

Food Defense Disaster Recovery Template



New Mexico Department of Agriculture Southwest Border Food Safety Defense Center

Innovative Food Defense Projects (R18)
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Agriculture in New Mexico is a primary engine for the state's economy. Recognizing the need to protect it and partnering with the FDA, the Southwest Border Food Safety and Defense Center at New Mexico State University and the New Mexico Department of Agriculture (NMDA) have taken steps to prevent, respond and recover from a food defense event.

The New Mexico Food Protection Alliance was created in 2010. This is a working group of industry, federal, state and local agencies representing agriculture, food production and public health to train, educate and inform members to build resilience in food protection.

The Alliance fosters a proactive exchange of information and training on topics of risk assessment and risk mitigation. It is an opportunity for the private sector, regulators, and educators to exchange information so that each learns and understands the role of the other in running a business and protecting public health and safety.

Members of the Alliance have performed vulnerability assessments and made changes to operations that have mitigated vulnerabilities thus lowering the risk of food defense incidents.

A food defense event is vastly different from a food safety event. **A food defense incident will be intentional, sudden and unexpected;** it can



reduce the confidence that we have in our food supply and those who protect it. It can make people sick, kill them and damage the economic infrastructure of our state and our nation.

To fully understand the concept of food defense recovery those involved in the feed and food industry must have a clear understanding of what food defense is and what it is not. According to the Food and Drug Administration (FDA), Center for Food Safety and Nutrition (CFSAN):

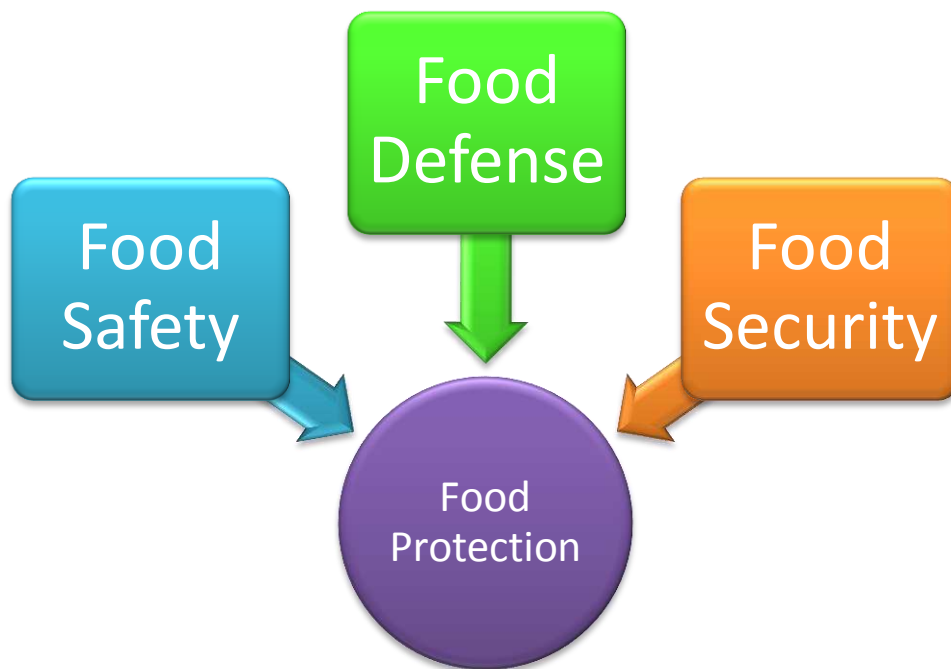
Food Defense is a term used to describe activities associated with protecting the nation’s food supply from intentional contamination.

Food Safety is a term used to describe activities associated with protecting the nation’s food supply from unintentional contamination.

Food Security is a term used to describe activities associated with ensuring the nation’s population has a wholesome and nutritious food supply.

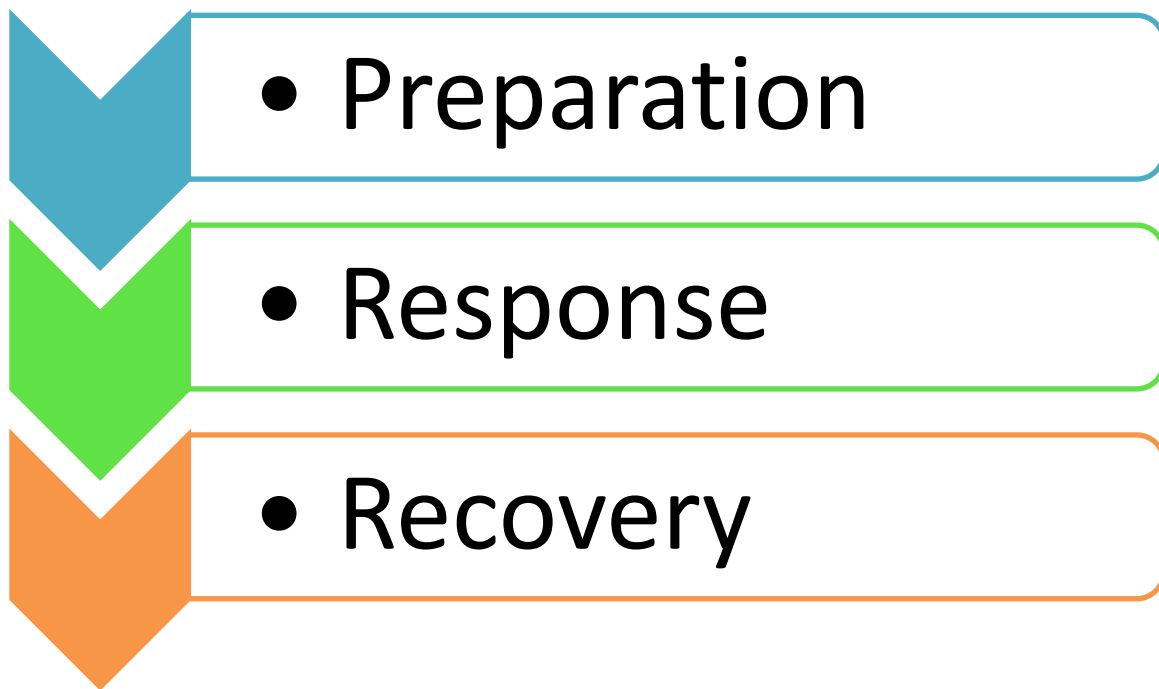
These three components comprise what have become to be known as **Food Protection**.

If it were to be diagrammed, it might look like the following:



For a feed or food producing business, a food defense incident can mean a severe loss of confidence of a company's brand, company leadership or specific products, even when the company is not at fault. Often times the company reputation and brand recognition has been built over many years. The hard work and the investment are suddenly in jeopardy. This event causes critical and unexpected disruption of business operations affecting the community, employees and customers of a company.

There are three elements to an effective food defense plan; all are important in a food defense recovery initiative. One cannot have a food defense recovery plan without creating a food response plan first; the two are intricately reliant on one another. Those elements include:



Preparation involves a number of sub elements including assessing vulnerability, understanding threat and calculating risk. Mitigation based on these factors is important. Preparation also includes taking into account steps and activities that are necessary to accomplish recovery.

Response has elements in common in food safety and food defense, however, in a food defense response there are unique and often times



competing elements. An example of this could be competing investigations between environmental, health and criminal investigators, leading to limited or no collaboration, negatively influencing recovery efforts. Unfortunately, the affected business is often not included or considered during the turmoil.

