DEVELOPING A RECALL PLAN:

A GUIDE FOR SMALL FOOD PROCESSING FACILITIES

UNIVERSITY OF GEORGIA
EXTENSION

Authors

Anand Mohan, Rebecca Fortner, and Debolina Chatterjee
Department of Food Science and Technology

TABLE OF CONTENTS

1.1 What is a recall?

The U.S. Food and Drug Administration (FDA) defines a recall as actions taken by a firm to remove a product from the market. A well-designed recall plan will help to effectively locate the recalled product, remove it from the market, and locate the source of error in the product. It serves a guide for the company to follow if a situation requiring a recall presents itself. Recalls can be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority. If a situation requiring a recall does present itself, it is in the company's best interest to recall a product before an outbreak occurs.

1.2 Who handles recalls?

The FDA and the Food Safety Inspection Services (FSIS) within the U.S. Department of Agriculture (USDA) are the government agencies responsible for the safety of the food supply in the U.S.[4] The FSIS is responsible for the safety of the meat and poultry industry (including catfish) and FDA ensures the safety of all other foods. If the company chooses not to do a product recall then FSIS or the FDA will have no choice but to remove the product or halt the processing of that food product. Your company should consider its type of food products and determine which agency you would work with in the case of a recall. This guide will focus more on the strategies for working with the FDA. According to your location, you are assigned a local FDA district recall coordinator with whom you will work closely in the case of a recall.

1.3 Developing a recall plan

Recall plans require careful attention and forethought. They are comprised of several parts, which must all be able to work together during a critical time. Because a recall plan can quickly become complicated, it is best to develop it in a series of steps that build on each other. The following pages will provide an outline of steps that can be followed to develop a useful recall plan.

1.4 Assembling a recall team

When you begin to consider how a recall in your company would be handled, you may find yourself forming a long list of responsibilities that span a variety of positions. If a recall situation does occur, it is important to know who will be in charge of overseeing each responsibility. Thus, it is helpful to begin making your recall plan by forming a list of specific people for a recall team.

A recall team is a group of trained individuals who can effectively execute the procedures of a product recall when needed. The team aspect is important because these individuals must be able to work together to execute an effective recall. Team members should represent a variety of departments within the company and each should act as a leader within his or her department. There should be a manager or coordinator of the recall team who is responsible for managing, maintaining and altering the recall plan when necessary.[1] The recall manager can recommend a recall but the final decision is up to management.

When a product is recalled, the team evaluates the severity of the recall and determines what actions need to be made. Once the decision to recall a product is finalized, the team should determine the avenue of communication and who is responsible for managing the recalled products. The severity of the recall will also affect how the announcement is made. Members of the recall team should be representatives from departments within the company including, but not limited to, quality assurance, product development, shipping and distribution, and accounting.[4] The recall manager should be able to contact the recall team members immediately in case of an emergency. The recall manager also serves as the liaison between the recall team and the company's managers.

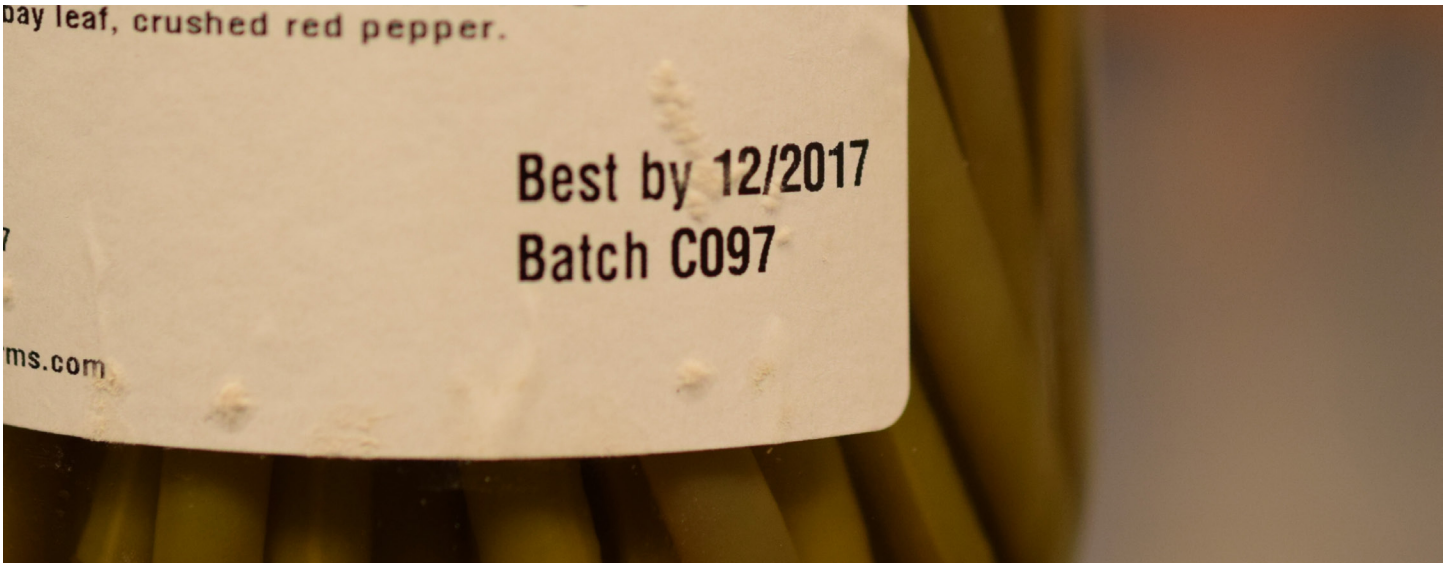
The local FDA district recall coordinator should be listed as part of your recall team. While this agent does not work directly in your company, they should be among the first to be notified of a recall and will be play an active role through the process. You can find the contact information for your FDA district coordinator at www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm.

