# Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry

## *Supplemental Draft Guidance*

**The additional chapters and appendices of this guidance are being distributed for comment purposes only.**

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For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-3712.

**U.S. Department of Health and Human Services**
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# Chapter 5: Mitigation Strategies Management Components: Food Defense Corrective Actions

This chapter provides an overview of the food defense corrective actions mitigation strategy management component and is intended to help you understand the requirements for food defense corrective actions as a part of your FDP. Food defense corrective actions is one of three mitigation strategies management components. The other two are food defense monitoring (See Chapter 4) and food defense verification (See Chapter 6). You must apply mitigation strategies management components as appropriate to ensure the proper implementation of the mitigation strategies, taking into account the nature of the mitigation strategy and its role in the facility's food defense system. (21 CFR 121.138). (See Chapter 3 of this guidance for information on identifying and implementing mitigation strategies). You have the flexibility to identify and implement food defense corrective actions procedures that are appropriate for your facility. Note that if, through your vulnerability assessment, you appropriately determine that your facility has no actionable process steps, then you would not need to establish mitigation strategies or associated mitigation strategies management components, including corrective actions.

## A. Overview of Food Defense Corrective Actions

You must establish and implement written food defense corrective actions procedures that must be taken if mitigation strategies are not properly implemented (121.145(a)(1)). The food defense corrective actions procedures must describe the corrective actions steps you would take to ensure that appropriate action is taken to identify and correct a problem that has occurred with implementation of a mitigation strategy (21 CFR 121.145(a)(2)(i)) and, when necessary, to reduce the likelihood that the problem will recur (21 CFR 121.145(a)(2)(ii)). Corrective actions must be appropriate to the nature of the actionable process step and the nature of the mitigation strategy (21 CFR 121.145(a)). As discussed in Chapter 3, mitigation strategies are usually implemented to reduce access to the product at a particular point, to reduce the ability of an attacker to contaminate the product at that point, or both. Food defense corrective actions are intended to address situations where those strategies are not properly implemented. Food defense corrective actions must be documented in records and are subject to food defense verification. (21 CFR 121.145(b)).

The tables at the end of this chapter (Tables 5.9 – 5.12) provide examples of food defense corrective actions procedures for the scenarios listed in Chapters 3 and 4 of this guidance.

## B. How Food Defense Corrective Actions Differ from Food Safety Corrective Actions

Some aspects of food defense corrective actions are similar to the food safety corrective actions in the PCHF rule. For example, corrective actions procedures for food safety require that you take steps to ensure that appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control (as with a mitigation strategy for food defense) and appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur. (21 CFR 117.150(a)(2)(i) and (ii)). However, because of the different nature

of intentional adulteration, your corrective actions procedures do not need to ensure that all affected food is evaluated for safety and that all affected food is prevented from entering into commerce if it cannot be ensured that the affected food is not adulterated or misbranded. (21 CFR 117.150(a)(2)(iii) and (iv)). Specifically, intentional adulteration of food requires not just the opportunity for a contamination event (i.e., failure to properly implement a mitigation strategy), but also someone with intent to cause harm (i.e., an inside attacker) attacking the food at the point where the mitigation strategy was not properly implemented at the time it was not properly implemented.

## C. Food Defense Corrective Actions Procedures

You must establish and implement written food defense corrective actions procedures that must be taken if mitigation strategies are not properly implemented. (21 CFR 121.145(a)(1)). You have the flexibility to identify and implement the procedures that are appropriate for your facility as long as they accomplish the following goals, as appropriate to the nature of the actionable process step and the nature of the mitigation strategy:

1. Ensure that appropriate action is taken to identify and correct the problem that has occurred with the implementation of a mitigation strategy (21 CFR 121.145(a)(2)(i)); and
2. Ensure that the appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur. (21 CFR 121.145(a)(2)(ii)).

Corrective actions are taken after food defense monitoring or verification determines that a mitigation strategy is not operating as intended. Through food defense monitoring, you may determine that a mitigation strategy is not operating as intended and immediately ensure appropriate action is taken to identify and correct a problem that has occurred with the implementation of a mitigation strategy. For example, monitoring may provide direct evidence of the problem (e.g., an employee conducting monitoring observes another employee not locking a gate after accessing a piece of equipment and implemented the corrective actions procedures to address the problem). Through food defense verification, you also may determine that a mitigation strategy is not operating as intended. This determination is likely to occur longer after the failure than a determination made via monitoring. In both cases, identifying the cause of the problem may be useful in determining how to prevent recurrence.

Food defense corrective actions must be written. (21 CFR 121.145(a)(1)). Written predetermined corrective actions in your FDP provide a "how-to" guide that describes the steps to take when a mitigation strategy is not properly implemented and enables you to act quickly and appropriately. Written food defense corrective actions procedures do not need to address every possible way a mitigation strategy may be improperly implemented but should address circumstances where improper implementation is most likely to occur. We expect most corrective actions procedures will be simple and easy to undertake.

For example, the mitigation strategy in Scenario 1 is to use a lock to secure the access hatch on an ingredient storage tank. Keys to the lock are held in the security office and can only be retrieved with good reason and approval from the facility security manager or food defense

coordinator. The facility concludes that the circumstances where improper implementation of this mitigation strategy will most likely occur is when the lock is not locked. If the lock is not properly engaged, a simple corrective actions procedure is to lock the lock. If it is determined that the employee assigned to implement the strategy did not properly engage the lock, a simple corrective actions procedure is to retrain the employee on the proper implementation of the strategy. Retraining reduces the likelihood of recurrence of the problem. If the lock is broken, a simple corrective actions procedure is to replace the lock. This action corrects the problem with implementation of the mitigation strategy and also reduces the likelihood of recurrence because an operational lock is more likely to be used. These corrective actions would be documented in the food defense corrective actions log as required by 21 CFR 121.145(b) (see Table 5-9).

In Scenario 3, the mitigation strategy is to inspect a liquid food storage tank prior to use. Immediately before reintroducing food, the quality control manager visually inspects the tank using high intensity flashlights and ultraviolet lights to ensure that no contaminant has been added to the tank while it was open and accessible after cleaning. The facility concludes that the circumstances where improper implementation of this mitigation strategy will most likely occur are when (1) the flashlights or ultraviolet lights malfunction, and (2) the quality control manager fails to inspect the tank prior to reintroduction of the food. For the first circumstance, the quality control manager identifies the problem (malfunctioning lights), corrects it (replaces the lights), and documents the actions in the food defense corrective actions log. (21 CFR 121.145(b)). For the second circumstance (failure to inspect the tank), an employee conducting monitoring identifies the problem (the tank was not inspected) and ensures it is corrected (the tank is inspected). The corrective actions procedure also includes retraining the quality control manager on the proper implementation of the mitigation strategy to reduce the likelihood that the manager will fail to inspect the tank in the future. Inspecting the tank and retraining would be documented in the food defense corrective actions log (see Table 5-11).

In Scenario 4, the mitigation strategy is to restrict access to the breader area to authorized personnel with specifically issued identification. The facility issues these employees special red caps and identifies their job functions on their employee identification badges. As part of their training in the proper implementation of the mitigation strategy, employees working at the breader are instructed to immediately escort any unauthorized individuals out of the area and notify security personnel or management of the intrusion. The facility concludes that the circumstances where improper implementation of this mitigation strategy will most likely occur are when (1) an employee fails to immediately escort any unauthorized individuals out of the restricted area, and (2) an authorized worker forgets his red cap or badge.

A simple corrective actions procedure for the first circumstance is to identify the unauthorized person and the employee who failed to escort the unauthorized person out of the area. To correct the problem, the unauthorized person is escorted out of the area, and the employee who failed to escort the person out of the area is immediately retrained on the proper implementation of the mitigation strategy. Retraining the employee also reduces the likelihood that the problem will recur. A simple corrective actions procedure for the second circumstance (authorized worker forgets cap or badge) is to give the authorized worker a replacement cap or badge for that day. These corrective actions would be documented in records in the food defense corrective actions log (see Table 5-12).

## D. Circumstances When an Improperly Implemented Mitigation Strategy May Be the Result of a Potential Intentional Adulteration Event - Using Corrective Actions and Awareness Training

Intentional adulteration of food requires more than an opportunity for a contamination event (i.e., failure to properly implement a mitigation strategy). It also requires a person with intent to cause harm (i.e., an inside attacker) attacking the food at the point where the mitigation strategy was not properly implemented at the time it was not properly implemented. Therefore, in most cases, the failure to properly implement a mitigation strategy would not be expected to result in an IA event.

However, some circumstances can raise significant enough concern that others should be notified. For example, in Scenario 4, if an unknown and suspicious person entered the restricted area of the actionable process step, the corrective actions include escorting the unauthorized person out of the area. However, if there is a question as to whether the food at that step was contaminated by the unauthorized person, this incident should be immediately reported to facility management, security personnel, or other individuals designated by facility management. The need for such reporting is typically addressed in food defense awareness training.

In addition, there may be times when a mitigation strategy is not operating as intended and a root cause cannot be determined. This may lead the facility to suspect that an IA event or attempt may have occurred. In this situation, it is our expectation that an employee or supervisor at that actionable process step would report the incident as taught in food defense awareness training. For example, in Scenario 2, if the tamper-evident tape on the hose capping indicates someone accessed the hose caps in an unauthorized manner, and no one in the receiving bay has knowledge of this activity, employees should report the incident to facility management, security personnel, or other individuals designated by facility management. In a similar set of circumstances, in Scenario 1, if the lock is cut but maintenance personnel have no knowledge of this activity, employees should report the incident (see Chapter 8.C for more information on awareness training and reporting suspicious events).

## E. Food Defense Corrective Actions Records

You must document the corrective actions you take. (21 CFR 121.145(b)). Records of corrective actions are necessary to determine whether corrective actions are being taken as specified in the FDP. Corrective actions records help to inform food defense verification activities, including identifying recurring problems with mitigation strategies, ensuring proper implementation of mitigation strategies, and determining whether a mitigation strategy needs to be reanalyzed.

All food defense corrective actions taken must be recorded at the time the activity is conducted. (21 CFR 121.305(d)). Each corrective actions record should be as detailed as necessary to provide a history of work performed, capture the time (if appropriate) and date that the activity was conducted, and include the signature or initials of the person who performed the activity. (21 CFR 121.305).

Food defense corrective actions records must include a description of the steps taken to identify and correct the problem with implementation of the mitigation strategy. (21 CFR 121.145(b)). For example, corrective actions records should document how you identified what went wrong with a mitigation strategy and then document the action(s) you took to resolve the problem. If it is necessary to take corrective actions to reduce the likelihood that the problem will recur, corrective actions records must also document these activities. (21 CFR 121.145(b)).

For example, in Scenario 1, the mitigation strategy is to use a lock to secure the access hatch on an ingredient storage tank. You find that the lock is not locked and follow your corrective actions procedure to secure the lock and retrain the responsible employee on lock use. To document the corrective actions taken, you could write in a food defense corrective actions log that "the lock was relocked," date/time, name of the employees that were retrained, date of the retraining, and name of the trainer.

## Table 5-9. Scenario 1.
## Worksheet 1-I: Mitigation Strategy Management Components

| (1) # | (2) Actionable Process Step | (3) Mitigation Strategy | (4) Food Defense Monitoring Procedure and Frequency | (5) Food Defense Corrective Actions Procedures | (6) Food Defense Verification Procedures | (7) Food Defense Records |
|---|---|---|---|---|---|---|
| | Liquid ingredient storage tank | Use a lock to secure access hatch on ingredient storage tank. Keys to the lock are held in the security office and can only be retrieved with good reason and approval from the facility security manager or food defense coordinator. | Employee assigned to ingredient storage observes whether the lock is in place and locked at the beginning and end of the tank's 48-hour cleaning cycle. | If lock is not locked, properly engage lock, and retrain employee on proper lock use.<br><br>If lock is broken, replace lock. | *See Chapter 6, Table 6.13*. | Liquid storage tank observations record<br><br>Food defense corrective actions log |

## Table 5-10. Scenario 2.
## Worksheet 1-I: Mitigation Strategy Management Components

| (1) # | (2) Actionable Process Step | (3) Mitigation Strategy | (4) Food Defense Monitoring Procedure and Frequency | (5) Food Defense Corrective Actions Procedures | (6) Food Defense Verification Procedures | (7) Food Defense Records |
|---|---|---|---|---|---|---|
| | Bulk liquid receiving | Use tamper-evident seals on inbound shipping conveyances. Match the numbers on the seals with the numbers provided on the shipping documentation from the supplier. If the seals do not match, the load will be rejected to prevent potentially adulterated ingredient from entering the facility. | Technician assesses whether the seal is intact and matches seal or documentation numbers upon arrival of the load before hooking up the hose for each delivery. | If seals do not match, are broken, or are missing, the load will be rejected. | *See Chapter 6, Table 6.14.* | Receiving/delivery paperwork that includes additional information to indicate monitoring was completed<br><br>Food defense corrective actions log |
| | Bulk liquid receiving | Use tamper-evident tape on hose ends after capping. | After daily operations, supply chain supervisor confirms that the hose caps are on and taped. | If caps are broken, replace caps. Clean and flush hose.<br><br>If tape is ripped, reapply tape. Clean and flush hose.<br><br>Retrain employee on capping and tape use. | *See Chapter 6, Table 6.14.* | Food defense monitoring log<br><br>Food defense corrective actions log |

| (1) # | (2) Actionable Process Step | (3) Mitigation Strategy | (4) Food Defense Monitoring Procedure and Frequency | (5) Food Defense Corrective Actions Procedures | (6) Food Defense Verification Procedures | (7) Food Defense Records |
|---|---|---|---|---|---|---|
| | Bulk liquid receiving | Use authorized personnel for visual observation of the unloading bay during the opening of the conveyance and the attachment of hoses and pumping equipment. | On a periodic basis, (but at least twice weekly), a manager observes whether personnel are visually observing the unloading bay during the opening of the conveyance and the attachment of hoses and pumping equipment. | Retrain employee on observation of the bay. | *See Chapter 6, Table 6.14.* | Food defense monitoring log<br><br>Food defense corrective actions log |