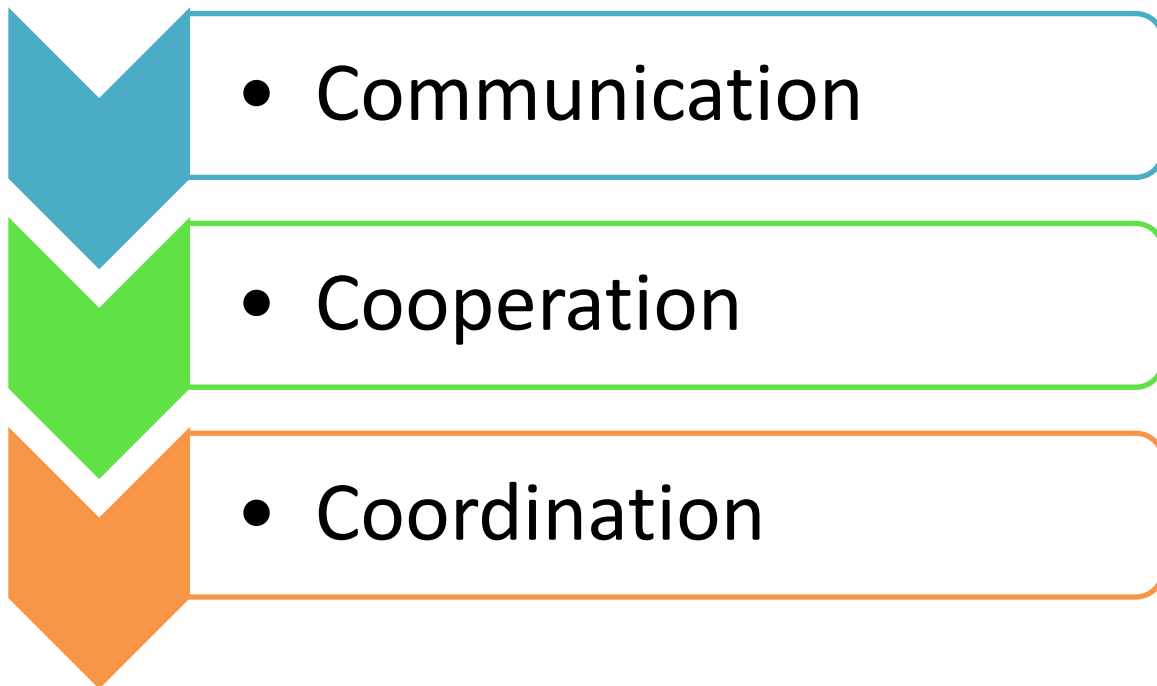
Recovery, the focus of this project and accompanying template, actually starts before and continues long after a response to a food defense-related incident is over. While it may seem paradoxical to regulators and investigators accustomed to investigating food safety incidents, a food defense incident must be treated differently. A food defense incident is an intentional act and solving the problem, without destroying a business, requires the regulatory community to work with the private sector on the recovery efforts. This approach is different from what we are accustomed to and it will prove not to be easy to accomplish. However, the earlier in the incident a joint recovery effort begins, the more rapid and effective recovery will be. A goal for the regulatory agency would be to activate a response immediately upon being notified that a food defense incident has occurred.

When an incident occurs, the burden is on the business to resolve the incident while the regulatory community in parallel takes steps to protect the public. While regulatory agencies have promulgated rules and regulations there is little in the way of guidance to help a business sort through the process; this template is intended to help provide that guidance.

As mentioned earlier, an interesting dichotomy can surface when regulators find themselves in the unfamiliar position of supporting the operational recovery of a business that they regulated in the past and may again in the future; this is done for the economic good of a community or nation. This is at its very core difficult to accomplish because of the traditional relationship between the private sector and the role of the regulatory community. As we become better at understanding the nuances of food defense, the purposes and objectives of the private and the regulatory sectors should blend together to achieve a goal of building resilience against the effects of intentional acts to our food supply. Recognizing the paradox early is important otherwise recovery will not be fully successful.



There are three basic principles that insure the success of this effort:



The formation provided by this food defense recovery template is based on these three seemingly basic concepts. They must be respected at every moment of the recovery initiative by all levels of involved personnel from both the private and public sectors.

According to the National Association of State Departments of Agriculture (NASDA) "...recovery will be critical to ensuring the ongoing viability of food and agriculture businesses affected by an incident." This philosophy must be understood and honored for a recovery effort to be successful.

Food Defense Recovery – Pre-Incident:

While the following template focuses on recovery from a food defense incident, before recovery can be implemented, certain things must occur in the process. The following are some of those general guidelines:

1. For the implementation of recovery actions, the company must employ an individual who during an incident would take on the

incident command role. The individual would have training and experience in those duties. This position would be integral in beginning recovery efforts at the very first knowledge of a food defense related incident and would insure that an incident command structure is maintained completely through the end of the recovery period.

This position should not be the President, Chief Operating Officer, Chief Financial Officer or Chief Executive Officer. It should, however, be someone who is vested in the success of the organization and understands the operational and inherent political intricacies of the organization.

2. Sustainability planning also referred to as Continuity of Operations Planning or COOP must be planned for and to the extent possible practiced long before a food defense incident occurs. Some of the components of this can include:
 - a. Identifying legal issues responsibilities and to the extent possible mitigating those;
 - b. Creating a financial plan and potential financial resources;
 - c. Designate an operational center or command room within the food processing facility, or in proximity to it such as a mobile trailer or separate building that will be used solely for managing the recovery of the food defense incident;
 - d. Identifying, fostering and maintaining a point of contact with investigative and regulatory entities at the local, state and federal levels, and
 - e. Creating and maintaining a public communications plan that will inform the public of what is occurring with the food product related to the food defense incident. This plan should involve



different type of mediums including social networking, pre incident web page development and rehearsed news releases.

Food Defense Recovery - During the Incident:

How events are managed during the incident is going to influence the recovery phase. The basic planning elements should include:

1. Activate the employee in the incident commander role who will manage the company's recovery efforts as diagramed below. Until the recovery effort is deemed complete, by upper management, this position should do nothing else other than manage the recovery.
2. Implement an operational response and recovery plan concept that closely aligns with those that are used by the public sector. As the nation's public sector continues to transition to a coordinated national response system, so should the private sector. Companies should understand and generally adopt the approach of the National Incident Management System to manage, respond and recover from a food defense related incident.
3. A company employee named in the incident commander role should receive incident command training. Their job immediately transitions to recovery efforts, once an incident has occurred as detailed in the preceding element #1. This person should do nothing else but coordinate the recovery effort. The basic diagram would look something like this for the structure of those involved in the recovery effort.





