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How Do You Develop a Recall Plan?

Writing a recall plan may seem daunting. Breaking down the plan into 10 parts, however, can make the task easier. Each part plays a different role in the plan and may be linked to existing food safety systems. A recall plan can be more or less complex depending on the grower's operation.

The 10 recall plan components are:

1. Prepare for recall
2. Identify the concern
3. Initiate the recall
4. Notify the regulatory agencies
5. Identify and trace affected products
6. Notify affected parties
7. Control and dispose of recalled products
8. Determine the recall's effectiveness
9. Terminate the recall
10. Remedy the recall's cause and restore operations

A Guide to Drafting a Recall Plan for Maryland Produce Growers

All Maryland produce growers have the shared goal of growing safe food for consumers. Despite growers' best efforts, however, foodborne illness outbreaks happen. When an outbreak occurs and can be traced to the source, it is usually followed by a recall of the product. A recall can result in substantial financial damage to the grower and have ripple effects throughout the industry. Having a recall plan in place lessens the confusion, delay, and financial repercussions which can stem from a recall.

Adulterated or mislabeled food is subject to recall. Food is adulterated if it:

- is impure, unsafe, or unwholesome;
- contains a pathogen (such as Listeria), a foreign material (such as plastic), or an undeclared allergen; or
- if packaging has failed.

Producers may recall food because of:

- hazards detected through tests or observations;
- test results from a regulatory agency; and/or
- local or State health department tracing a foodborne illness back to the source.

A recall plan is a documented, systematic strategy outlining how a grower will track and recall products. Plans can vary in specificity, but at a minimum a good recall plan should include the "who, what, and how." In other words, the plan should clearly state who in the operation will do each task, what steps should be taken, and how the recall procedures will be implemented.

Each section is described below and outlined in the Model Recall Plan, a companion document to this publication. A recall plan needs to be customized to each operation. While there is no "one size fits all" recall plan, this guide, together with the Model Recall Plan will help each farmer create a specific plan to fit his or her operation's needs.

The Best Way to Prepare for Recall is to Take Precautionary Recordkeeping Steps to Make Administering a Recall Less Stressful and More Streamlined

When a recall is initiated, it is extremely important that growers have good records and an effective traceability system for their farm products. To do this, a grower must maintain and continuously update a Customer/ Buyer Contact list (see sample in Appendix A to the Model Recall Plan).

Similarly, growers should maintain a list of people inside and outside of the operation who will need to be involved in a recall. Outside members include the regulatory agencies involved in the recall process. Internally, the grower should designate a recall team, with clearly defined roles and identities of the people who will serve in each role. The number of people on the recall team will depend on the size of an operation, but at a minimum, a team should include people responsible for:

- Making decisions;
- Coordinating the recall;
- Contacting and responding to regulatory agencies;
- Communicating with media and customers; and
- Addressing legal and insurance concerns.

A grower could designate the roles as:

Recall Team Leader - has the authority to initiate a recall, make critical decisions quickly, and designate team members as needed.

Recall Team Coordinator - oversees the complaint investigation, tracks recalled products, and coordinates the recall team. In small operations, this role could be combined with the Team Leader position.

Government Liaison - contacts the regulatory agencies and provides necessary information. This person should be well-versed in the operation's traceability procedures and able to access related records and documents.

Media/Customer Spokesperson - disseminates information about the recall to the media and customers, handles press releases, social media, etc.

Legal Counsel – advises the farm operation in the event of a recall. The attorney should be familiar with the

operation and asked in advance if he/she is qualified and willing to provide legal counsel during a recall. Legal counsel should review the farm's recall plan procedures and work directly with the Recall Team Leader to decide if it is necessary to initiate a recall. Counsel also will work with the Government Liaison to provide legal advice on communicating with regulatory agencies.

Insurance Agent – works with the grower if the farm operation has recall-related insurance coverage. The agent should be notified of a recall and may be a part of the team.

A grower should designate the recall team in writing (see sample Recall Team Contact List form in Appendix B of the Model Recall Plan). Because many recalls occur outside of regular working hours, the Recall Team Contact List should include after-hours information for all recall team members. The Contact List also should include contact information for the relevant regulatory agencies. When a grower suspects the farm operation sold or distributed an unsafe food product, it is his/ her duty to contact the applicable regulatory agency immediately, in order to assist with the investigation and collect the information needed to make the right decision.

To effectively trace products during a recall, a farmer will need to have good traceability procedures. (Appendix C of the Model Recall Plan contains a Produce Traceability Plan farmers can use to create their own plan.)

