Chapter 3

Creating a Food Defense/ Response Plan in Food Processing Facilities

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For the life of me, I cannot understand why the terrorists have not attacked our food supply, because it is so easy to do.

Tommy Thompson, Secretary of Health and Human Services, 2004.

Food safety and food defense programs are designed to protect food products. However, it is important to understand that food safety programs are developed to prevent *unintentional* contamination from items such as metal, plastic, pathogens, pesticides, or sanitizers entering the food supply. Food defense programs are intended to prevent *intentional* contamination by individuals who deliberately contaminate food products and cause harm to the company or to the consumer. This chapter will discuss the creation and implementation of food defense/response plans in food processing facilities. Discussion of food defense plan requirements by the Food and Drug Administration is current with the Federal Register Notice for Mitigation Strategies to Protect Food Against Intentional Adulteration 5/27/16, which is the final rule (Federal Register, 2016).

3.1 INTRODUCTION TO DEVELOPING A FOOD DEFENSE PLAN

3.1.1 What Are the Benefits of Developing a Food Defense Plan?

Having a food defense plan can reduce the risk of intentional contamination to production or processing operations and may ultimately benefit their bottom lines.

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Writing a food defense plan helps employees identify steps that can be taken to reduce the risk that food in a facility can be harmed by intentional contamination. In addition, thinking through the processes used in an operation while developing the food defense plan can help pinpoint inefficiencies and redundancies that are costing operations time and money.

A well-developed response plan also helps family members, employees, and disaster response personnel respond appropriately to a suspected intentional contamination incident. A plan will map out a way to contain the damage and get operations back to normal production levels more quickly. By helping a company avoid a prolonged period of nonproduction, a food defense plan increases a business's chance of surviving a negative event.

All told, a food defense plan will help companies provide safe, high-quality products to their customers, keep employees safe and well informed, and protect the economic viability of the business.

3.1.2 What Operations Are Required to Have a Food Defense Plan?

Food defense plans are either required or highly recommended, but not required, by the following agencies for the specified food operations or products at this time. The *United States Department of Agriculture (USDA)* is responsible for the protection of preharvest agriculture, *USDA Food Safety and Inspection Service (FSIS)* is responsible for regulating and ensuring the protection of meat, poultry, eggs, and catfish, while the *Food and Drug Administration (FDA)* is responsible for regulating foods other than those covered by FSIS. As of July 2016 FDA covered facilities are required to implement food defense plans on the following schedule: large plants must be in compliance by July 2019; small plants (with less than 500 employees) must be in compliance by July 2020; and very small plants (those with less than $10 million in receipts averaged over 3 years) by July 2021. In addition, any operation supplying food for USDA feeding programs (e.g., school lunch program) are legally required to have a food defense plan.

Over the last several years, FSIS has been conducting periodic surveys of inspected plants to determine the percent voluntary compliance, before deciding whether to seek regulations requiring meat and poultry slaughter or processing facilities to have a food defense plan. The most recent results from 2015 demonstrate 85% compliance by meat and poultry plants, 92% compliance by processed egg product plants, and 85% compliance by import inspection establishments (http://www.fsis.usda.gov/wps/portal/fsis/topics/food-defense-defense-and-emergency-response/preparation-and-prevention/food-defense-plan-survey-results/food-defense-plan-survey-results accessed 6/2/2016).

3.1.3 Assembling a Food Defense Team

Writing and managing the food defense plan for an operation should not be a one-person job. Instead, consider assembling a team made up of the key personnel who are familiar with most aspects of the operation. These personnel also should be in positions to take responsibility for enacting and helping manage the plan and must be trained in food defense awareness. University extension personnel, insurance agents, county emergency managers, or members of the law enforcement community can also be included on the initial team to help with vulnerability assessments. However, the team that manages the plan should consist of employees from the operation.

3.1.4 What Other Documentation and Supplemental Information Should Operations Gather for Developing the Food Defense Plan?