## Table 5-11. Scenario 3.
## Worksheet 1-I: Mitigation Strategy Management Components

| (1) # | (2) Actionable Process Step | (3) Mitigation Strategy | (4) Food Defense Monitoring Procedure and Frequency | (5) Food Defense Corrective Actions Procedures | (6) Food Defense Verification Procedures | (7) Food Defense Records |
|---|---|---|---|---|---|---|
| | Liquid food storage tank | Inspect liquid food storage tank prior to use. Immediately prior to reintroducing food, the tank is visually inspected by the quality control manager using high intensity flashlights and ultraviolet lights to ensure that no contaminant has been added to the tank while it was open and accessible after cleaning. | QA technician signs and dates log immediately prior to the liquid food being added to the tank after the monthly cleaning cycle. | If flashlights or ultraviolet lights are malfunctioning or broken, repair or replace them.<br><br>If tank is not inspected, technician directs quality control manager to inspect tank. Retrain quality control manager on procedures for inspecting the storage tank prior to use to determine whether a contaminant was added. | *See Chapter 6, Table 6.15.* | Storage tank cleaning sign off form kept with records for Preventive Controls for Human Food corrective actions log |

## Table 5-12. Scenario 4.
## Worksheet 1-I: Mitigation Strategy Management Components

| (1) # | (2) Actionable Process Step | (3) Mitigation Strategy | (4) Food Defense Monitoring Procedure and Frequency | (5) Food Defense Corrective Actions Procedures | (6) Food Defense Verification Procedures | (7) Food Defense Records |
|---|---|---|---|---|---|---|
| | Breader | Restrict access to breader to authorized personnel. The facility issues these employees special red caps and identifies their job function on their employee identification badges. Workers authorized to work at the breader will have attained at least the position of "Food Safety Technician Level 3" with at least 4 years of employment and be in good standing with human resources with no pending or previous disciplinary actions. Employees working at the breader will immediately escort out of the area anyone not authorized to be in the area surrounding the breader. | Employees assigned to the breader constantly monitor the area and ensure that only authorized employees (i.e., those wearing special badges and red caps) are in the area. The employees in the breader area will notify security personnel if an unauthorized person is in the restricted area. The security personnel will use exception records to record when a deviation from the strategy is observed. | Escort unauthorized personnel from restricted area.<br><br>Immediately retrain employees on identifying authorized personnel and escorting unauthorized personnel out of the area.<br><br>If red cap or identification badge is missing, provide worker with replacement cap or badge for that day. | *See Chapter 6, Table 6.16.* | Food defense monitoring log<br><br>Food defense corrective actions log |

# Chapter 6:
# Mitigation Strategies Management Components: Food Defense Verification

This chapter provides an overview of the food defense verification mitigation strategy management component and is intended to help you understand the requirements for food defense verification as a part of your FDP. Food defense verification is one of three mitigation strategies management components. The other two are food defense monitoring (see Chapter 4) and food defense corrective actions (see Chapter 5). Mitigation strategies management components ensure the proper implementation of the mitigation strategies, taking into account the nature of each mitigation strategy and its role in the facility's food defense system. (21 CFR 121.138). (See Chapter 3 for information on identifying and implementing mitigation strategies). You have the flexibility to identify and implement food defense verification procedures that are appropriate for your facility. Note that if, through your vulnerability assessment, you appropriately determine that your facility has no actionable process steps, then you would not need to establish mitigation strategies or associated mitigation strategies management components.

## A. Overview of Food Defense Verification

Food defense verification is the application of methods, procedures, and other evaluations, in addition to food defense monitoring, to determine whether a mitigation strategy or combination of mitigation strategies is or has been operating as intended according to the food defense plan. (21 CFR 121.3). Food defense verification activities must be documented (21 CFR 121.150(c)) and must include, as appropriate to the nature of the mitigation strategy and its role in the facility's food defense system:

- Verification that food defense monitoring is being conducted (21 CFR 121.150(a)(1));
- Verification that appropriate decisions about food defense corrective actions are being made (21 CFR 121.150(a)(2));
- Verification that mitigation strategies are properly implemented and are significantly minimizing or preventing the significant vulnerabilities. To do so, you must conduct activities that include the following, as appropriate to the facility, the food, and the nature of the mitigation strategy and its role in the facility's food defense system:
    - review of the food defense monitoring and food defense corrective actions records to ensure that the records are complete, the activities reflected in the records occurred in accordance with the FDP, the mitigation strategies are properly implemented, and appropriate decisions were made about food defense corrective actions (21 CFR 121.150(a)(3)(i)), and
    - other activities appropriate for verification of proper implementation of mitigation strategies (21 CFR 121.150(a)(3)(ii)) (requires written procedures); and
- Verification of reanalysis (21 CFR 121.150(a)(4)).

Written verification procedures are required for "[o]ther activities appropriate for verification of proper implementation of mitigation strategies." (21 CFR 121.150(a)(3)(ii) and (b)). If you conduct verification by reviewing food defense monitoring and corrective actions records,

although not required, we recommend that you include these activities and their frequency in your FDP to help ensure that the verification activities are conducted.

## B. How Verification of Mitigation Strategies Differs from Verification of Preventive Controls

Preventive controls are often process-based, and therefore require verification activities such as validation, calibration, product testing, and environmental monitoring (see 21 CFR 117.155 and 117.165). In contrast, mitigation strategies are implemented to either restrict access to a product or reduce the ability of an attacker to contaminate a product and therefore do not require the same verification activities. Consequently, the food defense verification requirements are more flexible and less resource intensive than those needed for preventive controls. Discussion of other differences between food defense verification and food safety verification are included in the specific sections below.

## C. Food Defense Verification Activities

Food defense verification activities must include, as appropriate to the nature of the mitigation strategy and its role in the facility's food defense system,

(1) verification that food defense monitoring is being conducted as required by 21 CFR 121.138 (and in accordance with 21 CFR 121.140) (21 CFR 121.150(a)(1));
(2) verification that appropriate decisions about food defense corrective actions are being made as required by 21 CFR 121.138 (and in accordance with 21 CFR 121.145) (21 CFR 121.150(a)(2));
(3) verification that mitigation strategies are properly implemented and are significantly minimizing or preventing the significant vulnerabilities (21 CFR 121.150(a)(3)); and
(4) verification of reanalysis in accordance with 21 CFR 121.157 (21 CFR 121.150(a)(4)).

Many of the examples of food defense verification activities in this chapter involve records review because we expect this activity will be the most common method used to conduct verification activities; however, records review is not always required for verification. You have flexibility to use activities other than records review when appropriate, and some of the examples in this chapter demonstrate that flexibility. For example, in Scenario 3 an employee verifies monitoring by observing whether another employee assigned to monitoring is doing so as required by the facility's monitoring procedure.

The following sections describe each of these verification activities in more detail, provide examples, and highlight areas of flexibility.

### 1. Verification that Food Defense Monitoring is Being Conducted

You must verify that food defense monitoring is being conducted. (21 CFR 121.150(a)(1)). You have flexibility to determine how you verify food defense monitoring is being conducted, how frequently you do so, and who conducts this activity. One way to verify that food defense monitoring is being conducted is to review food defense monitoring records. If you choose to

review monitoring records and do so consistent with the requirements in 21 CFR 121.150(a)(3)(i), then you are not required to conduct additional monitoring verification activities under 21 CFR 121.150(a)(3)(i).

Scenario 2 includes an example of reviewing records to verify monitoring. In this scenario, a mitigation strategy is to visually observe the unloading bay during the opening of the conveyance and the attachment of hoses and pumping equipment. The monitoring procedure consists of a manager observing (at least twice weekly) the unloading bay during the opening of the conveyance and the attachment of hoses and pumping equipment. To verify that monitoring is being conducted, a senior manager reviews the monitoring logs weekly.

Verification of monitoring does not always require review of monitoring records. For example, an activity to verify monitoring that does not involve records review is for an employee to perform a similar, but independent, monitoring activity (e.g., the monitoring procedure is to ensure a gate is locked every Monday and Friday; the verification procedure is for a different employee to ensure the gate is locked on Wednesdays). Another example of an activity to verify monitoring that does not involve records review is for a different employee to periodically observe the employee conducting the food defense monitoring activity. In Scenario 3, the quality control manager inspects the food storage tank to ensure that a contaminant has not been added. The food defense monitoring procedure is that the QA technician signs and dates a log immediately prior to the liquid food being added to the tank after the monthly cleaning cycle indicating whether the inspection has occurred. As part of verification for food safety, a senior manager visually observes, quarterly, whether the QA technician is performing monitoring activities, and documents the observation in the verification log. In this scenario, the technician was already monitoring the tank for food safety purposes (i.e., to determine whether the tank had been cleaned), and the senior manager was verifying that activity. This scenario provides an example where food safety activities can be leveraged to comply with the food defense verification requirement.

Another appropriate verification method that does not include review of records is described in Chapter 4.F of this guidance. A mitigation strategy restricts access to an area using a locking gate that is opened with a specially coded access card. If the gate is left ajar beyond a specified time period, an automated monitoring system alarm indicates that the gate is not secured and generates an exception record that documents the instance where the mitigation strategy was not operating as intended. To verify monitoring, the facility periodically checks whether the restricted access system is working properly (and therefore that monitoring is being conducted automatically) by leaving the door unlocked, and checking whether the alarm is activated.

### 2. Verification that Appropriate Decisions About Food Defense Corrective Actions are Being Made

You must verify that appropriate decisions about food defense corrective actions are being made. (21 CFR 121.150(a)(2)). You have flexibility to determine how you verify that appropriate decisions about food defense corrective actions are being made, how frequently you do so, and who conducts this activity. One way to verify that appropriate decisions about food defense corrective actions are being made is to review food defense corrective actions records. If you choose to review corrective actions records and do so consistent with the requirements in 21

CFR 121.150(a)(3)(i), then you are not required to conduct additional corrective actions verification activities under 21 CFR 121.150(a)(3)(i).

Scenario 2 includes an example of reviewing records to verify corrective actions. In this scenario, a mitigation strategy is to have authorized personnel visually observe the unloading bay during the opening of the conveyance and the attachment of hoses and pumping equipment. The corrective action is to retrain an employee who is not observing the unloading bay. To verify that the appropriate corrective action is being taken, a senior manager reviews the corrective actions logs weekly.

Verification of food defense corrective actions does not always require review of corrective actions records. An activity to verify that appropriate decisions are being made about corrective actions that does not involve records review is for an employee to observe the corrective actions being taken by another employee (e.g., when a broken lock is found, a senior manager visually observes replacement of the lock). Similarly, in Scenario 4, the manager visually observes whether corrective actions are being taken (e.g., the manager observes whether unauthorized personnel are escorted out of the restricted area and whether employees are being immediately retrained).

### 3. Verification that Mitigation Strategies are Properly Implemented and are Significantly Minimizing or Preventing the Significant Vulnerabilities

You must verify that mitigation strategies are properly implemented and are significantly minimizing or preventing the significant vulnerabilities. (21 CFR 121.150(a)(3)). To do so, you must review food defense monitoring and food defense corrective actions records and conduct other activities as appropriate to the facility, the food, and the nature of the mitigation strategy and its role in the facility's food defense system. The purpose of the records review is to ensure that the records are complete, activities reflected in the records occurred in accordance with the FDP, mitigation strategies are properly implemented, and appropriate decisions were made about food defense corrective actions (21 CFR 121.150(a)(3)).

#### a. Review of Food Defense Monitoring and Corrective Actions Records Within Appropriate Timeframes

If you conduct verification by reviewing monitoring and corrective actions records, you must review the records within appropriate timeframes. (21 CFR 121.150(a)(3)(i)). In Chapter 4.D.1 of this guidance, we discuss how to consider the nature of the mitigation strategy and its role in the facility's food defense system in determining the frequency of food defense monitoring. Because of their nature, most food defense mitigation strategies may be monitored less frequently than preventive controls for food safety, which are often monitored continuously. Similarly, food defense verification may occur less frequently.

Determining an appropriate timeframe to verify the records for monitoring should take into account the frequency of the monitoring activity, which reflects the nature of the mitigation strategy. Generally, the more frequently that monitoring occurs, the shorter the appropriate timeframe for records review is likely to be. In most cases there will be more than one appropriate timeframe possible for records review. For example, in Scenario 1, an employee assigned to ingredient storage monitors whether a lock is in place and locked at the beginning and end of a tank's 48-hour cleaning cycle. The facility determines that a QA technician will

review monitoring and corrective actions records once per week. The facility could have decided to review the records less frequently, e.g., every two weeks. In addition, more frequent records review is always an option. For example, the facility could have chosen to review monitoring and corrective actions records every other day to minimize the potential time between the occurrence of an implementation problem and the discovery and correction of the problem.