Once a recall plan is in place, staging a mock recall will help team members prepare for an actual event. To stage a mock recall, the grower should develop a

factual scenario involving an "affected" lot. The Recall Team should attempt to trace a lot from the farm to the buyer. Treating the scenario as if it were an actual event, the grower and recall team should run through the entire plan, including the team members' roles, so that everyone understands the recall system. However, the Recall Team should be sure to alert any buyers/ distributors contacted during a mock recall that the team is conducting an exercise. Every grower should conduct mock recalls annually, and the recall plan and food safety systems should be documented and updated to reflect any deficiencies in the process. See Appendix D of the Model Recall Plan for mock recall exercise documents.

Growers May Want to Consider Insurance Coverage to Defray Costs Related to Recalls

Growers should not assume that their existing insurance policy will cover costs related to a recall and should inquire as to whether additional insurance is needed to cover costs such as civil damages, business interruption, loss of products, etc. Insurance coverage can be expensive, but so can a wide-scale recall. A farmer who purchases recall insurance coverage should add the insurance agent to the Recall Team or, at the very least, include notifying the insurance carrier in the recall plan. Insurance policies often have very specific requirements for how and when notice must be given, and failure to follow the procedure may result in an insurer denying a claim.

Growers Well-Versed in the Recall Process Have a Better Chance of Successfully Completing a Recall and Returning to Business as Usual

A recall may be initiated by **1)** consumer complaint(s); **2)** notification by a regulatory agency of a food safety issue, such as a foodborne disease outbreak; or **3)** an internal discovery indicating a potential food safety issue.

Identify the Concern

Following a consumer complaint of adulterated food, the grower or the employee who received the complaint should establish a record of the notification. The record should include the complainant's name, address, phone number, and email address. The Consumer Complaint Form in Appendix E to the Model Recall Plan indicates the necessary information to obtain when identifying the concern. All farm employees should be trained to use the form when a consumer calls to complain about a farm product.

In some cases, a regulatory agency such as the local health department, Maryland Department of Health (MDH), Maryland Department of Agriculture (MDA), or the U.S. Food and Drug Administration (FDA) will notify the grower of a potential problem, and this type of notification should be documented. A notification record should be made and include the agency representative's name, position, agency, address, and phone number. The record should also include a detailed description of what is wrong with the food and what, if any, illness or injury was caused by the food, what type of product is implicated, where and when it was consumed, and the suspected contaminant.

If a grower makes an internal discovery or receives a water quality test indicating a potential food safety issue, a decision will need to be made whether a recall is required. A grower who is unsure whether a recall should be undertaken should consult the MDA's Food Quality Assurance Department at 410-841-5769 or after hours at 1-443-223-9408. In an emergency, a grower can also call the FDA's 24-hour emergency line at 1-866-300-4374 or 301-796-8240.

Initiate the Recall

When a farmer initiates a recall, the first steps include assembling the recall team and notifying applicable regulatory agencies. Appendix F to the Model Recall Plan contains an easy-to-use Model Recall Plan Checklist.

The farm owner should be notified immediately of any consumer complaint of foodborne illness in order to properly investigate the situation. Not every consumer

complaint will result in a recall but all complaints should be taken seriously and investigated to determine the severity and scope of the issue. The degree of health hazard will dictate the scope of the recall. See Appendix G of the Model Recall Plan for a health hazard evaluation questionnaire. However, there may be instances where, due to issues such as misbranding in violation of law, a recall is required in the absence of a health risk (see Class II below).

There are varying levels of food product recalls indicating the relative degree of health risk posed by a recalled product:

Class I - A situation where serious (possibly even fatal) health consequences may result from consuming the product. A public alert is usually issued by the applicable regulatory agencies.

Class II - A situation where a health hazard might exist but the probability is remote. A public alert may be issued.

Class III - A situation where a food violates federal or state regulations, but is not likely to cause adverse health consequences. A public alert is not usually issued.

Market Withdrawal: A situation where a food has a minor violation that is not in violation of any food safety laws. The products may be withdrawn from the market without initiating a recall.

A farmer should always notify a regulatory agency such as MDA and/or MDH before initiating a recall, seek legal counsel, and, if applicable, notify his or her insurance carrier. It is advisable to have a farm recall plan reviewed prior to implementation in order to expedite the legal review during an actual recall.

Delaying the initiation of a recall in the case of a foodborne illness outbreak may subject a grower to criminal consequences and/or increased civil damages. Once a grower receives notice of a foodborne illness outbreak or food safety risk, any failure to act to protect the public from the risk may be considered intentional.

Notify the Regulatory Agencies

If a farmer receives more than one consumer complaint about a farm product (i.e., consumption of a product resulted in illness) within a relatively short time, the grower should call the county health department to report a suspected foodborne outbreak within 24 hours. Maryland law defines a foodborne disease outbreak as two or more related cases of illness following consumption of common food item(s), or one case of certain illnesses including botulism, cholera, mushroom poisoning, etc. (Md. Code Regs. 10.06.01.02B(10)).