When ready to begin the plan, gather the following documents: a detailed and labeled map of the facility; all written operational procedures, such as Hazard Analysis Critical Control Point (HACCP) plans, Sanitation Standard Operating Procedures (SSOPs), Good Agricultural Practices (GAP), Good Manufacturing Practices (GMPs), Quality Assurance Plans and Standard Operating Procedures (SOPs); and procedures related to the workforce, such as preemployment screening and security training. Supplemental publications are available to help ensure the food defense team considers all of the important areas of the operation and can be found through USDA FSIS, FDA, university extension, and food industry websites. These websites offer potential worksheets, food defense planning exercises, and model plans.

3.2 ASSESS VULNERABILITIES (FSIS: CONDUCT FOOD DEFENSE ASSESSMENT; FDA: VULNERABILITY ASSESSMENT)

The first step in developing a food defense plan is to conduct a vulnerability assessment. Look for areas of the operation that are accessible to someone wanting to intentionally contaminate products. Remember that these vulnerabilities may arise from either internal (people employed or contracted with the operation) or external threats (e.g., people not employed by the operation, such as truck drivers or organized terrorist or activist groups) (FSIS, 2008). To find the vulnerabilities in an operation, think like a disgruntled worker, a member of a political group, or anyone wanting to harm the business, cause illness or death, or make a statement for a cause or disrupt the food supply chain. Consider various people who have access to the operation, such as workers, delivery employees, contract cleaners, and/or visitors. Think about the processes and procedures used in the operation, such as food processing, receipt of shipments and marketing and which processes and procedures

might be completed without supervision or in locations that are not visible. In the facility, identify locations where contamination would be easily distributed through normal operations, such as a feed or ingredient mixer. Consider points in the process or plant where a contaminant could be added and mixed easily. Also, identify critical areas that are not locked, as well as areas that are not visible to other employees, or where access is not limited. There are three specific elements in a vulnerability assessment that must be considered: (1) potential impact on public health; (2) physical access to the product; and (3) ability to successfully contaminate the product (Federal Register, 2016). When the vulnerability assessment is complete, keep the results and resulting plan confidential and shared only within the food defense team, to prevent it from being used as a tool for intentional contamination.

There are a number of vulnerability assessment tools, ranging from a series of questions to guide one through the planning process, to a more detailed approach, known as CARVER + Shock (Criticality, Accessibility, Recuperability, Vulnerability, Effect, and Recognizability). Establishments developing food defense plans will have the flexibility to choose the assessment tool that works best for them.

CARVER + Shock is an assessment tool that was commissioned by the Homeland Security Council, USDA-FSIS, and FDA for use in food processing facilities. The vulnerability assessment is a prioritization tool used in and by the food sector. It allows personnel to think like an attacker by identifying attractive targets at a food processing facility and then determining those vulnerable points in the infrastructure that personnel can focus on in order to prevent intentional contamination. The benefit of CARVER + Shock is that it standardizes the entire assessment process. So, any food processing facility can use this approach. CARVER + Shock also provides a scale for each characteristic, thereby facilitating a quantitative assessment. This assessment tool also provides for examination of public health, economic, and psychological consequences of an intentional attack, while breaking down the process into critical steps and evaluation of each node.

There are a number of key steps in CARVER + Shock:

Step 1. Establish Parameters

- Select the system to access.
- Develop an attacker profile—pick a worst-case scenario—inside versus outside threat.
- Identify an agent—consider biological, physical, chemical, or radionuclear agent, and pick the type of agent that takes the process and product into account.

Step 2. Assemble Subject Matter Experts

Choose individuals who understand the facility or system being assessed.

- Identify members of food defense team (see previous comments about suggested membership).

- Include external auditors for the team.
- Consider a number of individuals who can provide an overarching perspective on the process and can participate objectively in the activity.

Step 3. Detail Food Supply Chain

- Prepare a flow diagram with every step in the process.
- Validate the flow diagram by conducting a walk-through on the production floor.

Step 4. Assign Scores to Each Step in Flow/Node

- For each step in the process, evaluate the seven CARVER + Shock attributes and use this information to calculate an overall score for each step or node.
- Those steps with the highest score are those that are potentially the most vulnerable.
- Allocate financial and personnel resources to ensure the steps are protected from intentional contamination.

