

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

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

## ***Draft Guidance***

**This guidance is being distributed for comment purposes only.**

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 180 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2018-D-1398 listed in the notice of availability that publishes in the *Federal Register*.

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  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition**

**June 2018**

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

Table of Contents

<b>I. Introduction</b> .....	7
<b>II. Purpose of this Guidance</b> .....	9
<b>III. Glossary of Terms Used in This Guidance</b> .....	9
A. Definitions Established in 21 CFR 121.....	9
B. Other Terms Used in this Guidance.....	12
C. Table of Abbreviations Used in This Guidance.....	15
<b>IV. Exemptions</b> .....	15
A. Very Small Business .....	16
B. Holding of Food.....	16
C. Packing and Labeling .....	16
D. Farm Activities Covered by Standards for Produce Safety .....	16
E. Alcoholic Beverages.....	16
F. Animal Food.....	17
G. Low-Risk Activities at Farm Mixed-Type Facilities .....	17
<b>Chapter 1: The Food Defense Plan</b> .....	18
A. What is a Food Defense Plan?.....	18
B. Individuals to Assist with Developing Your Facility’s Food Defense Plan.....	19
1. Food Defense Qualified Individuals .....	19
2. Food Defense Team .....	19
C. Formatting a Food Defense Plan.....	20

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

D.	Determining When to Make Changes to a Food Defense Plan.....	20
E.	Maintaining a Food Defense Plan .....	21
<b>Chapter 2: Vulnerability Assessment to Identify Significant Vulnerabilities and Actionable Process Steps.....</b>		<b>22</b>
A.	What is a Vulnerability Assessment? .....	22
1.	The Scope of “Points, Steps, and Procedures” for Consideration in a Vulnerability Assessment.....	23
2.	Grouping of Similar Food Products.....	23
B.	Recommended Activities Prior to Conducting a Vulnerability Assessment.....	23
1.	Assemble a Food Defense Team.....	24
2.	Describe the Product Under Evaluation.....	24
3.	Develop a Process Flow Diagram .....	24
4.	Describe the Process Steps.....	24
C.	Key Activity Types as an Appropriate Method for Conducting a Vulnerability Assessment to Identify Significant Vulnerabilities and Actionable Process Steps.....	25
D.	Key Activity Type Descriptions .....	25
1.	Bulk Liquid Receiving and Loading.....	26
2.	Liquid Storage and Handling .....	26
3.	Secondary Ingredient Handling.....	27
4.	Mixing and Similar Activities.....	27
E.	Identifying Actionable Process Steps Using the Key Activity Types Method.....	28
<b>Chapter 2F: Evaluating the Three Fundamental Elements to Identify Significant Vulnerabilities and Actionable Process Steps (coming soon).....</b>		<b>38</b>
<b>Chapter 3: Mitigation Strategies for Actionable Process Steps.....</b>		<b>39</b>

*Contains Nonbinding Recommendations*  
*Draft-Not for Implementation*

A. Mitigation Strategies Requirement .....	39
B. Identifying Mitigation Strategies.....	40
1. Minimizing the Accessibility of the Product to an Inside Attacker.....	41
2. Reducing the Ability of an Inside Attacker to Contaminate the Product.....	45
C. Using Multiple Mitigation Strategies.....	47
D. Facility-wide Security Measures and Their Role in a Facility’s Food Defense System.....	48
E. The Role of Existing Measures .....	49
F. Accompanying Explanation for Mitigation Strategies in the Food Defense Plan .....	51
G. Mitigation Strategy Example Scenarios .....	52
1. Scenario 1 .....	52
2. Scenario 2.....	53
3. Scenario 3.....	54
4. Scenario 4.....	54
<b>Chapter 4: Mitigation Strategies Management Components: Food Defense Monitoring</b> ....	<b>61</b>
A. Overview of Food Defense Monitoring .....	61
B. How Food Defense Monitoring Differs from Food Safety Monitoring.....	61
C. What to Monitor.....	62
D. How to Monitor .....	63
1. How Often to Monitor (Frequency of Monitoring).....	63
2. Who Performs the Monitoring .....	65
E. Food Defense Monitoring Records.....	65
F. Exception Records .....	66

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

<b>Chapter 5: Mitigation Strategies Management Components: Food Defense Corrective Actions (coming soon)</b> .....	75
<b>Chapter 6: Mitigation Strategies Management Components: Food Defense Verification (coming soon)</b> .....	76
<b>Chapter 7: Reanalysis (coming soon)</b> .....	77
<b>Chapter 8: Education, Training, or Experience (coming soon)</b> .....	78
<b>Chapter 9: Records (coming soon)</b> .....	79
<b>Appendix 1: Food Defense Plan Worksheets</b> .....	80
A. Introduction .....	80
B. Food Defense Plan Cover Sheet .....	80
1. How to Fill in Worksheet 1-A: Food Defense Plan Cover Sheet .....	<b>80</b>
2. Worksheet 1-A: Food Defense Plan Cover Sheet .....	<b>81</b>
C. Food Defense Plan Product Description .....	82
1. How to Fill in Worksheet 1-B: Food Defense Plan Product Description .....	82
2. Worksheet 1-B: Food Defense Plan Product Description.....	83
D. Food Defense Plan Vulnerability Assessment.....	84
1. How to Fill in Worksheet 1-C: Vulnerability Assessment Analysis Summary .....	84
2. Worksheet 1-C: Vulnerability Assessment Analysis Summary .....	86
E. Food Defense Plan Mitigation Strategies .....	87
1. How to Fill in Worksheet 1-H: Mitigation Strategies .....	87
2. Worksheet 1-H: Mitigation Strategies .....	88
F. Food Defense Plan Mitigation Strategies Management Components .....	89
1. How to Fill in Worksheet 1-I: Mitigation Strategies Management Components .....	89

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

2. Worksheet 1-I: Mitigation Strategies Management Components .....91

**Appendix 2: Mitigation Strategies in the Food Defense Mitigation Strategies Database  
(coming soon).....92**

**Appendix 3: Calculating Small Business and Very Small Business Sizes (coming soon) .....93**

**References.....94**

# Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry <sup>1</sup>

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

## I. Introduction

The FDA Food Safety Modernization Act (FSMA) added to the Federal Food, Drug, and Cosmetic Act (FD&C Act) several new sections that reference intentional adulteration. For example, section 418 of the FD&C Act (21 U.S.C. 350g) addresses intentional adulteration in the context of facilities that manufacture, process, pack, or hold food, and that are required to register under section 415 (21 U.S.C. 350d). Section 420 of the FD&C Act (21 U.S.C. 350i) addresses intentional adulteration in the context of high-risk foods and exempts farms except for farms that produce milk.<sup>2</sup>

We implemented these intentional adulteration provisions through a rule entitled “*Mitigation Strategies to Protect Food Against Intentional Adulteration*” (IA rule). We published the final rule in the *Federal Register* of May 27, 2016. (81 FR 34166). The rule, which includes the requirements for food defense measures against intentional adulteration, and related requirements, can be found in 21 CFR part 121, as shown in Table 1.

**Table 1. Subparts Established in 21 CFR Part 121**

Subpart	Title
A	General Provisions
B	Reserved

---

<sup>1</sup> This guidance has been prepared by the Office of Analytics and Outreach, Food Defense and Emergency Coordination Staff, in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

<sup>2</sup> The IA rule did not include any requirements for farms that produce milk. As such, farms that produce milk are not covered under this draft guidance.

***Contains Nonbinding Recommendations  
Draft-Not for Implementation***

Subpart	Title
C	Food Defense Measures
D	Requirements Applying to Records That Must Be Established and Maintained
E	Compliance

As shown in Table 2 below, the amount of time we are allowing you to comply with the IA rule depends on your particular business.

**Table 2. Compliance Dates for IA Rule Based on Size of Business**

Size of Business	Compliance Date
Very small	July 26, 2021
Small	July 27, 2020
Other businesses that do not qualify for exemptions	July 26, 2019

The IA rule applies to the owner, operator, or agent in charge of a domestic or foreign food facility that manufactures/processes, packs, or holds food for consumption in the United States and is required to register under section 415 of the FD&C Act, unless one of the exemptions provided in 21 CFR 121.5 applies. (21 CFR 121.1). (See Section IV below for a list of the exemptions).

Acts of intentional adulteration may take several forms: acts intended to cause wide scale public health harm, such as acts of terrorism focused on the food supply; acts of disgruntled employees, consumers, or competitors; and economically motivated adulteration (EMA). Acts intended to cause wide scale public health harm are associated with intent to cause significant human morbidity and mortality. (Ref. 1, Ref. 2). The other forms are typically not intended to cause wide scale public health harm, although some public health harm may occur because of the adulteration. For example, acts of disgruntled employees, consumers, and competitors are generally intended to attack the reputation of a company, and EMA is intended to obtain economic gain. In the spectrum of risk associated with intentional adulteration of food, attacks intended to cause wide scale public health harm to humans are ranked as the highest risk.



***Contains Nonbinding Recommendations  
Draft-Not for Implementation***

Therefore, the IA rule is focused on addressing those acts and not acts of disgruntled employees, consumers, or competitors, or acts of EMA.<sup>3</sup>

This document is directed to those persons who are subject to the Intentional Adulteration (IA) requirements of 21 CFR part 121 (you). Identifying significant vulnerabilities at your facility and implementing mitigation strategies and mitigation strategy management components enables you to apply a proactive and systematic approach to your food defense program to protect your food from intentional adulteration intended to cause wide scale public health harm.

## **II. Purpose of this Guidance**

The purpose of this guidance is to help you develop and implement a food defense plan (FDP) in accordance with the IA rule's requirements. Specifically, this document provides guidance on:

- Understanding the components of an FDP and the importance of each component;
- Understanding how to conduct a vulnerability assessment to identify significant vulnerabilities and actionable process steps;
- Understanding how to identify and implement mitigation strategies for the actionable process steps associated with a facility's processes;
- Understanding how to identify and apply the mitigation strategies management components (i.e., food defense monitoring, food defense corrective actions, and food defense verification);
- Understanding the reanalysis requirements associated with the FDP;
- Understanding the education, training, and/or experience required for individuals who perform certain activities; and
- Understanding the recordkeeping requirements associated with the FDP and implementation of the FDP.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

## **III. Glossary of Terms Used in This Guidance**

### **A. Definitions Established in 21 CFR 121**

---

<sup>3</sup> As we noted in the final rule, the protections required by the rule will help minimize the likelihood of success of a disgruntled employee, consumer, or competitor who attempts an act of intentional adulteration at an actionable process step—even if that act is not intended to cause wide scale public health harm. (81 FR at 34183).

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

**Actionable process step** means a point, step, or procedure in a food process where a significant vulnerability exists and at which mitigation strategies can be applied and are essential to significantly minimize or prevent the significant vulnerability.

**Adequate** means that which is needed to accomplish the intended purpose in keeping with good public health practices.

**Affiliate** means any facility that controls, is controlled by, or is under common control with another facility.

**Calendar day** means every day as shown on the calendar.

**Contaminant** means, for purposes of this part, any biological, chemical, physical, or radiological agent that may be added to food to intentionally cause illness, injury, or death.

**Facility** means a domestic facility or a foreign facility that is required to register under section 415 of the FD&C Act, in accordance with the requirements of 21 CFR part 1, subpart H.

**Food defense** means the effort to protect food from intentional acts of adulteration where there is an intent to cause wide scale public health harm.

**Food defense monitoring** means to conduct a planned sequence of observations or measurements to assess whether mitigation strategies are operating as intended.

**Food defense verification** means 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.

**Full-time equivalent employee** is a term used to represent the number of employees of a business entity for the purpose of determining whether the business qualifies as a small business. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (i.e., 40 hours x 52 weeks). If the result is not a whole number, round down to the next lowest whole number.

**Holding** means storage of food and also includes activities performed incidental to storage of food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the FD&C Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

**Manufacturing/processing** means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

**Mitigation strategies** mean those risk-based, reasonably appropriate measures that a person knowledgeable about food defense would employ to significantly minimize or prevent significant vulnerabilities identified at actionable process steps, and that are consistent with the current scientific understanding of food defense at the time of the analysis.

**Mixed-type facility** means an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

**Packing** means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the FD&C Act.

**Qualified individual** means a person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required under 21 CFR subpart C, as appropriate to the individual’s assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

**Significant vulnerability** means a vulnerability that, if exploited, could reasonably be expected to cause wide scale public health harm. A significant vulnerability is identified by a vulnerability assessment conducted by a qualified individual, that includes consideration of the following: (1) Potential public health impact (e.g., severity and scale) if a contaminant were added, (2) degree of physical access to the product, and (3) ability of an attacker to successfully contaminate the product. The assessment must consider the possibility of an inside attacker.

**Significantly minimize** means to reduce to an acceptable level, including to eliminate.

**Small business** means, for purposes of this part, a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees.

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

**Subsidiary** means any company which is owned or controlled directly or indirectly by another company.

**Very small business** means, for purposes of this part, 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).

**Vulnerability** means the susceptibility of a point, step, or procedure in a facility's food process to intentional adulteration.

**You** means, for purposes of this part, the owner, operator, or agent in charge of a facility.

## **B. Other Terms Used in this Guidance**

**CARVER + Shock:** An adapted military targeting tool that assesses vulnerabilities of the food and agriculture sector. CARVER is an acronym for six attributes used to evaluate the attractiveness of a target for attack: Criticality, Accessibility, Recuperability, Vulnerability, Effect, and Recognizability.

**Facility-wide security measures:** general, non-targeted, protective measures that are implemented at the facility-wide level to protect personnel, property, or product. Such measures may include physical security, personnel security, securing hazardous materials, management practices, and crisis management planning. A facility-wide security measure could be identified as a mitigation strategy if it specifically addresses a significant vulnerability at an actionable process step.

**Farm** means:

(1) Primary production farm. A primary production farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term "farm" includes operations that, in addition to these activities:

- (i) Pack or hold raw agricultural commodities;
- (ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(1) of this definition; and
- (iii) Manufacture/process food, provided that:

(A) All food used in such activities is consumed on that farm or another farm under the same management; or

(B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:

***Contains Nonbinding Recommendations***  
***Draft-Not for Implementation***

(1) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);

(2) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and

(3) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or

(2) Secondary activities farm. A secondary activities farm is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraph (1)(ii) and (iii) of this definition. (See 21 CFR 1.227).

**Food** means food as defined in section 201(f) of the FD&C Act and includes raw materials and ingredients. Food is defined in section 201(f) as (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article and includes raw materials and ingredients.

**Food defense plan:** A set of written documents that is based upon food defense principles and incorporates a vulnerability assessment, includes mitigation strategies, and delineates food defense monitoring, corrective action, and verification procedures to be followed. (21 CFR 121.126).

**Food defense qualified individual:** An individual who meets the requirements in 21 CFR 121.4(c)(1) and (2) to do or oversee the activities listed in 21 CFR 121.4(c)(3).

**Food defense system:** The result of the implementation of the Food Defense Plan.

**Fundamental elements:** The three elements that must be evaluated for each point, step, or procedure in a facility's food process when conducting a vulnerability assessment. (21 CFR 121.130(a)). These elements are (1) The potential public health impact (e.g., severity and scale) if a contaminant were added; (2) The degree of physical access to the product; and (3) The ability of an attacker to successfully contaminate the product. (21 CFR 121.130(a)).

**HACCP (Hazard Analysis and Critical Control Point):** A system that identifies, evaluates, and controls hazards that are significant for food safety.

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

**Intentional adulteration:** The deliberate contamination of food with a biological, chemical, radiological, or physical agent by an individual or group of individuals with the intent to cause wide scale public health harm.

**Key Activity Types (KAT):** The four activity types identified by FDA through an analysis of the results of over 50 vulnerability assessments as the activities consistently ranked as the most vulnerable, regardless of the food commodity assessed. The KATs reflect significant vulnerabilities to intentional adulteration caused by acts intended to cause wide scale public health harm. The four KATs are: bulk liquid receiving and loading, liquid storage and handling, secondary ingredient handling, and mixing and similar activities.

**Preventive Controls for Human Food Rule (PCHF):** Refers to the preventive controls requirements of 21 CFR part 117 (primarily located in subparts C & G).

