Essentials to Building a
RECALL PLAN

NOTES

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INTRODUCTION

This template is intended to assist producers and facilities, who are regulated by the US Food and Drug Administration (FDA) under the Food Safety Modernization Act (FSMA), develop a basic understanding of the recall process, and anticipate the information that would be needed by a recall. Our goal is to help companies develop a recall plan to manage their response to a food recall.

While FDA has rules and procedures for conducting a recall there is little in the way of guidance to help a business sort through the process; this template is meant to help with that. FDA issued a guidance document to industry on March 20, 2020 (Product Recalls, Including Removals and Corrections, 2020) that tells industry what information to give to the FDA for a recall. But the guidance document does not explain how that information should be collected. That is left up to the industry to figure out.

The Southwest Border Food Protection and Emergency Preparedness Center at New Mexico State University has used the FDA's guidance document to prepare this Recall Essentials Workshop. A product recall is undesirable for any company. But small companies may lack the experience, staffing, or business recordkeeping systems to deal with a recall thereby finding themselves in difficult circumstances. Nevertheless, a successful outcome lies in knowing what is required ahead of time and then being prepared to satisfy those requirements quickly and effectively. Doing so will reduce the amount of time a company spends in crisis mode. Recalls can be highly stressful situations. As United Fresh Express Senior Vice President of Food Safety and Technology David Gombas said, "You don't want an actual recall to be a training exercise (Erin Grether, 2015)." Therefore, the template is organized to help a firm develop policies, procedures, and strategies ahead of time.

BASIC OVERVIEW OF A FOOD RECALL

What is a food recall?
A food recall is when a food producer takes a product off the market because there is reason to believe that it may cause consumers to become ill or cause injury. Food recalls may happen for many reasons, including but not limited to:

- *Discovery of organisms, including bacteria such as Salmonella, or parasites such as Cyclospora.*
- *Discovery of foreign objects, such as broken glass or metal.*
- *Discovery of a major allergen that does not appear on the product label (Recall and Outbreaks, 2020).*

Who initiates a food recall?
A firm may voluntarily initiate a recall at any time to protect the public from products that present a risk of causing illness or injury. Firms may also voluntarily initiate a recall when requested by the FDA or by a state agency. But in severe cases, the FDA may order a recall.

The burden is on the company to remove the affected product from the market while government agencies, in parallel, make sure steps are taken to protect the public. Because food recalls can be expensive and stigmatizing, it is in a business's best interest to do everything in its power to maintain consumer confidence during a recall event. The best way is through coordination with federal and state agencies to achieve a rapid and efficient recall of potentially harmful products, while maintaining honest communications with customers.

What are the goals and objectives of a recall?
Protecting the public from harm is the number one goal of a recall. The FDA's role is to ensure that you are taking steps that will protect the public. Your company should share this goal, and communications from your company should emphasize what you are doing to protect the public.

Other objectives include removing the affected product from the hands of consumers as quickly as possible and documenting the process carefully. Your business will be finished with a recall only when FDA is satisfied the public is safe.

Protecting your company's name is another objective and a key factor for emerging from a recall successfully. Every action needs to consider the long-term effects on your company's reputation and brand name. How you communicate, whether it be with a regulatory agency, your customers or the media, affects the recovery from a recall. Acting promptly and efficiently will demonstrate your concern for the safety of your customers, as well as serving to protect your brand. The longer a recall takes to resolve, the greater the complications will be to returning your business to normal.

FDA groups recalls into the following three severity classes:

- ***Class I Recall*** is the most urgent type of recall. In a Class I recall, there is a significant and immediate danger of death or serious injury from the use of the product being recalled. Class I recalls are rare, but they should be addressed as soon as you become aware of the situation. The FDA will develop an individual plan that is specific to the firm and the product involved, to make sure that compliance with the recall is complete and that the recall of the items involved is trackable.

  Reportable Food Registry (RFR) – If you decide that a Class I recall is necessary, then you will also need to file a report with the FDA Reportable Food Registry within 24 hours of making that decision (Reportable Food Registry for Industry, 2020). The report is filed online through the Safety Reporting Portal (The Safety Reporting Portal n.d.).

- ***Class II Recall*** is an intermediate threat level recall. A Class II recall is issued when there is no immediate danger of death or other serious injury linked to the product, yet the risk of death or a serious injury is still present. A Class II recall is more preventative, yet there are still health and safety risks involved. In a Class II recall, the FDA will work with the firm to help get the word out about the recall, as well as to create a plan to make sure that all recalled items are pulled from the market as quickly as possible.
- ***Class III Recall*** is the least serious recall. A Class III recall is typically issued where there is no immediate or perceived danger of any health issues, or where items have been released that are not in violation of FDA regulations (David Goguen, 2021).

A market withdrawal is not a recall. It occurs when a product has a minor violation that would not be subject to FDA legal action. The firm removes the product from the market or corrects the violation. For example, a product removed from the market due to tampering, without evidence of manufacturing or distribution problems, would be a market withdrawal (USFDA, 2014).

How does the recall process work?
The first step is to contact the FDA Recall Coordinator in your region as soon as the company decides to initiate a recall in order to coordinate the recall process between the company and the FDA. FDA has the legal authority to decide what the severity level of the recall should be and to ensure all reasonable efforts to remove or correct the problem are being made.

