

IV. REFERENCES

Federal Meat Inspection Act (FMIA)
Poultry Products Inspection Act (PPIA)
9 CFR Parts 329; 381, Subpart U
FSIS Directive 8091.1, Procedures for the FSIS Health Hazard Evaluation Board
FSIS Directive 8410.1, Detention and Seizure

V. BACKGROUND

A recall is a firm's action to remove product from commerce (e.g., by manufacturers, distributors, or importers) to protect the public from consuming adulterated or misbranded products. Although it is a firm's decision to recall product, the Food Safety and Inspection Service (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.

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 to issue public health alerts or perform 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 and, based on its findings, FSIS may seek enforcement action against the recalling firm or its consignees.

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: FDA oversees egg product recalls in accordance with two Memoranda of Understanding between the U.S. Department of Health and Human Services and the U.S. Department of Agriculture (dated June 7, 1983, and February 23, 1999, respectively).

VI. TERMINOLOGY

The following are common terms FSIS uses related to recalls:

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

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

C. Stock Recovery. A firm's removal or correction of product that has not been marketed or that has not left the direct control of the firm. For example, product is located on the premises owned by the producing firm or under its control, and no portion of the lot has been released for sale or use.

D. Recall Classifications. FSIS assesses the public health concern or hazard presented by a product being recalled, or considered for recall, whether firm-initiated or requested by FSIS, and classifies the concern as one of the following:

1. Class I. This is a health-hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death. 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 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. Examples of a Class II recall include the presence in a product of very small amounts of undeclared allergens typically associated with milder human reactions, e.g., wheat or soy or small sized, non-sharp edged foreign material in a meat or poultry product.

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.

E. 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 but has not yet been sold to consumers.

3. HRI level. The product has been received by hotels, restaurants, and other institutional customers.

4. Consumer level. The product has been sold to household consumers, although identifiable quantities may remain under the control of retailers.

F. Scope. This defines the amount and type of product in question. There are several factors 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). For example, in the absence of a plant having a scientific basis for how it defines a lot, all products produced under a single HACCP plan between performance of complete cleaning and

sanitation procedures (from clean-up to clean-up), or all products including any reworked product added to subsequent days' production, may be included in a recall (see Attachment 1, Section 2). The findings of epidemiological investigations that link certain lots of product with known cases of foodborne illnesses may also affect the scope of a recall.

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

H. 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", dated 10/22/01.)

I. Recall Committee. A committee of representatives from various FSIS offices and staffs assembled to respond to potential or real health hazard incidents reported to the Recall Management Staff (RMS). 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 expected 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 Staff (RMS), Office of Field Operations (OFO) - (chairperson) - Calls a committee meeting and distributes information about the recall to committee members. Invites other FSIS program areas to assist as necessary.

2. District Recall Officer (DRO), OFO - Clarifies and explains to the Committee the information collected during the preliminary inquiry. A Deputy District Manager (DDM) located in the district of the firm that is conducting the recall is to serve as the DRO. The DRO is the official responsible for coordinating field recall activities and providing direction to inspection program personnel 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 and 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, in situations where a recall action is not warranted. Ensures that information contained in the Recall Release or RNR is accurate.

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

Office of International Affairs (OIA)

- Import Recall Coordinator (IRC), OIA- Clarifies and explains to the Committee the information collected during the preliminary inquiry when the recalling firm is an importer of record. The Import Inspection Division (IID), OIA is to assign an IRC when a recall involves imported product. The IRC is the official responsible for coordinating field recall activities and providing direction to Import Surveillance Liaison Officers (ISLOs) and FSIS Compliance and Investigations Division (CID) Investigators when there is a recall of imported product.
- Import-Export Programs Staff, Office of International Affairs (OIA)

Office of Program Evaluation, Enforcement, and Review (OPEER)

- Compliance and Investigations Division (CID), OPEER- Participates in committee meetings upon request, provides assistance to OFO or OIA upon request, and conducts investigations of alleged criminal violations, such as those involving the sale, transport, or receipt of adulterated product.
- Data Systems Management Division, OPEER

Office of Food Defense and Emergency Response (OFDER)

- A representative from OFDER is invited to all Recall Committee meetings to participate as a non-voting member.

Other Federal or State agencies, as appropriate (e.g., Food and Drug Administration (FDA), Food and Nutrition Service, Centers for Disease Control and Prevention (CDC), Office of the General Counsel, State departments of public health, etc.)

NOTE: 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/her AA and report back to the Committee. If the Recall Committee is unable to come to consensus, the RMS representative is to notify the OFO AA, who will convene a meeting of the AAs and advise the Administrator that he/she is convening the meeting. Each AA should discuss the potential recall with his/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.

VII. PROCEDURES TO DETERMINE THE NEED FOR A RECALL

When firms decide to recall product on their own initiative, FSIS expects those firms to immediately notify RMS. However, if the firm contacts other FSIS personnel, those employees are to promptly contact RMS through supervisory channels.

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:

- the company that manufactures or distributes the product;
- test results from FSIS sampling programs;
- observations or information gathered by FSIS inspection program personnel in the course of their routine duties or investigations;
- consumer complaints reported through the FSIS Consumer Complaint Monitoring System (CCMS);
- epidemiological or laboratory data submitted by State or local public health departments, other USDA agencies, and other Federal agencies such as the FDA, CDC, and the Department of Defense; or
- information from other agencies such as the Department of Homeland Security, Customs and Border Protection, the Animal and Plant Health Inspection Service, and foreign inspection officials.

A. Preliminary Inquiry. When FSIS learns that there is a reason to believe that a product that is in commerce is adulterated or misbranded, FSIS will conduct a preliminary inquiry. The DRO is assigned to direct the activities of inspection program personnel when the firm is an official establishment.

