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

FSIS DIRECTIVE

8080.1, Revision 8 | 12/19/23

MANAGING ADULTERATED OR MISBRANDED MEAT, POULTRY, AND EGG PRODUCTS

CHAPTER I - GENERAL

I. PURPOSE

This directive provides the terminology, responsibilities, and public notification procedures regarding the assessment of adulterated and misbranded meat, poultry, and egg products that may have entered commerce, and the voluntary recall of such products. FSIS is revising this directive in its entirety to include egg products as an FSIS-regulated commodity subject to voluntary recall and to provide instruction regarding large volume recalls and recalls of ingredients regulated by the Food and Drug Administration (FDA). It also includes new definitions for Class III recalls; clarifies when FSIS may publish Public Health Alerts (PHAs); and makes clarifying revisions throughout.

II. CANCELLATION

FSIS Directive 8080.1, Revision 7, *Recall of Meat and Poultry Products*, dated 9/9/13

III. BACKGROUND

A. A recall is a firm's voluntary action to remove adulterated or misbranded products from commerce. Although it is a firm's decision to recall product, either at the firm's initiative or the Agency's recommendation, FSIS will coordinate with the firm to ensure it has properly identified and removed recalled product from commerce. FSIS also notifies the public about Class I and Class II recalls through press releases.

B. A recall may be an alternative to the detention or seizure of adulterated or misbranded products in commerce by FSIS. However, a recall does not preclude FSIS from ultimately detaining or seizing adulterated or misbranded products or from taking other appropriate actions, such as issuing PHAs, to mitigate public health risks. Additionally, FSIS may investigate and take additional actions if it appears that a firm's recall strategy or execution of that strategy is ineffective. Based on its findings, FSIS may seek enforcement action against the recalling firm or its consignees.

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

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

D. When FSIS finds that imported product should be recalled, the Agency will recommend that the importer recall the product. The importer would be responsible for recovering and properly disposing of the affected product. The importer may include: the consignee, the importer of record, the actual owner of the merchandise, or the transferee of the merchandise.

IV. TERMINOLOGY

Recall: A firm's voluntary removal of distributed meat, poultry, or egg 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, 21 U.S.C. 601 *et seq*.), Poultry Products Inspection Act (PPIA, 21 U.S.C. 451 *et seq*.), or Egg Products Inspection Act (EPIA, 21 U.S.C. 1031 *et seq*.) and that such product remains available in commerce, free to move to consignees or consumers. A recall is not a market withdrawal or a stock recovery.

Market Withdrawal: A firm's removal or correction, on its own initiative, of product that is in commerce, for any reason that would not ordinarily lead the Agency to pursue detention and seizure. This includes deviations from a company quality program or minor regulatory infractions. For example, a firm may conduct a market withdrawal of product that does not meet its quality standards because of discoloration. An example of a minor regulatory infraction could be when the product fails to bear an official inspection mark but otherwise includes the establishment number and information allowing traceability to the producing establishment. A company can remove product from commerce or have product returned from a customer at any time for any reason. This does not necessarily make that action a recall.

Stock Recovery: A firm's removal or correction of product that has not left the direct control of the firm. For example, product is located on the premises owned by the producing firm or stored offsite under its control at a consignee or third-party warehouse.

Hazard 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 recalls of ready-to-eat (RTE) meat, poultry, or egg products that contain pathogens or recalls of raw, ground beef that contains Shiga toxin-producing *E. coli* (STEC) or product that contains an allergen likely to elicit an adverse human health reaction, such as milk or soybeans, that is not declared on the product label.

2. Class II: This is a health hazard situation where there is a remote probability of adverse health consequences from the use of the product. An example of a Class II recall is a recall of product that contains a highly refined/denatured allergen not likely to elicit an adverse human health reaction, such as hydrolyzed soy protein, that is not declared on the product label.

3. Class III: This is a situation where the use of the product will not cause adverse health consequences or the risk is negligible. 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, which provide an unfair economic advantage to the producer.

Scope: This defines the amount and type of product in question. Several factors are used in determining the scope of product that is potentially adulterated or misbranded (product scope), as well as the scope of product meeting that determination and available in commerce (recall scope). Scope consideration includes multiple factors, such as processing and sanitation procedures, the definition of a lot or specific grouping of products, related records or lack thereof, and whether there is any affected finished product reincorporated into an earlier step of the process (rework). The findings of epidemiological investigations that link certain lots of product with known cases of foodborne illnesses may also affect the scope of product considered adulterated and product included in a recall.

Disposition: This is the firm's action with respect to adulterated or misbranded product to correct the applicable concern, such as relabeling, cooking, reworking, or destroying product.

Event Assessment Committee: A committee comprised of representatives from various FSIS program areas assembled to determine the best response to potential health hazard incidents escalated for analysis to the Recall Management and Technical Analysis Division (RMTAD).

Health Hazard Evaluation Board (HHEB): The HHEB addresses situations involving potential human health hazards (physical, biological, or chemical) when the Agency is uncertain about the nature or severity of the human health risk and needs additional information to inform its response. The HHEB reviews available scientific information to assess the public health risk associated with potential hazards and draws conclusions to inform Agency decisions. The HHEB does not decide what action the Agency should take in response to a potential hazard. If an Event Assessment Committee is unable to determine the public health risk associated with a novel event, it may convene the HHEB to assess the matter. (See FSIS Directive 8091.1, *Procedures for the FSIS Health Hazard Evaluation Board*.)

CHAPTER II – DETERMINING NEED FOR RECALL

I. BECOMING AWARE OF POTENTIAL NEED FOR A RECALL

A. When FSIS official establishments learn or determine that adulterated or misbranded meat or poultry products have entered commerce, they are required to notify FSIS OFO District Office (DO) personnel within 24 hours (9 CFR 418.2). This notification can be made through traditional methods (phone call, text message, or email) or can be made by the establishment through the Public Health Information System (PHIS). When official establishments notify FSIS personnel that adulterated or misbranded product has entered commerce, those FSIS personnel are to refer to FSIS Directive 8140.1, *Notice of Receipt or Distribution of Adulterated or Misbranded Product*, for actions to take in response to a report of adulterated or misbranded products.

B. If other firms responsible for products, such as importers or retailers, determine that adulterated or misbranded product have entered commerce or decide to recover product from commerce on their own initiative, they may notify RMTAD (formtad@usda.gov) or other FSIS personnel. If the firm contacts other FSIS personnel, those employees are to promptly contact RMTAD through supervisory channels.