The positions outlined in the above diagram are as follows:

- **Command Staff** - Those individuals, such as the Chief Operating Officer, Chief Financial Officer, Chief Executive Officer and/or President.
- **Incident Commander** - As described previously in #1 above and responsible for the recovery efforts.
- **Safety** - The safety portion of this recovery effort can be performed by the company's usual safety personnel.
- **Information** - Ideally, the company should employ a public information officer or contract with a company who specializes in risk communications.
- **Operations** – Responsible for the operations of the facility including microbiology support for the scientific investigation of the recall.
- **Planning** – Responsible for planning elements of the recovery in addition to the normal production and product flow reporting.
- **Logistics** – Responsible for information about product distribution.
- **Finance and Administration** – Responsible for financial information.
- **Liaison** - For the first three months of the recovery effort, the position must have daily contact with the responsible federal and state regulatory agencies. The Liaison function coordinates with regulatory agencies for the progress and status of their investigation. Daily, the liaison should ask the regulatory for the following information:

- a. Tell me what you know as a regulatory agency about this ongoing incident;
- b. Tell me what you don't know as a regulatory agency about this ongoing incident, and
- c. Based on that information, tell me what you think is going to happen.¹

Food Defense Recovery – Post Incident:

Why Plan?

The goal of food defense post incident recovery planning is for your company to be able to produce a healthy product and restore confidence in your company as quickly as possible. Ultimately, how well a company can recover from a food defense incident depends largely on pre incident planning and productive communication. The following questions set the stage for post incident planning.

Do you have a crisis plan and when was the last time it was reviewed and tested?

Businesses are dynamic and there are a multitude of factors that change the nature of your business, even on a daily basis. When preparing a recovery plan, build your plan to deal with a “worst case” scenario.

Have you done a food defense vulnerability assessment for your business and when was the last time it was updated?

A vulnerability assessment is a good place to start. It should thoroughly identify your vulnerabilities and then be used to calculate the food defense risks present in your facility. Your assessment should be updated to reflect changes in ongoing operations. People that helped to prepare the assessment are also people that would be helpful to the recovery planning and your recall team. Additional information about vulnerability

¹ This information briefing concept is attributed to General Colin Powell.



assessments process can be found at:
<http://www.fda.gov/Food/FoodDefense/ToolsResources/ucm295900.htm>.

A note of caution: identifying vulnerabilities and calculating risk is important, but you must then mitigate those risks through sound biosecurity mitigation measures. To identify vulnerabilities, calculate risk and do nothing is dangerous.

How quickly could you convene the right team to handle a complicated recall or consumer issue?

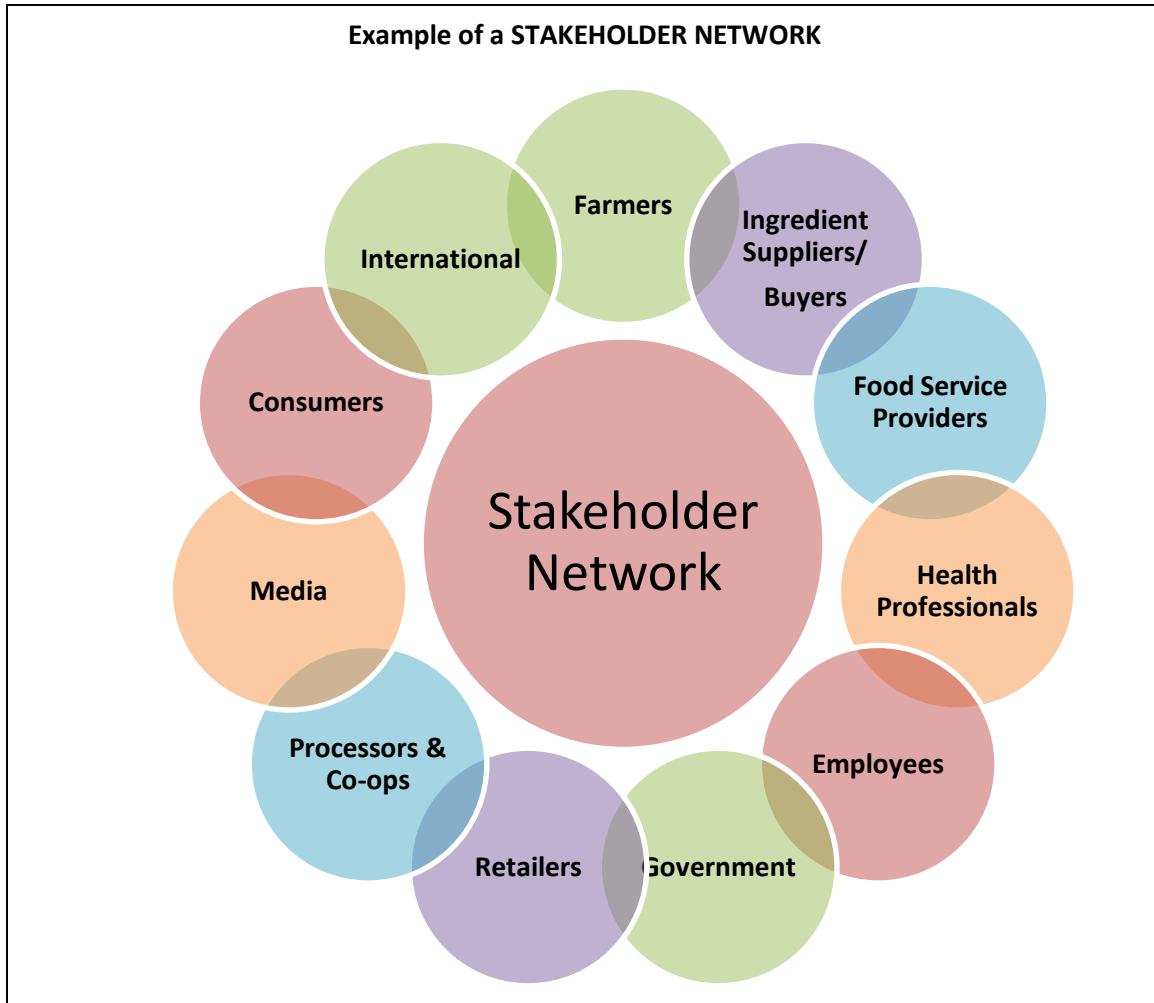
Surviving the first few hours of a crisis can save assets, markets and reputations. How you handle a crisis has residual effect on every part of your business, both now and for the future. Ideally, you should have a product recall team already established and should be able to begin a recall within 24 hours. Each person should know what their role is and you should have up to date records of your production and sales. Test your plan at least once a year with a made-up recall. Go so far as involving your suppliers and your customers too. That will inspire confidence and good will for your company. During the year sporadically test parts of your recall plan. That keeps your team sharp and focused.

Do you know who your most important stakeholders are?

The following figure illustrates the entities of a stakeholder network. Use this for determining the members of your stakeholder network. Involve your stakeholders in planning shows your concern for them and it builds confidence within your stakeholder network. It may also spur them to include your business in their planning as well.

Consider your employees too and how vital they are to your business. You will be relying heavily on the support of key people during a crisis. They will be expected to work longer hours doing their regular work as well as handling aspects of the crisis. They will be concerned for your business, but they will be thinking how the crises may affect their families too. They may not share these feelings openly with you.





If the “spotlight” shines on you, do you have a good story to tell and someone to tell it? In a food defense recovery situation your message must be simply stated and aligned with the consumer’s most pressing concerns. Look at possible scenarios that could affect your business and think like a consumer. Craft messages around: What is the problem? What is being done to control and manage the problem? Think about what else consumers need to know as the crisis unfolds. “You are the message” for your business.

Other entities involved such as governmental agencies, will be communicating to the public as well. Your message should focus on the issue, respond only as appropriate, be viewed as a reliable source of information and communicate as one voice. Identify someone who will be

your point of contact. Consider sending that person to specialized training. Practice your communications plan and prepare mock interviews with hard questions.