Listed below are responsibilities that should be delegated among individuals on the recall team. An individual may have more than one responsibility.

- Management
- Accounting
- Consumer relations
- Customer service
- Information and technology
- Legal counsel
- Marketing
- Operations
- Production
- Purchasing
- Quality assurance
- Sales
- Maintenance
- Records management
- Regulatory affairs
- Sanitation
- Distribution and supply

**See Appendix A for the recall team contact information worksheet.*

2.1 Determining when to issue a recall

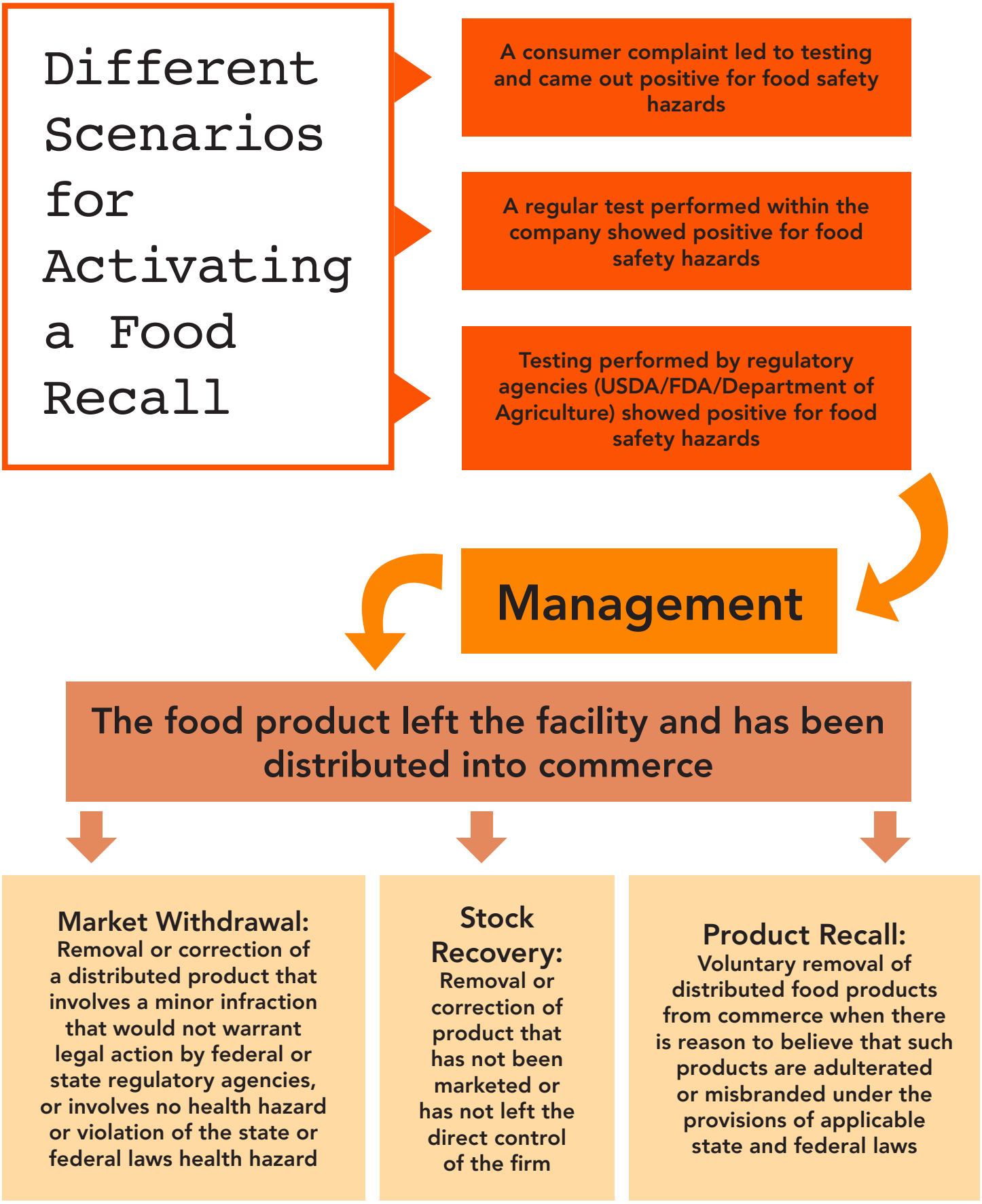


Once you have established who will be in charge of carrying out a recall, you should form a set of guidelines to help them decide when to enact a recall. The parameters for issuing a recall will most likely be a bit different for every company depending on its production.

