New Jersey Growers Guide to Recall Plans

RUTGERS
New Jersey Agricultural
Experiment Station

What would you do if the Food and Drug Administration showed up and said your produce must be recalled? Who do you contact? How do you let all your buyers know? Can you trace all your product if necessary? These are just a few questions that should be answered prior to any recall.

When an outbreak occurs, and a source is identified it is often followed by a recall of the product. Having a recall plan in place can make navigating the process more manageable.

This guide will walk you through the process of creating a recall plan and allow you to customize a plan for your farm. First fill in the pdf and then print pages 11-12.

Grower Responsibilities, Three R's

Readiness

- Documented Recall Plan
- Traceability Plan
- Staff training

Response

- Initiate recall
- Notify and/or communicate with agencies
- Inform consumers
- Respond to questions
- Dispose of product

Recovery

- Close out recall with government authority
- Evaluate food plan and consider lessons learned

Traceability Plan:

Traceability allows a grower to perform a recall of a product if there is contamination or some other food safety issue, so that the impact on consumers and the farm is as small as possible. Traceability allows growers to know how much was sold into the marketplace and who might be at risk. A written procedure customized to your farm should be created. Maintain as many detailed records as possible such as:

1. Harvest date
2. Specific field or orchard
3. Harvest Crew
4. Number of packages within a lot
5. Packing and shipping date
6. Inputs used during production

To develop traceability a lot number system must be developed that works for your farm. The bigger the lot, the more difficult it would be to recall, since the lot could have gone to many different buyers. Having small lots means keeping track of many different lots but the scope of a recall would be limited. The decision should be based on how the farm operates considering things like what is grown and how much. Each grower needs to decide the best system for their farm. A lot code can contain numbers, letters or both and should be attached with a label, stamp or sticker to the sellable or master container. For example:

IDEAL COS

Date: 8/12/19

Farm: Wright Farm

Block: 01

Crew: All

Lot Code: 01-10-02-222

Block: 01

Produce Type: 10 (Lettuce)

Variety: 02 (Ideal Cos)

Harvest date: 222 (Julian Date)

Recall Procedures:

There are several ways a recall may be started including A) customer complaints, B) notification from a regulator or C) a food safety issue found at the farm level.

A) Customer Complaints:

Employees are trained to collect specific information if a customer calls with a complaint including at minimum the following: (Appendix A)

1. Name
2. Date and time
3. Contact information
4. Description of complaint including symptoms, doctor diagnosis, product (including lot codes if available).
5. When and where the product was purchased.
6. How the product was stored
7. Other agencies customer has notified.
8. Any other person effected by product

Employees are also trained to let the customer know not to destroy any remaining product, so the farm can collect the product. Once this information is collected, the employee will notify the farm owner and the Recall Team Leader.

The Recall Team Leader will then conduct the following steps:

1. Assess the severity of the issue with the Recall Team. Using the health hazard evaluation factors if necessary. (Appendix B)
2. Consult with proper personnel listed on the State Recall Team Contact List.
3. Determine course of action whether it is a recall, market withdrawal or handled on farm by correcting procedures.