When is a Recall Necessary?

A recall can be a voluntary decision by a company when it is necessary to protect consumers from a potentially adverse effect of a contaminated, adulterated, or misbranded food product. In most cases, a recall is triggered when a company finds an issue with a product that becomes actionable according to the classification scheme in the table below. For example, a Class 1 recall would take place when there is a reasonable probability that the use of, or exposure to, that product will cause serious adverse health consequences or death to humans or animals.

Classification of Recalls.

FDA has defined four levels of severity for recalls depending on the risk to consumers. They are shown in the following table.

Two governmental agencies, the Food and Drug Association (FDA) and the Food Safety and Inspection Service (FSIS) have regulatory responsibility for food product recalls. They regulate different food commodities:

- FSIS is responsible for meat, poultry and egg products (eggs that have been removed from their shells for further processing), while
- FDA regulates all of the other food commodities including feed intended for animals.

While most recalls are done cooperatively, FDA and FSIS may ask the company to initiate a recall. If a company refuses, the FDA and FSIS have legal authority to detain the product and to stop operations if the product constitutes a danger to public health.



Classification	Definition	Examples
Class I	This type of recall involves a health hazard where a reasonable probability exists that eating the food would cause serious, adverse health consequences or death.	Meat contaminated with <i>L. monocytogenes</i> in a ready-to-eat food product; <i>E. coli</i> O157:H7 in raw beef; allergens such as peanuts or eggs (not listed on the label).
Class II	This type of recall indicates a potential health hazard where a remote probability of adverse health consequences from eating the food exists, or if the resulting condition is temporary or medically reversible.	Presence of FD&C Yellow #5 dye in candy; presence of dry milk, a Class II allergen, as an ingredient in sausage without mention of the dry milk on the label.
Class III	This type of recall involves situations in which eating the food will not or is not likely to cause adverse health consequences.	A package containing fewer or lower weight products than shown on the package label or improperly labeled processed meat in which added water is not listed on the label as required by federal regulations.
Market withdrawal	This type of recall 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.	A product that is tampered with, but without evidence of manufacturing or distribution problems.

Source: (Ohio State University 2002) and (FDA 2003).

What other agencies may be involved in a food defense incident?

- Federal Bureau of Investigation
- Tribal
- Departments of Agriculture
- Departments of Health
- Departments of Environment
- Environmental Protection Agency
- Local Departments
- Non-governmental organizations



The Reportable Food Registry (RFR) - Mandatory Reporting for Industry.

In 2007, FDA introduced the Reportable Food Registry (RFR) to enhance tracking patterns of foodborne incidents and targeting inspections. The RFR is a mandatory self-reporting system for Registered Food Facilities that manufacture, process, pack, or hold food for human or animal consumption.

The responsible party must report as soon as practicable, but in no case later than 24 hours, after determining that 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. This triggers a Class 1 recall situation.

The only exception to the RFR reporting requirements involves those businesses that produce infant formula and dietary supplements because FDA regulates these industries separately. The link to the FDA Website for a more detailed description of the RFR requirements can be found at <http://www.fda.gov/Food/ComplianceEnforcement/RFR/default.htm>

Besides industry, Federal, state, and local government officials may also report information about reportable foods incidents that come to their attention through the RFR portal.

A report filed in the RFR system is called a “safety report” and it is a description of the event. FDA reviews each report to judge the seriousness of the case. They may request more information from the responsible party and take action as appropriate. Taking action might lead to a product recall depending on the seriousness of the incident.

You should be prepared to submit the following information to the RFR site when there a reportable incident at your facility.

- Facility contact Information and registration number,



- Complete description of the incident, and
- A complete description of the food product including: packaging; product codes; use-by dates; other identifying marks; container description; quantities, and distribution information.

Epidemiological Investigations.

A recall may be triggered also when a contaminated food product reaches commerce and causes multiple illnesses or deaths. When health care providers begin to see large numbers of patients with similar illness symptoms, the public health system prompts an epidemiological investigation usually by a state public health agency to find the root cause of the illnesses. If a food item is the root cause, the state agency, possibly in conjunction with the FDA or FSIS, will contact the manufacturer.

Roadmap for Your Recall Plan.

A recall is always undesirable. Nevertheless, a successful outcome lies in knowing what is required and then being prepared to satisfy those requirements quickly and efficiently. A business with a recall plan is better able to streamline the response process. Doing so smoothly and efficiently will reduce the amount of time a business is in a crisis mode.

The following recall planning discussion is meant to raise awareness to the purpose of these steps and to encourage you to form a team to pre-plan for the possibility of a recall situation, which can occur in a food defense incident.

The following steps are part of the recall plan workbook found on page 28. Each step includes information to tailor the plan to your operations.

- **Goals** - The following material is drawn from literature reviews, discussion with FDA Recall Coordinators and business owners that have experienced a recall. Your plan may include additional goals as appropriate to suit your operations.
- **Protecting The Public** - Protecting the public from harm is the number one objective. The regulatory agency’s role is to ensure



that you are taking steps to protect the welfare of the public. Your business cannot return to normal until the agency, typically through an assigned recall coordinator, is satisfied the public is safe. Going forward any communications need to keep this goal in mind. You must work to ensure public safety by removing the affected product out of the hands of consumers as quickly as possible and document the process carefully.

- **Protecting your brand** – Protecting your company’s name is a key factor to emerging successfully. Every step needs to take into account the long term effects on your company’s reputation and brand name. How you communicate, whether it be with the regulatory agency, your customers or the media affects the recovery from an event. Demonstrating prompt and efficient actions will ensure public safety as well as serve to protect your brand.
- **Closing the Recall As Soon As Possible** – The longer a recall lasts the greater the ramifications are to returning a business to normal. Officially, this goal is out of your hands. The recall coordinator will decide when this occurs. Nonetheless, knowing what they need to make that decision and what is expected from you will help in the process. The amount of information that you will be required to submit will be overwhelming if you are not prepared. Take the time to review the Guidance for Industry about recalls on the FDA website. Be aware that the more risk there is to the public, the more data and documentation the agency will want. Are your business records centralized and can you compile information with custom queries to meet agency requests for information? Pre-plan how you would extract information from your records and discuss the supply chain issue with your downstream supply chain customers as well.



- **Information required for a recall submission** - Any firm with products that have the potential of being recalled should be prepared for the worst. If you suspect an issue with a food product might lead to a Class 1 recall, you should be ready to submit an initial Recall Submission Report to your District Recall Coordinator and through the RFR system to FDA's Center for Food Safety and Nutrition (CFSAN).

In the initial report, you should address the following points as thoroughly as possible:

- What is believed to have happened?
- What is the health hazard?
- Where is the affected product?
- How effectively did you notify the affected population?
- Can you prove by supporting written documentation?
- How much affected product is in the market?
- How much of the affected product was retrieved from the market?

Take the time to review the details of the submission requirements. They are available from the FDA web page - Guidance for Industry: Product Recalls, Including Removals and Corrections. The webpage address is <http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm>.

A FDA District Recall Coordinator and staff from CFSAN will assign a recall classification (Class 1, 2, etc.) based on an assessment of risk posed to consumers by the product. In New Mexico, the FDA District office is located in Denver, Colorado. For other states, names of the respective District Coordinators can be found on the FDA web page <http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm>.

