

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

FSIS DIRECTIVE

8080.1,
Revision 7

9/9/13

RECALL OF MEAT AND POULTRY PRODUCTS

CHAPTER I - GENERAL

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, Revision 6, Recall of Meat and Poultry Products dated 10/26/10

III. REASON FOR REISSUANCE

This directive is being reissued in its entirety to provide guidance regarding recall plans and to incorporate new regulations that address the following:

1. Official establishments are required to notify their local FSIS District Office (DO) personnel within 24 hours when they learn or determine that adulterated or misbranded product has entered commerce.
2. If an official establishment notifies FSIS personnel other than the DO that adulterated or misbranded product has entered commerce, those personnel are to contact the DO promptly, through supervisory channels. They are also to notify the establishment that it is still required to contact the DO directly.

IV. BACKGROUND

A. A recall is a firm's action to remove product from commerce to protect the public from consuming adulterated or misbranded products. Although it is a firm's decision to recall product, FSIS coordinates with the firm to ensure it has properly identified and removed recalled product from commerce by verifying the effectiveness of the firm's recall activities. FSIS also notifies the public about product recalls.

B. A recall may be an alternative to FSIS detention or seizure of adulterated or misbranded products. However, a recall does not preclude FSIS from taking other appropriate actions, such as issuing Public Health Alerts or performing product detentions and seizures, to mitigate the risk to the public when firms have inadequately removed recalled product from commerce. The Agency will investigate if it appears that a firm's recall strategy or execution of that strategy is ineffective. Based on its findings, FSIS may seek enforcement action against the recalling firm or its consignees.

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C. For recalls conducted by State-inspected firms or retail establishments, the appropriate State agency verifies the recall, in most cases. If requested to do so, FSIS will provide the State agencies with appropriate assistance and information.

NOTE: Recall procedures for meat and poultry products produced in an establishment operating under the Cooperative Interstate Shipment program are addressed in [FSIS Directive 5740.1](#), *Cooperative Interstate Shipment Program*.

D. When FSIS finds that imported product should be recalled, the Agency will request that the importer of record recall the product. The importer of record would be responsible for recovering the product involved and properly disposing of the affected product.

V. TERMINOLOGY

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

Market Withdrawal: A firm's removal or correction, on its own initiative, of a distributed product that involves a minor company quality program or regulatory program infraction that would not result in the product being adulterated or misbranded. For example, product does not meet company quality standards because of discoloration.

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 the premises owned by the producing firm or under its control.

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. Examples of a Class I recall include the presence of pathogens in ready-to-eat meat or poultry products, or the presence of *E. coli* O157:H7 or non-O157 Shiga toxin-producing *E. coli* (STECs) 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 II recall is a recall because of the presence in a product of very small amounts of undeclared allergens typically associated with milder human reactions, e.g., wheat.
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 in meat or poultry products.

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

1. **Wholesale level:** The product has been distributed to a warehouse or distribution center where it is not under the direct control of the producing company. This is the distribution level between the manufacturer and the retailer. This level may not be encountered in every recall situation (i.e., the recalling firm may sell directly to the retail or consumer level.)
2. **Retail level:** The product has been received by retailers for sale to household consumers.
3. **HRI level:** The product has been received by hotels, restaurants, and other institutional customers.

4. Consumer level: The product has been sold directly to household consumers.

Scope: This defines the amount and type of product in question. Several factors are used in determining the scope of a recall, such as the plant's processing and sanitation procedures, the definition of a lot, or specific grouping, and whether there is any finished product reincorporated into fresh product (rework). The findings of epidemiological investigations that link certain lots of product with known cases of foodborne illnesses may also affect the scope of a recall.

Disposition: This is the firm's action with respect to the recalled product to correct the situation leading to the recall, such as relabeling, cooking, reworking, or destroying product.

Health Hazard Evaluation Board (HHEB): The HHEB 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 Office of Public Health Science's (OPHS) HHEB. (See [FSIS Directive 8091.1](#), *Procedures for the FSIS Health Hazard Evaluation Board*.)

Recall Committee: A committee of representatives from various FSIS offices and staffs assembled to respond to potential or real health hazard incidents reported to the Recall Management and Technical Analysis Staff (RMTAS).

CHAPTER II – DETERMINING NEED FOR RECALL

I. BECOMING AWARE OF POTENTIAL NEED FOR A RECALL

A. When official establishments learn or determine that adulterated or misbranded product has entered commerce, they are required to notify FSIS DO personnel within 24 hours (9 CFR 418.2). If an official establishment notifies FSIS personnel other than the DO that adulterated or misbranded product has entered commerce, those personnel are to contact the DO promptly, through supervisory channels. They are also to notify the establishment that it is still required to contact the DO directly.

B. FSIS has informed other firms, including importers of record, that when they learn or determine that adulterated or misbranded product has entered commerce or decide to recall product on their own initiative, they are to immediately notify RMTAS or other FSIS personnel. However, if the firm contacts other FSIS personnel, those employees are to promptly contact RMTAS through supervisory channels.

C. FSIS may become aware of misbranded or adulterated product in commerce through its own resources and personnel activities or through other sources outside of FSIS. For example, FSIS may receive information from:

1. The company that manufactures, distributes, or receives the product;
2. Test results from FSIS sampling programs;
3. Observations or information gathered by FSIS inspection program personnel (IPP) in the course of their routine duties or investigations;
4. Consumer complaints reported through the FSIS Consumer Complaint Monitoring System (CCMS);
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), the Centers for Disease Control and Prevention (CDC), or the Department of Defense; or

6. Information from other agencies such as the Department of Homeland Security, Customs and Border Protection, the Animal and Plant Health Inspection Service, or foreign inspection officials.

II. PRELIMINARY INQUIRY

A. When FSIS learns that there is reason to believe that adulterated or misbranded product is in commerce, FSIS will conduct a preliminary inquiry. The Recall Officer (RO) is assigned to direct the activities of IPP. FSIS personnel are to begin the preliminary inquiry by gathering product information, contact information, and any additional relevant information. They are to forward the following to RMTAS:

1. **Contact Information for an Official Establishment:**

- a. Establishment number, name, and address;
- b. Company Recall Coordinator (name, title, and telephone number);
- c. Company Media Contact (name, title, and telephone number); and
- d. Company Consumer Contact (name, title, and telephone number).

2. **Contact Information for Imported Products:**

- a. Import establishment (number, name, address, and telephone number);
- b. Foreign establishment (number, name, address, and telephone number);
- c. Importer of Record (name, address, and telephone number);
- d. Importer of Record Company's Recall Coordinator (name, title, and telephone number);
- e. Importer of Record Media Contact (name, title, and telephone number); and
- f. Importer of Record Consumer Contact (name, title, and telephone number).

3. **Product Information:** For all products, including imported products, FSIS personnel are to gather the following product information:

- a. Reason for recall;
- b. Brand names;
- c. Product names;
- d. Packaging (Type & Size (pounds));
- e. Package codes (Use by/Sell by);
- f. Packaging dates;
- g. Photos of label or package;
- h. Case codes;
- i. Count/case;

- j. Production dates;
- k. Distribution areas;
- l. School lunch (yes/no);
- m. Department of Defense (yes/no); and
- n. Internet or catalog sales (yes/no).

4. Additional Product Information for Official Establishments:

- a. Amount produced (pounds);
- b. Amount held at establishment;
- c. Amount distributed (pounds/cases); and
- d. Distribution level (depth of the recall, if known).

5. Additional information for Imported Product:

- a. Amount imported (pounds/cases);
- b. Amount held at import establishment;
- c. Amount distributed (pounds/cases);
- d. Distribution level (depth of the recall, if known); and
- e. Foreign country notified (yes/no).

6. When appropriate:

- a. Violation reported to Import/Export Coordination and Policy Development Staff (yes/no);
- b. Health Hazard Evaluation Board (HHEB) convened (yes/no); and
- c. Emergency Coordination Staff (EMS) notified (yes/no).

B. During the preliminary inquiry, FSIS personnel are to gather additional information by taking the following steps, as necessary:

1. Collecting and verifying information about suspect product;
2. Documenting a chronology of events;
3. Contacting the company that manufactures or distributes the product for additional information;
4. Communicating with FSIS field inspection and FSIS enforcement personnel;
5. Interviewing any consumer who allegedly became ill or was injured from eating suspect product;
6. Collecting and submitting product samples for analysis;

7. Contacting other agencies, State and local health departments, or foreign governments;
8. Analyzing any available epidemiological data;
9. Reviewing supporting documentation and evidence (e.g., sanitation standard operating procedures, or HACCP and production records).

C. RMTAS is to collect all of the information gathered during the preliminary inquiry and forward the relevant materials to the Recall Committee. Firms are encouraged to submit product label information electronically, whenever possible, to minimize transcription errors and enable consignees and consumers to readily identify recalled product if FSIS must issue a Recall Release.