While most recalls are accomplished cooperatively, FDA may ask a company to initiate a recall. If a company refuses, the FDA has the legal authority to detain the product and to stop operations if the product constitutes a danger to public health. To find your Recall Coordinator, please check the following FDA website: https://www.fda.gov/safety/industry-guidance-recalls/oii-recall-coordinators (OII Recall Coordinators, 2020).

Product traceability is an essential part of a recall plan. Traceability means identifying where a commodity came from (one step back) and where it went (one step forward) including knowing what processing activities were done pre-and post-harvest. FDA added more rigorous traceability requirements when it announced the Food Traceability Rule on November 15, 2022.

The new Traceability Rule adds recordkeeping requirements for production activities in the supply chain called Critical Tracking Events (CTE). In general, CTEs involve activities like harvesting, transforming, shipping, and receiving food commodities that are on the Food Traceability List (FTL). Informative records are called Key Data Elements, which explain the "Who, What, Where, When and Why" of a CTE.

Stakeholders should first develop a Recall Plan before attempting to add-in the new Traceability Rule recordkeeping requirements. That is a separate effort beyond the scope of this recall template. A simple step stakeholders can do is examine the FDA Traceability Rule Exemption Tool on the FDA Website https://collaboration.fda.gov/tefcv13/ for exemptions that apply.

For more complete details of the Food Traceability Rule and whether it applies to you, please check the following FDA website: https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods

To review if food commodities that you produce are on the FTL, please check the following FDA website: https://www.fda.gov/food/food-safety-modernization-act-fsma/food-traceability-list

The reason that FDA developed the new Rule is to allow for faster identification and rapid removal of potentially contaminated food from the marketplace, resulting in fewer foodborne illnesses and/or deaths. If a recall is initiated, the FDA expects producers to supply records within 24 hours of request. The new Rule requires a great deal of supply chain data capture, reporting and communication to be done on a constant basis. Doing this with manual recordkeeping will be a challenge for smaller businesses.

This is another reason that producers should have a Recall Response Plan in place first before developing a Traceability Plan. A traceability plan is a summary of how your business collects CTE/KDE information, assigns lot codes and traces products throughout its supply chain.

The compliance date for entities subject to the recordkeeping requirements of the Food Traceability Rule is Tuesday, January 20, 2026.

Information about the Company

SECTION 1

Section 1 is the contact information for your company that you most likely will be asked to provide in a recall. This section ensures that the basic company information in your plan is accurate, minimizing the chances that inaccurate information is disseminated.

The window for each question will expand as you type. Complete as much of Section 1 as you can before coming to class, but expect that some lines may be left blank.

Company Name: _____

Name of the Company Recall Contact: _____

Street Address/Physical Location: _____

GPS Coordinates for the entry point of the physical location where food is grown and harvested:

Mailing Address: _____

Your Firm's Shipping Address for Returned Product: _____

Telephone Number for the General Public: _____

Telephone Number for the Media: _____

FAX Number: _____

Company Email Address: _____

Separate Email Address for the Media: _____

Company Web Address: _____

FDA Registration Number or other agency permitting numbers: _____

Section 1.1 Information for people or organizations that may be involved in the recall process (fill in as appropriate).

SECTION 1.1

FDA Recall Coordinator: _____

State Department of Agriculture Contact: _____

State Department of Health Contact: _____

State Department of Environment Contact: _____

Other State or Local Regulatory Contacts: _____

Financial Contacts: _____

Insurance Contacts: _____

Subject Matter Experts: _____

Transportation Contacts: _____

Security Company Contacts: _____

Media Contacts: _____

Evaluate your Capability to Assemble Records

SECTION 2

The challenge of a recall is running a business while also dealing with the myriad of requirements of a recall. Everyone on your recall team must know what a recall involves and what is going to be required by regulatory agencies and by your customers.

Instructions: *The following homework assignment should be completed before attending this class. Read and answer the questions in Sections 2.1 and 2.2. Addressing these items will guide you in tailoring a plan for your business. Your traceabillity planning strategy must include understanding your ability to assemble records quickly and accurately for the products produced and shipped by your facility.*

Instructors will organize the participants into teams during the class. The instructors will go around the class asking each participant to share the answers for their product.

2.1: Be Prepared to Describe the Following Information in Class

SECTION 2.1

Choose a popular product from your business and answer the following questions for that product covering the preceding 30 days. Keep a record of the time it takes to address each question.

a. What was the total quantity of your product produced in the last 30 days? _____

b. What was the quantity produced each day? _____

c. How is the product packaged and identified (package size, product codes, UPC coding, make copies of the affected product's label)? _____

_____

d. In the last 30 days, how much of the total was distributed and in what packaging? What quantity is still on hand at your facility? _____

_____

e. What is the estimated amount still in the marketplace and where (retail level, wholesale level, consumer-level)?

_____

f. What is the geographic area of distribution by city, region, state, and nationally? _____

_____

g. Create a consignee list of who first received the product including name, address, and telephone number. Who are the recall points of contact at each consignee? _____

_____

2.2: Judge the Effectiveness of Your Records.

SECTION 2.2

In an actual recall, you have very little time to gather and report information requested by the regulatory agencies. Now, assess the effectiveness of your process to gather information quickly and accurately. Keep in mind that a recall is taking place while you are still running your business, and the same people may be trying to do both at once.

a. Were you able to identify the total amount produced, the amount distributed, and the amount on hand?

