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

Revised Draft Guidance

This guidance is being distributed for comment purposes only.

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

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition**

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Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry¹

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic.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.²

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.

¹ 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.

² 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.

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Table 1. Subparts Established in 21 CFR Part 121

Subpart	Title
A	General Provisions
B	Reserved
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

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

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.

³ 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).

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III. Glossary of Terms Used in This Guidance

A. Definitions Established in 21 CFR 121

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

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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.

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.

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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.

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:

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(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:

(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)

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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.

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).

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C. Table of Abbreviations Used in This Guidance

Abbreviation	What It Means
FD&C Act	Federal Food, Drug, and Cosmetic Act
CCTV*	Closed-circuit television
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
HFCS*	High fructose corn syrup
IA	Intentional Adulteration
IA rule	Mitigation Strategies to Protect Food Against Intentional Adulteration (21 CFR part 121)
KAT	Key Activity Types
LD*	Lethal Dose
FDMSD	Food Defense Mitigation Strategies Database
PCHF	Preventive Controls for Human Food
VA	Vulnerability Assessment (as required in 21 CFR 121.130)

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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 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

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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 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.

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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. See Chapter 8 of this guidance for more information on education, training, or experience.

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,

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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. Appendix 1 of 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

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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

[New March 2019 - This chapter provides guidance to help you understand how to conduct a vulnerability assessment (VA) to identify significant vulnerabilities and actionable process steps. In a VA, 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 VA requirement is flexible. There are many possible approaches to conducting a vulnerability assessment. You may choose an approach based on considerations such as the time and resources available and the level of specificity desired. You have the flexibility to choose any VA approach, as long as your VA contains each required component (21 CFR 121.130).

In sections A and B of this chapter, we describe a VA, the general requirements of a VA, and recommended activities prior to conducting a VA. In sections C, D, and E, we describe a simple, less resource-intensive approach using KATs to identify significant vulnerabilities at actionable process steps. In Sections F and G, we describe how to conduct a VA using the three fundamental elements to identify significant vulnerabilities at actionable process steps. Finally, in section H, we describe how to conduct a VA using the hybrid approach (i.e., a combination of the KATs and the three fundamental elements).

In Appendix 4 of this guidance, there are two examples of vulnerability assessments – one conducted by evaluating the three fundamental elements, and another conducted using the hybrid approach.]

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

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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)). See section F.1.a. of this chapter for more information on the inside attacker.

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.

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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

- | |
|--|
| <ol style="list-style-type: none">1. Assemble a Food Defense Team2. Describe the product under evaluation3. Develop a process flow diagram4. Describe the process steps |
|--|

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.

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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 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

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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.

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.,

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- 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).

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.

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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);
- 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

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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 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.

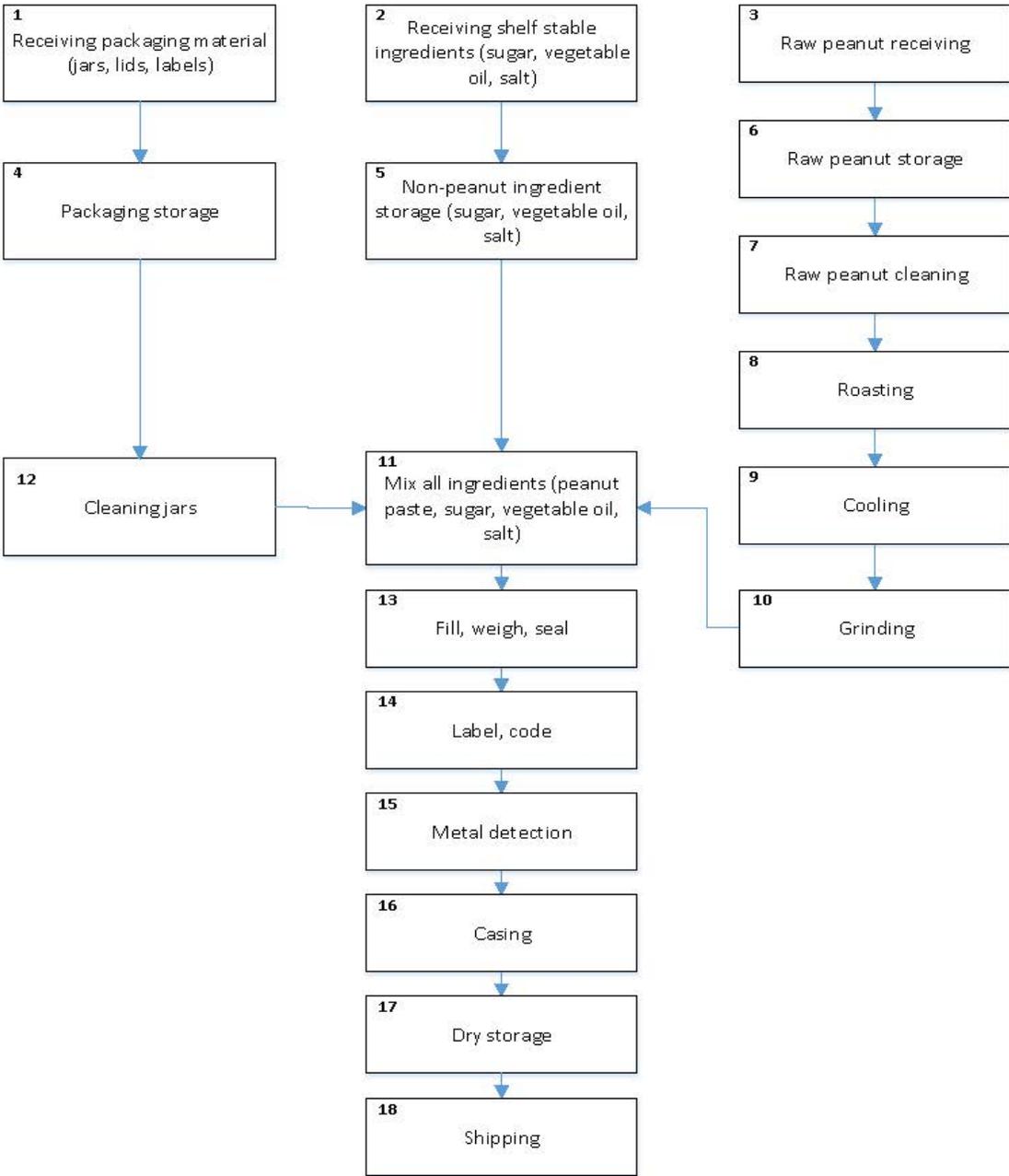
If a processing step does not align with any of the KATs, then that step is not an actionable process step and your written explanation may be: “This point, step, or procedure does not align with any of the KATs.”

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.

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Figure 2a-1. Smooth Peanut Butter Process Flow Diagram⁴



⁴ Courtesy of the Food Safety Preventive Controls Alliance. Used with permission.

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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

(1) #	(2) Process Step	(3) Process Description	(4) Vulnerability Assessment Method	(5) Explanation	(6) Actionable Process Step
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.	No
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.	No

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(1) #	(2) Process Step	(3) Process Description	(4) Vulnerability Assessment Method	(5) Explanation	(6) Actionable Process Step
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.	No
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.	No
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.	Yes

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(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.	No
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.	No
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.	No

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(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.	No
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.	Yes
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.	Yes
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.	No
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.	No

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(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.	No
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.	No
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.	No
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.	No
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.	No

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F. Evaluating the Three Fundamental Elements [New March 2019]

The IA rule requires that your vulnerability assessment include consideration of the following three fundamental elements at each point, step, or procedure you evaluate (21 CFR 121.130(a)):

Element 1: Potential public health impact (e.g., severity and scale) if a contaminant were added;

Element 2: Degree of physical access to the product; and

Element 3: Ability of an attacker to successfully contaminate the product.

All points, steps, and procedures have some degree of vulnerability. Evaluating the degree of vulnerability within each of the three fundamental elements, along with the consideration of an inside attacker, provides you a way to identify significant vulnerabilities. If the point, step, or procedure under evaluation has significant vulnerabilities, it is an actionable process step. In the following text, we outline some possible approaches for evaluating the three fundamental elements and determining the degree of vulnerability associated with each element. Note that if you are using KATs to conduct a VA, you do not need to separately consider the three fundamental elements because they are already incorporated into the KAT approach.

