocytogenes*

[State] Company Recalls [Product] For Possible *Listeria* Contamination

[City], [date]– [Company Name], a [city, state] company, is voluntarily recalling approximately [quantity] of ready-to-eat [product] that may be contaminated with *Listeria monocytogenes.*

Specific information on how to identify the product (e.g., the type of container [plastic/metal/glass], size or appearance of the product, product brand name, flavors, codes and expiration dates, etc.).

Product was distributed [Listing of the states and areas where the product was distributed and how it reached consumers (e.g., through retail stores, mail order, direct delivery)].

Description of illness: "Consumption of food contaminated with *Listeria monocytogenes* can cause listeriosis, an uncommon but potentially fatal disease. Healthy people rarely contract listeriosis. Listeriosis can cause high fever, severe headache, neck stiffness and nausea. Listeriosis can also cause miscarriages and stillbirths, as well as serious and sometimes fatal infections in those with weak immune systems – infants, the frail or elderly and persons with chronic disease, HIV infection or in chemotherapy." Status of the number of and types of related illnesses that have been confirmed to date (e.g., "No illnesses have been reported to date. Anyone concerned about an illness should contact a physician.").

Brief explanation about what is known about the problems, such as how it was revealed, and what is known about its source. An example of such a description: "The problem was discovered through routine FSIS microbiological testing."

Information on what consumers should do with the product and where they can get additional information (e.g., "Consumers who have purchased Brand X are urged to return it to the place of purchase for a full refund. Media with questions about the recall may contact [Name and position] at [phone number]. Consumers with questions about the recall may contact [Name and position] at [phone number].

Consumers with food safety questions can phone the toll-free USDA Meat and Poultry Hotline at 1-800-535-4555. The hotline is available in English and Spanish and can be reached from 10 a.m. to 4 p.m. (Eastern Time) Monday through Friday. Recorded food safety messages are available 24 hours a day.

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Factors That Are Considered by the FSIS Recall Committee in Evaluating the Public Health Significance of an Undeclared Allergen or Other Misbranding of a Meat or Poultry Product

Background

The Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), under which the Food Safety and Inspection Service (FSIS) operates, require that all ingredients used to formulate meat and poultry products be declared in the ingredients statement on product labeling according to their common or usual names. A product is misbranded under the FMIA or PPIA when it contains ingredients that are permitted but are not declared on product labeling.

The Agency recognizes that there are situations in which a meat or poultry product enters commerce with ingredients that are not declared on its labeling. In some cases, the undeclared ingredient may be an allergen, which would necessitate removal of the product from commerce. FSIS Directive 8080.1, Revision 4, entitled "Recall of Meat and Poultry Products" outlines the Agency's policies and procedures regarding the voluntary recall of FSIS-inspected meat and poultry products. FSIS Directive 8080.1 provides that each recall be classified into one of three classes (Class I, II, or III)[1] based on the likelihood that illness or other adverse effects will be caused by consumption of the recalled product. This guidance describes the factors that are considered in assigning a recall class in the situation involving an undeclared ingredient of health concern.

This is a particular concern about health situations in which a meat or poultry product is misbranded and contains ingredients that may cause an allergic response. A food allergy is a specific condition in which a person's immune system reacts to certain foods. Food allergies should be distinguished from food intolerances. Food allergy reactions range from mild to life-threatening and can include gastrointestinal upset, rash, wheezing, and shock. Food allergies are commonly associated with eight categories of foods; cereals containing gluten (i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these); crustacea; eggs and egg products; fish and fish products; peanuts; soybeans; milk and milk products; and tree nuts. In comparison, food intolerances are non-immunologically mediated reactions. They are caused by a reaction to the chemical composition of a food itself, or by an additive, (e.g., preservatives, colors, flavor enhancers). Some common examples of food intolerance are reactions to sulfites, monosodium glutamate (MSG), histamine, or

[1] Class I 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.
Class II is a health hazard situation where there is a remote probability of adverse health consequences from the use of the product.
Class III is a health hazard situation where the use of the product will not cause adverse health consequences.

tartrazine (FD&C Yellow No. 5). Thus, there are few foods or food ingredients to which some element of the population will not have some degree of allergic response or intolerance. For this reason, complete ingredient labeling is critical.