CHAPTER III – RECALL COMMITTEE

I. RECALL COMMITTEE MEMBERS

A. All members of the recall committee should be knowledgeable about the issues raised by a potential recall situation and should be empowered by their Assistant Administrator (AA) to represent his/her views. Committee members are to make every effort to achieve consensus on whether to recommend that the Agency request a recall. The primary members of the Committee and their roles are described below:

1. Recall Management and Technical Analysis Staff (RMTAS), Office of Field Operations (OFO) - (chairperson) - Calls a committee meeting and distributes information about the potential recall to committee members. Invites other FSIS program areas to assist as necessary.
2. FSIS Recall Officer (RO), OFO - Clarifies and explains to the Committee the information collected during the preliminary inquiry. Designated FSIS personnel with jurisdiction in the district of the firm that is conducting the recall are to serve as the RO. The RO is the official responsible for coordinating field recall activities and providing direction to IPP when there is recall.
3. Office of Policy and Program Development (OPPD) – Provides the statutory basis for each recall. OPPD also addresses other statutory issues, the regulations, and any regulatory policies that are relevant to the recall.
4. Office of Public Health Science (OPHS) - Addresses microbiological, epidemiological, and other scientific issues associated with the recall.
5. Congressional and Public Affairs Office (CPAO) (Media Relations), Office of Public Affairs and Consumer Education (OPACE) - Gathers information and generates a Recall Release or Recall Notification Report (RNR) if there is a recall. Gathers information and, when appropriate, generates public notification, such as a Public Health Alert or Press Release, in situations where a recall action is not warranted. Ensures that information contained in the Recall Release, RNR, Public Health Alert, or Press Release is accurate.
6. In addition, the Committee may also consist of representatives from the following program areas, at RMTAS's request:
 - a. Office of Investigation, Enforcement and Audit (OIEA), Compliance and Investigations Division (CID): Participates in committee meetings and provides assistance to OFO upon request. CID also conducts investigations of alleged criminal violations, such as those involving the sale, transport, or receipt of adulterated product, associated with the recall.
 - b. Office of Data Integration and Food Protection: A representative from ODIFP is invited to all Recall Committee meetings to participate as a non-voting member.

- c. Other Federal or State agencies, as appropriate (e.g., FDA, Food and Nutrition Service, CDC, Office of the General Counsel, State departments of public health).

II. DELIBERATIONS OF THE RECALL COMMITTEE

A. To convene the Recall Committee, RMTAS is to contact the Committee members, usually by e-mail, to inform them of the potential recall. RMTAS is to provide the time of the recall meeting and a conference call number so that the Committee members can call into the meeting at the designated time. RMTAS is to make every effort to ensure that the five (5) primary members of the Recall Committee are available to participate in the Recall Committee meeting.

B. After RMTAS convenes the Recall Committee, the members are to discuss the reason that a particular product may need to be removed from commerce and whether there is a statutory basis to recommend a recall. If the Recall Committee decides to recommend a recall, it is to also determine the appropriate recall classification.

C. When determining whether to recommend a product recall, the Recall Committee is to seek the answers to the following questions:

1. Does FSIS have reason to believe that the product in question is adulterated or misbranded under the FMIA or PPIA? For Example:
 - a. If the results of a laboratory analysis show that raw ground beef or beef manufacturing trimmings contains *E. coli* O157:H7, or that a ready-to-eat product contains *Listeria monocytogenes*, the product is clearly adulterated because it is likely to be injurious to health.
 - b. However, there may be situations in which laboratory results are not available or are inconclusive, but, that FSIS believes, on the basis of epidemiological evidence, that a specific meat or poultry product is associated with human illnesses. Under these circumstances, the Recall Committee is to consider the strength of the epidemiological evidence to determine whether there is a basis to conclude that a product contains a pathogen or is otherwise unhealthful and, therefore, adulterated.
2. Does any of the product in question remain in commerce or available to consumers?
 - a. Domestic product is considered in commerce if it has been shipped from an establishment without Agency or establishment controls or restrictions and is free to be moved to any consignee or to consumers.
 - b. Imported product is considered in commerce if it has moved, resulting in a change of ownership from the importer of record that presented the product for FSIS reinspection at the official import inspection establishment to any other entity prior to receipt of laboratory results, or if the importer of record has relinquished ownership of the product before receiving the laboratory results.
 - c. The Recall Committee and program employees are to consider all available information to determine whether product is in commerce, and whether any product that has been distributed in commerce has reached retail facilities, restaurants, or consumers.

D. If the Recall Committee finds that the establishment has recovered all products from commerce that would have been subject to recall, the Committee should not recommend a recall, as no product should remain available to consumers. Instead, FSIS personnel are to verify that the establishment has recovered all products involved and that it conducted proper disposition of the affected products.

E. To properly assess whether any of the product remains available to consumers, the Recall Committee is to seek responses to the following probing questions:

1. When was the product produced?
2. To whom has the product been distributed?
3. What type of product is involved (e.g., ready-to-eat, fresh packed, canned, frozen)?
4. What is the typical, usable shelf life of the product?
5. What are the typical consumer or user practices concerning handling and storing of the product in question (e.g., is the product typically prepared for immediate consumption and likely is not stored or frozen for later use)?
6. Is the Agency able to verify that the product that was distributed in commerce is no longer available to consumers at retail facilities, restaurants, or other institutions?

F. If the answers to the questions C.1. and 2. are “yes,” a recall should be recommended, unless, based on the answers to questions in paragraph E, the Committee determines that the product is long out of date and unlikely still to be available to consumers, or the Committee is unable to identify a responsible party for the product. In these circumstances, a recall should not be recommended. However, the Agency may decide to issue a Public Health Alert. See Chapter IV for information regarding Public Health Alerts.

G. If a Recall Committee member does not agree with the action that a majority of the committee has decided to recommend, the dissenting member should immediately discuss the issue with his or her AA and report back to the Committee. If the Recall Committee is unable to come to consensus, the RMTAS representative is to notify the OFO AA, who will convene a meeting of the AAs and advise the Administrator that he or she is convening the meeting. Each AA should discuss the potential recall with his or her Office’s representative to the Recall Committee or their designee. If the AAs are unable to resolve the matter, they are to report the situation as a potential significant incident to be resolved by the Emergency Management Committee (EMC), as provided in [FSIS Directive 5500.2, Significant Incidence Response](#).

H. If the Recall Committee agrees that a recall is not recommended, RMTAS is to document the results of the preliminary inquiry and evaluation with a Memo to the File.

I. If the Recall Committee agrees to recommend a recall, it is to consider the human health hazard presented by the product subject to recall to determine the appropriate recall classification. 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 the Recall Committee has questions, particularly about hazards or conditions that have not been previously encountered by the Agency, the HHEB will be convened to conduct a hazard evaluation. The HHEB’s evaluation will consider, at a minimum, the following factors:

1. The nature of the problem (i.e., what is the problem with the product and what health hazards does the problem create);
2. The occurrence of any illnesses or injuries;
3. The likelihood that illnesses or injuries may result; and
4. The types of illnesses or injuries that may result.

J. The Committee may also refer to “Factors That Are Considered by the FSIS Recall Committee in Evaluating the Public Health Significance of an Undeclared Ingredient in a Meat or Poultry Product” (Attachment 2) when considering the classification of a recall that involves a meat or poultry product that contains an ingredient that is not declared on the product labeling.

K. After the Committee members have discussed the issues described in the above paragraphs, and agreed to recommend a recall, RMTAS is to contact the company that produced the product to allow its representatives to join the Recall Committee discussion. During the discussion, the Recall Committee is to allow the firm to present information about the hazard or concern associated with the product to allow the Committee to clarify its position. The Committee is to evaluate all information received and determine whether to recommend a recall of the product. FSIS expects the firm to have available upon request its recall strategy, including how it intends to notify and instruct its consignees to retrieve or dispose of the recalled product.

III. RECALL RECOMMENDATION

A. When the Recall Committee recommends a recall, RMTAS is to submit a Recall Recommendation in the form of a memo for approval by the OFO AA. The recommendation is to contain:

1. The reason for the recall, including why there is a reason to believe that the product is adulterated or misbranded;
2. The recall classification (i.e., Class I, Class II, or Class III);
3. The ability of distributors, consumers, or users of the product to identify the products covered by the recall; and
4. The estimated amount of recalled product in distribution (the amount of product subject to recall that was distributed. In some cases, not all of the product in distribution will be recalled because some of it will be beyond the sell by/use by dates or codes at the time of recall. In these cases, the Recall Committee is to determine whether consumers might still have the product, and, if so, whether they would possibly consume it).

B. The Recall Committee generally determines much of the above information from the recalling firm through written documents or telephone conference calls. Before deciding on a recommendation, RMTAS may request that FSIS IPP verify the information provided by the firm. RMTAS is to strongly encourage firms to e-mail the information involved in the recall to facilitate the speed and accuracy of the information transfer.

C. If the OFO AA approves the Recall Recommendation, RMTAS is to follow-up by sending a letter to the firm confirming the evaluation of the hazard, the scope of the recall, the area of distribution and the Agency’s understanding of the firm’s recall strategy. If the OFO AA does not approve the Recall Recommendation, the OFO AA is to convene the AAs to discuss and resolve whether to request a recall. Each AA should discuss the potential recall with his or her Office’s representative to the Recall Committee. If the decision is made to request a recall, CPAO is to confirm the information necessary for a Recall Release. The OPACE AA may request that other AAs review the draft Recall Release before it is issued. The RO is to begin to coordinate effectiveness checks (see Chapter V), consistent with the class of the recall, and is responsible for directing the activities of FSIS IPP.

D. If product subject to recall has been exported to a foreign country, RMTAS is to notify the relevant FSIS personnel. FSIS will inform the foreign country of the recall.

CHAPTER IV - ANNOUNCING THE RECALL

I. ACTION BY FIRM

A. FSIS outlines in “Product Recall Guidelines for Firms” (Attachment 3) the actions a firm can take to ensure that it recovers the maximum amount of product in the shortest amount of time. This guidance includes information on complying with recordkeeping requirements and a model letter that a firm may use to communicate with its consignees.

B. If the firm decides not to accept the Agency’s recommendation and chooses not to conduct a recall, FSIS personnel are to detain any product found in commerce that would have been subject to a recall as set out in *FSIS Directive 8410.1, Detention and Seizure*. CPAO is to 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 Agency is detaining product in commerce.