The three fundamental elements approach allows you to consider detailed, facility-specific aspects of each point, step, or procedure in your VA. In Sections F and G of this chapter, we describe the following components of a vulnerability assessment conducted using this approach:

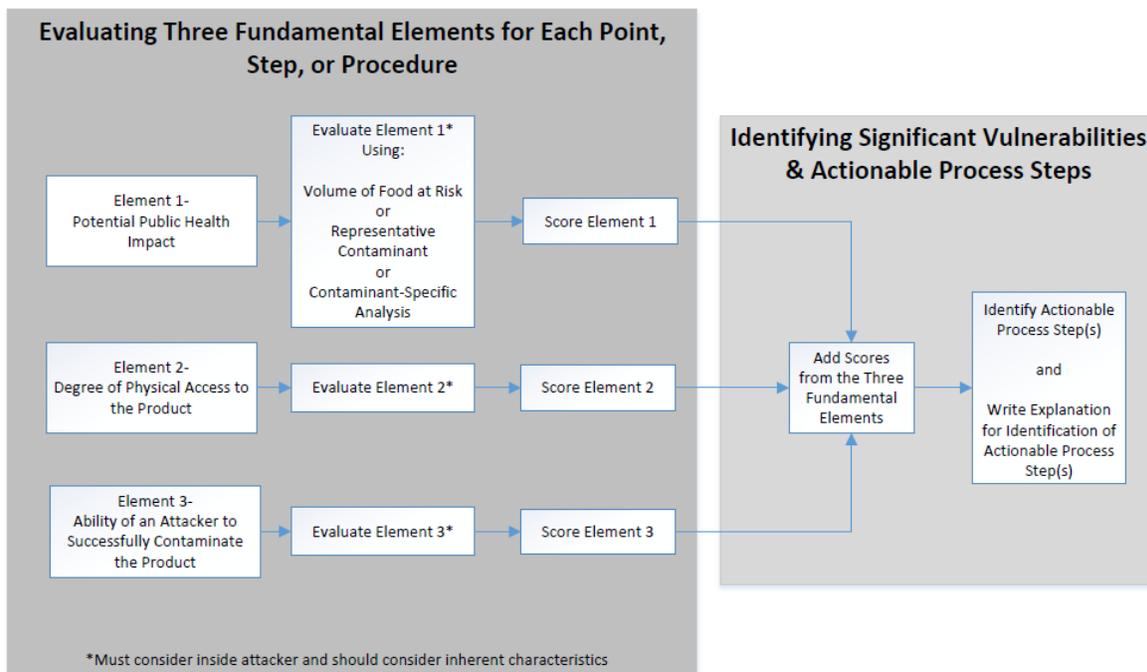
- Two important, overarching factors to consider while you are evaluating each fundamental element (i.e., the inside attacker and inherent characteristics);
- Element 1 characteristics, three ways you may choose to estimate Element 1 (i.e., “volume of food at risk,” “representative contaminant approach”, and “contaminant-specific approach”), additional factors you may choose to include in your estimate, and how to use this information to assign a score for this element;
- Element 2 characteristics and how to use this information to assign a score for this element
- Element 3 characteristics, additional factors you may choose to include in your evaluation if you use the contaminant-based approaches in Element 1, and how to use this information to assign a score for this element;
- Summing the individual element scores you assign, ranking the summed scores, and identifying which steps are actionable process steps that have significant vulnerabilities; and
- Writing the explanation for why you determined each step is, or is not, an actionable process step.

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Appendix 4 of this guidance includes an example of a vulnerability assessment conducted by evaluating the three fundamental elements.

Diagram 2a-1 provides a visual representation of how the three fundamental elements can be used to identify significant vulnerabilities and actionable process steps.

Diagram 2a-1. Identifying Significant Vulnerabilities & Actionable Process Steps Using the Three Fundamental Elements



1. Considerations in Evaluating the Three Fundamental Elements

a. Inside Attacker

When you evaluate each of the fundamental elements, you must consider the possibility of an inside attacker. (21 CFR 121.130(b)). This requirement is a critical component of a VA because it incorporates the highest risk related to intentional adulteration and subsequent public health harm. Therefore, your analysis should include a realistic consideration of the susceptibility of the process step to adulteration by someone with legitimate access to the facility. Failing to consider the possibility of an inside attacker likely would lead to artificially low scores for each of the fundamental elements and adversely affect identification of significant vulnerabilities.

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i. Background

The most effective means of protecting food from intentional adulteration intended to cause wide scale public health harm is to protect significantly vulnerable points, steps, or procedures in a food operation from an inside attacker. Law enforcement statements describe the insider threat as one “posed by an individual who exploits his/her position, credentials, or employment to achieve trusted access to the means, processes, equipment, material, location, facility, and/or target necessary to carry out a terrorist action.” (References 4-5). Recent reports have highlighted the risk from an inside attacker (References 4-7).

Current information related to intentional adulteration of food further emphasizes the importance of addressing the possibility of an inside attacker. Threats to the food supply from intentional adulteration by an inside attacker have increased since the publication of the IA final rule in 2016. Published reporting indicates terrorist groups have called on followers to intentionally adulterate food in different settings (References 8-9). Additionally, terrorist groups have experimented with food contaminants on prisoners to gauge the effects of various poisons (Reference 9). Recent reporting describes a foiled terror plot in the United Kingdom involving an employee at a food manufacturing plant who was interested in intentionally adulterating food and was investigating lethal substances to contaminate supermarket-ready foods (Reference 10). See also discussion of an intentional adulteration incident in Japan in the final rule at 81 FR 34166, 34172 (May 27, 2016).

ii. How to Consider an Inside Attacker

When you are conducting your vulnerability assessment, you should assume that an inside attacker has:

- Legitimate access to the facility (e.g., an employee, contractor, driver, authorized visitor);
- A basic understanding of the facility’s operations and the food product(s) under production;
- The ability to acquire and deploy a contaminant that is highly lethal, capable of withstanding the food production process, and undetectable via simple observation if added to food; and
- The intent to cause wide scale public health harm.

You should also consider the number and nature of individuals with legitimate access to the facility (e.g., permanent workers, temporary and seasonal workers, vendors, contractors, visitors, drivers, maintenance personnel, and customers), the ability of these individuals to move freely throughout the facility, and the personnel in the area around the point, step, or procedure (e.g., multiple workers in a well trafficked area or a single worker in an isolated area). When considering how an insider may be able to attack a process step, key parts of the analysis include the possibility that the process step employee is an inside attacker; factors related to workers, or a single worker, who have responsibilities associated with the process step (i.e., are stationed at the process step as a part of their job function); other people who have legitimate access to the

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facility who may have access to the area surrounding the process step; and whether there are any circumstances where an inside attacker could feasibly enter the area to adulterate the food without the process step employee(s) knowing. If a process step is generally accessible to any person working or traversing through the area, you should consider all such individuals and evaluate the degree of vulnerability of the process step should one of these persons attempt to intentionally adulterate the food. For example, you should consider drivers and pest control contractors with legitimate access at a receiving bay as potential attackers.

Recognizing the potential for an inside attacker importantly informs the decision-making for the evaluation of each of the three fundamental elements of a VA. The level of access an inside attacker may have is variable. Some points, steps, or procedures are completely open, while others, due to inherent characteristics, may be completely inaccessible to an insider (see Section 2.F.b for more information on inherent characteristics). Similarly, the ability of an inside attacker to successfully contaminate the food is variable. For some points, steps, or procedures, an inside attacker may have a relatively high level of ability to contaminate the product, while inherent characteristics of other points, steps, or procedures may result in a relatively low ability of an inside attacker to contaminate the product. The scoring tables for Elements 2 and 3 are specifically designed to facilitate the identification of differing degrees of accessibility to and ability to contaminate a point, step, or procedure, respectively.

b. Inherent Characteristics

Inherent characteristics are conditions, activities, practices, or characteristics that are integral to the operation of a point, step, or procedure; the point, step, or procedure could not properly operate without these inherent characteristics in place. Furthermore, inherent characteristics are not easily changed or altered. Properly evaluating inherent characteristics of a process step, and distinguishing these characteristics from those that are not inherent⁴, is critical to accurately conducting an adequate VA. The following are examples of inherent characteristics:

- Design of the food production area
 - e.g., the layout of permanent equipment
 - e.g., general level of visibility of activity in the area
- Type and nature of equipment
 - e.g., a process step that is entirely enclosed and inaccessible during operation, such as piping, pasteurization, retorting, or a similarly enclosed process step such that accessing the food anywhere at this step would interrupt the process operation
 - e.g., a process step that is pressurized so that access would result in noticeable ejection of the food or cause bodily harm to anyone accessing the food at this process step
- Nature of the food being processed (e.g., whether the food is solid or liquid)

⁴ In most instances, non-inherent characteristics include “existing measures.” See Chapter 3.E of this guidance for more information about existing measures.