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

### C. Table of Abbreviations Used in This Guidance

<b>Abbreviation</b>	<b>What It Means</b>
FD&C Act	Federal Food, Drug, and Cosmetic Act
CFR	Code of Federal Regulations
EMA	Economically motivated adulteration
FDA	U.S. Food and Drug Administration
FDP	Food defense plan
FDPB	Food Defense Plan Builder
FSPCA	Food Safety Preventive Controls Alliance
FSMA	FDA Food Safety Modernization Act
FSP	Food Safety Plan, as required under the PCHF rule
HACCP	Hazard Analysis and Critical Control Point
HEPA	High-Efficiency Particulate Air
IA	Intentional Adulteration
IA rule	Mitigation Strategies to Protect Food Against Intentional Adulteration (21 CFR part 121)
KAT	Key Activity Types
FDMSD	Food Defense Mitigation Strategies Database
PCHF	Preventive Controls for Human Food
VA	Vulnerability Assessment (as required in 21 CFR 121.130)

### IV. Exemptions

The owner, operator, or agent in charge of a facility that manufactures, processes, packs, or holds food for consumption in the United States and is required to register under section 415 of the FD&C Act (21 U.S.C. 350d) is subject to the requirements of the IA rule, with some exemptions, as provided in 21 CFR 121.5. (21 CFR 121.1). Some regulatory exemptions apply to entire

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

facilities and others apply to particular activities or food. If a facility satisfies the requirements for an exemption under 21 CFR 121.5, then it receives the exemption; no application is necessary but some documentation may be required.

### **A. Very Small Business**

The only IA rule requirement for a very small business (defined in 21 CFR 121.3) is that it 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)). The IA rule's requirements otherwise do not apply to a very small business.

### **B. Holding of Food**

The IA rule requirements do not apply to the holding of food, except the holding of food in liquid storage tanks. (21 CFR 121.5(b)). Examples of holding of food that are not covered by the IA rule include the storage of whole grains, shell eggs, fruits and vegetables, and packaged foods (including packaged orange juice). Examples of holding food that are covered by the IA rule include the storage of liquid milk, juice, or syrup in storage tanks.

### **C. Packing and Labeling**

The IA rule requirements do not apply to the packing, re-packing, labeling, or re-labeling of food where the container that directly contacts the food remains intact. (21 CFR 121.5(c)). Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the FD&C Act. (21 CFR 121.3). An example of packing is placing a variety of individually wrapped bite-sized candies into a larger variety pack.

### **D. Farm Activities Covered by Standards for Produce Safety**

The IA rule requirements do not apply to activities of a farm that are subject to section 419 of the FD&C Act (Standards for Produce Safety). (21 CFR 121.5(d)). The definition of "farm" is found at 21 CFR 1.227 and in Section IV.A. of this chapter.

### **E. Alcoholic Beverages**

The IA rule requirements do not apply with respect to alcoholic beverages at a facility that meets the following two conditions:

- Under the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 et seq.) the facility is required to obtain a permit from, register with, or obtain approval of a notice or



***Contains Nonbinding Recommendations  
Draft-Not for Implementation***

application from the Secretary of the Treasury as a condition of doing business in the United States, or is a foreign facility of a type that would require such a permit, registration, or approval if it were a domestic facility; and

- Under section 415 of the FD&C Act the facility is required to register as a facility because it is engaged in manufacturing, processing, packing, or holding one or more alcoholic beverages. (21 CFR 121.5(e)(1)).

Additionally, this exemption applies to food at these facilities that is not an alcoholic beverage, if such food is in prepackaged form that prevents any direct human contact with the food and constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury. (21 CFR 121.5(e)(2)).

## **F. Animal Food**

The IA rule requirements do not apply to the manufacturing, processing, packing, or holding of food for animals other than man. (21 CFR 121.5(f)). If a facility manufactures, processes, packs, or holds food for both humans and animals, only the activities related to human food are covered by the rule.

## **G. Low-Risk Activities at Farm Mixed-Type Facilities**

The IA rule requirements do not apply to on-farm manufacturing, processing, packing, or holding of the following foods on a farm mixed-type facility, when conducted by a small or very small business if such activities are the only activities conducted by the business subject to section 418 of the FD&C Act:

- Eggs (in-shell, other than raw agricultural commodities, e.g., pasteurized eggs in shell); and
- Game meats (whole or cut, not ground or shredded, without secondary ingredients). (21 CFR 121.5(g)).

(See the Final Evaluation of Food Manufactured, Processed, Packed, or Held (Outside the Farm Definition) in a Facility Co-Located on a Farm for Risk of Intentional Adulteration at <https://www.fda.gov/downloads/Food/FoodScienceResearch/RiskSafetyAssessment/UCM502783.pdf>).

## **Chapter 1: The Food Defense Plan**

This chapter is intended to help you understand what a food defense plan (FDP) is, the required components of a FDP, and the individuals needed and useful for developing or overseeing the development of the FDP. If the IA rule applies to you, you must prepare, or have prepared, and implement a written food defense plan. (21 CFR 121.126(a)).

### **A. What is a Food Defense Plan?**

An FDP is a set of written documents that is based upon food defense principles and incorporates a vulnerability assessment, includes mitigation strategies, and delineates food defense monitoring, corrective action, and verification procedures to be followed (21 CFR 121.126(b)). A written FDP is essential for you to significantly minimize or prevent significant vulnerabilities related to intentional adulteration of food. Documentation and implementation of the plan are necessary so that both your facility and FDA can ensure that significant vulnerabilities are properly addressed.

Below are the required FDP components in more detail:

- Vulnerability assessment to identify significant vulnerabilities and actionable process steps, including an explanation of why each point, step, or procedure was or was not identified as an actionable process step (See 21 CFR 121.130);
- Mitigation strategies for each actionable process step and written explanations of how each mitigation strategy sufficiently minimizes or prevents the significant vulnerability associated with the actionable process step (See 21 CFR 121.135);
- Food defense monitoring procedures for the implementation of the mitigation strategies, as appropriate to the nature of the mitigation strategy and its role in the facility's food defense system (See 21 CFR 121.140);
- Food defense corrective action procedures that must be taken if mitigation strategies are not properly implemented, as appropriate to the nature of the actionable process step and the nature of the mitigation strategy (See 21 CFR 121.145); and
- Food defense verification procedures for verification activities, as appropriate to the nature of the mitigation strategy and its role in the facility's food defense system (See 21 CFR 121.150).

Although the IA rule specifies the required contents of the FDP as described above, you can also use the FDP as a resource to capture additional food defense-related information. For example, you could include information such as process flow diagrams; general site security procedures or policies; emergency contact information for suppliers, customers, and government agencies; a crisis management plan; a risk communications plan; a supplier audits plan; and a recall plan.

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

## **B. Individuals to Assist with Developing Your Facility's Food Defense Plan**

In developing your FDP, you will need the assistance of individuals with knowledge and expertise of your facility's operations as well as general food defense principles.

### **1. Food Defense Qualified Individuals**

The IA rule requires special qualifications for individuals who do or oversee the following activities, which require the most food defense expertise:

- preparation of the FDP;
- conduct of a vulnerability assessment;
- identification and explanation of mitigation strategies; and
- performance of the reanalysis. (21 CFR 121.4(c)(3)).

Such an individual must meet the following requirements:

- 1) Education, training, or experience (or a combination thereof) necessary to properly perform the activities; and
- 2) Successful completion of training for the specific function that is at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to conduct the activities. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through a standardized curriculum recognized as adequate by FDA (e.g., the curriculum used in the Food Safety Preventive Controls Alliance (FSPCA) training). (21 CFR 121.4(c)(1) and (2)).

The individual you enlist to perform the specified activities does not have to be an employee of your facility, but it may be beneficial for you to have at least one food defense qualified individual on staff to provide expertise and insight if there are questions about the food defense plan or if the plan needs to be updated. If you do not have such an individual on your staff, you can enlist one from outside your facility to perform the specified activities.

### **2. Food Defense Team**

For some facilities, such as small companies, the responsibility for writing the FDP may fall to a single individual. For facilities that have sufficient resources, although it is not required, we recommend that you put together a team to help develop your FDP, including one or more food defense qualified individuals. Food defense team members should be knowledgeable about general food defense principles and concepts, and the team should include members who are directly involved with food processes and daily operations at your facility. Team members could include personnel from security, maintenance, food production (including equipment experts), sanitation, food safety quality assurance or quality control, engineering, purchasing, human resources, or laboratory. Additionally, colleges and universities, cooperative extensions,

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

consulting groups, and trade associations are potential sources of assistance in developing an FDP.

In addition to developing the FDP, the food defense team can also provide oversight or guidance on the implementation of the plan in the daily operations of the facility. This includes ensuring that appropriate people are trained to handle their FDP-related duties.

### **C. Formatting a Food Defense Plan**

There is no standardized or required format for an FDP. If your FDP includes all the components required by the IA rule, you have the flexibility to use whatever format works best for your facility and organize the content of the FDP in any way you would like. The appendix to this guidance includes sample FDP worksheets for particular components of an FDP. The format used in the included worksheets is just one possibility; you may format your FDP differently. In addition, FDA's software tool, the Food Defense Plan Builder (FDPB), may help you with compiling and organizing the content of your FDP. FDA intends to update the FDPB to align with the IA rule and guidance.

Your FDP could consist of multiple documents, some of which you developed specifically for the IA rule and others that may already exist for other purposes. Although you must sign and date the FDP, the information required in an FDP does not need to be kept in one set of records. (21 CFR 121.310). One approach for organizing the FDP to allow for signing and dating is to collect and maintain all the required documents in a single location (e.g., a binder or folder) with a cover page containing the required signature and the date on which the cover page was signed. Another approach is for you to sign and date a list of the relevant documents (e.g., a Table of Contents) that make up the FDP.

Some facilities may have already independently developed and implemented food defense plans that can be modified to fit the requirements of the IA rule. You may use existing records for your required FDP if the records satisfy all the requirements of the IA rule. If existing records contain only some of the required information, you may keep any additional required information either separately or combined with the existing records. (21 CFR 121.330).

### **D. Determining When to Make Changes to a Food Defense Plan**

The FDP is a dynamic document that reflects your current vulnerability assessment, actionable process steps, mitigation strategies, and applicable management component procedures. The FDP as a whole must be reanalyzed at least every 3 years. (21 CFR 121.157(a)). The following circumstances also necessitate reanalysis: whenever a significant change to activities creates a reasonable potential for a new vulnerability or a significant increase in an existing vulnerability; whenever you become aware of new information about potential vulnerabilities associated with the food operation or your facility; whenever you find that a mitigation strategy or the food defense plan as a whole is not properly implemented; and whenever FDA requires reanalysis to respond to new vulnerabilities, credible threats to the food supply, and developments in scientific understanding. (21 CFR 121.157(b)). For reanalysis conducted in response to such

*Contains Nonbinding Recommendations*  
*Draft-Not for Implementation*

circumstances, you may limit the reanalysis to the affected portions of your FDP. (See 21 CFR 121.157(b)).

### **E. Maintaining a Food Defense Plan**

The FDP is a record that is subject to the records requirements of the IA rule. (21 CFR 121.126(c)). You must sign and date the FDP upon initial completion and upon any modification. (21 CFR 121.310). The FDP must be retained at the facility for at least 2 years after its use is discontinued. (21 CFR 121.315(b)). The FDP must remain onsite. (21 CFR 121.315(c)). Electronic records are considered to be onsite if they are accessible from an onsite location. (21 CFR 121.315(c)).

As FDPs may contain information that present sensitivities not likely to be present in food safety plans, such as a facility's food defense vulnerabilities, we encourage facilities to adequately protect food defense plans and associated information and records.

## **Chapter 2: Vulnerability Assessment to Identify Significant Vulnerabilities and Actionable Process Steps**

This chapter is intended to help you understand how to conduct a vulnerability assessment (VA) to identify significant vulnerabilities and actionable process steps. In a vulnerability assessment, you identify and evaluate points, steps, and procedures in your manufacturing/processing operation where an act of intentional adulteration could occur; and, through that evaluation, identify mitigation strategies to significantly minimize or prevent any significant vulnerability associated with that point, step, or procedure (i.e., actionable process step). The vulnerability assessment requirement is flexible. A facility can choose the VA method that is most appropriate for it if the chosen method includes the elements listed in 21 CFR 121.130. One appropriate method for conducting a VA is the Key Activity Types (KAT) method. Forthcoming guidance will include information on conducting VAs using the three elements, as well as combination of the three elements and the KAT methods.

### **A. What is a Vulnerability Assessment?**

The VA is an essential component of your overall food defense plan (21 CFR 121.126(b)(1)). The VA provides a mechanism for you to identify, prioritize, and focus resources on preventing or significantly minimizing significant vulnerabilities at specific points, steps, or procedures. Your VA should reflect detailed knowledge of the points, steps, or procedures associated with your facility, relevant scientific expertise, and judgment. It is critical to carefully conduct a VA because it identifies those points, steps, or procedures within your facility where significant vulnerabilities exist. Furthermore, many of the other major parts of your FDP (e.g., mitigation strategies and mitigation strategy management components) are dependent upon your VA.

You must conduct or have conducted a vulnerability assessment for each type of food manufactured, processed, packed, or held at your facility using appropriate methods to evaluate each point, step, or procedure in your food operation to identify significant vulnerabilities and actionable process steps. (21 CFR 121.130(a)). A significant vulnerability means a vulnerability that, if exploited, could reasonably be expected to cause wide scale public health harm. (21 CFR 121.3). Although the IA rule does not specify a particular method that you must use to conduct your VA, the following elements must be considered during your evaluation of each point, step, or procedure:

1. The potential public health impact (e.g., severity and scale) if a contaminant were added (21 CFR 121.130(a)(1));
2. The degree of physical access to the product (21 CFR 121.130(a)(2)); and
3. The ability of an attacker to successfully contaminate the product (21 CFR 121.130(a)(3)).

When you are evaluating each of these three elements, you also must consider the possibility of an inside attacker. (21 CFR 121.130(b)). You should assume an inside attacker has legitimate access to the facility (e.g., an employee, contractor, driver, or visitor), a basic understanding of

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

the facility's operations and the food being produced, and the intent to cause wide scale public health harm.

**1. The Scope of "Points, Steps, and Procedures" for Consideration in a Vulnerability Assessment**

Your VA must evaluate each point, step, or procedure in your food operation to identify significant vulnerabilities and actionable process steps. (21 CFR 121.130(a)). Your VA should include only those points, steps, and procedures that are related to manufacturing, processing, packing, or holding of the food product. The phrase "point, step, or procedure" has a similar meaning as it does in the context of HACCP plans and PCHF food safety plans. These points, steps, and procedures include receiving and storage steps for each raw material or other ingredient, preparation, manufacturing, processing, packaging, storage, and load out of the product. You do not need to evaluate points, steps, and procedures that are not part of your food operation. For example, you would not consider mail handling procedures, human resources procedures, utilities and processing aids that do not come into contact with or that are not incorporated into the food, facility emergency evacuation procedures, and other business processes.

**2. Grouping of Similar Food Products**

Some facilities manufacture similar products using either the same equipment or very similar processes. In such instances, the facility could group these products or food types into one or more processes and conduct VAs on these groupings. For example, if a facility manufactures yogurt with different flavor add-ins, such as strawberry, raspberry, and blueberry and the processing steps for these lines are the same, the facility may group these food products into one food type (e.g., "yogurt with fruit add-ins") for the VA and consider them together.

**B. Recommended Activities Prior to Conducting a Vulnerability Assessment**

We recommend that you take certain preliminary steps to help you prepare, organize, and conduct your VA efficiently.

You may find that you have already completed these preliminary steps for other purposes; we recommend that you leverage whatever relevant existing resources and documents are available to you to improve efficiency and eliminate duplicative efforts. For example, you may have already developed a process flow diagram and process descriptions for your food production process.

**Box 2a-1. Preliminary Steps**

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

- |  |
|--|
| <ol style="list-style-type: none"><li>1. Assemble a Food Defense Team</li><li>2. Describe the product under evaluation</li><li>3. Develop a process flow diagram</li><li>4. Describe the process steps</li></ol> |
|--|

**1. Assemble a Food Defense Team**

Your written VA is part of your FDP (21 CFR 121.126(b)(1)), which must be prepared, or its preparation overseen, by one or more specially qualified individuals (21 CFR 121.4(c)(3)(i)). The individuals conducting the VA and their expertise related to your facility practices, food manufacturing processes, and food product(s) under evaluation will impact the quality and completeness of your VA. We therefore recommend that you assemble a food defense team of individuals with expertise in the day-to-day operations of your facility to conduct your VA. The food defense team could include, as appropriate, personnel from your facility's quality assurance or quality control, laboratories, management, security, sanitation, maintenance, and other relevant departments. Having people on the food defense team from different functions within the facility can help provide a complete understanding of the VA process. If necessary or desired, you can supplement the expertise of the food defense team with technical experts from other off-site functions within the firm, such as research and development, technical applications groups, and quality management, as well as outside experts from universities, cooperative extension services, trade associations, private consulting firms, or other sources.