If imported product is involved, OIA is to issue an internal import alert and OIA/IID is to assign an IRC to direct the activities of ISLOs and import field personnel. If requested to do so, CID Investigators are to also assist the IRC in gathering information.

FSIS program personnel are to begin the preliminary inquiry by gathering product and contact information, and any additional relevant information. They are to forward the following information to RMS:

1. Contact Information for an Official Establishment. Inspection program personnel are to gather the following contact information from an official establishment:

- Establishment number, name, and address
- Company Recall Coordinator (name, title, and telephone number)
- Company Media Contact (name, title, and telephone number)
- Company Consumer Contact (name, title, and telephone number)

2. Contact Information for Imported Products. CID Investigators and ISLOs are to gather the following information from an importer of record:

- Import establishment (number, name, address, and telephone number)
- Foreign establishment (number, name, address, and telephone number)
- Importer of Record (name, address, and telephone number)
- Importer of Record Company's Recall Coordinator (name, title, and telephone number)
- Importer of Record Media Contact (name, title, and telephone number)
- Importer of Record Consumer Contact (name, title, and telephone number)

3. Product Information. For all products, including imported products, CID Investigators, ISLOs, and inspection program personnel are to gather the following product information:

- Reason for recall
- Brand names
- Product names
- Packaging (Type & Size)
- Package codes (Use by/Sell by)
- Packaging dates
- Photos of label or package
- Case codes
- Count/case
- Production dates
- Distribution areas
- School lunch (yes/no)
- Department of Defense (yes/no)
- Internet or catalog sales (yes/no)

a. Additional Information for Official Establishments. Inspection program personnel are to gather the following product information:

- Amount produced (pounds)
- Amount held at establishment
- Amount distributed (pounds/cases)
- Distribution level (depth of the recall, if known)

b. Additional information for Imported Product. CID Investigators and ISLOs are to gather the following product information:

- Amount imported (pounds/cases)
- Amount held at import establishment
- Amount distributed (pounds/cases)
- Distribution level (depth of the recall, if known)
- Foreign country notified (yes/no)

CID Investigators and ISLOs are to also document the following during the preliminary inquiry or at a later stage when it occurs:

- Violation reported to Import-Export Program Staff (yes/no)
- Hazard Evaluation Committee (HEC) convened (yes/no)
- Emergency Management Committee (EMC) notified (yes/no)

4. During the preliminary inquiry, CID Investigators, ISLOs, inspection program personnel, and other appropriate FSIS personnel are to gather additional information by taking the following steps, as necessary:

- a. collecting and verifying information about suspect product;
- b. documenting a chronology of events;
- c. contacting the company that manufactures or distributes the product for additional information;
- d. communicating with FSIS field inspection and FSIS enforcement personnel;
- e. interviewing any consumer who allegedly became ill or injured from eating suspect product;
- f. collecting and analyzing product samples;
- g. contacting other agencies, State and local health departments, or foreign governments; and
- h. analyzing any available epidemiological data.

The RMS 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.

B. Deliberations of the Recall Committee

1. To convene the Recall Committee, RMS is to contact the Committee members, usually by e-mail, to inform them of the potential recall. RMS 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. RMS is to make every effort to ensure that the five primary members of the Recall Committee are available to participate in the Recall Committee meeting. When they receive RMS' notice of the Recall Committee meeting, the Committee members are to respond to RMS to confirm that they are available to participate.

2. After RMS 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.

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

a. Does FSIS have reason to believe that the product in question is adulterated or misbranded under the FMIA or PPIA? In many instances, the answer to this question is obvious. For example, if the results of a laboratory analysis show that raw ground beef 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.

However, there also may be situations in which laboratory results are not available or are inconclusive but, based on epidemiological evidence, FSIS has reason to believe 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 there is reason to believe that a product contains a pathogen or is otherwise unhealthful and is, therefore, adulterated.

b. Does any of the product in question remain in commerce or available to consumers? Product is considered in commerce if it is out of the producing establishment's direct control and is in distribution (e.g., in a warehouse, retail facility, restaurant or other institution). The Recall Committee and program employees are to consider all available information to determine whether the product is in commerce or is available to consumers, and are to determine whether any product that has been distributed in commerce has reached retail facilities, restaurants, or consumers.

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. Instead, FSIS personnel are to verify that the establishment has recovered all products involved, and that it conducted proper disposition of the affected products.

NOTE: 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 conducting proper disposition of the affected product.

To properly assess whether any of the product remains in commerce, the Recall Committee is to seek responses to the following probing questions:

- When was the product produced?
- To whom has the product been distributed?
- What type of product is involved (e.g., ready-to-eat, fresh packed, canned, frozen, etc.)?
- What is the typical, usable shelf life of the product?

- 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)?
- 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?

4. If the answers to the questions in the first sentences of paragraphs 3. a. and 3.b. are “yes,” the Committee should recommend a recall unless, in response to other questions in paragraph 3.b., the Committee determines that the product is so long out of date that it is unlikely to still be available to consumers, or the Committee is unable to identify a responsible party for the product. In these circumstances, the Committee should not recommend a recall. If the Committee does not recommend a recall, RMS is to document results of the preliminary inquiry and evaluation with a Memo to the File.

NOTE: When the product has entered commerce, i.e., when it is no longer under the establishment’s direct control, the Recall Committee is to recommend a recall even if the product has only been distributed to the wholesale level, e.g., the product has only been sent to the consignees’ warehouses or distribution centers rather than to retail facilities. In this situation, the procedures in section X. on public notification and verifying the effectiveness of wholesale level recalls may apply.