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- Nature of the processing
 - e.g., a process step where the food is moving at such a rate that adding enough contaminant to cause wide scale public health harm is highly unlikely or impossible (such as a belt, flume, bucket lift, vacuum, or pneumatic conveyor where product is moving at a high rate)
 - e.g., a process step where a contaminant, if added at the step under evaluation, will not be incorporated into the food due to minimal to no mixing or agitation
- Presence of employees in the immediate area
 - e.g., a process step that can function only when there are multiple employees working and constantly observing the step, such as where workers are lined up and manually working “assembly line style” and are constantly observing each other
 - e.g., a step requiring two workers to each perform an action for it to properly function, and if one worker is absent then the line would stop
- A process step where standard operating procedures would prevent or remove a contaminant added to the process step when not in use, such as flushing equipment or running a discard batch prior to the introduction of production batches
- Practices that are fundamental to a safe working environment such that a deviation of the safety practice would immediately result in a response by equipment (e.g., a safety mechanism would alarm or shut the equipment down if it is improperly accessed)

Non-inherent characteristics are unnecessary for a process step to function. Process steps will continue to function if non-inherent measures are improperly implemented (e.g., a worker neglects to verify a seal on a bulk tanker truck but still unloads the liquid food). Note that non-inherent characteristics may include practices to ensure their implementation (e.g., review of shipping documentation and verifying the presence of seals on transport conveyances), or they may not (e.g., requiring shipping documentation but accepting receipt of ingredients without verifying shipping documentation). The following are examples of measures that are not inherent characteristics:

- positioning a person of specific seniority or experience at a particular process step to protect food against intentional adulteration
- preventing delivery drivers from entering unauthorized areas in the facility
- requiring workers in specific areas or with specific responsibilities to wear specially colored uniforms or caps
- requiring seals on incoming bulk liquid tanker trucks

2. Potential Public Health Impact (Element 1)

The IA rule does not require you to use a specific method to estimate potential public health impact, but the estimate should include potential acute illnesses, deaths, or both (or proxies such as servings at risk), caused by the addition of a contaminant at each point, step, or procedure. We provide Table 1 as an optional tool to assist you in estimating potential public health impact.

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Table 1. Potential Public Health Impact ¹

Description	Score
Potential public health impact over 10,000 (acute illnesses, deaths, or both), or over 10,000 servings at risk	10
Potential public health impact between 1,001 – 10,000 (acute illnesses, deaths, or both), or 1,001 – 10,000 servings at risk	8
Potential public health impact between 100 and 1,000 (acute illnesses, deaths, or both), or 100 – 1,000 servings at risk	5
Potential public health impact between 1 - 99 (acute illnesses, deaths, or both), or between 1 – 99 servings at risk	3
No potential public health impact (i.e., no illnesses or deaths) or no servings at risk	1

¹ The range between scores of 5 and 8 is larger than the ranges between other scores to facilitate the separation between points, steps, or procedures that are significantly vulnerable compared to those that are not. This scoring scheme also is used in Table 2 and Table 3.

How to Use Table 1 to Estimate Potential Public Health Impact

The information included in Table 1 is explained below, along with recommendations on how to use this information to estimate the potential public health impact if a contaminant were added to food at a particular point, step, or procedure.

Description: Quantifies the potential public health impact related to the corresponding score. The descriptions provide information that will assist you in differentiating the potential extent of acute public health impact if a contaminant were added at the relevant point, step, or procedure. See Section 2.F.2.a for several alternative approaches you could use to determine this quantity.

Score: The potential public health impact score to be assigned for each relevant point, step, or procedure based on the corresponding potential public health impact “Description.”

a. Approaches to Evaluating Potential Public Health Impact

This subsection provides some possible approaches to evaluating the potential public health impact that include: (i) estimating the volume of food at risk; (ii) using a representative contaminant; and (iii) using specific contaminants. The severity and scale of the public health impact are incorporated into each approach in different ways. The “volume of food at risk” approach considers each serving at risk to be a potential acute illness or death. The “representative contaminant” approach considers only potential deaths. The “contaminant-specific” approach also estimates the scale of potential public health impact based on potential

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deaths, but includes flexibility to consider acute morbidity as well. Each of these approaches provides a way for you to estimate potential public health impacts that fall within the “Description” column that relates to the “Score” column in Table 1.

i. Calculating Volume of Food at Risk

This approach estimates the potential public health impact without the need to examine specific contaminants and their characteristics (e.g., consideration of lethal dose and quantity needed) by calculating the number of servings at risk. Calculating potential servings at risk in a batch-type process is typically straight-forward. For example, a facility estimating the potential public health impact of the intentional adulteration of its primary ingredient storage tank would consider the volume of food in the tank and the servings generated from this volume. If the facility has a 50,000 gallon primary ingredient liquid storage tank that would generate 800,000 one cup servings (50,000 gallons*16 cups/gallon), the facility would consider all 800,000 servings as being at risk.

Facilities also can use a time-factored analysis to consider the volume of food at risk. For example, a facility that has a bin of premixed seasoning blend staged for use for one day’s production could consider the day’s production as the volume of food at risk – and thus the servings generated from that volume would represent the potential public health impact if the bin of premixed seasoning were intentionally adulterated. For a continuous flow process, a facility would determine the flow rate of food through the process step and evaluate the potential time available to an attacker to introduce a contaminant without being discovered. The facility would then extrapolate the potential volume of food impacted within the time available to an attacker, and then calculate the total number of servings generated from that volume of food.

For example, at an open and accessible point of constant flow processing of a granular product, a facility could assess facility operations and personnel movement to determine that a person would have no more than 2 minutes to stand at the access point and introduce a contaminant to the food as it passes by the point of access. The facility determines that the flow rate of food is 1,000 pounds per minute and calculates that 2,000 pounds of product is at risk (1,000 lbs. per minute * 2 minutes). Based on a serving size of 4 ounces for this product, the facility determines that 8,000 servings (2000 lbs. = 32,000 oz. and 32,000 oz. / 4 oz. serving size = 8,000 servings) are at risk to an act of intentional adulteration at this step. Note that it is important to make sure your calculations consider any changes in units, as this will affect your public health impact estimates (e.g., 1 gallon = 128 fl. oz., 1 lb. = 16 oz., 1 g = .001 kg).

You can use Worksheet 1-D to organize your calculation of volume of food at risk. Regardless of whether you use Worksheet 1-D, we recommend that you include such information in your VA documentation if you use the volume of food at risk method to estimate potential public health impact.

How to Fill in Worksheet 1-D: Calculating Volume of Food at Risk

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The information included in Worksheet 1-D is explained below, along with recommendations on how to use this information to estimate the volume of food at risk if a contaminant were added to food at a particular point, step, or procedure.

- A. Process Step:** Provide the name of each of the process steps from the process flow diagram or other source.
- B. Batch Size:** Provide an estimate of the amount of product held or processed at the process step. The batch size is usually the volume of the process step's operation (e.g., the volume of food in a mixer or tank, or the amount of product in a constant flow process). For constant flow process steps, batch size is the amount of product you determine an attacker could contaminate, given the time the attacker would have to add a contaminant to a constant flow process and the flow rates of product at that step.
- C. Amount of Product (Ingredient) in Final Serving:** Provide the amount of the product being processed at the step under evaluation in the final consumable serving. For process steps that involve single ingredient products or that occur after all ingredients are added to the product line, this is likely the same as the serving size. For process steps that involve an ingredient, the amount of the ingredient in the final serving would not be the same as the serving itself. For example, the amount of concentrated fruit juice in a final serving of 8 ounces of fruit juice might be 0.8 ounces.