**2. Describe the Product Under Evaluation**

Including a description of the food product(s) under evaluation for the VA is critical for you and others (i.e., colleagues, corporate office, auditors, investigators) to know what food(s) are included in the VA. The description should include the full name(s) of the finished product and any other information that may be helpful to those conducting or reviewing the VA.

**3. Develop a Process Flow Diagram**

We recommend that a facility develop a list or draw a process flow diagram of each point, step, or procedure in the process under evaluation. A process flow diagram can provide a clear, simple description of the steps involved in the processing of your food product and its associated ingredients as they "flow" from receipt to product load out. Note that process flow diagrams developed for other purposes, such as food safety, can also be used for VA purposes.

**4. Describe the Process Steps**

A detailed process description explains what happens at each of the process steps listed in the process flow diagram. We have found through experience that a short description of what each process step entails can provide background information for a VA to assist in determining whether there is a significant vulnerability. This information, such as whether a food is handled manually, whether the processing equipment is in a high-traffic area, and whether rework is incorporated into product, can contribute to the accuracy of a VA. Additionally, information



*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

about the process step can assist in identifying and implementing mitigation strategies, as well as preparing the explanation for why mitigation strategies significantly minimize or prevent a significant vulnerability. For example, for a raw juice surge tank step, it would be helpful to include information in the description such as: “A surge tank is used to control flow rates into the pasteurizer. The surge tank has a maximum capacity of 200 gallons, but typical volumes of juice in the surge tank range from 130-150 gallons. Resident time of juice in the surge tank is approximately 8-10 minutes. The surge tank is generally not accessed during operations, but a lid does provide potential access at the top of the surge tank. The surge tank is cleaned during each weekly cleaning cycle.” Including information about how accessible the food is in the tank, cleaning frequencies, and volume of juice in the tank can assist during the VA. This information would also be helpful when identifying mitigation strategies. If access via the lid is the main reason the facility determined the tank is an actionable process step with a significant vulnerability, then the facility may identify and implement a mitigation strategy that significantly minimizes this access.

### **C. Key Activity Types as an Appropriate Method for Conducting a Vulnerability Assessment to Identify Significant Vulnerabilities and Actionable Process Steps**

FDA developed the KAT method based on our analysis of the results of over 50 vulnerability assessments that we conducted in partnership with other government agencies and the food industry that reflect the activities and associated vulnerabilities present in a wide array of food manufacturing settings. (Ref. 3). In conducting the VAs, FDA used an assessment methodology that included characteristics (e.g., lethal dose) of an unnamed, representative contaminant that is highly lethal and heat stable. This analysis resulted in two important findings: (1) Criticality, Accessibility, and Vulnerability were the three CARVER + Shock elements identified as the most important to consider when conducting facility-specific VAs, and (2) four general activity types (i.e., the key activity types), consisting of points, steps, or procedures consistently ranked as the most vulnerable, regardless of the food commodity assessed, and reflect significant vulnerabilities to intentional adulteration caused by acts intended to cause wide scale public health harm.

The KAT method is an appropriate method for conducting a VA because it reflects consideration of the three required elements and the inside attacker (21 CFR 121.130). Further, using the KAT method to identify actionable process steps is likely to require fewer resources (e.g., time, research, and technical analysis) than applying the three required elements to each point, step, or procedure. See Section E. of this chapter for an explanation of how a facility can use the KAT method to identify actionable process steps.

### **D. Key Activity Type Descriptions**

The four KATs are: bulk liquid receiving and loading, liquid storage and handling, secondary ingredient handling, and mixing and similar activities. Each are described below.

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

## **1. Bulk Liquid Receiving and Loading**

Bulk liquid receiving and loading includes a point, step, or procedure where the primary purpose or result is:

- Bulk liquid receiving at the facility from an inbound conveyance (the inbound movement of liquid product into a facility for its use in the food production process). This activity includes opening the inbound transport vehicle, the opening of venting hatches or other access points, attaching any pumping equipment or hoses, and unloading of the bulk liquid; or
- Bulk liquid loading into an outbound conveyance (the outbound movement of liquid product from a facility for further processing or use). This activity includes opening the outbound transport vehicle, attaching any pumping equipment or hoses, and opening any venting hatches at the facility.

These are key activities because there is a high probability of a contaminant, if intentionally added, to be mixed within the liquid due to significant sloshing, movement, or turbulence associated with the receiving or loading activity. These activities involve a large volume of liquid that, if contaminated, could cause wide scale public health harm. In addition, the need for worker activity associated with these processing steps provides access to hoses, the transport vessel, and potentially the product as it is being received or loaded.

Activities that do not fall under this KAT include the receiving or loading of sealed jugs, drums, jars, and totes because the liquid is not using the vehicle as the bulk container. The receiving or loading of these sealed containers are not included in this KAT regardless of the total volume of liquid received or loaded.

## **2. Liquid Storage and Handling**

Liquid storage and handling includes a point, step, or procedure where the primary purpose or result is:

- Storage or holding of liquids (bulk or non-bulk) either in storage tanks or in other tanks at the facility. This includes bulk or non-bulk liquids in storage silos. The KAT also includes the use of totes or other liquid storage containers where the tamper-evident seals are opened and the container itself is used for storage and where the container is not resealed in a tamper-evident fashion. Tanks can be used to store liquid ingredients (e.g., fats, oils, vitamin mixes, and sweeteners), hold liquid product for sample testing and other quality control activities, or to store liquid food for other processing purposes; or
- Handling, metering, surge, or other types of intermediate processing tanks used to control flow rates of liquid ingredients or product through the production system. Handling tanks also include tanks or totes where the tamper-evident seals are opened, and the container itself is used as a handling tank (e.g., when a drum is opened and a pump is attached directly onto the drum to meter an ingredient into the product line).

***Contains Nonbinding Recommendations***  
***Draft-Not for Implementation***

These are key activity types because if a contaminant were successfully introduced, there is a high probability of a contaminant mixing within the liquid due to the agitation commonly used to prevent separation within the liquid medium, the mixing or agitation caused as liquid enters or exits the tanks, or the likelihood that liquid ingredients will be metered or applied to a large amount of servings. Access necessary for the introduction of a contaminant is generally available through hatches, sample ports, or the container lid.

### **3. Secondary Ingredient Handling**

Secondary ingredient handling includes any point, step, or procedure where dry or liquid secondary ingredients (e.g., inclusions, minor ingredients, processing aids, and food additives) are manipulated by human contact prior to or during addition to the product stream.

Secondary ingredient handling includes a point, step, or procedure where the primary purpose or result is:

- Staging of secondary ingredients, i.e., the process of opening the tamper-evident packaging of a secondary ingredient and moving the ingredient to the production area in advance of being added into the primary product stream;
- Preparation of secondary ingredients. i.e., the process of measuring, weighing, premixing, or otherwise manipulating the ingredient prior to addition to the product stream;
- Addition of secondary ingredients, i.e., the process of physically adding ingredient directly into the product stream or into surge or meter hoppers to deliver the ingredient into the product stream; or
- Rework product, i.e., removing clean, unadulterated food from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

This KAT also includes the storage of partially used, open containers of secondary ingredients where the tamper-evident packaging has been breached.

These are key activities because a contaminant can be intentionally introduced into a relatively small amount of ingredient or rework and, if it is, it is likely that the contaminant will be distributed into a larger volume of food within the main product flow. Handling of secondary ingredients is generally open and accessible and that accessibility is an inherent component of the activity. Thus, these key activities provide a potential point of access where a contaminant could be introduced into the product stream.

### **4. Mixing and Similar Activities**

Mixing and similar activities includes a point, step, or procedure where the primary purpose or result is:

- Mixing (i.e., to blend a powder, dough, or liquid ingredient together);

***Contains Nonbinding Recommendations***  
***Draft-Not for Implementation***

- Homogenizing (i.e., to reduce the particle size of an ingredient and disperse it throughout a liquid);
- Grinding (i.e., to reduce the particle size of a solid ingredient or mass to a smaller granularity); or
- Coating (i.e., to layer a powder or liquid onto the surface of a product, such as a batter, breading, glazing, or flavoring).

Equipment associated with these activities include: mixers, blenders, homogenizers, cascade-style breaders, mills, grinders, and other similar equipment.

Process steps that are not specifically designed to evenly mix product may still be included in the KAT of mixing and similar activities because mixing is a result of the process conducted. For example, a roaster with a primary purpose of evenly roasting beans or nuts that uses paddles or other agitation mechanisms to achieve an even roast may effectively mix a contaminant into the food during the roasting process.

Mixing and similar activities are a key activity type because a potential contaminant successfully added at one of these steps would generally be readily dispersed throughout the product because of the nature of the activity (i.e., mixing, homogenizing, grinding, or coating).

### **E. Identifying Actionable Process Steps Using the Key Activity Types Method**

To conduct a VA using the KAT method, you should assess each point, step, or procedure to determine whether the activities at the point, step, or procedure fit within one or more of the KATs. Process steps that fit within one or more of the KATs are actionable process steps. Process steps that do not fit within any of the KATs are not actionable process steps and do not require mitigation strategies. For example, a process step where multiple ingredients are combined into one large bowl and mixed would fit within the activities in the “Mixing and Similar Activities” KAT. This process step would then be identified as an actionable process step. In contrast, the storage of dry ingredients that are sealed with tamper-evident packaging in a refrigerated storage room would not fit within any of the KATs, and therefore would not be an actionable process step. Figure 2a-2 is an example of a completed VA Analysis Summary worksheet showing how to use the KAT method to conduct a VA.

Your VA must include a written explanation as to why each point, step, or procedure was or was not identified as an actionable process step. (21 CFR 121.130(c)). For example, if a processing step fits within the Mixing and Similar Activities KAT, then you should identify that process step as an actionable process step and write an explanation as to why. This written explanation may be: “This point, step, or procedure fits within the KAT- Mixing and Similar Activities.” Abbreviations or footnotes may be used for written explanations, when appropriate. For example, if multiple processing steps do not fit within any of the KATs, then you may use a footnote where the written explanation “This point, step, or procedure does not fit within any of the KATs” is stated once, and a number, letter, or symbol is used in its place. Alternatively, if multiple processing steps do not fit within any of the KATs, then you may choose to write out all

***Contains Nonbinding Recommendations  
Draft-Not for Implementation***

of those steps, and state, with one sentence, that none of the listed steps fit within any of the KATs.

There may be instances where a process step fits within more than one KAT. In this case, you should include each applicable KAT in your explanation. Doing so would be helpful for the identification and implementation of mitigation strategies because the activity type may inform the mitigation strategies that will minimize or prevent significant vulnerabilities at the actionable process step. Including each applicable KAT also would be helpful when conducting a VA as part of a reanalysis of the food defense plan because if there are changes to the process step, such as a major equipment change, you can quickly determine whether the changes would affect whether the step fits within the KATs identified in the previous VA.

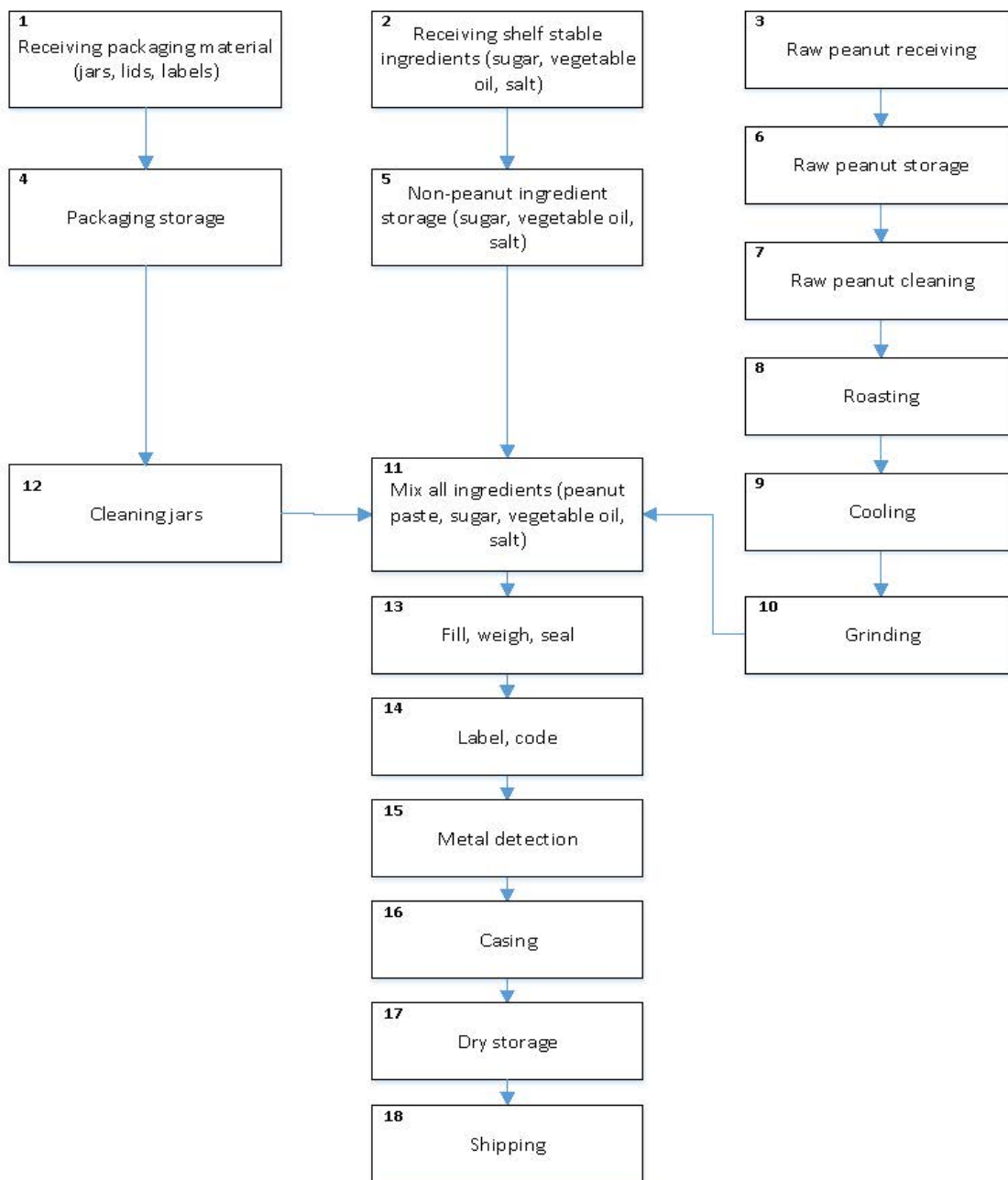
If a processing step does not align with any of the KATs, then that step is not an actionable process step and your written explanation may be: “This point, step, or procedure does not align with any of the KATs.”

There may be instances when facilities determine that their food production does not involve any of the KATs. In this situation, there would be no actionable process steps identified and no mitigation strategies or management components included in the FDP. However, the facility is still required to document its finding that none of the KATs apply to its food processes and include a written explanation of the conclusion. (21 CFR 121.130(c)). The documentation must be a part of the written FDP (121.126(b)(1)), and the facility must conduct a reanalysis when required by 21 CFR 121.157.

Figure 2a-1 is a sample process flow diagram for smooth peanut butter and Figure 2a-2 is an example of a completed VA Analysis Summary worksheet showing how to use the KAT method to conduct a VA.

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

**Figure 2a-1. Smooth Peanut Butter Process Flow Diagram<sup>4</sup>**



<sup>4</sup> Courtesy of the Food Safety Preventive Controls Alliance. Used with permission.