### b. Ensuring that Food Defense Monitoring and Corrective Actions Records are Complete

If you conduct verification by reviewing monitoring and corrective actions records, you must review the records to ensure that they are complete (i.e., that they contain the required information). (21 CFR 121.150(a)(3)(i)).

In Scenario 1, a monitoring procedure is for an employee assigned to ingredient storage to observe whether a lock is in place and locked at the beginning and end of a tank's 48-hour cleaning cycle. The monitoring is documented in a log entitled "liquid storage tank observations record" and includes the date, time, and a written "yes" or "no" to indicate whether the lock was locked. The food defense corrective actions are to properly engage the lock if it is unlocked and retrain the employee and to replace a broken lock. The food defense corrective actions are documented in the "food defense corrective actions log," which includes a description of the actions taken (e.g., the lock was relocked and an employee was retrained), the date and time the lock was relocked, the name of the employee who was retrained, the date of the retraining, and the name of the trainer. To ensure the records are complete, the following questions are considered:

- Are the records accurate, indelible, and legible, as required by 21 CFR 121.305(c)?
- Were the records created when the activities were performed, as required by 21 CFR 121.305(d)? For activities described in Scenario 1, did the employee create the monitoring record when she observed whether the lock was locked at the beginning and end of the tank's cleaning cycle? If corrective actions were required, were the corrective actions records created when the lock was properly engaged or replaced, and when the employee was retrained?
- Do the records contain the necessary details to provide the history of the work performed, as required by 21 CFR 121.305(e)? For activities described in Scenario 1, do the corrective actions records include details needed to determine if the lock was properly engaged or replaced, when the employee was retrained, who the employee was, and who retrained the employee? Additionally, does the monitoring record contain the actual values and observations obtained during monitoring—in this example, a "yes" or "no" indicating whether the lock was locked, as required by 21 CFR 121.305(b)?
- Do the records include the signature or initials of the individuals performing the activities, as required by 21 CFR 121.305(f)(3)? Do the records include the dates and, when appropriate, times the activities were documented, as required by 21 CFR 121.305(f)(2)? In this example, the monitoring procedure occurs at a set time, so the record should include the time the activity was documented.

### c. Ensuring that Activities Reflected in Food Defense Monitoring and Corrective Actions Records Occurred in Accordance with the Food Defense Plan

If you conduct verification by reviewing monitoring and corrective actions records, you must ensure that the activities reflected in the records occurred in accordance with the food defense plan. (21 CFR 121.150(a)(3)(i)). This verification can be done by comparing the written procedures for food defense monitoring and corrective actions in the FDP with the records documenting these activities.

In Scenario 2, a mitigation strategy is the use of tamper-evident tape on hose ends after capping. The monitoring procedure is for the supply chain supervisor to observe whether the hose caps are on and taped after daily operations. As part of verification, a supervisor conducts a weekly review of the information in the monitoring log to ensure that the facility followed its monitoring procedure. If the monitoring log indicates that the supply chain supervisor observed each day whether the hose caps were on and taped at the end of operations (i.e., the supply chain supervisor marked "yes" or "no" on the monitoring record and initialed and dated the monitoring record), the supervisor would conclude that the monitoring activities occurred in accordance with the FDP.

The corrective actions for this mitigation strategy include replacing broken caps, reapplying ripped tape, cleaning and flushing the hoses, and retraining the employee on capping and tape use. As part of verification, a supervisor conducts a weekly review of the information in the corrective actions log to ensure the that the facility followed its corrective actions procedure. If the corrective actions log indicates that, when the mitigation strategy was not properly implemented, appropriate corrective actions were taken (e.g., broken tape was reapplied, the hoses were cleaned and flushed, and the employee was retrained), the supervisor would conclude that the corrective actions occurred in accordance with the FDP.

Another mitigation strategy in Scenario 2 is to use tamper-evident seals on inbound shipping conveyances. The monitoring procedure is for a technician, upon arrival of the load and before hooking up the hose for each delivery, to observe whether the seal is intact and matches documentation numbers. As part of verification, a supervisor conducts a monthly review of the monitoring records (the receiving/delivery paperwork) to ensure that the facility followed its monitoring procedure. If the monitoring records indicate that, for each load, the technician checked upon arrival whether the seal was intact and matched documentation numbers, the supervisor would conclude that the monitoring activities occurred in accordance with the FDP.

The corrective action for this mitigation strategy is to reject the load. As part of verification, a supervisor conducts a monthly review of the information in the corrective actions log to ensure that the facility followed its corrective action procedure. If the corrective actions log indicates that whenever a seal was not intact or did not match documentation numbers upon arrival, the load was rejected, the supervisor would conclude that the corrective action occurred in accordance with the FDP.

### d. Review of Food Defense Monitoring and Food Defense Corrective Actions Records to Ensure that Mitigation Strategies are Properly Implemented

If you conduct verification by reviewing monitoring and corrective actions records, you must review the records to ensure that mitigation strategies are properly implemented. (21 CFR 121.150(a)(3)(i)). This review may overlap records review for other purposes (e.g., to ensure that activities occurred in accordance with the FDP) and may occur simultaneously with review for other purposes or sequentially with such review. Below we provide an example of sequential review.

First, a facility could review the monitoring and corrective actions logs for completeness (e.g., is the monitoring log legible? Do the entries indicate whether and when monitoring was performed? Were the entries made at the time of monitoring?). In Scenario 2, for the bulk liquid receiving actionable process step, the facility would review the food defense monitoring log to check whether it contains, among other things, entries made after daily operations indicating whether the hose caps were on and taped, and review the corrective actions log to determine whether, among other things, the corrective actions were documented when they occurred.

Next, the facility could determine whether monitoring was conducted and corrective actions were taken as required by the FDP. For example, did the supply chain supervisor conduct monitoring at the required frequency? Did the supervisor observe whether the hose caps were on and taped? Does the corrective actions log indicate that broken caps were replaced, ripped tape was reapplied, the hoses were cleaned and flushed, and that employees were retrained?

Next, as part of ensuring that mitigation strategies are properly implemented, the facility could consider the results of the monitoring, i.e., what did the monitoring show regarding whether the mitigation strategy was properly implemented? This might be as simple as a "yes" or "no" in the monitoring log for a particular date and time referring to whether the hoses were capped and taped. If a monitoring log indicates that the mitigation strategy was properly implemented on a specific occasion, no further records review regarding that monitoring result would be taken. If the monitoring log indicates that a mitigation strategy was not properly implemented (e.g., the hose caps were not taped), then the corrective actions log could be reviewed for that date to see whether appropriate corrective actions were taken (see next section for further discussion of review of corrective actions).

### e. Review of Food Defense Monitoring and Food Defense Corrective Actions Records to Ensure Appropriate Decisions were Made About Food Defense Corrective Actions

If you conduct verification by reviewing monitoring and corrective actions records, you must review the records to ensure that appropriate decisions about food defense corrective actions were made. (21 CFR 121.150(a)(3)(i)). If a monitoring record indicated a mitigation strategy was not properly implemented, a corrective actions record should indicate that corrective actions were taken. In reviewing the corrective actions records, you would determine whether appropriate action was taken to identify and correct an implementation problem and whether appropriate action was taken, if necessary, to reduce the likelihood that the problem will recur. For example, in Scenario 1, if a monitoring record indicates that the access hatch on the tank was not locked, a corrective actions record should reflect that the lock on the access hatch was

locked, and the responsible employee was retrained. If the corrective actions records reflect a sustained pattern of implementation failures (i.e., the lock on the hatch being left unlocked) after corrective actions were taken, you should consider whether the appropriate corrective actions were taken to reduce the likelihood of recurrence and consider whether a different mitigation strategy is needed. See Chapter 7.B.4 of this guidance for more information on when to conduct a reanalysis.

### f. Other Activities Appropriate for Verification of Proper Implementation of Mitigation Strategies

Section 121.150(a)(3)(ii) provides for "[o]ther activities appropriate for verification of proper implementation of mitigation strategies." We explained in the final rule that we made this addition "to allow for increased flexibility in verifying mitigation strategies are properly implemented beyond what is included in § 121.150(a)(3)(i) [review of monitoring and corrective action records]." 81 Fed. Reg. 34166 at 34205 (May 27, 2016). As explained below, you have the flexibility to conduct other activities appropriate for verification of proper implementation of mitigation strategies instead of the records review specified in 21 CFR 121.150(a)(3)(i). If you conduct other verification activities, you must have written procedures for them, including the frequency for which they are to be performed, in your FDP. (21 CFR 121.150(b)).

Scenario 4 contains an example of a verification activity that can substitute for records review under 21 CFR 121.150(a)(3)(i). In Scenario 4, the mitigation strategy provides that authorized employees in the breader area are to wear special red caps and identification badges that identify their job functions. Employees working at the breader are to immediately escort unauthorized individuals (i.e., individuals not wearing the cap and badge) out of the restricted area. To verify implementation of the mitigation strategy, the facility conducts a penetration audit once per month, which consists of sending an employee who is not wearing the cap or badge into the area and observing whether the authorized employees identify and escort the unauthorized individual out of the restricted area. If they do so, the manager would conclude the strategy is properly implemented. If this verification activity is used, records review is not required under 21 CFR 121.150(a)(3)(i).

In addition, it is possible for an "[o]ther activit[y] appropriate for verification of proper implementation of mitigation strategies" to satisfy some or all of the verification requirements in 21 CFR 121.150(a)(1) and (2). Those provisions require verification of monitoring and corrective actions but do not require that it be achieved via records review. To the extent a verification activity, such as a penetration audit, is able to verify that food defense monitoring is being conducted as required or that appropriate decisions about corrective actions are being made, no additional verification is required by 21 CFR 121.150(a)(1) and (2). The penetration audit described above is able to verify whether monitoring is occurring (i.e., the manager can observe if the employees are monitoring the area) as required by 21 CFR 121.150(a)(1). The audit also is able to verify whether appropriate decisions are made about corrective actions procedures (i.e., the manager can observe if the employees escort unauthorized employees out of the area, if employees are immediately retrained on escorting employees out of the area, and if caps or badges are given to authorized employees) as required by 121.150(a)(2). Note that because the penetration audit is not specified in 21 CFR 121.150(a)(3)(i), the procedure and its frequency must be written. (21 CFR 121.150(b)).

### 4. Verification of Reanalysis

You must verify that reanalysis of your FDP occurred when required by 21 CFR 121.157. (21 CFR 121.150(a)(4)). Verifying reanalysis is done by reviewing documentation of the basis for a conclusion that no revisions were needed or reviewing the revised FDP to ensure that reanalysis was conducted on the applicable portion(s) of the FDP. In Chapter 7.B.3 of this guidance, we provide an example involving reanalysis triggered by new information about potential vulnerabilities associated with a food operation (such as information from an equipment manufacturer that a newly identified equipment design flaw allows the integrated safety features to be easily disabled, providing access to the food). To verify reanalysis, the facility would consider whether a reanalysis of the relevant part of the vulnerability assessment was conducted to determine whether a significant vulnerability is present at this process step and, if so, what mitigation strategies and management components are necessary. (21 CFR 121.157(b)(2)).

In another example, a company installs an electronic badging/access system intended to give different levels of access to different categories of people inside the company's facilities (e.g., visitors are limited to the front lobby, contractors are given temporary access to designated areas, and the most trusted employees are assigned to restricted areas immediately surrounding actionable process steps). After the company becomes aware of new information about potential vulnerabilities (i.e., that the system will not be able to distinguish between contractors and the most trusted employees), a reanalysis of any mitigation strategies relying on the badging system to significantly minimize or prevent access to actionable process steps was required by 21 CFR 121.157(b)(2). During her verification of reanalysis, a headquarters official determines that no modifications were made to the FDP after the facility learned the new information about the system, and the facility did not document a determination that no changes were needed. The headquarters official therefore concludes that a reanalysis was required but did not occur and arranges for a reanalysis to be conducted.

## D. Documentation of Food Defense Verification Activities

You must document your food defense verification activities in records. (21 CFR 121.150(c)). Accurate recordkeeping provides documentation that verification activities are being conducted as required and as specified in the FDP. We discuss records requirements in detail in Chapter 9 of the guidance.

For example, in Scenario 2, a supervisor determines whether the hoses were monitored as required by the FDP and records this determination in a verification record that is signed and dated. The time period covered by the verification of monitoring should be indicated in the record. The supervisor also determines whether corrective actions were implemented as required by the FDP, including whether appropriate decisions were made, and records this determination in a signed and dated verification record. The supervisor also would record a determination that corrective actions should have been taken but were not and indicate the relevant date. For example, "on May 2, monitoring records show that the hoses were not capped and corrective actions do not indicate that any corrective actions were taken. The corrective actions procedures were not followed."

## E. Scenarios

Tables 6.13 – 6.16 below provide examples of food defense verification procedures for the scenarios listed in Chapters 3-5 of this guidance. Because in many cases food defense verification activities will be similar across mitigation strategies, you may choose to use short phrases, abbreviations, or footnotes to minimize repetition of text.