Again, the goal of using CARVER + Shock is to identify those critical nodes that are the most likely targets for a terrorist attack and allow personnel to design measures or mitigation strategies to reduce the risk. By using CARVER + Shock, personnel develop a systematic approach by going through each step in the flow diagram and assigning a number to each step, which can assist in prioritization of mitigation strategies; the higher the number, the more vulnerable the step. Based on the assessment, personnel can consider mitigation strategies that are inexpensive and can be done relatively quickly. Anything that requires more financial resources or more personnel involvement can be prioritized and implemented as time and finances allow.

With the facility map and operational and workforce procedures on hand, the food defense team should complete a comprehensive vulnerability assessment. The team should consider the security of the listed elements and additional elements specific to the operation. For broader food defense concerns, operations may find it easier to respond to a list of questions that cover vulnerable areas of concern (Table 3.1). Answer questions as "yes" if all the elements are secure; answer "no" if any elements are not secure, and indicate each insecure element and those not applicable (N/A) if the question does not apply to the operation. Only the questions that are answered "no" will need to be included in the food defense plan. The broad vulnerability assessment is designed to increase overall security and prevent intentional contamination in the most general sense.

The FDA has completed the CARVER + Shock process for the food industry in order to determine focused mitigation strategies. The more focused portion of the food defense plan should address the processes involved with producing high-risk foods, which would have large public health impacts. The characteristics of high-risk foods include having a likelihood of uniform mixing, being produced in high volumes, or having process

TABLE 3.1 Vulnerability Assessment Areas and Questions to Consider

Questions	Examples of Elements to Consider
Is the outside perimeter secure?	• Fencing restricts entry, within reason, and is inspected regularly. • Gates are locked when not in use, to limit access to the operation. • Locks are located on exterior doors (deadbolts with a minimum throw of 1.5 inches are recommended), windows, and other access points. • Vulnerable areas are well lit to make them more easily observable. • Cameras have been installed to make areas visible in a different way and to deter potential wrongdoers. • Exterior doors are metal or metal-clad and have tamper-resistant locking mechanisms. • Signage limits access to authorized persons or gives instructions for secure entry. • Area for vehicles is controlled and identification of vehicles is used.
Is access within the operation limited?	• Interior doors are locked to restrict access to sensitive areas. • Key inventory is kept up to date. Keys are returned by terminated employees. Keys are not left in machinery stored outside of buildings. • Exterior ladders used to access rooftops or storage bins are secured to prevent unauthorized access. • Interior windows are secured, as necessary, to limit access to sensitive areas. • Interior vents are locked, as necessary, to limit access to sensitive areas. • Interior signage limits access to sensitive areas. • A visitor log is maintained to record visitors' identification and the date and time of their visit. • Visitors park in a designated area that is monitored. • Computer system is password-protected, has limited access, and is protected from viruses. (Wrongdoers accessing an unprotected system can alter records to conceal tampering.)
Are processes or procedures secure?	• Procedures, in general, limit access to sensitive areas and ensure vulnerable production activities are observed by one or more employees, at all times. • Machines have locked lids or secure openings, or are observed by employees to prevent tampering.

(*Continued*)

TABLE 3.1 (Continued)

Questions	Examples of Elements to Consider
	• Production lines are enclosed, where possible, and observed at key points to limit opportunities for tampering. • Suppliers have a food defense plan. Contracts have been negotiated with suppliers, requiring seals or locks and a procedure for checking them upon delivery. • Uniforms do not leave the operation at any time, unless with a laundry service. • Laundry service can describe the security of their operation, as well as their pickup and delivery procedures. • In-house laundry facilities are secure and have procedures for daily uniform collection and distribution. Visitor and employee personal items are not taken into production or other sensitive areas. • Visitors are supervised by an appropriate employee at all times.
Is the shipping and receiving system secure?	• Loading area has limited access and procedures to deal with security issues, such as sealing loads and recording seal numbers. • Unloading area has procedures to deal with unscheduled deliveries, checking delivery invoices, and moving deliveries into storage. • A designated employee checks package integrity before supplies are placed in storage. • Trucks and trailer bodies within the facility are secured, even when empty. • Contracts have been negotiated with carriers so that liability is with the carrier while goods or products are in their possession.
Is there an inventory system for stored materials?	• Hazardous production inputs are secured when not in use, to prevent their being used to damage or intentionally contaminate the operation. • Inventory of raw materials is reconciled with shipping invoices to identify overages or shortages, which might be an indicator of contamination. • Inventory of packaging materials is reconciled with delivery invoices. • Chemical inventories are reconciled with records of delivery and usage. • Pharmaceutical usage is noted and reconciled with inventory.