For Class 1 recalls, you will have approximately 10 days to update the initial report. If your report indicates that the affected product has reached consumers, the FDA will insist on issuing a press release immediately.



FDA will be involved to make sure it reaches the affected parties. FDA will give you the opportunity to issue the press release first. Are you ready? Have you already written the release? Where does it need to be sent? How will you disperse it? A sample press release is found in Appendix D.

What about your customers when they hear about the recall? Do you want your customers to hear about the recall from an FDA Press Release? Probably not! Have you already discussed your response plan with them? How will it affect their business?

The point being made by these questions is that there isn't much time for you to do the things that you will be required to do unless you have a recall strategy in place and a team practiced to work the plan. When the public's health is at stake events will unfold rapidly and the burden is on the firm to stay ahead of the process. Even if the incident is no fault of your company, you still must act proactively to stay in business; sitting back and assuming the role of victim will not keep you in business!

Strategy.

As soon as there is any discussion of the possibility of a recall, your team should begin addressing the following facets of the recall.

- Obtain the total quantity of the affected product produced;
- Find out when it was produced;
- Obtain the quantity that was distributed;
- Obtain the quantity being held;
- Find out how the affected product is quarantined;
- Obtain the amount estimated in the marketplace and where (retail level, whole sale level, consumer level);
- Identify the geographic area of distribution, and
- Create a list of consignees that received the product and who may have re-sold the recalled product.



On the surface, the questions seem reasonably straightforward to answer. However, that depends on how well a firm keeps information on production, sales, customer contact information, shipping and returns. Are those data centralized in one system? Can you make custom queries to pull production data of the affected product by date and quantity, cross reference that to customer sales records to know how much of the affected product was shipped and when? Can you find out how much of your product was re-sold by your customers? Can you pull information into a single report automatically or do you have to compile the information by hand? How long does that take?

FDA will expect continual updates of the status and disposition of the product throughout the recall process. The scale and the extent of a recall may be enormous if the distribution chain for your product is long or if your product is a raw material used in making other products. The following figure is a simple illustration of where records may reside in your business that would need to be compiled into a product disposition report.



District Recall Coordinator.

Despite the fact that FDA guidance recommends comprehensive recall planning, many companies do not consider talking with their District Recall Coordinator as a proactive planning step. They have goals in common with your firm and one of these is closing the recall as quickly as possible.

A recall will not be closed until the Recall Coordinator is satisfied that following has been completed and has issued recall termination notice.

- The public health is protected;
- The root cause of the hazard resulting in the recall is known;
- Corrective actions have been developed and approved to prevent future occurrence;
- All affected product is removed from commerce, and
- You have completed a final status report that has been approved.

Each district handles recalls slightly differently. Consider talking with your coordinator as a proactive planning step of your plan. Know the level of detail and supporting facts that they expect to see in a report for the products that have a potential to be recalled.

Determine Your Stakeholders and the Proper Form of Communication.

Determining who to notify and how to notify them is a critical initial step. This activity can be quite an undertaking and has many downstream effects (Rozembajgier, 2008).

Consider the regulatory agency as a stakeholder. They have the difficult job of protecting the public health of consumers from a potentially hazardous food item. The recall submission document for example is a challenge to complete and it will require updating throughout the recall process.

Are you capable of producing voluminous reports to meet with FDA's requirements? Most likely FDA will also send other staff to your facility as well. Should you have a single point of contact to correspond with the FDA?



Obviously, your business customers are stakeholders in the outcome of the recall. Their businesses are in jeopardy too. What is your message to them? Who will deliver that message, how often and by what means? Will you help them communicate with their customers? Should you practice your response at a recall by conducting a mock recall with your customers?

Consider the consumer as a stakeholder. Their perception of the recall and the risk that your product poses to their family will be tied to your brand name. You would like them to be your customer after the recall is over. Is the consumer just at the retail store level, or has the affected product been shipped directly to consumers via catalog or internet sales? How do you contact them? Do you have lists of customers complete with residential and shipping address information? Are the lists accurate? Are you sure? How quickly can you pull customer names and addresses from your company records? What is your message to them? How often do you want to contact them? Do your business customers share the same consumer base or do they have a different set of customers to reach?

The point of these questions is to emphasize that a recall is more than just making sure the affected product is removed from commerce. That is already challenging enough, but keeping good customer relations during the recall makes sure you still have a business to recover once the recall is closed.

Establish the Capability to Process Information.

By now the argument has been made that dealing with a recall will stress the resources of a business and preplanning is necessary. Interviews with those that have been involved in a recall make us emphasize the importance of being able to satisfy requests for information by the regulatory agency in the most effective and timely manner possible. Make sure of what they need and develop the information accurately so it does not have to be re-done and time wasted.

The FDA Guidance for Industry document is a good reference to review, but know that most reports and documents will change as the dynamics of



the recall evolve. Consider how you will prepare a comprehensive report of the recall from start to finish by pulling from reports and records generated during the recall.

Item 10 of FDA's Guidance for Industry (FDA 2003) gives instructions for contacting customers and about keeping records to document the effectiveness of the recall process. The public can be notified in a number of ways, but FDA advises a written notification as well. It is the recalling firm's responsibility to determine whether the recall is progressing satisfactorily. This includes knowing that those contacted have followed your corrective actions.

Effectiveness checks need to be conducted during the recall. You will need to contact non-responders via telephone. In your tracking efforts, you must consider documenting the conversations; are you prepared to show proof of any attempts, if required by the FDA?

Your notification plan is something that can be pre-planned. Deciding how to contact the public and customers, must involve documentation (email, postcard, website login) and if they took appropriate corrective action. You must have a written record by date of the following:

- Persons contacted;
- Those who confirmed taking corrective action,
- Those that did not reply, and
- Those that were re-contacted and their status.

It is vital to the recall closeout that a reputable written record exists documenting the effectiveness of your recall strategy. Recall effectiveness is followed very closely by the regulatory agencies. Therefore, as part of its audit responsibilities, FDA will conduct audits of your recall effectiveness assessments.

Product Retrieval.



Instructions for removing the product from commerce to prevent it from reaching the consumer should be part of your recall strategy. Getting affected product out of commerce is the primary goal to protect the public. How that is accomplished is critical to the regulatory agency.

Will the affected product be shipped back to your facility? Do you have room for the affected product and is it necessary to store the returned product? Can you safely quarantine the affected product from any non-affected product? How quickly can you dispose of the affected product?

To measure the effectiveness of the recall, you must accurately be able to account for the quantity of affected product. Know what method or approach will be acceptable. Can you destroy the affected product without returning it to your facility? Who will witness the destruction and accurately quantify the amount destroyed for you?

Protecting your brand is a goal of the recall strategy and there is a lot for you at stake. Depending on the scope of the recall, consider conducting on-site effectiveness checks at your customer to ensure product has been removed from various locations. Who, from your company, will do this can be part of your pre-plan.

Realize too that regulatory agencies will conduct random on-site checks to judge the effectiveness of the recall.

Closing out the Recall.

You may ask for permission to close a recall when the public has been notified and the affected product is off the street and removed from commerce. However, a final status report will be required with documentation that covers the following before the recall will be closed.

