# MSA DIRECTIVE	8080.1 Rev. 8.1	03/12/2025

RECALL OF MEAT AND POULTRY PRODUCTS

I. PURPOSE

This directive provides the terminology, responsibilities, and public notification procedures regarding the voluntary recall of meat and poultry products under Texas Meat Safety Assurance (MSA) jurisdiction.

II. CANCELLATION

MSA Directive 8080.1, Revision 8, Dated 11/01/2024

III. REASON FOR REISSUANCE

This directive is being reissued to define the term Processing Authority as it relates to Meat Safety Assurance and to make minor edits throughout.

IV. REFERENCES

Texas Meat and Poultry Inspection Act (TMPIA)
Texas Administrative Code (TAC)
Federal Meat Inspection Act (FMIA)
Poultry Products Inspection Act (PPIA)

V. BACKGROUND

A recall is a firm's action to remove product from commerce (e.g., by manufacturers, distributors) to protect the public from consuming adulterated or misbranded products. Although it is a firm's decision to recall product, the Texas Department of State Health Services (DSHS) Meat Safety Assurance (MSA) coordinates with the firm to ensure it has properly identified and removed recalled product from commerce by verifying the effectiveness of the firm's recall activities. DSHS may also notify the public about product recall.

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

VI. TERMINOLOGY

The following are common terms used related to recalls:

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

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

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

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

    1. Class I. This is a health-hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death. Examples of a Class I recall include the presence of pathogens in ready-to-eat meat or poultry products, or the presence of *E. coli* O157:H7 in raw ground beef.

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

    3. Class III. This is a situation where the use of the product will not cause adverse health consequences, 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.

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

    1. Wholesale level. The product has been distributed to a warehouse or distribution center where it is not under the direct control of the producing company. This is the distribution level between the manufacturer and the retailer. This level may not be encountered in every recall situation (i.e., the recalling firm may sell directly to the retail or consumer level.)

    2. Retail level. The product has been received by retailers for sale to household consumers but has not yet been sold to consumers.

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

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

f. **Scope.** This defines the amount and type of product in question. There are several factors used in determining the scope of a recall, such as the plant's processing and sanitation procedures, the definition of a lot, or specific grouping, and whether there is any finished product reincorporated into fresh product (rework). For example, in the

absence of a plant having a scientific basis for how it defines a lot, all products produced under a single HACCP plan between performance of complete cleaning and sanitation procedures (from clean-up to clean-up), or all products including any reworked product added to subsequent days' production, may be included in a recall The findings of epidemiological investigations that link certain lots of product with known cases of foodborne illnesses may also affect the scope of a recall.

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

h. **Processing Authority (PA)**. For Texas Meat Safety Assurance purposes Processing Authority shall mean any person with expert knowledge in the harvesting and processing of red meat and/or poultry food products. Though this knowledge may be gained through training and experience, it typically includes graduate level formal education (Masters or Doctorate level).

i. **Recall Committee.** A committee of representatives from DSHS assembled to respond to potential or real health hazard incidents reported to the Recall Management Staff (RMS). All members of the recall committee should be knowledgeable about the issues raised by a potential recall situation and should be empowered by the RMS to represent his/her views. Committee members are expected to make every effort to achieve consensus on whether to recommend a recall. The primary members of the Committee and their roles are described below:

1. **Recall Management Staff (RMS),** MSA Director and or Assistant Director calls a Recall Committee meeting and distributes information about the recall to committee members. The RMS invites other DSHS program areas to assist as necessary.
2. **Recall Officer (RO), MSA** – State Inspection Process Coordinator (SIPC) clarifies and explains to the Committee the information collected during the preliminary inquiry. The RO is the official responsible for coordinating field recall activities and providing direction to inspection program personnel when there is a recall. The RO is responsible for documenting factual information and minutes of Recall Committee meetings and communications with the recalling firm. The information should include factual information and capture the reasoning to recommend or not to recommend a recall.