*Contains Nonbinding Recommendations*  
*Draft-Not for Implementation*

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

**Figure 2a-2. Worksheet 1-C: Vulnerability Assessment Analysis Summary– Smooth Peanut Butter**

**PRODUCT(S):** Smooth Peanut Butter

**FACILITY NAME:** PB #12345

**ADDRESS:** 123 Main Street, Anytown, USA

**SIGNED DATE:** February 28, 2018

<b>(1) #</b>	<b>(2) Process Step</b>	<b>(3) Process Description</b>	<b>(4) Vulnerability Assessment Method</b>	<b>(5) Explanation</b>	<b>(6) Actionable Process Step</b>
1	Receiving packaging material	Corrugated shippers, shrink film, plastic containers, plastic lids, and labels are received individually cased. Supplier specifications require food grade material for packaging material that is compatible with ambient storage of food products.	Key Activity Types	This point, step, or procedure does <u>not</u> fit within any of the KATs.	<b>No</b>
2	Receiving shelf stable ingredients (sugar, vegetable oil, salt)	Sugar and salt are received in 50 lb. tote bags. Hydrogenated vegetable oil (rapeseed and refined soy) is received in 5-gallon plastic pails that are sealed with tamper-evident packaging.	Key Activity Types	This point, step, or procedure does <u>not</u> fit within any of the KATs.	<b>No</b>



*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

<b>(1) #</b>	<b>(2) Process Step</b>	<b>(3) Process Description</b>	<b>(4) Vulnerability Assessment Method</b>	<b>(5) Explanation</b>	<b>(6) Actionable Process Step</b>
3	Raw peanut receiving	Shelled peanuts are received on trucks from several sheller domestic locations in 2000 lb. super sacks.	Key Activity Type	This point, step, or procedure does <u>not</u> fit within any of the KATs.	<b>No</b>
4	Packaging storage	Corrugate, shrink film, plastic containers, plastic lids, and labels are stored in a dry storage area and segregated from raw food material. Packaging is used on a first-in-first-out basis.	Key Activity Type	This point, step, or procedure does <u>not</u> fit within any of the KATs.	<b>No</b>
5	Non-peanut ingredient storage	Sugar, hydrogenated vegetable oil, and salt are received and stored at ambient conditions in an area separate from raw peanuts. Ingredients are stored in tamper-evident sealed containers. These materials are used on a first-in-first-out basis. Open containers of partially used ingredients may be put back into storage for later use.	Key Activity Type	This point, step, or procedure fits within the KAT- Secondary Ingredient Handling since partially used ingredient containers are open containers that are accessible.	<b>Yes</b>

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

(1) #	(2) Process Step	(3) Process Description	(4) Vulnerability Assessment Method	(5) Explanation	(6) Actionable Process Step
6	Raw peanut storage	Raw peanuts are stored in a segregated area at ambient temperature and <70% relative humidity. Raw peanuts are used on a first-in-first-out basis.	Key Activity Type	This point, step, or procedure does <u>not</u> fit within any of the KATs.	<b>No</b>
7	Raw peanut cleaning	Prior to roasting, shelled raw peanuts are visually inspected and passed over a vibratory conveyor to remove residual foreign material, including sticks, rocks, or metal pieces. A high-efficiency particulate air (HEPA) filtered air stream is used to remove light extraneous material such as shell fragments.	Key Activity Type	This point, step, or procedure does <u>not</u> fit within any of the KATs.	<b>No</b>
8	Roasting	Raw peanuts are conveyed through a roaster in a continuous process that applies forced heated air uniformly from above and below the peanut bed at a uniform bed depth. No mixing occurs during the roasting process. The roaster is not accessible.	Key Activity Type	This point, step, or procedure does <u>not</u> fit within any of the KATs.	<b>No</b>

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

(1) #	(2) Process Step	(3) Process Description	(4) Vulnerability Assessment Method	(5) Explanation	(6) Actionable Process Step
9	Cooling	Roasted peanuts are cooled on the conveyor under ambient conditions prior to grinding.	Key Activity Type	This point, step, or procedure does <u>not</u> fit within any of the KATs.	<b>No</b>
10	Grinding	Peanuts are conveyed across a magnet to a grinder where the peanuts are coarse ground to a paste consistency.	Key Activity Type	This point, step, or procedure fits within the KAT- Mixing and Similar Activities.	<b>Yes</b>
11	Mixing all ingredients	The peanut paste is pump-conveyed to a mixer to which sugar, salt, and oil are added. The batch is mixed until ingredients are adequately dispersed.	Key Activity Type	This point, step, or procedure fits within the KAT- Mixing and Similar Activities.	<b>Yes</b>
12	Cleaning jars	Inverted jars are blown with HEPA-filtered, de-ionized air to remove foreign material prior to filling.	Key Activity Type	This point, step, or procedure does <u>not</u> fit within any of the KATs.	<b>No</b>
13	Fill, weigh, seal	Peanut butter is dispensed into cleaned jars to the appropriate fill weight. Nitrogen is injected into the headspace after filling; thin foil induction seal (compatible with metal detection) and the plastic caps are applied.	Key Activity Type	This point, step, or procedure does <u>not</u> fit within any of the KATs.	<b>No</b>

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

(1) #	(2) Process Step	(3) Process Description	(4) Vulnerability Assessment Method	(5) Explanation	(6) Actionable Process Step
14	Label, code	Immediately after the capping, the lot identifier code is printed on each jar and labels are applied. Labels are checked prior to adding to the labeler to ensure the correct label is used. The label contains an allergen declaration statement that this product contains peanuts.	Key Activity Type	This point, step, or procedure does <u>not</u> fit within any of the KATs.	<b>No</b>
15	Metal detection	The product is passed through a metal detector.	Key Activity Type	This point, step, or procedure does <u>not</u> fit within any of the KATs.	<b>No</b>
16	Casing	Jars are placed by hand into corrugate cases, with 12 jars per case. Cases are sealed and coded with lot information.	Key Activity Type	This point, step, or procedure does <u>not</u> fit within any of the KATs.	<b>No</b>
17	Dry storage	Finished product is stored in ambient warehouses until distributed.	Key Activity Type	This point, step, or procedure does <u>not</u> fit within any of the KATs.	<b>No</b>
18	Shipping	Finished product is shipped in ambient trucks to customers.	Key Activity Type	This point, step, or procedure does <u>not</u> fit within any of the KATs.	<b>No</b>

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

**Chapter 2 F: Evaluating the Three Fundamental Elements to Identify Significant Vulnerabilities and Actionable Process Steps (coming soon)**

## **Chapter 3: Mitigation Strategies for Actionable Process Steps**

This chapter provides guidance to help you identify and implement mitigation strategies for the actionable process steps identified during your vulnerability assessment (VA). It includes an overview of common mitigation strategies that you could use to significantly minimize or prevent intentional adulteration at actionable process steps. This chapter also provides information on how to consider existing measures when identifying mitigation strategies, selecting mitigation strategies to address specific aspects of an actionable process step's vulnerability, and the contribution of facility-wide security measures in a facility's food defense system.

In this chapter, we provide recommendations for the types of mitigation strategies you can implement and what you should consider when choosing mitigation strategies, but you have the flexibility to identify and implement mitigation strategies from among all procedures, practices, and processes available to you that would provide assurances that you are significantly minimizing or preventing the significant vulnerabilities.

### **A. Mitigation Strategies Requirement**

“Mitigation strategies” are those risk-based, reasonably appropriate measures that a person knowledgeable about food defense would employ to significantly minimize or prevent significant vulnerabilities identified at actionable process steps, and that are consistent with the current scientific understanding of food defense at the time of the analysis. (21 CFR 121.3).

The nature of mitigation strategies is different from the nature of preventive controls put in place for food safety purposes. Mitigation strategies are intended to minimize or prevent intentional adulteration while preventive controls are intended to minimize or prevent the occurrence of an unintentionally introduced food safety hazard. Further, mitigation strategies are typically implemented to reduce physical access to a point, step, or procedure, or reduce the opportunity for an attacker to successfully contaminate the food, and do not lend themselves to scientific validation in most instances. In contrast, preventive controls are more likely to be process-oriented and lend themselves to scientific validation. Mitigation strategies are practices or conditions that are not inherent to the operation of a process step. That is, the process step could still function if the mitigation strategy was not applied. The inherent characteristics of a process step should be evaluated during a VA. We intend to publish additional guidance on conducting VAs, which will cover inherent characteristics of process steps and how they should be considered in VAs.

You must identify and implement mitigation strategies at each actionable process step to provide assurances that the significant vulnerability at each step will be significantly minimized or prevented and the food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 of the FD&C Act. For each mitigation strategy implemented at each actionable process step, you must include a written explanation of how the mitigation strategy sufficiently minimizes or prevents the significant vulnerability associated with the

***Contains Nonbinding Recommendations***  
***Draft-Not for Implementation***

actionable process step. (21 CFR 121.135(a)). Abbreviations or footnotes may be used for written explanations, when appropriate. For example, if locks are used as mitigation strategies at multiple actionable process steps, and the written explanations for how the locks significantly minimize or prevent the significant vulnerabilities at each of these steps is the same (e.g., “the lock prevents an inside attacker from accessing the food at this point, step, or procedure”), then you may choose to use a footnote or abbreviation when this explanation appropriately applies to each mitigation strategy. Additionally, the information in the explanation can assist you in identifying the most appropriate mitigation strategies management components. (See Chapter 4 of this guidance for food defense monitoring. We intend to publish additional chapters at a later date addressing food defense corrective actions and food defense verification).

After you have conducted a VA and identified any actionable process steps, the next step is to choose mitigation strategies for the actionable process steps. Mitigation strategies are:

- Customized to the process step at which they are applied;
- Tailored to existing facility practices and procedures; and
- Directed toward the actionable process step’s vulnerability, including vulnerability to an inside attacker.

Consistent with the requirements, you have the flexibility to choose which mitigation strategies are appropriate for your facility’s particular vulnerabilities. You must prepare written explanations that describe how the strategies sufficiently minimize or prevent each significant vulnerability. (21 CFR 121.135(a)). These explanations will help you to verify the proper implementation of mitigation strategies. (21 CFR 121.150(a)(3)). It is important to note that mitigation strategies that increase food safety risks or negatively impact worker safety should not be implemented. Due to the degree of flexibility you have in choosing mitigation strategies appropriate for your facility, we expect facilities will be able to identify strategies that do not negatively impact food safety or worker safety.

## **B. Identifying Mitigation Strategies**

As discussed in Chapter 2 of this guidance, there are three elements of a VA: (1) public health impact; (2) physical access; and (3) likelihood of successful attack—which, when taken together along with considering the possibility of an inside attacker, characterize a process step’s degree of vulnerability to intentional adulteration. You must evaluate each of these elements (21 CFR 121.130(a)), and, in doing so, you should consider and understand how each element contributes to the overall vulnerability of each process step. This analysis should help you identify the mitigation strategies that your facility should implement to significantly minimize significant vulnerabilities at actionable process steps. When identifying and implementing mitigation strategies, the consideration of these three elements will help to form the written explanations for your mitigation strategies, as required by 21 CFR 121.135(b).

Because of efficiencies and economies of scale from processing large batches of products in a single step, we generally expect that you would not implement mitigation strategies to reduce the volume of food being processed and thus would not identify strategies designed to address



***Contains Nonbinding Recommendations***  
***Draft-Not for Implementation***

element 1 (public health impact) of the elements of the VA. It is likely that you will generally design your mitigation strategies to address element 2 (degree of physical access) or element 3 (likelihood of successful attack). Accordingly, in most circumstances, you should design your mitigation strategies to either:

- 1) minimize the accessibility of the product to an inside attacker (e.g., physically reducing access to the product, such as by locking storage tanks); or
- 2) reduce the opportunity for an inside attacker to contaminate the product (e.g., increasing observation of the area through supervision or use of the buddy system);

or a combination of both.

As discussed in Chapter 2 of this guidance, we consider use of FDA's Key Activity Types to be an appropriate method for conducting a facility VA because we included the three elements and the consideration of an inside attacker in our analysis that identified the Key Activity Types. So, while a Key Activity Type-based VA may not include detailed evaluation of each of the three elements specifically for each process step, when you consider mitigation strategies for actionable process steps identified using Key Activity Types, you should still focus your consideration on minimizing an inside attacker's accessibility to the product and reducing the opportunity for an inside attacker to contaminate the product.

Mitigation strategies found within FDA's Food Defense Mitigation Strategies Database (FDMSD) are generally designed to address one or both elements (degree of physical access and an attacker's ability to contaminate the food). We derived the content of the FDMSD from our experience conducting VAs with industry, and it can serve as a resource for facilities to identify mitigation strategies. We expect that the strategies in the database will provide general ideas of mitigation strategies that facilities can then tailor to the specific characteristics of their actionable process steps. The explanation of how the mitigation strategy sufficiently minimizes or prevents the significant vulnerability associated with the actionable process step would, generally, address the mitigation strategy's impact on element 2 or element 3, or both. See Section F. of this chapter for additional information about the required explanations.

Finally, you have the flexibility to implement whichever mitigation strategy, or strategies, is most appropriate for your facility. We expect that facilities will implement the most cost effective mitigation strategy that addresses their significant vulnerabilities, (with some instances, such as the use of existing measures, resulting in minor to no implementation costs), and not implement strategies that would be prohibitively expensive when other, cheaper strategies would suffice.

**1. Minimizing the Accessibility of the Product to an Inside Attacker**

Mitigation strategies designed to reduce an inside attacker's access to a product can take many specific forms, but all such strategies perform the same essential function – reducing or eliminating physical access to the product at the actionable process step. Access-based mitigation strategies can be physical in nature, such as using locking hatches, or they can be

*Contains Nonbinding Recommendations*  
*Draft-Not for Implementation*

personnel-management or operations-based strategies that prevent an attacker from accessing a sensitive area or piece of equipment, or contacting the food.

**a. Personnel and Operations-Based Mitigation Strategies**

Personnel-based mitigation strategies are specific actions conducted by personnel to significantly minimize or prevent significant vulnerabilities at actionable process steps. The actions should not be inherent characteristics of the process step, which are considered during the VA<sup>5</sup>. Once an actionable process step is identified, personnel-based mitigation strategies should be designed and applied to mitigate a significant vulnerability present at the actionable process step through consistent and proper implementation of a specific practice that reduces the vulnerability of the step.

Personnel-based mitigation strategies that can reduce accessibility involve establishing who is authorized to be present at an actionable process step and prohibiting individuals from being there if not required by work function. You can establish who should be authorized to be in a particular area based on an evaluation of the actionable process step, the specific job function requiring human presence, and the quantity and skill level of workers needed to perform the function. You should also evaluate the skill set of the workers in this area, their seniority, level of responsibility, and other factors that may contribute to their trustworthiness for working in a sensitive area of the facility. For example, you may authorize senior or long-term employees, or those who have otherwise established elevated trust by management to work at a particular actionable process step, as a mitigation strategy. For personnel-based mitigation strategies, authorized employees would be responsible for excluding unauthorized persons from the area.

One way employee vetting can serve as a mitigation strategy that is directed towards an actionable process step is to apply the vetting process in a progressive nature such that employees working in less vulnerable areas receive a less intrusive level of vetting than workers at actionable process steps. For example, a facility may determine that workers responsible for unloading dry ingredients in sealed, tamper-evident packaging need only a basic level of vetting, such as a reference check conducted as a standard part of pre-employment screening. This facility also identifies an actionable process step at its secondary ingredient premixing station. As one of its mitigation strategies for this step, the facility requires that workers at this step undergo a more robust vetting process that includes a criminal background check and credit check. Due to the vulnerability associated with the actionable process step, the facility has

---

<sup>5</sup> Inherent characteristics are conditions, activities, practices, or characteristics that are integral to the operation of a process point, step, or procedure. These characteristics, such as integrated equipment safety features that stop operation of the processing line to prevent bodily harm when equipment is accessed, or a processing step that is pressurized to an extent that makes access to the food and introducing a contaminant improbable, should be considered when conducting the vulnerability assessment. Guidance related to how to consider inherent characteristics in the VA is forthcoming.

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

determined that workers in this area require elevated levels of vetting, which would work in concert with a second mitigation strategy to clearly identify the authorized individuals (such as by color-coded hats) and restricts access to the area to only those authorized individuals.

A facility can also establish standards for workers that are assigned to actionable process steps that are more stringent than the standards that may be required for workers in less vulnerable areas. For example, a facility that conducts criminal background and credit checks on all employees may allow a worker with minor infractions in their past to work at a process step of relatively low vulnerability, but for workers assigned to actionable process steps, the facility requires these workers to have a clear background check with no infractions and not have any other history of behavior that may show potential for poor decision making, being extorted or coerced, or other concerning behavior (e.g., excessive debt, substance abuse).

You can use several methods to vet employees, for example: performing criminal background checks, reference checks with previous employers, and credit checks; however, we caution against using cursory background checks as the sole determination for establishing who is authorized access to a particular actionable process step because information obtained through a background check may be outdated or missing more recent key information that could be valuable in assessing the potential for an insider threat.

Typically, mitigation strategies that restrict access to, and prohibit unauthorized individuals from, entering an area would be designed around an existing, facility-wide security measure of positively identifying people in the facility and employing some practice to easily identify workers who are authorized to work in the particular area. For example, a facility may have an actionable process step with a mitigation strategy designed to restrict access to only those employees whose job function is to oversee the actionable process step. The facility identifies these individuals by issuing them distinct (e.g., specially colored) uniforms enabling management and other staff to easily determine whether they are authorized to be in the area. If an unauthorized person enters the area, they would be immediately identifiable due to the lack of distinct uniform, and should be removed from the area. Implementation of the access restriction is paramount to these types of mitigation strategies, and you should take steps to ensure that authorized individuals and management know how to respond to the presence of an unauthorized person in a particular area.