The column is used to calculate the number of finished servings an ingredient may affect if that ingredient were intentionally adulterated. You should consult your finished product formulations to determine the amount of product (ingredient) in final servings.

- D. Servings per Batch:** Divide the value in Column B by the value in Column C. This number is the estimate of the volume of food at risk.
- E. Score from Table 1:** Provide the number from the "Score" column in Table 1 associated with the servings per batch from Column D in this worksheet. For example, if Column D in this worksheet shows 3,000 servings per batch, then you would determine that it corresponds to a score of 8 in Table 1. The score from Column E of this worksheet goes into Column 4 (Element 1) in Worksheet 1-F.
- F. Notes:** Provide any information that would assist review of this VA, such as how batch size was calculated.

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Worksheet 1-D: Calculating Volume of Food at Risk

A Process Step	B Batch Size	C Amount of Product (Ingredient) in Final Serving	D Servings per Batch B ÷ C	E Score from Table 1	F Notes

Contaminant-Based Approaches

Rather than estimating volume of food at risk, you may wish to estimate potential public health impact using a contaminant-based approach, which would give you the information on deaths or deaths and acute illnesses for use in Table 1. A contaminant is any biological, chemical, physical, or radiological agent that may be added to food to intentionally cause illness, injury, or death. (21 CFR 121.3). Food safety and food defense approaches consider contaminants differently. For food safety purposes, contaminants are often considered based on their historical association with a commodity and outbreaks of foodborne illness; whereas food defense considers intelligent adversaries who may attempt to contaminate food with a wide range of potential contaminants.

ii. Using a Representative Contaminant

We have found that focusing on individual contaminants is generally not effective or efficient in evaluating the potential public health impact from the addition of a contaminant to food because there are many potential contaminants that could be used in such an attack. Therefore, FDA used the best available data to create a representative contaminant. The characteristics of the representative contaminant do not reflect a single, actual contaminant; they are based on an amalgam of characteristics from actual contaminants. The representative contaminant reflects contaminants whose acquisition is possible, and in some cases, readily so. The representative contaminant incorporates characteristics that would allow the attacker to achieve the goal of causing wide scale public health harm (i.e., the mortality rate and amount of contaminant needed per serving of a highly lethal contaminant that would survive the food production process and would be undetectable via simple observation if added to the food).

In our experience conducting VAs, we have used a representative contaminant approach to estimate potential public health impact for each process step under evaluation. We have found that using a representative contaminant significantly decreases the time, resources, and expertise needed to estimate potential public health impact as compared to performing contaminant-specific analyses. When compared to approaches that do not include the consideration of a contaminant (e.g. volume of food at risk), this approach allows for a higher degree of specificity for a potential public health impact estimate because contaminant characteristics, such as a lethal dose (LD) value and associated mortality rate, are included in this approach. Toxic dose

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information is commonly reported as LD50 (i.e., the amount of contaminant sufficient to kill 50% of a population). Using the LD50 is one way to measure the acute poisoning potential (acute toxicity) of a contaminant.

In addition to providing more specificity for consideration of Element 1, the calculation of the amount of contaminant needed (Column J in Worksheet 1-E) facilitates considering this factor as part of your analysis of Element 3 (the ability of an attacker to successfully contaminate the product). See Section 2.F.4 “Amount of Contaminant Needed” for more information related to this consideration.

If you choose to use a representative contaminant, we recommend that you use representative contaminant values used in this guidance because they reflect the best available data.⁵ Additionally, associating agent-specific information, such as mortality rate and public health estimates of an intentional adulteration event, with a specific agent can generate results that are particularly important to protect from disclosure because of their usefulness to a potential attacker. While estimates derived from the representative contaminant approach should be protected from disclosure, these estimates may be of relatively less value to a potential attacker because these estimates are not associated with a specific contaminant.

You can use Worksheet 1-E to organize your potential public health impact estimate using a representative contaminant. Regardless of whether you use Worksheet 1-E, we recommend that you include such information in your VA documentation if you use this method to estimate potential public health impact.

How to Fill in Worksheet 1-E: Calculating Potential Public Health Impact using a Representative Contaminant

The information included in Worksheet 1-E is explained below, along with recommendations on how to use this information to calculate potential public health impact using a representative contaminant if a contaminant were added to food at a particular point, step, or procedure. For Columns A – D, please see descriptions provided in “How to Fill in Worksheet 1-D: Calculating Volume of Food.

E. Mortality Rate of Representative Contaminant: We use an LD50 value to calculate the dose needed per serving (See Column I); therefore, the mortality rate value is 50%. The representative contaminant approach relies on this value to estimate potential public health impact.

⁵ As new, pertinent information becomes available, FDA will reevaluate the representative contaminant values to determine whether revisions should be made to the values. As appropriate, FDA may require facilities to conduct a reanalysis of their food defense plans to respond to new vulnerabilities, credible threats to the food supply, or new developments in scientific understanding. (21 CFR 121.157(b)(4)). In this circumstance, FDA would communicate that a reanalysis is required and would provide the associated industry or industries with information needed to conduct the reanalysis.

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F. Number of Potential Deaths: Multiply the value of Column D by the value of Column E (D x E).

G. Score from Table 1: Provide the number from the “Score” column in Table 1. Determine into which “Description” from Table 1 the number of potential deaths from Column F in this worksheet fits and then find the corresponding “Score” in Table 1. For example, if Column F in this worksheet shows 3,000 potential deaths, then you would determine it fits into the Table 1 “Description” of “Potential public health impact between 1,001 – 10,000 (acute illness or deaths), or 1,001 – 10,000 servings at risk” which corresponds to a score of 8. The score from column G of this worksheet goes into Column 4 (Element 1) in Worksheet 1-F.

H. Notes: Provide any information that would assist during review of this VA.

I. Representative Contaminant Dose Needed per Serving: We use the value of 40 milligrams per serving. We derived this dose value, in consultation with our interagency governmental partners, from the LD50 data of a compilation of potential contaminants that are applicable to food. LD50 is typically expressed in dose per kg body weight. We converted this into a dose per serving value based on a typical adult body weight of 85 kg.⁶

J. Amount of Representative Contaminant Needed per Batch: Multiply the value in Column D by the value in Column I (D x I). This will provide the total amount of contaminant the attacker needs to intentionally adulterate the food at this process step to achieve wide scale public health harm. This estimate informs the amount of the contaminant the attacker needs to carry out the attack, which is a component of Element 3.

⁶ When conducting its vulnerability assessments, FDA has historically used 85 kg as a representative adult body weight to calculate potential LD50 dose amounts of contaminants. This value represents an amalgamation of anthropometric data from the National Health Examination Survey published periodically by Centers for Disease Control and Prevention (CDC).(Ref. 11)

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Worksheet 1-E: Calculating Potential Public Health Impact using a Representative Contaminant

Element 1 Calculations using Representative Contaminant								Element 3 Calculations	
A	B	C	D	E	F	G	H	I	J
Process Step	Batch Size	Amount of Product (Ingredient) in Final Serving	Servings per Batch B ÷ C	Mortality Rate of Contaminant (<i>FDA provided value = 50%</i>)	Number of Potential Deaths D x E	Score from Table 1	Notes	Representative Contaminant Dose Needed per Serving (<i>FDA provided value = 40 milligrams</i>)	Amount of Representative Contaminant Needed per Batch D x I

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iii. Performing a Contaminant-Specific Analysis

Although you have the flexibility to evaluate potential public health impact using specific contaminants of concern, it is difficult and resource-intensive to consider the multiple combinations of potential contaminants at each point in a food operation. Moreover, in many cases, the limited information publicly available to support contaminant-specific analyses makes this type of analysis particularly challenging. Additionally, individual facilities may find it difficult to remain up-to-date on the threat landscape regarding contaminants, which may change quite rapidly. For these reasons, we encourage you to carefully weigh the advantages and disadvantages before undertaking contaminant-specific analyses to perform your VA and encourage you to first explore using Key Activity Types to perform your VA or use one of the other methods we describe for evaluating potential public health impact (i.e., volume of food at risk and representative contaminant), which do not require an in-depth knowledge of a wide array of potential contaminants.

