EXTENSIONBULLETIN Model Recall Plan

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UNIVERSITY OF MARYLAND AGRICULTURE LAW EDUCATION INITIATIVE MPOWERING THE STATE







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Disclaimer: This model plan is intended to provide general information and should not be construed as providing legal advice.

Introduction

This is the recall plan for _____ Farm. This plan does not address recall provisions related to meat or egg products. This plan will be periodically updated.

Recall Policy

In the event of a food safety issue related to our products, _____ Farm will protect the public health by efficiently identifying and removing unsafe food from the distribution chain and informing consumers of potentially hazardous food in the marketplace. This plan will be tested annually through a mock recall to ensure it functions effectively.

Preparing for a Recall

CUSTOMER/BUYER CONTACTS

Appendix A contains a list with the names and available contact information for all customers/buyers of our products. _____ Farm will use this list to contact customers in the event of a recall and will update the list as needed.

RECALL TEAM

The list in Appendix B describes the various roles of the Recall Team, the staff members assigned each role, and the contact information for the regulatory agencies involved in a recall. The Recall Team is responsible for coordinating all aspects of a product recall. The roles and responsibilities of each Recall Team member are as follows:

- *Recall Team Leader* has the ultimate authority to make the decision to initiate a recall, make critical decisions quickly, and designate team members as needed.
- *Recall Team Coordinator* oversees the complaint investigation and the trace-back process, and coordinates the recall team to address the issues at hand.
- *Government Liaison* contacts the regulatory agencies, is knowledgeable about the farm's traceability procedures, and is prepared to provide the necessary information, as well as able to access related records and documents
- Media/Customer Spokesperson disseminates information about the recall to the media and customers, and handles press releases, social media, etc.
- *Legal Counsel* provides legal advice in the event of a recall or food safety event, is familiar with our farm, and has reviewed this recall plan.
- *Insurance Agent* provides information relating to insurance coverage.

TRACEABILITY PLAN

Appendix C contains a copy of our traceability plan. Being able to effectively trace products is a key component of a recall. Our farm utilizes a system that allows us to trace products one step forward and one step back. We keep records of all our agricultural inputs including soil amendments, fertilizers, seeds/transplants, and agricultural chemicals so we can link them with each of our crop types and ultimately to our buyers. We also assign our products a traceability code (lot number) based on harvest date, crop, and field number.

Mock Recall

Once during each growing season, we conduct a mock recall for our farm and markets which mimics the process of an actual recall. We use mock recalls to determine whether the recall plan and procedures are capable of 1) identifying and quickly controlling a given lot of potentially affected product and 2) reconciling the quantities produced, in inventory, and distributed. A mock recall will help us evaluate the effectiveness of our plan and procedures by identifying potential problems and ensuring employees are familiar with recall procedures. Appendix D lists the materials used during a mock recall. If problems are identified during the mock recall, this plan will be amended.

Recall Procedures

In the event of a recall, the Recall Team Leader will take the following steps to ensure successful retrieval of products, communication with all necessary parties, and restoration of normal business.

IDENTIFY THE CONCERN

A recall may be initiated in a few ways: 1) consumer complaint(s); 2) notification by a regulatory agency of a food safety issue; or 3) an internal operations discovery or laboratory report indicating a potential food safety issue.

We take all consumer complaints related to our products very seriously and record them on a Consumer Complaint Form in Appendix E. The employee who takes the call should ask all questions on the Consumer Complaint Form and record all pertinent information. As soon as possible after receiving the complaint, the employee is required to inform the owner/manager of ______Farm and/ or the Recall Team Leader.

After receiving a consumer complaint, notification by a regulator of a food safety issue, or an internal discovery of a condition that could create a food safety risk, the owner/manager of ______ Farm and/ or the Recall Team Leader will assess the severity of the issue. If the consumer complaints are related to adverse health effects caused by the farm's products, we will use the Health Hazard Evaluation Questionnaire in Appendix G to assess the concern. In addition, ______ Farm will also assess the concern by consulting the Maryland Department of Agriculture's (MDA) Food Quality Assurance Department at 1-410-841-5769 or after hours at 443-223-9408.

The speed with which the health hazard must be evaluated will depend on the nature of the alleged violation or defect. The more serious the potential health effects, the greater the need for an urgent response. If ______ Farm receives more than one consumer complaint about adverse health effects caused by one of our products, we will consider the situation to be a potential foodborne disease outbreak and will contact the local health department.

