VERMONT AGENCY OF AGRICULTURE, FOOD AND MARKETS
FOOD SAFETY CONSUMER PROTECTION DIVISION
MEAT INSPECTION SERVICE
MONTPELIER, VT

VT MIS DIRECTIVE **Adopted from FSIS Directive 8080.1 Revision 8**	8080.1, Revision 8	02/23/24

MANAGING ADULTERATED OR MISBRANDED MEAT AND POULTRY

CHAPTER I - GENERAL

I. PURPOSE

This directive provides the terminology, responsibilities, and public notification procedures regarding the assessment of adulterated and misbranded meat and poultry that may have entered commerce, and the voluntary recall of such products. The Vermont Agency of Agriculture, Food and Markets (VAAFM), Meat Inspection Service (MIS) is revising this directive in its entirety 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 MI may publish Public Health Alerts (PHAs); and makes clarifying revisions throughout.

II. CANCELLATION

MIS Directive 8080.1, Revision 7, *Recall of Meat and Poultry Products*, dated 11/12/2013

III. BACKGROUND

A. A recall of meat or poultry products is a firm's voluntary action to remove adulterated or misbranded products from commerce. Although it is a firm's decision to recall products, either at the firm's initiative or the VAAFM recommendation, MIS will coordinate with the firm to ensure it has properly identified and removed recalled product from commerce. MIS 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 MIS. However, a recall does not preclude MIS 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, MIS 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, MIS may seek enforcement action against the recalling firm or its consignees.

C. MIS will verify recalls conducted by VT State-inspected firms or retailers located in Vermont. MIS may request assistance from FSIS or the Vermont Department of Health Food & Lodging program.

D. For recalls conducted by Federallyinspected firms, the United Stated Department of Agriculture's Food Safety Inspection Service (USDA/FSIS) leads, manages, and verifies the recall, in most cases. If requested to do so, MIS will provide FSIS with appropriate assistance and information.

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

IV. TERMINOLOGY

Recall: A firm's voluntary removal of distributed meat or poultry 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 the Vermont Meat and Poultry Inspection Laws (6 V.S.A. Chapter 204), 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 MIS 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: MIS assesses the public health concern or hazard presented by a product being recalled, or considered for recall, whether firm-initiated or requested by MIS, 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 or poultry 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.

Vermont Department of Health (VDH): VDH is the primary group that would be consulted about 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, VAAFM may consult the VDH.

Recall Committee: A committee of representatives from VAAFM assembled to respond to potential or real health hazard incidents to VAAFM. All members of the recall committee should be knowledgeable about the issues raised by a potential recall situation and should be empowered 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.

CHAPTER II – DETERMINING NEED FOR RECALL

I. BECOMING AWARE OF POTENTIAL NEED FOR A RECALL

A. When MIS official establishments learn or determine that adulterated or misbranded meat or poultry products have entered commerce, they are required to notify the Meat Inspection office within 24 hours (9 CFR 418.2). This notification can be made through traditional methods (phone call, text message, or email). When official establishments notify MIS personnel that adulterated or misbranded product has entered commerce, those MIS personnel are to refer to VT Directive 8140.1 Revision 2, *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 the Meat Inspection Office (AGR.Meatinspection@Vermont.gov) (or other MIS personnel. If the firm contacts other MIS personnel, those employees are to promptly contact Meat Inspection Office through supervisory channels.

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

1. The company that manufactures, distributes, or receives the product;

2. Test results from MIS sampling programs;

3. Observations or information gathered by MIS personnel in the course of their routine duties or investigations;

4. Consumer complaints reported through the Meat Inspection Office;

5. 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

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

II. PRELIMINARY INQUIRY

A. When there is reason to believe that adulterated or misbranded product is in commerce, MIS will conduct a preliminary inquiry. The Meat Program Section Chief or Meat Safety Compliance & Enforcement Specialist (MSCES) is to assign personnel to lead this effort. MIS 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 Chief or MSCES determine the event should be escalated for further 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 the members of the Recall Committee. Firms may complete FSIS Form 5020-3. If the firm elects to complete this form the information should be verified by the Chief or MSCES.