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

1. The company that manufactures, distributes, or receives the product;
2. Test results from FSIS sampling programs;
3. Observations or information gathered by FSIS personnel in the course of their routine duties or investigations;
4. Consumer complaints reported through the FSIS Consumer Complaint Monitoring System (CCMS);
5. Complaints reported to FSIS through sources other than CCMS;
6. Epidemiological or laboratory data submitted by State or local public health departments or authorities, other USDA agencies, and other Federal agencies such as the FDA, the Centers for Disease Control and Prevention (CDC), or the Department of Defense; or
7. Information from other agencies, such as the Department of Homeland Security, Customs and Border Protection, the Animal and Plant Health Inspection Service, or foreign inspection officials.

II. PRELIMINARY INQUIRY

A. When there is reason to believe that adulterated or misbranded product is in commerce, FSIS will conduct a preliminary inquiry. The applicable FSIS OFO District Manager (DM) or Office of Investigations, Enforcement and Audit (OIEA) Regional Director (RD) is to assign personnel to lead this effort. FSIS personnel are to begin the preliminary inquiry by gathering relevant information about the products in question, contact information for the firms involved in production and distribution, and any information that might affect the scope of involved product or mitigate the need for a recall. If the applicable DM or RD determine the event should be escalated for further RMTAD analysis, the personnel assigned to lead this effort are to work with the firm to complete and forward a copy of FSIS Form 5020-3, *Preliminary Inquiry Worksheet*, to RMTAD for assessment and escalate the event by creating an Agency Report of Adulteration (ARA) in PHIS. Firms may complete FSIS Form 5020-3. If the firm elects to complete this form the information should be verified by District or Regional Office personnel before submission to RMTAD.

NOTE: Information about creating and escalating cases in PHIS Adulterated Product Monitoring (APM) can be found in FSIS Directive 8140.1.

B. FSIS personnel are to gather product label information, including photographs or digital scans of labels, and submit to RMTAD via email whenever possible, to minimize transcription errors and enable consignees and consumers to readily identify affected product if FSIS issues public notification.

C. While investigating and assessing potential adulteration and misbranding events, OFO or OIEA personnel may coordinate with other program areas to perform some of the following activities, as necessary, to gain a full understanding of the event being investigated or assessed. This list is not exhaustive:

1. Collecting and verifying information about suspect products and ingredients;

2. Documenting a chronology of events;

3. Contacting the company that manufactures or distributes the product for additional information;

4. Communicating with FSIS field inspection and FSIS enforcement personnel;

5. Interviewing any consumer who allegedly became ill or was injured from eating regulated product;

6. Collecting and submitting product samples for analysis;

7. Contacting other agencies, State and local health departments, or coordinating with the Office of International Coordination (OIC) to contact foreign governments;

8. Coordinating with OPHS during the analysis of any available epidemiological data; and

9. Reviewing supporting documentation and evidence (e.g., Sanitation Standard Operating Procedures, Hazard Analysis and Critical Control Point (HACCP) and production records, risk assessments, etc.).

D. RMTAD is to assess all information gathered during the preliminary inquiry.

1. If RMTAD determines that the Event Assessment Committee should be engaged, RMTAD is to provide the relevant materials to committee members. To facilitate committee deliberations and ensure the appropriate disposition of products, RMTAD is to ensure that firms have an opportunity to submit any mitigating information that the Committee will consider.

2. RMTAD may determine that further recall consideration is unnecessary.

a. RMTAD may determine that the product in question is not, in fact, adulterated or misbranded. In such cases, engagement of the Event Assessment Committee is unnecessary.

b. RMTAD may determine that adulterated or misbranded product had been in commerce but is unlikely to be either still available for sale or still in the possession of end consumers, e.g., RMTAD may learn that fresh, perishable meat or poultry product entered U.S. commerce but is well past its use by date and highly unlikely to be stored by consumers.

c. If RMTAD determines that further recall consideration is unnecessary per D.2.a or D.2.b above, RMTAD is to document the result of the assessment in the ARA in PHIS.

d. RMTAD may determine that adulterated or misbranded products entered commerce, are no longer for sale, but are likely in the possession of consumers and may present a public health risk. In such cases, RMTAD is to engage the Event Assessment Committee to discuss whether a PHA may be necessary.

e. If RMTAD determines that product in commerce is adulterated or misbranded because it contains an ingredient subject to an FDA recall, RMTAD is to engage the Event Assessment Committee to discuss whether a PHA may be necessary.

CHAPTER III – EVENT ASSESSMENT COMMITTEE

I. EVENT ASSESSMENT COMMITTEE MEMBERS

A. All members of the Event Assessment Committee are to be knowledgeable about the issues raised by an escalated event and are to be empowered to represent their respective AA's views. Committee members are to make every effort to achieve consensus on whether to recommend a recall, formally consider recovery actions already planned or initiated by a firm to be a recall necessitating public notification and FSIS verification, issue a PHA, or consider recommending other appropriate actions. The primary members of the Committee and their roles are described below:

1. RMTAD, OFO – (chair) – Gathers and analyzes information regarding escalated events. Calls a committee meeting, when necessary, and distributes information about the escalated event to committee members. RMTAD invites other FSIS program areas to assist as necessary.

2. Office of Policy and Program Development (OPPD) – Provides the statutory basis for each action recommended by the Committee and addresses any policy questions relevant to the event being assessed.

3. OPHS – Addresses microbiological, epidemiological (including CCMS queries), and other scientific issues associated with the event. OPHS also assesses the public health impact of the event. If the Committee recommends a recall, OPHS proposes the classification.

4. Office of Public Affairs and Consumer Education (OPACE), Congressional and Public Affairs Staff (CPAS) – Gathers information and generates a Recall Release or Recall Notification Report if there is a recall. When appropriate, OPACE generates a PHA in situations where a recall action is not warranted, or the firm does not accept the Agency's recommendation for a recall. OPACE ensures that information contained in the Recall Release, PHA, or Press Release is accurate.

5. OIEA, CID: - Assists OFO upon request. OIEA may lead preliminary inquiries when an escalated event involves products in commerce that did not originate from an official establishment or involves imported products. OIEA also conducts investigations of alleged criminal violations, such as those involving the sale, transport, or receipt of adulterated or misbranded product associated with the event.

6. Reporting Office (OFO or OIEA) – Clarifies and explains to the Committee the information collected during the preliminary inquiry.

B. The Committee may also consist of representatives from the following program areas in a supporting role at RMTAD's request and in accordance with any existing Memorandum of Understanding:

1. Significant Incident Preparedness and Response Staff (SIPRS) – A representative from SIPRS is invited to all Event Assessment Committee meetings. If a recall involves illness or injury, the SIPRS representative records the information from the recall so that it may be entered into the FSIS Incident Management System (FIMS).

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

3. OIC: A representative from the OIC is invited to all Event Assessment Committee meetings to participate as a non-voting member when the event involved imported product. OIC notifies foreign governments when FSIS becomes aware that domestically produced recalled product was exported from the United States to a foreign country.