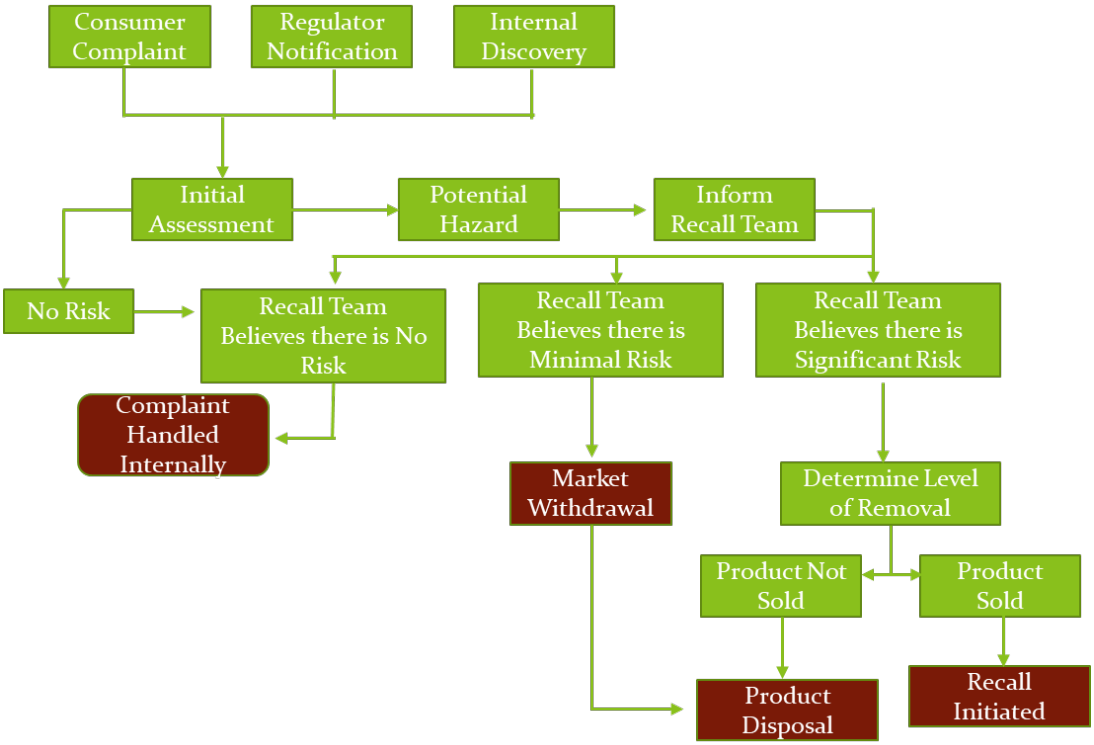
B) Regulator Notification

After notification is received from a regulator about a food safety issue the recall team coordinator will assess the severity of the food safety issue, using the health hazard evaluation factors (Appendix B) if necessary and determine the course of action.

C) Food Safety Issue Found at the Farm

The Recall Team Leader will determine whether any farm factors require a recall or are able to be handled internally by repairing, correcting or adjusting procedures.

Figure 1 illustrates the typical evaluation of complaints or conditions which may lead to a recall.



If a recall decision is made the Recall Team will:

1. Notify regulatory agencies on State Contact List.
2. Begin trace back to determine the products involved and the scope of the recall.
3. Record all information and collect documents to show traceability.
4. Work with regulatory agencies to notify customers.
5. Separate affected product.
6. Consult with regulatory agency on method of disposal required.
7. Document retrieval and product disposal.

As soon as the recall team identifies the cause of the recall, corrective action will be taken, and the farm can restore operations and assess if changes need to be made to the recall plan.

Glossary

Advisory warning- An announcement from the FDA about the potential contamination of a product. If an advisory is issued for product you have and you have not sold it yet, it cannot be sold. If the product was already shipped the seller may voluntarily recall the produce based upon the advisory.

Recall- An action taken by a grower, packer or distributor to remove a product from the market. Recalls may be voluntary or by FDA request.

Traceability- A system in which fruits and vegetables can be traced from the field to the buyer by lot through unique codes. Each farm should have a traceability system in place that allows the grower to track the produce from the field (one step back) to the buyer (one step forward).

Withdrawal- A grower's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the regulatory agency or which involves no violation.

Recall Classification

Recalls are classified by the Food and Drug Administration by the likelihood of harm to humans or animals from the product.

Class I – There is a reasonable probability that the use of or exposure to the product will cause serious adverse health consequences or death. Examples include contamination from *E coli 0157:H7, Salmonella or Listeria monocytogenes*. The regulatory agency may issue a public alert prior to any traceback.

Class II – There is a reasonable likelihood that use of or exposure may cause temporary or medically reversible adverse health affect. An example is food adulterated with wood fragments. A public alert may be issued.

Class III – Use of or exposure to the product is not likely to cause adverse health consequences. An example is mouse hairs in a food, above allowable regulatory levels, but does not present health concerns. A public alert is usually not issued.

References

21 C.F.R. 7.41- Health Hazard and Recall Classification. https://www.govregs.com/regulations/expand/title21_chapterI_part7_subpartC_section7.41

A Guide to Drafting A Model Recall Plan for Maryland Produce Growers by Sarah Everhart and Ashley Ellixson, September 2017. http://umaglaw.org/download/guide-drafting-model-recall-plan-maryland-produce-growers/

Sample Recall Plan, California Department of Health,

https://www.cdph.ca.gov/Programs/CEH/DFDCS/CDPH%20Document%20Library/FDB/FoodSafetyProgram/FoodRecalls/SampleRecallPlan.pdf

FDA Industry Guidance, Guidance for Industry: September 25, 2018, https://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm

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.

This recall plan is for _____Farm Name_____.