II. PUBLIC NOTIFICATION

A. Following approval of the recall by the OFO AA, RMTAS notifies CPAO to issue a Recall Release. CPAO is to distribute the Recall Release to media wire services, media outlets in areas that received recalled products, the FSIS e-mail subscription service, and the @USDAfoodsafety Twitter Feed. CPAO will also post it on the FSIS website. Generally, FSIS will issue a Recall Release for Class I and Class II recalls. However, if the recalled product has not been distributed beyond the wholesale level and has only been sent to warehouses or distribution centers where it is not likely to be sold directly to consumers, a Recall Release would not be necessary, even for Class I or Class II recalls. Instead, the Agency would issue an RNR (see section III below). FSIS will typically not issue a Recall Release for Class III recalls unless there are overriding public welfare reasons, such as a case of egregious economic adulteration.

B. The Recall Release will:

1. Clearly describe what product the firm is recalling, along with any identifying marks or codes, explain the reason for the recall, and describe the risks involved in consuming the product;
2. Instruct the public on how to properly handle the product if consumers have it in their possession;
3. Provide the name and telephone number of a company contact for consumers and media to call with any questions; and
4. Provide general information about the product’s destination. For example, “Ham and turkey products were distributed to retail stores and institutions in the States of....”

C. When possible, and without slowing the public notification of the recall, FSIS will post an electronic picture of the product label that clearly describes the product to the public on the FSIS website.

D. CPAO is to fax or e-mail a draft copy of the Recall Release to the recalling firm 30 minutes prior to its release. At this time, CPAO is to inform the firm that it may review the Recall Release to verify that the product description, the company contact information, and product distribution information are accurate. CPAO is to inform the firm that if it does not respond to CPAO within 30 minutes of receiving the Recall Release, FSIS will proceed to issue the Recall Release. CPAO is to also inform the firm that if it notifies CPAO of typographical or other inadvertent errors, CPAO is to correct them before issuing the Recall Release.

E. For Class I recalls related to human illness, an Incident Report (IR) will be posted on the FSIS Incident Management System (FIMS) by OPACE. The Recall Release will be attached to the IR. Program areas will update the IR, as appropriate, until the recall is complete.

III. RECALL NOTIFICATION REPORT (RNR)

A. RMTAS coordinates with CPAO to issue an RNR for Class III recalls or for Class I or Class II recalls in situations where FSIS does not issue a Recall Release. Unlike a Recall Release, an RNR is not distributed to media wire services or media outlets in areas that received recalled products. However, RNRs are posted on the FSIS website and are distributed to FSIS e-mail subscribers and the @USDAfoodsafety Twitter Feed. CPAO is to develop the RNR and post it to the FSIS website. RNRs are posted and distributed during normal business hours. If a draft RNR is not completed by close of business, it can be done so the next business day.

B. The RNR will:

1. Clearly describe what product the firm is recalling, along with any identifying marks or codes, and explain the reason for the recall;
2. Provide the name and telephone number of a company contact for consumers and media to call with any questions; and
3. Provide general information about the product's destination. For example, "Ham and turkey products were distributed to a warehouse in the State of..."

C. When possible, FSIS will post an electronic picture of the product label that clearly describes the product to the public on the FSIS website.

D. CPAO is to fax or e-mail a draft copy of the RNR to the recalling firm 30 minutes before it is posted to the FSIS website. At this time, CPAO is to inform the firm that it may review the RNR to verify that the product description, the company contact information, and the product distribution information are accurate. CPAO is to inform the firm that if it does not respond to CPAO within 30 minutes of receiving the RNR, FSIS will proceed to post the RNR on the FSIS website. CPAO is to inform the firm that if it notifies CPAO of typographical or other inadvertent errors, CPAO is to correct them before posting the RNR.

IV. PUBLIC NOTIFICATION OF RECALLED STATE-INSPECTED OR FOREIGN PRODUCT

A. When a recall is conducted by a retail establishment under a State's inspection program, FSIS may issue a Press Release announcing the intrastate recall to provide factual information, including identification of the State that is verifying the recall and a description of the affected product. A Press Release provides general public notification through the general news media, either national or local, as appropriate.

B. When FSIS is informed by a foreign government's food inspection agency or a company under its jurisdiction that the foreign government or the company is recalling product that may be available to United States (U.S.) consumers, FSIS is to issue a Press Release that provides information similar to FSIS Recall Releases or RNRs. For example, FSIS may issue a Press Release that contains information about a Canadian recall if U.S. consumers could have purchased the product in Canada and then brought it into the U.S. FSIS will also conduct effectiveness checks whenever a foreign government or a company under the jurisdiction of the foreign government recalls product available in the U.S., unless, on review, the Agency determines that effectiveness checks are not necessary in a specific situation. FSIS will follow the same procedure in similar cases when the information is received from other foreign government officials that product is adulterated or misbranded.

V. PUBLIC HEALTH ALERTS

A. If FSIS personnel have reason to believe that a meat or poultry product may be associated with human illnesses, but they cannot identify a specific product that FSIS could recommend be recalled, they should

report the incident through supervisory channels. FSIS typically becomes aware of these situations from the findings of a foodborne illness investigation conducted by, or reported to, OPHS's Applied Epidemiology Staff. If appropriate, the situation should be referred to the EMS, as provided in [FSIS Directive 5500.2](#). If the situation is referred to the EMS, the EMS will decide whether FSIS should issue a Public Health Alert.

B. There may be situations in which the Recall Committee determines that a specific product may present a risk to human health, but the Committee cannot recommend a recall. In these circumstances, the RMTAS Director is to notify the OFO AA, and the other Recall Committee members are to notify their AAs. The OFO AA is to convene a meeting of the AAs and advise the Administrator that he/she is convening this meeting. The AAs will decide whether to issue a Public Health Alert or to take no action on the incident. If the AAs cannot resolve the matter, they are to report the situation as a potential significant incident to be resolved by the ECS, as provided in [FSIS Directive 5500.2](#).

C. If FSIS issues a Public Health Alert the alert will, to the extent possible:

1. Identify the firm that produced the product;
2. Clearly describe the product involved, along with any identifying marks or codes;
3. Identify whether the product presents any health risk;
4. Explain the reason the product is adulterated or misbranded and describe the risks involved in consuming the product;
5. Provide an electronic picture of the product label, if one is available, that clearly describes the product to the public;
6. Instruct consumers on how to properly handle the product if, by some remote chance, they have it in their possession; and
7. If available, provide the name and telephone number of a company contact for consumers and media to call with any questions.

VI. RETAIL CONSIGNEE LISTS

A. For every Class I recall, OFO develops a list of retail consignees that may have, or may have had, the recalled products in their possession. OFO gathers the retail consignee information by first contacting all of the recalling establishment's directly affected consignees. Then, all subsequent consignees to whom the recalling establishment's direct consignees distributed the recalled product are contacted. OFO asks all consignees if they have the recalled products in their possession. OFO also collects retail consignee information while conducting effectiveness checks. If the recalled product is not distributed to the retail level, OFO does not develop a list of retail consignees.

B. FSIS personnel enter the name, street address, city, and state of each retail consignee into an electronic database. As soon as an initial list of retail locations can be prepared from this information, RMTAS does so. RMTAS then sends the list of retail consignees to the FSIS Web Services Staff for posting on the FSIS website. The initial list is posted within approximately 3 to 10 days of the date of the recall.

C. The FSIS Web Services Staff posts to the list periodic updates from RMTAS as additional retail consignee information becomes available. After the initial posting, updates may be frequent for the first several days, and then less often, as new information becomes less available.

VII. SPECIAL CONSIDERATIONS FOR WHOLESALE LEVEL RECALLS

A. There may be instances in which adulterated or misbranded product that is implicated in a recall is not available to consumers because, although the product is in commerce, it has been distributed only to consignees at the wholesale level (i.e., to warehouses or distribution centers) and the producing company was able to regain control over the product before it could be further distributed to the retail, hotels, restaurants and similar institutions (HRI), or consumer level. In this situation, issuing a Recall Release to inform the public of the recall would not be useful to consumers. FSIS will not issue a Recall Release or conduct effectiveness checks beyond the wholesale level for recalls in which a company is able to regain control over adulterated or misbranded product distributed solely to the wholesale level. Instead, the following public notification and recall verification procedures will apply:

1. **Public Notification:** If the distribution of adulterated or misbranded product is limited to the wholesale level, and the company is able to account for and regain control over all recalled product, FSIS will issue an RNR instead of a Recall Release. The Agency will follow the procedures for issuing an RNR in Chapter IV, section III, above. The Agency will issue an RNR instead of a Recall Release even if the recall is classified as Class I or II.
2. **Recall Verification:** If the distribution of adulterated or misbranded product is limited to the wholesale level, and the company is able to account for and regain control over all recalled product, FSIS personnel are to verify that the recalling company conducted proper disposition of the product in question. FSIS personnel are to report their findings to RMTAS through supervisory channels. If during their verification checks, FSIS personnel determine that the recalling firm does not have control over all recalled product, and that product may have been distributed to the retail, HRI, or consumer level, they are to notify RMTAS and the RO.

NOTE: Upon the determination that a recall will involve the issuance of an RNR, but not a Recall Release, RMTAS will typically complete the recall during normal business hours.

CHAPTER V – EFFECTIVENESS CHECKS

I. GENERAL

A. The recalling firm is responsible for developing and implementing an effective recall strategy to notify all consignees of the need to remove recalled product from commerce. Consignees are then expected to notify their consignees of the recall. FSIS personnel are to conduct effectiveness checks to 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. FSIS will conduct effectiveness checks throughout the distribution chain. Effectiveness checks are risk-based and dependent on the class of the recall (which is based on the hazard and any available epidemiological data), the number of consignees, and other relevant factors. If the recalled product was distributed to the wholesale level only, and the producing company has regained control over the recalled product, FSIS personnel are to verify that the producing establishment has retrieved and conducted proper disposition of the recalled product, as described in Chapter IV section VII of this directive.