- What is the root cause of the recall;
- What corrective actions have been put into place to prevent future occurrence, and



- What is the recall status from start to finish with detailed descriptions of the number of customers contacted, number of customer that responded, the amount of the product recalled and accounted for and finally an analysis of the recall effectiveness.

The final status report must be submitted to the recall coordinator for final approval. Be prepared if the recall lasts longer than you anticipated.

Communications Planning.

After an incident, communication in all directions is vital to the successful recovery for any business. You must effectively and genuinely communicate with staff of the regulatory agency, with investigators of the incident and with your customers. Using the following points will help get you started with your communications planning.

- Focus on issues that directly impact the food product and the public's confidence in your product and business. You must convey a message backed up with facts that the situation is being addressed properly.
- Follow the government's lead. They will have a communications plan too. The similarities between viewpoints are that you both want to protect the public health of the consumer and maintain consumer confidence. Expect that when the government releases information that the media will contact you next for your side of the story....be ready. Stay on message.
- Respond only as appropriate. Your messages should be aligned with consumers' concerns. Monitor the news and the social media to listen to what is being said about the event, your product and your business. Decide when to respond and keep your messages simple and factual.
- Become the source of credible information about the incident.
- Speak with one voice. This means being consistent, credible and factual with your messaging. The following template will help with the process.



- Be ready for the situation and the facts to change rapidly. Uncertainty is high and information is in high demand.
- Once you know that you have a problem activate the plan. Be out front.
- Do not allow others to drive the discussion as this will result in your stakeholders losing confidence in your business. This will make recovery from the crisis that much more expensive and difficult.
- Select your spokesperson carefully. Experts say communication is 10 percent what you say, 30 percent how you say it and 60 percent your persona. The spokesperson symbolizes the organization and gives your stakeholders someone to identify with; a good spokesperson has the ability to effectively connect with an audience. General recommendations for a spokesperson to follow in all media settings include:
 - Know your organization's policies about the release of information;
 - Stay within the scope of your responsibilities, unless you are authorized to speak for the entire organization or a higher headquarters;
 - Do not answer questions that are outside the scope of your organizational responsibility;
 - Tell the truth and be open as possible;
 - Follow up on issues, and
 - Use visuals when possible.
- The information about social media comes from the website Social Grow.com. Social media can be a factor in judging the mood and opinion of your customers and the direction a recall may take. Social media can be part of your communications plan. Create a social media listening post by subscribing to a collection of RSS subscriptions from food safety and news blogs that can be sent to your feed reader program or e-mail. This approach allows you to



monitor news, in real-time to be ready for situations when news changes rapidly (Sartor, 2010).

- Finding good content starts with determining the best keywords to use for your listening post. Start with your name. If you have a common one, you will have to use additional keywords to make the search unique. Add in business terms, your company, competitors, industry, and products. Use [Google Ad Words](#) to find additional keywords.
- Now that you have decided on the most relevant keywords, you need to create your RSS feeds. [Google Alerts](#) is a good first option. Enter in your keyword phrases and choose the option to deliver your content through feeds or email. [Twitter Search](#) can be valuable source for getting real-time content, just scroll down to RSS icon on the right side.
- While there are a number of RSS feed readers, [Google Reader](#) is one of the best. If you chose feed delivery in Google Alerts, your feeds will already be populated in Google Reader. Start by reading the content from the feeds and keep only those feeds that you find valuable. Use [Google Wildcards](#) to refine your searches.
- You may find it useful to categorize your feeds into different folders within your feed reader. You can name your folders by subject, or even day of the week, so you can organize your listening. If you want to share important content that you discover, tag these posts to create a new feed, to which others in your organization can subscribe. After a couple of weeks, you will be able to determine the best process to monitor and share your feeds.

Through a three-step process outlined in the following section, you can now begin to create your own recovery plan. The elements of the process are diagrammed below.



Step I

- Create Recovery Goals
- Collect Information
- Compile Contact Information

Step II

- Create Recovery Strategy
- Create Communications Plan

Step III

- What Worked?



Food Defense Recovery Template

Step I

Create recovery goals for your company: One of the key components to recovery and working within the nation's incident command system is managing by objectives. Tailor the following to your overall objectives:

- **Protecting the Public** is the number one initial objective of a response strategy and it is an initial goal that is in common between you, investigative agencies and regulatory agencies. *Create your goal below for protecting the public, keep it concise and informative. Drag to enlarge the text box:*

- **Protecting your brand** is a key factor to emerging successfully in the recovery phase. *Create your goal below for protecting the public:*

- **Close the recall as soon as possible** so that you can begin the process of restoring your operations back to normal. *Create your goal below for closing your recall and resuming normal operations:*



Ensure that basic company information is readily available for easy dissemination. Use the table below in your plan; it is expandable and can be printed off separately as needed:

Company Name	
Company Contact	
Physical Location	
GPS Coordinates	
Mailing Address	
Shipping Address	
Carrier Shipping Address	
Employee Telephone	
Public Telephone	
Media Telephone	
Fax Number	
Employee Email Contact	
Media Email Contact	
Web Address	
Registration Number	
Company Incident Liaison	



Contact information for those who will be helpful in your recovery:

Local Law Enforcement	
State Law Enforcement	
Federal Law Enforcement	
Local Regulatory	
State Regulatory	
Federal Regulatory	
Department of Health	
Department of Environment	
Department of Agriculture	
Financial	
Insurance	
Transportation	
Security Company	
FDA Recall Coordinator	



Step II

This document is created in Word format so that you can answer the questions that apply to you by simply typing in your thoughts and answers.

Create and record an effective recovery strategy:

In successful recovery, everyone involved must be quick, but they must be right. Working a problem quickly and efficiently takes forethought and anticipation of what could occur. Address each for the following items in writing and this will help guide you to tailoring a plan for your business.

1. Evaluate your capability to assemble records:

Your planning strategy must include knowing your capability to assemble reports for the products produced and shipped from your facility quickly. As a test of the effectiveness of your business recordkeeping system pick a representative product from your business and answer the following questions for that product covering the preceding 30 days:

- a. What was the total quantity of 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. How much of the total was distributed, in what packaging and 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 received the product including name, address and telephone number; recall contact and consignees who may have re-sold the product.

In an actual recall, you have very little time to gather and report the information. Now, assess the effectiveness of your process.

- Were you able to identify the produced and amount on hand? _____
- Could you compile information from your business records automatically and easily into a single report or did you have to compile information by hand? _____
- How long did it take to make the consignee list? _____
- Did you have customers contact information on hand? _____
- How long did it take to answers questions a-g above? _____
- How many people from your business were involved and from which departments? _____
- If necessary, could you pull the same information for other products that you produce? _____
 - All at the same time? _____
- If two products were involved how much more difficult would this process be? _____
- What improvements would allow you to extract records and compile reports quicker? _____

Based on the results of the limited mock recall, what do you need to do to improve the process? Be sure to conduct the preceding exercise at least quarterly.

2. Create a Notification Plan

How will you notify your customers when something happens? Investigate the most efficient process for your business, based on your products. Implement as many of these steps as you can; prepare to implement the others. Even if some questions cannot be fully answered, they can refine the number of strategic options available to you creating your plan.