II. DELIBERATIONS OF THE EVENT ASSESSMENT COMMITTEE

A. The Event Assessment Committee meets when an adulteration or misbranding event requires the committee's consideration. To convene the Event Assessment Committee, RMTAD is to contact the Committee members via the Agency's messaging application to inform them of the event and arrange a meeting to discuss. RMTAD is to make every effort to ensure that the six (6) primary members of the Recall Committee are available to participate in the Committee meeting.

B. The Event Assessment Committee is to discuss the details of the escalated event, including the applicable statutory requirements to determine the Agency's best approach for addressing the event. This may include the reasons that a particular product may need to be removed from commerce and whether there is a statutory basis to recommend a recall. If the Event Assessment Committee decides to recommend a recall, it is to also determine the appropriate recall classification.

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

1. Does FSIS have evidence to demonstrate that the product in question is adulterated or misbranded under the FMIA, PPIA, or EPIA? For example:

    a. If the results of a laboratory analysis show that raw ground beef or beef manufacturing trimmings contain *E. coli* O157:H7 or non-O157 STEC, or that an RTE product contains *Listeria monocytogenes or Salmonella* spp., the product is adulterated because it is likely to be injurious to health;

    b. Situations in which laboratory results are not available or are inconclusive, but FSIS believes, on the basis of epidemiological and traceback evidence, that a specific meat, poultry, or egg product is associated with human illnesses. Under these circumstances, the Event Assessment Committee is to consider the strength of the epidemiological and traceback evidence to determine whether there is evidence to conclude that a specific lot or lots of product contain the pathogen causing illness or is otherwise unhealthful and, therefore, adulterated.

2. Does any of the product in question remain in commerce, available for sale or use?

a. Domestic product is considered "in commerce" if it has been shipped from an establishment without Agency or establishment controls or restrictions and is free to be moved to any consignee or to consumers. This does not include product that is only in the possession of end consumers at their personal residences.

b. Imported product is considered ''in commerce'' when it has been released by CBP and is offloaded at a location other than the official import inspection establishment or the official establishment designated on the import inspection application. Imported product held offsite pending laboratory results or otherwise is not considered "in-commerce," provided the importer maintains product control over the entire lot as identified on the foreign inspection certificate.

c. The Event Assessment Committee and program employees are to consider all available information to determine whether product remains in commerce, and whether any product that has been distributed in commerce remains available to consumers at retail facilities, restaurants, etc.

D. To properly assess whether any of the product remains available for sale to consignees or consumers, the Event Assessment Committee is to seek responses to the following questions:

1. Is the product readily identifiable and able to be differentiated from similar unaffected product?

2. When was the product produced?

3. To whom has the product been distributed?

4. What type of product is involved (e.g., RTE, fresh-packed, canned, frozen)?

5. What is the typical, usable shelf life of the product?

6. What are the typical consumer or user practices concerning handling and storage 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/consumption)?

7. Is the Agency able to verify that the product previously distributed in commerce is no longer free to move to consignees or otherwise available to consumers at retail facilities, restaurants, or other institutions? To verify whether product remains free to move to consignees or consumers, the Committee may consider records provided by the establishment or its consignees.

E. If the answers to questions C.1. and C.2. are both "yes," the Committee should recommend a recall. The Committee should not recommend a recall under the following circumstances:

1. FSIS does not have sufficient evidence to support that product is adulterated or misbranded according to the Acts.

2. Adulterated or misbranded product is no longer available for sale or use in commerce.

3. FSIS is unable to identify the responsible party.

4. FSIS is unable to readily identify the scope of product that may be adulterated or misbranded.

5. The product in question is already recovered or under control.

6. The product in question is long past its usable shelf life.

7. FSIS identifies an ineligible foreign product imported by multiple importers or through nefarious means.

8. FSIS identifies FSIS-regulated products that contain ingredients already subject to recall.

9. FSIS, working with its Federal and State partners, determines that a meat, poultry, or egg product may be associated with human illnesses, but it cannot identify a specific product (e.g., lot or lots) that it could recommend be recalled.

F. If the Committee determines the answer to C.1 and C.2. are "yes," but the Committee is unable to identify the responsible party for the product or cannot readily identify the scope of the issue, the Committee should recommend a PHA. See Chapter IV for information regarding PHAs.

G. If the Event Assessment Committee finds that the establishment has recovered or controlled all products from commerce that would have been subject to recall, the Committee should not recommend a recall, as no product should remain available for sale or use in commerce. Instead, FSIS personnel are to verify that the product is under control and that the firm conducts proper disposition of the affected products. If a portion of such product had been previously sold to consumers, the Committee should consider whether typical consumer or user practices concerning handling and storage indicate that product may remain in the possession of end consumers at their private residences (e.g., stored or frozen for later consumption). In these circumstances, the Committee should consider recommending a PHA.

H. If one or more Committee members do not agree with the action that a majority of the committee has decided to recommend, all members of the Committee are to immediately discuss the issue with their respective AAs and report back to the Committee. If the Event Assessment Committee is unable to come to consensus, the RMTAD representative is to notify the OFO AA or designee, who is to discuss the issue with the dissenting AA(s). The OFO AA may decide to convene a meeting of the AAs and advise the FSIS Administrator that they are convening the meeting. Each AA is to discuss the potential recall with their Office's Event Assessment Committee representative or their designee. If the AAs are unable to resolve the matter, they are to report the situation to the Administrator to make a final decision.

I. If the Event Assessment Committee agrees that a recall is not recommended, RMTAD is to document the results of the preliminary inquiry in a memorandum and upload it to the ARA.

J. If the Event Assessment Committee agrees to recommend a recall, the OPHS representative is to recommend a classification for consideration by the Committee, which is to reach consensus on the classification. The classification is to consider the human health hazard presented by the specific product subject to recall, as well as any precedents for determining the significance of the health hazard presented by an adulterated product and the classification of the hazard. The Event Assessment Committee generally is to be guided by these precedents in classifying recalls. However, if the Event Assessment Committee has questions about hazards or conditions that have not been previously encountered by the Agency, the OPHS representative may request OPHS to convene the HHEB, which is to consider, at a minimum, the following factors:

1. The nature of the problem (i.e., what is the problem with the product and what health hazards does the problem create);

2. The occurrence of any illnesses or injuries;

3. The likelihood that illnesses or injuries may result; and

4. The types of illnesses or injuries that may result.

K. The Committee may also refer to the guidance document "Factors That Are Considered by the FSIS Event Assessment Committee in Evaluating the Public Health Significance of an Undeclared Ingredient in a Meat, Poultry, or Egg Product" when considering the classification of a recall that involves a meat, poultry, or egg product that contains an ingredient that is not declared on the product labeling.