Unlike technology-assisted mitigation strategies (such as locks and seals) that physically restrict access (further discussed in Section B.1.b. of this chapter), worker attentiveness and action may be the only access barrier to an actionable process step covered by a personnel-based mitigation strategy. When you rely on workers to implement a mitigation strategy that restricts access to only employees authorized to be in the area, proper training of employees on the consistent and proper implementation of this mitigation strategy is critical. We will provide further guidance on training for workers and supervisors working at actionable process steps in forthcoming guidance.

Operations-based mitigation strategies are specific operational actions to significantly minimize or prevent significant vulnerabilities at actionable process steps. These actions should not be inherent characteristics of the process step. For example, a facility may have a process step

***Contains Nonbinding Recommendations***  
***Draft-Not for Implementation***

where ingredients are staged, in an accessible manner, overnight. This procedure may be identified as an actionable process step because a facility determines that any time these containers are accessible, there is a potential opportunity for an attacker to introduce a contaminant into the ingredient or rework material. The mitigation strategy the facility implements reduces the staging time (i.e., ingredients are not staged overnight) in order to reduce access to staged ingredients and limit the opportunity for intentional adulteration. This minor operational change significantly reduces the significant vulnerability associated with staging of ingredients over extended timeframes. This mitigation strategy can be implemented with little to no cost incurred by the facility. Reducing the time ingredients and rework materials are staged in unsecured containers reduces the time ingredients are potentially accessible for an attacker to adulterate the ingredient or rework material.

Another operations-based mitigation strategy to reduce access is to relocate the staging or short-term storage of partially-used, open ingredient containers to a secure, limited-access part of the facility. Moving the location where this activity is conducted to an area that already has restricted access significantly reduces the accessibility of an attacker to the open containers.

**b. Technology-Assisted Mitigation Strategies**

Technology-assisted mitigation strategies generally rely on the implementation of a physical access barrier or the implementation of tamper-evident seals or other detection mechanisms that would prevent access to someone intending to adulterate the food without leaving detectable evidence. The most illustrative and intuitive example of a technology-assisted mitigation strategy that reduces access is that of a lock on a hatch, inspection port, lid, or other access point.

Additional examples of technology-assisted mitigation strategies to reduce access to the food include:

- Using tamper-evident tape or seals to reseal ingredient storage containers when tamper-evident packaging has been opened (e.g., for staging, handling, or ingredient sampling);
- Restricting access to the area around an actionable process step with locking gates, doors, or other barriers where only authorized persons can open the barrier by using specially-issued keys or other authority-based access mechanisms such as radio-frequency identification cards or swipe cards;
- Securing loading/unloading hoses in locking cabinets or by securing the hose opening with tamper-evident caps or seals;
- Blocking access pathways by implementing barriers to reduce access to food and equipment;
- Employing seals on a shipping conveyance to reduce the likelihood that the shipping conveyance is accessed during transport;
- Using automated and enclosed equipment, such as automated computer-weighing, measuring, and addition equipment, to reduce human contact with secondary ingredients or rework;
- Using enclosed tanks and transfer systems to move materials to reduce the potential for an attacker to access the product.

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

## **2. Reducing the Ability of an Inside Attacker to Contaminate the Product**

In addition to reducing access to actionable process steps, you can also significantly minimize or prevent significant vulnerabilities by using mitigation strategies that reduce or eliminate the ability of an inside attacker to introduce a contaminant into the product to achieve wide scale public health harm. These types of mitigation strategies may be appropriate in situations where reducing access to the food is not feasible, would be cost prohibitive, or poses challenges to the operations of the facility. Reducing the ability of an inside attacker to contaminate the food such that the outcome of the contamination may result in wide scale public health harm can include several types of measures. Facilities should consider the environment surrounding the actionable process step, equipment used, the number and nature (e.g., seniority, education, training, experience, status (i.e., temporary, seasonal, permanent)) of employees in the area, and other factors that may inform the identification of mitigation strategies that would significantly reduce the ability of an inside attacker to successfully contaminate food.

Mitigation strategies of this type can include increased observation of an actionable process step so that an inside attacker's actions would be readily evident and, thus, prevented or interdicted. They can also include, for example, strategies that make the carry and introduction of a contaminant extremely challenging or impossible, or strategies that would require the inside attacker to undertake implausible or impossible actions to carry out the attack. Like mitigation strategies that reduce access, mitigation strategies that reduce the ability of an inside attacker to introduce a contaminant into the product also can generally be broken down into those strategies that focus on managing personnel behavior or process operations and those that are technology assisted.

### **a. Personnel and Operations-Based Mitigation Strategies**

Personnel-based mitigation strategies that reduce the ability of an inside attacker to adulterate a product typically include strategies that increase observation of a significantly vulnerable area such that an attacker's actions would be easily detected. Generally, increased observation is facilitated by adequate lighting, clear sight lines, and/or eliminating visual obstructions. We do not expect that most facilities will reengineer processing lines or undertake other major structural changes to facilitate clear lines of sight or eliminate visual obstructions. We expect that more commonly facilities may choose to move easily movable objects that are blocking lines of sight.

One personnel-based mitigation strategy is to use peer monitoring at an actionable process step by requiring at least two staff members to be in the area at any given time during operations. This can reduce the opportunity for an attacker to discreetly introduce a contaminant into the food. In addition to increasing visibility and observation of an attacker's actions once they have accessed the actionable process step, peer monitoring can make it more difficult for an attacker to bring the contaminant into the area. Peer monitoring need not require hiring additional personnel. It may be feasible to incorporate peer monitoring into the existing job functions of workers in the area. Peer monitoring is one of many possible strategies. Other strategies that can reduce an attacker's ability to successfully adulterate the food include:

***Contains Nonbinding Recommendations  
Draft-Not for Implementation***

- Increasing the supervision of highly vulnerable activities, such as bulk liquid receiving or loading;
- Moving highly vulnerable activities to easily observable areas;
- Requiring workers at actionable process steps to wear uniforms or clothing without pockets or other means of concealing items;
- Implementing procedures where workers are required to check in with a supervisor or security personnel before entering highly vulnerable areas to ensure workers are not carrying in a potential contaminant;
- Altering existing operations, such as visual inspection procedures, to ensure that a contaminant has not been introduced into a tank, mixer, or other piece of equipment prior to the introduction of food;
- Using cleaned-in-place equipment or flushing equipment, or running a discard batch prior to resuming production after equipment has been idle and accessible to eject an intentionally introduced contaminant from the system and prevent it from adulterating the food;
- Requiring driver check-in and identification to confirm driver identity matches shipping documentation; and
- Accepting only previously scheduled shipments from known suppliers.

**b. Technology-Assisted Mitigation Strategies**

Technology-assisted mitigation strategies that reduce the ability of an inside attacker to introduce a contaminant to the product typically include measures that would detect an attacker's actions, alert management of a problem, and thereby prevent an attacker's actions from resulting in public health harm, or would neutralize the threat if an act of intentional adulteration occurred.

Technology-assisted mitigation strategies that reduce the ability of an inside attacker to contaminate a product may include strategies that alert management when a person accesses an actionable process step or unusual activity occurs. Alerts, notifications, alarms, and other similar measures can make a suspicious action noticeable, thereby enabling workers or supervisors in the area to investigate the action and disrupt an attempted intentional contamination of the food. For example, an alarm could notify personnel in a control room that a mixing tank, which is typically not opened during operation, has been accessed. Similarly, motion detection equipment could notify supervisors or security personnel when a person enters a secure area around an actionable process step. You could also use sensors and other similar technologies to detect whether there is a difference in the volume, mass, or density of ingredients that are added to a product to ensure that no additional material is added and that an ingredient is not replaced, in part, by a contaminant.

You may also use technology-assisted mitigation strategies to enhance human supervision or observation of actionable process steps. For example, using closed-circuit television (CCTV) systems or other monitoring devices can support observation of highly vulnerable areas and actionable process steps. The mitigation strategy in this case is the act of observation and CCTV or other technologies can be used to facilitate the increased observation. Additionally, a CCTV system may support this mitigation strategy even without constant observation or an employee

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

tasked solely with observing the CCTV feed. For example, workers might monitor several processing activities from a control room, including an actionable process step through a CCTV monitor. The facility's evaluation of that mitigation strategy could conclude that the CCTV monitor elevates observation of the actionable process step to the point that the significant vulnerabilities associated with the actionable process step have been significantly minimized because one or more workers in the control room would notice the actions of an attacker while routinely, but not constantly, watching the CCTV monitor as part of their duties.

### **C. Using Multiple Mitigation Strategies**

In some cases, one mitigation strategy significantly minimizes or prevents the significant vulnerability at an actionable process step. In other cases, a facility may choose to use more than one strategy to minimize or prevent the significant vulnerability. When appropriate, a facility may use a single mitigation strategy to significantly reduce vulnerabilities, but facilities may want to consider layering mitigation strategies together to achieve protection rather than focusing only on single mitigation strategies to protect actionable process steps. In some instances, using two or more relatively inexpensive mitigation strategies at an actionable process step may be as effective at significantly reducing a vulnerability as a more expensive single mitigation strategy, while being more cost effective.

In some cases, a facility may employ multiple mitigation strategies together to achieve sufficient protection of an actionable process step. For example, a facility may restrict access to an actionable process step, such as a mixing tank, by issuing specially colored helmets only to those employees working at the actionable process step and train those employees, or security personnel, to identify authorized workers and to limit unauthorized workers from accessing the mixing tank. While in many facilities, colored helmets for authorized employees would be a sufficient mitigation strategy for a mixing tank, in this example, the facility concludes that, due to the number and variety of workers who are required in the area as part of their job function, restricting access to the area by requiring employees to wear specially colored helmets contributes to reducing the significant vulnerability but does not sufficiently reduce access to the area around the mixing tank to significantly minimize the significant vulnerability. The facility determines an additional mitigation strategy is needed. The facility secures the access hatch to the equipment and uses an alarm system to alert when the hatch is opened. The facility determines that these two strategies work synergistically to significantly minimize the significant vulnerability at the mixing tank.

Another example of using multiple mitigation strategies involves bulk liquid receiving operations. Here, a facility concludes that solely using shipping seals on the transport vehicle does not ensure the actionable process step is adequately protected from an act of intentional adulteration, but it does contribute to the minimization of the significant vulnerability; it also determines that it needs to increase observation of the unloading process itself to ensure that a contaminant is not introduced into the food while the conveyance is open for unloading. This example illustrates that more than one characteristic of the process (e.g., both the potential accessibility of the product and the ability of an attacker to adulterate the product) may contribute to an actionable process step's vulnerability and further that addressing multiple

***Contains Nonbinding Recommendations***  
***Draft-Not for Implementation***

drivers of vulnerability may require more than one mitigation strategy. In other cases, a single mitigation strategy may address both drivers of vulnerability.

The number of mitigation strategy(ies) needed is dependent on the specific conditions around a given actionable process step. For example, a facility using the same liquid storage tank configuration, but in two different locations in the facility, may find it needs a different number and/or type of mitigation strategy(ies) at each location, based on the nature of the environment surrounding each respective tank, such as number of employees routinely working in the area, or number of times during a shift the storage tank is accessed. It is up to the facility to evaluate the process step and identify and implement the most appropriate mitigation strategy(ies) necessary to address the significant vulnerability(ies) present at the actionable process step.

Using another example, a facility protects its secondary ingredient preparation area that is identified as an actionable process step by implementing a mitigation strategy of conducting premixing and measuring of secondary ingredients behind a locked gate. The facility determines that this mitigation strategy contributes to reducing the significant vulnerability at this actionable process step, but does not sufficiently reduce the access to the area around the secondary ingredient preparation area to significantly minimize the significant vulnerability here. The facility determines an additional strategy is necessary at this step because of the number of people who require access to the area and have keys to the gate. The facility determines that it is important to be able to observe who is accessing the secondary ingredient preparation area. Therefore, the facility uses an existing measure (for more details about the role of existing measures, see Section E. of this chapter), that redirects a security camera, which is already installed and primarily used for worker safety purposes, to observe the area when the gate is opened, with the camera feeding to a manned control room where personnel, who are already monitoring multiple camera feeds, can observe whoever enters the secondary ingredient prep area. In this case, the facility employs an access restriction mitigation strategy (the locking gate) and an additional mitigation strategy (supported by the camera, which is an existing measure) to increase observation of the actionable process step. The facility determines that these two strategies work synergistically to significantly minimize the significant vulnerability at the secondary ingredient preparation area.

#### **D. Facility-wide Security Measures and Their Role in a Facility's Food Defense System**

Facilities may have implemented general, non-targeted practices to protect personnel, property, or product. We refer to these practices as facility-wide security measures. Facility-wide security measures are generally not targeted to particular processing steps but are rather practices that address the security of the facility as a whole (e.g., a perimeter fence and locking exterior doors, securing hazardous materials) or are practices internal to the facility but that are conducted broadly throughout the facility (e.g., requiring employees, visitors, contractors and other persons in the facility to wear ID badges). Importantly, facility-wide security measures do not require a VA to inform their identification and implementation. Mitigation strategies are identified and implemented based on a vulnerability assessment that considers an inside attacker, and are specially tailored to significantly reduce or prevent the significant vulnerabilities associated with



***Contains Nonbinding Recommendations  
Draft-Not for Implementation***

actionable process steps. There are cases when a facility-wide security measure could be identified as a mitigation strategy if it specifically addresses a significant vulnerability at an actionable process step. In other cases, facility-wide security measures, such as a fence or locking exterior doors, would not provide appropriate protection at actionable process steps, particularly from an attacker who has achieved legitimate access to the facility and has a basic understanding of facility operations and the food product(s) under production. Facilities may choose to implement facility-wide security measures to protect against outside attackers, but such measures are not required by the rule. There are also cases when mitigation strategies and facility-wide security measures can complement each other and support the facility's overall food defense system. Further, some mitigation strategies may leverage an existing facility-wide security measure as part of its implementation.

For example, a facility that uses identification badges to identify employees could use the pre-existing badging process to implement a strategy to restrict access at an actionable process step to only those authorized individuals who work in the area. The badging process is a facility-wide security measure upon which the facility builds a mitigation strategy—the restriction of non-authorized persons from a specific area associated with an actionable process step and the monitoring or enforcement of the restriction by authorized workers and supervisors. The facility may elect to issue specially colored badges to authorized people, or use some other method of delineating authorization on the ID badges, which could serve to further facilitate access restriction to the actionable process step.

## **E. The Role of Existing Measures**

For reasons other than food defense (e.g., quality control, worker safety), you may already have certain measures in place at a particular process step that also could serve as mitigation strategies. Generally, such measures are not, by nature, inherent characteristics of the process step's operation and the VA should not consider these practices when identifying whether the process step is an actionable process step. Rather, you should evaluate these measures when determining whether these practices could serve as a mitigation strategy in their current or altered form and whether you need an additional mitigation strategy to augment the existing practice. Examples of existing measures that may serve as mitigation strategies include:

- A process step where a worker is a senior employee or an employee who has undergone additional vetting to establish increased trustworthiness. For example, the more trusted employee may be posted there because the step is sensitive due to ingredient cost, or as a preferred position for senior employees due to working conditions. In this case, the process step would be able to operate without a more trusted employee working there (i.e., it is not inherent to the process step), and the facility has implemented the practice of positioning more trusted employees in this area for a business purpose. If the presence of the senior employee is relied upon by the facility as the protective measure to minimize an otherwise significant vulnerability at the process step, then the presence of this senior employee is a mitigation strategy.

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

- A process step where you require a buddy system for worker safety. For example, your cold storage facility uses buddy systems to prevent workplace injury when working in an area. This practice could be identified by the facility as a food defense mitigation strategy if the area was identified as an actionable process step. If the actionable process step is dependent upon the buddy system as the protective measure, then it should be identified as a mitigation strategy because there would be an unmitigated significant vulnerability without the buddy system procedure.
- A process step such as bulk liquid receiving where procedures to confirm the veracity of the shipment, identity of the driver, and the integrity of seals already exist and are applied for quality or product integrity reasons but also protect against intentional adulteration of the load during transport.

Your facility may already have multiple policies or procedures in place that you can use as mitigation strategies or modify to serve as mitigation strategies to provide protection against acts of intentional adulteration. When identifying mitigation strategies, we suggest you first consider these existing policies and procedures, because they have the benefit of already being familiar to employees and could reduce costs if fewer new mitigation strategies need to be implemented. For example, when the liquid food storage tank with an inward opening hatch in Scenario 3 (see Table 3-3) is full, the pressure of the liquid prevents the hatch from being opened, rendering the interior of the tank inaccessible. However, when the tank is empty, the hatch may be opened and, therefore, an attacker could add a contaminant. It may be part of normal facility practice for a supervisor to conduct a visual check of the storage tank after a cleaning cycle to ensure proper cleaning. The facility may elect to implement a food defense mitigation strategy by altering its visual check procedure so that the supervisor conducts the visual check immediately prior to food being added to the storage tank instead of after the cleaning, thereby inspecting the tank after it has been empty and accessible for an extended period. Alternatively, the facility could elect to secure the tank's hatch with a tamper-evident seal or tape after a visual inspection. Either of these slight modifications to an existing facility practice could be implemented to protect the actionable process step from an attacker.