B. Depending on the availability of Agency personnel and the type of firm conducting the recall, Enforcement Investigations and Analysis Officers (EIAOs) or CID Investigators are to conduct effectiveness checks. Generally, if the recalling firm is an official establishment, the RO is to coordinate and direct IPP to conduct effectiveness checks. If the recalling firm is an importer of record, the RO is to coordinate and direct IPP to conduct the checks and contact the CID Regional Director to obtain assistance from CID investigators to conduct checks. If at any time during the effectiveness checks FSIS personnel discover that a firm did not contact the consignees promptly with recall instructions or that the consignees are not handling product in the manner requested by the firm, FSIS personnel are to detain any product found in commerce as set out in [FSIS Directive 8410.1](#). FSIS personnel are to notify the RO immediately when the recalled product remains available to the consumer and when the recalling firm has not properly implemented its recall strategy.

II. FIELD RECALL RESPONSIBILITIES UPON NOTICE OF A RECALL

A. The RO is to:

1. Serve as the primary point of contact for the recalling firm;
2. Immediately request that the recalling firm provide information regarding product distribution, including the names, addresses, and phone numbers of its consignees (Attachment 1);
3. Review any notice of recall issued by the firm to its consignees or to the public for accuracy of product information, risk, and clarity (e.g., verify that the firm discloses the reason for the recall and describes the product defect or adulterant) and verify that the recall notice does not contain promotional or company information that obscures the risk of the product. If the recall notice is incomplete or inaccurate, the DO is to immediately call the firm and explain the reasons why the notification or instructions are inadequate and follow up the call with a letter to the firm and a courtesy copy to RMTAS;
4. Inquire how the firm plans to control recovered product; and
5. Inquire how the firm plans to handle product disposition.

B. If the firm's recall strategy includes destroying product on site, the RO may assign FSIS personnel to witness destruction of the product in accordance with 9 CFR part 329 or part 381, Subpart U. FSIS personnel are to document this on FSIS Form 8400-4, Report of Recall Effectiveness, as product disposition verification.

III. RO RESPONSIBILITIES FOR COORDINATING FSIS PERSONNEL ACTIVITIES IN EFFECTIVENESS AND PRODUCT DISPOSITION VERIFICATION CHECKS

The RO is to:

1. Coordinate effectiveness checks and direct the activities of FSIS personnel;
2. Determine product distribution and request assistance from Assisting Offices (AOs) in districts/regions where product was distributed. The DDMs/RDs are to determine whether additional consignees should be included on the initial distribution list; and
3. Select a sample of consignees based on product distribution information using an appropriate sampling plan (Attachment 1).

IV. FSIS PERSONNEL RESPONSIBILITIES FOR CONDUCTING EFFECTIVENESS CHECKS

A. 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 less than or equal to the critical number in the sampling plan applied to the effectiveness check (Attachment 1). Using the sampling plan selected by the RO, FSIS personnel are to:

1. Contact or visit the consignees to determine whether they were notified of the recall and have removed the recalled product from commerce;

2. Take appropriate action to detain any recalled product found in commerce in accordance with [FSIS Directive 8410.1](#);
3. Determine the amount of recalled product received by consignees. In cases where a consignee cannot document the amount of the recalled product it actually received, FSIS personnel are to explain this on FSIS Form 8400-4, Report of Recall Effectiveness,
4. Verify that the consignees are handling the product in accordance with regulatory requirements and the instructions of the recalling firm by reviewing records and observing or verifying product disposition. If product is to be destroyed at a Federal establishment, in-plant IPP may be asked to witness the destruction of product; and
5. Record the effectiveness checks on FSIS Form 8400-4 and submit the completed forms to the appropriate district or regional office.

B. In cases where a product disposition verification cannot be made upon an initial check, FSIS personnel are to conduct a follow-up check to verify that the product was handled in accordance with the instructions and regulatory requirements, document this on FSIS Form 8400-4 as a follow-up, and

C. In cases where prohibited acts, such as introducing product that the Agency has reason to believe is adulterated into commerce, are noted or suspected, FSIS personnel are to document the occurrence and contact the RO. The RO is to issue, if indicated, a letter to the firm describing the circumstances of the prohibited act and the potential enforcement or criminal action the Agency may pursue. The RO is then to refer the matter to OIEA/CID. If the recall involves imported product, FSIS personnel are to document the occurrence and contact the RO, who is to refer the matter to OIEA/CID.

D. If, when conducting effectiveness checks, FSIS finds recalled product in commerce, the Agency will consider whether the recalling establishment clearly communicated the recall notification to its consignees. FSIS may find that the recalling firm effectively communicated the recall, but that the recalling firm's consignees failed to ensure that the recalled product was removed from commerce. As necessary, FSIS personnel will follow [FSIS Directive 8410.1](#) and notify the consignee of any prohibited activity.

V. RO RESPONSIBILITIES FOR REVIEWING EFFECTIVENESS CHECKS AND CONFIRMING THE FIRM'S CONTROL AND DISPOSITION OF THE PRODUCT

The RO is to:

1. Compile the recall effectiveness reports from all AOs and State programs to make an overall assessment of recall effectiveness following the criteria and decision guidance in Attachment 1;
2. Analyze the information that is submitted by FSIS personnel on FSIS Form 8400-4 and review any instances in which recalled product was found in commerce. For example, the RO should review the effectiveness check findings to determine whether a pattern or trend exists that may suggest certain consignees were not contacted; and
3. Contact the firm and verify that the firm:
 - a. Controlled the recalled product as planned;
 - b. Disposed of the product as planned; and
 - c. Considers the recall closed.

VI. THE RO DETERMINATION ON THE EFFECTIVENESS OF THE RECALL

A. The RO may determine that the recall was effective based on his or her review of the effectiveness and product disposition verification checks, and that the firm has gained control and made proper disposition of the products. If so, the RO is to send a Final Recall Effectiveness Report (FRER) to the RMTAS Director.

B. The FRER is to include:

1. A summary of the findings of the recall effectiveness and product disposition verification checks; and
2. Any supporting documentation voluntarily provided by the firm, including information about the amount of recalled product recovered.

C. In consultation with RMTAS, the RO may determine that the recall action is ineffective based on his or her review of the effectiveness and product disposition verification checks because of the firm's failure to control and dispose of the product. The RO is to notify the recalling firm, in writing, and provide a courtesy copy of the notification to the RMTAS Director, explaining why the recall action is deemed to be ineffective. The RO is to ask how the recalling firm intends to address the situation. If the recalling firm is unwilling or unable to correct its recall strategy, the RO is to recommend that the Agency take further action to mitigate the risk to the public. The recommended actions may include public warnings, product detentions and seizures, or other appropriate actions.

D. FSIS personnel conducting effectiveness and disposition checks should continue with all assigned checks even though a recall may appear ineffective. The recall activities should be classified as effective or ineffective after consideration of the number of consignees at which product was available to consumers.

CHAPTER VI – CLOSURE AND POST RECALL ASSESSMENT REPORT

I. CLOSURE

A. RMTAS is responsible for submitting a recommendation for closing a recall to the AA OFO. RMTAS's recommendation to close the recall should summarize the recall efforts by the firm and the findings of the effectiveness and product disposition checks.

B. Before submitting the recommendation, RMTAS is to review the recall termination report from the RO and, if a recall is associated with a reported illness, ask the Applied Epidemiology Staff, OPHS, whether there are any current illnesses associated with the recalled product.

1. If data indicate that illnesses continue to occur because product remains in commerce, the recall case will remain open. RMTAS may request that the firm expand the recall if evidence indicates that additional products are causing illness.
2. If data indicate that no additional illnesses associated with the recalled product are being reported, and there are no signs that recalled product remains in commerce, RMTAS may proceed to recommend closing the recall.

C. After receiving concurrence from the OFO AA, RMTAS is to notify the recalling firm, in writing, that the recall is closed and notify the FSIS Web master to move the case from the "open" to the "archived" recall case files on the FSIS Website. RMTAS will provide notification to the Emergency Coordination Staff mailbox.

II. POST RECALL ASSESSMENT REPORT

- A. On a quarterly basis, or when the OPPD AA determines that it is necessary, OPPD will review the events leading to the recall, as well as FSIS's response, to assess whether the Agency can improve its policies and recall procedures.
- B. OPPD is responsible for coordinating the post-recall assessment meeting. Participants in the meeting may include, but are not limited to, the following Agency personnel:
1. Recall Management and Technical Analysis Staff
 2. OFO program personnel:
 - a. Executive Associate for Regulatory Operations;
 - b. District Manager or DDMs participating in the recall;
 - c. Case Specialist from the recalling district; and
 - d. IPP.
 3. OIEA program personnel:
 - a. CID Regional Director;
 - b. CID Supervisory Investigator; and
 - c. CID Investigator.
 4. Other Agency personnel that participated in the recall activities, including personnel from ODIFP, OPPD, OPHS, and OPACE.
- C. When conducting the post-recall assessment, the meeting participants should consider pertinent information within and across program areas, such as, but not limited to, the following information:
1. Recall Effectiveness Checks Reports;
 2. Food Safety Assessments (FSAs);
 3. Enforcement History;
 4. Failures of the establishment's food safety programs;
 5. Reports of Consumer Illness; and
 6. Any pertinent information collected during the preliminary inquiry, as described in Chapter II.
- D. After the close of the post-recall assessment meeting, OPPD will draft a written report. The post recall assessment report should focus on the circumstances that led to the recall and suggest areas where new policy or policy clarification may be needed.

E. The official that drafted the report is to provide a copy to the OPPD AA and to the RMTAS Director. RMTAS is to include the post-assessment report in the official recall file. OPPD will use the information in the report to support new policy development as the need arises.

III. QUESTIONS

Refer questions through supervisory channels.

A handwritten signature in black ink, appearing to read "Rachel A. Edelstein". The signature is written in a cursive, flowing style.

Assistant Administrator
Office of Policy and Program Development

EFFECTIVENESS CHECKS

Effectiveness checks constitute a process by which Food Safety and Inspection Service (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.