L. After the Committee members have discussed the issues described in the above paragraphs and agreed to recommend a recall, RMTAD is to contact the firm to allow its representatives to join the Event Assessment Committee discussion. RMTAD is to present the Committee's recommendation to the firm. During the discussion, the Event Assessment Committee is to provide the recalling firm with an opportunity to present information about the hazard or concern associated with the affected product. Based on the merits of this information, RMTAD may decide to clarify the Committee's position or to temporarily adjourn and re-engage Committee deliberations. FSIS expects the firm to have its recall strategy available upon request, including how it intends to notify and instruct its consignees to retrieve or dispose of the recalled product.

III. RECALL RECOMMENDATION

A. When the Event Assessment Committee recommends a recall, RMTAD is to submit a Recall Recommendation in the form of a memo for approval by the OFO AA or designee. 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 and the applicable statutory citations;

2. An explanation of how, when, and by whom the problem was discovered;

3. The recall classification (i.e., Class I, Class II, or Class III);

4. The ability of distributors, consumers, or users of the product to identify the products covered by the recall;

5. How the scope of the recall was determined; and

6. The estimated amount of recalled product in distribution (the amount of product subject to recall that was distributed). In some cases, not all product in distribution will be recalled because some of it will be beyond the sell by/use by dates or codes at the time of recall. In these cases, the Event Assessment Committee is to determine whether consumers might still have the product, and, if so, whether they would possibly consume it.

B. The Event Assessment Committee generally determines much of the above information from the recalling firm through written documents or telephone conference calls. Before deciding on a recommendation, RMTAD may request that FSIS inspection or enforcement personnel verify the information provided by the firm. RMTAD is to strongly encourage firms to digitally provide the information involved in the recall to facilitate the speed and accuracy of the information transfer.

C. If the OFO AA or designee approves the Recall Recommendation, RMTAD is to follow up in writing with an email to the firm memorializing its discussion with the Committee. If the OFO AA or designee does not approve the Recall Recommendation, the OFO AA is to convene the AAs to discuss and resolve whether to recommend a recall. Each AA is to discuss the potential recall with their Office's Event Assessment Committee representative. If the decision is made to recommend a recall, CPAS is to confirm the information necessary for a Recall Release. The OPACE AA may request that other AAs review the draft Recall Release before it is issued. The applicable District or Regional Office is to assign a Recall Officer (RO) to begin coordinating effectiveness checks (see Chapter VI), consistent with the class of the recall, and is responsible for directing the activities of FSIS field personnel.

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

CHAPTER IV - ANNOUNCING THE RECALL

I. ACTION BY FIRM

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

B. If the firm decides not to accept the Agency's recommendation and chooses not to conduct a recall, FSIS personnel are to follow the instructions in FSIS Directive 8410.1, *Detention and Seizure,* to detain any product found in commerce that would have been subject to a recall and petition the Department of Justice to seize these products on behalf of FSIS. CPAS is to issue a Press Release informing the public that adulterated or misbranded product has been shipped by the responsible firm, that the firm has declined to recall the product, and that the Agency is detaining product in commerce. If a firm is already adequately recovering adulterated or misbranded product from commerce (e.g., firm proactively notified customers to return, destroy product, etc.) but declines to accept the Agency identifying their action as a recall, FSIS may still issue a recall release as described below on the basis that the voluntary actions already initiated by the firm constitute, by definition in this Directive, a recall.

II. RECALL RELEASE

A. Following approval of the recall by the OFO AA or designee, RMTAD notifies CPAS to issue a Recall Release and upload a copy of the Recall Release to the ARA case. CPAS is to distribute the Recall Release for Class I and Class II recalls to media wire services, media outlets in areas that received recalled products, the FSIS email subscription service for recalls, and FSIS-affiliated social media outlets. FSIS will not distribute a Class III Recall Release to the media. CPAS will also post all Recall Releases on the FSIS website.

B. The Recall Release will:

1. Identify the firm that produced the product;

2. Clearly describe the product involved, along with any identifying marks or codes;

3. Explain the reason for the recall, including the reason the product is adulterated or misbranded and how the problem was discovered, and describe the risks involved in consuming the product;

4. 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;

5. Instruct the public on how to properly handle the product if consumers have it in their possession, including specific recommendations for affected consumers when the product contains an allergen;

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

7. Provide general information about the product's known destination. For example, "Ham and turkey products were distributed to retail stores and institutions in the States of…."

C. For Class I recalls related to human illness, an Incident Report (IR) will be posted on the FSIS FIMS by OPACE if one has not already been created. The Recall Release will be attached to the IR. Program

areas are to update the IR, as appropriate, until the recall is complete. RMTAD will enter the IR case link in the ARA case.

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

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

A. When adulterated or misbranded product produced by an establishment under a State's Meat and Poultry Inspection (MPI) program enters intrastate commerce, FSIS will expect the State's MPI program to take the lead on mitigating these issues and notifying the public, when necessary, as part of its agreement with FSIS to administer an MPI program at least equal to that of FSIS.

B. When FSIS is informed by a foreign government's food inspection agency or a company under its jurisdiction that the foreign government or the company is recalling product that may be available to U.S. consumers, FSIS is to issue a PHA or Press Release that provides information similar to FSIS Recall Releases. For example, FSIS may issue a PHA or Press Release that contains information about a Canadian recall if that product was exported to the United States. FSIS may also conduct ad hoc effectiveness checks whenever a foreign government or a company under the jurisdiction of the foreign government recalls product available in the United States, unless, on review, the Agency determines that effectiveness checks are not necessary in a specific situation. FSIS may issue a PHA or Press Release to notify the public and identify any downstream products included in the scope of the recall (e.g., product further processed and repackaged without sufficient mitigation of public health hazards).

C. When FSIS becomes aware that meat, poultry, or egg products are implicated in a recall of source material or ingredients used in such products, FSIS will verify that firms that have received these ingredients are following the instructions received from their suppliers. FSIS may conduct ad hoc effectiveness checks if deemed necessary and may issue a PHA or Press Release to notify the public and identify such products that are not referenced by the source material or ingredient recall release.

IV. PUBLIC HEALTH ALERTS

A. FSIS may issue a PHA instead of or in addition to recommending a recall. PHAs inform the public of specific public health risks posed by products in commerce or in the possession of end consumers when there is no product recall (See Chapter III.II.F) or when available product has already been recovered from commerce and controlled prior to FSIS notification or engagement but may still pose a risk to consumers at their homes. FSIS also issues PHAs when firms decline to initiate a recall upon FSIS recommendation.

1. There may be situations in which the Event Assessment Committee determines that one or more products that have entered commerce may pose a public health risk, but the Committee cannot recommend a recall (See Chapter III.II.F).

2. The committee is to consider whether the known information that could be communicated in a PHA would be meaningful to the public and end consumers (e.g., how would consumers identify the potentially adulterated products in their possession) and if this information adds to any public messaging previously made by other partners (e.g., does the known information only repeat what has already been communicated).