Figure 1 provides a visual of the paths that can be taken depending on how the recall process begins.

- A recall can begin when testing/monitoring within the company reveals that a product is adulterated, misbranded, contaminated, or defective. From that point, the problem can be taken directly to management, who will decide what action to take depending on whether he product has left the facility and activate the recall accordingly.
- If a government agency requests that a product be recalled, the product can either be tested to confirm or deny the problem, or management can decide to activate the recall immediately.
- If your company receives enough customer complaints about a product, it may be necessary to test the product, and management will decide if it is necessary to activate a recall.

Figure 1. Diagrammatic representation of a food recall activation scenario showing different recall types (e.g., stock recovery, market withdrawal, and recall).



Customer Complaints

If your company receives feedback on a regular basis, it is likely that some customer complaints will be a regular occurrence. For the benefit of your recall plan, you should keep a record of the complaints, and determine a set number of complaints that is considered normal. Then, if the number of complaints over a period exceeds the "normal" amount, you will know to begin testing for problems and considering a recall.

2.2 Ensuring traceability of products

The success of a product recall will largely depend on how accurately the company's records can identify specific products by parameters such as model numbers, serial numbers, and batch numbers. It is vital to keep records (invoices, bills of sale, shipping documentation, etc.) on file to aid in tracing all of the raw ingredients included in the product. Product traceability should start with the supply of raw materials and progress through the production and distribution system. It is critical to have an effective document control system in place in the event that a recall of a product is needed. Management should be able to identify products by a batch number, serial number, lot number, and/or expiration date. A practical and efficient tracking and identification records system must be established before products are distributed. It is best to have two or more methods of identifying the product. Recorded information that should be provided includes:

- Product identification
- Production records
- Microbial/safety testing data
- Distribution information

2.3 Classification of a recall

A recall plan should be developed according to the classification that the recall may fall under. When determining how to proceed with the recall, the recall coordinator should start off by evaluating the risk associated with the recall. This will allow the recall team to classify the recall and determine its urgency. You can find a list of the risk classifications as stated by the USDA and FDA and examples of each below.[1]

Class I:

- **There is a high probability that exposure or consumption of the product will cause adverse health consequences or death**
- ***Clostridium botulinum* toxin is in the food**
- **An allergen is incorrectly labeled**

Class II:

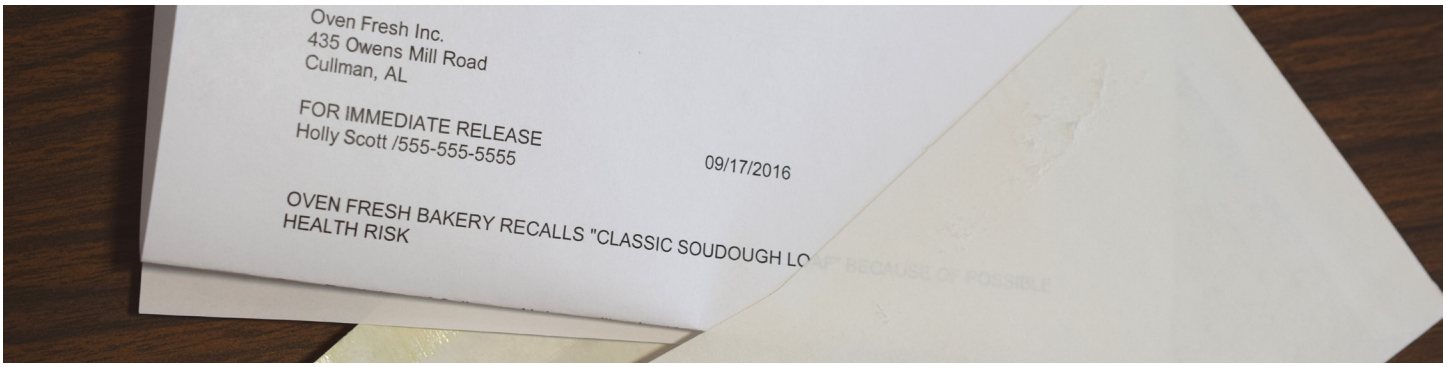
- **Use of or exposure to a product may put the consumer at risk of temporary reversible adverse health consequences**
- **Presence of undeclared allergens like milk, soy that are associated with mild human reactions**
- **Improper seal on a product causing potentially harmful mold or bacteria growth**

Class III:

- **The product is defective but is not likely to pose a risk of health consequences**
- **Damaged packaging that does not compromise food safety**
- **Failure to label an ingredient that is not a known allergen**

2.4 Recall communication

Any time a recall is being made, it is recommended that you begin communication with your local FDA district recall coordinator immediately. You will need to provide them with a recall submission containing various details about the recall. While it is best to have this information readily available to send to the coordinator, you should contact them as soon as possible, even if all of the information is not yet fully compiled. The sooner the FDA is notified, the more helpful they can be.