When contemplating a recall, the owner/manager of ______ Farm and/or the Recall Team Leader will also contact legal counsel for advice pertaining to the applicable legal standards before deciding to initiate a recall.

 of _____ Farm and/or the Recall Team Leader must document all information available to support the decision—either to recall, or not.

If _____ Farm is notified by the county health department, the Maryland Department of Health, the MDA, or the federal Food and Drug Administration (FDA) that our products could be implicated in a foodborne illness outbreak, we will make a record of the communication, assemble the recall team, contact our legal counsel and insurance agent, if applicable, and start an internal investigation in coordination with the agencies.

INITIATE THE RECALL

After the decision to initiate a recall, the Recall Team will assemble, notify regulatory agencies (if not previously notified), and determine the recall's scope. To determine the class and scope of the recall, ______ Farm will consider 1) whether any disease or injuries have already occurred from use of the product; 2) the seriousness of the health hazard; 3) the immediate and long-range consequences; and 4) the ability to identify and quantify the defective product in the marketplace.

_____ Farm will use the following FDA class levels of recall:

- *Class I:* A situation where serious (possibly even fatal) health consequences may result if the product is consumed. Examples include Listeria or Salmonella in food. A public alert is usually issued.
- *Class II:* A situation where a health hazard might exist but the probability is remote. A public alert may be issued. An example is a food containing an undeclared allergen.
- *Class III:* A situation where a food violates federal regulations, but is unlikely to cause adverse health consequences, and where a public alert is not usually issued. An example is a food with a minor labeling issue.
- *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.

The Recall Team will use the Recall Plan Checklist in Appendix F to stay on track of all necessary steps in the recall process.

Notify the Regulatory Agencies

When the decision to initiate a recall based on consumer complaints is made, the Government Liaison member of the Recall Team will contact the county health department. If the issue is serious or life-threatening, the Government Liaison will call the FDA's 24-hour emergency line at 1-866-300-4374 or 301-796-8240. If the Recall Team initiates a recall because of an internal discovery, the Government Liaison will also contact the MDA's Food Quality Assurance Department at 1-410-841-5769 or after hours at 443-223-9408. The federal, state, and local regulatory agencies will work with ______Farm on the recall process. Appendix B lists the contact numbers for the regulatory agencies.

Identify and Trace Affected Products

Identifying and tracking affected products are crucial during a recall and will be done in accordance with ______ Farm's traceability plan. The Recall Team Coordinator will initiate trace-back procedures to determine the products, number of units, units of measure, farm, harvest date, and lot numbers involved. All information pertaining to the trace back will be recorded in the Traceability Log found in Appendix H. The Coordinator will also collect all pertinent documentation regarding the affected product such as inputs and outputs of the field associated with the lot number, harvesting methods, and any other details that could aid in the investigation (for example: ill employees). The Government Liaison will work with the Coordinator to make sure the required information is provided to the overseeing regulatory agencies throughout the investigation.

Notify Affected Parties

The Media/Customer Spokesperson member of the Recall Team will work with the overseeing regulatory agencies to send out all press releases and customer notifications. If the products pose a significant health hazard and the recalled products are in the hands of consumers, a press release is usually appropriate.

_____ Farm will notify all wholesale, retail, and direct customers as soon as possible about the recall. Notifications will be done through a telephone call, in person, or in writing (the preferred form of notification). If produce was distributed at a farm-owned retail stand, a notice will be posted there. See Appendix I for a form to use for recall notification by telephone.

The notification must include:

- A complete description of the product and any codes used to identify the product,
- A description of the problem and any potential associated health hazards,
- The scope of the recall (wholesale, retail, or user level),
- Clear instructions regarding removing the product from sale, ceasing distribution, sub-recalling (if appropriate), returning the product, or modifying the product, and
- A return response form for all written notifications so that customers can indicate they received the notification and followed the instructions.

Links to model press releases and recall notifications can be found in Appendix I. _____ Farm will retain evidence of all communications. We will record all communications during the recall in the Communications Log found in Appendix J.

Control and Dispose of Recalled Products

The Recall Coordinator or a designated member of the Recall Team is responsible for ensuring all recalled products are controlled and disposed of appropriately. _____Farm will make all reasonable efforts to remove affected products from the commerce stream.