- a. Identify how far into the product distribution chain you might extend the recall: wholesale/distributor, retail (internet and/or catalog). If the recall only extends to the wholesale/distributor level, explain your rationale for not recalling to retail level.
- b. Maintain a consignee list including the name and title of the recall contact for each consignee.
- c. Indicate the method of notification (i.e. mail, phone, internet, facsimile, e-mail). It is advisable to include a written notification so customers will have a record of the recall and your instructions.
- d. Indicate how letters will be sent to customers (e.g. overnight mail, first class mail, and certified mail, facsimile).
- e. If your initial notification is by phone, write a phone script and have a copy available for the FDA.
- f. If you have a web site, post the recall notification on the web site as an additional method of recall notification.
(Note: This is **not** recommended as a sole means of customer notification.)
- g. Describe in detail what you want your customers to do with recalled product this may depend where they are located.
- h. Explain the mechanics of the process if the product is to be returned.
- i. What is your course of action for out-of-business distributors?
- j. How would you propose to destroy an affected product and witness the destruction?
- k. Could your products be "reconditioned", if so explain how and where the reconditioning would take place.
- l. All reconditioning must be conducted under any applicable GMPs. Note: the FDA will expect you to give details to your FDA District Recall Coordinator before implementation.
- m. Explain how you identify a reconditioned product so it is not confused with recalled (pre-reconditioned) product or non-recalled products.



3. Plan for Measuring the Recall Effectiveness

How will you explain the effectiveness of your recall? The following are guide lines and sample written formats for you to adopt.

A. Distributing Notifications by Mail.

Your written notification 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.

- a. Prepare a letter to each consignee. See Appendix B for sample.
- b. Address envelope to consignee and on the envelope prominently inscribe with **“IMPORTANT RECALL INFORMATION INSIDE.”**
- c. Prepare a questionnaire asking about the disposition of the recalled product. See Appendix C for an example.
- d. Prepare a self-addressed, stamped envelope for the consignee to return with the completed questionnaire.
- e. Re-contact with a follow-up letter to those that do not respond.
- f. Keep records to know how effectively your recall is progressing.

B. Preparing Product Recall Status Reports

You will need to produce recall status reports. It is necessary that you prepare a system that documents the following:

- a. Dates customers notified.
- b. Number of customers notified.
- c. Number of customers responding.
- d. Quantity of recalled product returned or accounted for ultimately.
- e. Monthly reports to FDA of the details of your recall effectiveness checks.



C. Product Retrieval

It is important to plan how you will get your product out of commerce. Basic decisions to deal with a product should be part of your recall strategy. Getting affected product out of commerce is the primary goal for protecting the public. How this is accomplished to the satisfaction of the regulatory agency is critical. However, it is also critical that nothing you do will compromise the criminal element of the investigation.

- a. Will the affected product be shipped back to your facility?
- b. Do you have room for the affected product?
- c. Can you safely quarantine the affected product away from any non-affected product and avoid a product mix-up?
- d. Is it necessary to store the returned product?
- e. How quickly can you dispose of the affected product?
- f. Can you plan to conduct on-site effectiveness checks at your customer to ensure appropriate removal of product from various locations? Who from your company will do this?
- g. Can you destroy the affected product without returning it to your facility?
- h. Who will witness the destruction and accurately quantify the amount destroyed?
- i. Discuss with the regulatory agency recall coordinator what documentation needs to be kept.

D. Closing Out the Recall

How quickly you may ask regulatory agencies for permission to close a recall depends largely on if the public has been notified and the affected product is off the street and removed from commerce. But you will also need to address the following subjects. Consider whether you will need outside subject matter experts and identify those as part of your pre-planning.

- a. What is the food defense incident that promoted the recall?



- b. What actions have been put into place to prevent future occurrence?
- c. What is the status of any criminal investigations that are occurring?
- d. What is the recall status from start to finish with detailed descriptions of the number of customers contacted, number of customer that responded, the amount of the product recalled and accounted for and finally an analysis of the recall effectiveness.
- e. Once the final status report is written, it should be submitted to the recall coordinator for final approval. Be prepared if the recall lasts longer than you anticipated.

E. Selecting the Recall Team.

Recall teams are best comprised of people from various departments that will likely be involved in developing your plan. Reading through the template helps to give you, based on your knowledge of your facility and product line, an idea of the complexity of the process. Using your team from the vulnerability assessment results also helps to build continuity into the process. List those that you would have for your recall team and make them familiar with this process:

4. Elements of a Communications Plan.

Ultimately, how well a company fairs during and after an incident depends on communication from start to finish.

A. Pre-Planning Prior to a Crisis.

Effective food defense risk communication helps to inform consumers without causing panic and alarm. Communications must take place at multiple levels and it is an absolute crucial part of response and recovery planning. Working a problem quickly and efficiently takes forethought and



anticipation of what could occur to affect your business before something happens.

B. Create a Communications Plan.

Be ready for the situation and the facts to change rapidly. Uncertainty during a response is high and information is in high demand. Use the following format to prepare a communiqué. By answering each of the questions you will be addressing the facts. The template forces you through a logical progression of information that consumers and your stakeholder can easily follow and understand. Use the same approach to prepare messaging throughout as a crisis evolves.

- A. What is the problem?
 - a. What is it?
 - b. Where is it?
 - c. Who is being affected?

- B. How is the problem being controlled and managed?
 - a. What are government and industry leaders doing to control and manage the problem?
 - b. Reinforce coordination between government and your business.
 - c. Use caution that you do not compromise any criminal investigation through media releases.

- C. What else can you say about the steps you are taking to protect consumer and their families while also building empathy for your actions?
 - a. Provide specific action steps and precautions that consumers can take such as *“do not consume our product,*

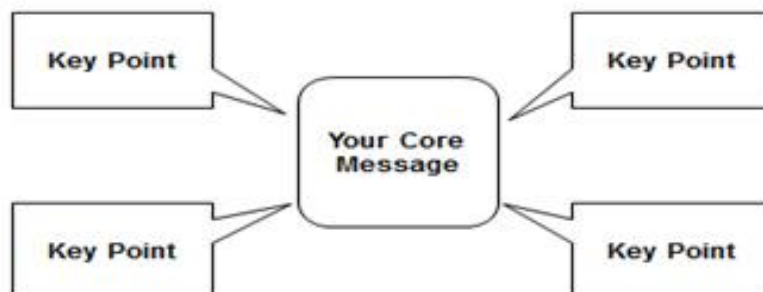


but return the product to the store where it was purchased for a full refund”.

- b. Communicate symptoms. For example “*our product is being recalled.....*”
- c. How can a consumer contact you? Do you have a dedicated telephone number that consumers can call for more information? If you have a business website use it to post a running series of updates to the crisis.
- d. Explain what actions are being taken to prevent this situation from happening again.

D. The interview is your chance is a time to tell your story. Making a plan for an interview is similar to preparing a written message. The template format is a good way to gather your facts and to stay on message.

- a. What is the core message for your interview?
 - a. What do you want the audience/person to remember?
 - b. How do you want the audience/person to feel?
- b. Steps to creating a core message:
 - a. Identify 3-4 main points that you want to make in the interview.
 - b. The following figure illustrates how key points should support a core message.



- c. Prioritize (find out how much time the interview is planned for and that will help you to know which points to bring out).
- d. 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 for each key point.
- e. Highlight your core message using examples and analogies



Step III

The lessons that you will learn throughout the response and recovery planning process and event should be re-invested into your planning efforts. Keep a record of the details of the response and recovery process to use to refine your plans. It is recommended that one person have the responsibility to keep exact details of every event that occurs.