_____

b. Could you compile information from your business records electronically and easily into a single report, or did you have to compile information by hand? _____

_____

c. How long did it take to make the consignee list? _____

d. Did you have contact information for consignees/customers on hand? _____

e. How long did it take to answers questions d -to-g in Section 2.1 above? _____

_____

f. How many people from your business were involved in the process and from which departments?

_____

g. If two or more products were involved in a recall, how much more difficult would this process become?

_____

_____

h. If necessary, could you pull the same information for all the products that you produce at the same time?

_____

_____

i. What improvements would allow you to extract records and compile reports quicker?

_____

_____

_____

_____

j. What improvements do you need to make to pull records more efficiently based on the results of this limited exercise?

_____

_____

_____

_____

Notification Plan

SECTION 3

Notifying your customers quickly is very important to maintaining good customer relations and to satisfying the concerns of the FDA. How will you notify customers when something happens? Investigate the most efficient process for your business based on your products and customer base using the following steps.

Your recall strategy is a course of action, which addresses the depth of recall, the need for public warnings, and the effectiveness of notifying your customers. The supply chain can extend to the wholesaler, retailer, and consumer depending on the hazard and extent of the product distribution.

3.1: Creating a Notification Plan

SECTION 3.1

Answer as many questions in Section 3 as you can. You may not know the answers to these questions yet. The class discussion will help you to identify decisions for completing your plan later.

a. Identify how far into the product distribution chain you would extend a recall: e.g., wholesale/distributor, retail (internet and/or catalog). If the recall only extends to the wholesale/distributor level, explain your rationale for not extending a recall to the retail level.

b. Maintain an up-to-date consignee list, including the name and contact information of the recall contact for each consignee.

c. How you will notify your customers (i.e., mail, phone, internet, fax, email)? Note: Notifying customers in writing affords a written record of when customers were notified and your instructions to them of what to do.

d. Decide how letters to customers will be sent (e.g., overnight mail, first-class mail, certified mail, fax, or email).

e. If your initial notification is by phone, prepare a script (see APPENDIX A page 22) and have a copy available for the FDA Recall Coordinator to review.

f. If you have a website, post the recall notification on the website as an additional form of recall notification. (Note: This is not recommended as a sole means of customer notification.)

g. Decide in detail what you want your customers to do with recalled products. This may depend on where they are located and/or what product is being recalled (How to Dispose of Contaminated or Spoiled Food, 2018).

h. Explain the mechanics of the return process if the product is to be returned to you.

i. What is your course of action for out-of-business distributors?

j. How do you propose to destroy affected products and witness the destruction?

k. Could your product be “reconditioned”? If so, explain how and where the reconditioning would take place. All reconditioning must be conducted under any applicable current Good Manufacturing Processes (cGMPs). Note: The FDA will expect you to give details to your FDA Recall Coordinator before implementation.

l. Explain how to identify a reconditioned product, so it is not confused with a recalled (pre-reconditioned) product or non-recalled products.

Create a Plan for Measuring the Recall Effectivenes

SECTION 4

The FDA Recall Coordinator will ask for monthly updates to judge the effectiveness of the recall process. The recall is not finished unless the FDA judges that your recall process has been effective at protecting the public from the recalled product. *The following are guidelines and sample formats for you to adapt that explain the effectiveness of your recall.*

SECTION 4.1

4.1: Notification by Phone

If you are notifying your consignees by telephone, look at the guidance in Appendix A page 22 for a script to follow. The conversation that you have with your consignee should state the reason for the recall with a complete description of the product being recalled or corrected. It should also contain instructions regarding the disposition of the recalled product, and it should request cooperation in completing and returning a questionnaire to you.

You must keep an accurate written log of the conversation and for that reason, notifications by telephone are not recommended. Call your customers if you plan to recall a product out of courtesy, however, distribute the official notification by mail.

SECTION 4.2

4.2: Distributing Notifications by Mail

Notifying your consignees by mail is preferred. The notification letter should state exactly the reason for the recall with a complete description of the product being recalled or corrected. It should also contain instructions regarding the disposition of the recalled product, and it should request cooperation in completing and returning a questionnaire to you.

Steps to follow include:

a. Prepare a basic notification letter to each consignee. Look at a sample in Appendix B page 23.
b. Address an envelope to each consignee and prominently inscribe with "IMPORTANT RECALL INFORMATION INSIDE" on the envelope.
c. Prepare a questionnaire that asks about the disposition of the recalled product. See Appendix C page 24 for examples.
d. Prepare and enclose a self-addressed, stamped envelope for the consignee to return with the completed questionnaire to you.
e. Re-contact those that do not respond with a follow-up letter.
f. Keep records of who has and who has not responded to know how effectively your recall is progressing.

SECTION 4.3

4.3: Preparing Product Recall Status Reports

You will need to prepare recall status reports. Prepare a monthly report to the FDA Recall Coordinator of the details of your recall effectiveness checks. You must create a system that documents the following information:

a. Dates you notified your customers.
b. The number of customers notified and who they are.
c. The number of customers that responded and who they are.
d. The number of customers that did not respond and who they are.
e. Quantity of recalled product returned or accounted for by the customer.