**Table 6-13. Scenario 1.**
**Worksheet 1-I: Mitigation Strategies Management Components**

| (1) # | (2) Actionable Process Step | (3) Mitigation Strategy | (4) Food Defense Monitoring Procedure and Frequency | (5) Food Defense Corrective Actions Procedures | (6) Food Defense Verification Procedures | (7) Food Defense Records |
|---|---|---|---|---|---|---|
| | Liquid ingredient storage tank | Use a lock to secure access hatch on ingredient storage tank. Keys to the lock are held in the security office and can only be retrieved with good reason and approval from the facility security manager or food defense coordinator. | Employee assigned to ingredient storage observes whether the lock is in place and locked at the beginning and end of the tank's 48-hour cleaning cycle. | If lock is not locked, properly engage lock, and retrain employee on proper lock use.<br><br>If lock is broken, replace lock. | QA technician reviews tank observation records to verify monitoring (weekly), and reviews correction action log (weekly)<br><br>Review records to verify reanalysis every 3 years and when required by 21 CFR 121.157(b) | Liquid storage tank observations record<br><br>Corrective actions log<br><br>Food defense verification log |

**Table 6-14. Scenario 2.**

**Worksheet 1-I: Mitigation Strategies Management Components**

| (1) # | (2) Actionable Process Step | (3) Mitigation Strategy | (4) Food Defense Monitoring Procedure and Frequency | (5) Food Defense Corrective Actions Procedures | (6) Food Defense Verification Procedures | (7) Food Defense Records |
|---|---|---|---|---|---|---|
| | Bulk liquid receiving | Use tamper-evident seals on inbound shipping conveyances. Match the numbers on the seals with the numbers provided on shipping documentation from the supplier. If the seals do not match, the load will be rejected to prevent potentially adulterated ingredient from entering the facility. | Technician assesses whether the seal is intact and matches seal or documentation numbers upon arrival of the load, before hooking up the hose for each delivery. | If seals do not match, are broken, or are missing, the load will be rejected. | Supervisor reviews receiving/delivery paperwork, and reviews corrective actions log (monthly)<br><br>Review records to verify reanalysis every 3 years and when required by 21 CFR 121.157(b) | Receiving/delivery paperwork that includes additional information to indicate monitoring was completed<br><br>Food defense corrective actions log<br><br>Food defense verification log |

| (1) # | (2) Actionable Process Step | (3) Mitigation Strategy | (4) Food Defense Monitoring Procedure and Frequency | (5) Food Defense Corrective Actions Procedures | (6) Food Defense Verification Procedures | (7) Food Defense Records |
|---|---|---|---|---|---|---|
| | Bulk liquid receiving | Use tamper-evident tape on hose ends after capping. | After daily operations, supply chain supervisor confirms that the hose caps are on and taped. | If caps are broken, replace caps. Clean and flush hose.<br><br>If tape is ripped, reapply tape. Clean and flush hose.<br><br>Retrain employee on capping and tape use. | Supervisor reviews monitoring and corrective actions logs (weekly)<br><br>Review records to verify reanalysis every 3 years and when required by 21 CFR 121.157(b) | Food defense monitoring log<br><br>Food defense corrective actions log<br><br>Food defense verification log |
| | Bulk liquid receiving | Use authorized personnel for visual observation of the unloading bay during the opening of the conveyance and the attachment of hoses and pumping equipment. | On a periodic basis, (but at least twice weekly), a manager observes whether personnel are visually observing the unloading bay during the opening of the conveyance and the attachment of hoses and pumping equipment. | Retrain employee on observation of the bay. | Senior manager reviews monitoring and corrective actions logs (weekly)<br><br>Review records to verify reanalysis every 3 years and when required by 21 CFR 121.157(b) | Food defense monitoring log<br><br>Food defense corrective actions log<br><br>Food defense verification log |

**Table 6-15. Scenario 3.**
**Worksheet 1-I: Mitigation Strategies Management Components**

| (1) # | (2) Actionable Process Step | (3) Mitigation Strategy | (4) Food Defense Monitoring Procedure and Frequency | (5) Food Defense Corrective Actions Procedures | (6) Food Defense Verification Procedures | (7) Food Defense Records |
|---|---|---|---|---|---|---|
| | Liquid food storage tank | Inspect liquid food storage tank prior to use. Immediately prior to reintroducing food, the tank will be visually inspected by the quality control manager using high intensity flashlights and ultraviolet lights to ensure that no contaminant has been added to the tank while it was open and accessible after cleaning. | QA technician signs and dates log immediately prior to the liquid food being added to the tank after the monthly cleaning cycle. | If flashlights or ultraviolet lights are malfunctioning or broken, repair or replace them.<br><br>If tank is not inspected, technician directs quality control manager to inspect tank. Retrain quality control manager on procedures for inspecting the storage tank prior to use in order to determine whether a contaminant was added. | Senior manager observes QA technician performing monitoring activities (quarterly) and reviews corrective actions log (quarterly)<br><br>Review records to verify reanalysis every 3 years and when required by 21 CFR 121.157(b) | Storage tank cleaning sign off form kept with records for Preventive Controls for Human Food<br><br>Food safety corrective actions log<br><br>Food safety verification log |

**Table 6-16. Scenario 4.**
**Worksheet 1-I: Mitigation Strategies Management Components**

Table 6.16 appears on the next page

| (1) # | (2) Actionable Process Step | (3) Mitigation Strategy | (4) Food Defense Monitoring Procedure and Frequency | (5) Food Defense Corrective Actions Procedures | (6) Food Defense Verification Procedures | (7) Food Defense Records |
|---|---|---|---|---|---|---|
| | Breader | Restrict access to breader to authorized personnel. Issue these employees special red caps and identify their job function on their employee identification badges. Authorize only workers to work at the breader who have attained at least the position of "Food Safety Technician Level 3" with at least 4 years of employment and are in good standing with human resources with no pending or previous disciplinary actions. Employees working at the breader immediately escort out of the area anyone not authorized to be in the area surrounding the breader. | Employees assigned to the breader constantly monitor the area and ensure that only authorized employees (i.e., those wearing special badges and red caps) are in the area. The employees in the breader area notify security personnel if an unauthorized person is in the restricted area. The security personnel use exception records to record when a deviation from the strategy is observed. | Escort unauthorized personnel from restricted area.<br><br>Immediately retrain employees on identifying authorized personnel and escorting unauthorized personnel out of the area.<br><br>If red cap or identification badge is missing, provide worker with replacement cap or badge for that day. | Once per month, and on an unannounced, irregular basis, a manager conducts a penetration audit, which consists of sending an employee, who is not wearing the cap or badge, into the area and observing whether the authorized employees adhere to mitigation strategy implementation responsibilities. The audit verifies food defense monitoring is being conducted because it provides the manager the opportunity to observe whether the employees are implementing the monitoring procedure. The audit verifies whether appropriate decisions about corrective actions were made because the manager can observe whether the unauthorized personnel are escorted from the area, and whether immediately retraining of employees occurred. The manager can also observe whether the red cap or identification badge was provided for the day.<br><br>Review records to verify reanalysis every 3 years and when required by 21 CFR 121.157(b) | Food defense monitoring/ exception records log<br><br>Food defense corrective actions log<br><br>Food defense verification log |

# Chapter 7: Reanalysis

This chapter describes food defense plan (FDP) reanalysis activities and is intended to help you understand when to conduct a reanalysis of your FDP, how to conduct the reanalysis, and what aspects of the reanalysis you should document.

## A. Overview of Reanalysis

The purpose of the reanalysis is to determine whether your FDP continues to be current and accurately reflects your significant vulnerabilities and to determine whether your mitigation strategies and mitigation strategy management components remain appropriate for your facility.

You must conduct a reanalysis of your FDP as a whole at least once every 3 years. (21 CFR 121.157(a)). You also must conduct a reanalysis of the FDP as a whole, or the applicable portion of the FDP, whenever:

> (1) A significant change made in the activities conducted at your facility creates a reasonable potential for a new vulnerability or a significant increase in a previously identified vulnerability (21 CFR 121.157(b)(1));
>
> (2) You become aware of new information about potential vulnerabilities associated with the food operation or facility (21 CFR 121.157(b)(2));
>
> (3) You find that a mitigation strategy, a combination of mitigation strategies, or the FDP as a whole is not properly implemented (21 CFR 121.157(b)(3)); and
>
> (4) FDA requires reanalysis to respond to new vulnerabilities, credible threats to the food supply, and developments in scientific understanding including, as appropriate, results from the Department of Homeland Security biological, chemical, radiological, or other terrorism risk assessment (21 CFR 121.157(b)(4)).

The results of your reanalysis will vary depending on each situation and may not always lead to changes to your FDP. If your reanalysis concludes that a significant change in the activities conducted at your facility has created a reasonable potential for a new vulnerability or a significant increase in a previously identified vulnerability, then you must revise your written FDP or document the basis for the conclusion that no revision is needed. (21 CFR 121.157(d)). For example, if your reanalysis concludes that implementation of additional mitigation strategies is needed, you would need to revise your FDP to include the new strategies and associated management components.

## B. Circumstances Requiring a Reanalysis

The FDP is a dynamic document that includes your current vulnerability assessment, mitigation strategies, mitigation strategy management components, and other documents. It is important that you update your FDP so that it remains current and relevant. The FDP as a whole must be reanalyzed at least once every 3 years. (21 CFR 121.157(a)). In addition, several situations may trigger a reanalysis of your entire FDP or portions of the plan, which we refer to as a "situational reanalysis."

### 1. Every Three Years

You must reanalyze your entire FDP at least once every 3 years. (21 CFR 121.157(a)). For example, if your FDP was last fully reanalyzed on July 1, 2019, you must fully reanalyze it again by July 1, 2022. However, if you reanalyze the entire plan before three years have elapsed— for example, you perform a reanalysis of the whole FDP two years later (on March 3, 2021) — then the three years begins again starting with the date that the entire plan was reanalyzed (March 3, 2021), and you would have until March 3, 2024 to perform the next full reanalysis under this requirement. Note that a reanalysis that does not include the entire FDP does not restart the three-year time period. Further, when the full reanalysis is conducted, it must include those parts that were previously reanalyzed during a partial reanalysis. (21 CFR 121.157(a)).

### 2. Significant Changes in Activities

The first trigger for a situational reanalysis is a significant change in the activities conducted at your facility that creates a reasonable potential for a new vulnerability or a significant increase in a previously identified vulnerability. (21 CFR 121.157(b)(1)). A reasonable potential for a new vulnerability could arise, for example, from installation of new equipment that includes an access hatch not present on the previous equipment. Because the access hatch provides a greater degree of physical access to the product, it could increase the score you assign to Element 2 (degree of physical access to the product). A reasonable potential for a significant increase in a previously identified vulnerability could arise, for example, from new equipment with increased capacity. The increased capacity could increase the score you assign to Element 1 (potential public health impact) because a greater number of servings could now be adulterated, leading to more potential illnesses and deaths. In your situational reanalysis you should reanalyze the applicable sections of your FDP (at a minimum, the step where it occurs) to see what, if any, effect the change has on your current vulnerabilities, mitigation strategies, and mitigation strategy management components. (21 CFR 121.157(b)(1)). Your reanalysis will help you determine whether you need to make changes to your existing FDP.

Whether a change creates a "reasonable potential" for a new vulnerability or a significant increase in a previously identified vulnerability depends on the circumstances. For example, if you replace a piece of aging equipment with a newer version of the same equipment (i.e., same design, features, and specifications), this will most likely have little to no effect on the evaluation

of the three fundamental elements and, in most cases, would not constitute a reasonable potential for a new vulnerability or a significant increase in a previously identified vulnerability at this point, step, or procedure. On the other hand, if you replace a piece of equipment with a newer model that has a different design, different features, or larger capacity, your original evaluation of the three fundamental elements is likely outdated. The significant changes in this equipment create a reasonable potential for a new vulnerability or a significant increase in a previously identified vulnerability. This equipment change should trigger a reanalysis of at least the portion of the FDP that addresses the vulnerability at this point, step, or procedure to determine whether the change has created a new vulnerability or an increase in an existing vulnerability, and whether any changes in mitigation strategies are necessary.

In some circumstances, a permanent equipment change may alter inherent characteristics of a processing step to such a degree that a reanalysis of the vulnerability of this step would determine that a significant vulnerability no longer exists. Once the permanent equipment change has occurred, you may choose to reanalyze the FDP so that new inherent characteristics associated with the process step are considered in determining whether a significant vulnerability exists. If the reanalysis determines that the permanent equipment change results in no significant vulnerability now being present at this step, the process step is no longer an actionable process step and does not require mitigation strategies. (See Chapter 2.F for detailed discussion on inherent characteristics). The facility would update the FDP to reflect these changes.

For example, based on its VA, a facility determines that a liquid holding tank with a hatch at the top is an actionable process step because the hatch is accessible via a ladder that is affixed to the side of the tank. A lock is chosen as the mitigation strategy to reduce access to the hatch. Subsequently, the facility notices that the hatch is rarely opened and concludes that the ladder on the side of the tank is not necessary. The facility then permanently removes the ladder from the tank, which eliminates access to the hatch and changes the inherent characteristics of the tank. In the reanalysis, because physical access (Element 2) to the hatch has been eliminated, the facility assigns Element 2 a score of 1. Based on this reanalysis of the holding tank, the facility concludes the holding tank is not an actionable process step and no mitigation strategies are needed.