Health care providers such as doctors' offices and hospitals may also report foodborne illnesses to the MDH or a county health department. If a consumer exhibiting signs of a foodborne illness seeks medical treatment, the treating physician will report the illness to the local county

health department. Depending on the circumstances, the health department may initiate an investigation which may lead to a recall (Md. Code Regs. 10.06.01.09B).

Alternatively, a grower can initiate a recall based on an internal discovery such as irrigation water quality testing or other discovery that would give a grower reason to believe a distributed food is likely to cause adverse health consequences. In that case, the farmer should contact the county health department as well as the MDA's Food Quality Assurance Department. The MDH and MDA will coordinate the recall process if the outbreak is within the state. If the outbreak is interstate, the federal FDA also will be involved in the recall process.

The state or federal governments can also initiate a recall. For example, a state or federal regulatory agency may sample a farm's products and find them to be unsafe, which can lead to a recall. A recall will most likely trigger an investigation by state and/or federal regulatory agencies. A good way for growers to prepare for an FDA investigation is to review the FDA's guide for produce farm investigations, available online at: https://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074962.htm.

If a Maryland farmer is implicated in an outbreak, the county health department, the MDH, and the MDA will assist the farmer in notifying consumers and removing the product from circulation. The goals of the state agencies during a foodborne outbreak are to provide

support to the farmer and to protect the public health. To achieve these goals, however, it is vital that the regulatory agencies are notified as soon as possible of a potential food safety threat.

Identify and Trace Affected Products

How a grower identifies inventory, such as lot coding, batch numbers, dates, or exact product name, is critical for tracing adulterated products and for public notification. Appendix H to the Model Recall Plan contains a sample traceability log. Grower records also should include information about field inputs and outputs associated with each affected lot number, including harvesting methods, wildlife activity, and factors such as ill employees which could contribute to contamination.

Easily identifying and tracking affected products will depend on whether the grower has an established inventory traceability plan and sanitation "clean break" process. A sanitation clean break in production involves documented, verified, and validated cleaning and sanitizing processes for all food contact surfaces. These procedures should be documented for each lot or defined group of products. Good records related to sanitation allow a grower to pinpoint when the problem occurred and limit the number of lots affected. A grower without a "clean break" system will have difficulty tracing a food safety concern to a specific lot, and could face disposal of huge amounts of product.

Notify Affected Parties

A grower implementing a recall needs to notify consumers and all parties in the distribution chain. Growers can notify contacts in the distribution chain by telephone, in person, or by a letter. The Model Recall Plan in Appendix I contains links to examples of recall notification documents. The recalling operation must retain records showing that the recall communications reached the intended recipients. Therefore, all phone communications should be documented in a log and all letters should contain a response form that the recipient can send back to prove receipt of the notice. The Model Recall Plan has a sample Communications Log in Appendix J.

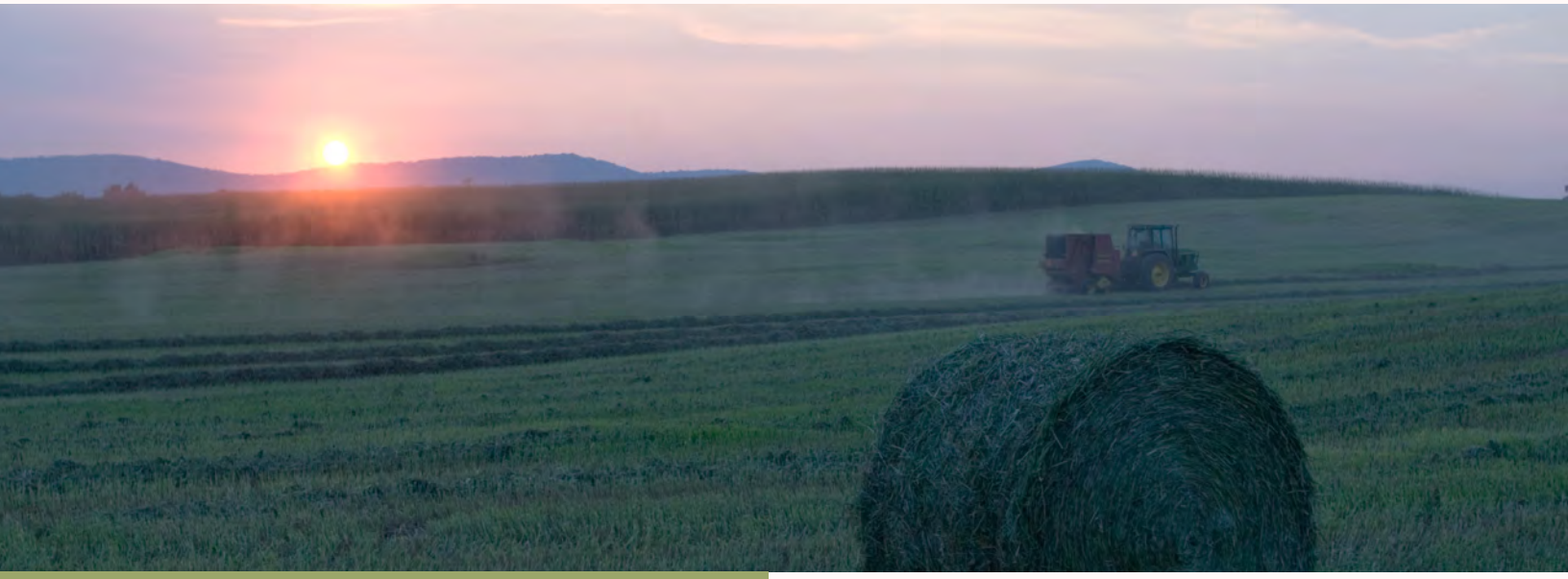
The regulatory agencies overseeing the recall will help the grower write and send out a press release to let consumers know about the recall using social media and regular media sources. The Model Recall Plan contains a link to a sample press release in Appendix I. Recall notifications and press releases should identify the problem, explain the potential threat, and inform a customer what to do to minimize the risk, such as destroying the product or returning it to the grower.