The classification of the recall will determine who else needs to be notified. Notifications during a recall must be done in a timely manner and should include appropriate regulatory agencies, the product distribution chain, and consumers, when necessary. The higher the risk and the more consumers that your product has reached, the broader the necessary distribution of recall alerts.

Once the classification is determined, a notice should be prepared to send to retailers, distribution centers, and wholesalers, which should include the following:

Identify the product by including some or all of the following:

- **Product/brand name**
- **Product code**
- **Package/case size**
- **Package/case date code**
- **Establishment number**
- **Lot number/expiration date**
- **Universal Product Code (UPC)**
- **Risk assessment if the product is consumed**
- **Reasons for recalling the product**
- **Instructions for what to do with the recalled products**
- **How the recipient can confirm to the recalling agency whether it has any of the product**
- **Contact information for further questions**

2.5 Distribution level

In addition to determining the risk classification of a recall, your company should also take into consideration the distribution levels when planning recall communication. Distribution levels are classified as wholesale, retail, hotel/restaurant/institutional, and consumer users. As expected, when more levels of distribution are affected, there will be a need for more communication efforts.

- On the wholesale level, the product is distributed to a warehouse or distribution center from which it will be sold to a retailer.
- At the retail level, the retailer receives the product then sells it directly to consumers.
- "HRI level" is the term used when the product is received by hotels, restaurants, or institutional customers to be used in food service.
- Consumer level distribution cuts out any middlemen and involves the sale of the product directly to the end user from the manufacturer.

Just like there are various levels of distribution, there are various levels of recall communication. Recalls can be announced via a press release through national or local news media, via a company website, personal visits, telephone, fax, or point-of-sale posters. Be sure to include contact information for all of the media outlets that you may use in your recall plan.

If the recall is deemed Class I, it is recommended that you alert the media immediately. Written notices should have a striking heading to indicate the level of importance. A confirmation letter should follow communication that is conducted over the telephone, email or fax to provide proof that everyone was notified.

Your recall team should discuss these options and determine which communication avenues would be best for your company according to each risk classification and distribution level. These decisions should be made and approved by management well before a recall is needed so that there is no loss of time when a recall is in action. Your recall plan should include the list of contacts with whom you will work in the case of a recall.

**Refer to Appendix B for sample recall notices and Appendix F for a FDA recall submission template.*

2.6 Recall procedure

Now that you have planned who will manage a recall within your company, how you will trace recalled products and classify them by risk, and how you will communicate recall information to the public, you can culminate these elements to be used in your recall procedure. All of the parts must be planned first so that the recall procedure can run as smoothly as possible if it has to be implemented. The way that the recall procedure is carried out from company to company may vary slightly, but most will follow the general steps found in Figure 2. More information to help you with steps 10-13 will be covered next.

Figure 2. The general steps for carrying out a recall procedure.

1. **Compile a list of all of the distribution outlets of the product under recall.**
2. **Notify everyone along the distribution chain through the decided communication forms.**
3. **Send out a press release if management deems it necessary.**
4. **Gain control of all of the recalled products.**
5. **Verify the recall effectiveness.**
6. **Take the appropriate corrective action (by disposal or fixing the problem).**
7. **Terminate the recall.**
8. **Determine the problem that necessitates a recall.**
9. **Assemble the recall team to begin working.**
10. **Determine risk classification of the product under recall.**
11. **Send notification of the problem to your FDA district recall coordinator.**
12. **Identify and locate all products subject to recall according to their tracking information.**
13. **Quarantine any affected products that are still under the company's control.**

**Further guidance on how to alert government agencies can be found at www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm*

2.7 Gaining control of the recalled product

When planning your recall, it is important to make plans for how your company will get the product under its control and what to do with it next.

Removal

Removing your recalled products from the market can be fairly simple or very complicated depending on how widely the product is distributed. The best way to ensure that you can successfully remove the product is to have an effective tracking system and keep thorough records. If you have all of this information on hand, it should be simple to find the products that have left the company and regain control. Your company's shipping and logistics personnel will be essential in formulating and executing this part of the plan.

The notifications to your distribution outlets and consumers should have included instructions to help them get return the products to you. If the products are still centrally located at a wholesaler, they can be easily collected and returned to the company. If the product has been sold to consumers, it is best to have consumers return the products to the place of purchase and then collect the products from there. Once these products have been retained, they should be segregated, detained, and clearly marked "not for sale or distribution." Recalled products that have not yet left the company's control should also be immediately segregated and detained in an area with clear identification that they are not for sale. While this process is being carried out, it is crucial to keep accurate records of all of the products that have been located and/or removed and their current location. The documentation should be as thorough as possible, including identification codes and exact quantities.