5. If the Committee decides not to recommend a recall because of the circumstances listed in paragraph 4 above, the Agency may decide to issue a public health alert. The Agency has experimented with issuing a public health alert when, for example, the product in question was past its typical, usable shelf life and is no longer available for sale at the retail level but, based on typical consumer practices for the particular product, may be stored in consumers’ home freezers. After analyzing its experience with this approach, the FSIS has decided that it would be more appropriate in these circumstances for the Committee to recommend a recall. See section IX.D. for additional information regarding public health alerts.

6. If the Committee decides to recommend a recall, it is to consider the human health hazard presented by the product subject to the 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:

- a. the nature of the problem (i.e., what is the problem with the product, and what hazards to health does the problem create);
- b. the occurrence of any illnesses or injuries;
- c. the likelihood that illnesses or injuries may result; and
- d. the type of illnesses or injuries that may result.

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.

7. After the Committee members have discussed the issues described in paragraphs 3 through 6 above and agree to recommend a recall, RMS is to contact the company that produced the product to allow the company’s 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. Although not required, FSIS expects the firm to provide to the Committee its recall strategy, including how it intends to notify and instruct its consignees to retrieve or dispose of the recalled product.

C. Recall Recommendation. When the Recall Committee recommends a recall, RMS 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 (amount of product subject to recall that was distributed and is still within the sell by/use by dates or codes at the time of the recall).

NOTE: 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, RMS may request that FSIS inspection program personnel verify the information provided by the firm. RMS is to strongly encourage firms to e-mail the information involved in the recall to facilitate the speed and accuracy of the information transfer.

If the OFO AA approves the recall recommendation, RMS 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/her Offices representative to the Recall Committee. If the decision is made to request a recall, CPAO is to confirm the information necessary for a recall. The OPACE AA may request that other AAs review the draft Recall Release before it is issued. The DRO/IRC is to begin to coordinate effectiveness checks (see

Section XI.), consistent with the class of the recall, and is responsible for directing the activities of FSIS field personnel.

NOTE: If product subject to recall has been exported to a foreign country, RMS is to notify OIA. OIA will inform the foreign country of the recall.

VIII. ACTION BY FIRM

A. FSIS outlines in “Product Recall Guidelines for Firms” (Attachment 1) 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 model letters that a firm may use to communicate with its consignees (including providing instructions for product retrieval and extending the recall to additional consignees), model press releases, and recordkeeping requirements.

B. 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.

IX. PUBLIC NOTIFICATION

A. Recall Release. Following approval of the recall by the OFO AA, RMS notifies CPAO to issue a Recall Release to the media and to ensure that the Recall Release is made available to public health partners through FSIS’ e-mail subscription service. CPAO is to distribute the Recall Release to media wire services, media outlets in areas that received recalled products, and the FSIS e-mail subscription service, and post it on the FSIS Web site. 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 X. of this directive). 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.

1. The Recall Release will:

- a. 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;
- b. instruct the public on how to properly handle the product if consumers have it in their possession;
- c. provide the name and telephone number of a company contact for consumers and media to call with any questions; and

d. 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...."

2. 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.

3. CPAO is to fax or e-mail a draft copy of the Recall Release to the recalling firm thirty (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 thirty (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.

4. For Class I recalls related to human illness, an incident report (IR) will be posted on the FSIS Incident Management System (FIMS) by OPACE. FIMS was formerly known as the Non-Routine Incident Reporting System (NRIMS). The Recall Release will be attached to the IR. Program areas will update the IR, as appropriate, until the recall is complete.

B. Recall Notification Report (RNR). RMS coordinates with CPAO to issue an RNR for Class III recalls or for Class I or Class II recalls described in IX. A. and in section X for which 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 Web site and are distributed to FSIS e-mail subscribers. CPAO is to develop the RNR and post it to the FSIS Web site.

1. The RNR will:

a. clearly describe what product the firm is recalling, along with any identifying marks or codes, and explain the reason for the recall;

b. provide the name and telephone number of a company contact for consumers and media to call with any questions; and

c. provide general information about the product's destination. For example, "Ham and turkey products were distributed to a warehouse in the State of...."

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

3. CPAO is to fax or e-mail a draft copy of the RNR to the recalling firm before it is posted to the FSIS Web site. 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 thirty (30) minutes of receiving the RNR, FSIS will proceed to post the RNR on the FSIS Web site. 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.

C. Public notification of recalled State-inspected or foreign product

1. 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.

2. When a foreign government's food inspection agency informs FSIS that a company under its jurisdiction is recalling product that may be available to U.S. consumers, FSIS will 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 United States. FSIS will follow the same procedure in similar cases when the information is received from other government officials that product is adulterated or misbranded.

D. Public Health Alerts.

1. 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' Foodborne Disease Investigation Branch (FDIB). If appropriate, the situation should be referred to the EMC as provided in FSIS Directive 5500.2. If the situation is referred to the EMC, the EMC will decide whether FSIS should issue a public health alert.

2. 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 because the product is long out of date as provided in section VII. B. of this directive. In these circumstances, the RMS 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, to direct the Recall Committee to request that the responsible firm recall the product, 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 EMC as provided in FSIS Directive 5500.2.

3. If FSIS issues a public health alert under the circumstances described in IX.D.2. the alert will:

- i. identify the firm that produced the product;
- ii. clearly describe the product involved, along with any identifying marks or codes;
- iii. identify whether the product presents any health risk;

iv. explain the reason the product is adulterated or misbranded, and describe the risks involved in consuming the product;

v. provide an electronic picture of the product label, if one is available, that clearly describes the product to the public;

vi. instruct the consumers on how to properly handle the product if, by some remote chance, they have it in their possession; and

vii. provide the name and telephone number of a company contact for consumers and media to call with any questions.

E. Retail Consignee Lists. For every Class I recall, the Office of Field Operations (OFO) develops a list of retail consignees that have, or have had, the recalled products in their possession. OFO gathers the retail consignee information by contacting all of the recalling establishment's directly affected consignees and all of the subsequent consignees to which the recalling establishment's direct consignees distributed the recalled product to find out if they have the recalled products in the 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.