CHAPTER II – DETERMINING NEED FOR RECALL

I. PROCEDURES TO DETERMINE THE NEED FOR A RECALL

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

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

A. The company that manufactures or distributes the product;

B. Test results from MSA sampling programs;

C. Observations or information gathered by MSA inspection program personnel in the course of their routine duties or investigations;

D. Consumer complaints;

E. Epidemiological or laboratory data submitted by State or local public health departments, USDA agencies, and other Federal agencies such as the FDA, CDC, and the Department of Defense; or

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

II. PRELIMINARY INQUIRY

A. When DSHS learns that there is a reason to believe that a product in commerce is adulterated or misbranded, DSHS will conduct a preliminary inquiry. The preliminary inquiry should focus on determining if the recalling firm correctly identified all affected product subject to the recall and ascertain the distribution information of the affected product. Inspection program personnel at the official establishment or MSA personnel may conduct preliminary inquiries.

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

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

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

2. **Product Information.** For all products, including imported products, MSA inspection program personnel are to gather the following product information:

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

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

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

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

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

a. Collecting and verifying information about suspect product;
b. Documenting a chronology of events;
c. Contacting the company that manufactures or distributes the product for additional information;
d. Communicating with MSA field inspection and compliance personnel;
e. Interviewing any consumer who allegedly became ill or injured from eating suspect product;
f. Collecting and analyzing product samples;
g. Contacting other agencies, state and local health departments, or foreign governments; and
h. Analyzing any available epidemiological data.

C. Preliminary information will be submitted to the RO. The RO will present all of the information gathered during the preliminary inquiry to the RMS and Recall Committee. Firms are encouraged to submit product label information electronically, whenever possible, to minimize transcription errors and enable consignees and consumers to readily identify recalled product if DSHS must issue a Recall Release.

CHAPTER III – RECALL COMMITTEE

I. DELIBERATIONS OF THE RECALL COMMITTEE

A. To convene the Recall Committee, RMS contacts the Recall Committee members to inform them of the potential recall. RMS is to schedule the time of the recall meeting and make arrangements for external Recall Committee members to attend via conference call if needed. RMS is to make every effort to ensure that the primary members of the Recall Committee are available to participate in the Recall Committee meeting. Recall Committee members are to respond to RMS request for a recall committee meeting in a timely fashion.

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

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

1. Does DSHS have reason to believe that the product in question is adulterated or misbranded under the TMPIA, FMIA or PPIA? In many instances, the answer to this question is obvious.

2. Do any of the products in question remain in commerce or is the product available to consumers?

D. If the Recall Committee finds that the establishment has recovered all products from commerce that would have been subject to recall, the Committee should not recommend a recall. Instead, DSHS personnel are to verify that the establishment has recovered all products involved, and that it conducted proper disposition of the affected products.

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

1. When was the product produced?

2. To whom has the product been distributed?

3. What type of product is involved (e.g., ready-to-eat, fresh packed, canned, frozen, etc.)?

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

5. What are the typical consumer or user practices concerning handling and storing of the product in question (e.g., is the product typically prepared for immediate consumption and likely is not stored or frozen for later use)?

6. Is the Agency able to verify that the product that was distributed in commerce is no longer available to consumers at retail facilities, restaurants, or other institutions?

F. If the answers to the questions in Section C are both "yes," the Committee should recommend a recall unless, in response to other questions in Section E., the Committee determines that the product is so long out of date that it is unlikely to still be available to consumers, or the Committee is unable to identify a responsible party for the product. In these circumstances, the Committee should not recommend a recall. If the Committee does not recommend a recall, RMS is to document results of the preliminary inquiry and evaluation with a Memo to the File.

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

G. If the Committee decides to recommend a recall, it is to consider the human health hazard presented by the product subject to the recall to determine the appropriate recall classification. Typically, there are precedents for determining the significance of the health hazard presented by an adulterated product and the classification of the hazard. The Recall Committee will be guided by these precedents in classifying recalls.

H. The Recall Committee may also refer to "*Factors That Are Considered by the MSA Recall Committee in Evaluating the Public Health Significance of an Undeclared Ingredient in a Meat or Poultry Product* " (Attachment 1) 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.

I. After the Committee members have discussed the issues described in the paragraphs above and agree to recommend a recall, RMS is to contact the company that produced the product to allow the company's representatives to join the Recall Committee discussion. During the discussion, the Recall Committee is to allow the firm to present information about the hazard or concern associated with the product to allow the Committee to clarify its position. The Committee is to evaluate all information received and determine whether to recommend a recall of the product. Although not required, DSHS expects the firm to provide to the Committee its recall strategy, including how it intends to notify and instruct its consignees to retrieve or dispose of the recalled product.