If you choose to perform a contaminant-specific analysis, you should estimate potential public health impact using many contaminants from different classes of contaminants. You will need to research numerous contaminants to identify those that are relevant to the food being produced in the facility and to estimate the potential public health impact of an intentional adulteration event. In rare circumstances, you might identify certain food products that may only be vulnerable to certain types of contaminants because of the use of certain process steps; volumes of food being manufactured, processed, or held; the nature of the food itself (e.g., water activity, pH); or other factors. In this situation, your VA should include an explanation of why you limited your consideration of contaminants.

Your analysis should include contaminants that survive the food production process, are undetectable via simple observation, and are similar in lethality to the representative contaminant. Incorporating these characteristics provides for an adequately robust vulnerability assessment because there are numerous lethal contaminants that exhibit these characteristics, and such contaminants could be selected by an attacker for intentional adulteration with the goal of causing wide scale public health harm. Conducting a VA using only contaminants that are neutralized by a process step (e.g., neutralized by heat or pressure) or are easily detectable by simple observation would omit potential contaminants that would survive that step and/or would not be readily detectable. Similarly, conducting a VA using only contaminants that are less lethal than the representative contaminant would omit potential contaminants that are highly lethal and available. If your VA fails to incorporate an adequate range of contaminants, it is likely to significantly underestimate potential public health impact. If you choose to use the contaminant-specific approach, we recommend focusing on potential acute public health impact because this is the type of harm most associated with the goals of an attacker intending to cause wide scale public health harm. We provide further detail below regarding the types of contaminants facilities should assess when using a contaminant-specific analysis.

Types of Contaminants

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A contaminant-specific approach should consider biological, chemical, radiological, and physical contaminants. We do not provide a list of specific contaminants you should consider because of their large number and constant evolution. There may be a scarcity of data related to lethality, toxicity, infectivity, and organoleptic properties for uncommon and exotic contaminants. As such, we expect that many facilities will not be able to use this method because of insufficient information to make contaminant-specific estimates for all relevant contaminants.

Biological Contaminants

Potential biological contaminants include microbiological hazards such as parasites, environmental pathogens, and other pathogens. Bacterial pathogens can be classified based on whether they form spores (“sporeformers”) or exist as vegetative cells and do not form spores (“non-sporeformers”). Spores are not hazardous if they remain in the spore state. Spores are very resistant to heat, chemicals, and other treatments that would normally kill vegetative cells of both sporeformers and non-sporeformers. When spores survive a processing step designed to kill vegetative bacteria, they may become a hazard in the food if they are exposed to conditions that allow germination and growth as vegetative cells.

Chemical Contaminants

Potential chemical contaminants include pesticide and drug residues, heavy metals, environmental contaminants, histamine due to decomposition, chemicals used to clean manufacturing equipment, natural toxins (e.g., mycotoxins), and synthetically derived compounds. Chemical contaminants have the potential to be heat resistant and soluble in water or fats. Chemical contaminants can be in powdered or liquid form, and they can be colorless, odorless, and tasteless.

Radiological Contaminants

Consuming food contaminated with radionuclides will increase the amount of radioactivity a person is exposed to, which could have adverse health effects that depend on the radionuclide and the amount of radiation to which a person is exposed. Radiological hazards can be in solid, powdered, or liquid form.

Physical Contaminants

Physical contaminants are broadly classified as “hard/sharp” physical contaminants or “choking” contaminants. Physical contaminants from either category can injure consumers. These injuries may include dental damage, laceration of the mouth or throat, laceration or perforation of the intestine, or choking, and may even lead to death. Physical contaminants cover a broad range of contaminants, such as glass, metal, plastic, wood, and stone. Because it would be difficult to use a physical contaminant to cause wide scale public health harm, this type of contaminant is unlikely to create a significant vulnerability for most facilities.

We are providing Worksheet 1-E as an example of how to organize your potential public health impact estimate using a contaminant-specific analysis. If you choose this type of analysis and

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use Worksheet 1-E, you will need to replace the FDA-provided values in Columns E and I with contaminant values from your own research. Regardless of whether you use Worksheet 1-E, we recommend that you include such information in your VA documentation if you use a contaminant-specific analysis to estimate potential public health impact.

How to Fill in Worksheet 1-E: Calculating Potential Public Health Impact using a Contaminant-Specific Analysis

Calculating potential public health impact using specific contaminants is essentially the same as using the representative contaminant approach already discussed. The calculation should be repeated for each contaminant considered. The contaminant with the largest estimated public health impact should be used to identify the appropriate score from Table 1, as this is the estimate that adequately captures the full extent of the potential public health impact. To use Worksheet 1-E in considering individual contaminants, you should use values you have determined are appropriate to the analysis. At a minimum you will need to update the following Columns from Worksheet 1-E:

E. Mortality Rate of Contaminant: Provide the mortality rate for the specific contaminant. If an LD50 value is used to calculate the dose per serving, 50% should be placed in this Mortality Rate column. The mortality rate should be from the same source (e.g., scientific literature) used for the contaminant dose needed per serving calculation.

H. Notes: Provide any information that would assist during review of this VA, such as the source of information for the contaminant under evaluation, including characteristics and toxicity information.

I. Contaminant Dose Needed Per Serving: Provide an estimated contaminant dose per serving derived from oral toxic dose information found in scientific literature. The value is typically reported as the dosage per kilogram of bodyweight, which is then converted to a dose per serving. For example, if a substance has a reported LD50 of 1 mg/kg and you assume a typical adult male weighs 85 kg, then the LD dose is $85 \text{ kg} * 1 \text{ mg/kg} = 85 \text{ mg/serving}$. Only oral routes of exposure should be considered.

Estimating Morbidity for the Contaminant-Specific Analysis

If you perform a contaminant-specific analysis, you could choose to include estimates of acute morbidity (i.e., acute illnesses) and mortality in your Element 1 evaluation. Columns E, I, and J in Worksheet 1-E could be used for morbidity by replacing the mortality-specific information with morbidity-specific information. Morbidity and mortality estimates should then be added together, and this sum entered into Column F. The score in Column G will be based on the summed estimate from Column F.

b. Additional Considerations for Evaluating Potential Public Health Impact

Although not required, you have the flexibility to consider additional factors (i.e., factors not included in the worksheets) in your evaluation of potential public health impact. Such factors

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include end use of the food and consumer packaging. The food system is complex, and this complexity can make incorporation of such factors into the estimate of the potential public health impact challenging. Therefore, we recommend that you only consider other factors if you have enough information to adequately incorporate them into your analysis.

i. End Use of the Food

If you have information to support this consideration, you may consider the end use of a food product being manufactured, processed, packed, or held at your facility. Considering end use is most useful for facilities manufacturing/processing, packing, or holding ingredients used in other products because it may be difficult to determine a serving size for an ingredient without doing so (see juice example in explanation of Column C in Worksheet 1-D). We recommend that you determine the amount of the ingredient used in the end product based on the most common use of your ingredient. The most common use may be different for the same product made by two different facilities. For example, consider two facilities that manufacture high fructose corn syrup (HFCS). Facility A primarily sells its HFCS to a manufacturer for use in soft drinks. Facility B primarily sells its HFCS to a bakery for use in cookies and cakes. Given the different uses of HFCS by these facilities' different customers, the amount of HFCS in the final product (soft drinks and baked goods respectively) would be different. Each facility should evaluate the potential public health impact of its HFCS operation based on the most common use of its products. As another example, if a facility sells HFCS to both soft drink manufacturers and bakeries, the facility should evaluate the potential public health impact of its HFCS operation based on which customer receives the most HFCS, by volume. If a facility does not know the final use of its product, it could assume the most likely use based on industry-wide usage.

ii. Consumer Packaging

Food is commonly packaged in units that include many servings, and a facility may choose to consider how its food is packaged in its analysis of potential public health impact. For example, a manufacturer of breakfast cereal may package its product in boxes that contain multiple servings. The manufacturer could consider this in its evaluation of potential public health impact by converting the number of servings at risk into the number of consumer packages for those servings. Next, the manufacturer would multiply the number of packages by the average number of consumers per package. Considering consumption in this way may reduce the number of potential exposures to contaminated product because a single packaged product typically is consumed by fewer consumers than the number of servings it contains.