When conducting effectiveness checks, FSIS will verify that:

1. The recalling firm has notified all of its consignees about the recall,
2. Consignees have located, retrieved, and are controlling recalled products, and
3. Consignees are following the recalling firm's instructions with regard to the disposition of recalled product, e.g., destruction or return.

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

In some cases, FSIS discovers that the firm is able to account for all adulterated or misbranded product that is in distribution, but is not available to consumers (e.g., in a warehouse or distribution center). If this occurs, and the firm is able to regain control of its product, FSIS personnel will verify that the firm has conducted proper disposition of the product in question. FSIS personnel will report their findings through supervisory channels to the Recall Management and Technical Analysis Staff (RMTAS). The RO will submit a summary memo to RMTAS.

A. Roles and Responsibilities

1. Industry - The recalling firm is responsible for conducting the recall and for ensuring that its actions have been effective in removing the product from the marketplace. Recall activities by firms are to start immediately upon deciding to conduct a recall or upon receiving notification of a recall.

2. FSIS – FSIS will use effectiveness checks to verify that the recalling firm is conducting the recall effectively, i.e., that the firm is locating, retrieving, and controlling the product and that recalled product does not remain available to consumers. FSIS personnel conduct effectiveness checks by visiting consignees or contacting consignees by phone. As part of its effectiveness checks, FSIS will verify the disposition of the recalled product. 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.

B. Coordinating Effectiveness Checks

A district official is responsible for coordinating all field recall activities and will serve as the primary point of contact with the recalling firm. A Deputy District Manager (DDM) or other relevant program personnel in the Office of Field Operations (OFO) or a managing official from another appropriate program area (e.g., OIEA Regional Director (RD)) will serve as the Recall Officer (RO) and coordinate the effectiveness checks. If the recall spans across multiple districts or regions, the RO that has the jurisdiction over the recalling firm will coordinate activities across those lines with Assisting Offices (AO).

The RO will:

1. Determine the number of consignees that will receive effectiveness and on-site product distribution checks by using risk-based tables (Tables 2-5) to develop an appropriate sampling plan.
2. Direct FSIS personnel and coordinate with AOs located in other districts or regions.
3. Review the effectiveness check reports and respond by adjusting the sampling plan, as needed, to ensure consignees have removed product from commerce.
4. Compile all findings and report its overall assessment of the firm's recall effectiveness to the RMTAS.

Effectiveness Checks:

1. Are risk-based and dependent on the class of the recall (the hazard) and the number of consignees (the product exposure to consumers). FSIS personnel will verify that the firm is locating, retrieving, and controlling the product and that recalled product does not remain available to consumers. The checks will verify that the consignees are handling the product in accordance with regulatory requirements and the instructions provided by the recalling firm, including those for product destruction or return,
2. Are performed by on-site verification or by phone. FSIS personnel will contact 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, and
3. May disclose that product subject to recall remains available to consumers and in commerce. FSIS inspection program personnel will immediately notify the DDM or RD in their district or region for further instructions and may detain the product.

C. Effectiveness Checks Sampling Plan

The RO will use a risk-based sampling plan to determine the number of consignees that FSIS personnel will contact during the effectiveness checks. The number of consignees that FSIS will contact will depend on the class of the recall and the number and type of consignees that received the recalled product.

D. Timeliness of Effectiveness Checks

Upon notice of a recall, the RO will immediately request information and records of the recalling firm and subsequent consignees regarding the distribution of recalled product (*per* 9 CFR 320.1). The information should contain sufficient details to allow FSIS personnel to understand the distribution patterns and make contacts without further delay.

The RO will be able to develop the recall effectiveness check sampling plan in a more efficient manner if the recalling firm's distribution records, as well as those of any subsequent consignees, are in an electronic format. Therefore, when the RO requests consignee records from the recalling firm, or the AO requests subsequent consignee records, they should ask whether the firm maintains electronic records. If the firm does, then the RO/AO should request that the firm provide its distribution information in an electronic format.

The Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and their implementing regulations require that companies give FSIS personnel access to their places of business and the opportunity to examine and make copies of their records (21 U.S.C. 642(a) and 460(b); 9 CFR 320.1 and

381.178). If a recalling firm maintains electronic records, FSIS personnel are authorized to gain access to and make copies of such records.

The RO will attempt to obtain the complete distribution information regarding the recalled product within the timeframe recommended in Table 1. Each district/region should consider 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. 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 AO to notify the RO.

During the recall, the RO also has an oversight function of assessing whether the recalling firm has in fact initiated and is performing the recall activities necessary for there to be a successful recall.

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:
<i>Class I</i>	3 days*	10 days
<i>Class II</i>	5 days	12 days
<i>Class III</i>	10 days	17 days
* Working days: Working days may include Saturday and Sunday, depending upon the risk associated with a recalled product.		

E. Determining the Total Number of Consignees and Compiling the Master Consignee List.

1. The RO will, in discussion with the recalling firm, and, if some consignees are distributors, in consultation with AOs, determine the best estimate of the number of consignees and begin to develop a master list of consignees, i.e., entities that received the recalled product or that 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 1,200. The effectiveness checks are done based on 1,200 consignees.

Note: Consignees that are identified after FSIS has started conducting effectiveness checks are to be added to the end of the master consignee list and included in the sampling plan. If necessary, the sampling plan is to be updated to ensure that consignees that are added to the master list receive an appropriate number of effectiveness checks. Additional consignees added to the master list will also need to be randomized as provided in section E.3. below.

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 its best estimate to FSIS by phone or e-mail before sending more detailed distribution information. However, care must be taken that the estimate does not significantly differ from the actual distribution information.

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

2. Eliminating duplicate consignee listings: After the RO has started the master consignee list and has obtained more detailed distribution information about the recalled product, he or she is to examine the consignee list for duplicate entries of the same consignee and remove any consignees that are listed more than once.

- If the consignee list is provided in an electronic spreadsheet format, the RO can sort the list by consignee or address to easily identify and remove any duplicate consignee entries.

- If there are multiple consignee lists, the RO can consolidate the lists into one electronic format. The RO can then sort the electronic consolidated list by consignee or address and remove any duplicate entries.

- If the consignee list is only available as hard copies, the RO can either: 1) consolidate the hard copies into an electronic spreadsheet format and eliminate the duplicates as described above or 2) approximate the procedure described above using the hard copies, e.g., examine the hard copies and cross out duplicate or multiple consignee listings.

3. Randomize the consignee list: After eliminating duplicate listings of the same consignee, the RO is to randomize the consignee list. Randomization can be accomplished through either of the following methods.

a. If the master consignee list is in an electronic format, the RO can use the electronic spreadsheet program to assign a random number to each consignee on the list and then sort the consignees by random number. After randomizing the consignee list, the RO should follow the instructions in Section I. 3 of this attachment when preparing the sampling plan, or

b. If the master consignee list cannot be sorted electronically, the RO can generate a list of random numbers as provided in Section I. 4 of this attachment and use these numbers to randomly select consignees for effectiveness checks. If this method is used, the RO should follow the instructions in Section I. 4 of this attachment when preparing the effectiveness checks sampling plan.

States with a Memorandum of Understanding (MOU). Under 9 CFR 390.9, FSIS may have an MOU with one or more States. The specifics of each MOU will vary. In general, when States and FSIS have MOUs to conduct their own 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.

NOTE: Recall procedures for meat and poultry products produced in an establishment operating under the Cooperative Interstate Shipment program are addressed in Chapter IV, Section I, Paragraph D of [Directive 5740.1, Cooperative Interstate Shipment Program](#).

F. Determining the Total Number of Effectiveness Checks to Conduct

After the RO has removed duplicate consignee entries from the master consignee list and has determined the total number of consignees, the RO will determine the total number of effectiveness checks that will be performed by on-site verification and by telephone. These numbers are derived from values given in the sampling tables in this document. If there is sufficient information, the RO may decide to group effectiveness checks by special consignee categories (e.g., schools, day care centers, hospital cafeterias, or retirement homes). If the RO decides to group effectiveness checks by special categories, he or she is to determine the number of effectiveness checks based on each consignee category as provided in Section G of this attachment.

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 (see Section G: Special Considerations for Sorting the Consignees List).

Table 2. Effectiveness checks to conduct and critical limits for <i>all</i> Class I recalls involving an illness or outbreak, or school lunch implications.		
Number of Consignees	Number of Effectiveness Checks to Make	Recall Considered Ineffective if the Number of Consignees at which Product was Available to Consumers Exceeds:
1 to 200	100% of consignees	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

1. 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 at which Product was Available to Consumers Exceeds:
1 to 20	100% of consignees	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

2. Table 4 is used for Class II recalls.

Table 4. Effectiveness checks to conduct and critical limits for Class II recalls.		
Number of Consignees	Number of Effectiveness Checks to Make	Recall Considered Ineffective If the Number of Consignees at which Product was Available to Consumers Exceeds:
1 to 5	100% of consignees	0
6 to 25	5	0
26 to 150	13	0
151 to 280	15	0
281 to 500	32	1
501 to 1,200	37	1
1,201 to 2,300	42	1
2,301 to 10,000	64	2
10,001 and over	91	3

3. Table 5 is used for Class III recalls.

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 at which Product was Available to Consumers Exceeds:
1 to 8	100% of consignees	0
9 to 50	5	0
51 to 90	7	0
91 to 150	10	0
151 to 280	20	1
281 to 500	25	1
501 to 1,200	30	1
1,201 and over	42	2

Effectiveness and disposition checks for Class III recalls will be performed by telephone, unless the RO determines that on-site verification is necessary.