The RO will document all deliberations and recommendations made by the Recall Committee.

II.RECALL RECOMMENDATION

A. When the Recall Committee recommends a recall, the RMS is to inform the firm of the recommendation to recall affected products. The recall recommendation is to contain:

1. the reason for the recall, including why there is a reason to believe that the product is adulterated or misbranded;

2. the recall classification (i.e., Class I, Class II, or Class III);

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

4. the estimated amount of recalled product in distribution (amount of product subject to recall that was distributed and is still within the sell by/use by dates or codes at the time of the recall).

In the event that the producer or distributor of adulterated or misbranded product elects to not recall affected products, the RMS will contact the DSHS Director of Environmental and Consumer Safety (ECS). The Director, DSHS, ECS will evaluate the Recall Committee recommendation. The primary duty of DSHS is to ensure public health of consumers. DSHS actions taken to ensure public health include public advisories to inform consumers of potential negative consequences of consumption of affected products. The Director of ECS RMS will initiate appropriate actions to ensure adulterated or misbranded product is no longer available in commerce and will inform the public appropriately as detailed in Chapter IV.

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

CHAPTER IV - ANNOUNCING THE RECALL

I. PUBLIC NOTIFICATION

Public notification is important, particularly in situations where the recalled product entered commerce and poses a significant health hazard to the public. Public notification may be issued to media outlets in areas where the product was distributed, shared via email, posted on the company's website, and posted to the DSHS/MSA website.

A. When the recalling firm determines public notification is necessary, the firm shall issue public notification as soon as the recall situations are identified.

B. In the event the firm fails to provide proper public notification, and the Recall Committee believes public notification is warranted, the firm will be informed if it does not issue proper public notification, DSHS/MSA will issue its own press release.

C. Essential elements of public notification include the following:

1. **Establishment** – The name and address of the firm with points of contact for recall information as appropriate (e.g., Compliance/Recall Coordinator, Recall Management, Media Inquiries, Consumer Inquiries, website) and phone or fax number(s);

2. **Product Recalled** – Exact and complete description of the specific product(s) recalled, when possible, the notification should also include pictures of the recalled product(s) and the associated label(s);

3. **Production Dates/ID Codes** – Specific identifying codes or marks on the packages; specific dates of production including plant codes, sell-by dates, expiration dates;

4. **Quantity Recalled** – The product quantity;

5. **Recall Classification** – Class I, II, and III;

6. **Recall Notification Level** – Wholesale, retail, consumer;

7. **Problem/Reason for Recall** – The problem with the product or the reason for the recall;

8. **Specific Nature of Potential Hazard** – Examples; allergic reaction, infection;

9. **How and When Discovered** – Details regarding the discovery of the hazard;

10. **Distribution** – Geographic (nationwide, statewide, specific counties);

11. **Media and Consumer Contacts and Instructions** – Two different contacts are often given. Instructions to the public regarding typical symptoms of illness and what to do with the recalled product if they have it, including the name and telephone number of a company contact for consumers with any questions.

12. **Risk Information** – Succinct information about specific steps consumers can take to reduce their risk of illness. An explanation of the risk involved in consuming the product including typical signs and symptoms of adverse health effects caused by the agent.

13. **Follow-up Activities** – A statement regarding the status of the investigation and agencies involved, as appropriate.

CHAPTER V – SPECIAL CONSIDERATION

I. 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 MSA-regulated products. If the MSA/USDA 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 MSA-regulated products, MSA will consider the new products subject to the original recall. MSA 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).

A. MSA personnel are to verify that the MSA 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, MSA personnel are to detain those new products.

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. MSA compliance 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. MSA 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. Effectiveness checks are risk-based and dependent on the class of the recall (which is based on the hazard and any available epidemiological data), the number of consignees, and other relevant factors. If the recalled product was distributed to the wholesale level only, and the producing company has regained control over the recalled product, MSA compliance personnel are to verify that the producing establishment has retrieved and conducted proper disposition of the recalled product.