Staff members in OFO's District Offices 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, the Recall Management Staff (RMS) does so. RMS then sends the list of retail consignees to the FSIS Web Services Staff for posting on the FSIS Web site. The initial list is posted within approximately 3 to 10 days of the date of the recall.

The FSIS Web Services Staff posts to the list periodic updates from RMS as additional retail consignee information becomes available. After the initial posting, updates may be every other day for the first several days, then less frequent as the availability of new information becomes less frequent.

X. Special Considerations for Wholesale Level Recalls

There may be instances in which adulterated or misbranded product that is the subject of a recall is not available to consumers because, although the product is in commerce, it has only been distributed 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, HRI, or consumer level. In this situation, issuing a Recall Release to inform the public of the recall would not be useful to consumers. Therefore, 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:

A. 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 section IX.B. of this directive. The Agency will issue an RNR instead of a Recall Release even if the recall is classified as Class I or II.

B. 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 RMS 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 RMS and the DRO/IRC.

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

XI. EFFECTIVENESS CHECKS

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 section X of this directive.

Depending on the availability of Agency personnel and the type of firm conducting the recall, Enforcement Investigations and Analysis Officers (EIAOs), ISLOs, or CID Investigators are to conduct effectiveness checks. Generally, if the recalling firm is an official establishment, the DRO is to coordinate and direct inspection program personnel to conduct effectiveness checks. If the recalling firm is the importer of record, the IRC is to coordinate and direct ISLO's or CID Investigators to conduct the 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, "Detention and Seizure." FSIS personnel are to notify the DRO/IRC immediately when the recalled product remains available to the consumer, and when the recalling firm has not properly implemented its recall strategy.

A. Field Recall Responsibilities upon Notice of a Recall

The DRO/IRC responsibilities are 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 3);
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 to 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 DRO/IRC 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 RMS;
4. inquire how the firm plans to control recovered product; and
5. inquire how the firm plans to handle product disposition.

NOTE: If the firm's recall strategy includes destroying product on site, the DRO/IRC 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 (b), Report of Recall Effectiveness: Part B – Product Disposition Verification, as product disposition verification.

B. DRO/IRC Responsibilities for Coordinating FSIS Program Personnel's Activities in Effectiveness and Product Disposition Verification Checks

The DRO/IRC responsibilities are to:

1. coordinate effectiveness checks and direct the activities of FSIS program personnel;
2. determine product distribution and request assistance from DDMs/Regional Import Field Supervisors (RIFS)/ OPEER Regional Managers (RMs) in districts/regions where product was distributed. The DDMs/RIFS/RMs 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 3). In cases where the recalling firm does not have a recall plan (see Attachment 1), the DRO/IRC may instruct FSIS personnel to conduct more effectiveness checks than if the firm did have a recall plan.

C. Inspection Program Personnel, CID Investigator, and ISLO Responsibilities for Conducting Effectiveness Checks

1. For a recall to be deemed effective, the number of consignees checked that are found to have the product available to the public must be equal to, or less than, the critical number in the sampling plan applied to the effectiveness check (Attachment 3). Using the sampling plan selected by the DRO/IRC, FSIS personnel are to:

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

b. take appropriate action to detain any recalled product found in commerce in accordance with FSIS Directive 8410.1, "Detention and Seizure";

c. determine the amount of recalled product received by consignees. In cases where a consignee cannot document how much of the recalled product it actually received, inspection program personnel are to explain this on FSIS Form 8400-4 (a), Report of Recall Effectiveness: Part A – Effectiveness Checks;

d. verify that the consignees are handling the product in accordance with regulatory requirements and the instructions of the recalling firm by reviewing records and by observing or verifying product disposition. If product is to be destroyed at a Federal establishment, in-plant inspection program personnel may be asked to witness the destruction of product;

e. record the effectiveness checks on FSIS Form 8400-4 (a) and submit the completed forms to the DRO/IRC;

2. 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 and document this on FSIS Form 8400-4 (b) as a follow-up; and

3. 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 DRO. The DRO is to issue, when the facts indicate, a letter to the firm describing the circumstances of the prohibited act and the potential enforcement or criminal action the Agency may pursue. The DRO is to then refer the matter to OPEER/CID. If the recall involves imported product, FSIS personnel are to document the occurrence and contact the IRC, who is to refer the matter to OPEER/ CID.

NOTE: 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, program employees will follow FSIS Directive 8470.1 and notify the consignee of any prohibited activity.

D. DRO/IRC Responsibilities for Reviewing Effectiveness Checks and Confirming the Firm's Control and Disposition of the Product

The DRO/IRC is to:

1. compile the recall effectiveness reports from all assisting districts/regions and State programs to make an overall assessment of recall effectiveness following the criteria and decision guidance in Attachment 3;

2. analyze the information that is submitted by FSIS inspection program personnel on FSIS Forms 8400-4 (a & b) and review any instances in which recalled product was found in commerce. For example, the DRO/IRC 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.

E. The DRO/IRC Determination on the Effectiveness of the Recall

1. The DRO/IRC may determine that the recall was effective based on his/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, he/ she is to send a Final Recall Effectiveness Report (FRER) to the RMS Director.

2. The FRER is to include:

- a. a summary of the findings of the recall effectiveness and product disposition verification checks; and

- b. any supporting documentation voluntarily provided by the firm, including information about the amount of recalled product recovered.

3. In consultation with the RMS, the DRO/IRC 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 DRO/IRC is to notify the recalling firm, in writing, and provide a courtesy copy of the notification to the RMS Director, explaining why the recall action is deemed to be ineffective. The DRO/IRC 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 DRO/IRC 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.

NOTE: 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.