G. Schools and other Special Consignee Categories

If information is available, the RO may group effectiveness checks by identified special categories (e.g., schools, day care centers, hospital cafeterias, and retirement homes), to mitigate risk to populations that may be more susceptible to foodborne illness. If the RO decides to separate groups by special categories, then each group of consignees should be considered separately. Use the tables to determine the number of effectiveness checks to be conducted for each special group. This will have the effect of increasing the number of effectiveness checks to be conducted at these facilities.

During Class II and Class III recalls, schools may also be grouped into a special category of consignees for conducting effectiveness checks. FSIS typically does not conduct effectiveness checks on schools that participate in the School Lunch Program or other assistance program administered by USDA’s Food and

Nutrition Service (FNS) and that receive reimbursement for the cost of the recalled product by FNS. However, FSIS may determine that effectiveness checks or other actions are necessary at such schools, on a case-by-case basis. During Class III recalls, all checks may be conducted by telephone.

In special limited circumstances, to protect public health, FSIS may decide to conduct a greater number of effectiveness checks than the number provided in the tables. For example, FSIS may increase the number of effectiveness checks if the recall involves a product that has been implicated in human illnesses and the Agency continues to receive reports of new illnesses after the issuance of the Recall Release.

H. Determining the Number of Disposition Verification Checks

The purpose of disposition verification checks is to verify the disposition of the recalled product. A subset of the total number of effectiveness checks for Class I and Class II recalls will be selected for on-site visits to verify that consignees have located, retrieved, and controlled recalled product according to the recall notification. Class III recalls are discussed below. All firms that received the recalled products are expected to remove that product from commerce.

1. For Class I recalls involving illness, outbreaks, or school lunch implications, the RO will consult with RMTAS on the number of on-site verifications.

2. For Class I recalls that do not involve illnesses, outbreaks, or school lunch implications and Class II recalls, 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.

3. For Class III recalls, which by definition have no public health implications, effectiveness checks will generally be conducted by telephone. However, if determined to be necessary, they may be conducted on-site.

FSIS personnel are to document recall effectiveness checks findings on FSIS Form 8400-4, Report of Recall Effectiveness. Information collected on-site or by telephone should be recorded on FSIS form 8400-4. This form should also be used to document findings by FSIS personnel conducting disposition verification checks.

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 37. Using the same table, this time inserting 37, 13 of those 37 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.

Number of Consignees	Number of Effectiveness Checks to Make	Recall Considered Ineffective if the Number of Consignees at which Product was Available to Consumers Exceeds:
1 to 5	100%	0
6 to 25	5	
26 to 150	13	
151 to 280	15	
281 to 500	32	1
501 to 1200	37	
1201 to 2300	42	
2301 to 10,000	64	2
10,001 to and over	91	3

I. Preparing the Effectiveness Checks Sampling Plan

The RO prepares an effectiveness checks sampling plan in consultation with AOs.

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

For a Class II recall and 600 consignees, the appropriate table is Table 4 and the number of effectiveness checks to conduct is 37.

2. If the RO decides to group effectiveness checks into special categories (e.g., schools, day care centers, hospital cafeterias, and retirement homes), then each group of consignees is considered separately. Use the tables to determine the number of effectiveness checks to be conducted for each group.

In the example above, if the 600 consignees include three (3) special consignee groups of 200 consignees each, then Table 4 shows that each group would have 15 effectiveness checks conducted. Thus, the total sampling number of effectiveness checks for all three (3) groups would be 45.

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

3. If the master consignee list has been randomized as provided in Section E.3.a., determine a sampling interval by dividing the total number of actual or estimated consignees by the number of effectiveness checks to be performed.

In this example, divide 600 by the minimum sample size (example 37). The sampling interval would be 16 (600/37 = 16.2 rounded to the lower whole number).

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

For this example, select number 3.

b. Start at the top of the master consignee list and count down until reaching the consignee located at the randomly selected starting point. This will be the first consignee selected for an effectiveness check. Then select subsequent consignees from the list according to the predetermined sampling interval.

In the example above, the sampling interval is 16, and the starting point is 3. Beginning at the 3rd consignee, add the sampling interval (16). Select the 19th, 35th, 51th ... and so on until enough consignees are identified for the effectiveness checks.

4. If the master consignee list has not been randomized as provided in Section E.3.a., use random numbers to select consignees from the master list for effectiveness checks. This can be done by using the random number generator that has been loaded on all FSIS computers.

a. Open the random number generator (Start→FSIS Applications→Other Tools→Random Number Generator).

b. Generate a list of random numbers. Use one as the lower bound number, use the total number of consignees for the upper bound number, and use the number of effectiveness checks needed as the number of random numbers to be generated. Do not allow the program to generate duplicate numbers by checking the “no duplicates” box.

In the example above, there are 600 consignees and the tables provide for 37 effectiveness checks. In the random number generator, enter 1 as the lower bound number, 600 as the upper bound number, and 37 for the random numbers that need to be generated. The random number generator will create a list of 37 random numbers, e.g., 5, 8, 14, 22, 44, 47, 51...

c. After generating the random numbers, select consignees for effectiveness checks. Start at the top of the list and count down to the consignee that corresponds with each random number. Select these consignees for effectiveness checks.

In the example above, 37 random numbers will be generated, e.g., 5, 8, 14, 22, 44, 47, 51. Counting down from the top of the consignee list, select the 5th, 8th, 14th, 22nd, 44th, 47th, 51st, , consignee for effectiveness checks.

5. Provide information on the consignees selected for effectiveness checks to the FSIS personnel that will be conducting the checks. If the recalled product was distributed to consignees in more than one district or region, distribute the sampling plan to the appropriate AOs. The AOs will assign FSIS personnel to perform the effectiveness checks in their district or region.

The information that the RO provides to the FSIS personnel conducting the effectiveness checks should include the consignees selected for effectiveness checks, the consignees that will need product disposition verification checks, the recommended timeframes for completion, the related recall numbers, and any other details that may help conduct the verification activities more effectively.

J. FSIS Personnel Responsibilities for Conducting Effectiveness Checks

Based on Agency resources and the FSIS field office responsible for coordinating the effectiveness checks, the following FSIS personnel could be responsible for conducting effectiveness checks: Enforcement, Investigations, and Analysis Officers (EIAOs), Public Health Veterinarians (PHVs) trained in EIAO methodology or OIEA/CID.

FSIS personnel will conduct an appropriate 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.

FSIS personnel also will assist the RO in identifying consignees, selecting consignees in accordance with the sampling plan, conducting effectiveness checks, and taking appropriate corrective actions.

If FSIS personnel are unable to perform an effectiveness check (e.g., a consignee in the sampling plan did not receive the recalled product or is no longer in business), they are to contact the RO so a replacement effectiveness check can be selected and assigned. The RO will use the master distribution list to identify the substitute consignee by selecting the next consignee on the master list. After making this substitution, the RO will assign this effectiveness check to the applicable AO and FSIS personnel will conduct effectiveness checks on the remaining consignees as if there had been no substitution.

Example: *Using the example discussed in 1.3.b., if the 19th consignee was designated for an effectiveness check but the consignee was no longer in business, the RO would select the 20th consignee on the master list as the substitute effectiveness check. The RO would then assign the substitute effectiveness check to the applicable district/region. In the instance where the last consignee in the sampling frame is ineligible for an effectiveness check, substitute the consignee immediately preceding the ineligible consignee.*

If the consignee selected for substitution is also ineligible for an effectiveness check, the RO is to select another substitute consignee. The second substitution can either be the next consignee on the list or a consignee that the RO believes is likely to have received the recalled product (biased substitution). The RO should make a reasonable attempt to find a substitute consignee until the effectiveness check can be completed.

If both the 19th and the 20th consignees in the example above were out of business, the RO would select the next effectiveness check using either the 21st consignee on the master list or another consignee that the RO believes is likely to have received the recalled products (a biased substitution).

If FSIS personnel are having difficulty locating a substitute consignee that received the recalled product, the RO is to contact RMTAS.

Note: There can be no substitutions if the sampling plan provides for effectiveness checks on all consignees.

When conducting effectiveness checks, FSIS personnel are to:

1. Ensure that copies of the Recall Release or Recall Notification Report (RNR) and labels of the recalled product are on hand when conducting verification activities. These documents can then be referenced or left with consignees, if needed.

2. Conduct checks to determine whether consignees have received notification of the recall action from the recalling firm or other consignees and have taken the prescribed action regarding product, such as returning it to the recalling firm or identifying and holding it for pick-up. If available, FSIS personnel are to obtain from the consignee documentation regarding recall notification (e.g., copy of e-mail notification) and documentation of product disposition (e.g., reclamation documentation from distributor or electronic notification from consignee to corporate office identifying product disposition).

3. Conduct checks by on-site observation, records review, or telephone, based on resources and knowledge of the recalling firm's and consignees' practices.

4. Determine whether any recalled product remains available to consumers, e.g., by checking store shelves, storage, or freezers during on-site visits.

5. Conduct checks to determine whether the recalling firm or consignees have disposed of the recalled product according to the prescribed action.

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

7. In cases where consignees were not notified of the recall, ensure that the appropriate

associated firms, including distributor, chain store head office, or individual store, are notified and take action if necessary to detain product that is recalled.

8. Continue with all the assigned checks.

Submit verification results, including findings of product in commerce, and the names of consignees that were not notified by the recalling firm to the RO via the fastest possible means (e-mail, fax, telephone) as soon as possible.

K. “Findings of Product in Commerce” is defined as those occurrences where recalled product remains available to consumers.

1. When the DDM/RD is notified by personnel in his or her district/region of findings of recalled product in commerce, he or she will immediately notify the RO.

2. The RO 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 of consignees 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 recalled product that is available to consumers. As deemed appropriate and necessary, the RO will notify the Director of the Compliance and Investigations Division (CID), OIEA.