In some instances, you may be able to use existing measures or facility-wide security measures to serve as mitigation strategies; in other cases, existing measures or facility-wide security measures may need modification in order for them to be used as mitigation strategies. For example, a facility might already have a standard operating procedure to prohibit personal items, such as backpacks, in food production areas. In its VA, the facility identifies the process step of flavor addition as an actionable process step because this step aligns with the Key Activity Types of secondary ingredient handling and mixing and similar activities. When evaluating potential mitigation strategies, the facility also concludes that the existing practice of prohibiting personal items from food production areas contributes to the reduction of a significant vulnerability associated with an actionable process step, such as a secondary ingredient preparation area, by reducing the ability of an inside attacker to carry enough volume of a contaminant into the area to adulterate the food. With this rationale, this facility-wide prohibition against personal materials in food production areas can be used as a mitigation strategy for the actionable process step. The facility then would evaluate if any additional mitigation strategies are needed to significantly reduce any additional components of the significant vulnerability associated with

***Contains Nonbinding Recommendations***  
***Draft-Not for Implementation***

this actionable process step. Since the prohibition against personal materials in the secondary ingredient preparation area is a mitigation strategy, it must have associated management components to ensure its proper implementation, considering the nature of the mitigation strategy and its role in the food defense system. Additionally, management components for this mitigation strategy are required only for the implementation of the strategy at the secondary ingredient preparation area and not more broadly throughout the facility. This ensures that resources are used in a targeted manner, and not diluted to multiple areas of the facility that are not the most vulnerable.

If the facility determines through the course of the VA that an existing measure – that is not an inherent characteristic of a process step – is specifically important to the reduction of a significant vulnerability (e.g., because a significant vulnerability would exist at the process step absent the consistent implementation of the existing measure), the facility should identify that measure as a mitigation strategy and manage it accordingly with applicable mitigation strategy management components.

Actionable process steps identified through a VA do not cease to become actionable process steps just because they are protected with mitigation strategies. Actionable process steps are process steps that a facility identifies as significantly vulnerable and requiring protection; the facility makes this determination before implementing mitigation strategies. Facilities still need to identify as actionable process steps in the food defense plan those process steps that are protected by mitigation strategies.

For example, a facility identifies a liquid ingredient storage tank as an actionable process step. The VA identifies the tank as significantly vulnerable due to the accessibility to a hatch at the top of the tank via a ladder and gangway and the tank's location in a relatively isolated part of the facility, where it is rarely observed and not easily viewable. A contaminant added into the tank would be evenly applied to many consumer servings of the final product. The facility decides to mitigate the significant vulnerability associated with this actionable process step by installing a ladder cage secured with a lock to prevent access to the hatch at the top of the tank. If the mitigation strategy is not properly applied, the significant vulnerability of the tank would remain. If the existing mitigation strategy is properly implemented (i.e., the ladder cage remains locked when not in use), the facility would conclude that it is significantly minimizing the significant vulnerability at the actionable process step. The facility would not need to implement additional or alternative mitigation strategies unless it determined – via the mitigation strategy management components – that the previously identified strategy is not adequate when properly implemented.

## **F. Accompanying Explanation for Mitigation Strategies in the Food Defense Plan**

Your food defense plan must identify your mitigation strategies, and each mitigation strategy must include an explanation of how the facility expects the mitigation strategy(ies) to significantly minimize or prevent the significant vulnerabilities associated with the actionable process step. (21 CFR 121.135(a)). In identifying and implementing mitigation strategies, you

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

will need to explain how each mitigation strategy will protect the respective actionable process step.

We expect the mitigation strategy explanations to be relatively brief and straightforward. For example, for a mitigation strategy that consists of a lock to protect access to a storage tank, your explanation may be simply that the lock prevents unauthorized access to the food in the tank, thereby minimizing the significant vulnerability of the storage tank.

An actionable process step where several mitigation strategies have been identified may require a slightly lengthier explanation. For example, if your facility restricts access around a mixing tank only to those employees required by job function to be in the area and implements an alarm tone on the mixing tank hatch to notify personnel that someone has accessed the tank, that combination of mitigation strategies would require more explanation than the lock on the storage tank, though it still need not be lengthy. You could explain that restricting the area only to those workers required to be there reduces the number of potential individuals who could reasonably intentionally adulterate the food at this step. You could further explain that the alarm tone on the mixing tank lid provides additional protection to the actionable process step by alerting other personnel that someone is accessing the mixing tank, thereby elevating awareness and observation of the mixing tank; both mitigation strategies, used together, minimize the significant vulnerability associated with the mixing tank.

Mitigation strategy explanations have the benefit of clarifying the facility's thinking and supporting the consistent implementation of the mitigation strategy(ies), especially if there is staff turnover or changes in responsibility. The written explanations help ensure that the rationale for the identification and implementation of each mitigation strategy is clear to persons responsible for its implementation as well as the monitoring of the mitigation strategy, correcting any deviations of its intended operation, and verifying its proper implementation. Further, the explanation for how the mitigation strategies minimize the significant vulnerability will also be highly beneficial in supporting your choice of mitigation strategies, if needed, during an inspection or audit.

## **G. Mitigation Strategy Example Scenarios**

### **1. Scenario 1**

A facility identified the primary ingredient storage tank as an actionable process step because of the public health impact that would occur if the tank were contaminated, the presence of physical access via a hatch, and the likelihood that an inside attacker could contaminate the food in the tank without being detected or the contamination being discovered. The VA identified that the unsecured access hatch at the top of the tank provided unrestricted access to the ingredient in the tank and would enable an attacker to intentionally contaminate the food. The facility, in considering mitigation strategies, concludes that there is no legitimate need to open the hatch when liquid food is in the tank and that locking the hatch would be a simple, cost effective way of significantly reducing accessibility to the ingredient in the tank and would significantly

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

minimize or prevent the significant vulnerability identified in the vulnerability assessment. The facility specifies that the security office will hold the keys to the lock and will allow access to the keys only for those persons with a legitimate need based on their job duties and approval from the facility security manager or food defense coordinator.

The facility's food defense plan should identify the lock on the hatch as the mitigation strategy and explain that the lock on the hatch renders the food in the tank inaccessible to an attacker, including an inside attacker, thereby significantly reducing the vulnerability present at this actionable process step.

## **2. Scenario 2**

A facility's VA identified the receiving of bulk liquid ingredients as an actionable process step. The facility recognizes that there are several factors in this process that are relevant to the food defense vulnerability of receiving bulk liquid ingredients. The facility identifies a multi-strategy approach to mitigate the significant vulnerabilities associated with the receipt of bulk liquids.

The facility concludes that its existing measure of using seals on inbound shipping conveyances significantly reduces vulnerability of the food during transport and that this measure is a mitigation strategy. The facility documents this existing measure in its food defense plan as a mitigation strategy that significantly minimizes or prevents significant vulnerabilities associated with receiving bulk liquid ingredients.

The facility determined that transfer hoses used to unload the liquid food from the conveyance and pump it to a storage tank in the facility provided an access point for an attacker to introduce a contaminant. During operations, the facility is constantly receiving liquid ingredients and hoses are in near constant use. Outside of operating hours, however, the hoses are open and accessible. The facility implemented a mitigation strategy for the hoses after daily operations: the hose ends must be capped and the cap must be taped with tamper-evident tape, which would prevent an inside attacker from accessing the hose openings when not in use and introducing a contaminant.

The facility also identified other aspects of the receiving process as significant vulnerabilities; namely, the opening of venting and sampling hatches on the transport conveyance. To address this, the facility implements slight changes to its unloading procedures. The facility implements a mitigation strategy of increasing observation of unloading operations by having the worker responsible for reviewing shipping documentation witness the opening of the transport conveyance and the attachment of transfer hoses and pumping equipment. This increases the level of observation of the activity in the receiving bay, thereby significantly reducing the ability of an attacker to bring a contaminant into the area and introducing it to the food during the opening of venting or sampling hatches on the tanker truck without being detected.

The facility documents each mitigation strategy in its food defense plan and provides an explanation for how the strategies reduce different aspects of the significant vulnerability of the bulk liquid receiving process that was identified in the VA.

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

### **3. Scenario 3**

A facility identified the liquid food storage tank as an actionable process step. The tank is accessible with an inward opening hatch. When the tank is full, the pressure of the liquid ingredient inside prevents the hatch from being opened, rendering the tank inaccessible. However, a significant vulnerability exists when the tank is empty—a person could open the hatch and add a contaminant. Normal facility practice is for a supervisor to conduct a visual check of storage tanks after a cleaning cycle to ensure the cleaning has been conducted as intended. The tank is then accessible and empty for an extended period. The facility considers potential mitigation strategies and rather than installing a lock or other access control or seal on the hatch, the facility elects to implement a modification to its existing visual check procedure so that the visual check by the supervisor is conducted immediately prior to food being added to the storage tank. The open hatch provides clear visibility of the interior of the tank, allowing the supervisor to inspect the condition of the tank walls and floor to ensure that there is no residue in the tank that may indicate the introduction of a contaminant. To facilitate a thorough inspection, the quality control manager will use high intensity flashlights as well as ultraviolet lights to detect any potential contamination. The mitigation strategy is that personnel observe the tank after it has been cleaned and sat empty and accessible for an extended period, but immediately prior to the introduction of food into the tank to ensure that a contaminant has not been added to the empty tank. This mitigation strategy, the facility explains, would significantly reduce or eliminate the vulnerability associated with an attacker, including an inside attacker, introducing a contaminant to the empty tank while it is open and accessible after the cleaning cycle.

The facility would document this mitigation strategy in its food defense plan along with the associated explanation.

### **4. Scenario 4**

A facility identifies a process step where a breading coating is applied to food as an actionable process step. The facility concludes in its vulnerability assessment that the hopper that feeds the breader at this step allows both significant physical access to the product as well as a sufficient likelihood that an inside attacker could contaminate the food without detection. To mitigate an attacker's physical access to the product, the facility implements a mitigation strategy that restricts access only to specific employees who directly work at or supervise the breading process step. The facility issues those employees special red caps and identifies their job function on their employee identification badges. This allows their fellow authorized workers, supervisors, management, and security personnel to easily determine whether persons in the area surrounding the breader are authorized. As part of the mitigation strategy, the facility requires workers who are permitted access to the breading area to be with the company for at least 4 years, have no disciplinary or job performance issues during that time, and be approved by company human resources and security offices. The mitigation strategy requires that authorized workers immediately escort any unauthorized person out of the area, and notify security personnel or management of the intrusion. As part of their training on proper implementation of the mitigation strategy, workers are specifically trained on how to address the access restriction.

***Contains Nonbinding Recommendations***  
***Draft-Not for Implementation***

Any person who requires access to the area and is not previously cleared (e.g., contractors) would be escorted and observed by an authorized employee or other authorized personnel.

The facility details this mitigation strategy in its food defense plan and provides rationale in its explanation that this mitigation strategy significantly reduces the ability of an inside attacker to enter the area to contaminate the food. The facility also explains that the additional vetting of employees authorized to be in the area around the breeder appropriately considers the actions of an inside attacker by ensuring that workers in this highly vulnerable area have consistently demonstrated their responsibility and trustworthiness. Also, the facility explains that the mitigation strategy that authorized workers escort from the area anyone who is not cleared also significantly reduces the ability of an inside attacker to approach the breeder and introduce a contaminant without being detected and interdicted.

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

**Table 3-1. Scenario 1.  
Worksheet 1-H: Mitigation Strategies**

**PRODUCT(S):** FOOD XYZ

**FACILITY NAME:** Anytown #12345

**ADDRESS:** 1245 Washington Street, Anytown, USA

**SIGNED DATE:** March 7, 2018

<b>(1) #</b>	<b>(2) Actionable Process Step</b>	<b>(3) Mitigation Strategy</b>	<b>(4) Explanation</b>
	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.	The lock on the hatch renders the food in the tank inaccessible to an attacker, including an inside attacker, thereby significantly reducing the vulnerability present at this actionable process step.



*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

**Table 3-2. Scenario 2.  
Worksheet 1-H: Mitigation Strategies**

**PRODUCT(S):** FOOD XYZ

**FACILITY NAME:** Anytown #12345

**ADDRESS:** 1245 Washington Street, Anytown, USA

**SIGNED DATE:** March 7, 2018

(1) #	(2) Actionable Process Step	(3) Mitigation Strategy	(4) Explanation
	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.	Using numbered wire or plastic seals to secure hatches, ports, and other access points to the transport conveyance significantly reduces the ability of an attacker to successfully contaminate the product without being detected. Tamper-evident seals will indicate if the product has been interfered with during transport.
	Bulk liquid receiving	Use tamper-evident tape on hose ends after capping.	Using tamper-evident tape to seal the hose caps when not in use limits the ability of an attacker to successfully contaminate the product without being detected.

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

<b>(1) #</b>	<b>(2) Actionable Process Step</b>	<b>(3) Mitigation Strategy</b>	<b>(4) Explanation</b>
	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.	Having the employee responsible for reviewing shipping documentation visually observe the opening of venting and sampling hatches as well as the hooking up of hoses and pumping equipment significantly reduces the ability of an attacker to introduce a contaminant either to the conveyance via the venting or sampling hatches, or into the hoses prior to unloading without being detected.

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

**Table 3-3. Scenario 3.  
Worksheet 1-H: Mitigation Strategies**

**PRODUCT(S):** FOOD XYZ

**FACILITY NAME:** Anytown #12345

**ADDRESS:** 1245 Washington Street, Anytown, USA

**SIGNED DATE:** March 7, 2018

(1) #	(2) Actionable Process Step	(3) Mitigation Strategy	(4) Explanation
	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.	The use of both high intensity flashlights and ultraviolet lights will enable the quality control manager to make a thorough inspection of the tank to ensure no contamination occurred. The hatch is wide enough to provide a clear view of both the walls and floor of the tank, enabling inspection of all surfaces of the tank interior.

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

**Table 3-4. Scenario 4.  
Worksheet 1-H: Mitigation Strategies**

**PRODUCT(S):** FOOD XYZ

**FACILITY NAME:** Anytown #12345

**ADDRESS:** 1245 Washington Street, Anytown, USA

**SIGNED DATE:** March 7, 2018

(1) #	(2) Actionable Process Step	(3) Mitigation Strategy	(4) Explanation
	Breeder	Restrict access to breeder 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 breeder 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 breeder will immediately escort out of the area anyone not authorized to be in the area surrounding the breeder.	This mitigation strategy significantly reduces the ability of an attacker to enter the area to contaminate the food. Restricting this area to only Food Safety Technician Level 3 workers significantly reduces the number of people who are authorized to be in the area and significantly minimizes the vulnerability posed by an attacker, including an inside attacker. Food Safety Technician Level 3 workers in good standing and with more than 4 years of employment have demonstrated their level of responsibility and trustworthiness to work in this highly vulnerable area and to restrict access to the area.

## **Chapter 4:**

### **Mitigation Strategies Management Components: Food Defense Monitoring**

This chapter provides an overview of the food defense monitoring mitigation strategy management component, and is intended to help you understand the requirements for food defense monitoring as a part of your FDP. Food defense monitoring is conducted to assess whether mitigation strategies are operating as intended (21 CFR 121.3) and with adequate frequency to provide assurances strategies are consistently performed (21 CFR 121.140(b)). Food defense monitoring is one of three mitigation strategies management components. The other two are food defense corrective actions and food defense verification. You must apply appropriate mitigation strategies management components by considering the nature of the mitigation strategy and its role in the facility's food defense system to ensure the proper implementation of the mitigation strategy. (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 monitoring 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 Monitoring**

The purpose of food defense monitoring is to conduct a planned sequence of observations or measurements to assess whether mitigation strategies are operating as intended. You must establish and implement written procedures, including the frequency with which they are to be performed, for food defense monitoring of the mitigation strategies. (21 CFR 121.140). In an FDP, each mitigation strategy is monitored as appropriate to the nature of the mitigation strategy and its role in the facility's food defense system. As discussed in Chapter 3 of this guidance, most mitigation strategies are implemented to reduce access to the product at a particular point, reduce the ability of an attacker to contaminate the food at that point, or reduce both access to the product and ability of an attacker to contaminate the product. Monitoring procedures should be appropriate to assess whether the mitigation strategy is operating as intended, as detailed in the mitigation strategy's accompanying explanation. Monitoring must be documented in records and is subject to food defense verification (21 CFR 121.140(c)).