3. If OPHS personnel have reason to believe that a meat, poultry, or egg product may be associated with human illnesses, but there is not sufficient information available for RMTAD to convene an Event Assessment Committee (e.g. during the initial phases of an outbreak investigation where the

Agency is still working to identify a specific product or specific lot or lots of product that FSIS could recommend be recalled or otherwise identified to the public), OPHS personnel are to report the incident through supervisory channels. FSIS typically becomes aware of these situations from the findings of a foodborne illness investigation conducted by, or reported to, OPHS's Applied Epidemiology Staff (AES). If appropriate, the OPHS AA or designee is to notify SIPRS and request activation of the Emergency Management Committee (EMC), as provided in FSIS Directive 5500.2, *Significant Incidence Response*. If the situation is considered by the EMC, the EMC is to decide whether FSIS should issue a PHA. OPHS is to communicate the EMC recommendation for a PHA to RMTAD, which will document this event in APM.

B. When the Event Assessment Committee recommends a PHA, RMTAD is to submit a PHA recommendation in the form of a memo for approval by the OFO AA or designee. The recommendation is to contain:

1. The reason for the PHA, including why there is a reason to believe that the product is adulterated or misbranded and why a PHA is appropriate;

2. An explanation of how, when, and by whom the problem was discovered; and

3. The estimated amount of adulterated or misbranded product in distribution, when available.

C. If the OFO AA or designee approves the PHA recommendation and the firm responsible for the adulterated or misbranded product is known, RMTAD is to contact the firm and inform them of the Agency's decision to issue a PHA. CPAS is to confirm the information necessary for the PHA. The OPACE AA may request that other AAs review the draft PHA before it is issued.

D. If the OFO AA or designee does not approve the PHA recommendation, the OFO AA is to convene the AAs to discuss and resolve whether to issue a PHA. Each AA is to discuss the potential PHA with their Office's Event Assessment Committee representative.

E. If FSIS issues a PHA, the alert will, to the extent possible:

1. Identify the firm that produced the product;

2. Clearly describe the product involved, along with any identifying marks or codes;

3. Explain the reason the product is adulterated or misbranded and describe the risks involved in consuming the product;

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

5. Instruct consumers on how to properly handle the product if they have it in their possession, including specific recommendations for affected consumers when the product contains an allergen; and
6. If available, provide the name and telephone number of a company contact for consumers and media to call with any questions.

F. When the firm responsible for the adulterated or misbranded product is known, CPAS is to email a draft copy of the PHA to the firm prior to its release. At this time, CPAS is to inform the firm that it may review the PHA to verify that the product description, the company contact information, and product distribution information are accurate. CPAS is to inform the firm that if it does not respond to CPAS within 30 minutes of receiving the PHA, FSIS will proceed to issue the PHA. If the firm notifies CPAS of any typographical or other inadvertent errors, CPAS is to correct them before issuing the PHA.

G. FSIS notifies the public about PHAs through press releases.

V. RETAIL CONSIGNEE LISTS

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

B. The RO, or designee, is to use the PHIS-reporting feature to generate the retail consignee list, including the name, street address, city, and state of each retail consignee in a spreadsheet matching the standard Agency format as soon as the initial list of retail locations can be prepared. The RO, or designee, is to submit the list to RMTAD. RMTAD is then to review and send the list of retail consignees to the OPACE Digital and Executive Communications Staff (DECS) for posting on the FSIS website. FSIS will aim to post an initial list within approximately 10 days of the date of the recall. Developing the retail consignees list may take longer than this if the recalling firm also sells the recalled product to distributors. The RO is to periodically re-run the PHIS report for retail recall consignees when new retail locations are added to the Master Consignee List (MCL) and provide the update to RMTAD.

C. DECS is to post to the list periodic updates from the list to RMTAD as additional retail consignee information becomes available. After the initial posting, updates may be frequent for the first several days, and then less often, as new information becomes less available.

CHAPTER V – SPECIAL CONSIDERATIONS FOR LARGE VOLUME RECALLS

A. There may be situations involving recalls that include large volumes of product and numerous product labels, dates, and establishment numbers due to the inclusion of the recalled product in other FSIS-regulated products. If the FSIS establishment or FDA-regulated firm that produced the adulterated source materials has already recalled the affected product and receiving establishments have used the affected product as source materials to produce additional new FSIS-regulated products, FSIS will consider the new products subject to the original recall and will not ordinarily announce multiple separate recalls for the same issue. However, FSIS would expect any receiving establishment that has used the affected product to produce a new product to follow the instructions received from their supplier (e.g., recover or dispose) unless, as determined by the Agency, the process under which the new product was produced is sufficient to have mitigated the specific hazard (e.g., raw ground beef recalled for STEC was previously utilized by a downstream establishment to produce fully cooked sausage).

B. FSIS personnel are to verify that the establishment or FDA-regulated firm that produced the adulterated source materials or ingredients has recalled the affected product, including product incorporated into new products. If any receiving establishment refuses to recover new products containing adulterated source materials or ingredients implicated in the recall, FSIS personnel are to detain and seize those new products.

C. If new products are produced using affected product or if the scope of a recall or details about recalled product change, FSIS will publish a notification to the public that this has occurred. This may or may not necessitate convening an Event Assessment Committee, as determined by RMTAD.

CHAPTER VI – EFFECTIVENESS CHECKS

I. GENERAL

A. Each official establishment is required to develop written procedures to specify how they will decide whether and how to conduct a recall, should they decide that one is necessary (9 CFR 418.3). Establishments and recalling firms are responsible for notifying all consignees of the need to remove recalled product from commerce. 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.

B. Depending on the availability of Agency personnel and the type of firm conducting the recall, Enforcement Investigations and Analysis Officers (EIAOs) or CID Investigators are to conduct effectiveness checks. Generally, if the recalling firm is an official establishment, the RO is to coordinate and direct OFO personnel to conduct effectiveness checks. If the recalling firm is an importer or otherwise not an FSIS-inspected establishment, the RO is to coordinate and direct OIEA personnel to conduct the checks and contact the CID RD to obtain assistance from CID investigators to conduct checks. Assigned personnel are to contact the recalling firm's distribution consignees to collect customer information and provide it to the RO. The RO is to compile an MCL by uploading consignees to APM. Personnel assigned to contact distribution consignees are to verify the same information gathered as part of an effectiveness check, including interviewing the consignees to ensure they were notified of the recall and that they communicated appropriate instructions to their customers. If at any time during the effectiveness checks FSIS personnel discover that a firm did not contact the consignees promptly with recall instructions or that the consignees are not handling product in the manner requested by the firm, FSIS personnel are to detain any product found in commerce as set out in FSIS Directive 8410.1. FSIS personnel are to notify the RO immediately when the recalled product remains available to the consumer and when the recalling firm has not properly implemented its recall strategy. The RO is to notify RMTAD and take immediate action to address identified concerns including, but not limited to, conducting follow-up with distributor consignees and notifying the recalling firm of insufficiencies or ineffectiveness of its recall, and ensuring the recalling firm takes appropriate measures to correct any insufficiencies that may lead to an ineffective recall when necessary. The recalling firm is ultimately responsible for all aspects of the recall.