XI. 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' 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:

- Recall Management Staff
- OFO program personnel:
 - o Executive Associate for Regulatory Operations
 - o District Manager or Deputy District Managers participating in the recall
 - o Case Specialist from the recalling district
- OIA program personnel:
 - o Headquarters personnel
 - o Regional Import Field Office
 - o ISLO
 - o Import Inspector
- OPEER program personnel
 - o CID Regional Manager
 - o CID Investigator
 - o Program Evaluation Staff
- Other agency personnel that had participated in the recall activities, including personnel from OFDER, 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:

- Recall Effectiveness Checks Reports
- Food Safety Assessment (FSA)
- Enforcement History
- Failures of the establishment food safety programs
- Reports of Consumer Illness
- Any pertinent information collected during the preliminary inquiry as described in Section VII A.

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 Director RMS. RMS 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.

XII. CLOSURE

A. RMS is responsible for submitting a recommendation for closing a recall to the AA OFO. RMS' 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, RMS is to review the recall termination report from the DRO, and if a recall is associated with a reported illness, ask the Human Health Sciences Division, 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. RMS 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, RMS may proceed to recommend closing the recall.

C. After receiving concurrence from the Assistant Administrator/OFO, RMS is to notify the recalling firm, in writing, that the recall is closed and notify the FSIS Web master to remove the case from the "open" to the "archived" recall case files on the FSIS Web site. RMS is also to send a copy of the latter notification to the IF-OFDER mailbox.



Assistant Administrator
Office of Policy and Program Development

PRODUCT RECALL GUIDELINES FOR FIRMS

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1. Background and Objectives

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

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

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

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

encourages the management of all firms to prepare themselves, and their personnel regularly employed, for the potential of having to conduct a recall.

2. The Recall Plan

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

A recall plan should address the following elements:

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

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

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

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

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

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

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

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

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

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

records could be used to demonstrate limiting factors that may narrow the scope of a recall by a particular plant. Moreover, the records would be essential in facilitating the traceback of the contamination to its source.

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

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

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

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

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

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

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

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

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

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

In the event of a recall, this establishment will be able to identify the more likely sources of contamination from its production records. To illustrate, suppose subplot 5 from the chart above was the only lot that tested positive for *E. coli* O157:H7. The establishment could review their records and identify two sources of raw materials, Est. 42 boneless veal and Est. 38 head/cheeks (103103) that

were not used in the other sublots. These two source materials would be more likely than the others to be the vector of contamination in the finished product.

Given this information, the establishment could:

1. Review its dressing procedures and the boning and handling of its head/cheek meat in order to find and eliminate any potential causes of contamination;
2. Confirm the test results for the lot that had the screen test positive;
3. Divert the rest of that lot of head/cheek meat away from ground beef production and into a process with an adequate kill step;
4. Notify its supplier of boneless veal, Est. 42, of its findings regarding that establishment's product; and
5. Inform the Agency of its findings, conclusions and actions taken.

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

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

- 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.)
- Retail level. The product has been received by retailers for sale to household consumers but has not yet been sold to consumers.
- HRI level. The product has been received by hotels, restaurants, and other institutional customers.

- Consumer level. The product has been sold to household consumers, although identifiable quantities may remain under the control of retailers.

g. Recall Communications - A recalling firm is responsible for promptly notifying each of its affected consignees about the recall. The plan should specify what means of communication will be used and should include sample communication for various scenarios and contingencies. The format, content, and extent of a recall communication should be commensurate with the hazard associated with the product being recalled, the strategy developed, and the recall plan. In general terms, the purpose of a recall communication (see attached sample letter) is to convey:

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

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

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

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

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

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

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

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

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

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

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

NOTE: Regardless of the public notification action taken by the recalling firm, FSIS will generally issue a Recalls 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 re-gain 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 Web site (www.fsis.usda.gov/OA/recalls/rec_actv.htm).

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

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

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

m. Returned Product Control and Disposition - The means of controlling and disposing of or correcting the defect in the stock returned during a recall should be specified in the recall plan. Remember to check with the Agency before destroying product; FSIS may wish to witness the destruction. (Destroy means to render inedible for humans and animals, and all labeling is made unusable for trade.)

n. Recall Simulations - In order to evaluate how well its plan will work in the event of an actual recall situation, the establishment should conduct periodic simulations. A simulated recall should involve the selection, without prior notice

to personnel involved in the simulated recall, of at least one lot of product that has been distributed in commerce. A hypothetical reason for recalling the product should be specified, and the recall plan should be followed to establish a strategy for recalling the product. Such scenarios may be simple (e.g. one contaminated lot of product) or very complex (e.g. contaminated ingredient used in multiple products and involving rework). A firm may wish to begin with simple scenarios and work up to more complex simulations for their operation. The simulation should proceed at least to the point at which communication is to be made beyond the firm's organizational limits; however, full details of who will be contacted at that point, and how contact will be established, should be specified. Firms, especially those with products distributed by multi-layer distribution systems, may wish to consider conducting at least one simulation in which the product to be recalled has been shipped beyond the firm's initial customer to one or more of the consignee's customers. Taking the simulation beyond the recalling firm's organization could reveal potential problems in the retrieval process that possibly could be addressed before a "live" recall occurs.

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

3. Notifying FSIS of Recalls

FSIS expects that, once it is determined that a recall will be undertaken, the recalling firm will immediately notify FSIS. When doing so, the firm should notify the Recall Management Staff (RMS), the District Office in the FSIS district where the firm is located, or if the firm is an importer of record, the Office of International Affairs (OIA), Import Inspection Division (IID), Headquarters . The basic information that should be conveyed to FSIS includes, but is not limited to, the following (see FSIS Directive 8080.1 and attached worksheet):

- 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.
- An evaluation of the risk associated with consumption of the product, and how the evaluation was made (although FSIS will make its own determination of risk).