C. If at any time during the effectiveness checks MSA compliance 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, MSA compliance personnel are to advise the firm of the recall and provide the firm the opportunity to voluntary remove

the product from commerce and abide by the recall notice instructions. MSA personnel may detain any product found in commerce as set out in MSA Directive 8410.1, "Detention and Seizure" when voluntary removal is not achieved. MSA compliance personnel are to notify the RO immediately when the recalled product remains available to the consumer, and when the recalling firm has not properly implemented its recall strategy.

II. FIELD RECALL RESPONSIBILITIES UPON NOTICE OF A RECALL

A. The RO 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;

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.

4. If the recall notice is incomplete or inaccurate, the RO is to immediately call the firm and explain the reasons why the notification or instructions are inadequate and follow up the call with a letter to the firm;

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

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

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

III. RESPONSIBILITIES FOR COORDINATING MSA COMPLIANCE PROGRAM PERSONNEL'S ACTIVITIES IN EFFECTIVENESS AND PRODUCT DISPOSITION VERIFICATION CHECKS

The RO responsibilities are to:

1. Coordinate effectiveness checks.

2. Select a sample of consignees based on product distribution information using an appropriate sampling plan.

3. Disseminate consignee lists to MSA compliance personnel conducting effectiveness checks.

4. Receive completed recall effectiveness check reports.

5. Evaluate effectiveness reports to determine if the recall was effective.

IV. MSA 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 equal to, or less than, the critical number in the sampling plan applied to the effectiveness check. Using the sampling plan selected by the RO, MSA compliance personnel are to:

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

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

3. determine the amount of recalled product received by consignees. In cases where a consignee cannot document how much of the recalled product it actually received, program personnel are to explain this on the Report of Recall Effectiveness: Part A – Effectiveness Checks;

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

5. record the effectiveness checks on MSA form 8400-4 and submit the completed forms to the RO;

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

C. In cases where prohibited acts, such as introducing product that the Agency has reason to believe is adulterated into commerce, are noted or suspected, MSA compliance personnel will document the occurrence and notify the RO. The RMS will issue, when the facts support, a letter to the firm describing the circumstances of the prohibited act and the potential enforcement or criminal action the Agency may pursue.

D. If, when conducting effectiveness checks, MSA finds recalled product in commerce, the Agency will consider whether the recalling establishment clearly communicated the recall notification to its consignees. MSA 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. Program employees will follow MSA Directive 8010.2 as appropriate and notify the consignee of any prohibited activity.

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

The RO is to:

1. Compile the recall effectiveness reports to make an overall assessment of recall effectiveness following the criteria and decision guidance in Attachment 2;

2. Analyze the information that is submitted on Forms 8400-4 and review any instances in which recalled product was found in commerce. For example, the RO should review the effectiveness check findings to determine whether a pattern or trend exists that may suggest certain consignees were not contacted; and

3. Contact the firm and verify that the firm:

   a. Controlled the recalled product as planned;

   b. Disposed of the product as planned; and

   c. Considers the recall closed.

VI. THE RO DETERMINATION ON THE EFFECTIVENESS OF THE RECALL

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

NOTE: MSA compliance 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. The RO is responsible for submitting a recommendation for closing a recall to the RMS. The RO recommendation to close the recall should summarize the recall efforts by the firm and the findings of the effectiveness and product disposition checks.

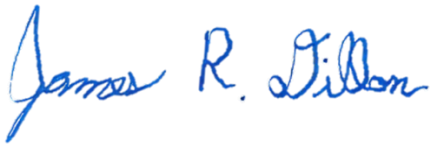
B. Before submitting the recommendation, the RO will verify that there are no current reports of illness associated with the recalled product.

1. If data indicate that illnesses continue to occur because product remains in commerce, the recall case will remain open. RMS may request that the firm expand the recall if evidence indicates that additional products are causing illness.

2. If data indicate that no additional illnesses associated with the recalled product are being reported, and there are no signs that recalled product remains in commerce, RMS may proceed to recommend closing the recall.

II. QUESTIONS

Refer questions through supervisory channels.