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

C. While investigating and assessing potential adulteration and misbranding events, MIS 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 MIS field inspection and MIS 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, including VDH Food and Lodging program (VDHFL) and Infectious Disease Epidemiological section (IDEpi),
8. Reviewing supporting documentation and evidence (e.g., Sanitation Standard Operating Procedures, Hazard Analysis and Critical Control Point (HACCP) and production records, risk assessments, etc.).

CHAPTER III – RECALL COMMITTEE

RECALL COMMITTEE MEMBERS

A. All members of the Recall Committee are to be knowledgeable about the issues raised by an event and are to be empowered to represent their respective 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 MIS verification, issue a PHA, or consider recommending other appropriate actions. The primary members of the Committee and their roles are described below:

1. Meat Program Section Chief: Calls a committee meeting and distributes information about the recall to committee members. They may also provide the statutory basis for each recall, and addresses other statutory issues and the regulations and any regulatory policies that are relevant to the recall.

2. Enforcement Investigation and Analysis Officer: Participates in committee meetings upon request, provides assistance and conducts investigations at the state inspected facility where alleged misbranded or adulterated product was produced.

3. VT Department of Health (VDH) on an as needed consultation basis - Addresses microbiological, epidemiological, and other scientific issues associated with the recall.

4. VAAFM Public Information Officer- 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 coordination with the Vermont Department of Health.

5. MSCES- Participates in committee meetings upon request, provides assistance and conducts investigations of alleged criminal violations, such as those involving the sale, transport, or receipt of adulterated or misbranded product.

6. Other Federal or State agencies, as appropriate (e.g., Food and Drug Administration (FDA), Food and Nutrition Centers for Disease Control and Prevention (CDC), Office of the Attorney General)

II. DELIBERATIONS OF THE RECALL COMMITTEE

A. The Recall Committee meets when an adulteration or misbranding event requires the committee's consideration. The Recall 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 Recall Committee decides to recommend a recall, it is to also determine the appropriate recall classification.

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

1. Does MIS have evidence to demonstrate that the product in question is adulterated or misbranded under the FMIA, PPIA, or 6 V.S.A. Chapter 204? 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 MIS believes, on the basis of epidemiological and traceback evidence, that a specific meat or poultry product is associated with human illnesses. Under these circumstances, the Recall Committee is to consider the strength of the epidemiological 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. The Recall 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 Recall 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. MIS 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. MIS is unable to identify the responsible party.

4. MIS 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. MIS identifies an ineligible foreign product imported by multiple importers or through nefarious means.

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

9. MIS, working with its Federal and State partners, determines that a meat or poultry 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 Committee finds that the establishment has recovered or controlled all products from commerce that would have been subject to a recall, the Committee should not recommend a recall, as no product should remain available for sale or use in commerce. Instead, MIS 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 the Recall Committee agrees that a recall is not recommended, is to document the results of the preliminary inquiry in a memorandum and upload it to the S. Drive.

I. If the Recall Committee agrees to recommend a recall, the committee will try to reach a consensus on the classification of the recall. 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 Recall Committee may also consider the following factors:

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

2. The occurrence of any illnesses or injuries;

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

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

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

K. After the Committee members have discussed the issues described in the above paragraphs and agreed to recommend a recall, MIS is to contact the firm to allow its representatives to join the Recall Committee discussion. MIS is to present the Committee's recommendation to the firm. During the discussion, the Recall 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, MIS may decide to clarify the Committee's position or to temporarily adjourn and re-engage Committee deliberations. MIS 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 Recall Committee recommends a recall, 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 Recall Committee is to determine whether consumers might still have the product, and, if so, whether they would possibly consume it.

B. The Recall Committee generally determines much of the above information from the recalling firm through written documents or telephone conference calls. Before deciding on a recommendation, the Committee may request that MIS inspection or enforcement personnel verify the information provided by the firm. The Committee 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. The Chief is to follow up in writing with an email to the firm memorializing its discussion with the Committee. The Chief is to confirm the information necessary for a Recall Release. The MSCES is to begin coordinating effectiveness checks (see Chapter VI), consistent with the class of the recall, and is responsible for directing the activities of MIS field personnel.