Your food defense monitoring procedures should answer four questions: (1) What will be monitored? (2) How will monitoring be done? (3) How often will monitoring be done (frequency)? and (4) Who will do the monitoring? Facilities have significant flexibility in how to accomplish each of these aspects of monitoring.

The tables at the end of this chapter provide examples of food defense monitoring procedures for the scenarios listed in Chapter 3 of this guidance.

#### **B. How Food Defense Monitoring Differs from Food Safety Monitoring**

***Contains Nonbinding Recommendations***  
***Draft-Not for Implementation***

Some aspects of food defense monitoring are similar to the food safety monitoring requirement in the PCHF rule. For example, each preventive control is monitored as appropriate to the nature of the preventive control and its role in the facility's food safety system in a food safety plan (FSP). However, some aspects of food defense monitoring are different than food safety monitoring, primarily because of the different nature of mitigation strategies and preventive controls. Food safety monitoring is more likely than food defense monitoring to document that the minimum or maximum values for a parameter have been met, and food safety monitoring frequently is continuous. Food defense monitoring, in comparison, observes whether the mitigation strategy is operating as intended and often occurs less frequently, and is therefore less resource intensive. For example, in Scenario 1 (first described in Chapter 3), the 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.

### **C. What to Monitor**

What you monitor should be directly related to the implementation and nature of the mitigation strategy. You have the flexibility to determine what to monitor, how often the monitoring will occur, and who will monitor the mitigation strategy, as long as your monitoring procedures allow you to assess whether the mitigation strategies are operating as intended. In Scenario 1, the facility has identified a liquid ingredient storage tank as an actionable process step, and identified the mitigation strategy of using a lock to secure the access hatch. In this scenario, the facility would monitor whether the storage tank is locked. In Scenario 2, the facility has identified bulk liquid receiving as an actionable process step, and one of the mitigation strategies is to use tamper-evident tape on pump hose ends after a cap is placed on the end; the facility would monitor whether the tamper-evident seal is in place on the ends. In Scenario 3, the facility has identified the liquid food storage tank as an actionable process step; the mitigation strategy chosen is to inspect the liquid food storage tank prior to use. For this strategy, the facility would monitor the inside of the liquid food storage tank.

Additionally, there may be instances when food defense monitoring coincides with activities already being conducted for either food safety purposes or as part of pre-existing operational procedures. In Scenario 3, the QA technician may be inspecting the food storage tank for food safety purposes (i.e., cleaning) as well as mitigation strategy implementation and monitoring. In a different example, a facility identifies bulk liquid receiving as an actionable process step, and implements a mitigation strategy to use only known shippers. The monitoring procedure for this strategy is that a technician assesses the delivery paperwork to determine whether the stated shipment and shipper information matches that of the scheduled delivery to ensure the mitigation strategy of using known shippers is operating as intended. The technician then documents that the paperwork has been checked by recording the date and time that the documentation was checked, and initials the document. This documentation check may already be occurring in your facility each time you receive bulk liquids to ensure the receipt of the appropriate type and amount of ingredient from the shipper. Existing quality and food safety activities may also function as food defense monitoring procedures. In the FDP, the facility should indicate that the food defense monitoring procedure will be the same as the existing food safety monitoring procedure for this mitigation strategy.

*Contains Nonbinding Recommendations*  
*Draft-Not for Implementation*

## **D. How to Monitor**

Once you determine what to monitor, you have flexibility regarding how you monitor the mitigation strategy. In some cases, it may be necessary to develop a new procedure to adequately monitor a mitigation strategy. In many instances, facilities may elect to have an employee observe whether the mitigation strategy is operating as intended; however, facilities have the flexibility to monitor mitigation strategies in other ways, such as electronic monitoring of an access control device (e.g., automated monitoring of electronic locks on a door or gate that prevents access to an actionable process step). When considering monitoring procedures for mitigation strategies, it is important to consider what existing practices, procedures, and conditions are in place around the actionable process step and to consider the nature of the mitigation strategy and its implementation.

Facilities also have the flexibility to consider the existing presence of employees and supervisors, and how monitoring of a mitigation strategy could be incorporated into normal operations or job duties. In some circumstances, food defense monitoring may be incorporated into other security, maintenance, quality, or worker safety procedures performed at the facility—which decreases additional human or other resources the facility uses to monitor some mitigation strategies. For example, it may be most efficient to task an employee who frequently traverses the area to monitor the implementation of that mitigation strategy as part of their normal duties. Furthermore, there may be some cases when monitoring of the mitigation strategy may occur concurrently with the implementation of the mitigation strategy itself. For example, in Scenario 3, the mitigation strategy is to visually inspect the tank immediately prior to the introduction of food. In this case, the QA manager is implementing the mitigation strategy and is also monitoring its implementation by completing monitoring documentation. The documentation is being completed, for food safety purposes, using the “Storage tank cleaning sign off form.” Because this food safety record is fulfilling food defense monitoring record requirements as well, the facility may decide to use it as the food defense monitoring record (See Table 4-7). In Scenario 4, the authorized workers are implementing the mitigation strategy to restrict access to the area around the breeder to only authorized personnel wearing special red caps and identification badges listing their job function. Concurrently, these employees also are constantly monitoring the implementation of the mitigation strategy by observing whether other people in the area are wearing the cap and the badge; if an unauthorized person is identified in the restricted area, employees implementing this strategy escort the person out of the area, and notify security personnel of the deviation from the strategy. Security personnel then document deviations to the strategy by using exception records (See Section F. of this chapter). In other cases, you may choose to periodically monitor a mitigation strategy to ensure it is operating as intended. For example, the lock on the tank in Scenario 1 is periodically monitored (e.g., at the beginning and end of the tank’s 48-hour cleaning cycle) at a frequency sufficient to provide assurances that it is in place and reducing access to the tank.

Regardless of how a mitigation strategy is monitored, monitoring activities must be documented (21 CFR 121.140(c)).

### **1. How Often to Monitor (Frequency of Monitoring)**

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

The frequency of monitoring depends on the nature of the mitigation strategy and the facility's food defense system. You have the flexibility to determine the frequency of monitoring needed so long as the frequency is adequate to provide assurances that the mitigation strategies are consistently performed. (21 CFR 121.140(b)).

For food defense, many mitigation strategies may be monitored less frequently than preventive controls for food safety, which are often monitored continuously. In large part, preventive controls for food safety are monitored continuously because they relate to physical or chemical parameters of the process, such as the temperature of a pasteurizer. These types of controls lend themselves to continuous monitoring and necessitate that level of monitoring to ensure that the process is under control. On the other hand, most mitigation strategies for food defense are put in place to reduce accessibility to the food at a particular step or reduce the ability of an attacker to contaminate the food at that step. In Scenario 1, the mitigation strategy of using a lock to secure the access hatch on the ingredient storage tank would not require continuous monitoring. Part of this mitigation strategy is to keep keys to the lock in a security office, and restrict access to the keys to predesignated times when the keys would be needed to access the food in the tank. The employee assigned to ingredient storage would observe whether the lock is in place and locked at the beginning and end of the tank's 48-hour cleaning cycle. This frequency will help the manager ensure that the lock stayed locked during the food processing because it would not be possible to check out the key during an unapproved time. In another example, a facility uses an existing camera to facilitate the implementation of a mitigation strategy that increases observation of a liquid storage tank the facility identified as an actionable process step. The facility determines that the camera feed can be monitored, by an employee already monitoring other feeds, periodically throughout his shift.

Non-continuous monitoring is appropriate in many other circumstances as well. For example, a facility identifies bulk liquid receiving as an actionable process step, and implements a mitigation strategy of restricting drivers to a lounge area. The facility determines this strategy should be monitored periodically, but at least once a week. This monitoring activity can be done any time there is a driver in the facility, but the monitoring procedure requires that it be done at least once per week. A monitoring procedure occurring on a periodic basis but at irregular intervals can be beneficial for the facility in two ways: 1) it is more difficult for an inside attacker to anticipate, and 2) it requires less human and other resources than more frequent monitoring.

For mitigation strategies that are monitored concurrently with the mitigation strategy's implementation, the monitoring frequency would depend on the mitigation strategy frequency. For example, consider the mitigation strategy in Scenario 2, use of tamper-evident seals on transport conveyances. The monitoring procedure would be to check the seals for integrity or indications of tampering and match seal or documentation numbers upon arrival of the load, before hooking up the hose for each delivery. This monitoring frequency is dictated by the frequency of inbound shipments – which may vary depending on seasonality, the nature of the ingredient, and other factors not associated with the mitigation strategy itself. In this case, the FDP would provide that this monitoring procedure would occur concurrently with receiving.



*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

## **2. Who Performs the Monitoring**

You have the flexibility to decide who will monitor your mitigation strategies. You should specify in the written procedures the position of the employee who will do the monitoring and describe how they are to perform the monitoring procedure. The employee's duties should include notifying management and following the food defense corrective actions procedures as specified in the food defense plan when observations or measurements indicate mitigation strategies are not operating as intended.

When a person is assigned to perform monitoring, that person must have the education, training, or experience (or a combination thereof) necessary to perform the individual's assigned duties. (21 CFR 121.4(b)(1)). You have flexibility to assign monitoring responsibilities consistent with this requirement. Such individuals who perform these duties may include, among others:

- Line personnel;
- Equipment operators;
- Supervisors;
- Maintenance personnel; or
- QA personnel.

You may choose to assign monitoring duties to personnel who actively and constantly watch the product or equipment as a part of their regular jobs, such as line personnel and equipment operators. In addition, including production workers in food defense activities can help build a broad base of understanding and commitment to food defense.

In the liquid storage tank lock example in Scenario 3, the person doing the monitoring may be the line operator (e.g., kettle cook, baker), quality control personnel, or any other person who understands the nature of the mitigation strategy and has the required training to properly implement the strategy.

See Tables 4-5 through 4-8 for examples of some of the other individuals who you may choose to monitor the mitigation strategies and record their findings.

## **E. Food Defense Monitoring Records**

In addition to documenting the monitoring procedures in the FDP (21 CFR 121.126(b)(3)), you must document the monitoring of mitigation strategies in records that are subject to verification and records review (21 CFR 121.140(c)(1)). All food defense monitoring information must be recorded at the time the observation is made. (21 CFR 121.305(d)). Accurate recordkeeping provides documentation that mitigation strategies are operating as intended. Each monitoring record should capture the observations or actual values for the mitigation strategy, along with the time (if appropriate) and date that the observation was made, and the signature or initials of the person who made the observation. (21 CFR 121.305).

Using Scenario 1, one example of what to document in records of monitoring activities is a determination of whether the lock is in place and locked. The monitoring record could be

***Contains Nonbinding Recommendations  
Draft-Not for Implementation***

written in a log entitled “liquid storage tank observations record” and include the date, time, and a written “yes” or “no” to indicate whether the lock was locked. If you are using the mitigation strategies management components table (Worksheet 1-I in the appendix to this guidance), the name of the monitoring record should also be documented under the “Food Defense Record” column in the table. For example, in Scenario 1, in the “Food Defense Record” column, you would write “Liquid storage tank observations record” (See Table 4-5).

## **F. Exception Records**

In some cases, you can document monitoring of a mitigation strategy with a record of when the mitigation strategy is not functioning, or operating, as intended. In this case, the monitoring record generated would be an exception record demonstrating a deviation (compared to affirmative records, which demonstrate that the mitigation strategy is functioning as intended). Exception records demonstrating the mitigation strategy is not functioning as intended are adequate in some, but not all, circumstances. (21 CFR 121.140(c)(2)).

In a food safety context, exception records are used when an automated monitoring system detects a deviation from food safety parameter limits. For example, under the PCHF rule, records of refrigeration temperature during storage of food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens may be affirmative records demonstrating temperature is controlled or exception records, via an automated system constantly monitoring the temperature, demonstrating loss of temperature control. (See 21 CFR 117.145(c)(2)).

Some mitigation strategies may lend themselves to constant monitoring, and exception records to document monitoring may be appropriate. This can be through an automated system that is put in place to monitor whether the mitigation strategy is operating as intended. For example, a mitigation strategy may be to restrict access using a locking gate that is opened only by a specially coded access card. If the gate is left ajar for any period beyond the time it takes to enter and re-secure the gate, an automated monitoring system alarm indicates that the gate is not secured. Whenever the system alarms, an automatically generated exception record documents the instance where the mitigation strategy was not operating as intended.

In addition to technology-based mitigation strategies, there also may be personnel-based mitigation strategies that lend themselves to constant monitoring. Mitigation strategies that are personnel-based and restrict unauthorized access to designated areas rely on personnel to ensure the mitigation strategy is operating as intended. The mitigation strategies may rely on these personnel to constantly monitor an area. In the example in Scenario 4, the employees working in the restricted access area surrounding the breeder both implement the mitigation strategy of preventing unauthorized persons from entering the area and constantly monitor the implementation of the mitigation strategy (with the monitoring being incorporated into the employees’ current responsibilities). In this case, it may be appropriate to generate an exception record when an unauthorized person is discovered in the area, rather than proactively generating monitoring records, on a predetermined frequency that indicate whether unauthorized individuals have entered the area. In this case, the presence of an unauthorized person in the area would be

***Contains Nonbinding Recommendations***  
***Draft-Not for Implementation***

documented by security personnel after they were notified by the employees implementing this strategy, as a deviation from the mitigation strategy.

In another example, a facility identifies a liquid ingredient holding tank as an actionable process step. The facility uses an existing measure, prohibiting personal items from the food production area (which includes the area around the liquid ingredient holding tank), as a mitigation strategy to significantly minimize the significant vulnerability associated with the tank by reducing the ability of an inside attacker to carry enough volume of a contaminant into the area to adulterate the food. There are personnel working in the area around the tank (although their presence is not an inherent characteristic of the step (i.e., the tank can operate without their presence)), and their current responsibilities are modified to include monitoring the area for personal items. In this case, it may be appropriate to generate an exception record when an unauthorized personal item is discovered in the area, rather than proactively generating monitoring records, on a predetermined frequency that indicate whether personal items are in the area. In this case, the presence of a personal item in the area would be documented by a supervisor after she was notified by the employees implementing this strategy, as a deviation from the mitigation strategy.

There are instances where exception records are not appropriate to monitor the operating of a mitigation strategy. Generally, situations where a mitigation strategy is implemented to maintain a static situation that is not under constant monitoring do not lend themselves to a monitoring procedure that uses an exception record approach. For example, a lock on a hatch of a storage tank typically requires a monitoring procedure that generates an affirmative record as to the mitigation strategy's functioning. Because this mitigation strategy is not under constant monitoring by an automated system or a personnel-based monitoring procedure, it would be difficult, or impossible, to conclude that the mitigation strategy is operating as intended based only on exception records. This mitigation strategy should have an accompanying monitoring procedure that, at an appropriate frequency, includes an observational determination whether the lock is securing the hatch. A record must be generated to document this monitoring activity (121.140(c)(1)). A record documenting the date and time the lock was observed and whether the mitigation strategy was operating as intended will enable the facility to determine whether the strategy was properly implemented, and that monitoring was properly conducted during food defense verification procedures.

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

**Table 4-5. Scenario 1.  
Worksheet 1-I: Mitigation Strategies Management Components**

**PRODUCT(S):** FOOD XYZ

**FACILITY NAME:** Anytown #12345

**ADDRESS:** 1245 Washington Street, Anytown, USA

**SIGNED DATE:** March 7, 2018

(1) #	(2) Actionable Process Step	(3) Mitigation Strategy	(4) Food Defense Monitoring Procedure and Frequency	(5) Food Defense Corrective Action 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.	<i>Guidance forthcoming</i>	<i>Guidance forthcoming</i>	Liquid storage tank observations record

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

Table 4-6. Scenario 2.