For example, consider a facility that manufactures breakfast cereal. At the cooking step the facility toasts 1,000 pounds of cereal at a time (batch size). A typical serving size is one ounce, so this 1,000 pounds of cereal would generate 16,000 servings (1,000 lbs. x 16 oz./lb.). However, the 16,000 one-ounce servings will be packaged into 24-ounce boxes, yielding 666 boxes ($16,000 / 24 = 666.67$). Based on market research or other information, the manufacturer determines that, on average, a household of 3 persons will consume its breakfast cereal from a single box. With this information, the manufacturer concludes that the potential public health impact from its cooking step is 1998 potential exposures ($666 \text{ boxes} \times 3 \text{ consumers/box} = 1,998$).

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Facilities that use multiple package sizes may wish to evaluate a selection of packages (such as the smallest, a medium size, and largest units), or identify the most common package size to inform their analysis.

Note that the calculation is based on how the food is purchased by consumers. If a food is packaged in individual sizes, then packed in cases for distribution, and then unpacked and sold in individual packages, the total number of servings should be divided by the number of servings in a consumer package, not the servings in a case.

3. Degree of Physical Access to the Product (Element 2)

In this element, you consider an inside attacker's level of accessibility to the product at each point, step, or procedure. You may find the accessibility of the product to intentional adulteration to be the most straightforward element to evaluate, and we therefore suggest you consider starting your evaluation with this element. As discussed in Section 2.F.1.a, you should consider the accessibility of the product to an insider. Further, as discussed in Section 2.F.1.b, when evaluating accessibility, you should consider the presence of inherent characteristics that may increase or decrease accessibility.

The IA rule does not require you to use a specific method to evaluate the degree of physical access to the product. We provide Table 2 as an optional tool to assist you in estimating the degree of physical access to the product for each point, step, or procedure under evaluation.

Table 2. Degree of Physical Access to the Product

Description¹	Score
Easily Accessible. <ul style="list-style-type: none">• Inside attacker has access to the product (e.g., attacker can physically touch the product).• There are no inherent characteristics that would make access to the product difficult (e.g., enclosed systems, pressurized equipment, railings, equipment safety features, or shields).• Product is open and unsecured by packaging, equipment, or other physical access barriers.• Product is handled, staged, or moved in an easily accessible manner.	10

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<p>Accessible.</p> <ul style="list-style-type: none"> • There are limited inherent characteristics that would make access to the product difficult (e.g., enclosed systems, pressurized equipment, railings, equipment safety features, or shields). • Product is in equipment that can be accessed without tools or specialized supplies. • Access to the food is not difficult (e.g., there are minimal physical space constraints that limit access to food) but may require opening equipment, access points, or non-tamper-evident packaging. 	8
<p>Partially Accessible.</p> <ul style="list-style-type: none"> • Inside attacker has partial access to the product. • There are some inherent characteristics that would make access to the product somewhat difficult (e.g., enclosed systems, pressurized equipment, railings, equipment safety features, or shields). 	5
<p>Hardly Accessible.</p> <ul style="list-style-type: none"> • There are significant inherent characteristics that would make access to the product very difficult (e.g., enclosed systems, pressurized equipment, railings, equipment safety features, or shields). • Product is in equipment that make access difficult without tools or specialized supplies. • Physical space constraints limit access to food being processed or stored. 	3
<p>Not Accessible.</p> <ul style="list-style-type: none"> • Inside attacker has no access to the product (e.g., attacker cannot physically touch the product). • There are significant inherent characteristics that would make access to the product impossible (e.g., enclosed systems, pressurized equipment, railings, equipment safety features, or shields). • Product is enclosed and secured by packaging, equipment, or other physical access barriers. • Product is handled, staged, or moved in an inaccessible manner (e.g., bucket conveyors being moved via elevated track, an elevated ingredient surge tank with no means of access). 	1

¹ Descriptions are meant to be illustrative of the conditions that may be present at a process step that can indicate the nature of the vulnerability. Every condition need not be present to warrant the corresponding score.

How to Use Table 2 to Evaluate the Degree of Physical Access to the Product

The information included in Table 2 is explained below, along with recommendations on how to use this information to evaluate the degree of physical access to the product.

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Description: The level of access around or near each point, step, or procedure under evaluation.

Score: The degree of physical access score to be used for each point, step, or procedure under evaluation. After determining the most appropriate description of the level of access at each point, step, or procedure, as provided in the “Description” column, assign the appropriate score and record that score in Worksheet 1-F, Column (5) Element 2.

4. Ability of Attacker to Successfully Contaminate the Product (Element 3)

In this element, you consider how easy or difficult it is for an attacker, who has obtained access to the product (which is assessed in Element 2), to introduce a contaminant, and remain undetected, to achieve the attacker’s goal of causing wide scale public health harm. As discussed in Section 2.F.1.a, you should consider the possibility of an inside attacker when evaluating this element. Further, as discussed in Section 2.F.1.b, when evaluating this element, you should consider the presence of inherent characteristics that may increase or decrease the ability of an attacker to successfully contaminate the product. Some considerations for Element 3 are only applicable if you are doing a contaminant-based analysis (i.e., either a representative contaminant or contaminant-specific analysis) for Element 1. These considerations are addressed separately after Table 3.

The IA rule does not require you to use a specific method to evaluate Element 3. We provide Table 3 as an optional tool to assist you in evaluating the ability of an attacker to successfully contaminate the product at each point, step, or procedure under evaluation.

Table 3. The Ability of an Attacker to Successfully Contaminate the Product

Description ¹	Score
Highest Ease of Successful Contamination. <ul style="list-style-type: none">• The process step is in an isolated area, or obscured from view, enabling an inside attacker to work unobserved with little or no time limitations.• It is easy to successfully add sufficient volume of contaminant to the food.• Inherent characteristics of the point, step, or procedure (e.g., uniform mixing) would evenly distribute the contaminant into the food.• It is highly unlikely the inside attacker would be detected adding a contaminant to the food; an attacker would need to act with little to no stealth to introduce the contaminant.• There are no, or few, workers in the area, and it is highly unlikely that they would notice a contamination attempt by an inside attacker.• There is a low likelihood of the contaminant being removed (e.g., by washing, screening, vibration), diluted, or neutralized at this or later points, steps, or procedures in the process.	10

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<p>Moderately High Ease of Successful Contamination.</p> <ul style="list-style-type: none"> • The process step is seldom observed, enabling an inside attacker to work unobserved with minor time limitations. • It would be relatively easy for an inside attacker to successfully add a contaminant in sufficient volume. • It is unlikely the inside attacker would be detected adding a contaminant to the food; an inside attacker would need to act with minimal stealth to introduce the contaminant. • There are few workers in the area, and it is unlikely that they would notice a contamination attempt by an inside attacker. • Mixing, or agitation, is present but the contaminant may not be evenly distributed throughout the food because of inherent characteristics of the point, step, or procedure. • There is a moderately low likelihood of the contaminant being removed (e.g., by washing, screening, vibration), diluted, or neutralized at this or later points, steps, or procedures in the process. 	8
<p>Moderate Ease of Successful Contamination.</p> <ul style="list-style-type: none"> • The process step is observed about half of the time, or semi-obscured from view; an inside attacker would be under time limitations. • It would be somewhat difficult for an inside attacker to successfully add a contaminant in sufficient volume without being detected. • An inside attacker only would be able to add a reasonably small volume of contaminant (e.g., what can be carried in a pocket) without being detected. • It is moderately likely the inside attacker would be detected adding a contaminant to the food; an inside attacker would need to act with some degree of stealth, irregular, or suspicious activity to introduce the contaminant. • There is no intended mixing or agitation of the product, but processing conditions may distribute the contaminant into the surrounding food because of inherent characteristics of the point, step, or procedure. • There is a moderate likelihood of the contaminant being removed (e.g., by washing, screening, vibration), diluted, or neutralized at this or later points in the process. 	5