In some cases, management may decide that it is not necessary to actually remove all of the recalled product that has gone out to customers. Consumers who have already purchased the product must be notified of its recall, but they are left with the option to either return it for a refund or simply discard the product at their convenience. In this case, effectiveness check surveys are useful to make sure that the products that have not been removed are accounted for.

**Refer to Appendix C: A recalled product tracking worksheet is provided to help record the location of recalled products.*

Product disposition

Once the products are detained, the recall team will need to decide the fate of the recalled products. It will be helpful to set guidelines for disposition of your products with hypothetical but reasonable problems specific to the products that your company produces in the recall plan. In the event of an actual recall, the problem may be unique and unexpected, but having a general idea of disposition options will still help the process run more smoothly. Your options for disposition will be limited by the severity of the problem. Severe situations may call for the complete destruction of the product. Conversely, with an issue as simple as an omitted ingredient on the ingredient list can be relabeled and redistributed. The options for disposition of the product can be summarized by the following list:[11]

- **Redirection –** Products are reused for a purpose other than what was originally intended, which generally excludes human consumption.
- **Destruction –** It is determined that the product is unsafe for consumption and must be destroyed before disposing.
- **Recondition –** Products have a safety risk that can be fixed and then allow the products to be redistributed.

Before redirecting, destroying or reconditioning the recalled products, the appropriate regulatory agencies should be contacted. It is important to gain their approval of the disposition plan before proceeding to avoid problems later on. In some cases, they may require that a representative of their agency witness the disposition or destruction.

3.1 Recall effectiveness

The records that your company keeps during the removal process will be the key to determining the effectiveness of the recall. Determining the effectiveness of the recall will allow you to verify that all of the possible recipients of the recalled products have been notified and have taken action. In order to verify this, you must examine the percentage of the number of units of affected product that have left the warehouse to the number of units that were returned or accounted for. If 100% of the recalled products are not accounted for, it may be necessary to reassess the recall strategy. The effectiveness numbers should be reported to management, who will decide if the severity of the problem necessitates revisiting the recall procedure.

Since some recall situations do not require that the entire supply of the product be returned to the company, questionnaires can be distributed to everyone along the distribution chain to account for the recalled products. This provides another reason for keeping accurate distribution records and customer contacts.

The FDA may perform a recall audit check by contacting a percentage of your customers to ensure that your company has fulfilled the responsibilities of a recall. If the audit shows that your recall strategy was not effective, the FDA may require that you revisit the recall communication. Additionally, your district recall coordinator may request periodic status reports after a recall has been initiated. They will indicate what information should be included.

**Refer to Appendix D for a sample effectiveness check letter and questionnaire.*

3.2 Reportable Food Registry for industry[12]

About the Reportable Food Registry (RFR)

- The RFR is an electronic portal for industry to report when there is reasonable probability that an article of food will cause serious adverse health consequences. The RFR helps the FDA better protect public health by tracking patterns and targeting inspections. The Food and Drug Administration Amendments Act of 2007 (Pub. L.110-085), section 1005 directs the FDA to establish a Reportable Food Registry for Industry.
- The RFR applies to all FDA-regulated categories of food and feed, except dietary supplements and infant formula.

Who should use the RFR?

- Registered food facilities that manufacture, process, pack, or hold food for human or animal consumption in the U.S. under section 415(a) of the FD&C Act (21 U.S.C. 350d) are required to report when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals.
- Federal, state, and local government officials may voluntarily use the RFR portal to report information that may come to them about reportable foods.

Where should consumers, food retailers, and food service operators report a problem with food?

- In emergencies, consumers, food retailers and food service operators should continue to call the FDA at 1-866-300-4374 or 301-796-8240. For less urgent problems, contact the FDA consumer complaint coordinator in your geographic area or see the guide to reporting problems to FDA.

What to do if the Safety Reporting Portal is not operating

- The FDA intends to post an announcement on www.fda.gov as to how to submit a reportable food report in the event that the Safety Reporting Portal is not operating. If www.fda.gov is not operating, The FDA recommends that you contact the FDA district office serving your area. If the FDA district office for your area is not listed in your local telephone directory under "U.S. Government," call 1-888-SAFEFOOD (Monday-Friday, 8:00 a.m. to 4:00 p.m. Eastern Standard Time) or 1-888-INFO-FDA. The FDA further recommends that a report be submitted by the responsible party to the Safety Reporting Portal as soon as it resumes operation.

3.3 Recall termination

The recall team may consider termination of the recall once every effort has been made to correct the problem. This includes carrying out all of the previous steps to the best ability of the company to prevent sickness or injury form occurring as a result of the recalled product. When developing your recall plan, you should work with management and the FDA to set parameters for the acceptable effectiveness of each step. This will provide a guideline for the recall team to use when considering a recall. Management and the involved regulatory agencies should be informed and give their approval before the recall is officially terminated.