All affected products still in the control of ______ Farm (e.g., inventory located onsite, in transit, in off-site storage, and in off-site distribution) will be detained and segregated to prevent reentry into the commerce stream. The Team will document all quantities and identification codes to help with

reconciling product amounts and will clearly mark all affected product "not for sale or distribution." ______ Farm will work with the overseeing regulatory agencies to decide on the appropriate disposition of recovered recalled products. Products deemed unsafe for human consumption may be returned, destroyed, and disposed of by appropriate means. No products will be destroyed without first notifying the regulatory agencies. The team will quarantine all returned products until the recall ends. The Recall Coordinator or another member of the Recall Team will document quantities, identification codes, and disposition on the Product Retrieval Log in Appendix K.

Determine the Recall's Effectiveness

The Recall Team will need to determine the level of the recall's effectiveness. To do so, the team will perform and document effectiveness checks of the recall to prove that all known, affected customers were notified of the recall and have taken appropriate action. See links to model effectiveness check documents in Appendix I.

Terminate the Recall

Remedy the Cause and Restore Operations

As soon as the Recall Team identifies the reason for the recall, it will take corrective and/or preventative measures to remedy the issue. After the recall, the team will update, revise, and make all necessary amendments to this plan. Finally, _____ Farm will focus on fully restoring operations. _____ Farm will not only remedy the physical issues associated with the cause of the recall but will also focus on rebuilding public trust in our products. Upon completion of a recall, the Media/Customer Spokesperson member of the Recall Team will craft a statement announcing the end of the recall to advise customers that they may once again enjoy our products.

Following a recall, _____ Farm will assess what changes, if any, need to be made to this plan to make it more efficient and effective.

Appendix A: Customer/Buyer Contact list

Customer/buyer name	Address	Email	Business phone	Mobile phone	Product sold

Appendix B: Recall Team Contact List

Role	Name	Business Phone	After Hours Phone	Responsibilities During Recall
Recall Team Leader				 Serves as recall team leader Makes final decisions on recovery of products Reassigns team members
Recall Team Coordinator				Oversees complaint investigationCoordinates the recall team actions
Government Liaison				Communicates with regulatory agencies and works with legal counsel and provides information to regulatory agencies
Media/Customer Spokesperson				 Handles all media and customer communication Works with regulatory agencies on press releases and customer letters
Legal Counsel				 Handles liability questions Advises government liaison on regulatory responses
Insurance Agent				Addresses insurance coverage issues
Local Health Dept. (Contact info for Md. health departments: http://dhmh. maryland.gov/Pages/ departments.ASPX)				
MD Dept. of Ag.		410-841-5769	443-223-9408	Oversees recalls for food distributed intrastate
MD Dept. of Health	State of Maryland Rapid Response Team	410-767-8400	410-795-7365	Oversees recalls for food distributed intrastate
FDA Baltimore District Office	Recall Coordinator	410-799-5414		• Oversees all product recalls for FDA-regulated product within the Baltimore District (MD, D.C., VA, WV)
FDA Emergency		1-866-300-4374	301-796-8240	

Appendix C: Produce Traceability Plan

Trace back records: Our farm uses a traceability system allowing us to trace a product one step forward and one step back. We keep records of all our agricultural inputs including soil amendments, fertilizers, seeds/transplants, and agricultural chemicals so that we can link them with each of our crop types and ultimately, if necessary, to the buyer(s).

[DESCRIBE YOUR SYSTEM HERE – THIS IS AN EXAMPLE – YOUR SYSTEM AND THE INFORMATION YOU RECORD MAY BE DIFFERENT]

- 1. All products produced by the farm will be assigned a traceability code (lot number) based on harvest date, crop, and field number.
- 2. Harvested product will be tagged, stamped, or labeled by marketing unit (examples: bin, box, case, pallet, bag, etc.) to show the following information:
 - a. The type of crop
 - b. The name and address of our farm
 - c. The field the crop was grown in [IF APPLICABLE]
 - d. The harvest date [OR PACK DATE- WHICHEVER YOU USE ON YOUR LABELS]
 - e. The lot number [IF USED]
- 3. All product is invoiced as it is shipped from the farm.
- 4. Invoices include: farm name and information, buyer name and information, and inventory amounts transferred/ exchanged.
- 5. Invoice should be signed or initialed by the customer (receiving party) when product is delivered.
- 6. All unused/unsold inventories are accounted for including quantity, date, and method of disposal.