II. FIELD RECALL RESPONSIBILITIES UPON NOTICE OF A RECALL

A. The RO is to:

1. Serve as the primary point of contact for the recalling firm;

2. Immediately request that the recalling firm provide information regarding product distribution, including the names, addresses, and phone numbers of its consignees (Attachment 1);

3. Obtain a copy of any notice of recall issued by the firm to its consignees or to the public for accuracy of product information, risk, and clarity (e.g., verify that the firm discloses the reason for the recall and describes the product defect or adulterant), and verify that the recall notice does not contain promotional or company information that obscures the risk of the product. Upload a copy of the written recall notice to the APM Recall case. If the recall notice is incomplete or inaccurate, the RO 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 RMTAD;

4. Inquire how the firm plans to control recovered product; and

5. Inquire how the firm plans to handle product disposition.

B. If the firm's recall strategy includes destroying product on site, the RO may assign FSIS personnel to witness destruction of the product in accordance with 9 CFR part 329, part 381, Subpart U, or 590.422.

FSIS personnel are to document this on the Report of Effectiveness Check in APM as product disposition verification.

III. RO RESPONSIBILITIES FOR COORDINATING FSIS PERSONNEL ACTIVITIES DURING EFFECTIVENESS CHECKS

A. The RO is to:

1. Coordinate effectiveness checks and direct the activities of FSIS personnel;

2. Determine product distribution and request assistance from Assisting Offices (AOs) in Districts/ Regions where product was distributed. The Deputy District Managers (DDMs)/RDs of the AOs are to determine whether additional consignees need to be added to the distribution list. When contacting all primary, secondary, and tertiary distributors to compile the MCL, the RO and AOs are to treat these interactions in the same way as an effectiveness check and interview the subject firm as outlined in Chapter VI, Section IV, A directly below;

3. The RO will eliminate duplicate consignee listings and upload the list of consignees into APM;

4. The RO will determine the appropriate table in Attachment 1 to assign a total number of effectiveness checks in APM that will be performed by on-site verification and by telephone. If there is sufficient information, the RO may decide to group effectiveness checks by special consignee categories (e.g., schools, day care centers, hospital cafeterias, or retirement homes). If the RO decides to group effectiveness checks by special categories, the RO is to apply the appropriate table in Attachment 1 to each consignee category in APM, as provided in Section G of this attachment; and

5. Select a sub-set of consignees for effectiveness checks using the appropriate selection criteria (Attachment 1).

B. The RO is to add any additional consignees identified after FSIS has started conducting effectiveness checks to the MCL in the APM. These consignees will be randomly selected for recall effectiveness checks until the number of required effectiveness checks as defined by Tables 2-5 (Attachment 1) below are met. If additional consignees are identified and added to the MCL after the required number of effectiveness checks is met, the RO will review the outcome of the conducted checks to determine whether additional biased checks should be selected from the newly identified consignees.

IV. FSIS PERSONNEL RESPONSIBILITIES FOR CONDUCTING EFFECTIVENESS CHECKS

A. For a recall to be deemed effective, the number of consignees checked that are found to have the product available to the public must be less than or equal to the critical number applied to the effectiveness check plan (Attachment 1). Using the selections generated by the RO in the APM Recall case, FSIS personnel are to:

1. Contact or visit the consignees to determine whether they were notified of the recall and have removed the recalled product from commerce (e.g., located, segregated, and appropriately controlled affected product pending disposition);

2. Verify that the consignees are handling the product in accordance with regulatory requirements and the instructions of the recalling firm by reviewing records and observing or verifying product disposition, when necessary;

3. Determine whether any recalled product remains available to consumers (e.g., by checking store shelves, storage areas, or freezers during on-site visits). Take appropriate action to detain any recalled product found available for sale or use in accordance with FSIS Directive 8410.1;and

4. Record the effectiveness checks on the Report of Effectiveness Check in APM and submit the completed reports to the appropriate District or Regional office. Supervisors are to review and approve the completed checks, including determining whether any follow-up actions are needed for ineligible checks or locations that did not receive a recall notification.

B. FSIS may verify the disposition of the recalled product during an effectiveness check. In cases where product disposition is still pending during the on-site effectiveness check, FSIS personnel may request that the location provide documentation, when it becomes available, sufficient to demonstrate that the product was handled in accordance with the recalling firm's instructions and regulatory requirements and document this on the Report of Effectiveness Check in APM as a follow-up.

C. If, when conducting effectiveness checks, FSIS finds recalled product offered for sale or use in commerce, the Agency will consider whether the recalling establishment clearly communicated the recall notification to its consignees and whether those consignees adequately relayed the notification down through the distribution chain. When a trend is identified, the RO may assign additional effectiveness checks by biased selection.

D. The RO is to issue a letter to the violating firm describing the circumstances of any prohibited acts and the potential enforcement or criminal action the Agency may pursue. In this scenario, the violating firm may be a recalling firm or consignee that failed to adequately notify downstream consignees, or it may be a consignee that received adequate notification but failed to follow the recalling firm's instructions to remove product from sale or use. FSIS may find that the recalling firm effectively communicated the recall, but that the recalling firm's consignees failed to ensure that the recalled product was removed from commerce. As necessary, FSIS personnel are to follow FSIS Directive 8410.1 and notify the consignee of any prohibited activity. FSIS personnel are to notify the recalling firm immediately of any instances involving recalled product found available for sale or use. When the prohibited activity is a result of a failure to provide adequate recall notification to consignees, in addition to issuing notification of the prohibited act, FSIS personnel are to contact the firm that failed to notify consignees and request information on how the firm will ensure all consignees are notified of the recall. The RO is to refer all instances of prohibited activity to OIEA/CID for investigation and enforcement.

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

The RO is to:

1. Continually monitor recall effectiveness reports from all AOs in APM;

2. Analyze the information that is submitted by FSIS personnel on the Report of Effectiveness Check in APM and review any instances in which recalled product was found in commerce or consignees did not receive recall notification. The RO is to immediately contact RMTAD and the recalling firm regarding any pattern or trend that may suggest certain consignees were not contacted or any other issues that may result in an ineffective recall (see VI below); and

3. Maintain contact with the recalling firm and verify that the firm:

    a. Completed execution of the recall as planned;

    b. Controlled, recovered, or confirmed disposition of the product as planned; and

    c. Considers the recall closed.