CHAPTER IV - ANNOUNCING THE RECALL

I. ACTION BY FIRM

A. MIS 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, MIS personnel are to follow the instructions in VT Directive 8410.1, *Detention and Seizure,* to detain any product found in commerce that would have been subject to a recall. MIS is to seek approval from the VT Secretary of Agriculture 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, VAAFM 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, if it is deemed necessary by the VAAFM in consultation with the VDH, the VAAFM PIO issues a joint Recall Release to the media and other appropriate outlets. Generally, VAAFM 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. VAAFM will typically not issue a Recall Release for Class III recalls unless there are overriding public welfare reasons such as a case of egregious economic adulteration.

B. The Recall Release will:

1. 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, MIS 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. The Chief is to email a draft copy of the Recall Release to the recalling firm prior to its release. At this time, the Chief 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. The Chief is to inform the firm that if it does not respond within 1 hour of receiving the Recall Release, VAAFM will proceed to issue the Recall Release. If the firm notifies the Chief of any typographical or other inadvertent errors, the Chief is to correct them before issuing the Recall Release.

III. PUBLIC NOTIFICATION OF RECALLED STATE-INSPECTED

A. When a recall is conducted by an 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.

C. When MIS becomes aware that meat or poultry products are implicated in a recall of source material or ingredients used in such products, MIS will verify that firms that have received these ingredients are following the instructions received from their suppliers. MIS 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. VAAFM 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 MIS notification or engagement but may still pose a risk

to consumers at their homes. VAAFM also issues PHAs when firms decline to initiate a recall upon MIS recommendation.

1. There may be situations in which the Recall 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 VAAFM 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 VAAFM could recommend be recalled, they should report the incident through supervisory channels. VAAFM typically becomes aware of these situations from the findings of a foodborne illness investigation conducted by, or reported to, the Vermont Department of Health. It will be decided whether VAAFM should issue a public health alert.

B. When the Recall Committee recommends a PHA, The Chief is to submit a PHA recommendation in the form of a memo for approval by the Secretary of Agriculture. 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 Secretary of Agriculture approves the PHA recommendation and the firm responsible for the adulterated or misbranded product is known, the Chief is to contact the firm and inform them of the Agency's decision to issue a PHA. The Chief is to confirm the information necessary for the PHA.

D. If VAAFM 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.

E. When the firm responsible for the adulterated or misbranded product is known, the Chief is to email a draft copy of the PHA to the firm prior to its release. At this time, the Chief 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. The Chief is to inform the firm that if it does not respond to CPAS within 1 hour of receiving the PHA, VAAFM will proceed to issue the PHA. If the firm notifies the Chief of any typographical or other inadvertent errors, the Chief is to correct them before issuing the PHA.

F. VAAFM notifies the public about PHAs through press releases.

V. RETAIL CONSIGNEE LISTS

A. For every Class I recall, a list of retail consignees that have, or have had, the recalled products in their possession is developed. The information is gathered 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. If the recalled product is not distributed to the retail level, a list of retail consignees is not developed.

The VAAFM may post this information on its website.

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 -MIS regulated products. If the 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 MIS-regulated products, VAAFM will consider the new products subject to the original recall and will not ordinarily announce multiple separate recalls for the same issue. However, VAAFM 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. MIS 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, MIS 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, VAAFM will publish a notification to the public that this has occurred. This may or may not necessitate convening the Recall Committee.

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. MIS 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. MIS 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 Compliance Investigators are to conduct effectiveness checks. 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 MIS 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, MIS personnel are to detain any product found in commerce as set out in VT Directive 8410.1.

MIS personnel are to notify the Chief immediately when the recalled product remains available to the consumer and when the recalling firm has not properly implemented its recall strategy. The Chief is to 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 VAAFM meat inspection office 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 VAAFM meat inspection office 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;
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 VAAFM meat inspection office may assign VAAFM personnel to witness destruction of the product in accordance with 9 CFR part 329 or part 381, Subpart U. VAAFM personnel are to document this on MI-C&E-31E Report of Recall Effectiveness: Part B – Product Disposition Verification, as product disposition verification.

III. CHIEF RESPONSIBILITIES FOR COORDINATING MIS PERSONNEL ACTIVITIES DURING EFFECTIVENESS CHECKS

A. The Chief is to:

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

2. 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 VAAFM personnel may be instructed to conduct more effectiveness checks than if the firm did have a recall plan.

IV. MIS COMPLIANCE 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 Chief, MIS 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 VT Directive 8410.1; and

4. Record the effectiveness checks on the Report of Effectiveness Check on Form MI-C&E-31E, and submit the completed reports to the Chief. 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. MIS 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, MIS 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 as a follow-up.