We use a lot number system which identifies the harvest date and field (example: 072417-2 means harvested on July 24, 2017 from field 2. Add any other information you use in your lot tracking system.) When we make a sale, the invoice includes information on boxes shipped, to whom, the date of shipment, and the harvest date and field code number. We keep copies/have electronic copies of all invoices so that the buyer and our farm have the same information. If a product is comingled during or after harvest, the above label information for EACH crop type and block of land is provided to the buyer.

Appendix D: Mock Recall Exercise

Once during each growing season, we conduct a trace forward/mock recall exercise to verify that we can match each lot sold to the specific buyer and that we can recall a product if needed. As part of the exercise, we contact a buyer to identify a load received from our company. **Make sure to inform the buyer that this is a mock recall exercise!** We ask how much of the product has been sold, how much they have in inventory, and if any has been disposed of for other reasons (fell on floor, etc.). This information is recorded on our Mock Recall form and kept on file. After a selected lot is sold and shipped, we go through our records to verify that we can match each box shipped to the destination buyer.

Our goal is to achieve 100% effectiveness of reconciliation of product to recipients within _____ hours. The percent effectiveness of the recall is calculated in the following way:

- A = total amount of product
- B = amount still in inventory
- C = amount delivered to customers
- D = incidental usage if any (e.g. product dropped on ground, etc....)
- $(B+C+D) / A \ge 100 = \%$ effectiveness of recall

The gwoal of the exercise is to demonstrate that we have open communication with our buyers and if necessary, we can work with them to remove any of our shipped products from their inventory.

Mock Recall Log

	Date Buyer/customer name		Date			Buy	yer contact i	nfo	
Product	ID/ Lot #	Harvest date	Ship date	Amt. shipped, PO #, & container type	Date & time of buyer contact	Amt. of product remaining in buyer possession	Amt. of product sold by buyer & to whom	Amt. of product returned/ destroyed	Initials
	Comments: Determine the percent effectiveness of the (mock) recall. The total amount of suspect product must equal the sum of the product shipped and the amount still in inventory. $\underline{B+C+D} \times 100 = \%$ Effectiveness A								
	 A – Total amount of product produced B – Amount still on inventory C – Amount delivered to customers D – Incidental usage (product dropped on ground, etc.) 								

Appendix E: Consumer Complaint Form

Name of person who received call:
Date and time of incoming call:
Name of person calling:
Contact phone number for person calling:
Name/contact information of person ill or injured, if not caller:
Age of person ill or injured:
Allergies or pre-existing conditions of consumer:
Description of the consumer's complaint (odor, color, taste, allergic reaction, object in food, illness, etc.:
Injured person's symptoms:
Date and time symptoms occurred:
Date the consumer saw a doctor, if any:
Doctor's name and contact information:
Doctor's diagnosis:
Description of the product the consumer is complaining about (include specific packaging info/product codes, etc.)
Amount of the product consumed:
Names of other consumers of the product:
Symptoms of other consumers, if any:
Date and location of product purchase:
Storage of the product before consumption:
Use of or preparation of the product before consumption:
Other agencies/persons the consumer has notified Contact information

Status of any remaining product ______ If there is remaining product, tell the injured person not to dispose of the product and ask if the farm could retrieve the product for testing.

Any specific requests from the consumer:

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

Appendix F: Recall Plan Checklist

BEFORE A RECALL:

- Create a Customer/Buyer Contact list (Appendix A). Update names, phone numbers, and emails annually or as needed.
- Create a Recall Team Contact list (Appendix B) including names and phone numbers of recall team and regulatory agencies.
- Create an effective Produce Traceability Plan and Mock Recall exercises (Appendices C & D).

ONCE A PROBLEM IS IDENTIFIED:

- Collect information and consider the health hazard evaluation factors:
 - Document consumer complaints using Consumer Complaint Form (Appendix E).
 - Consider the health hazard evaluation factors using Health Hazard Evaluation Checklist (Appendix G).
- Consult with the county health department if we have received more than one consumer complaint about adverse health effects caused by one of our products.
- Consult with the Maryland Department of Agriculture's Food Quality Assurance Department.
- Consult with legal counsel.
- Determine actionable items: Is this a recall? Market withdrawal? Or handled internally by correction (repairing, relabeling, or other adjustments to product)?