- How much of the product in question was produced and during what period of time.
- An estimate of how much of the product is in distribution, and how long it has been in distribution.
- Area of the geographical distribution of the recalled product by state and, if exported, by country.
- Information about which distributors and customers received the product.
- Copies of any firm correspondence with distributors, brokers, or customers relating to the recall strategy or actions, and a copy of any proposed press release.
- The name, title, and telephone number of the recall coordinator for the firm.

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

4. Recall Assessment

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

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

- The number of consignees notified of the recall, the dates notifications were made, and the method of notification that the firm used for each consignee.
- The number of consignees responding to the recall communication.
- The quantity of product each consignee had on hand at the time the communication was received.
- The number and identity of consignees that did not respond.
- The quantity of product returned or held by each consignee.
- An estimated time for completion of the recall.

5. Recall Termination

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

6. Recall Follow up

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

MODEL RECALL NOTIFICATION LETTER**DATE****CUSTOMER FIRM NAME & ADDRESS**ATTN: **CONTACT PERSON NAME & TITLE**Re: RECALL OF **TYPE OF PRODUCT**

Dear Sir or Madam:

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

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

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

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

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

Thank you for your cooperation.

Sincerely,

Company Official Name and Title

**[STATE] FIRM RECALLS [PRODUCT] DUE TO POSSIBLE
LISTERIA CONTAMINATION**

[CITY], [DATE] – [COMPANY], an [CITY, STATE], establishment, is recalling approximately [AMOUNT] pounds of [PRODUCT] that may be contaminated with *Listeria monocytogenes*, the U.S. Department of Agriculture’s Food Safety and Inspection Service announced today.

The following products are subject to recall:

- [IDENTIFYING INFO: TYPE OF CONTAINER, WEIGHT, “BRAND NAME AND OTHER LABEL INFORMATION,” ESTABLISHMENT NUMBER, CASE AND/OR DATE CODES]

The products were produced [DATE] and distributed to [LEVEL OF DISTRIBUTION I.E. RETAIL ESTABLISHMENTS, INSTITUTIONS, ETC] in [STATES].

The problem was discovered through [SPECIFY HOW PROBLEM WAS DISCOVERED]. There have been [# or NONE] reports of illness associated with consumption of these products.

Consumption of food contaminated with *Listeria monocytogenes* can cause listeriosis, an uncommon but potentially fatal disease. Healthy people rarely contract listeriosis. However, listeriosis can cause miscarriages and stillbirths, and can also cause serious and sometimes fatal infections in those with weak immune systems, such as infants, the elderly, and persons with HIV infection or undergoing chemotherapy. Infection can spread to the nervous system, resulting in high fever, severe headache, neck stiffness, nausea, confusion and convulsions.

Consumers with questions about the recall may contact [CONTACT TITLE AND NAME], at [TELEPHONE NUMBER]. Media with questions about the recall may contact [CONTACT TITLE AND NAME], at [TELEPHONE NUMBER].

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**[STATE] FIRM RECALLS [PRODUCT] DUE TO UNDECLARED
ALLERGEN**

[CITY], [DATE] – [COMPANY], an [CITY, STATE], establishment, is recalling approximately [AMOUNT] pounds of [PRODUCT] due to an undeclared allergen

[SPECIFY ALLERGEN], the U.S. Department of Agriculture's Food Safety and Inspection Service announced today.

The following products are subject to recall:

- [IDENTIFYING INFO: TYPE OF CONTAINER, WEIGHT, "BRAND NAME AND OTHER LABEL INFORMATION," ESTABLISHMENT NUMBER, CASE AND/OR DATE CODES]

The products were produced [DATE] and distributed to [LEVEL OF DISTRIBUTION I.E. RETAIL ESTABLISHMENTS, INSTITUTIONS, ETC] in [STATES].

The problem was discovered through [SPECIFY HOW PROBLEM WAS DISCOVERED]. Anyone concerned about an allergic reaction should contact a physician.

Consumers with questions about the recall may contact [CONTACT TITLE AND NAME], at [TELEPHONE NUMBER]. Media with questions about the recall may contact [CONTACT TITLE AND NAME], at [TELEPHONE NUMBER].

#

[STATE] FIRM RECALLS [PRODUCT] THAT MAY CONTAIN [GLASS, PLASTIC, ETC]

[CITY], [DATE] – [COMPANY], an [CITY, STATE], establishment, is recalling approximately [AMOUNT] pounds of [PRODUCT] that may contain pieces of [SPECIFY MATERIAL], the U.S. Department of Agriculture's Food Safety and Inspection Service announced today.

The following products are subject to recall:

- [IDENTIFYING INFO: TYPE OF CONTAINER, WEIGHT, "BRAND NAME AND OTHER LABEL INFORMATION," ESTABLISHMENT NUMBER, CASE AND/OR DATE CODES]

The products were produced [DATE] and distributed to [LEVEL OF DISTRIBUTION I.E. RETAIL ESTABLISHMENTS, INSTITUTIONS, ETC] in [STATES].

The problem was discovered through [SPECIFY HOW PROBLEM WAS DISCOVERED]. There have been [# or NONE] reports of injury from consumption

of these products. Anyone concerned about an injury from consumption of the products should contact a physician.

Consumers with questions about the recall may contact [CONTACT TITLE AND NAME], at [TELEPHONE NUMBER]. Media with questions about the recall may contact [CONTACT TITLE AND NAME], at [TELEPHONE NUMBER].

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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 of such an ingredient would be a potential food allergen, such as peanuts. FSIS Directive 8080.1, Revision 4, titled "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: cereals containing gluten (i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these); crustacea; eggs and egg products; fish and fish products; peanuts; soybeans; milk and milk products; and tree nuts.

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.