Various factors are considered in assessing the public health significance of a meat or poultry product that is misbranded because of an undeclared ingredient, and thus, the class to which a recall involving the product should be assigned. The following questions convey examples of factors that are considered in determining the public health significance of a misbranding situation.

What Amount or Dose of an Ingredient is Required to Elicit an Adverse Health Effect?

The significance of this factor for recall classifications is that, for some allergens, there exists a "no observed adverse effect level" that can be used in estimating risk. Thus, in these cases, the higher the amount of the ingredient, the more likely it is to elicit an adverse effect, the more reason to classify the recall as one in which there is a significant public health concern, that is, Class I. Conversely, the lower the amount of the ingredient, the more reason there is to classify the recall as Class II. However, for most known allergens, there is no conclusive scientific evidence to establish threshold levels for eliciting an adverse reaction. Consequently, in most cases, the presence of an undeclared substance that is a known allergen, at any level, poses a public health risk and thus should be classified as Class I unless other factors justify a different, lower classification.

What is the Likelihood, Magnitude, and Severity of an Adverse Effect Among Sensitive Consumers from a Food Containing an Undeclared Ingredient?

The probability of adverse effects among sensitive populations plays a large role in determining a recall classification. The likelihood that an adverse effect will occur as a result of human consumption of a misbranded meat or poultry product is based on probability. Specifically, it is the probability that someone in the most sensitive subpopulation may be exposed to an ingredient that is not declared on a product's labeling. The magnitude and severity of the adverse reaction, should it occur, are also significant. Generally, the greater the likelihood, magnitude, and severity of an adverse effect in a sensitive population, the more reason to classify it as Class I.

Once Ingested, Are There Circumstances That May Lead to the Bioactivation, Bioconcentration, or Detoxification of a Substance?

This factor directly relates to the level of the hazard posed by an undeclared allergen. It should be considered that, in some limited cases, the presence of a potentially allergenic substance in a food may be innocuous until metabolic systems in a person bioactivate or bioconcentrate the substance, or the substance may be detoxified by the body after it is consumed. The smaller the

population capable of deactivating an allergen, the more reason to classify any recall of product that contains the substance as Class I.

What is the Overall Health Risk Associated with the Consumption of the Product by Various Human Populations, Including the Most Sensitive Subpopulation?

The significance of an undeclared ingredient relates to the most sensitive subpopulation that may be affected. In the case where the ingredient is among the "big eight" categories of allergens, the issue of the number of sensitive individuals is irrelevant because, for any sensitive individual, there is no established threshold, and an allergic reaction is potentially catastrophic. However, in the case where nondeclaration involves ingredients that are *not* among the "big eight" allergens or that are not known to cause food intolerances, the most sensitive individuals in the population that have consumed or may consume the product should be determined. The more significant the reaction to consuming the substance, the more reason to classify it as Class I.

Summary and Conclusion -- What is the Public Health Impact?

The factors identified in this document are central in the evaluation of situations in which a meat or poultry product is misbranded and of the significance of this misbranding for the public health. The public health impact is estimated by the probability that vulnerable individuals will experience an adverse health effect as a result of exposure to an undeclared ingredient. This estimate of impact will ultimately be translated into a recall classification by the FSIS Recall Committee. The Recall Committee may request that a Health Hazard Evaluation Board convene to assist in estimating the risk.

For further guidance on factors to consider in evaluating the public health significance of a misbranded meat or poultry product, contact the Risk Assessment Division, Office of Public Health and Science, FSIS.

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. 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.

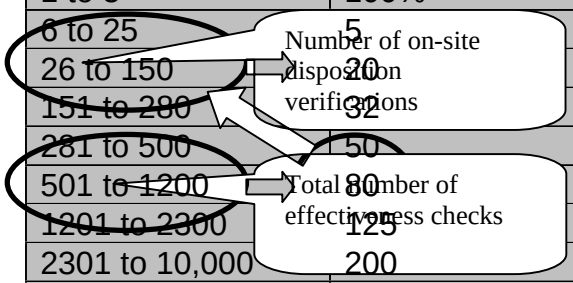
a. For Class I recalls involving illness, outbreaks, or school lunch implications the DRO will consult with RMS on the number of on-site verification.

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



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.

Example, 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, then 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.