RECALL DECISION:

- Activate the Recall Team
- Contact the proper regulatory agencies and provide information
- Perform trace-back procedures to determine the product(s), number of units, units of measure, farm, harvest date, and lot numbers involved (one commodity, or one day, all commodities, etc.) (Appendix H).
- Collect pertinent documentation regarding the affected product.
 - Inputs and outputs of affected field associated with the lot number such as notes on harvesting methods, wildlife activity, ill employees, manure application, etc.
- Work with regulatory agencies to initiate necessary recall notice, customer notifications, and press release (Appendix I).
- Record all communications related to the recall (Appendix J).
- Track, remove, and dispose of recalled products (Appendices H & K).
- Determine the percent effectiveness of the recall.
- Determine if the recall is over/terminate.
- Update the recall plan if necessary.
- Restore operations.

Appendix G: Health Hazard Evaluation Questionnaire

To perform the health hazard evaluation, work through all questions below and attach all supporting documentation.

1. What is the nature of the violation or defect—adulterated product (physical, chemical, or microbial contamination), misbranded product, improperly labeled product, etc.?

2. What illnesses or injuries have already occurred from use of the product?

3. What documentation is there to support the association of the illnesses or injuries with the use of the product?

4. Was the product used in conformance with its labeled directions for use? If so, were the illnesses or injuries due to a) product quality (contamination); b) inadequate directions for use; or c) other known or unknown causes?

5. Are there any existing conditions that could contribute create a health hazard? If so, name the specific conditions (ex. unsafe irrigation water) and explain how these conditions could contribute to a health risk. Document harvest dates, irrigation water source, use of biological soil amendments, mechanical or machine harvest, field pack or packing house, water used post-harvest, or any other processes which could result in product contamination to adequately evaluate existing conditions.

6. What segments of the population— children, elderly, expectant mothers, persons with compromised immune systems, etc. — could be exposed to the affected product? What is the degree of seriousness of this hazard to these specific population segments?

7. What is the degree of seriousness of the health hazard to which the population at risk would be exposed (life threatening, severe, moderate, limited, or none)? Express in terms of:

- **A.** Life threatening: death could occur
- B. Severe: permanent significant disability
- C. Moderate: transient but significant disability; permanent minor disability
- D. Limited: transient minor disability; annoying complaints
- E. None: no disability or physical complaints anticipated

8. What is the likelihood of occurrence of the hazard? What is the frequency of illness or injuries or other adverse reactions which have already occurred? If no illnesses or injuries have occurred yet, what is the likelihood of occurrence in each segment of the population at risk?

9. What are the immediate or long-term consequences of occurrence of the hazard?

For more information see, 21 C.F.R. 7.41- Health Hazard and Recall Classification.

Appendix H: Traceability Log

SHIPPED TO								
Lot number/ code/date	Lot quantity	Name/location	Date shipped	Quantity left on-farm	Quantity shipped and requiring recovery			
				τοται =				
	Lot number/ code/date	Lot number/ code/date Lot quantity	Lot number/	Lot number/	Lot number/			

Appendix I: Communication Document Links

MODEL PRESS RELEASES (FDA)

Allergens: http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129262.htm Clostridium botulinum: http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129273.htm E. coli 0157:H7: http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129287.htm Listeria monocytogenes: http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129267.htm Salmonella: http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129275.htm

MODEL NOTIFICATION LETTERS/ENVELOPE

Envelope: http://www.fda.gov/downloads/Safety/Recalls/IndustryGuidance/UCM214973.pdf Letter: http://www.fda.gov/downloads/Safety/Recalls/IndustryGuidance/UCM214960.pdf Return Response Form: http://www.fda.gov/downloads/Safety/Recalls/IndustryGuidance/UCM214967.pdf

MODEL EFFECTIVENESS LETTERS

Check Letter: http://www.fda.gov/downloads/Safety/Recalls/IndustryGuidance/UCM214958.pdf Effectiveness Check Questionnaire: http://www.fda.gov/downloads/Safety/Recalls/IndustryGuidance/UCM214971.pdf Check Response Format: http://www.fda.gov/downloads/Safety/Recalls/IndustryGuidance/UCM214963.pdf

Appendix J: Communications Log

Quantity shipped and requiring recovery	Date/ time	Person contacted	Quantity recovered or destroyed	Quantity remaining with contact	Action taken and description (e.g., picked up, returned, destroyed, etc.)	Quantity recovered
					TOTAL =	

Appendix K: Product Retrieval Log

Company or organization	Contact	By phone	By letter	ln person	Recall team- member	Copy on file	Reason or description

References

21 C.F.R. § 7.40-7.59 (2017).

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

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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.

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FDA, 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.

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