### 3. New Information about Potential Vulnerabilities

The second trigger for a situational reanalysis is when you become aware of new information about potential vulnerabilities associated with your food operation or facility. (21 CFR 121.157(b)(2)). New information about potential vulnerabilities could come from many possible sources (e.g., media, the food industry, equipment manufacturers), and may provide information related to reanalysis activities for the entire FDP or specific portions of it. For example, your processing line may include a piece of equipment with integrated safety features that you considered as inherent characteristics in your VA. Based in part on the integrated safety features, you determine that this process step was not significantly vulnerable and therefore is

not an actionable process step. After conducting your VA, you receive a letter from the equipment manufacturer informing you that a newly identified design flaw allows the integrated safety features to be easily disabled, providing access to the food. This new information about a potential vulnerability of this equipment requires that you conduct a reanalysis of the relevant part of your vulnerability assessment to determine whether a new significant vulnerability is present at this process step and whether associated mitigation strategies and management components are necessary. (21 CFR 121.157(b)(2)).

**4. Improper Implementation**

The third trigger for a situational reanalysis is when you find that a mitigation strategy, a combination of mitigation strategies, or the FDP as a whole is not properly implemented. (21 CFR 121.157(b)(3)).

For example, an FDP provides that a mitigation strategy for a bulk liquid storage tank is to use a lock to secure the access hatch when unattended or not in use.

A verification review of food defense monitoring and corrective actions records shows that the lock was not consistently being placed on the access hatch to the storage tank (i.e., the hatch on the tank was left unlocked on multiple days). The improper implementation of the mitigation strategy triggers a reanalysis. As a result, the facility might determine that a new mitigation strategy is needed (e.g., restrict access to the storage tank to authorized personnel). Note that if a mitigation strategy is changed, mitigation strategy management components (i.e., food defense monitoring, corrective actions, and verification) must be reanalyzed because they are dependent on the nature of the mitigation strategy.

You are also required to conduct a reanalysis when the FDP as a whole is not properly implemented. For example, a facility identifies background checks as a mitigation strategy to be used in combination with other mitigation strategies for all actionable process steps within the facility. The monitoring procedure is to assess whether the checks were completed prior to assigning the employee to an actionable process step. The corrective actions procedure is to conduct the check prior to assigning the employee to an actionable process step if the check has not yet been conducted and to reassign an employee who has been assigned to an actionable process step without a background check. A manager discovers that there are no monitoring or corrective actions records for the background checks and determines the background check program was never implemented. Further, the manager determines it is no longer feasible to implement the program. In this example, the entire FDP must be reanalyzed because the mitigation strategies at each actionable process step were determined to be adequate based on the inclusion of background checks which were not conducted. Without the implementation of background checks, the mitigation strategies may not be adequately minimizing or preventing the significant vulnerabilities at each actionable process step.

### 5. Reanalysis Required by FDA

The final trigger for a situational reanalysis is whenever FDA requires a reanalysis to respond to new vulnerabilities, credible threats to the food supply, or new developments in scientific understanding. (21 CFR 121.157(b)(4)). These new developments could include results from the U.S. Department of Homeland Security biological, chemical, radiological or other terrorism risk assessments.

## C. Voluntary Reanalysis

A voluntary reanalysis can occur at any time. For example, after you have conducted a VA and during your consideration of mitigation strategies for an actionable process step, you conclude that making a permanent change to the equipment at the process step is the most appropriate and cost-effective way to significantly minimize the significant vulnerability at the step. After the permanent equipment change has been made, you can choose to immediately conduct a reanalysis of that process step, which may result in a determination that you no longer have a significant vulnerability at that process step.

## D. Conducting a Reanalysis

Once you have determined the need to conduct a reanalysis, you should determine how much of the FDP should be reanalyzed.

Verifying that the FDP is still applicable and relevant and making any necessary changes is the focus of reanalysis. Depending on the reason for the reanalysis, reanalysis activities may include:

- Confirming the accuracy of the product description and flow diagram;
- Checking for new guidance or information related to vulnerabilities;
- Ensuring that any changes at the facility are assessed to determine whether there is a change in the vulnerabilities;
- Ensuring that mitigation strategies are operating as intended;
- Ensuring that mitigation strategies are monitored as specified by the FDP;
- Ensuring that appropriate corrective actions have been taken and verification activities have been completed;
- Ensuring that records are completed accurately and at the appropriate time intervals.

**Determining How Much of the Plan Needs Reanalysis**

A situational reanalysis may include all or part of the FDP, depending on the circumstances. Once you have determined that a certain circumstance triggers a reanalysis, you should decide whether you need to reanalyze the entire FDP or whether only a part of the FDP is implicated.

If you have not reanalyzed your plan for three years, you must reanalyze the entire plan. Many other situations will require that you reanalyze only part of your FDP. For example, your facility adds an entirely new stand-alone production line for a new type of product, and this line has no effect on any of the other activities at your facility. This would trigger a reanalysis because there is a potential that this change may create a new vulnerability. (21 CFR 121.157(b)(1)). Your reanalysis should include a VA for this new product and each point, step, or procedure associated with it. (21 CFR 121.130(a)). Your reanalysis would not need to include parts of the FDP not associated with the new production line.

In another situation, your facility replaces a grinder with a new one with different attributes and access controls that trigger a reanalysis because there is a reasonable potential that this change may create a new vulnerability or a significant increase in a previously identified vulnerability. (21 CFR 121.157(b)(1)). Your VA was conducted using the Key Activity Types method (see Chapter 2.E). This grinding step aligned with the Mixing and Similar Activities KAT and was identified as an actionable process step. The new grinder would still align with this KAT, but you should reanalyze the mitigation strategies previously chosen to determine whether these strategies provide assurances that the significant vulnerability at the grinding step will be significantly minimized or prevented. If changes are made to the mitigation strategies, the mitigation strategies management components must also be updated.

## E. Timeframe for Completing a Reanalysis

You must complete a reanalysis of your FDP as a whole within 3 years from the date of your previous complete reanalysis. (21 CFR 121.157(a)). See Section B.1 of this chapter for more information on the 3-year reanalysis timeframe.

To ensure adequate protection of the food at your facility, we recommend that you perform a situational reanalysis and make any necessary changes as quickly as possible after you determine that a situational reanalysis is needed. You must complete your reanalysis and implement any necessary additional mitigation strategies before changes in activities become operative and, when necessary, within 90 calendar days after production. A time period exceeding 90 days after production of the applicable food first begins is permissible if the time period is reasonable and a written justification is prepared. (21 CFR 121.157(c)). What constitutes a reasonable timeframe beyond the 90 day requirement will depend on the relevant circumstances, which you should describe in your justification.

For anticipated changes in your facility (e.g., installation of new equipment, modifications to a production line, or adding a new product), you should conduct your reanalysis in advance of production, once you have all relevant information to inform the reanalysis. For example, if you are planning on upgrading processing equipment due to advances in technology and the age and wear of your existing equipment, you should conduct the reanalysis and implement mitigation strategies before the changes you make are operational. In contrast, if a sudden equipment

failure causes you to upgrade processing equipment, you may need additional time to perform a reanalysis and implement mitigation strategies. If necessary, you would have 90 days after production with the new equipment begins and a longer time period if reasonable and you prepare a written justification. (21 CFR 121.157(c)(3)).

## F. Documenting the Reanalysis

If you revise the FDP as a result of a reanalysis, the results of the reanalysis will be reflected in your newly signed and dated FDP. If you conduct a reanalysis and determine that no revisions are needed, you must document the basis for this conclusion (i.e., an explanation for why there were no changes needed). (21 CFR 121.157(d)).

# Chapter 9: Records

This chapter provides guidance on the general recordkeeping requirements that apply to all required records, including identifying the records you are required to keep and their format, location, and length of required retention. This chapter also provides recommendations on how you can protect your records from unauthorized release and describes FDA's protection of your records in our possession.

## A. Required Records

You are required to make and keep records related to the following:

- Food defense plan, including vulnerability assessment, mitigation strategies, food defense monitoring procedures, food defense corrective actions procedures, and food defense verification procedures (21 CFR 121.126(b) and (c));
- Documentation of food defense monitoring of mitigation strategies (21 CFR 121.140(c));
- Documentation of food defense corrective actions taken (21 CFR 121.145(b));
- Documentation of food defense verification activities (21 CFR 121.150(c));
- Documentation of food defense plan reanalysis (21 CFR 121.157(d)); and
- Records documenting required training (21 CFR 121.4(e)).

For detailed guidance on the specific records required, see Chapters 1-8 regarding the food defense plan, vulnerability assessment, mitigation strategies, mitigation strategy management components, reanalysis, and training.

## B. Generally Applicable Requirements

You should evaluate which records are required and that are applicable to your facility, and develop an approach to complete and maintain the required records. You must incorporate all of the general requirements of 21 CFR 121.305 into each record, as applicable. (21 CFR 121.301(a)). You should ensure that any personnel tasked with developing, creating, completing, or reviewing records are aware of the applicable requirements.

### 1. Records Format

You have the flexibility to maintain your records in multiple formats: original records, true copies, or electronic records. (21 CFR 121.305(a)). True copies include photocopies, pictures, scanned copies, microfilm, microfiche, or any other accurate reproduction of the original record. True copies of records should be of sufficient quality to reveal whether the original record was changed in a manner that obscured an original entry (e.g., through the use of liquid correction fluid).

As long as they meet the requirements of 21 CFR 121.305, many types of records are acceptable, including original handwritten logs, forms with handwritten entries, and true copies of invoices or shipping documentation. Paper and electronic records can co-exist as long as they both meet the records requirements. Electronic records are subject to the same requirements as paper records.

### 2. Accurate, Indelible, and Legible

Your required records must be accurate, legible, and indelible. (21 CFR 121.305(c)). Legibility is particularly important for any record involving handwritten entries. For example, if the only person who can interpret the handwriting on a record is the individual who created the handwritten part of the record, then you should not consider this record legible. Indelibility—markings that cannot be erased or removed—is important to ensure that the original content has not been altered; therefore, records should not be erasable. If changes are necessary, your personnel should correct the original marking in a way that allows both the original content and the updated content to be read; in other words, removing, erasing, or marking over the original content in a way that prevents reading is not appropriate. For example, if an employee writes an incorrect time of "12:45 PM" in permanent ink, the employee can correct the error by drawing a single line through the "12:45 PM," adding the accurate value of "1:45 PM," and writing their initials nearby.

### 3. Created when Activity is Performed

Your required records must be created concurrently with performance of the activity documented. (21 CFR 121.305(d)). This requirement is intended to ensure that the accuracy of recorded information is not impacted because of lapses in memory. If an individual does not immediately document the information related to a record, they may create an inaccurate record because they have forgotten the exact activity performed or confused information among multiple activities.

For example, in Scenario 2, a mitigation strategy is to use tamper-evident seals on inbound shipping conveyances and match the numbers on the seals with the numbers provided on the shipping documentation from the supplier. The food defense monitoring procedure states: "Technician assesses whether the seal is intact and matches seal or documentation numbers upon arrival of the load, before hooking up the hose for each delivery." The technician who conducts the monitoring should immediately write down whether the seal is intact, whether the seal and documentation numbers match, the date and time, and any other relevant information for that activity to ensure accuracy of the record. This is an example of using concurrently created affirmative records for food defense monitoring; exception records must also be created concurrently. (21 CFR 121.305(d)).

### 4. As Detailed as Necessary

Your required records must be as detailed as necessary to provide history of the work performed. (21 CFR 121.305(e)). For example, a facility implements a mitigation strategy of only accepting scheduled deliveries from known and secure shippers. The monitoring record likely should include details about the shipment, including the date and time that it arrives, the name and driver's license number of the driver, what is delivered in the shipment, and any other details that might be helpful for implementing corrective actions procedures and conducting verification. In a scheduled delivery, an employee who is monitoring this step may simply be checking that all of this information matches that provided in the scheduled shipment paperwork and indicating this with a checkmark, the employee's signature, and the date and time. However, there may be an unscheduled shipment that comes in from a known and secure shipper. In this example, the employee would record the additional details described above.

### 5. Information Adequate to Identify the Facility

Your required records must include information adequate to identify your facility. (21 CFR 121.305(f)(1)). This may include, for example, the facility name, location or address, or facility identifying numbers. We do not specify which identifier must be on the record, only that some identifier is included. If you keep your records offsite or electronically, having facility-identifying information on records is especially important so that one facility's records can be easily distinguished from those of another facility kept at the same location.

### 6. Date and Time

You must record the date and, when it is appropriate, the time of the activity documented. (21 CFR 121.305(f)(2)). There may be instances where documenting the time of an activity is not necessary. For mitigation strategies that are not time-dependent, facilities are likely not required to document the time the activity was performed. Food defense monitoring records are an example of when documenting the time of the activity may be appropriate.

For example, in Scenario 3, a quality control manager visually inspects the liquid food storage tank immediately before reintroducing food to ensure that no contaminant has been added to the tank while it was open and accessible after cleaning. When monitoring this mitigation strategy, the QA technician documents on the "storage tank cleaning sign-off form," the date and time that the tank was inspected before the food was added to the tank. (See Table 4-7 in Chapter 4). The liquid storage tank is cleaned on a time-dependent schedule (e.g., every 48 hours), so documenting the date and time of this activity is critical for food defense monitoring to assess whether the mitigation strategy is operating as intended.

### 7. Signature or Initials of the Individual Performing the Activity Recorded

Each required record must include the signature or initials of the person who performed the activity recorded. (21 CFR 121.305(f)(3)). This ensures that you can identify the individual who performed the activity recorded and that the activity is not recorded as completed based on the assumption that someone else performed the activity. While this provision allows for the use of initials instead of a signature, there may be circumstances in which initials alone may be confusing. For example, if you have multiple employees with the same initials (e.g., John Dab, Jane Dell, and Jennifer Doe), your policies or procedures may direct those employees to sign their full name or provide some additional identifier (e.g., "JD1" or "J. Dab" or "JWD") instead of using only their first and last initials. Such policies or procedures could help to provide clarity if you, a supervisor, or another responsible party need to quickly determine who performed a particular activity.