4. Obtain the recalling firm's request to close the recall either verbally or in writing.

NOTE: RMTAD and the RO are not to leave a recall case open pending disposition of recovered product. Control and disposition of recovered product will be monitored by FSIS in the same manner that it would have had the adulterated or misbranded product not entered commerce.

VI. THE RO DETERMINATION ON THE EFFECTIVENESS OF THE RECALL

A. The outcome of the recall is deemed effective or ineffective based on the number of locations where products were found to be available for sale (*see* Attachment 1).

B. In consultation with RMTAD, the RO may determine that the recall action is ineffective based on their review of the effectiveness checks because of the firm's failure to control and dispose of the product. The RO is to make this determination as early as possible, even if effectiveness checks are ongoing. The RO is to notify the recalling firm immediately upon determining an active recall may be ineffective, follow up in writing, and provide a courtesy copy of the notification to RMTAD, explaining why the recall action is deemed to be ineffective. The RO is to ask how the recalling firm intends to address the situation. If the recalling firm is unwilling or unable to correct its recall strategy, the RO is to recommend that the Agency take further action to mitigate the risk to the public, if necessary. The recommended actions may include public warnings, product detentions and seizures, or other appropriate actions.

C. FSIS personnel conducting effectiveness checks should continue with all assigned checks even though a recall has been determined ineffective.

VII. RMTAD REVIEW OF ACTIVE RECALL DATA

RMTAD is to perform periodic review of active recall data in APM to assess recall case progress and ongoing issues identified during recall effectiveness checks.

CHAPTER VII – CLOSURE AND POST-RECALL ASSESSMENT REPORT

I. CLOSURE

A. The RO is to provide a memo to RMTAD with a request to close the recall and include the amount of product recovered, if any, and disposition. If the amount of product recovery or disposition is unknown, the memo is to include any available known product recovery or disposition information. The RO is to upload the memo to the APM Recall case.

B. Before closing a recall, RMTAD is to review the recall effectiveness check summary and the RO summary of findings.

C. If a recall is associated with a reported illness, RMTAD is to ask AES, 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. RMTAD 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, RMTAD may proceed to recommend closing the recall.

D. RMTAD is to submit a Recall Termination memo to the OFO AA that summarizes the recalling firm's efforts and the findings of the FSIS effectiveness checks.

E. RMTAD is to close the APM Recall case, notify the recalling firm in writing through email that the recall is closed and notify DECS to identify the recall as closed on the FSIS website.

II. POST-RECALL ASSESSMENT

A. When the OPPD AA determines that it is necessary, OPPD will review the events leading to recall recommendations, 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:

1. RMTAD.

2. OFO program personnel:

    a. Executive Associate for Regulatory Operations;

    b. District Manager or DDMs participating in the recall;

    c. Case Specialist from the recalling district;

    d. Supervisory EIAOs and EIAOs designated by the recalling district; and

    e. IPP as designated by the District Manager or designee through the supervisory chain of command.

3. OIEA program personnel:

    a. CID RD;

    b. CID Supervisory Investigator; and

    c. CID Investigator.

4. Other Agency personnel that participated in the recall activities, including personnel from SIPRS, OPPD, OPHS, and OPACE.

C. When conducting the post-recall assessment, the meeting participants should consider pertinent information within and across program areas, such as, but not limited to, the following information:

1. Recall Effectiveness Checks results;

2. Food Safety Assessments;
3. Enforcement history;
4. Failures of the establishment's food safety programs;
5. Reports of consumer illness; and

Any pertinent information collected during the preliminary inquiry, as described in Chapter II.

CHAPTER VIII. QUESTIONS

Refer questions through supervisory channels.

Assistant Administrator
Office of Policy and Program Development

EFFECTIVENESS CHECKS

A. Determining the Total Number of Effectiveness Checks to Conduct

1. After the recall officer (RO) has removed duplicate consignee entries from the master consignee list (MCL) and has determined the total number of consignees, the RO will determine the appropriate table in this document to assign a total number of effectiveness checks in APM that will be performed by on-site verification and by telephone. If there is sufficient information, the RO may decide to group effectiveness checks by special consignee categories (e.g., schools, day care centers, hospital cafeterias, or retirement homes). If the RO decides to group effectiveness checks by special categories, the RO is to apply the appropriate table in this document to consignee category in APM, as provided in Section B of this attachment. The RO and FSIS personnel are to use the timeframes in Table 1 as a goal for completing a substantial portion of verification activities. Verification has begun when FSIS contacts any consignee of the recalling firm.

2. ROs are to be aware that large corporate chains which have numerous retail locations may provide a single report for all their locations or individual reports for selected locations, provided the chain has a robust system that allows for reporting recall notification and product disposition. The RO may review such reports to verify the FSIS selected retail locations in lieu of conducting phone checks.

3. Table 2 is used to determine the number of checks for all Class I recalls when there has been an illness, outbreak, or school distribution (*see* Section B: Schools and Other Special Consignee Categories).

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

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

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

Table 2. Effectiveness checks to conduct and critical limits for ***all*** Class I recalls involving an injury, illness outbreak, or distribution to schools.			
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:**	**Number of On-site Effectiveness Checks**
1 to 200	100% of consignees	0	RO will consult with RMTAD on the number of on-site verifications
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	

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

Table 3. Effectiveness checks to conduct and critical limits for Class I recalls when there are **no** injuries, illnesses, outbreaks, or distribution to schools			
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:**	**Number of On-Site Effectiveness Checks**
1 to 20	100% of consignees	0	100%
21 to 150	20	0	100%
151 to 1,200	80	1	20
1,201 to 2,300	125	2	20
2,301 to 10,000	200	3	80
10,001 to 35,000	315	5	80
35,001 to 150,000	500	8	80
150,001 to 500,000	800	12	80
500,001 and over	1250	18	125

5. Table 4 is used for Class II recalls.

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

6. Table 5 is used for Class III recalls.

Table 5. Effectiveness checks to conduct and critical limits for Class III recalls.*			
Number of Consignees	**Number of Effectiveness Checks to Make**	**Recall Considered Ineffective if the Number of Consignees at which Product was Available to Consumers Exceeds:**	**Number of On-Site Effectiveness Checks**
1 to 8	100% of consignees	0	0
9 to 50	5	0	0
51 to 90	7	0	0
91 to 150	10	0	0
151 to 280	20	1	0
281 to 500	25	1	0
501 to 1,200	30	1	0
1,201 and over	42	2	0

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

B. Schools and Other Special Consignee Categories

If information is available, the RO may group effectiveness checks by identified special categories (e.g., schools, day care centers, hospital cafeterias, or retirement homes), to mitigate risk to populations that may be more susceptible to foodborne illness. If the RO decides to separate groups by special categories, then each group of consignees should be considered separately. Apply the appropriate table in APM for the recall classification and type of special consignee category to select the number of effectiveness checks to be conducted for each special group. This will have the effect of increasing the number of effectiveness checks to be conducted at these facilities. Schools may also be grouped into a special category of consignees for conducting effectiveness checks during Class II and Class III recalls. During Class III recalls, all checks may be conducted by telephone.