Control and Dispose of Recalled Products

During a recall all affected products in the grower's possession or control should be segregated and clearly marked to prevent the products from entering the commerce stream. The grower should consult with the overseeing regulatory agencies on the preferred form of disposal of recalled wholesale, retail, and customer-purchased products. These products may be destroyed or modified to remove the food safety risk. The grower needs to have an effective plan for disposing of any unsafe food products that are returned. The grower should document the retrieval in a product retrieval log. See a sample in Appendix K to the Model Recall Plan.

Determine the Recall's Effectiveness

It is the grower's responsibility to determine and document, through effectiveness checks, that all known affected customers were notified about a recall and have taken appropriate action. A grower may not be able to verify that every customer was reached, depending on the scope of the recall or the willingness of the customers to cooperate. However, a grower should make the best possible effort and gather evidence to prove the recall's effectiveness. Appendix I to the Model Recall Plan contains links to model documents to use in effectiveness checks.



References

21 C.F.R. § 7.40-7.59 (2017).

Md. Code Regs. 10.06.01.02B(10) (2017).

Md. Code Regs. 10.06.01.09B (2017).

Douglas L. Archer, Keith R. Schneider, Ronald H. Schmidt, W. Steve Otwell, Renee M. Goodrich, and Chris Thomas, ***The Food Recall Manual***, 2004,THE UNIVERSITY OF FLORIDA, http://edis.ifas.ufl.edu/pdffiles/fs/fs10800.pdf.

Diane T. Ducharme, *Draft Recall Plan Workbook*, March 2016, North Carolina State University, (Adapted for UVM by Ginger Nickerson) https://www.uvm.edu/~susagctr/whatwedo/producesafety/GAPsResources/gapresRTSampleRecallPlanMarch62016GNRevised.docx.

Food and Drug Administration Industry Guidance, ***Guidance for Industry: Product Recalls, Including Removals and Corrections***, November 3, 2003, https://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm.

Food and Drug Administration, ***Guide to Produce Farm Investigations*** (11/05), May 3, 2006, https://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074962.htm.

Philip Gruber, ***Farmers Should Plan for Food Recall*** (Apr. 16, 2015), LANCASTER FARMING, http://www.lancasterfarming.com/news/main_edition/farmers-should-plan-for-food-recall/article_85dc2db6-7aee-5ad2-8759-c93335127d9c.html.

Winifred W. McGee & Lynn F. Kime, PENN STATE EXTENSION, ***Proactive Recall Plans***, http://extension.psu.edu/business/farm/management/risk/my-food-venture-risk-management-plan/proactive-recall-plans.

Sample Recall Plan, CALIFORNIA DEPARTMENT OF PUBLIC HEALTH, https://archive.cdph.ca.gov/pubsforms/Documents/fdbRIgde23.pdf.

Terminate the Recall

A recall is considered complete after all possible customer responses indicating receipt of a recall notice have been received and it is reasonable to assume that the recalled product has been recovered, corrected, reconditioned, or destroyed.

Remedy the Recall's Cause and Restore Operations

A recall plan should account for how the source(s) of the foodborne illness will be remedied and farm operations restored. Regaining the trust of the public, customers, and supply chain partners will not be easy, but it can be done.

Showing that the farm has been proactive in preventing any further outbreak and provided all relevant documentation will help restore trust. The media communications member(s) of the recall team can play an important role by providing a unified statement to media outlets. Although it may take time, consumers and supply chain partners will trust the farm again if a recall is handled efficiently.

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