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<p>Moderately Low Ease of Successful Contamination.</p> <ul style="list-style-type: none"> • The process step is observed more than half of the time; an inside attacker would be under relatively strict time limitations. • It would be difficult for an inside attacker to successfully add a contaminant in sufficient volume without being detected. • It is highly likely the inside attacker would be detected adding a contaminant to the food; an inside attacker would have to conduct suspicious or irregular activities to contaminate the product. • There are some, or many, workers in the area, and it is highly likely that they would notice a contamination attempt by an inside attacker. • Mixing or agitation is not present, and the contaminant would not be effectively distributed into surrounding food because of inherent characteristics of the point, step, or procedure. • There is a high chance that the contaminant would be removed (e.g., by washing, screening, vibration), diluted, or neutralized at this or later points in the process. 	3
<p>Lowest Ease of Successful Contamination.</p> <ul style="list-style-type: none"> • The process step is under constant observation, or the view of the step is unobscured, preventing an inside attacker from adding a contaminant without being detected. • It is extremely likely the inside attacker would be detected adding a contaminant to the food due to the need to conduct highly irregular or suspicious activities to contaminate the food; successful introduction of a contaminant at the point, step, or procedure is extremely difficult or impossible. • There are numerous workers in the immediate area that would notice a contamination attempt by an inside attacker. • An inside attacker would need to add a large volume of contaminant without being detected. • The contaminant likely would be removed (e.g., by washing, screening, vibration), diluted, or neutralized at this or later points in the process. • Other inherent characteristics of the point, step, or procedure (e.g., multiple workers are required to be present for the step to function; positive airflow would prevent introduction of a contaminant; product is moving at a high rate of speed; introduction of a contaminant would result in human injury such as burns, cuts, or lacerations) significantly reduce the ability of an inside attacker to contaminate the product. 	1

¹ Descriptions are meant to be illustrative of the conditions that may be present at a process step that can indicate the nature of the vulnerability. Every condition need not be present to warrant the corresponding score.

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How to Use Table 3 to Evaluate the Ability of an Attacker to Successfully Contaminate the Product

The information included in Table 3 is explained below, along with recommendations on how to use this information to evaluate the ability of an attacker to contaminate the product.

Description: Characteristics of the relevant point, step, or procedure that can assist you in differentiating the level of ability of an attacker to contaminate the product at each point, step, or procedure under evaluation. Some characteristics (e.g., amount of contaminant needed, concentration, dilution, removal) are only applicable if you are using a contaminant-based approach to estimate potential public health impact for Element 1.

Score: The score associated with the ability of an attacker to contaminate the product at each point, step, or procedure under evaluation. After determining the most appropriate description of the degree of difficulty for an attacker to contaminate the product at each point, step, or procedure, as provided in the “Description” column, assign the appropriate score and record that score in Worksheet 1-F, Column (6) Element 3.

Considerations Applicable to Element 3 if You Perform a Contaminant-Based Analysis

Amount of Contaminant Needed

If you have determined the amount of contaminant needed as part of a contaminant-based approach to evaluating Element 1 (Column J in Worksheet 1-E), you can use this information as part of your consideration of the difficulty of an attacker introducing that volume of the contaminant to the point, step, or procedure under evaluation. For example, a few ounces of contaminant, which could easily fit in a pocket, would be less difficult to introduce than 5 gallons of contaminant, which would be difficult to conceal. There are no definitive criteria regarding the volume of contaminant that would be considered large enough to impact the ability of an attacker to successfully contaminate the product. Each food processing facility is unique but knowing your facility’s practices should help you determine whether the amount of contaminant could realistically be concealed, moved, and introduced into the product without being detected.

Even if an attacker could bring enough contaminant into the area without detection, some process steps may make it very difficult to introduce sufficient volume of the contaminant to cause wide scale public health harm. For example, a narrow aperture sample port on an otherwise enclosed tank might make it difficult to introduce a large amount of contaminant into the tank in the time available for an attacker. Similarly, a rapidly moving conveyor where an attacker would need to stand at the point of introduction for an extended period while constantly adding the contaminant over food as it passes might make it difficult to contaminate many servings.

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Concentration or Dilution of a Contaminant

The volume of a contaminant that needs to be added at the current step under evaluation to cause wide scale public health harm may be affected by processing activities that concentrate or dilute the contaminant at downstream points, steps, or procedures. For example, food paste at a holding step may be followed by a process step where the volume of liquid is reduced. The subsequent process step that removes liquid may increase the concentration of a contaminant and thereby decrease the amount of contaminant needed to cause wide scale public health harm. By decreasing the amount of contaminant needed, the downstream process step may increase the score you assign to Element 3 at earlier steps. Conversely, a downstream process step that increases the amount of contaminant needed (e.g., adds a significant amount of liquid), may decrease the score you assign to Element 3 at earlier steps.

Removal of a Contaminant

Steps that are intended to remove contaminants, such as screening or washing processes, may reduce the ability of an attacker to successfully contaminate a product. Washing, screening, distillation, and other methods intended to remove natural contaminants may also remove intentionally introduced contaminants. Further, if a contaminant added to the product would be discarded as waste (e.g., a contaminant applied to the exterior of a product that will be peeled), this would significantly reduce the ability of an attacker to successfully contaminate the product and lead to a lower score for Element 3. The evaluation as to whether a process step would remove a contaminant should consider the removal of all contaminants. Processes that are designed only to remove common food safety hazards or detritus may not remove the types of contaminants that an attacker may select.

Neutralization of Contaminant

Although facilities could exclude some specific contaminants from consideration for specific process steps based on neutralization, in almost every instance other contaminants will not be neutralized during those processing steps. For example, there are many chemical contaminants that would not be neutralized by a thermal processing step designed to kill spore forming bacteria. Furthermore, even if a particular contaminant can be neutralized at one process step, an attacker could potentially contaminate the food after the neutralization step. Therefore, you should evaluate subsequent process steps to determine the ability of an attacker to successfully introduce a contaminant at those points. We expect the consideration of contaminant neutralization to be uncommon, given the numerous contaminants that could potentially be used and the level of knowledge needed to determine whether each contaminant can be neutralized for each of a facility's process steps.

**G. Identifying Significant Vulnerabilities and Actionable Process Steps
Using the Three Fundamental Elements [New March 2019]**

If a step has a significant vulnerability, all three elements will have some elevated presence—i.e., there will be some level of public health impact, there will be some level of access to the

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product, and the attacker will have some ability to contaminate the product. A high score for one element does not automatically result in identification of a significant vulnerability at an actionable process step. For example, a process step could have an estimated potential public health impact of over 100,000 illnesses or deaths, but either be inaccessible or have the highest difficulty of successful contamination. Such a step would not be an actionable process step, regardless of the potential number of illnesses or deaths caused if a contaminant were added at this point, because the vulnerability of the step could not be exploited (e.g., the process step is completely inaccessible). In contrast, a different process step with a much lower potential public health impact could be an actionable process step based on the other two elements. For example, a process step with a potential public health impact between 100 - 1000 servings at risk that is accessible to an inside attacker and has a moderate ease of attack may be an actionable process step. Because each of the three elements are important to evaluating vulnerability, identification of significant vulnerabilities and actionable process steps is not based on a single element, no matter how high the score.

1. Using the Scores from the Three Fundamental Elements to Identify Significant Vulnerabilities and Actionable Process Steps

Generally, you will assign scores for each of the process steps and add them to calculate a total score for each step. However, if one of the elements is assigned a score of 1, then the step does not have a significant vulnerability and is not an actionable process step—regardless of the scores of the other two elements. Therefore, you do not need to calculate a total score for that process step. For example, if there is some level of public health impact (i.e., the Element 1 score >1), and the step is accessible (i.e., the Element 2 score > 1), but the attacker has no ability to contaminate the product (i.e., the Element 3 score =1), then the step would not be an actionable process step because the inability of the attacker to contaminate the product prevents it from being significantly vulnerable (See Appendix 4, Figure 2b-2, process step 1 for more details regarding a similar scenario).

Once you have calculated scores for the points, steps, and procedures where each of the three elements scored greater than 1, rank order the process steps by the sum value from highest to lowest. There is typically a group of process steps that have higher total scores, with other process steps differentiated from this grouping by a noticeable separation in sum score (See Appendix 4, Figure 2b-3 for an example of score grouping and separation). You should consider steps in this highest grouping of sum scores as significantly vulnerable and identify these process steps as actionable process steps. In our experience, including in the identification of the KATs⁷, this grouping of the highest scoring process steps includes approximately the top 20-25% of the scores for the rank ordered process steps, but this distribution is not universal – especially in facilities with a small number of points, steps, or procedures.

⁷ In the analysis that identified the Key Activity Types, we observed that, at approximately the top 25% of process step sum scores in a given VA, a noticeable separation in scoring occurred among all points, steps, or procedures.

