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.

DISTRIBUTION: Inspection Offices; T/A Inspectors; Plant Mgt; T/A Plant Mgt; TRA; ABB; TSC, Import Offices

OPI: OPPED

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

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