3.4 Recall simulations

Conducting mock recalls regularly is a practical way to test and work out any problems in your recall plan. A recall simulation will also allow the recall team and all involved personnel to become familiar with their responsibilities throughout the recall procedure. This gives them time to effectively communicate any concerns about the plan while the company isn't dealing with the pressure of an actual recall. Mock recalls should be performed at least once a year and whenever there are significant changes in the structure or personnel of the company and distribution chain or changes to the plan.[11]

Appendix A — Recall Team Contact Worksheet[1,11]

Recall Coordinator:
Work Phone Number:
Alternate Phone Number:
Email:

FDA District Recall Coordinator:
Work Phone Number:
Alternate Phone Number:
Email:

Recall Team

Name	Contact (phone numbers and email)	Department or Other Agency	Responsibilities

All members of the recall team within the company should be listed here, along with members of any other necessary parties. This would include representatives from regulatory agencies, technical consultants, distribution chain contacts, and media representatives from different media outlets.

Appendix B – Determining When to Issue a Recall[1]

1. Is there an allergen present in a product that is not declared on the label?

□ Yes □ No

If yes, provide details. _____

_____

2. Is there potential pathogenic microbial contamination in a product?

□ Yes □ No

If yes, provide details. _____

_____

3. Have we received an unusual number of consumer complaints about a product?

□ Yes □ No

If yes, provide details. _____

_____

4. Is there reason to believe that a product package or seal has been compromised?

□ Yes □ No

If yes, provide details. _____

_____

5. Is there reason to believe that a product could contain unwanted foreign material?

□ Yes □ No

If yes, provide details. _____

_____

6. Have there been reports of disease or injury associated with a product?

□ Yes □ No

If yes, provide details. _____

_____

7. Has a regulatory agency requested that we recall a product?

□ Yes □ No

If yes, provide details. _____

_____

8. Are there further details about the problem?

□ Yes □ No

If yes, provide details. _____

_____

Undeclared Allergens Model Recall Notice[5]

Adventure Eats Inc.
123 Smith Lane
Cornelia, GA

FOR IMMEDIATE RELEASE 10/17/2016
Daniel Smith/555-555-5555

ADVENTURE FOODS ISSUES ALLERGY ALERT ON UNDECLARED PEANUTS IN "HARVEST ENERGY BAR"

Adventure FOODS Inc. of Cornelia, Georgia, is recalling its 5-ounce packages of "Harvest Energy Bar" granola bars because they contain undeclared peanuts. People who have allergies to peanuts are at risk of a serious or life-threatening allergic reaction if they consume these products.

The recalled "Harvest Energy Bars" were distributed nationwide in retail stores and through mail orders.

The product comes in a 5 ounce, foil-wrapping package marked with lot No. 67890 on the top and with an expiration date of 10/17/2018 stamped on the side.

No illnesses have been reported to date in connection with this problem.

The recall was initiated after it was discovered that the peanut-containing product was distributed in packaging that did not specify the presence of peanuts. Any consumers who have concerns relating to an allergic reaction should contact a physician immediately.

Production of the product has been suspended until the FDA and the company is certain that the problem has been corrected.

Consumers who have purchased 5-ounce packages of "Harvest Energy Bar" are urged to return them to the place of purchase for a full refund. Consumers with questions may contact the company at 1-800-345-5678.

Microbial Contamination Model Recall Notice[6]

Daisy Valley Deli Inc.
543 Daisy Avenue
Harpswell, ME

FOR IMMEDIATE RELEASE 03/25/2016
Emily Thomas/555-555-5555

DAISY VALLEY DELI RECALLS "APPLE SMOKED CHICKEN SAUSAGE" BECAUSE OF POSSIBLE HEALTH RISK

Daisy Valley Deli Inc. of Harpswell, Maine, is recalling its 5-ounce packages of "Apple Smoked Chicken Sausage" meat product due to potential contamination with Listeria monocytogenes. This organism can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Healthy individuals may suffer only short-term symptoms such as high fever, headache, muscle stiffness, nausea, abdominal pain and diarrhea. However, contraction Listeria infection by pregnant women can cause miscarriages and stillbirths.

The recalled packages of "Apple Smoked Chicken Sausage" were distributed nationwide in retail stores.

The product is sold in a 5-ounce, clear plastic package marked with lot No. 396725 on the top and with an expiration date of 05/25/2016 stamped on the side.

No illnesses have been reported to date in connection with this problem. If any consumers have concerns about illness in connection with this product, they should contact a physician immediately.

The potential for contamination was discovered after routine testing by the company revealed the presence of Listeria monocytogenes in 17-ounce packages of "Apple Smoked Chicken Sausage.

The production of the product has been suspended while the FDA and the company continues to investigate the source of the problem.

Consumers who have purchased 17-ounce packages of "Apple Smokes Chicken Sausage" are urged to return them to the place of purchase for a full refund. Consumers with questions may contact the company at 1-800-594-9647.