SECTION 4.4

4.4: Product Retrieval

It is important to explain how you will get your product out of commerce. Decisions to deal with a product should be part of your recall strategy. These decisions can be made now. *How this is accomplished to the satisfaction of the FDA Recall Coordinator is critical.*

a. Will the recalled product be shipped back to your facility?

b. Do you have room for the recalled product?

c. Can you safely quarantine the affected product away from any non-recalled product and avoid a product mix-up?

d. Is it necessary to store the returned product?

e. How quickly can you dispose of the recalled product?

f. Can you plan to conduct on-site effectiveness checks at your customer(s)' location to ensure the appropriate removal of the product from various locations? Who from your company will do this?

g. Can you destroy the recalled product without returning it to your facility?

h. Who will witness the destruction and accurately document the amount destroyed?

i. Discuss with the FDA Recall Coordinator what documentation needs to be kept.

Closing out a Recall

SECTION 5

Closing a recall is an FDA decision that depends largely on if the public has been notified and the recalled product is removed from commerce.
In addition, FDA will ask for the root cause of the problem that resulted in the recall. It is important to establish a root cause to take appropriate preventative measures for the problem. In addition to the root of the cause, follow guidance in Appendix D on page 25 for level of detail that FDA will ask your firm to submit in a final summary report. Consider if help from outside subject matter experts might be needed and identify them as part of your basic plan.

Once the final report is written, it should be submitted to the FDA Recall Coordinator for review. Be prepared if the recall lasts longer than you anticipated.

Selecting the Recall Team

SECTION 6

Recall teams are best comprised of people from various departments of your business. By now, after reviewing each section of the template, you should have a sense for how complex a recall to your business would be and whom to include on the recall team.

Select those that you would have for your recall team and familiar with this process. Also, understand that the best people drafted for a recall team may also be the same people who are important to keep the business running during the recall.

a. *Make a list of the Recall Team members and their contact information.*
   e.g., John Doe mobile XXX-XXX-XXXX

Elements of a Communications Plan

SECTION 7

Ultimately, the well-being of your company depends on how well you communicate with your customers, consumers, and employees about the recall without causing panic, alarm, and jeopardizing business reputation.

The purpose of a communications plan in a recall is to release information strategically while the company is performing the following actions.

1) Notifying the direct consignees of the food being recalled.
2) Notifying the public about any hazard presented by the food.
3) Conducting effectiveness checks to verify that the recall is being carried out.
4) Appropriately disposing of the recalled food.

Putting careful thought into a communications plan is a crucial part of the Recall Plan. Being able to communicate quickly and effectively takes forethought and anticipation of what could occur so that your business is prepared when a real recall occurs.

7.1: The Basics of a Pre-Incident Communications Plan

SECTION 7.1

Keep basic information, such as an up-to-date list of customers, distributors, suppliers, and vendors and their contact information for the products they buy from you or sell to you.

Get the recall team together, and for each product that you sell, make a list of Frequently Asked Questions (FAQ) you think would be asked if that product was recalled by customers, consumers/media, and employees, and any of the other groups of the Recall Audience with which you think you may interact.

There is a class activity to practice this approach. Use the 5 Ws: Who-What-When-Where-Why and How. For each product, develop a basic message that includes:

- *Acknowledging the issue. Do not try to hide from the issue .*
- *Showing empathy and caring. Remember – people will not care what you say if they sense you do not care about them.*
- *Explain what you are doing about the recall.*
- *Explain what you will do to prevent the recall in the future.*

Then test the basic message to see how well it holds up against questioning, and keep improving the message as necessary. Remember – you will be communicating on multiple levels, including with the employees of your business. This is a list of the audiences that you might communicate with during a recall; therefore, keep the contact information for all these people and organizations readily on hand. (Jennifer McEntire, David Durkin, & Amy Philpott, 2018).

Internal
Employees, Customers, Suppliers, Vendors, Transportation, Legal/Attorney

External
The FDA Recall Coordinator, Consumers, Subject Matter Experts, Insurance, Bank, Auditors, Media, Law Enforcement

Class Activity:
Basic Messaging for a Cheese Company Making Queso Fresco Cheese for the Possible Health Risk to Listeria

SCENARIO:
Pretend that we are a cheese producer of XYZ Queso Fresco, which is a fresh, soft cheese. For this exercise, we are developing a basic message about our cheese becoming contaminated by Listeria monocytogenes, which is a bacterium. The disease primarily affects pregnant women, newborns, older adults, and people with weakened immune systems. It can be fatal to people in those groups. It is rare for people in other groups to get sick with Listeria infection (El Abuelito Recalls Queso Fresco Products Because of Possible Health Risk, 2021). The situation would likely prompt FDA to issue a Class I recall. This is an actual recall that occurred in 2021.

Here are some examples that can be used as answers for the class activity:
Who – How many people are sick because of this outbreak?
What – What happened to cause the cheese to become infected with Listeria. Am I going to be compensated?
When – When was Listeria first detected? Was the cheese shipped after Listeria was detected?
Where – Was this product made in Mexico?
Why – Why was I not notified sooner? How many people are sick? Why is the FDA involved?
How – How long is the investigation going to take? How am I going to be compensated?

Next, develop a basic message and talking points that cover the following:

- Acknowledge the issue.
- Show empathy and caring.
- What are you doing about it?
- What will you do to prevent it in the future?