FSIS typically does not conduct effectiveness checks on schools that participate in the School Lunch Program or other assistance program administered by USDA's Food and Nutrition Service (FNS) and that receive reimbursement for the cost of the recalled product by FNS. However, FSIS may determine that effectiveness checks or other actions are necessary at such schools, on a case-by-case basis.

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.

C. Selecting the Effectiveness Checks

The RO defines the criteria for selecting effectiveness checks in the APM Recall case. The RO should consult with RMTAD for any questions regarding which table in this document is appropriate for effectiveness checks selection.

1. Using the number of consignees and any decision to group effectiveness checks into special categories, the RO should determine the appropriate table to assign a selection rate.

For a Class I recall with no illnesses, outbreaks, or school lunch distribution, the appropriate table

is Table 3.

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

For a Class I recall with school lunch distrbution and retail/restaurant distribution, the appropriate table for the Schools consignee group is Table 2 and the appropriate table for the retail/restaurant consignee group is Table 3.

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

2. Once the MCL has been compiled, the RO, or designee, is to upload the MCL to the APM Recall case, enter the criteria for selecting checks, and follow the steps in APM for selecting checks. APM will generate a list of randomly selected effectiveness checks based on the tables and any grouping selected by the RO.

NOTE: The RO is to refer to Attachment 2 for instructions on how to select recall effectiveness checks in the event of a widespread system outage or other extenuating situation requiring a contingency plan.

APM will send a daily alert including information on the consignees selected for effectiveness checks to the Supervisory users that will assign the checks. If the recalled product was distributed to consignees in more than one District or Region, the appropriate AO is to assign FSIS personnel to perform the effectiveness checks in their District or Region.

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

If FSIS personnel are unable to perform an effectiveness check (e.g., a consignee selected for an effectiveness check did not receive the recalled product or is no longer in business) and determine that the check is ineligible, they are to contact the RO through their supervisory chain as soon as possible so that a replacement effectiveness check can be selected and assigned. The RO will use APM to select a replacement effectiveness check by substituting a consignee by random selection or a biased replacement consignee that the RO believes is likely to have received the recalled product. After making this substitution, APM will designate this effectiveness check to the applicable AO for assignment.

If the consignee selected for substitution is also ineligible for an effectiveness check, the RO is to select another substitute consignee. The second substitution should be a biased replacement consignee that the RO believes is likely to have received the recalled product. The RO should make a reasonable attempt to find a substitute consignee so the effectiveness check can be completed.

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

NOTE: There can be no substitutions if all consignees are selected for effectiveness checks.

D. "Findings of Product in Commerce" is defined as those occurrences where recalled product remains available to consumers.

1. When the DDM/RD or designee is notified by personnel in their district/region of findings of recalled product in commerce, they will immediately notify the RO.

2. The RO is to determine whether the findings follow a pattern or trend. During the evaluation, it is important to distinguish between isolated reasons (e.g., the product was removed from the store shelf but was re-shelved by mistake) and widespread systemic reasons (e.g., breakdown in the notification of consignees or delay caused by the schedule of sales personnel). This is important to do, even if the recall itself is effective, because there may be subgroups of consignees that have recalled product that is available to consumers. When a trend is identified, the RO may assign additional effectiveness checks by biased selection to verify that recalled product is not available to consumers. As deemed appropriate and necessary, the RO will notify the Director of the Compliance and Investigations Division (CID), OIEA.

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

There may be instances in which FSIS personnel may need statistical guidance when performing recall effectiveness checks. For example, FSIS personnel may not be able to contact consignees selected as effectiveness checks because the consignees are mobile (e.g., the product was distributed to a cruise ship).

In these circumstances, FSIS personnel are to inform RMTAD. RMTAD will contact the Office of Planning, Analysis, and Risk Management (OPARM) statistician assigned to assist with recalls and will refer the statistician to the appropriate RO. The OPARM statistician will work directly with the RO to provide any needed statistical guidance.

CONTINGENCY PLAN FOR SELECTING EFFECTIVENESS CHECKS

Effectiveness checks are selected using the guidance in Attachment 1 of this document whenever possible. However, should a widespread PHIS/APM outage or other extenuating circumstance that prevents the selection of effectiveness checks in PHIS/APM occur, the Recall Officer (RO), after consultation with RMTAD, is to compile the electronic Master Consignee List (MCL) and remove duplicates as instructed in Attachment 1 of this document.

A. Randomizing the MCL

After eliminating duplicate listings of the same consignee, the RO is to randomize the consignee list. The RO can use the electronic spreadsheet program to assign a random number to each consignee on the list and then sort the consignees by random number. After randomizing the consignee list, the RO should follow the instructions in Section C of this attachment when preparing to select effectiveness checks.

B. Determining the Total Number of Effectiveness Checks

After eliminating duplicate listings and randomizing the MCL, the RO will determine the total number of effectiveness checks that will be performed by on-site verification and by telephone derived from the values given in Tables 2-5 of Attachment 1 of this document. A subset of the total number of effectiveness checks for Class I and Class II recalls will be selected for on-site visits to verify that consignees have located, retrieved, and controlled recalled product according to the recall notification (see Tables 2, 3, 4, and 5 for the number of verification disposition checks to be conducted for each recall class).

NOTE: The RO should refer to Attachment 1 for information about grouping special consignee categories.

C. Preparing to Select Effectiveness Checks

The RO is responsible for selecting effectiveness checks.

1. Using the appropriate table, determine the selection frequency.

For a Class II recall and 600 consignees, the appropriate table is Table 4 and the number of effectiveness checks to conduct is 37, including 13 onsite disposition checks.

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

In the example above, if the 600 consignees include three (3) special consignee groups of 200 consignees each, then Table 4 shows that each group would have 15 effectiveness checks conducted including 5 on-site disposition checks. Thus, the total sampling number of effectiveness checks for all three (3) groups would be 45, including 15 on-site disposition checks.

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

3. The RO will determine a selection interval by dividing the total number of actual or estimated consignees by the number of effectiveness checks to be performed.

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

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

For this example, select number 3.

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

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

4. Provide information on the consignees selected for effectiveness checks to the FSIS personnel that will be conducting the checks. If the recalled product was distributed to consignees in more than one District or Region, distribute the list of selected effectiveness checks to the appropriate AOs. The AOs will assign FSIS personnel to perform the effectiveness checks in their District or Region.

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