C. If, when conducting effectiveness checks, MIS 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 Chief may assign additional effectiveness checks by biased selection.

D. The Chief 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. VAAFM 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, MIS personnel are to follow VT Directive 8410.1 and notify the consignee of any prohibited activity. MIS 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, MIS 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 Chief is to refer all instances of prohibited activity to the MSCES for investigation and enforcement.

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

The Chief is to:

1. Make an overall assessment of recall effectiveness following the criteria and decision guidance in Attachment 3;
2. Analyze the information that is submitted by VAAFM inspection program personnel on MIS Forms MI-C&E-31E (a & b) and review any instances in which recalled product was found in commerce to determine whether a pattern or trend exists that may suggest certain consignees were not contacted; and
3. Contact the firm and verify that they:

    a. Controlled the recalled product as planned;
    b. Disposed 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.

VI. THE CHIEF DETERMINATION ON THE EFFECTIVENESS OF THE RECALL

A. The Chief 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.

B. If it is determined that the recall action is ineffective based on review of the effectiveness and product disposition verification checks because of the firm's failure to control and dispose of the product, the recalling firm will be notified, in writing, explaining why the recall action is deemed to be ineffective. It will ask how the recalling firm intends to address the situation. If the recalling firm is unwilling or unable to correct its recall strategy, it is recommended 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.

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

CHAPTER VII – CLOSURE AND POST-RECALL ASSESSMENT REPORT

I. CLOSURE

A. VAAFM is responsible for closing a recall by taking into account the recall efforts by the firm and the findings of the effectiveness and product disposition checks.

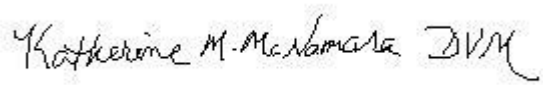
B. If a recall is associated with a reported illness, ask the VDH whether there are any current illnesses associated with the recalled product.

1. If data indicate that illnesses continue to occur because product remains in commerce, the recall case will remain open. The firm may be requested to 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, may proceed to recommend closing the recall.

CHAPTER VIII. QUESTIONS

Refer questions through supervisory channels.



Head of Service
VT Meat Inspection Service

EFFECTIVENESS CHECKS

A. Determining the Total Number of Effectiveness Checks to Conduct

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

1. The Chief will, in discussion with the recalling firm, and, if some consignees are distributors, in consultation with AOs, determine the best estimate of the number of consignees and begin to develop a master list of consignees, i.e., entities that received the recalled product or that will be notified of the recall.

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

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

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

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

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

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

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

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

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

a. If the master consignee list is in an electronic format, the Chief 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 chief should follow the instructions in Section I. 3 of this attachment when preparing the sampling plan, or

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

States with a Memorandum of Understanding (MOU). Under 9 CFR 390.9, FSIS may have an MOU with one or more States. The specifics of each MOU will vary. In general, when States and FSIS have MOUs to conduct their own effectiveness checks, the Agencies will collaborate in sharing resources and information whenever possible. FSIS will work with States to ensure that effectiveness checks are conducted in a manner consistent with FSIS procedures.

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

B. Determining the Total Number of Effectiveness Checks to Conduct

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

1. 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, MIS verification activities should begin as soon as possible within a period of:**	**Following their initiation, MIS 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	Chief will consult with MSCES 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 Chief determines that on-site verification is necessary.

C. Schools and Other Special Consignee Categories

If information is available, the Chief 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 Chief decides to separate groups by special categories, then each group of consignees should be considered separately. Apply the appropriate table 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.

MIS 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, MIS 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, MIS may decide to conduct a greater number of effectiveness checks than the number provided in the tables. For example, MIS 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.

D. Randomizing the Master Consignee List (MCL)

After eliminating duplicate listings of the same consignee, the Chief is to randomize the consignee list. The Chief 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 Chief should follow the instructions in Section C of this attachment when preparing to select effectiveness checks.

Determining the Total Number of Effectiveness Checks

After eliminating duplicate listings and randomizing the MCL, the Chief 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 Chief should refer to Attachment 1 for information about grouping special consignee categories.

A. Preparing to Select Effectiveness Checks

The Chief 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 Chief 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.