(*Continued*)

TABLE 3.1 (Continued)

Questions	Examples of Elements to Consider
Is access to the water supply limited?	• Water source is tamper-resistant, wellhead is locked, and external water pipes do not have openings. • Inside water lines either have locks on access points or have access points that are easily observed by multiple employees. • Ice-making facilities have limited access. For facilities separate from processing areas and not easily observed, steps have been taken to increase observation or otherwise limit the opportunity for tampering.
Is mail opened away from sensitive areas?	• Mail is opened in a room separate from production areas with a separate ventilation system.
Are there screening and training procedures for the workforce?	• Before an employee is hired, background, reference, and credit checks are run. • Employees receive basic security training on how to recognize and deal with suspicious activities and to whom to report such activities.
Is access to sensitive areas limited?	• Storage area access is limited by locked doors, entry logs, or employee observation. • Processing and packaging area access is limited by locked doors, signage that restricts access, or employee badges or color-coded uniforms that designate work areas. • Chemical storage area access is limited by locked doors, signage, entry logs, or chemical usage logs. • Maintenance area access is limited by locked doors, signage or color-coded uniforms for maintenance employees.

Source: Adapted from Lorenzen, C.L., Hendrickson, M.K., Weaber, R.L., Clarke, A.D., Shannon, M.C., and Savage-Clarke, K.L. 2010. Food Defense: Protecting the Food Supply From Intentional Harm. University of Missouri Extension MP912.

steps that are easily accessible. The FDA has designated foods that include one or more of the following processes as high risk: bulk liquid receiving and loading, liquid storage and handling, secondary ingredient handling, or mixing and similar activities. To conduct this assessment, evaluate agents of intentional contamination and identify significant vulnerabilities, which are steps that are the most vulnerable; these are termed “actionable process steps” and will become the heart of the food defense plan.

3.3 WRITE THE FOOD DEFENSE PLAN

Once an operation's vulnerabilities and actionable process steps have been identified, it is time to write the food defense plan. The general areas addressed in a food defense plan include: processing, storage, shipping and receiving, and water and ice security (FSIS, 2008). Using the questions listed in Table 3.1 will reduce these broad areas into smaller, addressable vulnerabilities. In the food defense plan, address each vulnerable element and determine whether a simple, practical, and/or economical countermeasure could be implemented to make the element more secure. For each vulnerability considered practical to address, write down a countermeasure and indicate who is responsible for implementing it and by what date. Once the countermeasure has been implemented, have the person responsible date and initial the plan.

In addition to the vulnerability assessment, it may be helpful to develop a map and operational and workforce procedures available to work through the Food Defense Work Sheet. Once the work sheet is completed and assessed, a food defense plan that can stand alone or be added to any HACCP or other plans will be available.

3.3.1 Developing Countermeasures and Mitigation Strategies

Remember, the purpose of a food defense plan is to reduce the risk of intentional contamination in an operation. Countermeasures are actions taken to make vulnerable elements of the operation more secure. These countermeasures protect employees and customers, product, reputation and livelihood, and the business, property and assets. The goal of this exercise is to provide protection in the most economical ways possible.

As a general rule, procedural changes are the most economical. For example, checking references of potential employees is easy and inexpensive. Eligibility of new hires and validity of their Social Security numbers can be checked using the free E-Verify system (http://www.uscis.gov/e-verify). Another example is repositioning employees so that they face or are seen by other employees to reduce the chance of an intentional contamination.