### 8. Identity of Product and Lot Code

Where appropriate, your records must include the identity of the product and the lot code, if any. (21 CFR 121.305(f)(4)). The identity of the product and the lot code in your records may be helpful for linking a record to a specific product and, when applicable, the lot code would enable you to isolate a product if necessary.

## C. Additional Requirements for Food Defense Monitoring

In addition to the requirements described in Section B above, your food defense monitoring records must contain the actual values and observations obtained during the monitoring. (21 CFR 121.305(b)). Vague or generalized notations provide minimal information and make it difficult for reviewers to verify compliance, note potential trends, or identify deviations.

You have the flexibility to tailor the amount of detail recorded based on the nature of the record. However, you should ensure that your monitoring records include actual observations with sufficient detail to allow accurate assessment of the performance of your mitigation strategies. These records will assist you in determining the extent to which, and identifying when and how, a mitigation strategy was not properly implemented, and whether the mitigation strategy is appropriate to the actionable process step. For example, you identify a mixer as an actionable process step. The mitigation strategy you implement is to use a lock to secure the access hatch on the mixer. During monitoring, an employee could record "yes" or "no" in response to whether the lock was locked. If the lock was unlocked, a facility may choose to document additional observations. For example, the record may state: "the lock was on the access hatch with the key in the keyhole, but the lock was not engaged" or "the lock was removed from the access hatch and placed on a surface adjacent to the mixer."

As another example, one of the mitigation strategies implemented at an actionable process step at an unloading bay where bulk liquids are received is to maximize visibility through use of

adequate lighting in the truck unloading bay. Personnel performing food defense monitoring of the adequate lighting at a truck unloading bay could record "yes" or "no" in response to one or more items in either a narrative or checklist format. The employee may also choose to record the actual observations that provide sufficient detail to assess the extent to which the strategy was not operating as intended. If the employee sees that half of the lights in bay number 5 are not illuminated, then he would document this in the record. This information would be helpful to facility management to first identify the source of the problem (i.e., why the lights were not illuminated) and then to determine whether the mitigation strategy is properly implemented and appropriate to the actionable process step in question. In this case, the employee performing monitoring may also document that he observed that the switches controlling the relevant light fixtures had been turned off.

## D. Additional Requirements for the Food Defense Plan

The FDP is a record and must comply with all of the generally applicable records requirements. (21 CFR 121.126(c)). In addition, the owner, operator, or agent in charge of the facility must sign and date the FDP upon completion and upon any modification. (21 CFR 121.310). For example, if you conduct a reanalysis, and it results in changes in the FDP, the owner, operator, or agent in charge of the facility must sign and date the new FDP. (21 CFR 121.310(b)).

## E. Record Retention Requirements

You are required to retain records for at least 2 years after they were prepared. (21 CFR 121.315(a)(1)). You must retain a food defense plan for 2 years after you have stopped using it. (21 CFR 121.315(b)).

Records must be retained at the facility for as long as necessary to support the facility's very small business (VSB) status for the applicable calendar year. (21 CFR 121.315(a)(2)). FDA considers this to be 2 years from the applicable calendar year (21 CFR 121.5(a)). For example, if the applicable calendar year is 2023, FDA would expect that the required records from the previous 3 years (2020-2022) would be kept at the facility until 2025 (i.e., 2 years after the applicable calendar year).

## F. Offsite Storage of Records

You have the flexibility to store your records in a way that allows you to easily access them as necessary and to organize them consistent with your operating procedures. You should evaluate how frequently you need to access your records and how you use them at your facility, and then develop a record management strategy that best fits your needs.

You can store required records, except for the FDP, either at your facility (i.e., "onsite") or offsite (i.e., away from your facility), as long as you can retrieve and provide them onsite within

24 hours of an FDA request for official review. (21 CFR 121.315(c)). For example, if you have multiple facilities at different locations, you may choose to keep relevant records at each site or consolidate all records from each site at a single location. Alternatively, you may store certain records for each site at that site while storing other records at a central office. As another example, your facility may generate some daily records that you need to easily access for a period of time, such as one month. After that time, you may choose to transfer the records for long-term storage to a central storage location that is not part of your facility.

Note that the FDP must remain onsite. (21 CFR 121.315(c)). Electronic records, including the FDP, are considered onsite if they are accessible from an onsite location. (21 CFR 121.315(c)). If your facility is closed for a prolonged period, you may transfer the FDP to some other reasonably accessible location but you must be able to retrieve it and make it available within 24 hours of an FDA request. (21 CFR 121.315(d)).

## G. Existing Records

You may use existing records kept for other purposes (e.g., records that you have already developed and maintain during your normal course of business, including for compliance with other Federal, state, or local regulations, or for any other reason) to meet the requirements of the IA rule, if those records contain all of the required information and satisfy all of the requirements of the IA rule. (21 CFR 121.330(a)). You may supplement existing records as necessary to include all of the required information. In addition, you do not need to keep all of the information required by this rule in only one set of records, nor do you need to duplicate already existing records.

If existing records contain only some of the required information, you may keep any additional information this rule requires either separately or in combination with the existing records (21 CFR 121.330(b)). For example, if your facility had already conducted a VA prior to the publication of the IA rule and you have records that document the public health impact determinations for each of the points, steps, and procedures on all your food processing lines, you may use those records as a part of your VA records, assuming that those public health impact determinations are calculated correctly and still relevant. If so, you could use the existing records to comply with the VA component required under 21 CFR 121.130(a)(1). In some instances, you may also use existing food safety records for IA rule compliance. For example, you may have records that document that a liquid food storage tank has been cleaned for food safety and sanitation purposes prior to use for food processing. As seen in Scenario 3, a mitigation strategy at this same step is to inspect the liquid food storage tank prior to use to ensure no contaminant has been added after cleaning and prior to the introduction of food. If the tank is checked prior to use for food safety reasons, you can use the same monitoring records for both food safety and for food defense. If you choose to use existing food safety records for some

or all of your required records, you should indicate the use of existing records in the appropriate section of the FDP. (See Table 4-7 in Chapter 4).

In some cases, there may be several ways (i.e., using several different types of existing records) for you to document compliance with a specific requirement of the IA rule. For example, to document your status as a VSB, you may find that your existing invoices, tax records, and other financial records each provide the necessary information to meet the requirement; therefore, you would only need to provide one of these types of records to satisfy the requirement for documentation, as long as it includes all of the necessary information.

## H. Protecting Records

FDPs, as well as many other required records, contain information about your facility's potential vulnerabilities and may contain other sensitive information related to food defense. As such, it is important for you to protect your facility's FDP and any accompanying records from improper or unauthorized disclosure.

### 1. Protection of Records in FDA's Possession

You must have all required records, including your FDP, available for official review and copying upon oral or written request of an authorized official. (21 CFR 121.320). FDA will copy or collect records when, for example, FDA investigators need assistance reviewing a certain record from other FDA subject matter experts. Records that FDA obtains to determine compliance with this rule will be protected from public disclosure to the extent allowable under 21 CFR part 20 and other applicable statutory and regulatory provisions. (See 21 CFR 121.325). FDPs generally will include information that meets the definition of "trade secret" in 21 CFR 20.61(a). FDA's general policies, procedures, and practices relating to the protection of information received from third parties also apply to information we receive pursuant to this rule.

### 2. Protection of Records at the Facility

Because of the sensitive nature of some food defense information, we recommend that you limit access to your facility's FDP and associated records to only those trusted individuals who have a need to see or access the records to perform an assigned duty at the facility. Examples of limiting access may include: keeping hard copies of records in a secure location (e.g., locked drawer) when not in use; maintaining electronic records on updated operating systems with current antivirus software and establishing password protection; and ensuring that access is controlled when employees change duties or cease employment with your facility.

# Appendix 2: Mitigation Strategies in the Food Defense Mitigation Strategies Database

FDA's online Food Defense Mitigation Strategies Database (FDMSD) contains a collection of potential mitigation strategies that could be implemented to significantly minimize or prevent significant vulnerabilities at actionable process steps. This collection of strategies was developed in collaboration with other government partners and food industry representatives who participated in the vulnerability assessments that FDA conducted. The FDMSD is intended as a starting point for facilities to consider when identifying potential mitigation strategies. Facilities can customize and tailor strategies listed in the FDMSD to apply to their specific circumstances. Use of the FDMSD is voluntary. Chapter 3 of this guidance includes details about the requirements for mitigation strategies and information to help you identify and implement mitigation strategies for the actionable process steps identified during your vulnerability assessment.

The FDMSD includes mitigation strategies for some common points, steps, and procedures that are often found at facilities covered under the IA rule.

The FDMSD is not an exhaustive list of potential mitigation strategies or associated points, steps, or procedures; facilities have the flexibility to identify and implement mitigation strategies that are not contained in the FDMSD. Although in some instances, a single strategy may be sufficient to significantly minimize or prevent significant vulnerabilities, some strategies in the FDMSD may not be suitable alone and may need to be complemented with additional strategy(ies) to sufficiently reduce significant vulnerabilities at an actionable process step. The content in this appendix is the same on the FDMSD. The FDMSD can be accessed at https://www.fda.gov/food/food-defense-tools-educational-materials/mitigation-strategies-database.

## Appendix Organization

The mitigation strategies within the FDMSD are organized by category, subcategory (if applicable), and points, steps, or procedures. In this Appendix, we list the categories and subcategories (if applicable), and the points, steps, and procedures under each category/subcategory. We also provide a table (Table 2) that includes the mitigation strategies and the associated categories under which they appear in the FDMSD. The mitigation strategies are listed in the left column, and the categories are listed across the top row. An "X" indicates that the mitigation strategy is associated with a point, step, or procedure in that category.
The categories are:

- Conveyance
- Material Handling
- Packaging
- Processing
- Storage

- Transportation/Distribution
- Key Activity Types (KAT)

Some categories include subcategories. For example, under the Processing category there are several subcategories (e.g., Chilling/Cooling, Cooking/Heating, and Cutting/Grinding). Table 1 includes the points, steps, and procedures organized by categories and subcategories (if applicable). There are no points, steps, or procedures under the Key Activity Types (KAT) category. See Chapter 2.D for descriptions of each of the KATs and the general activities that fall under each KAT.

## Table 1. Points, Steps, or Procedures by Category/Subcategory

Below is the list of the categories and subcategories (if applicable), and the points, steps, and procedures under each category/subcategory.

| **Category** | **Subcategory** | **Points, Steps, or Procedures** |
|---|---|---|
| Conveyance | None | Bin Dumping; Blower; Conveyor Belt; Conveyor, Bucket; Conveyor, Pneumatic; Direct Line; Flume; Forklift; Hose; In-Feed Conveyor; Pump; Tote, Conveyance; Valve; Valve Matrix |
| Material Handling | None | Ingredient Addition; Ingredient Preparation; Measuring; Premixing; Processing Aids; Reject Materials; Reworked Product; Staging, Dry Ingredients; Staging, Liquid Ingredients; Weighing |
| Packaging | Packaging Materials | Bags; Bottles; Boxes; Cans; Drums; Paper; Plastic Container; Plastic Wrap; Pouches; Super Sack |
| Packaging | Packaging Processes | Aseptic Packager; Bottle Hopper; Bottler, Capper; Caser; Hand/Manual Packer, Labeler; Modified Atmospheric Packaging; Packer, Packager; Palletizer, Sacker; Scanner; Sealer; Seamer; Shrink Bander; Shrink Wrapper; Vacuum Sealer |
| Processing | Chilling/Cooling | Blast Freezer; Chiller/Cooler; Cold Press; Cooling Tunnel; Freezer; Hydro-Cooler; Spray Cooler |
| Processing | Cooking/Heating | Blancher; Boiler; Broiler; Browner; Cooker; Evaporator; Fryer; Heat Exchanger; Heater; Hot Press; Incinerator; Microwave; Oven/Baking; |

| | | |
|---|---|---|
| | | Pasteurizer; Pre-Heater; Proofer; Renderer; Retort; Roaster; Rotary Cooker; Scalder; Screw Cooker; Singer; Smoker; Sterilizer; Thermal Processor |
| Processing | Cutting/Grinding | Chopper; Corer; Cracker/Breaker; Crusher; Cutter; Dicer; Disintegrator; Flaker; Grinder; Husker; Mill; Peeler/Parer; Pulper; Pulverizer; Shredder; Splitter; Trimmer |
| Processing | Drying | Air Dryer; Drum Dryer; Dryer; Freeze Dryer; Osmotic Dryer; Spin Dryer; Spray Dryer |
| Processing | Filling | Drum Filler; Filler; Load Out Spout; Tank Truck Filler |
| Processing | Meat Processing | Butcher; Eviscerater; Scraper; Slaughter; Stuffer |
| Processing | Mixing | Blender; Homogenizer; In-Line Mixer; Liquefier/Emulsifier; Mixer |
| Processing | Other Processing | Batterer; Bottle Cleaner/Soaker; Breader; Briner; Coater; Concentrator; Condenser; Disinfecting Equipment; Dry Ice Blaster; Enzyme Treatment; Finisher; Fluidized Bed; Formulator; Fruit Processing; Glazer; Hopper; Hopper, Meter; Hopper, Surge; Husker; Inversion Equipment; Ion Exchanger; Magnet; Metal Detector; Pitter/Destoner; Rinsing Equipment; Sheller; Stemmer; Tempering; Vacuum Pump; Washer; Waxer |
| Processing | Processing Tanks | Auger Tank, Balance Tank, Batch Tank, Blend Tank, Cooling Tank, Culturing Tank, Make-up Tank, Mixing Tank, Neutralization/Buffer Tank, Reaction Tank, Standardization Tank; Vacuum Tank, Wetting Tank |
| Processing | Separation/Extraction | Centrifuge; Clarifier; Decanter; Distiller; Drainer; Entolator; Extractor; Filter; Freeze Concentrator; Grader, Size; Gravity Separator; Osmotic Filter; Screen; Separator; Sifter; Skimmer; Solvent Extractor; Sorter |