1. The Chief 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 MIS personnel that will be conducting the checks.

The information that the Chief provides to the MIS 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.

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

1. When personnel find recalled product in commerce, they will immediately notify the Chief.

2. The Chief 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 Chief may assign additional effectiveness checks by biased selection to verify that recalled product is not available to consumers.

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

There may be instances in which MIS personnel may need statistical guidance when performing recall effectiveness checks. For example, MIS 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, MIS personnel are to inform the chef. The Chief will work directly with the personnel to provide any needed statistical guidance.

Factors That Are Considered by the 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), and 6 VSA Chapter 204, under which the Food Safety and Inspection Service (FSIS) and VT MIS operates, require that all ingredients used to formulate meat and poultry products be declared in the ingredients statement on product labeling according to their common or usual names. A product is misbranded, and in some instances adulterated, under the FMIA or PPIA if it contains ingredients that are not declared on the product labeling.

The Agency recognizes that there are situations in which a meat or poultry product enters commerce with ingredients that are not declared on its labeling. In some cases, the undeclared ingredient may present a health risk to individuals that are allergic or sensitive to the ingredient, which would necessitate removal of the product from commerce. The most common example would be a potential food allergen, such as peanuts. VT Directive 8080.1, Managing Adulterated and Misbranded Meat and Poultry, outlines the Agency's policies and procedures regarding the voluntary recall of MIS-inspected meat and poultry products. VT Directive 8080.1 provides that each recall be classified into one of three classes (Class I, II, or III) based on the likelihood that illness or other adverse effects will be caused by consumption of the recalled product. This guidance describes the factors that are considered in assigning a recall class in the situation involving an undeclared ingredient of health concern.

There is a particular concern about health situations in which a meat or poultry product contains an undeclared ingredient that may cause an adverse reaction in allergic or sensitive individuals. Such a reaction may occur when a person has either an allergy or intolerance to a particular food or substance. A food allergy is a specific condition in which a person's immune system reacts to certain foods. Food allergy reactions range from mild to life-threatening and can include gastrointestinal upset, rash, wheezing, and shock. Food allergies are commonly associated with eight categories of foods (known as the "big nine"): wheat (including rye, barley, oats, spelt or their hybridized strains and products of these); shellfish; egg products; fish products; peanuts; soy; milk products; sesame seeds; and tree nuts.

In comparison, food intolerances are non-immunologically mediated reactions. They are caused by a reaction to the chemical composition of a food itself or by an additive (e.g., preservatives, colors, flavor enhancers). Some common examples of food intolerance are reactions to sulfites, monosodium glutamate (MSG), histamine, or tartrazine (FD&C Yellow No. 5). There are few foods or food ingredients to which some element of the population will not have some degree of allergic response or intolerance. For this reason, complete ingredient labeling is critical.

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

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

The significance of this factor for recall classifications is that, for some allergens, there exists "no observed adverse effect level" that can be used in estimating risk. In these cases, a higher amount of the ingredient is more likely to elicit an adverse effect, giving support to classifying the recall as one in which there is a significant public health concern, that is, Class I. The lower the amount of the ingredient, the more reason there is to classify the recall as Class II. For most known allergens, there is no conclusive scientific evidence to establish threshold levels for eliciting an adverse reaction. In most cases, the presence of an

undeclared substance that is a known allergen, at any level, poses a public health risk and thus the recall should be classified as Class I, unless other factors justify a different, lower classification.

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

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

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

This factor directly relates to the level of the hazard posed by an undeclared ingredient. It should be considered that, in some limited cases, the presence of a potential allergen or other substance of public health concern in a food may be innocuous until metabolic systems in a person bioactivate or bioconcentrate the substance, or the substance may be detoxified by the body after it is consumed. The smaller the population that is capable of deactivating an allergen or other substance, the more reason to classify any recall of product that contains the ingredient as Class I.

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

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

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

This document identifies the factors that are central in the evaluation of situations in which a meat or poultry product contains an undeclared ingredient that may have implications for public health. The public health impact is estimated by the probability that vulnerable individuals will experience an adverse health effect as a result of exposure to an undeclared ingredient. The estimate of this impact will ultimately be translated into a recall classification by the FSIS Recall Committee. The Recall Committee may request Vermont Department of Health assistance in estimating the risk.