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). Thus, there are few foods or food ingredients to which some element of the population will not have some degree of allergic response or intolerance. For this reason, complete ingredient labeling is critical.

Various factors are considered in assessing the public health significance of a meat or poultry product that contains an undeclared ingredient, and thus, the class to which a recall involving the product should be assigned. The following questions convey examples of factors that are considered in determining the public health significance of 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 a “no observed adverse effect level” that can be used in estimating risk. Thus, in these cases, the higher the amount of the ingredient, the more likely it is to elicit an adverse effect, the more reason to classify the recall as one in which there is a significant public health concern, that is, Class I. Conversely, the lower the amount of the ingredient, the more reason there is to classify the recall as Class II. However, for most known allergens, there is no conclusive scientific evidence to establish threshold levels for eliciting an adverse reaction. Consequently, in most cases, the presence of an undeclared substance that is a known allergen, at any level, poses a public health risk and thus 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 probability of adverse effects among allergic or sensitive populations plays a large role in determining a recall classification. The likelihood that an adverse effect will occur as a result of human consumption of a meat or poultry product that contains an undeclared ingredient is based on probability. Specifically, it is the probability that someone in the most sensitive subpopulation may be exposed to an ingredient that is not declared on a product’s labeling. The magnitude and severity of the adverse reaction, should it occur, are also significant. Generally, the greater the likelihood, magnitude, and severity of an adverse effect in a sensitive population, the more reason to classify 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 issue of the number of sensitive individuals is irrelevant because, for any sensitive individual, there is no established threshold, and an allergic reaction is potentially catastrophic. However, in the case where 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.

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:

- The recalling firm has notified all of its consignees about the recall; and
- Consignees have located and are controlling products and are following the recalling firm's instructions.

NOTE: The District Recall Officer (DRO)/Import Recall Coordinator (IRC) must be notified if the firm's recall strategy includes destroying product on site. The DRO/IRC may assign FSIS program personnel to witness destruction of the product in accordance with 9 CFR 329 and 9 CFR 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 their 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 RMS. The DRO will submit a summary memo to RMS.

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.

2. FSIS – FSIS will use effectiveness checks to verify that the recalling firm is conducting the recall effectively. FSIS program 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 or regional official is responsible for coordinating all field recall activities and will serve as the primary point of contact with the recalling firm. When the recalling firm is a Federal establishment, the Deputy District Manager (DDM) in the Office of Field Operations (OFO) will coordinate the effectiveness checks. If the recall spans across multiple districts, the DRO that has the jurisdiction over the recalling firm will coordinate activities across the districts.

When the recalling firm is an importer of record, the IID Headquarter Program Analyst, Office of International Affairs (OIA) will coordinate the effectiveness checks. Both OFO and OIA will address effective checks in the manner described in this document to ensure consistency.

The DRO/IRC will:

- Determine the number of consignees that will receive effectiveness checks by using risk-based tables (Tables 2-5) to develop an appropriate sampling plan.
- Direct FSIS program personnel and coordinate with their counterparts located in other regions or districts.
- Review the effectiveness check reports and respond by adjusting the sampling plan, as needed, to ensure consignees have removed product from commerce.
- Compile all findings and report its overall assessment of the firm’s recall effectiveness to the Recall Management Staff (RMS).

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 program 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 and by phone. FSIS program personnel will visit the consignees of the firm conducting the recall to verify that they have received appropriate notification of the recall, and that they are acting on the basis of that notification. Recall effectiveness checks will be conducted based on resource considerations and knowledge of the recalling firm’s and consignee’s practices; 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 in their district for further instructions and may detain product.

C. Effectiveness Checks Sampling Plan

The DRO/IRC will use a risk-based sampling plan to determine the number of consignees that FSIS program 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 DRO/IRC will immediately request information and records in accordance with 9 CFR 320.1 of the recalling firm and subsequent consignees regarding the distribution of recalled product. The information should contain sufficient details to allow FSIS personnel to understand the distribution patterns and make contacts without further delay.

The DRO/IRC will attempt to determine the 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. However, when situations arise that may delay the verification or reporting activities, or affect the timeframes presented in this table, it is the responsibility of each district/region to notify the DRO/IRC.

The DRO/IRC prepares a sampling plan in consultation with other districts/regions based on the percentage of distribution. The DRO/IRC should sort the information according to geographical regions and by type of consignees. The type of consignee may include retailers, hospitals, independent retailers, restaurants, and food service institutions, as well as distributors. The DRO/IRC will coordinate with program personnel to contact these consignees without delay.

The time standards presented in Table 1 are also for FSIS verification activities. Recall activities by firms are to start immediately upon deciding to do a recall or upon receiving notification of a recall. During this time, the DRO will also have an oversight function to assess whether the recalling firm has in fact initiated the recall activities.

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.

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

Example: If the recalling firm has 50 retailers and 5 distributors, and the 5 distributors in turn have 400, 200, 300, 100 and 150 retailers, the best estimate of the number of consignees is 1,200. The effectiveness checks are done based on 1,200 consignees.

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

Where there is concern that the distribution information is not accurate or complete, (i.e., a generic list of chain stores is missing a few known stores), where necessary, the DRO/IRC will prepare a list identifying other potential consignees and/or distributors who may carry the recalled products but were not included in the distribution information given by the firm.

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 MOU’s 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.

F. Determining the Total Number of Effectiveness Checks to Conduct

After the DRO/IRC groups the consignees and determines the total number of consignees, the DRO will determine the total number of effectiveness checks that will be performed by on-site verification and by phone. These numbers are derived from values given in the sampling tables in this document.

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

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 <u>all</u> 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%	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 and Table 5 are used for Class II and Class III recalls, respectively.