Finally, test your basic message again using the Who, What, When, Where, Why, and How questions, and come up with tough questions.

Are you comfortable with your answers? If not, make adjustments and improvements, as necessary.

7.2: Picking and Preparing Your Spokesperson

SECTION 7.2

Decide who your business spokesperson is going to be and consider a backup. TIP! Do not necessarily put the highest-ranking person in the company in charge of communications, because they will have plenty to do during a recall. This position should not be the President, Chief Operating Officer, Chief Financial Officer, or Chief Executive Officer. It should be someone vested in the success of the organization and who understands the operational and inherent political complexities of the organization. A spokesperson is a demanding job, so consider providing them with message and media training (Jennifer McEntire, David Durkin, & Amy Philpott, 2018).

Here are some of the duties of a spokesperson:

- *Work with the recall team on a basic communications plan to prepare a basic communications strategy for your customers, your consumers and the public, your company employees, and the regulators.*
- *Be the primary spokesperson for the company in a recall.*

SECTION 7.3

7.3: Key Principles of a Communications Plan

You will be communicating with customers, consumers, and the public, as well as your employees. The objectives and your messaging for each group will be different.

For customers, the objective is to remove the recalled product from sale to protect the consumer and to be able to prove the effectiveness of the recall effort to the FDA. Being a good business partner to your customers is another objective.

For consumers, your messaging needs to protect the reputation of your business.
For employees, the objective is to avoid the spread of rumors and misinformation.

Key principles in communications are:
- *Tell the truth, but avoid saying too much.*
- *Show genuine compassion.*
- *Do not be defensive.*
- *Stay cool.*
- *Always know what your business stands for.*

Use the following format to prepare a company statement. By answering each of the following questions, you will be addressing the facts of the recall. The template forces you through a logical progression of information that consumers and your customers can easily follow and understand.

Use the same approach to prepare messages as the recall crisis evolves (Jennifer McEntire, David Durkin, & Philpott, 2018).

a. Describe the problem? What is it? Where is it? Who is affected?

b. How is the problem being coordinated and managed? What are the government and the company doing to control and manage the problem? Reinforce coordination between the government and your business.

c. What else can you say about the steps you are taking to protect the consumer and their families, while also building empathy for your actions?
- *Provide specific action steps and precautions that consumers can take. For example, "Do not consume our product, but return the product to the store where it was purchased for a full refund."*
- *Communicate the warning signs. For example, "Our product is being recalled because of foreign metal objects…"*
- *How can a consumer contact you? Do you have a dedicated telephone number those consumers can call for more information? If you have a business website, use it to post a running series of updates of the crisis.*

d. Explain what actions are being taken to prevent this situation from happening again.

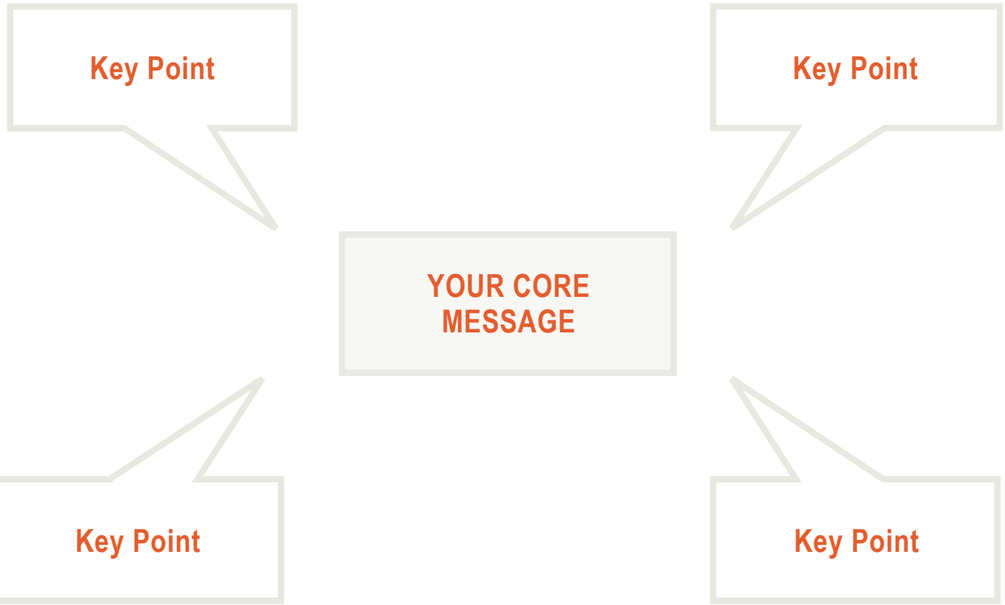
e. You may be contacted by the media for information. The media interview is a time to tell your story. Planning for an interview is like preparing a written message. The template format is a good way to gather your facts and stay on message (Jennifer McEntire, David Durkin, & Philpott, 2018).

f. What is the core message for your media interview?

g. What do you want the audience/person to remember after the interview?

h. How do you want the audience/person to feel?

i. Steps to creating a core message include identifying only 3 or 4 key points that you want to make in the interview that support your core message. The following figure illustrates how key points should support a core message.



j. Prioritize. Find out how much time the interview is planned for, and that will help you to know which points to bring out.

k. Edit the points down to their briefest form. Try this technique: Read the key point you have just written and ask the question, "So what?" Keep refining the key point until you feel you have reached the heart of each key point.

l. Highlight your core message using examples and analogies.

m. Do not stray from the core message during the interview.

n. At the end of an interview, the interviewer will often ask if you have anything that you would like to say. Be ready to make an honest and sincere statement of what you stand for. (Jennifer McEntire, David Durkin, & Philpott, 2018).