PRODUCT RECALL GUIDELINES FOR FIRMS

TABLE OF CONTENTS

1. Guiding Principles for Recall Plans

Introduction

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

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

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

A recall can be disruptive to a firm's operation and business; however, there are several steps that can be taken to minimize this disruption. An operator of an inspected establishment should take measures that will ensure rapid and effective response if products that appear to be adulterated have entered commerce. Official establishments are required to have recall plans that describe the actions they will take to recall adulterated or misbranded products that are in commerce, as provided by 9 CFR 418.3. A recall plan must consist of written procedures that specify how the official establishment will decide whether to conduct a product recall and how it will affect the recall, should it decide that one is necessary.

Recall Plan

The guidance presented here is intended for all meat and poultry firms that may need to conduct a recall, without regard to plant size or the number of people employed. Some of the recommendations may speak in terms of forming teams of employees to conduct certain activities related to recalls or may seem to imply that sophisticated analyses of potential health hazard situations need to be conducted. However, the key activities discussed below can be performed by one (1) or two (2) individuals in circumstances where there are limited resources. For example, in a small plant operation, the owner or manager of the establishment may be the recall coordinator as well as the contact for the Agency, the firm's consignees, and the public. The Agency does not expect smaller establishments to hire personnel simply to prepare

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

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

A. Recall Team Members.

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

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

B. Procedures for Determining Whether a Recall is Necessary.

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

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

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

C. Scope of Recall.

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

FSIS suggests that the plan specify how the amount of product affected under various scenarios will be determined. Some examples of how to define the scope of product removal actions include: the contamination of a vat of product with a foreign object, the use of an incorrect label, or the use of the same source of raw materials in other lots on other days of production. FSIS will consider such factors as the establishment's coding of product; the pathogen of concern; processing and packaging operations; equipment; the establishment's HACCP plan monitoring and verification activities (including microbiological testing); the establishment's Sanitation SOP records; and whether some or all of the products controlled by the same or substantially similar HACCP plans have been affected. Clean up times do not necessarily define the scope of a recall.

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

D. Records.

All firms should use a system of product coding sufficient to permit positive product identification and to facilitate effective recalls. Records should be maintained for a period of time that exceeds the shelf life and expected use of the product and at least the length of time specified in FSIS regulations concerning record retention (9 CFR 320; 381.175). Records are vital in tracing product forward to consignees and back to potential suppliers. They include invoices, bills of sale, and shipping documents. Records a firm should have on hand include:

1) Records for positive identification of products produced (labels, lot numbers, Julian codes,), and

2) Distribution information for recalled products. These records may include names/addresses of consignees, method of shipment, date of shipment. It is also useful to note consignees that are schools, hospitals, and distributors.

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

Regarding *Escherichia coli O157:H7* and non-O157 STECS, establishments are expected to maintain supplier records for their raw ground beef components and to make these records available to Agency personnel upon request. Then, if a sample of raw ground beef is reported positive, suppliers may be notified that their product may have been the source of contamination. The information FSIS personnel collect includes the name of the supplying establishment, the supplier's lot number, and production date of the product. This information has proven to be an effective tool for initiating traceback in an effort to find the source of contamination.

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

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

E. Recall Communications.

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

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

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

F. Public Notification.

Identify if and how the public will be notified of the recall. Recalls are often announced via a press release through national or local news media or via a company website. Include contact information for all potential media outlets, such as television stations, radio stations, and newspapers, and with local, state, and regional coverage areas, as well as the national wire services. The class of a recall and the extent to which the product was distributed in commerce (wholesale, retail, or hotel/restaurant/institutional (HRI)) will determine the distribution of public notification.
NOTE: Regardless of the public notification action taken by the recalling firm, FSIS will generally issue a Recall Release for Class I and Class II recalls, unless the recall involves product that has only been distributed to the wholesale level and the recalling firm is able to regain control over it before it can be further distributed to the retail, HRI, or consumer level. For these wholesale level recalls, and for Class III recalls, FSIS will generally only issue a Recall Notification Report (RNR) that is not distributed to media outlets. The Agency will also post all Recall Releases and RNRs on the FSIS website (www.fsis.usda.gov/OA/recalls/rec_actv.htm).