The next most economical option may be inclusion of technology. Will technology, such as dusk-to-dawn lighting or a lock, reduce the risk of intentional contamination? If not, additional personnel may be needed, which may become the least economical option.

Be freethinking and creative in countermeasure development, and keep in mind the three Ls suggested by the National Food Processors Association: light it, lock it, and limit access (Hollingsworth, 2002).

Mitigation strategies are required under the Food Safety Modernization Act and there is guidance from both FDA and USDA. Mitigation strategies are designed to minimize chances of adulteration by minimizing accessibility

TABLE 3.2 Example of Focused Mitigation Strategies

Actionable Process Step	Mitigation Strategy
Outside security	• Secure the facility perimeter from unauthorized persons using a locked gate. • Locate visitor parking away from the main production facility. • Establish procedures for issuing, tracking, and retrieving keys to equipment and facilities.
Inside security	• Do not allow personal items into the production, storage, and loading areas. • Limit access to in-plant laboratories to authorized personnel only. • Ensure firewalls are built into the computer network.
Ingredient preparation area	• Examine packaging and containers for signs of tampering. • Maintain access log for ingredient preparation area. • Use peer monitoring for those handling ingredients.
Mixing process	• Ensure adequate lighting around mixer. • Use clean-in-place equipment when possible. • Conduct a visual inspection before mixing.
Blast freezer	• Install surveillance cameras in the freezer area. • Secure all cleaning supplies. • Ensure that the freezer equipment is cleaned and sanitized between uses.

Source: Mitigation strategies adapted from USDA and FDA websites (FDA. 2014. Vulnerability Assessment Software. Accessed 2/22/14 at: <www.fda.gov/food/fooddefense/toolseducationalmaterials/ucm295900.htm>. and FSIS. 2008. Developing a Food Defense Plan for Meat and Poultry Slaughter and Processing Plants. United States Department of Agriculture Food Safety and Inspection Service.

of an attacker to the product, reducing the opportunity for an attacker to successfully contaminate a product, or both, and mitigation strategies should be specific and customized to the product and process. These strategies need to be effective even when an attacker has legitimate access to the facility. Examples of mitigation strategies are found in Table 3.2 and more comprehensive suggestions can be found through both the FDA and USDA websites. The mitigation strategies need to be justified and documented as part of the food defense plan.

3.3.2 Marketing Challenges

Once the more obvious vulnerabilities and countermeasures have been addressed, one will need to address some of the challenges presented by marketing. The biggest challenge marketing presents is assignment of

liability; that is, determining who is responsible for protecting produce or food products from contamination at each step along the way from operation to the consumer's table. For example, one will need to determine who is liable for the food product while it is in transit or awaiting auction. Liabilities must be considered for those operations that encompass niche marketing, contract marketing, or direct marketing.

A two-pronged approach to liability is recommended. Consider the double Cs approach: check and challenge. *Check* the contract, whether oral or written, and negotiate the liability. The goal here is to make sure that companies are liable only when the food is in their possession. *Challenge* those who might want to contaminate the product by making contamination more difficult with physical barriers, such as packaging or a lock on a trailer in transit, or procedural barriers, such a supervising visitors during tours.

3.4 PREPARE A RESPONSE PLAN

The countermeasures that are developed can reduce the risk of intentional contamination, but cannot prevent it. Companies still need to prepare to deal with an intentional contamination incident so that, should one occur, the organization can quickly and efficiently contain the damage and get the operation back to normal production levels. Getting back into production as quickly as possible is key to keeping the business afloat.

In preparing a response plan, have the facility map on hand, as well as contact information for all suppliers, customers and local emergency responders. Companies also may need to refer to operational plans, such as HACCP, GAPs, GMPs, and SOPs, which may contain information valuable to the response plan, such as regulatory agency phone numbers, emergency protocols or recall plans.

To contain and minimize an emergency situation, understanding what needs to happen and in which order is essential. In the case of possible intentional contamination, the steps that need to be addressed immediately include: containment, diagnosis, recall, and disposal. Each of these steps needs to be addressed in the response plan.