Refine your plan and keep parts of the plan that work and function well, and conversely, improve those parts of the plan that did not function well.

Borrowed from the United States Department of Homeland Security, the following diagram suggests a cycle of preparedness which is applicable as well for preparing for recovery from a food defense incident.



References

FDA 2003, Guidance for Industry: Product Recalls, Including Removals and Corrections,

<http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm>

FDA 2012, Investigation Operations Manual. Inspections, Compliance, Enforcement, and Criminal Investigations - Chapter 7 - Recall Activities,

<http://www.fda.gov/ICECI/Inspections/IOM/ucm123363.htm>

FDA 2013, ORA District and Headquarters Recall Coordinators,

<http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm>

Percy, 2010, "Ensuring Efficient Recall Management," *Medical Product Outsourcing*, December 2010, <http://www.mpo->

[mag.com/articles/2010/09/ensuring-efficient-recall-management](http://www.mpo-mag.com/articles/2010/09/ensuring-efficient-recall-management)

Ohio State University, 2002, "Understanding the Recall Concept in the Food Industry," *Ohio State University Extension Fact Sheet*, AEX-251-02,

<http://ohioline.osu.edu/aex-fact/0251.html>

Rozembajgier, 2008, "Recall Management: Planning for the Unexpected,"

Medical Product Outsourcing, September 2008, <http://www.mpo->
[mag.com/articles/2008/09/recall-management-planning-for-the-unexpected](http://www.mpo-mag.com/articles/2008/09/recall-management-planning-for-the-unexpected)

Sartor, 2010, "Create Your Own Social Media Listening Post in Four Easy Steps," *SocialGrow*, September 2010, <http://socialgrowblog.com/create->

[your-own-social-media-listening-post-in-four-easy-steps-by-olivier-sartor/](http://socialgrowblog.com/create-your-own-social-media-listening-post-in-four-easy-steps-by-olivier-sartor/).

Lorenzen 2009, Carol L. Lorenzen - Division of Animal Sciences, Mary K. Hendrickson - Division of Applied Social Sciences, Robert L. Weaver - Division of Animal Sciences, Andrew D. Clarke- Division of Food Systems and Bioengineering, Marcia Carlson Shannon - Division of Animal Sciences, Kristi L. Savage-Clarke - Division of Animal Sciences, "Food Defense: Protecting the Food Supply from Intentional Harm," *University of Missouri Extension Service*, November 2009,

<http://extension.missouri.edu/publications/DisplayPub.aspx?P=MP914-2#benefits>



Appendix A - SAMPLE RECALL 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 GIVE 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 card 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 B –SAMPLE RECALL EFFECTIVENESS CHECK LETTER (Send to Your Customers)

Date

Your Business Name and Letterhead

City, State Zip Code

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

Dear *Name of the Consignee Recall Coordinator*

On (*date*), you were notified by letter that *NAME OF YOUR FIRM, Someplace, Somewhere 12345*, is recalling (product name), container size, and product code number. All products were manufactured by *NAME OF YOUR FIRM* and distributed solely under the manufacturer's label.

Recall of the product was initiated *GIVE THE REASON FOR THE RECALL*.

Using the recalled product represents a potential health hazard. The recall notice from *NAME OF YOUR FIRM* requested consignees (wholesalers and retailers) to discontinue selling their existing stock and return existing inventories of the recalled product to *NAME OF YOUR FIRM and Shipping Address*.

In order to advise the Food and Drug Administration about the effectiveness of this *NAME OF THE PRODUCT* recall, you are requested to complete and return the enclosed questionnaire promptly using the prepaid self-addressed envelope. If you have further sold our product to other distributors or to retail outlets, please conduct sub-recalls by notifying your customers of the recall situation as well.

If you have any questions or problems with this request, please call (*YOUR FIRM* Point of Contact name and telephone number).

Thank you for your cooperation.

Sincerely,

J. Doe

President, *Your Firm Name*



**APPENDIX C - SAMPLE QUESTIONNAIRE - EFFECTIVENESS CHECK
CONSIGNEE RESPONSE (Send to Your Customers)**

Date

Consignee Business Name and Letterhead

City, State Zip Code

Subject: Recall Effectiveness NAME of *PRODUCT RECALL*

PLEASE READ EACH QUESTION AND CHECK THE PROPER ANSWER YOU HAVE CHOSEN. PLEASE CHECK WITH ANYONE WHO MAY HAVE RECEIVED THIS NOTIFICATION BEFORE ANSWERING.

1. Did your firm receive notification that the John Doe Company is recalling its (Add Name of Product)? YES _____ NO _____
2. Did your firm receive shipments of the product being recalled? (If NO, please sign and return). YES _____ NO _____
3. Do you now have any of the recalled products on hand? (Please check inventories before answering). YES _____ NO _____
4. If the answer to question 3 is YES, do you intend to return the product to the John Doe Company as requested? YES _____ NO _____
5. If the answer to question 4 is NO, please explain your intentions _____

Have you received any reports of illness or injury related to this product?
YES _____ NO _____ If YES, Please provide details.



Appendix D –SAMPLE PRESS RELEASE

EXTRA FINE Chicken Company Announces a Recall of its Brand Chicken Breasts and Chicken Drumsticks

Consumer Hot Line: 1-877-XXX-XXXX

Media Contact:

Ms. Jane Doe

1-800-XXX-XXXX

media.relations@EXTRAFINE.com

FOR IMMEDIATE RELEASE – January 1, 2013 - EXTRA FINE Chicken Company today announced that it is voluntarily recalling its EXTRA FINE Brand Chicken Breasts and Chicken Drumsticks from retailer shelves nationwide. No other EXTRA FINE products are affected.

On Monday, New Mexico's Department of Agriculture (NMDA) informed the U.S. Food and Drug Administration (FDA) and EXTRA FINE that that residual antibiotics had been found in several lots of EXTRA FINE Brand Chicken Breasts. After consultation with the NMDA and FDA, we decided to voluntarily recall EXTRA FINE Brand Chicken Breasts. As an added precaution to consumers EXTRA FINE Chicken Drumsticks are being recalled too because both are sourced from the same chicken suppliers.

Antibiotics are used to keep chickens healthy and disease-free and this is standard practice in poultry production for both human and pet food. However, the antibiotics found in the products were unapproved and should not be present in the final food product.

EXTRA FINE Chicken Company has a comprehensive safety testing program in place for its products from procurement through manufacturing and distribution. Part of that program involves extensive testing for a wide range of substances commonly used to ensure the health of chickens. However, - EXTRA FINE Chicken Company did not test for all of the specific antibiotics found by the NMDA.

"Pet safety and consumer confidence in our products are our top priorities," said Rob Smith, general manager, EXTRA FINE Chicken Company. "While there is no known health risk, the presence of even trace amounts of these antibiotics does not meet our high quality standards. Therefore, today we decided to recall both products and asked retailers to remove the products from their shelves. In addition, we are expanding our testing program so that so this will not occur in the future.

"Consumers who discard these products will receive a full refund," said Smith. "We are committed to EXTRA FINE Chicken Company and stand by our guarantee of complete consumer satisfaction."

Consumers with questions about EXTRA FINE Chicken Company products can get further information at 1-877-228-6493 or from our website www.EXTRAFINECHICKENS.com.