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

- How much product is implicated in the recall?
- How is this product identified to a customer/retailer (e.g., lot markings)?
- How many locations did the firm ship the product to, and where are those locations?
- How did the firm communicate the product removal action to those who received the product? Did the firm document this contact? Did the firm ask for and receive a written response acknowledging receipt of the information?
- What actions were taken with the product and by whom?
- If product was destroyed, was destruction witnessed and documented? Were Agency personnel present?

- Is there a written record of when the issue was identified, when customers were notified, and when the firm received notification that product was placed on hold or was no longer in a customer's control?

MIS will conduct effectiveness checks.

H. Returned Product Control and Disposition.

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

I. Recall Simulations

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

A simulated recall should involve the selection of at least one lot of product that has been distributed in commerce. The recall plan should specify a hypothetical reason for recalling the product and it should be followed to establish a strategy for recalling the product. The mock recall should occur without prior notice to personnel involved. Such scenarios may be simple (e.g., one contaminated lot of product) or very complex (e.g., contaminated ingredient used in multiple products and involving rework). A firm may wish to begin with simple scenarios and work up to more complex simulations for their operation. The simulation should proceed at least to the point at which communication occurs with the firm's primary consignees. Full details of who will be contacted at that point and how contact will be established should be specified. Firms, especially those with products distributed by multi-layer distribution systems, may wish to consider conducting at least one simulation in which the product to be recalled has been shipped beyond the firm's initial customer to one or more of the consignee's customers. Taking the simulation beyond the recalling firm's organization could reveal potential problems in the retrieval process that might be addressed before an actual recall occurs.

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

J. Final Actions

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

K. Functional Food Defense Plan

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

2. Notifying VAAFM MIS of Recalls

An official establishment has 24 hours in which to notify VAAFM that adulterated or misbranded product is in commerce. If it determines that a recall will be undertaken, it should notify VAAFM immediately. When doing so, the official establishment should notify DO personnel in the district where it is located. When

other firms, including importers of record, learn or determine that adulterated or misbranded product has entered commerce, MIS expects those firms to immediately notify the Section Chief or MSCES personnel. The basic information that should be conveyed to MIS includes, but is not limited to, the following:

- Complete and accurate product identity, including product labels (electronic images whenever possible)
- The reason for the recall and details about when and how any defect or deficiency was discovered
- How much of the product in question was produced and during what period of time
- An estimate of how much of the product is in distribution and how long it has been in distribution
- Area of geographic distribution of the recalled product within the state.
- Information regarding distributors and customers who received the product
- Copies of any firm correspondence with distributors, brokers, or customers relating to the recall strategy or actions, as well as a copy of any proposed press release
- The name, title, and telephone number of the recall coordinator for the firm

The firm may provide this information orally, initially, but VAAFM MIS will confirm it. For clarity, it is recommended that the recalled product information listed above be submitted via e-mail. Doing so will prevent errors resulting from hard-to-read handwriting or illegibility because of poor fax transmission. Early on in the recall process, VAAFM MIS will generally send a program employee to the establishment to verify distribution records and confirm facts.

3. Recall Assessment

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

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

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

4. Recall Termination

A recall will be terminated when FSIS has:

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

To effect a timely termination of the recall, the firm should provide all relevant information to the Agency once the firm has determined that it has retrieved all possible product. The firm should create a “closeout memo” containing a list of customers, the amount of product retrieved, and the actions taken. This memo should be sent to the To the Chief or MSCES. Once the Agency determines that the firm has made all reasonable efforts to recall the product, RMTAS will notify the firm in writing.

5. Recall Follow-up

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

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

Dear Sir or Madam:

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

Describe the product, including name, brand, code, package size and type, establishment number,
We request that you review your inventory records and segregate and hold the above product. If you have shipped any of this product, we request that you contact your customers and ask them to retrieve the product and return it to you. Once you have retrieved all of the product, please contact us. We will arrange to have the product shipped to our facility. Please do not destroy the product. We will credit your account for product returned.
We are undertaking this action in cooperation with the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture. FSIS officials may contact you to confirm that you have received this notice and are cooperating in this action.
Your prompt action will greatly assist ***Company Name*** in this action. If you have any questions, please do not hesitate to contact ***Company Recall Coordinator*** at ***Phone Number or e-mail address***.

Thank you for your cooperation.

Sincerely,
Company Official Name and Title