3.4.1 Containment

As soon as an intentional contamination incident is suspected, isolate all product that may have been contaminated. In the food defense plan, identify a location within the facility where potentially contaminated food can be quarantined, separate from uncontaminated products. Facilities need to determine what procedures will be used to contain contaminated food products and the exact location for the containment.

3.4.2 Diagnosis

To respond to the emergency appropriately, facilities need to know what contaminant was used and how. As soon as possible, contact the appropriate person to diagnose the contaminant. If there are issues, a food processing plant will need to call a food inspector: FSIS for meat, poultry, eggs, or catfish; FDA for other foods. In the plan, include a list of emergency telephone numbers. The numbers on the list will vary, depending on the operation and its location.

3.4.3 Recall

In the event of an intentional contamination incident, contaminated food that has already left the facility will need to be recalled and contained. To effectively recall these types of products, the organization must know where all of the food or livestock has gone. Keeping reliable contact information for suppliers, customers, and processing lots will make this process much easier. Include all contact information in the plan. HACCP plans or similar operational documents will contain information related to trace forward/trace back procedures, which is a requirement for food processors. Also, because recalls often result from contamination that has been unwittingly passed on to the company by suppliers, organizations will need to prepare for that possibility in the response plan. In addition, a recall may require e-notification of customers and communicating with specific media outlets.

3.4.4 Disposal

Contaminated food must not be allowed to enter the food chain, so the response plan must include a plan for disposal of contaminated livestock or food products and possible decontamination of the facility. Regulatory agencies such as FSIS or FDA are valuable sources to help determine what type of disposal will be needed and who will need to sign off on the plan before contaminated food can be disposed of.

3.4.5 Decontamination of Facilities

A specific plan for general decontamination of the facility, including chemicals and fumigants used to clean the facility, also is needed. Areas that may require decontamination include equipment, vehicles, facilities, personnel, and grounds. Decontamination procedures, beyond general procedures, will be directed by emergency responders and regulatory authorities.

3.4.5.1 Facility Map

A map of the operation or facility will be vital to emergency responders in any situation. The map should provide contact information for the owner or operator of the facility and show the following:

- The facility in relationship to other properties, structures, or environmental landmarks, such as streams;
- Road access, transportation routes, perimeter boundaries, and gates, including their dimensions;
- Locations of utilities, septic, and sewer systems; and
- Buildings, with doors and windows marked, and outbuildings, as well as building systems, such as ventilation, air conditioning, and heating.

3.4.5.2 Emergency Phone List

When compiling an emergency or other contact lists, be sure to include the area code, even with local telephone numbers. During an emergency, calls may be made from a nonlocal phone. The numbers on an emergency phone list will vary by location and type of operation, but in general should include the following categories:

- Emergency responders, including sheriff, highway patrol, police, fire, hospital, and poison control;
- Utilities, including electricity, water, phone, and gas;
- Regulatory groups, including FSIS for meat, poultry, eggs, and catfish; FDA for other food; Animal and Plant Health Inspection Service (APHIS) for animals (the responding vet will likely start the chain of phone calls); and
- Other state agencies, including the state's Department of Health and Senior Services, Emergency Management Agency, and Department of Homeland Security.

Supplier/customer phone list: To effectively respond to an emergency that is unfolding at a fast pace, maintain a list containing the names and contact information of all suppliers and customers.

Employee emergency contacts: Maintain an emergency contact list for all employees that includes their phone numbers and addresses. Keep the list where it can be accessed quickly in an emergency.

3.5 MANAGING THE FOOD DEFENSE PLAN

Store copies of the completed food defense and response plans in more than one secure location. Keep one copy on the facility's premises and a second in a secure but accessible location outside of the operation, such as a home. Also consider saving a copy of the food defense plan online using a virtual document storage service.

Once the food defense plan has been written and implemented, the team needs to consider how the plan will be managed for the long term. Managing the plan may include periodic tests and annual reviews to see if the plan is still effectively reducing the risk of intentional contamination or if it needs to be updated to reflect changes in the operation. In addition to changes in the operation, a critical contamination event at another operation may prompt a test or review of the plan to ensure that the organization has sufficient countermeasures in place to reduce the risk of a similar incident. The food defense plan team should determine practical guidelines for managing the plan. Once the guidelines are in place, the food defense coordinator will be responsible for notifying the team when action is required.