L. Special Circumstances -- Determining the Need to Consult a Statistician

Although rare, there may be instances in which FSIS personnel may need statistical guidance when performing recall effectiveness checks. For example, FSIS personnel may not be able to contact consignees in the sampling plan because the consignees are mobile (e.g., the product was distributed to cruise ship or for door-to-door sales) or the recalling firm sold recalled products directly to consumers.

In these circumstances, FSIS personnel are to inform RMTAS. RMTAS will contact the Office of Data Integration and Food Protection (ODIFP) statistician assigned to assist with recalls and will refer the statistician to the appropriate RO. The ODIFP statistician will work directly with the RO to provide any needed statistical guidance.

M. RO Determines the Effectiveness of the Recall

1. 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 recalled product in commerce must be equal to, or less than, the critical number in the sampling plan as shown in the corresponding tables 2,3,4 and 5.

(2) The RO should review the results of the recalling firm’s effectiveness checks. This activity is most effective when conducted on-site and 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 recalled product from commerce, 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.

2. Examples of Effective and Ineffective Recalls:

a. The RO makes the determination of whether a recall is effective or ineffective in consultation with RMTAS. FSIS 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 may differ (generally be higher) from the count listed in the 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 the number of consignees at which product was available to consumers.

b. Using the previous example 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 five (5). There can be no more than five (5) consignees with recalled product available to consumers.

Example I: All consignees checked have received the Notice of Recall from the recalling firm and have removed the product from sale. *The recall is deemed effective.*

Example II: Nine (9) 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 (6) of the nine (9) consignees have removed the product from sale. The remaining three (3) consignees have identified and segregated the product awaiting shipment to the recalling firm. No product is available to consumers. *The recall is deemed effective because no product is available at the nine (9) consignees and the number of consignees at which product was available to consumers is not exceeded.*

Example III: FSIS personnel find that four (4) consignees have not received the Notice of Recall and are still offering the product for sale. Five (5) more consignees received the notice but have not taken the requested product action. *The recall is deemed ineffective because the product remains available to consumers at a total of nine (9) consignees, exceeding the critical number of five (5) consignees.*

3. Whenever recalled product is found in commerce during an on-site verification check at a consignee (or sub-consignee), FSIS personnel will detain any of the products on hand in accordance with [FSIS Directive 8410.1](#).

4. FSIS personnel will ascertain whether the business received a recall notification and instructions from the recalling firm or one of its consignees.

5. FSIS personnel will notify the RO of their 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 RO will proceed as discussed below in Section 4.

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 RO will issue, when the facts indicate, a letter to the firm describing the circumstances of the prohibited act and the potential enforcement or criminal actions that the Agency may pursue. If the recall affects multiple districts/regions, the district/region with jurisdiction over the consignee that may have committed the prohibited activity will issue the letter. When applicable and deemed necessary, the district that issued the letter will also refer the matter to the OIEA/CID.

6. When applicable and deemed necessary, the RO will also notify any State or local food or health authorities with jurisdiction over the business involved for their appropriate follow-up action in conjunction with OIEA.

7. Responding to an ineffective recall -

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

b. The RO will write a letter to the recalling firm detailing the reasons why the recall has been found to be ineffective. The RO 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 their 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 the issuance of public warnings, product seizures, or other appropriate legal or compliance actions in accordance with the FMIA and PPIA.

N. Verification Result Summaries

1. The RO will prepare a summary of recall activities and provide it to RMTAS. The summary should:

a. State the total number of assigned effectiveness checks and disposition verification checks performed and the numbers conducted both on-site and by telephone, as well as the number of invalid consignee locations for which substitutions were requested.

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

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

d. Identify reasons for continued sale.

e. Identify other deficiencies in the firm's recall process (if applicable).

f. Summarize actions taken by FSIS in the case.

2. The summary should include a description of the corrective actions taken to address each identified deficiency (i.e., the product was removed and segregated in the shipping area and re-notification was issued for all convenience stores, including names of affected distributors, as applicable).

3. The RO will send the memo to the RMTAS Director.

Factors That Are Considered by the FSIS Recall Committee in Evaluating the Public Health Significance of an Undeclared Ingredient in 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, and in some instances adulterated, under the FMIA or PPIA if it contains ingredients that are not declared on the 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 present a health risk to individuals that are allergic or sensitive to the ingredient, which would necessitate removal of the product from commerce. The most common example would be a potential food allergen, such as peanuts. FSIS Directive 8080.1, *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.

There is a particular concern about health situations in which a meat or poultry product contains an undeclared ingredient that may cause an adverse reaction in allergic or sensitive individuals. Such a reaction may occur when a person has either an allergy or intolerance to a particular food or substance. A food allergy is a specific condition in which a person's immune system reacts to certain foods. 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 (known as the "big eight"): wheat (including rye, barley, oats, spelt or their hybridized strains and products of these); shellfish; egg products; fish products; peanuts; soy; 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 tartrazine (FD&C Yellow No. 5). 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 an undeclared ingredient in a meat or poultry product, 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 an undeclared ingredient.

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 "no observed adverse effect level" that can be used in estimating risk. In these cases, a higher amount of the ingredient

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.

is more likely to elicit an adverse effect, giving support to classifying the recall as one in which there is a significant public health concern, that is, Class I. The lower the amount of the ingredient, the more reason there is to classify the recall as Class II. For most known allergens, there is no conclusive scientific evidence to establish threshold levels for eliciting an adverse reaction. In most cases, the presence of an undeclared substance that is a known allergen, at any level, poses a public health risk and thus the recall 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 Allergic or Sensitive Consumers from a Food Containing an Undeclared Ingredient?

The likelihood that an adverse effect will occur as a result of human consumption of a meat or poultry product that contains an undeclared ingredient plays a large role in determining recall classification. The probability that someone in the most sensitive subpopulation may be exposed to an ingredient that is not declared on a product's labeling must be taken into account. The magnitude and severity of an adverse reaction, should it occur, are also significant. The greater the likelihood, magnitude, and severity of an adverse effect in a sensitive population, the more reason to classify the recall 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 ingredient. It should be considered that, in some limited cases, the presence of a potential allergen or other substance of public health concern 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 that is capable of deactivating an allergen or other substance, the more reason to classify any recall of product that contains the ingredient 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" category of allergens, 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 non-declaration involves ingredients that are *not* among the "big eight" allergens or that are not known to cause food intolerances, the most allergic or 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 the recall as Class I.

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

This document identifies the factors that are central in the evaluation of situations in which a meat or poultry product contains an undeclared ingredient that may have implications for 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. The estimate of this 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.

PRODUCT RECALL GUIDELINES FOR FIRMS

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1. Guiding Principles for Recall Plans

Introduction

A recall is an effective method of removing product that may be adulterated or misbranded from commerce. Firms, including manufacturers, distributors, or importers of record, take these actions as part of their responsibility to protect the public health and welfare. A recall is voluntary, and the firm takes responsibility for the decision to recall product. FSIS coordinates with the firm to ensure that it has properly identified and removed recalled product from commerce by verifying the effectiveness of recall activities. FSIS also notifies the public about product recalls.

A recall may be an alternative to FSIS detention or seizure of adulterated or misbranded products. However, a recall does not preclude FSIS from taking other appropriate actions, such as issuing Public Health Alerts or performing product detentions and seizures, to mitigate the risk to the public when firms have inadequately removed recalled product from commerce. The Agency will investigate if it appears that the recall strategy or execution of that strategy is ineffective. Based on its findings, FSIS may seek enforcement action against the firm or its consignees.

A recall can occur for many different reasons. Typically, the reason for the recall is not discovered until the product is already in distribution channels. Ways a firm may learn about the problem include through FSIS, the firm's customers, consumer complaints, or its own review of company or laboratory documents. When an official establishment believes or has reason to believe that adulterated or misbranded product has been shipped into commerce, it must inform its district office (DO) of the type, amount, origin, and destination of the product. Early detection and recognition that a problem may exist is essential to a successful recall action.

A recall can be disruptive to a firm's operation and business; however, there are several steps that can be taken 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.

Official establishments are required to have recall plans that describe the actions they will take to recall adulterated or misbranded products that are in commerce, as provided by 9 CFR 418.3. A recall plan must consist of written procedures that specify how the official establishment will decide whether to conduct a product recall and how it will affect the recall, should it decide that one is necessary.

Recall Plan

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 need to be conducted. However, the key activities discussed below can be performed by one (1) or two (2) 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 regularly employed personnel, for the potential of having to conduct a recall.

FSIS regulations require official establishments that produce meat and poultry products to prepare and maintain written recall plans. The plan must specify how the firm will decide whether to conduct a product recall, and describe, step-by-step, the procedures to follow if a product recall is necessary. In addition, FSIS requires that the recall plan be available for review upon request. The following is a list of factors to consider when formulating an effective recall plan.

A. Recall Team Members.

One person should be identified as the recall coordinator. The recall coordinator should be authorized to make decisions regarding recall implementation. This person is responsible for managing and coordinating all recall-related activities. The Recall Coordinator will have access to the recall plan and should be knowledgeable about the firm's operations, including purchasing, processing, quality assurance, distribution, and consumer complaints. The recall coordinator should select people to form a recall team. In establishments with only a few employees, one person can have multiple roles. There is no need to hire additional personnel to execute a recall plan.

For each internal and external member involved in the recall action, contact information (telephone, facsimile numbers, and e-mail addresses, as appropriate) should be identified. In the event that the primary team member is absent, an alternate should be specified. All contact information should be reviewed regularly for accuracy. The roles and responsibilities of every person should be clearly defined.

A firm's recall plan should include the telephone number of its FSIS DO.

B. Procedures for Determining Whether a Recall is Necessary.

The recall plan should specify, in detail, actions that the firm will take. All information should be reviewed in determining whether to implement a recall. Factors to consider include:

- 1) Has adulterated or misbranded product been produced?
- 2) Has adulterated or misbranded product been shipped?
- 3) Where has the product been shipped?
- 4) Is the product in commerce?
- 5) Is the product available to consumers?