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

**PRODUCT(S):** FOOD XYZ

**FACILITY NAME:** Anytown #12345

**ADDRESS:** 1245 Washington Street, Anytown, USA

**SIGNED DATE:** March 7, 2018

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

<b>(1) #</b>	<b>(2) Actionable Process Step</b>	<b>(3) Mitigation Strategy</b>	<b>(4) Food Defense Monitoring Procedure and Frequency</b>	<b>(5) Food Defense Corrective Action Procedures</b>	<b>(6) Food Defense Verification Procedures</b>	<b>(7) Food Defense Records</b>
	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.	<i>Guidance forthcoming</i>	<i>Guidance forthcoming</i>	Receiving/delivery paperwork that includes additional information to indicate monitoring was completed
	Bulk liquid receiving	Use tamper-evident tape on hose ends after capping.	After daily operations, supply chain supervisor confirms that the hose cap is on and taped.	<i>Guidance forthcoming</i>	<i>Guidance forthcoming</i>	Food defense monitoring log

***Contains Nonbinding Recommendations  
Draft-Not for Implementation***

	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.	<i>Guidance forthcoming</i>	<i>Guidance forthcoming</i>	Food defense monitoring log
--	-----------------------	--	--	-----------------------------	-----------------------------	-----------------------------

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

**Table 4-7. Scenario 3.  
Worksheet 1-I: Mitigation Strategies Management Components**

**PRODUCT(S):** FOOD XYZ

**FACILITY NAME:** Anytown #12345

**ADDRESS:** 1245 Washington Street, Anytown, USA

**SIGNED DATE:** March 7, 2018

(1) #	(2) Actionable Process Step	(3) Mitigation Strategy	(4) Food Defense Monitoring Procedure and Frequency	(5) Food Defense Corrective Action 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.	<i>Guidance forthcoming</i>	<i>Guidance forthcoming</i>	Storage tank cleaning sign-off form kept with records for Preventive Controls for Human Food requirements



*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

**Table 4-8. Scenario 4.  
Worksheet 1-I: Mitigation Strategies Management Components**

**PRODUCT(S):** FOOD XYZ

**FACILITY NAME:** Anytown #12345

**ADDRESS:** 1245 Washington Street, Anytown, USA

**SIGNED DATE:** March 7, 2018

(1) #	(2) Actionable Process Step	(3) Mitigation Strategy	(4) Food Defense Monitoring Procedure and Frequency	(5) Food Defense Corrective Action Procedures	(6) Food Defense Verification Procedures	(7) Food Defense Records
	Breeder	Restrict access to breeder 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 breeder will have attained at least the position of “Food Safety Technician Level 3” with at least 4 years of employment and be	Employees assigned to the breeder 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 breeder 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	<i>Guidance forthcoming</i>	<i>Guidance forthcoming</i>	Food defense monitoring log

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

<b>(1) #</b>	<b>(2) Actionable Process Step</b>	<b>(3) Mitigation Strategy</b>	<b>(4) Food Defense Monitoring Procedure and Frequency</b>	<b>(5) Food Defense Corrective Action Procedures</b>	<b>(6) Food Defense Verification Procedures</b>	<b>(7) Food Defense Records</b>
		in good standing with human resources with no pending or previous disciplinary actions. Employees working at the breeder will immediately escort out of the area anyone not authorized to be in the area surrounding the breeder.	deviation from the strategy is observed.			

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

**Chapter 5: Mitigation Strategies Management Components: Food Defense  
Corrective Actions (coming soon)**

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

**Chapter 6: Mitigation Strategies Management Components: Food Defense  
Verification (coming soon)**

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

**Chapter 7: Reanalysis (coming soon)**

*Contains Nonbinding Recommendations*  
*Draft-Not for Implementation*

**Chapter 8: Education, Training, or Experience (coming soon)**

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

**Chapter 9: Records (coming soon)**

## **Appendix 1: Food Defense Plan Worksheets**

### **A. Introduction**

This appendix includes sample worksheets FDA developed to help facilities develop a written food defense plan (FDP). There is no standardized or required format for a FDP. Using these worksheets is voluntary, and using a different format for your FDP is acceptable if it includes the required components. (21 CFR 121.126, 121.305, and 121.310.) If facilities choose to use worksheets, abbreviations or footnotes may be used when appropriate.

### **B. Food Defense Plan Cover Sheet**

Your facility's FDP contains sensitive information about its vulnerabilities and mitigation strategies. We recommend that you store the FDP in a secure location (either electronic or physical) and restrict access to the FDP. Access to the FDP should be granted only on a need-to-know basis; not all employees at the facility or company may need to have access to the whole FDP. In some cases, you may want to provide access only to parts of the FDP.

We also recommend that you include a cover sheet on the FDP that clearly notes that the information it contains is sensitive and should be protected from unauthorized access or disclosure. Such a cover sheet can remind those who have access to the FDP of the need to take appropriate measures to protect the FDP when it is in their possession.

#### **1. How to Fill in Worksheet 1-A: Food Defense Plan Cover Sheet**

The information included in Worksheet 1-A are listed and explained below.

- **Product Name(s):** Provide the full name of the finished product(s).
- **Facility Name:** Include the facility name.
- **Company Name:** Include the company name.
- **Facility Identifier/Address:** Provide a facility identifier and/or the address of the facility.
- **Facility Contact Information:** Provide the name and contact information for someone at the facility who is in charge of or who can answer questions about the FDP.
- **Signature:** Include the signature of the owner, operator, or agent in charge of the facility.
- **Date Signed:** Provide the date that the FDP was signed.



**2. Worksheet 1-A: Food Defense Plan Cover Sheet**

**The information contained in the Food Defense Plan is sensitive and should be protected from unauthorized access or disclosure.**

**FOOD DEFENSE PLAN**

**PRODUCT NAME(S):** \_\_\_\_\_  
**FACILITY NAME:** \_\_\_\_\_  
**COMPANY NAME:** \_\_\_\_\_  
**FACILITY IDENTIFIER/ADDRESS:** \_\_\_\_\_  
**FACILITY CONTACT INFORMATION:** \_\_\_\_\_  
**SIGNATURE:** \_\_\_\_\_  
**DATE SIGNED:** \_\_\_\_\_

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

## **C. Food Defense Plan Product Description**

Including information about the food product in your FDP helps you and others (i.e., colleagues, corporate officials, auditors, and investigators) know what food is included in the FDP and any relevant characteristics that may help better understand the FDP.

In Chapter 2 of this guidance, we recommend that you take certain preliminary steps before conducting your VA. One of these preliminary steps is to describe the product under evaluation. Worksheet 1-B: Food Defense Plan Product Description is similar to the FSPCA food safety plan form for Product Description, Distribution, Consumers, and Intended Use. If you have already completed the FSPCA form for your FSP for the same food products, you may save time and resources by copying over the information from that worksheet to use for your FDP.

Some of the information in the product description may not be important or necessary to inform your VA if you use the KAT method. This worksheet is voluntary, and you have the flexibility to use as much or as little of the worksheet as you choose.

### **1. How to Fill in Worksheet 1-B: Food Defense Plan Product Description**

The information included in Worksheet 1-B are listed and explained below. Regardless of whether you use Worksheet 1-B, you may find that having such information is helpful in any product description that you develop.

- **Product Name(s):** Provide the full name of the finished product.
- **Company Name, Facility Name, Address:** Include the company and facility names, and addresses.
- **Product Description:** Describe the food product—what it is and include descriptors such as packaging type.
- **Ingredients:** List the ingredients used to make the food product.
- **Intended Use:** Describe the intended use of the food product, e.g., for retail, foodservice, or further processing.
- **Intended Consumers:** Describe the intended end consumer, if known, of your product. Usually this would be the general public; however, some food product is intended specifically for specific populations such as those in hospitals, infants, or the elderly.
- **Storage and Distribution:** Describe the nature of how the food is stored and distributed into the marketplace (e.g., speed of distribution from processor to consumer; local, regional, national, or global distribution patterns).

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

**2. Worksheet 1-B: Food Defense Plan Product Description**

**PRODUCT NAME(S):** \_\_\_\_\_  
**COMPANY NAME:** \_\_\_\_\_  
**FACILITY NAME:** \_\_\_\_\_  
**ADDRESS:** \_\_\_\_\_

<b>Product Name(s)</b>	
<b>Product Description</b>	
<b>Ingredients</b>	
<b>Intended Use</b>	
<b>Intended Consumers</b>	
<b>Storage and Distribution</b>	

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

## **D. Food Defense Plan Vulnerability Assessment**

In Chapter 2 of this guidance, we provide guidance on how to conduct a vulnerability assessment using the Key Activity Types method to identify significant vulnerabilities and actionable process steps. The VA must be written (21 CFR 121.126(b)(1)), and Worksheet 1-C can assist you in conducting and documenting your VA. Even if you do not use Worksheet 1-C, we recommend that you include similar information in your VA documentation.

### **1. How to Fill in Worksheet 1-C: Vulnerability Assessment Analysis Summary**

Once you have assembled the Food Defense Team and started gathering the information you will use in your VA, we recommend that you create a document that you will use to organize the vulnerability assessment results. Below is a description of each of the columns in the VA analysis summary worksheet and how you should fill them out to document your VA. In Chapter 2 of this guidance, we provide an example of a completed VA analysis summary worksheet for a VA using the KAT method.

- (1) Number (#):** Number each process step from your process flow diagram.
- (2) Process Step:** List the name of each of the process steps. We recommend that you draw out a process flow diagram or use an existing process flow diagram as a preliminary step. If you already have this process flow diagram completed, simply list the names of the process steps in each row of this column.
- (3) Process Description:** Describe the process step. We have found it helpful to include a short description of what each process step involves so that when you are conducting the VA you have the background information you would need to justify whether it presents a significant vulnerability. Additionally, if mitigation strategies are required at this process step, information about the process step can assist with identifying and implementing the mitigation strategies.
- (4) Vulnerability Assessment Method:** Note the methodology that was used to conduct the VA. For example, if you used FDA’s Key Activity Type methodology as described in Chapter 2 of this guidance, then you will write “Key Activity Types” in this column.
- (5) Explanation:** Include the reasons that led to the conclusions of your VA (i.e., the reasons for the Yes/No conclusions listed in column (6) for each process step). Your VA must include an explanation as to why the process step was or was not identified as an actionable process step. (21 CFR 121.130(c)). Explaining your reasons for a “No” conclusion can be just as important as explaining your reasons for a “Yes” conclusion. Including more details in this column will help you during your own review of your FDP and during review of your FDP by others – e.g., if an inspector or auditor questions why a process step was not identified as an actionable process step.

***Contains Nonbinding Recommendations***  
***Draft-Not for Implementation***

Having the appropriate amount of detail for the explanations in this column will also help you during a reanalysis of your FDP.

- (6) Actionable Process Step:** Record the conclusions of your vulnerability assessment for the process step as “Yes” if that process step has a significant vulnerability and is an actionable process step, or “No” if that process step is not an actionable process step.

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

**2. Worksheet 1-C: Vulnerability Assessment Analysis Summary**

**PRODUCT(S):** \_\_\_\_\_

**FACILITY NAME:** \_\_\_\_\_

**ADDRESS:** \_\_\_\_\_

**SIGNED DATE:** \_\_\_\_\_

<b>(1) #</b>	<b>(2) Process Step</b>	<b>(3) Process Description</b>	<b>(4) Vulnerability Assessment Method</b>	<b>(5) Explanation</b>	<b>(6) Actionable Process Step</b>

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

## **E. Food Defense Plan Mitigation Strategies**

Chapter 3 of this guidance provides detailed guidance on identifying and implementing mitigation strategies for the actionable process steps identified during the vulnerability assessment. The IA rule requires that mitigation strategies and their accompanying explanations be written (21 CFR 121.135(b)), and Worksheet 1-H can assist you in creating that documentation. Regardless of whether you use Worksheet 1-H, we recommend that you include similar information in your mitigation strategies documentation in the FDP.

### **1. How to Fill in Worksheet 1-H: Mitigation Strategies**

Below is a description of each of the columns in this worksheet and how you should fill them out to document your mitigation strategies and explanations.

- (1) Number (#):** Include the numbers for the process steps identified as actionable process steps during the vulnerability assessment. If you used Worksheet 1-C to document the vulnerability assessment, you should only carry over to this worksheet those process steps that have a “Yes” in column (6) Actionable Process Step. Note that this column may not include every consecutive number (e.g., 1 through 20) used in Worksheet 1-C unless every process step has been identified as an actionable process step. If you identify and implement more than one mitigation strategy for an actionable process step, we recommend that you use a numbering system such as 1a, 1b, 1c to denote this, with the first mitigation strategy for process step 1 being 1a, the second mitigation strategy being 1b, and so on. This will make it easier to connect the mitigation strategies with the appropriate process steps as you work through the other worksheets within this appendix, and it will help you keep track of the management components for each mitigation strategy.
- (2) Actionable Process Step:** Insert the process step names that correspond to the process step numbers in column (1) identified as actionable process steps during the vulnerability assessment. If you used Worksheet 1-C to document the vulnerability assessment, you can copy over the process steps from column (2) of Worksheet 1-C.
- (3) Mitigation Strategy:** Include the mitigation strategy identified for implementation at the applicable actionable process step.
- (4) Explanation:** Provide the explanation(s) for how the mitigation strategy sufficiently minimizes or prevents the significant vulnerability associated with the actionable process step. See Chapter 3 of this guidance for detailed guidance on how to write this explanation.

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

**2. Worksheet 1-H: Mitigation Strategies**

**PRODUCT(S):** \_\_\_\_\_

**FACILITY NAME:** \_\_\_\_\_

**ADDRESS:** \_\_\_\_\_

**SIGNED DATE:** \_\_\_\_\_

<b>(1) #</b>	<b>(2) Actionable Process Step</b>	<b>(3) Mitigation Strategy</b>	<b>(4) Explanation</b>



*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

## **F. Food Defense Plan Mitigation Strategies Management Components**

As appropriate to 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, you must have mitigation strategy management components (i.e., written procedures for food defense monitoring, food defense corrective actions, and food defense verification) for each mitigation strategy (21 CFR 121.138). Worksheet 1-I will assist you in documenting your mitigation strategy management components. Regardless of whether you use Worksheet 1-I, we recommend that you include such information in your food defense monitoring, food defense corrective actions, and food defense verification procedures documentation in your FDP. Chapter 4 of this guidance includes guidance on food defense monitoring. Guidance related to food defense corrective actions and food defense verification is forthcoming.

### **1. How to Fill in Worksheet 1-I: Mitigation Strategies Management Components**

Below is a description of each of the columns in this worksheet and how you should fill them out to document your mitigation strategies management components procedures.

- (1) **Number (#):** Include the process step numbers for the process steps identified as actionable process steps during the vulnerability assessment. If you used Worksheet 1-H to document the mitigation strategies, you should carry over the process step numbers from column (1) of that worksheet.
- (2) **Actionable Process Step:** Insert the process step names that correspond to the process step numbers in column (1). If you used Worksheet 1-H to document the mitigation strategies, you should copy over the process steps from column (2) of that worksheet.
- (3) **Mitigation Strategy:** Include the mitigation strategy identified for each of the actionable process steps. If you used Worksheet 1-H to document the mitigation strategies, you can copy over the mitigation strategies from column (3) of that worksheet.
- (4) **Food Defense Monitoring Procedure and Frequency:** Provide the food defense monitoring procedures for each mitigation strategy as well as the frequency with which the procedure will be performed. See Chapter 4 of this guidance for detailed guidance on food defense monitoring procedures.
- (5) **Food Defense Corrective Action Procedures:** Provide the food defense corrective action procedures for each mitigation strategy.
- (6) **Food Defense Verification Procedures:** Provide the food defense verification procedures for each mitigation strategy.

*Contains Nonbinding Recommendations*  
*Draft-Not for Implementation*

- (7) **Records:** List the names of the records that will document the implementation of the mitigation strategies management components (e.g., cleaning/sanitizing records, monitoring records, security patrol records, corrective action records, verification records).

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

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

**PRODUCT(S):** \_\_\_\_\_

**FACILITY NAME:** \_\_\_\_\_

**ADDRESS:** \_\_\_\_\_

**SIGNED DATE:** \_\_\_\_\_

<b>(1) #</b>	<b>(2) Actionable Process Step</b>	<b>(3) Mitigation Strategy</b>	<b>(4) Monitoring Procedure and Frequency</b>	<b>(5) Corrective Action Procedures</b>	<b>(6) Verification Procedures</b>	<b>(7) Records</b>

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

**Appendix 2: Mitigation Strategies in the Food Defense Mitigation Strategies  
Database (coming soon)**

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

**Appendix 3: Calculating Small Business and Very Small Business Sizes  
(coming soon)**

*Contains Nonbinding Recommendations  
Draft-Not for Implementation*

## References

We have placed the following references on display at the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of April 9, 2018, FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after April 9, 2018.

1. Norton, R.A., "Food Defense in the Age of Domestic Terrorism." Food Safety Magazine (<https://www.foodsafetymagazine.com/enewsletter/food-defense-in-the-age-of-domestic-terrorism/>), December 15, 2015. Accessed December 15, 2015.
2. Valdmanis, R., "Boston Bomb Suspect Influenced by Al Qaeda: Expert Witness." Reuters (<http://www.reuters.com/article/us-boston-bombings-trial-idUSKBN0MJ0Z620150323>), March 23, 2015. Accessed December 15, 2015.
3. FDA. "Analysis of Results for FDA Food Defense Vulnerability Assessments and Identification of Activity Types." (<http://wayback.archive-it.org/7993/20170722031143/https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm347023.htm>), April 2003. Accessed December 5, 2017.