Class Activity: Write a Company Press Release

Take 20 minutes with your team to prepare a one-page company statement about a pretend recall of lettuce. Answer the following questions, and address the facts of the recall. Once you are finished, pick a spokesperson who will read the team's company statement to the class.

The facts surrounding the recall at your farm are as follows:

- Single heads of iceberg lettuce were packed on October 1, 2020 and October 2, 2020.
- E.coli O157:H7 bacteria were found on lettuce harvested on these dates only.
- The brand name is Sunshine Valley Produce.
- Packages contain the UPC number 0-29718-29526-9.
- No other products or pack dates are being recalled.
- There have been no reported illnesses associated with the recalled product.
- This is a voluntary recall.
- The recall is being conducted in coordination with the FDA.
- The recall is based on test results of random samples of the product by the New Mexico Department of Health as part of its random sampling program.
- A total of 2,157 cartons were distributed to the following states: NM, TX, CO, AZ, CA, NY, RI, and MA.
- The product was shipped in cases packed in either 12, 15, or 24 heads per case.
- Retailers and distributors can identify the cases through traceability stickers from your farm with Codes SVP101-802-2020 and SVP102-803-2020.

Some additional information to include in the company statement:

- 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. If consumers are experiencing any of the above symptoms, please contact your physician.
- Food safety is our number one priority, and we pride ourselves on growing safe and healthy produce. We are asking that if any of the packaged single head iceberg described above is in the possession of consumers, retailers, or distributors,

Write a one-page company statement to your customers and the public by answering the following questions surrounding the recall.

Answer These Questions:

- Describe the problem? What is it? Where is it? Who is affected?
- How is the problem being coordinated and managed? What are the government and the company doing to control and manage the problem? Emphasize coordination between the government and your business.
- What else can you say about the steps you are taking to protect the consumers and their families while also building empathy for your actions? Such as include a statement, "food safety is our number one priority, and we take great pride in producing healthy food."
- Provide specific action steps and precautions that consumers can take such as "Do not consume our product, but return the product to the store where it was purchased for a full refund."
- Explain why the product is being recalled; for example, "Our product is being recalled because of ……"
- How can a consumer contact you? Do you have a dedicated telephone number that they can call for more information? If you have a business website, use it to post a running series of updates of the crisis.
- Explain what actions are being taken to prevent this situation from happening again.

SUMMARY

The lessons learned throughout the planning process and from an actual recall event should be re-invested in your recall planning to refine your plan, as necessary. Also, be aware that plans should be updated whenever new products are produced and sold and the customer base changes.

It is recommended that one person has the responsibility to keep exact details for the plan. Refine the plan and keep the parts of the plan that work and function well, and conversely, improve those parts that do not serve a useful purpose.

Useful Information

SECTION 8

1. There is a wealth of information available on the FDA website. Write down the contact information for the FDA Office of Inspections and Investigation (OII – formerly known as Office of Regulatory Affairs (FDA-ORA) https://www.fda.gov/about-fda/office-inspections-and-investigations/contact-office-inspections-and-investigations

2. Write down the FDA Recall Coordinator for your region. The link to FDA Recall Coordinators is US FDA OII Recall Coordinators, https://www.fda.gov/safety/industry-guidance-recalls/oii-recall-coordinators

APPENDIX A:
CONTENT OF A SAMPLE PHONE SCRIPT NOTIFYING A CUSTOMER OF A RECALL

This is a sample phone script if contacting your consignees about a recall by telephone.

1. Contact the consignee and ask to speak to the person responsible for handling recall notifications.
2. "This is (*the name of the person from your firm*). I am calling for (*recalling firm name*) to tell you that we are initiating a company recall of (*product name and product description, including lot codes*).
3. Explain in detail how the product is defective, e.g., "*We are recalling the product because recent tests show that LOT NUMBER, NAME OF THE PRODUCT contains STATE THE REASON; therefore, represents a potential health hazard.* Other lot numbers are not involved.
4. "Please examine your stocks immediately to determine if you have any of recalled product on hand. If so, please discontinue distributing the affected lot and promptly return it." Give the consignee the shipping method and address of your facility accepting returned goods. Label the shipment "ATTENTION: RETURNED GOODS."
5. "If you have further distributed any of Lot 1234, please immediately contact your accounts, advise them of the recall situation, and have them return their outstanding recalled stocks to you."

Examples of Reasons for a Recall

1. Explain if the recall is due to the presence of a foreign object, describe the foreign objects' size, composition, hardness, and sharpness.
2. Explain if the recall is due to the presence of a biological pathogen such as Salmonella.
3. Explain if the recall is due to an allergen label/ingredient issue, provide and identify the correct and incorrect label(s), description(s), and formulation(s).
    a. Explain how the problem occurred and the date(s) it occurred.
    b. Explain how the problem was discovered and the date discovered.
    c. Explain if the problem/defect affects ALL units in the lot or just a portion of the units in the lots subject to recall.
    d. Explain why this problem affects only those products/lots subject to recall.