Note: If adulterated or misbranded product is in commerce, the firm must notify the applicable FSIS DO within 24 hours. FSIS will then determine the class of the recall based on the potential health risk.

C. Scope of Recall.

The plan should outline how the establishment will assess the amount and kind of product that is implicated in a problem. It is the firm's responsibility to define when the problem began, when it was resolved, and what products are affected. As much of this information as possible should be available when the FSIS DO is contacted.

FSIS suggests that the plan specify how the amount of product affected under various scenarios will be determined. Some examples of how to define the scope of product removal actions 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; processing and packaging operations; equipment; the establishment's HACCP plan monitoring and verification activities (including microbiological testing); the establishment's Sanitation SOP records; and whether some or all of the products controlled by the same or substantially similar HACCP plans have been affected. Clean up times do not necessarily define the scope of a recall.

It is to the firm's benefit to identify correctly the scope of the recall. If the recall needs to be expanded, additional FSIS Recall Releases may be issued, resulting in further media postings. If the firm cannot be certain of the amount of product affected, it is better to be more inclusive in the estimate than to risk an expansion. Good recordkeeping is often the easiest way to maintain accuracy.

D. Records.

All firms should use a system of product coding sufficient to permit positive product identification and to facilitate effective recalls. 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). Records are vital in tracing product forward to consignees and back to potential suppliers. They include invoices, bills of sale, and shipping documents. Records a firm should have on hand include:

- 1) Records for positive identification of products produced (labels, lot numbers, Julian codes,), and
- 2) Distribution information for recalled products. These records may include names/addresses of consignees, method of shipment, date of shipment. It is also useful to note consignees that are schools, hospitals, and distributors.

Firms should maintain production records that would facilitate the traceback of product ingredients. This will help determine causes of adulteration and define the scope of recalls. In the event a recall is necessary because of a positive result on an Agency sample or an outbreak of foodborne illness, verifiable records may be used to demonstrate limiting factors to narrow the scope of a recall. Moreover, the records would be essential in facilitating the traceback of the contamination to its source.

Regarding *Escherichia coli* O157:H7 and non-O157 STECS, establishments are expected to maintain supplier records for their raw ground beef components and to make these records available to Agency personnel upon request. Then, if a sample of raw ground beef is reported positive, suppliers may be notified that their product may have been the source of contamination. The information FSIS 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 traceback in an effort to find the source of contamination.

If a recall is necessary, a prudent establishment may be able to limit the amount of affected product if it has a detailed record keeping system in place. Carefully maintained production records can serve a vital public health purpose. They provide the establishment and the Agency with a 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 and supplier lot identification; the finished product lot and subplot identification; and any microbial data or other information that may indicate microbial independence. The records should indicate and track which lots or sublots of a grinding establishment's ground beef or other raw materials were used. The records should also track the amounts of each that were used.

Here's a practical example. If a recall of raw ground beef products is necessary because of contamination with *E. coli* O157:H7, a key factor in limiting the scope of the recall would be if the establishment (or retail store) is cleaning the grinding equipment between lots. If not, there could be residue contamination from one lot to another. A grinding log indicating lot numbers, supplier, and clean up times, may help limit the scope of the recall. Having these records be clear and easily available will also help the recall process to occur more smoothly.

E. Recall Communications.

Firms should issue a recall notice to consignees by e-mail, telephone, letter, or fax. Written notices should bear a prominent heading to indicate the importance of the communication. For example, a letter might bear a bold red declaration, "URGENT FOOD RECALL." If communication is conducted by phone, it should be followed with a letter, e-mail, or fax. When drafting your recall notice to your direct consignees, consider the following:

- 1) Be brief and direct;
- 2) Explain the reason for the recall and the associated hazard;
- 3) Clearly describe the product and provide sufficient information to enable the accurate and immediate identification of the product including:
 - product/brand name
 - product code
 - package/case size
 - package/case date code
 - lot number/expiration date
 - UPC code;
- 4) Provide an explanation of the risk involved if product is used;
- 5) Request an official, written response from the consignee firm. Provide a ready means for the recipient of the communication to report to the recalling firm whether it has any of the product. Consider allowing the recipient to place a collect call to the recalling firm;
- 6) Provide instructions on what to do with the recalled products. Those instructions can include anything from destruction at the consignee location to return to the official plant; and
- 7) Provide plant contact information (for questions).

The recall communication should not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message.

F. Public Notification.

Identify if and how the public will be notified of the recall. Recalls are often announced via a press release through national or local news media or via a company website. 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. The class of a recall and the extent to which the product was distributed in commerce (wholesale, retail, or hotel/restaurant/institutional (HRI)) will determine the distribution of public notification.

NOTE: Regardless of the public notification action taken by the recalling firm, FSIS will generally issue a Recall Release for Class I and Class II recalls, unless the recall involves product that has only been distributed to the wholesale level and the recalling firm is able to regain control over it before it can be further distributed to the retail, HRI, or consumer level. For these wholesale level recalls, and for Class III recalls, FSIS will generally only issue a Recall Notification Report (RNR) that is not distributed to media outlets. The Agency will also post all Recall Releases and RNRs on the FSIS website (www.fsis.usda.gov/OA/recalls/rec_actv.htm).

G. Effectiveness Checks.

The purpose of effectiveness checks is to verify that all consignees identified by the recalling firm have received notification about the recall and have taken appropriate action. The methods for contacting consignees should be specified and may be accomplished by personal visits, telephone calls, e-mails, letters, facsimile transmissions, or a combination thereof. This is a means of assessing the progress and efficacy of a recall.

The firm should consider the following information:

- How much product is implicated in the recall?
- How is this product identified to a customer/retailer (e.g., lot markings)?
- 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? 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 placed on hold or was no longer in a customer's control?

FSIS will conduct effectiveness checks.

H. Returned Product Control and Disposition.

The recalling firm must specify how the recalled product will be disposed and how it will be controlled pending disposition. Agency personnel should be notified prior to disposition actions (e.g., destruction or relabeling) of product returned to the firm. (Destroy means to render inedible for humans and animals and to make all labeling unusable for trade.)

I. Recall Simulations

To evaluate how well its plan will work in the event of an actual recall, the establishment should conduct periodic simulations. A recall simulation or mock recall is used to determine whether the firm's recall plan is effective at identifying and quickly controlling a given lot of potentially affected product and reconciling the quantities produced, in inventory, and distributed.

A simulated recall should involve the selection of at least one lot of product that has been distributed in commerce. The recall plan should specify a hypothetical reason for recalling the product and it should be followed to establish a strategy for recalling the product. The mock recall should occur without prior notice to personnel involved. 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 occurs with the firm's primary consignees. 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 might be addressed before an actual recall occurs.

Mock recalls will identify potential problems and allow personnel to become familiar with recall procedures. The results of conducting mock recalls should be documented and reviewed by the recall team to improve the written recall plan. If problems are identified during a recall simulation, the recall plan and procedures should be revised to correct the problems. Mock recalls will make a recall process run smoother, keep the recall team prepared, and provide the recall team with confidence to implement a successful recall action.

J. Final Actions

The firm's plan should also include procedures for notifying FSIS once all reasonable efforts to recover and dispose of the recalled products have been made. The firm should provide the relevant information to the Agency to permit official recall termination.

K. Functional Food Defense Plan

Firms are not required to have food defense plans. However, a voluntary functional food defense plan is an important tool that can enhance the protection of an establishment and its products from vulnerabilities that can cause a potential threat to the food supply. One potential threat is the intentional adulteration of products that the establishment manufactures. In such an event, swift removal of the adulterated materials is essential to protect the public health and welfare. One mechanism for doing this would be a recall. By having an integrated recall-food defense plan, a firm can implement either one, or both, of these measures at a moment's notice, as needed.

2. Notifying FSIS of Recalls

An official establishment has 24 hours in which to notify FSIS that adulterated or misbranded product is in commerce. If it determines that a recall will be undertaken, it should notify FSIS immediately. When doing so, the official establishment should notify DO personnel in the district where it is located. When other firms, including importers of record, learn or determine that adulterated or misbranded product has entered commerce, FSIS expects those firms to immediately notify RMTAS or other FSIS personnel. The basic information that should be conveyed to FSIS includes, but is not limited to, the following:

- Complete and accurate product identity, including product labels (electronic images whenever possible)
 - The reason for the recall and details about when and how any defect or deficiency was discovered
 - 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 geographic distribution of the recalled product by state and by country, if exported
 - Information regarding distributors and customers who received the product
 - Copies of any firm correspondence with distributors, brokers, or customers relating to the recall strategy or actions, as well as a copy of any proposed press release
- The name, title, and telephone number of the recall coordinator for the firm

The firm may provide this information orally, initially, but FSIS will confirm it. For clarity, it is recommended that the recalled product information listed above be 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 to the establishment to verify distribution records and confirm facts.

3. Recall Assessment

FSIS expects to be kept apprised by the firm on the status of a recall in progress. The firm is expected to regularly report, in a timely manner, the results of its efforts to retrieve the product. 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, *Recall of Meat and Poultry Products*. 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
- 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

4. Recall Termination

A recall will be terminated when FSIS has:

- Completed the recall effectiveness checks;
- Determined that the recalling firm has made all reasonable efforts to recall the product; and
- Determined that the product is under control or that the recalling firm has disposed of the recovered product.

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 create a “closeout memo” containing a list of customers, the amount of product retrieved, and the actions taken. This memo should be sent to the relevant FSIS personnel. Once the Agency determines that the firm has made all reasonable efforts to recall the product, RMTAS will notify the firm in writing.

5. Recall Follow-up

Once a recall action has been completed, the establishment should notify its customers of this, 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,

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 or e-mail address.

Thank you for your cooperation.

Sincerely,

Company Official Name and Title