Foreign Material Contamination Model Recall Notice[6]

Oven Fresh Inc.
435 Owens Mill Road
Cullman, AL

FOR IMMEDIATE RELEASE 09/17/2016
Holly Scott/555-555-5555

OVEN FRESH BAKERY RECALLS "CLASSIC SOURDOUGH LOAF" BECAUSE OF POSSIBLE HEALTH RISK

Oven Fresh Inc. of Cullman, Alabama, is recalling its 12-ounce loaves of "Classic Sourdough Loaf" bread because they have the potential to contain pieces of broken glass. If ingested, broken glass can cause serious internal bodily damage.

The recalled packages of "Classic Sourdough Loaf" were distributed nationwide in retail stores.

The product comes in a 12-ounce, clear plastic package marked with lot No. 74254 on the top and with an expiration date of 05/25/2016 stamped on the side.

No illnesses or injuries have been reported to date in connection with this problem. If any consumers have concerns about illness or injury associated with this product, they should contact a physician immediately.

The potential for contamination was discovered after routine manufacturing line inspection by the company revealed a damaged piece of equipment that was used in manufacturing 12-ounce packages of "Classic Sourdough Loaf."

The production of the product has been suspended while the FDA and the company continues to investigate the source of the problem.

Consumers who have purchased 12-ounce packages of "Classic Sourdough Loaf" are urged to return them to the place of purchase for a full refund. Consumers with questions may contact the company at 1-800-745-9273.

Appendix D – Effectiveness Letter and Questionnaire Template

Sample Questions for Effectiveness Check Questionnaire[9]

The following questions give you an idea of what to ask in an effectiveness check questionnaire. The questions you ask should not be limited to those listed below; they should include questions specific to your market. The questions can be printed and mailed with a letter that briefly explains the situation and requests their participation. A model letter is given on the next page. Also, these questions could be inquired through in-person interviews or by telephone. However you choose to present the questionnaire, make sure to calmly explain the situation, politely request the customer's participation, and gather information on the respondent's name and title in the company.

1. Were you notified that products manufactured by your company are being recalled?

   □ Yes □ No

2. Did you order and receive shipments of the product matching the recall description? (If no, skip to the closing.)

   □ Yes □ No

3. Did you notify consumers who purchased the product from you of the recall?

   □ Yes □ No

4. Do you currently have any of the recalled items in stock? (Please check inventories.)

   □ Yes □ No

5. How many units of the recalled product did you remove from circulation?

   □ Yes □ No

6. If you do have recalled product in stock, are you planning to return the product to your company as requested?

   □ Yes □ No

7. If you answered "no" to the previous question, please explain.

_____

8. Have you received any reports of illness or injury related to this product?

   □ Yes □ No

If you answered "yes" to the previous question, please provide details. _____

_____

_____

Template for Effectiveness Check Introduction Letter[9]

Name of party being contacted

Name, address, date

Dear ***sir or madam***:

On ***date of recall notification*** you were sent a notification letter that your company had issued a recall for our product, container size and product name, with the tracking number and code number. The recall was issued when ***description of the problem and its discovery***.

The recall notice from ***your company*** requested that all wholesalers and retailers immediately stop selling their stock of the products matching the description given above and return this inventory of the recalled product to ***your company***.

So that ***your company*** may confirm the effectiveness of this recall with the U.S. Food and Drug Administration, we request that you participate in the enclosed questionnaire then return it promptly using the prepaid self-addressed envelope.

If you have any questions or problems with this request, please call ***your company*** at ***your phone number***.

Thank you for your cooperation.

Sincerely,
Your company

NOTE: If you are sending this letter to distributors who have potentially sold the product to other distributors or to retail outlets, you should include that primary distributors are asked to contact the secondary distributors (their customers) in regard to the recall.

Appendix E – Recall Notice and Recalled Product Tracking Worksheet

Company or customer name	How were they notified?	Date of notice	Date of response to notice
Name of company or individual customer	Email, phone, letter, fax, other	Date the notification was sent	Date that customer responded

Company or customer name	Number of units shipped	Date of units were returned	Number of returned units	Identification codes	Units accounted for
Name of company or individual customer	Number of units the customer received	Date the units were returned or removed	Number of units returned to your company	Identification codes from returned products	Number of units not returned but accounted for

Appendix F – FDA Recall Submission Worksheet[12]

The following information should be provided to the FDA in the recall submission through the local FDA recall coordinator. If some of the information is not yet available, submit what you already have, and submit the rest as it becomes available.