| | | |
|---|---|---|
| Processing | Sizing/Shaping | Former; Granulator; Press; Roller; Standardizer |
| Storage | None | Bin/Tub; Bulk Storage; Drum Storage; Dry Storage; Dump Pit; Equipment Storage; Holding Tank; Ingredient Storage; Liquid Storage; Metering Tank; Product Storage; Refrigerated/Frozen Storage; Silo Storage, Liquid; Storage Tank, Dry/Solid; Silo Storage, Solid; Storage Tank, Liquid; Storage Tank, Refrigerated; Surge Hopper; Surge Tank; Thaw Room; Tote, Storage; Warehouse; Warehouse, Refrigerated/Frozen |
| Transportation/ Distribution | None | Distribution/Transport; Hopper Truck; LTL (Less-than Truckload); Liquid Loading; Liquid Receiving; Loading Materials at Multiple Stops; Railcar; Receiving; Refrigerated Transport; Shipping; Tanker Truck; Vehicle Storage; Transportainer; Truck; Vehicle Cleaning; Vehicle Loading; Stock Truck; Vehicle Maintenance; Vehicle Unloading |
| Key Activity Types | Bulk Liquid Receiving and Loading | None |
| Key Activity Types | Liquid Handling and Storage | None |
| Key Activity Types | Mixing and Similar Activities | None |
| Key Activity Types | Secondary Ingredient Handling | None |

## Table 2. Mitigation Strategies and Associated Categories

| # | Mitigation Strategies | Conveyance | Material Handling | Packaging | Processing | Storage | Transportation/ Distribution | Key Activity Types (KATs) |
|---|---|---|---|---|---|---|---|---|
| 1 | Clean / sanitize equipment and components periodically (e.g., immediately prior to use, after maintenance) | X | X | X | X | X | X | X |
| 2 | Clean / sanitize locations immediately around the step periodically (e.g., immediately prior to use, after maintenance, when security devices are breached) | X | X | X | X | X | X | X |
| 3 | Conduct periodic checks of both vehicle and products prior to loading/unloading for suspect items (e.g., seals not present or intact; product and packaging integrity compromised; abandoned, removed, or returned items; lacks proper identification; lacks proper documentation) | | | | | | X | X |
| 4 | Conduct periodic checks of package integrity (e.g., upon receipt and prior to use), including for products, ingredients, and processing aids | X | X | X | X | X | X | X |
| 5 | Keep one authorized operator with transportation vehicle at all times (e.g., use relay operators, relief driver, team driving) | | | | | | X | X |
| 6 | Maximize visibility of operations, equipment, and locations (e.g., install mirrors, light adequately, keep area clear of visual obstructions) | X | X | X | X | X | X | X |

| # | Mitigation Strategies | Conveyance | Material Handling | Packaging | Processing | Storage | Transportation/ Distribution | Key Activity Types (KATs) |
|---|---|---|---|---|---|---|---|---|
| 7 | Require driver check-ins | | | | | | X | X |
| 8 | Restrict access of drivers to specified locations | | | | | | X | X |
| 9 | Restrict access to equipment and controls to authorized personnel | X | X | X | X | X | X | X |
| 10 | Restrict access to ingredients, products, and/or cargo to authorized personnel | X | X | X | X | X | X | X |
| 11 | Restrict access immediately around the step to authorized personnel | X | X | X | X | X | X | X |
| 12 | Restrict access to openings or access points (e.g., to bins, tanks, vats, ports/valves, inspection points, system openings) to authorized personnel | X | X | X | X | X | X | X |
| 13 | Restrict access to supplies (e.g., containers/tanks/sacks, packaging, coverings, trays, pads, wrappings, uniforms, gloves) to authorized personnel | | | X | X | X | | X |
| 14 | Restrict access to transport operations to authorized personnel | | | | X | | X | X |
| 15 | Restrict operations to authorized personnel | X | X | X | X | X | X | X |

| # | Mitigation Strategies | Conveyance | Material Handling | Packaging | Processing | Storage | Transportation/ Distribution | Key Activity Types (KATs) |
|---|---|---|---|---|---|---|---|---|
| 16 | Schedule deliveries (e.g., schedule departure/arrival time, confirm driver identity, confirm on-time delivery, and report schedule deviation) | | | | X | | X | X |
| 17 | Use a dedicated trip plan that schedules stops at well-lit and public locations, prohibits unscheduled/unattended stops, and requires reporting of unscheduled stops | | | | | | X | X |
| 18 | Store equipment and components (e.g., bins, scoops, measuring cups) in a secured location | | X | X | X | X | | X |
| 19 | Store ingredients and products in a secured location | | X | X | X | X | | X |
| 20 | Use an alarm system to alert access breaches to location, equipment, controls, and coverings for openings or access points (e.g., contact, motion, infrared) | X | X | X | X | X | X | X |
| 21 | Use an alarm system to detect suspect events (e.g., motion detection in restricted area where personnel should not be present) | X | X | X | X | X | X | X |
| 22 | Use automated equipment (e.g., for dispensing, injection, incorporating, packing) to restrict access to product | X | X | X | X | X | X | X |

| # | Mitigation Strategies | Conveyance | Material Handling | Packaging | Processing | Storage | Transportation/ Distribution | Key Activity Types (KATs) |
|---|---|---|---|---|---|---|---|---|
| 23 | Use Clean in Place (CIP) equipment and prescribed CIP procedures (e.g., pre-rinse, wash, post-rinse, drain, and sanitize) | X | X | X | X | X | X | X |
| 24 | Use coverings to secure openings, access points and open systems/operations (e.g., shrouds, covers, lids, panels, seals) to restrict access to product | X | X | X | X | X | X | X |
| 25 | Use electronic access control system to restrict access to location and/or controls (e.g., cipher lock, swipe cards, biometric devices, RFID) | X | X | X | X | X | X | X |
| 26 | Use GPS/RFID (Radio Frequency Identification) or similar security measures to track transport vehicles | | | | | | X | X |
| 27 | Use locks to secure location, equipment, and controls when not in use or unattended (e.g., use tamper-proof containers, locks) | X | X | X | X | X | X | X |
| 28 | Use one-way valves, sample ports to restrict access to product | X | X | X | X | X | X | X |
| 29 | Use peer monitoring (e.g., buddy system) during operations | X | X | X | X | X | X | X |
| 30 | Use peer monitoring (e.g., buddy system) to supervise deliveries | | | | | | | X |

| # | Mitigation Strategies | Conveyance | Material Handling | Packaging | Processing | Storage | Transportation/ Distribution | Key Activity Types (KATs) |
|---|---|---|---|---|---|---|---|---|
| 31 | Use personnel (e.g., guards, supervisors, trusted employees) for visual observation | X | X | X | X | X | X | X |
| 32 | Use personnel identification (e.g., color coded uniforms, badges) to clearly identify authorized personnel around restricted locations, equipment, controls, and operations | X | X | X | X | X | X | X |
| 33 | Use physical barriers to restrict access to location, operations, and equipment (e.g., locate in secure room, enclose with a fence, cage, gate, ladder locks, or panel) | X | X | X | X | X | X | X |
| 34 | Use packaged, pre-measured portions for food additives and ingredients to minimize access to these materials while weighing/measuring | | X | | | | | |
| 35 | Use tamper-evident packaging (e.g., self-voiding tape, shrink wrapped pallets) | | | X | | | X | X |
| 36 | Use surveillance equipment (e.g., cameras) to increase observation | X | X | X | X | X | X | X |
| 37 | Use tamper-evident devices (e.g., seals, covers, locks) to secure openings, access points, equipment and components | X | X | X | X | X | X | X |
| 38 | Use tamper-evident devices (e.g., seals, covers, locks) to secure packaging and storage containers | X | X | X | X | X | X | X |

| # | Mitigation Strategies | Conveyance | Material Handling | Packaging | Processing | Storage | Transportation/ Distribution | Key Activity Types (KATs) |
|---|---|---|---|---|---|---|---|---|
| 39 | Use tamper-evident devices (e.g., seals, covers, locks) to secure transport operations or vehicles | | | | | | X | X |
| 40 | Visually inspect equipment, equipment components, and supplies prior to use | X | X | X | X | X | X | X |
| 41 | Prohibit personal items from production, storage or other restricted areas | X | X | X | X | X | X | X |
| 42 | Accept goods and packages that includes proper documentation review, screening procedures and chain-of-custody | | | | | | X | X |

# Appendix 3: Determination of Status as a Very Small Businesses or Small Businesses Under Part 121: Mitigation Strategies to Protect Food Against Intentional Adulteration

The IA rule includes an exemption for very small businesses. Small businesses are subject to the full requirements of the IA rule but are given additional time to comply. Both "very small business" and "small business" are defined in the rule (see 21 CFR 121.3). Section I of this appendix explains how to determine whether you are a very small business, and Section II of this appendix explains where to find guidance regarding determining the number of employees for purposes of the "small business" definition.

The process to determine whether your facility is a very small business for the purposes of Part 121 is the same as for determining whether a facility is a very small business for purposes of Parts 117 and 507 (Preventive Controls rules). We have addressed the latter in previous guidance. *See* Determination of Status as a Qualified Facility Under Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food and Part 507: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, which can be found at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-determination-status-qualified-facility. Because the dollar threshold for being a very small business in Part 121 is higher than for Parts 117 and 507, in this guidance we use higher dollar amounts in example calculations. In addition, we have made editorial changes and shortened the length of this guidance as compared to the guidance for the Preventive Controls rules.

## I. Very Small Business Under the IA Rule

The IA requirements do not apply to a very small business, except that a very small business must, upon request, provide for official review documentation sufficient to show that the facility meets the criteria for the exemption; such documentation must be retained for 2 years. (21 CFR 121.5(a)).

### A. Definition of Very Small Business Under Part 121

#### 1. How does part 121 define "very small business"?

Very small business means, for purposes of the IA rule, a business (including any subsidiaries and affiliates) averaging less than $10,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee). See the definition of "very small business" in 21 CFR 121.3.

#### 2. How does part 121 define "affiliate"?

Part 121 defines "affiliate" as any facility that controls, is controlled by, or is under common control with another facility. See the definition of "affiliate" in 21 CFR 121.3.

#### 3. How does part 121 define "subsidiary"?

Part 121 defines a subsidiary as any company which is owned or controlled directly or indirectly by another company. See the definition of "subsidiary" in 21 CFR 121.3.

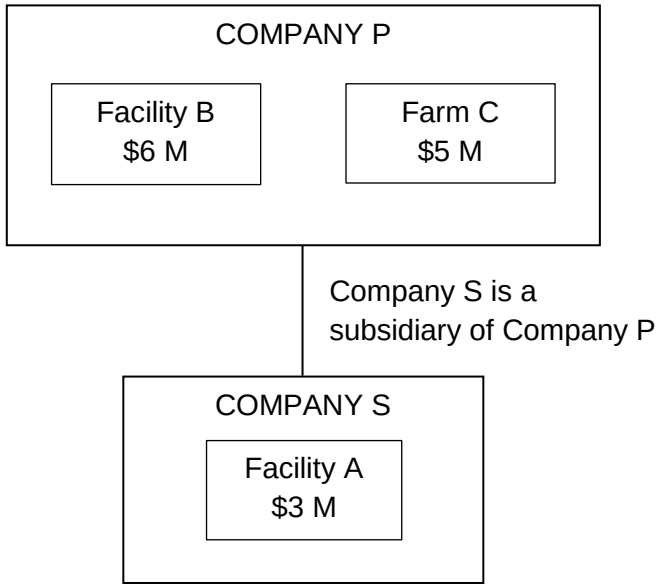
**4. Who determines whether my business meets the definition of a very small business under part 121?**

You are responsible for determining whether your business meets the definition of a very small business under part 121, subject to verification by FDA. Although we do not intend to review financial records supporting your status as a very small business during routine inspections, you must, upon request, provide for official review of documentation sufficient to show that the facility meets this exemption (21 CFR 121.5(a)).

**5. Can a facility that is a subsidiary meet the definition of "very small business" under part 121 even if its parent company is not a very small business?**

Yes. It is possible for a facility that is a subsidiary to be a very small business even if its parent company is not a very small business because not all human food sold or manufactured, processed, packed, or held without sale by the parent company is counted in a subsidiary facility's calculation of whether it is a very small business. Specifically, a subsidiary facility only includes operations of the parent company in the calculation if the parent company is an affiliate of the subsidiary facility.