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

Number of Consignees	Number of Effectiveness Checks to Make	Recall Considered Ineffective If the Number of Consignees at which Product was Available to Consumers Exceeds:
1 to 5	100%	0
6 to 25	5	0
26 to 150	20	1
151 to 280	32	2
281 to 500	50	3
501 to 1,200	80	5
1,201 to 2,300	125	8
2,301 to 10,000	200	12
10,001 and over	315	18

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

Number of Consignees	Number of Effectiveness Checks to Make	Recall Considered Ineffective if the Number of Consignees at which Product was Available to Consumers Exceeds:
1 to 8	100%	1
9 to 50	8	1
51 to 90	13	2
91 to 150	20	3
151 to 280	32	5
281 to 500	50	8
501 to 1,200	80	12
1,201 and over	125	18

G. Special Considerations for Sorting the Consignees List

If information is available, the DRO/IRC will 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 DRO/IRC has enough information to separate groups by special categories, then he/she is to consider each group of consignees separately, and use the tables to determine the number of effectiveness checks to be conducted for each 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.

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. FSIS program personnel will document the checks on FSIS Form 8400-4, (Report of Recall Effectiveness).

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

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

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

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

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

Number of Consignees	Number of Effectiveness Checks to Make	Recall Considered Ineffective if the Number of Consignees at which Product was Available to Consumers Exceeds:
1 to 5	100%	0
6 to 25	5	
26 to 150	20	
151 to 280	32	
281 to 500	50	3
501 to 1200	80	
1201 to 2300	125	
2301 to 10,000	200	12
10,001 to and over	315	18

Number of on-site disposition verifications

Total number of effectiveness checks

I. Preparing the Effectiveness Checks Sampling Plan

The DRO/IRC prepares a sampling plan in consultation with other Districts/ Regional Offices based on the percentage of distribution.

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

Example: For a Class II recall and 600 consignees, the appropriate table is Table 4 and the number of effectiveness checks to conduct is 80.

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

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

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

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

In this example divide 600 by the minimum sample size (example 80). In this

example, the sampling interval would be 7 ($600/80 = 7.5$ rounded to the lower whole number).

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

For this example, select number 3.

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

J. FSIS Program 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 (EIAO), Public Health Veterinarians (PHVs) trained in EIAO methodology, Program Investigators (PI), or Import Surveillance Liaison Officers (ISLO).

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

FSIS program personnel will:

1. Use the predetermined sampling interval and the random starting point to select the consignees for verification.
2. List consignees in any order; count from the top until reaching the starting point; then choose consignees according to the predetermined sampling interval.

Example: *In the previous example, the sampling interval is 7, and the starting point is 3. Beginning at the 3rd consignee, add the sampling interval (7). Select*

the 10th, 17th, 24th ... and so on until enough consignees are identified for the effectiveness checks.

3. Ensure that copies of the recalling firm letter to its consignees informing them of the recalling action, Recall Notification Report (RNR) (for Class III or wholesale level recalls), and as applicable, copies of the Recall Release and labels are on hand when conducting verification activities. These documents can then be referenced or left with consignees, if required.

4. Conduct checks to determine whether consignees have received the recalling firm notification of the recall action and have taken the prescribed action regarding product, such as returning it to the recalling firm, or identifying and holding it for pick-up.

5. Conduct checks by on-site observation, records review, or phone, based on resources and knowledge of the recalling firm and consignees practices.

6. Determine whether any recalled product remains available to consumers.

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

8. 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.

9. 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.

10. Continue with all the assigned checks.

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

K. "Findings of Product in Commerce" is defined as those occurrences where recalled product remains available to the consumer.

1. When the DDM or Regional Import Field Supervisor (RIF) is notified by program personnel in their district/region of findings of product in commerce, he or she will immediately notify the DRO/IRC.

2. The DRO/IRC is to determine whether the findings follow a pattern or

trend. During the evaluation, it is important to distinguish between isolated reasons (i.e., the product was removed in a store but was re-shelved by mistake) and widespread systemic reasons (i.e. breakdown in the notification process or delay caused by the schedule of sales personnel). This is important to do even if the recall itself is effective because there may be subgroups of consignees that have product that is available to consumers. As deemed appropriate and necessary, the DRO/IRC will notify the Director of the Compliance and Investigations Division, OPEER.

L. DRO/IRC 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 product in commerce must be equal to, or less than, the critical number in the sampling plan.

(2) The DRO/IRC 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 product from commerce that is recalled, FSIS will take the appropriate measures, including detaining product, to protect consumers.

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

2. Examples of Effective and Ineffective Recalls:

a. The DRO/IRC makes the determination of whether a recall is effective or ineffective in consultation with RMS. FSIS program personnel conducting checks would need to continue with all the assigned checks even though a recall may appear ineffective. Depending upon the actual sampling calculations, the final sample count would likely differ (generally be higher) from the count listed in 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 5.

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

Recall is deemed effective.

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

Recall is deemed effective. No product is available at the nine consignees. The number of consignees at which product was available to consumers is not exceeded.

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

Recall is deemed ineffective.

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

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

5. FSIS program personnel will notify the DRO/IRC of his/her findings at the business regarding the detained product and whether or not adequate recall instructions were received.

a. If a recall notification and product instructions were not received, the DRO/IRC 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 DRO 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. The DRO is to then refer the matter to the OPEER Compliance and Investigation Division (CID). The IRC will immediately refer the matter to OPEER/CID.

7. The DRO/IRC 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 OPEER.

8. Responding to an ineffective recall -

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

b. The DRO/IRC will write a letter to the recalling firm detailing the reasons why the recall has been found to be ineffective. The DRO/IRC 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.

M. Verification Result Summaries

1. The DRO/IRC will prepare a summary of recall activities and provide it to the RMS. The focus of the summary should be to:

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

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 correct 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 DRO/IRC will send the memo to the RMS Director.