Product Information

- Full name of product:
- Model, catalog, or product order number(s):
- Description of the product
  - Appearance and state:
  - Intended use:
  - Expiration or "best before" date:
  - Type of packaging:
  - Lot/Unit Numbers (provide an explanation of your lot numbering system if necessary):
  - UPC codes:
- Two complete sets of all labeling including:
  - Product labeling (including ALL private labels)
  - Individual package label
  - Case label (photocopy acceptable)
  - Package Inserts
  - Directions for Use
  - Promotional material (if applicable)

Recalling Firm (Your Company) Information

- Firm name:
- Firm's full address:
- Involvement of recalling firm (manufacturer, importer, co-packer, distributer, etc.):
- Contact information:
  - Contact information for main recall contact:
  - Contact information for head of recalling firm:
  - Contact information for public contact:

Manufacturer

- Manufacturer name and address
- FDA registration number

Firm Responsible for Problem:

- Firm name and address (may already be listed):

Reason for Recall

- How the product is defective or problematic:
- How the defect affects the safety of the product:
- Description of the foreign object, if applicable:
- Level of contaminant, if applicable:
    - Provide labeling, ingredients and MSDS of contaminant
- For products failing to meet specifications provide the following:
    - Specifications
    - Test results and copies of sample analysis
- For mislabeling or ingredient issues, provide the incorrect and correct labels descriptions and formulations
- How the problem occurred
- Date that the problem occurred:
- What portion of the lots are subject to recall (may be all):
- Why the problem affects only the products under recall and not others:
- Information about complaints
    - Date of complaints:
    - Details (including illness or injury) of complaints:
    - Lot number involved:
- Information on any state agency that may already be involved with the recall:

Health Hazard Assessment

- Your assessment of the health risk resulting from the defective product:

Volume of Recalled Product:

- Recalled total product produced (with units):
- Dates produced:
- Quantity Distributed:
- Dates Distributed:
- Quantity under control of your company (on hold):
- Your method of quarantining the product:

- Estimates of amount of product still in the market at each level:
  - Distributor
  - Retail
  - Consumer

Distribution Pattern

- Number of wholesalers/distributors to whom you sell:
- Number of repackers to whom you sell:
- Number of manufacturers to whom you sell:
- Number of consumers to whom you sell:
- Number of foreign consignees to whom you sell:
- All geographic areas of distribution:
- All involved consignees including foreign and federal agencies with contact information and their involvement in the recall:
- If applicable, the government contract number, contract date, and implementation date under which the product was sold:
- If the product was sold to any agency involved in the school lunch program, list the consignees, quantity of sale and shipment date:
- "Ship to" customers to be involved in direct retrieval of product:
- "Bill to" customers to be involved in secondary recall strategies:

Recall Strategy

- Level of distribution to whom you are extending the recall:
- Methods of communication:
- How communication will be distributed:
- Copies of any applicable phone scripts:
- What the customers have been instructed to do with recalled product:
- Methods of retrieving the product/how it will be returned, if applicable:
- Explanation of any market shortage that may occur as a result of the recall:
- Explanation of effectiveness check strategy:
- Course of action for dealing with out-of-business distributers, if applicable:
- Details of reconditioning plan, if applicable. This should include how the reconditioned product will be distinguished from the original product:

References:

[1] U.S. Department of Agriculture. Food Safety and Inspection Services. (2013). FSIS Directive 8080.1 How to develop a meat and poultry product recall plan. Retrieved from http://www.fsis.usda.gov/wps/wcm/connect/d87d635d-75fa-4a9b-8301-378675435a68/RecallPlanBooklet_0513.pdf?MOD=AJPERES

[2] Abbott, H. (1991). Managing product recall. Long Acre, London: Pitman Publishing.

[3] Frush, K., Pleasants, J., Shulby, G., Hendrix, B., Berson, B., Gordon, C., & Cuffe, M. (2009). Blending technology and teamwork for successful management of product recalls. (12 ed., Vol. 84, pp. 1713-1718). Association of American Medical Colleges.

[4] Kramer, M., Coto, D., & David, W. (2005). The science of recalls. (1 ed., Vol. 71, pp. 158-163). Baltimore, MD: EHA Consulting Group.

[5] U.S. Food and Drug Administration: Industry Guidance. Allergens Model Press Release.

[6] U.S. Food and Drug Administration: Industry Guidance. Listeria Monocytogenes Model Press Release.

[7] U.S. Food and Drug Administration: Industry Guidance. Clostridium botulinum Model Press Release.

[8] U.S. Food and Drug Administration: Industry Guidance. Salmonella Model Press Release.

[9] U.S. Food and Drug Administration: Industry Guidance. Information on Recalls of FDA Regulated Products.

[10] U.S. Food and Drug Administration: Industry Guidance. E. coli Model Press Release.

[11] California Department of Public Health. Sample Recall Plan. Retrieved from https://www.cdph.ca.gov/Programs/CEH/DFDCS/CDPH%20Document%20Library/FDB/FoodSafetyProgram/FoodRecalls/SampleRecallPlan.pdf

[12] U.S. Food and Drug Administration: Industry Guidance. Product Recalls, Including Removals and Corrections. Retrieved from https://www.fda.gov/safety/recalls/industryguidance/ucm129259.htm

Published by the University of Georgia in cooperation with Fort Valley State University, the U.S. Department of Agriculture, and counties of the state. For more information, contact your local UGA Cooperative Extension office.