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Factors That Are Considered by the MSA Recall Committee in Evaluating the Public Health Significance of an Undeclared Ingredient in a Meat or Poultry Product

Background

The Texas Meat and Poultry Inspection Act under which the Meat Safety Assurance (MSA) 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 TMPIA, FMIA or PPIA if it contains ingredients that are not declared on the product labeling.

The Agency recognizes that there are situations in which a meat or poultry product enters commerce with ingredients that are not declared on its labeling. In some cases, the undeclared ingredient may present a health risk to individuals that are allergic or sensitive to the ingredient, which would necessitate removal of the product from commerce. The most common example of such an ingredient would be a potential food allergen, such as peanuts. MSA Directive 8080.1, titled "Recall of Meat and Poultry Products" outlines the Agency's policies and procedures regarding the voluntary recall of MSA-inspected meat and poultry products. MSA Directive 8080.1 provides that each recall be classified into one of three classes 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 nine categories of foods: cereals containing gluten (i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these); crustacea; eggs and egg products; fish and fish products; peanuts; soybeans; milk and milk products; tree nuts, and sesame.

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

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

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

The significance of this factor for recall classifications is that, for some allergens, there exists a "no observed adverse effect level" that can be used in estimating risk. Thus, in these cases, the higher the amount of the ingredient, the more likely it is to elicit an adverse effect, the more reason to classify the recall as one in which there is a significant public health concern, that is, Class I. Conversely, the lower the amount of the ingredient, the more reason there is to classify the recall as Class II. However, for most known allergens, there is no conclusive scientific evidence to establish threshold levels for eliciting an adverse reaction. Consequently, in most cases, the presence of an undeclared substance that is a known allergen, at any level, poses a public health risk and thus the recall should be classified as Class I unless other factors justify a different, lower classification.

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

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

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

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

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

The significance of an undeclared ingredient relates to the most sensitive subpopulation that may be affected. In the case where the ingredient is among the "big nine " category of allergens, the issue of the number of sensitive individuals is irrelevant because, for any sensitive individual, there is no established threshold, and an allergic reaction is potentially catastrophic. However, in the case where non-declaration involves ingredients that are *not* among the "big nine" 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 MSA Recall Committee. The Recall Committee may request that a Health Hazard Evaluation Board convene to assist in estimating the risk.

EFFECTIVENESS CHECKS

A. Determining the Total Number of Effectiveness Checks to Conduct

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

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

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

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

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

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

Table 2. Effectiveness checks to conduct and critical limits for ***all*** Class I recalls involving an injury, illness outbreak, or distribution to schools.			
Number of Consignees	**Number of Effectiveness Checks to Make**	**Recall Considered Ineffective if the Number of Consignees at which Product was Available to Consumers Exceeds:**	**Number of On-site Effectiveness Checks**
1 to 200	100% of consignees	0	RO will consult with RMS on the number of on-site verifications
201 to 10,000	200	0	
10,001 to 35,000	800	1	
35,001 to 500,000	800	1	
500,001 and over	1,250	2	

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

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

5. Table 4 is used for Class II recalls.

Table 4. Effectiveness checks to conduct and critical limits for Class II recalls.

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

6. Table 5 is used for Class III recalls.

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

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

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

B. Schools and Other Special Consignee Categories

If information is available, the RO may group effectiveness checks by identified special categories (e.g., schools, day care centers, hospital cafeterias, or retirement homes), to mitigate risk to populations that may be more susceptible to foodborne illness. If the RO decides to separate groups by special categories, then each group of consignees should be considered separately. 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.

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

C. Selecting the Effectiveness Checks

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

For a Class I recall with no illnesses, outbreaks, or school lunch distribution, the appropriate table is Table 3.

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

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

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

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

If MSA personnel are unable to perform an effectiveness check (e.g., a consignee selected for an effectiveness check did not receive the recalled product or is no longer in business) and determine that the check is ineligible, they are to contact the RO as soon as possible so that a replacement effectiveness check can be randomly selected and assigned. If the consignee selected for substitution is also ineligible for an effectiveness check, the RO is to select another substitute consignee. The second substitution should be a biased replacement consignee that the RO believes is likely to have received the recalled product. The RO should make a reasonable attempt to find a substitute consignee so the effectiveness check can be completed.

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

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

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

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