Keep a Telephone Log with the Following Information:

1) Name of company contacted.
2) Person and title contacted.
3) Date and time of the call.
4) Questions asked by the customer and answers that were given.
5) Any follow-up necessary.

APPENDIX B
SAMPLE RECALL NOTIFICATION LETTER

Date
Your Business Name and Letterhead
City, State Zip Code

Subject: URGENT: FOOD RECALL
RE: XYZ BRAND PRODUCT: Lot No. 1234, UPC CODE # 5678

Recent tests show that the above lot number of this product contains STATE THE REASON, therefore, represents a potential health hazard. Consequently, we are recalling this lot from the market. Other lot numbers are not involved.

Please examine your stocks immediately to determine if you have any of Lot 1234 on hand. If so, please discontinue distributing the lot and promptly return via **GIVING SHIPPING METHOD AND ADDRESS OF FACILITY ACCEPTING RETURNED GOODS. ATTENTION: RETURNED GOODS.**

(NOTE: If a sub-recall is indicated in a particular recall situation, the following paragraph should be added :)

If you have further distributed any of Lot 1234, please immediately contact your accounts, advise them of the recall situation, and have them return their outstanding recalled stocks to you. Return these stocks as indicated above. You will be reimbursed by check or credit memo for the returned goods and postage.

Please return the enclosed questionnaire (See Appendix C page 24) immediately providing the requested information.
This recall is being made with the knowledge of the US Food and Drug Administration.

If you have any questions, please contact us at *1-800-XXX-XXXX*. We appreciate your assistance in this matter.

Sincerely,
J. Doe
President

APPENDIX C:
SAMPLE QUESTIONNAIRE - RECALL RETURN RESPONSE
(Send to Your Consignee. Ask Them to Complete and Return)

Date
Include Your Business Name and Letterhead
City, State Zip Code

Subject: *XYZ BRAND PRODUCT RECALL INVENTORY STATUS UPDATE*: Lot No. 1234, UPC CODE # 5678

Dear Name of the Consignee Recall Coordinator:

So that we may advise the Food and Drug Administration about the effectiveness of this NAME OF THE PRODUCT recall, please complete and return the following questionnaire using the enclosed pre-paid self-addressed envelope. You may also return the questionnaire by FAX at (123) 456-7890.

If you have any questions or concerns with this request, please call *(INCLUDE THE RECALLING FIRM POINT OF CONTACT NAME AND TELEPHONE NUMBER).*

Thank you for your cooperation.

Sincerely,
J. Doe
President, Your Firm Name

Please check ALL appropriate boxes.

☐ I have read and understand the recall instructions provided in the <include date> letter I received.

What is the disposition of the recalled product?

_____ <units or cases> for return.

☐ I have returned (specify quantity, date, and method) _____

_____ <units or cases>

☐ I have destroyed (specify quantity, date, and method) _____

_____ <units or cases>

☐ I have identified and notified my customers that were shipped or may have been shipped this product by (specify date and method of notification);) _____

_____

☐ Attached is a list of customers who received/may have received this product.

☐ CIRCLE ONE: I will notify my customers OR please notify my customers for me.

Have there been any adverse events associated with recalled product? CIRCLE Yes or NO If yes, please explain:

_____

_____

_____

Please circle the appropriate description of your business: wholesaler/distributor; retailer; food processing facility; grocery store; food service/restaurant; re-packer; other (describe).

_____

Appendix D
The Closeout Report - Information that FDA will ask Your Firm to Submit

This is the product information the FDA Recall Coordinator will expect your firm to begin producing when your firm contacts FDA about initiating a product recall.

PRODUCT INFORMATION:

- **Product Name (include brand name and generic name)**

- **Model, catalog, or product order number(s)**

- **Description of the product**
  - Include if the product is powder, liquid, tablet, capsule, etc.
  - Include the intended use or indications.
  - If the product is perishable, include the expected shelf life.
  - Include the type of packaging (i.e., box, flexible plastic, glass).

TWO COMPLETE SETS OF ALL labeling (photocopies are acceptable)

- Product labeling (including ALL private labels).
- Individual package label.
- Case label.
- Package inserts.
- Directions for use.
- Promotional material (if applicable).

CODES (Production Identification Numbers):

- Lot/Unit Numbers

(NOTE: If "all lots" are involved or the product is not coded, explain how non-recalled, or reintroduced product may be distinguished from product subject to recall. Explain your lot number coding system.)

  - Expiration date(s) or use-by-date(s) or expected shelf life of the product.
  - Serial numbers (medical devices).
  - UPCs.

NAME OF THE FIRM THAT IS INITIATING THE RECALL (YOUR FIRM):

- Firm name, address, city, state, zip code
- Identify the firm type (i.e., manufacturer, importer, broker, re-packer, own-label distributor).

CONTACTS OF YOUR FIRM:

- Name/title/phone/fax number/e-mail address for RECALL contact.
- Name/title/address/phone/fax number of the most responsible individual for the recalling firm.
- Name/title/phone/fax number/e-mail address for public contact.

IF YOU ARE A MANUFACTURER:

- Firm name, address, city, state, zip code.
- FDA registration number, if applicable.