**Figure 1**




In the example in Figure 1, a subsidiary (Company S) consists of Facility A with $3 million in annual human food sales. The subsidiary's parent Company P includes Facility B, a manufacturer/processor with $6 million in annual human food sales, and Farm C with $5 million in annual human food sales. Facility A would include Facility B's sales in its calculation because Facility B is an affiliate of Facility A. Facility A would not include Farm C's sales in its calculation because Farm C is not an affiliate or a subsidiary. Therefore, Facility A would

determine that it has $9 million ($6 million + $3 million) in annual human food sales for its business. If the average over three years was less than $10 million adjusted for inflation for the most recent of the three years, then Facility A would be a very small business.

Facility B's calculation to determine whether it is a very small business would be different. Facility B would include its own sales ($6 million) plus Farm C's sales ($5 million) because Farm C is part of the same company (Company P). Note that a subsidiary is not considered to be part of the same company as its parent company for this calculation. Facility B would also include Facility A's sales ($3 million) because Facility A is a subsidiary of the parent Company P that includes Facility B. Therefore, Facility B would determine that it has $14 million in annual human food sales for its business. (Note, in this example none of the entities have human food manufactured, processed, packed, or held without sale that must be included in the calculation).

**6. What does "food manufactured, processed, packed, or held without sale" mean in the definition of very small business in part 121?**

Food manufactured, processed, packed, or held without sale means any food for human consumption that you manufacture, process, pack or hold at your facility and do not offer for sale. This does not include food that you will sell at a later date. Examples of food manufactured, processed, packed, or held without sale include food held for a fee (e.g., by a warehouse), food processed for a fee (e.g., by a contract processor (such as a facility that irradiates spices)), and food packaged for a fee (e.g., by a contract packager).

## B. Calculations to Determine Status as a Very Small Business Under Part 121

**1. Which products do I include in, and which products do I exclude from, the calculation of annual sales plus market value to determine my status as a very small business under part 121?**

Include all human food, including food manufactured, processed, packed, or held by all subsidiaries and affiliates, regardless of whether the human food is subject to part 121. For example, you would include fruits and vegetables on a produce farm that is exempt from the rule under 21 CFR 121.5(d). Likewise, you would include human food subject to the jurisdiction of the U.S. Department of Agriculture (e.g., meat products for human consumption). You do not need to include the value of food that you have processed but not yet sold. Do not include animal food or other items not intended for human consumption.

**2. Do I include human food sold in countries other than the United States in the calculation of total sales?**

Yes. Include sales of all human food in the calculation of total sales, regardless of where the food is sold. For example, if you are a domestic facility and you export some of your food to other countries, you would include sales of food for export in your calculation of total annual sales. If you are a foreign facility, you would include sales of human food in all countries,

including sales in your own country, sales in the United States, and sales in other countries. See Question I.B.8 on what currency conversion rates to use for a foreign facility.

**3. How do I determine whether my average annual sales plus market value of human food manufactured, processed, packed, or held without sale is under the inflation-adjusted cut-off?**

We have outlined what we believe to be the simplest method below. You are free to choose a different method (e.g., deflating average annual sales to 2011-dollars).

One method of determining whether your annual sales plus market value of human food manufactured, processed, packed, or held without sale is below the inflation-adjusted threshold for a "very small business" is to:

- Determine which three years to include in the average;
- Determine annual sales and market value of food manufactured, processed, packed, or held without sale for each of the three years;
- Calculate the average for the three years; and
- Determine whether your three-year average is less than $10,000,000 adjusted for inflation by comparing your average to the three-year average value posted on FDA's website at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs.

**4. How do I determine which three years to include for determining the inflation-adjusted average annual sales plus market value of human food?**

The definition of a very small business (21 CFR 121.3) specifies that the average is based on the three-year period preceding the applicable calendar year. The applicable calendar year is the current year. If the current year is 2019, the three preceding calendar years would be 2016, 2017, and 2018.

See question I.B.5 if you don't have three years of financial records to use for your calculations.

**5. How do I determine average annual sales plus market value of human food if I don't have three years of financial documentation to use for my calculations?**

Note that if you have been operating for three years prior to the IA rule applying to you, it is likely that you have financial records kept for other purposes (e.g., accounting, taxes, calculating size under Part 117). If you have just begun operations, we recommend you project average annual sales plus market value of human food for your first three years of operation. After you have been operating for one or more years, you could make the calculation based on the records you have (i.e., for one or two preceding calendar years).

**6. How do I determine annual sales of human food?**

Determine your annual sales using resources such as:

- Tax Forms, e.g. Gross Receipts or Sales (Line 1a) from Internal Revenue Service (IRS) Form 1120;
- Accounting documents, e.g., Total Sales or Revenues from an Income Statement; or
- Invoices and bills of lading.

You should not adjust the total sales for the year to include the cost of the sales – for example, you should not adjust total sales for the cost of labor.

Table 1 provides an example of determining annual sales for Business L for the years 2016-2018 based on tax documents. Business L does not process, pack, or hold human food without sale, and, thus, does not calculate market value. Business L consists of a facility (Facility L) that does not have any subsidiaries or affiliates.

**Table 1: Determining Annual Sales of Human Food for Business L for the Years 2016-2018**

| Source | 2016 | 2017 | 2018 |
|---|---|---|---|
| Facility L: Gross Sales of Human Food (Item 1a, IRS Form 1120) | $8,000,000 | $8,005,000 | $9,000,000 |
| Facility L: Market Value of Human Food Manufactured, Processed, Packed, or Held Without Sale | Not Applicable* | Not Applicable* | Not Applicable* |
| Total Non-Inflation Adjusted Annual Sales + Market Value of Human Food Manufactured, Processed, Packed, or Held Without Sale | $8,000,000 | $8,005,000 | $9,000,000 |

*There is no entry for market value of human food manufactured, processed, packed, or held without sale because Facility L does not manufacture, process, pack, or hold human food without sale.

Table 2 below provides a more complex example of determining annual sales for Business M for the years 2016-2018 based on tax documents. Business M consists of Facility M and one affiliate (Affiliate M1), which produced and sold human and animal food. Neither Facility M nor Affiliate M1 manufactures, processes, packs, or holds human food without sale and, thus, neither Facility M nor Affiliate M1 calculates market value.

**Table 2. Determining Annual Sales of Human Food for Business M (Facility M and its Affiliate) for the Years 2016-2018**

| Source | 2016 | 2017 | 2018 |
|---|---|---|---|
| Facility M: Gross Sales of Human Food (Derived | $8,000,000 | $8,005,000 | $9,000,000 |

| | | | |
|---|---|---|---|
| from Item 1a, IRS Form 1120) | | | |
| Facility M: Market Value of Human Food Manufactured, Processed, Packed, or Held Without Sale | Not Applicable* | Not Applicable* | Not Applicable* |
| Affiliate M1: Gross Sales of Human Food (Item 1a, IRS Form 1120) | $1,900,000 | $2,000,000 | $2,000,000 |
| Affiliate M1: Market Value of Human Food Manufactured, Processed, Packed, or Held Without Sale | Not Applicable* | Not Applicable* | Not Applicable* |
| Affiliate M1: Gross Sales of Animal Food (Derived from Item 1A, IRS Form 1120) | $500,000** | $550,000** | $600,000** |
| Total Non-Inflation Adjusted Annual Sales + Market Value of Human Food Manufactured, Processed, Packed, or Held Without Sale | $9,900,000 | $10,005,000 | $11,000,000 |

*There is no entry for market value of human food manufactured, processed, packed, or held without sale because neither Facility M nor Affiliate M1 manufactures, processes, packs, or holds human food without sale.
**Gross sales of animal food is not included in the calculation because the total annual sales includes only human food.

### 7. How do I determine the market value of human food manufactured, processed, packed, or held without sale?

Use the value of the food, not the fee for the service (e.g., for holding, processing, or packing), to calculate the market value of food that you manufacture, process, pack or hold without sale. We recommend you determine the market value of human food manufactured, processed, packed, or held without sale by considering factors such as:

- The market value of incoming food obtained from the customer for whom the food is being manufactured, processed, packed, or held;
- The amount of insurance that a warehouse holds for its products;
- The value obtained by multiplying market price by volume of food manufactured, processed, packed, or held; or
- Assets on a balance sheet.

See Section I.C of this appendix for examples of how to determine market value for human food manufactured, processed, packed, or held without sale. The examples describe the calculation for a cold storage warehouse that holds human food. In one example (Question I.C.1), the warehouse calculates market value using the value of an insurance policy. In a second example (Question I.C.2), the same warehouse calculates market value using the market value of incoming food using information or accounting documents from the customer. In these examples, the warehouse reaches the same conclusion regardless of the method used to do the calculation.

**8. What conversion rate should a foreign facility use when converting annual sales plus market value of human food to U.S. dollars?**

A foreign facility should use the exchange rate in effect as of the ending date of the period during which it collected the reported receipts or sales. For example, for sales during 2019 a foreign facility would use the conversion rate in effect on December 31, 2019.

**9. What documentation must I keep to demonstrate my facility's status as a very small business under part 121?**

The IA rule requires that you keep documentation sufficient to show that your facility qualifies as a very small business, but does not otherwise specify the types of documentation that you must keep. (see 21 CFR 121.5(a)). You should keep the documentation that you use to determine your annual sales and the market value of human food manufactured, processed, packed, or held without sale. You also should keep documentation of the actual calculations that you make. You must, upon request, provide for official review documentation sufficient to show that your facility meets the exemption. (21 CFR 121.5(a)).

You must retain for two years the documentation that you rely on (e.g., tax and/or insurance documents) to show that your facility meets the very small business exemption. (21 CFR 121.5(a)). Generally, these records will cover the three years preceding the applicable calendar year. You would keep these records for two years from the time when you rely on them to establish your very small business status (the applicable calendar year). You would keep these records at your facility as long as necessary so that you have them until two years after the applicable calendar year (21 CFR 121.315(a)(2)). For example, if the applicable calendar year is 2021 and a facility calculates its average annual sales by using financial records from 2020, 2019, and 2018, then the facility would keep records that it relies on from those years until 2023 (two years from 2021).

## C. Examples of Calculations to Determine Market Value of Food Held Without Sale Under Part 121

**1. How can I calculate market value of human food held without sale in my warehouse using the values in my insurance policy for the warehouse?**

In this example, Warehouse N is a cold storage warehouse. Its inventory turns over approximately every two months. It has an insurance policy that covers the market value of food stored at any given time. Because the inventory turns over approximately every two months,

Warehouse N could multiply the value of the insurance policy times six to arrive at an approximate value of the food stored for the entire year.

See Table 3 for an example of how Warehouse N could do its calculation of market value on an annual basis for the years 2016, 2017, and 2018. Warehouse N can then determine whether the three year average is less than $10,000,000 adjusted for inflation by comparing its three-year average market value to the inflation-adjusted value for the most recent year included in the average posted on FDA's website at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs.

**Table 3. Calculation of Market Value of Human Food Held Without Sale by Warehouse N Using the Value of an Insurance Policy**

| Item | 2016 | 2017 | 2018 |
|---|---|---|---|
| Value of Insurance Policy | $2,000,000 | $2,255,000 | $2,500,000 |
| Number of times inventory turns over during the year | 6 | 6 | 6 |
| Total Market Value of human food manufactured, processed, packed, or held without sale | ($2,000,000)(6) = $12,000,000 | ($2,225,000)(6) = $13,530,000 | ($2,500,000)(6) = $15,000,000 |

Warehouse N does not meet the definition of a very small business because the three-year average value of $13,510,000 is greater than $11,011,028 (inflation adjusted value of $10,000,000 in 2018).

Because an insurance policy may cover a slightly higher value than is in the warehouse at any given time, Warehouse N may decide to calculate the market value using information or accounting documents from their customer to determine the actual value of product received each year. See Question I.C.2 for an example of how one could calculate the market value using information or accounting documents from the customer.

**2. How can I calculate the market value of human food held without sale as a contract processor using information or accounting documents from the customer?**

In this example, Contract Processor O uses information on the value of the food received from the customer to determine the total market value of all food held without sale for each year. Using this method, Contract Processor O would add up the value of food for each shipment received throughout the year. Contract Processor O can then compare its three-year average market value to the inflation-adjusted value for the most recent year included in the average posted on FDA's website at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs.

**Table 4. Calculation of Market Value of Human Food Held Without Sale by Contract Processor O Using Information from the Customer to Determine the Value of Human Food for Each Shipment**

| Item | 2016 | 2017 | 2018 |
|---|---|---|---|
| Total Market Value of human food manufactured, processed, packed, or held without sale | $8,700,000 | $10,300,000 | $10,400,000 |

Three-year average = ($8,700,000 + $10,300,000 + $10,400,000) ÷ 3 = $9,800,000.

Contract Processor O does meet the definition of a very small business because the three-year average value of $9,800,000 is less than $11,011,028 (inflation adjusted value of $10,000,000 in 2018).

## II. Small Business Under the IA Rule

Small businesses are subject to the full requirements of the IA rule but are given additional time to comply. The definition of a small business is "a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees" (21 CFR 121.3). Because the definition for small business and how to determine whether your business is a small business for the purposes of the IA rule in Part 121 is the same as for Parts 117 and 507 (Preventive Controls Rules), rather than repeating the comprehensive guidance on this same topic for Preventive Controls Rules, we refer you to the final guidance entitled, "Determining the Number of Employees for Purposes of the "Small Business" Definition in Parts 117 and 507 (Preventive Controls Rules): Guidance for Industry," which can be found at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-determining-number-employees-purposes-small-business-definition-parts-117-and-507. Specifically, we refer you to Sections III.A. and III.B. of that guidance.