This plan was reviewed by _____Food Safety Coordinator_____ on

_____Date_____.

Customer Contact List:

Company Name	Contact Name	Address	Email	Phone	Product Sold

Farm Recall Team:

Role	Name	Phone	After Hours Phone	Responsibilities
On-Farm Recall Team Leader				Makes decisions on initiating a recall and designating team members.
Recall Team Coordinator				Oversees the complaint investigation, tracks products and coordinates team.
Government Liaison				Contacts the regulatory agencies.
Media Spokesperson				Handles all media and customer communication.
Legal Counsel				Handles liability questions.
Insurance Agent				Addresses insurance coverage issues.

State Recall Team Contact List:

Role	Name	Phone	After Hours Phone	Responsibilities
NJ Dept. Of Agriculture	Chris Kleinguenther Jeff Beach	856-839-3388 609-292-5531	609-439-2203 609-439-2038	Oversees recalls for food distributed intrastate
Rutgers Extension, South of I-95	Wesley Kline (Contact Meredith Melendez if Unavailable)	856-451-2800, ex 1	732-354-9128	Provides technical assistance and guidance
Rutgers Extension North of I-95	Meredith Melendez (Contact Wes Kline if Unavailable)	609-989-6830	732-354-9135	Provides technical assistance and guidance
NJ Dept of Health	Loel Muetter Alan Talarsky	609-826-4935 609-826-4935	609-947-8571 609-947-8595	Oversees recalls for food distributed intrastate
FDA District Office	Ruark Lanham Recall Coordinator Nina Patel Recall Coordinator	215-717-3738 410-387-3852 410-779-5132		Oversees all product recalls for FDA regulated product in NJ
FDA Emergency		1-866-300-4374		Connects producer to appropriate assistance
NJ Farm Bureau	Ben Casella	609-393-7163 609-320-6701		Provides assistance to NJFB members
FDA Produce Safety Network	Cullen Wilson	207-221-0053 240-234-0879		Provides technical/outreach assistance

Traceability Plan:

_____Farm Name_____has implemented a traceability plan to track produce one step forward and one step back.

Type in Farm Traceability Plan

Appendix A: Customer Complaint Form

Name of Customer: _____

Date and time of call: _____

Phone Number for customer: _____

Description of customer's complaint:

_____

_____

_____

_____

_____

Doctor's name and contact information:

_____

Doctor's diagnosis:

_____

_____

Description of product including lot codes:

_____

_____

_____

Other agencies the customer notified:

_____

_____

Any other person effected by the product:

_____

_____

Additional notes:

_____

_____

_____

_____

_____

_____

Appendix B: Health hazard evaluation and recall classification.

(1) Whether any disease or injuries have already occurred from the use of the product.

(2) Whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.

(3) Assessment of hazard to various segments of the population, e.g., children, surgical patients, pets, livestock, etc., who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.

(4) Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed.

(5) Assessment of the likelihood of occurrence of the hazard.

(6) Assessment of the consequences (immediate or long-range) of occurrence of the hazard.

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

Appendix C: Model Press Release from the FDA

FOR IMMEDIATE RELEASE
COMPANY CONTACT AND PHONE NUMBER
DATE
FOOD CO. RECALLS PRODUCT BECAUSE OF POSSIBLE HEALTH RISK

Company Name of City, State is recalling Quantity and/or Type of Product because it may be contaminated with *Escherichia coli O157:H7 bacteria (E. Coli O157:H7). E. coli O157:H7* causes a diarrheal illness often with bloody stools. Although most healthy adults can recover completely within a week, some people can develop a form of kidney failure called Hemolytic Uremic Syndrome (HUS). HUS is most likely to occur in young children and the elderly. The condition can lead to serious kidney damage and even death.

Product was distributed Listing of states and areas where the product was distributed and how it reached consumers (e.g., through retail stores, mail order, direct delivery).

Specific information on how the product can be identified (e.g., type of container [plastic/metal/glass], size or appearance of product, product brand name, flavor, codes, expiration dates, etc.).

Status of the number of and types of related illnesses that have been CONFIRMED to date (e.g., "No illnesses have been reported to date."

Brief explanation about what is known about the problem, such as how it was revealed, and what is known about its source. An example of such a description -- "the recall was initiated after it was discovered that product was contaminated with *E. coli O157:H7*. Subsequent investigation indicates the problem was caused by a temporary breakdown in the company's production and packaging processes."

Information on what consumers should do with the product and where they can get additional information (e.g., "consumers who have purchased Brand X are urged to return it to the place of purchase for a full refund. Consumers with questions may contact the company at 1-800-XXX-XXXX.)

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