IDENTIFY FIRM RESPONSIBLE FOR THE VIOLATION/PROBLEM
(If your firm purchased a recalled product from the recalling firm):

- Firm name, address, city, state, zip code.

REASON FOR THE RECALL:

- **Explain in detail how a product is defective and/or violative.**
  - Explain how the defect affects the performance and safety of the product.
  - If the recall is due to the presence of a foreign object, describe the foreign objects' size, composition, hardness, and sharpness.

- If the recall is due to the presence of a contaminant (cleaning fluid, machine oil, paint vapors), explain the level of a contaminant in the product. Provide labeling, a list of ingredients, and the Safety Data Sheet for the contaminant.

- If the recall is due to failure of the product to meet product specifications, provide the specifications and report all test results. Provide copies of any sample analysis.

- If the recall is due to a label/ingredient issue, provide and identify the correct and incorrect label(s), description(s), and formulation(s).

- Please explain how the problem occurred and the date(s) it occurred.

- Explain how the problem was discovered and the date discovered.

- Please explain if the problem/defect affects ALL units subject to recall, or just a portion of the units in the lots subject to recall.

- Explain why this problem affects only those products/lots subject to recall.

- Provide detailed information on complaints associated with the product/problem:
  - Date of complaint.
  - Description of complaint (include details of any injury or illness).
  - Lot number/serial number involved.

HEALTH HAZARD ASSESSMENT:

- Please provide your assessment of the health risk associated with the deficiency.
  NOTE: A recall decision does not depend solely on the health risk of the product. Defective products and misbranded products where no health hazard exists are still in violation of the law and should be recalled.

VOLUME OF RECALLED PRODUCT:

- Total quantity produced.

- Date(s) produced.

- Quantity distributed.

- Date(s) distributed.

- Quantity on HOLD by the recalling firm and its distribution centers.

- Indicate how the product is being quarantined.

- Estimate the amount remaining in the marketplace.
  - Distributor level.
  - Detail level.

- Provide the status/disposition of marketed product, if known, (e.g., used, transfused, implanted, used in further manufacturing, or destroyed).

DISTRIBUTION PATTERN:

- The number of DIRECT accounts (customers you sell directly to) by type, for example:
  - Re-packers.
  - Manufacturers.
  - Consumers (internet or catalog sales).
  - Federal government consignees.
  - Foreign consignees (specify whether they are wholesale distributors, retailers, or users) .

- Geographic areas of distribution, including foreign countries.

- Provide a consignee list (names/address/city/state/contact name/phone number) to the local Recall Coordinator. Be sure to include any foreign (including Canadian) customers and federal government consignees (USDA agencies, Veterans Affairs, Department of Defense).

- Indicate what the consignee list represents (i.e., all customers who were shipped recalled product; all customers who were sold recalled product; all customers who may have been shipped or sold the recalled product because it was sold to them within the applicable time).

- Was the product sold under a government contract? If yes, provide a contract number, contract date, and implementation date. If no, indicate so.

- Was the product sold to any federal, state, or local agency involved in the school lunch program? If yes, list the consignees and provide quantity and sale and shipment date.

In addition, it is recommended that you notify both "ship to" and "bill to" customers of the recall so that:

- "Ship to" customers retrieve the product from their location.
- "Bill to" customers, if responsible, initiate the sub-recall.

RECALL STRATEGY:

- Indicate the level in the distribution chain to which you are extending the recall. (i.e., wholesale/retail).

- If the recall only extends to the wholesale/distributor level, we recommend that you explain your rationale for not recalling to the retail level.

- Indicate the method of notification (i.e., mail, phone, fax, e-mail). It is advisable to include a written notification so customers will have a record of the recall and your instructions.

- Indicate how letters will be sent to customers (e.g., overnight mail, first-class mail, certified mail, facsimile).

- If initial notification is by phone, provide a copy of the phone script to FDA.

- If you have a website, you should consider posting the recall notification on the website as an additional method of recall notification. (Note: This is not recommended as a sole means of customer notification.)

- Report on what you have instructed customers to do with the recalled product.

It helps Recall Firms to know the name and title of the Recall Contact for each of its consignees. Addressing a recall notification letter to a recall contact by name will expedite the recall process and reduce the potential for the notification letter to get misdirected.

- If the product is to be returned, explain the mechanics of the process.

- Explain if this recall creates a market shortage that will impact the consumer.

- Report on recall effectiveness check strategy. Include your actions for non- responders. See: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm>

- Determine and provide your course of action for out-of-business distributors.

- Provide a proposed method of destruction, if applicable.

- If the product is to be "reconditioned," explain how and where the reconditioning will take place. Please provide details of the reconditioning plan to your local FDA Recall Coordinator before implementation. All reconditioning must be conducted under any applicable cGMPs.

- Describe how the reconditioned product will be identified, so it is not confused with the recalled (pre-reconditioned) product.

In addition, final recommendations include:

- Contact your FDA Recall Coordinator before product destruction. FDA will review your proposed method of destruction and may choose to witness the destruction.
- The Recalling Firm and customers keep adequate documentation of product destruction (and whether the destruction was witnessed by an FDA investigator).
- Field corrections, (i.e., product relabeling), are to be performed by Recalling Firm representatives, or under their supervision and control. It is not recommended that a disinterested party such as a wholesaler or retailer be responsible for field corrections.
- Contact your Recall Coordinator before the release of reconditioned goods.

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