3.5.1 Employee Training

Management of the food defense plan must also include ongoing employee training. New employees must receive basic instruction about their responsibilities with regard to the food defense plan. Training is a requirement by the FDA, along with documentation of the training. However, as of June 2016, the specific training has not been defined. All employees need to know what type of suspicious individuals or activities should be reported, who they should report suspicious individuals or activities to, which employee will be responsible for calling the authorities in a case of suspected intentional contamination, and what each employee's responsibilities are regarding security procedures, such as locking up or filing inventory or accessing log sheets at the end of the day. The team should set up procedures to ensure all employees are updated on changes to the food defense plan and to record employee food defense training activities. A record should be used to track employee food defense training and ensure these records are kept with the food defense plan.

The objective of a food defense plan is to help establishments provide a safe, high-quality product to their customers, keep employees safe and well informed, and protect the economic health of the business. A well-thought-out management plan will help the food defense plan work for companies for the long term.

3.5.2 Corrective Actions

Corrective actions are taken when a focused mitigation strategy has not been implemented properly. Currently, they do not apply to broad mitigation strategies. Corrective actions need to be detailed for each focused mitigation strategy in the food defense plan and require documentation, when implemented. Corrective actions are those activities focused on the proper implementation or the proper action to take when a focused mitigation

TABLE 3.3 Examples of Corrective Actions for Mitigation Strategies

Actionable Process Step	Mitigation Strategy	Corrective Action
Ingredient preparation area	• Examine packaging and containers for signs of tampering. • Maintain access log for ingredient preparation area. • Use peer monitoring for those individuals handling ingredients.	• Reeducate employees on the importance of examining packaging, maintaining log, peer monitoring, and recheck to determine if packaging is now being examined, access log is now maintained, and that peer monitoring is now being done.
Mixing process	• Ensure adequate lighting around mixer. • Use clean-in-place equipment, when possible. • Conduct a visual inspection before mixing.	• Increase lighting until it is adequate. • When purchasing new equipment, purchase equipment that can be cleaned in place. • Inspect product after mixing for signs of contamination.
Blast freezer	• Install surveillance cameras in the freezer area. • Secure all cleaning supplies. • Ensure that the freezer equipment is cleaned and sanitized between uses.	• Install surveillance camera. • Resecure all cleaning supplies. • Empty freezer and inspect for signs of contamination on the product and then clean and sanitize freezer.

Source: Mitigation strategies adapted from USDA and FDA websites.(FDA. 2014. Vulnerability Assessment Software. Accessed 2/22/14 at: < http://www.fda.gov/food/fooddefense/toolseducationalmaterials/ucm295900.htm > and FSIS. 2008. Developing a Food Defense Plan for Meat and Poultry Slaughter and Processing Plants. United States Department of Agriculture Food Safety and Inspection Service).

strategy is not sufficient, such as tampered packaging, which would be addressed by GMPs. Corrective actions for food defense plans, unlike HACCP, do not require that the affected food be tested for food safety, due in part to the low frequency of intentional contamination events (Table 3.3).

3.5.3 Verification

3.5.3.1 Plan Reviews

Reviews of the food defense plan must be conducted every 3 years, at a minimum, but also can be triggered by changes in the operation, such as a new product line or category of livestock, change of supplier, expanded customer base, addition of new technology, newly developed or updated procedures,

or change of food defense coordinator. The review should answer the following questions:

- Are the countermeasures continuing to reduce the risk of intentional contamination in vulnerable areas?
- Do new products or categories require additional countermeasures to reduce the risk of intentional contamination?
- Do new or updated procedures require additional countermeasures?
- Has supplier, customer, and employee contact information been updated?

3.5.3.2 Plan Tests

Tests of the food defense plan can be conducted randomly or scheduled two to four times a year, as determined by the food defense team, which should select an interval that is practical for the operation. The general purpose of these tests is to determine if the countermeasures are reducing the risk of intentional contamination. If the countermeasures are not adequately reducing risk, then new countermeasures should be developed and implemented. Tests that might be used include exercises in mock tampering, product quarantine, product recall, random food security checks, and computer system challenges. Specific areas to be checked include entry points to ensure that they are locked or secured, signage to ensure it is in place and legible, procedural compliance regarding uniforms and employee personal items, inventory log sheets to ensure they are being filed and properly maintained, and entry logs maintained for sensitive areas to be sure they are accurate and up to date.

3.5.3.3 Conducting a Food Defense Audit

Audits can be as simple as "...an official inspection of...an organization's accounts, typically by an independent body" or detailed such that they entail "...a systematic examination and verification of...accounts, transactions or other relevant documents, and physical inspection...by qualified auditors." Just like yearly reassessments of HACCP plans, periodic assessments or audits of food defense plans should be completed to ensure that the process and plan are sound. When it comes to auditing food defense plans, it is recommended that internal as well as external audits be performed with some degree of frequency. For internal audits, establishments may want to consider quarterly evaluation by management, while external audits may need to be conducted annually by an outside agency or third party. Either way, the goals of the audit(s) should be to ensure that the food defense plan remains relevant to the operation. It is important that audit information and frequency also be included in the food defense plan. There are several third-party auditors or audit programs, including self-assessments that can be applied to food manufacturing and/or processing facilities (see Table 3.4).

TABLE 3.4 Food Defense Self-Assessment or Checklists

US Food and Drug Administration	http://www.fda.gov/downloads/Food/GuidanceRegulation/ucm125192.pdf
USDA-FSIS: Industry Self-Assessment Checklist for Food Security	http://www.fsis.usda.gov/shared/PDF/Self_Assessment_Checklist_Food_Security.pdf
New York Department of Health	http://www.health.ny.gov/publications/7079.pdf
Ohio Department of Agriculture	http://medinahealth.org/images/company_assets/d98a6e31-3e37-43ff-bc1a-ecc84e8f1117/SelfAssessmentChecklist_4e66.PDF
USDA-FSIS Slaughter and Processing Establishments	http://www.fsis.usda.gov/wps/wcm/connect/63b6a057-ee99-41a0-813a-557cfb7f1c05/Slaughter_Plant_Checklist.pdf?MOD=AJPERES
Connecticut Department of Public Health Food Protection Program	http://ccthd.org/documents/foodoperatorsguide122310.pdf

3.5.4 Record Keeping

Record keeping starts with developing and writing the food defense plan. Establishments will want to have at least two copies of the food defense plan: one that will be kept in the food processing facility and one that will be kept offsite in the event that an intentional contamination or other emergency occurs and the team does not have access to the facility. The food defense plan will include the food defense team, vulnerability assessment with justification, mitigation strategies with documentation of implementation and justification, and monitoring procedures, including frequency, corrective actions, and verification activities. The second part of record keeping, which should be kept in a separate notebook or file in the facility, would include records relating to monitoring activities, corrective actions, and verification. Records have to be maintained for 2 years to comply with US government regulations; however, records must be accessible within 24 h when requested by regulatory agencies. Examples of methods for retaining records include keeping the original document, scanning the original document into an electronic database, or collecting data in an electronic form.

REFERENCES

Federal Register. 2016. Mitigation Strategies to Protect Food Against Intentional Adulteration: Final Rule. 81(103) part IV, May 27, 2016.

FDA. 2014. Vulnerability Assessment Software. Accessed 2/22/14 at: <http://www.fda.gov/food/fooddefense/toolseducationalmaterials/ucm295900.htm>.

FSIS. 2008. Developing a Food Defense Plan for Meat and Poultry Slaughter and Processing Plants. United States Department of Agriculture Food Safety and Inspection Service.

Hollingsworth, P., 2002. Hot topics address terrorism, fickle consumers, and obesity. Food Technol. 58 (8), 48, 50-52.

Lorenzen, C.L., Hendrickson, M.K., Weaber, R.L., Clarke, A.D., Shannon, M.C., and Savage-Clarke, K.L. 2010. Food Defense: Protecting the Food Supply From Intentional Harm. University of Missouri Extension MP912.