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Vulnerability assessments using the three fundamental elements are specific to a facility and its policies and processes. The combination of individual element scores that together sum to create a single score may reflect a wide variety of circumstances. As a result, it is not appropriate to specify a universally-applied sum score at which all greater sum scores are always actionable process steps and all lesser sum scores are never actionable process steps. Therefore, we have not specified such a value as a single threshold for the identification of actionable process steps. However, it is possible to provide upper and lower thresholds for vulnerability. We expect significant vulnerabilities will exist when each of the elements are highly scored, i.e., when a process step sum score is greater than or equal to 26 (≥ 26). Similarly, we expect that significant vulnerabilities will not exist when each of the elements score low, i.e., when a process step sum score is less than or equal to 13 (≤ 13).

When a process step sum score is within 14-25, whether significant vulnerabilities are present depends on the nature of the vulnerability at the process step under evaluation and the contribution of each of the three elements in each case. Within this range of sum scores (14-25), the nature and degree of each of the three elements is such that a process step at one facility with a sum score within this range might have a significant vulnerability while a step at another facility with the same score does not have a significant vulnerability. Significant vulnerabilities are more likely to exist at the upper range of sum scores in this range, but there is no specific number within this grouping that indicates that a significant vulnerability is present in all cases.

For example, a process step at one facility has a sum score of 18 (Element 1 = 8, Element 2 = 5, Element 3 = 5). Given the potential for a large public health impact, this facility may identify this step as an actionable process step because of the moderately high presence of Elements 2 and 3. Another process step in this facility also has a sum score of 18 (Element 1 = 5, Element 2 = 10, Element 3 = 3). In this case, the facility may consider that while Element 1 is scored a 5, the actual calculated public health impact is at the bottom of the scale for the 5 score. Further, the facility may consider that while this process step is easily accessible, there is only a moderately low ease of a successful contamination at this step because the inherent characteristics of the process step would make the introduction of a sufficient volume of contaminant difficult. The facility may also consider that there is no mixing at the step and that there is a high likelihood that an attack would be detected because of the high number of workers in the area observing the process step. Considering the nature of each element, and their combined contributions to the overall vulnerability of the step, the facility might conclude that this process step is not significantly vulnerable and thus, not an actionable process step.

In a different facility, a process step has a sum score of 21 (Element 1 = 3, Element 2 = 10, Element 3 = 8). At this step, a limited number of open cans of a liquid food that are gathered and lined up prior to capping pose a highly accessible target (Element 2 = 10) and the ease of successful contamination is moderately high (Element 3 = 8). However, the facility calculates that only a small public health impact would result because of the small amount of food available for attack (Element 1 = 3). Despite a sum score of 21, the facility determines this step is not an actionable process step because, even if successfully adulterated, wide scale public health harm would not be the result. The facility may identify another process step with a similar sum score elsewhere in the facility. The facility may determine that this other process step is an actionable

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process step because the food is partially accessible (Element 2 = 5), successfully contaminating the food would be relatively easy (Element 3 = 8), and there would be a large public health impact at this step (Element 1 = 8).

You can use Worksheet 1-F to organize the three fundamental elements of the vulnerability assessment. Regardless of whether you use Worksheet 1-F, we recommend that you include similar information in your VA documentation.

How to Fill in Worksheet 1-F: Identifying Significant Vulnerabilities and Actionable Process Steps using the Three Fundamental Elements

The information included in Worksheet 1-F is explained below, along with recommendations on how to use this information to determine actionable process steps using the three fundamental elements.

- (1) **Number (#):** Provide a number for each process step evaluated, e.g., process steps from a process flow diagram.
- (2) **Process Step:** Provide the name of each of the process steps.
- (3) **Process Step Description:** Explain what happens at the process step under evaluation.
- (4) **Element 1: Score and Rationale:** Provide the score that corresponds to the potential public health impact if a contaminant were added at the relevant process step. Also include an explanation or notes on why you chose this score for the process step. See Section F.2 of this chapter for possible methods to estimate the public health impact and how to score this element using Table 1.
- (5) **Element 2: Score and Rationale:** Provide the score that corresponds to the degree of physical access to the product at the relevant process step. Also include an explanation or notes on why you chose this score for the process step. See Section F.3 of this chapter for a possible method to estimate the degree of physical access to the product and how to score this element using Table 2.
- (6) **Element 3: Score and Rationale:** Provide the score that corresponds to the ability of an attacker to successfully contaminate the product at the relevant process step. Also include an explanation or notes on why you chose this score for the process step. See Section F.4 of this chapter for a possible method to estimate the ability of an attacker to successfully contaminate the product and how to score this element using Table 3.
- (7) **Sum:** Calculate the sum of the scores entered in Columns 4 - 6.
- (8) **Explanation:** Explain why you determined that the point, step, or procedure is or is not an actionable process step, based on the evaluation of the three fundamental elements and the rationale as to the element scores.

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- (9) Actionable Process Step:** Indicate “Yes” or “No” regarding whether the process step is an actionable process step. If you organize your vulnerability assessment by using Worksheet 1-C, you would have the same response for this column and Column 6 of that worksheet because both columns indicate whether a step is an actionable process step.

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Worksheet 1-F: Identifying Actionable Process Steps Using the Three Fundamental Elements

PRODUCT(S): _____

FACILITY NAME: _____

ADDRESS: _____

DATE SIGNED: _____

(1) #	(2) Process Step	(3) Process Step Description	(4) Element 1: Score and Rationale	(5) Element 2: Score and Rationale	(6) Element 3: Score and Rationale	(7) Sum	(8) Explanation	(9) Actionable Process Step

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2. Written Explanation for Identification of Actionable Process Steps

Your vulnerability assessment must include a written explanation as to why each point, step, or procedure either was or was not identified as an actionable process step. (21 CFR 121.130(c)). Because the three fundamental elements must be considered in the vulnerability assessment, we expect most explanations to include information about these elements. Depending on the amount of information a facility incorporates into its analysis for each point, step, or procedure, the complexity of the explanation can vary from simple to more detailed. A more complex vulnerability assessment would, in many, but not all, instances, be accompanied by a more detailed explanation. On the other hand, a vulnerability assessment based on the KAT method (see Section 2.E) would not need explanation beyond addressing whether the step fits within one of the four KAT descriptions.

You have flexibility in how you write the VA explanations. As seen in Appendix 4, Figure 2b-2, process step 1, Columns 4 - 6 include rationale about the bulk dry ingredient receiving step's vulnerability based on each of the three elements. These rationales include specifics about the large public health impact if a contaminant were added at this receiving step, how the bulk dry ingredient receiving is accessible, and the very low likelihood that an inside attacker could contaminate the product at this step due to the infeasibility of introducing a very large amount of contaminant at this step. The final explanation in Column 8 states, "No significant vulnerability is present because Element 3 = 1." In this example, the information supporting the explanation is found in the columns for each of the elements (Columns 4 - 6). In process step 2 of Appendix 4, Figure 2b-2, there is scoring rationale in each of Columns 4 - 6, but the explanation column, Column 8, includes more detail stating, "This step is significantly vulnerable. If successfully contaminated, it is anticipated that the result would be a very large public health impact. An intentional contamination by an insider at this step would not be prevented by any inherent characteristics of this step. Observation of this process is low since the design of the receiving bay presents visual obstructions." This summary explanation emphasizes the high scores for each of the elements.

Your required explanation as to whether a process step is significantly vulnerable requires the most detail for process steps that score within the range of 14 – 25 because such process steps may or may not be actionable process steps, depending on the particular circumstances. For scores that are less than or equal to 13 or greater than or equal to 26, the required explanation may be less detailed, such as "No significant vulnerability is present because score is less than 14" or "This step is significantly vulnerable because score is greater than 25."

Written explanations can include abbreviations or footnotes when appropriate. If you rely on the same reason for determining that multiple processing steps are not actionable process steps, then you could state the written explanation once, and subsequently use a number, letter, or symbol in its place from then on. For example, process steps 23-27 of Appendix 4, Figure 2b-2 describe a food being packaged into consumer-ready packages. The steps following packaging may not be actionable process steps because the individual packages are enclosed and not easily accessible to an inside attacker. An attacker would have to contaminate the tamper-evident package one package at a time, making it very difficult to contaminate enough food to cause wide scale public

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health harm. After writing the explanation for why the food at this step has very low physical accessibility, you could use a footnote for the additional steps where this explanation is also applicable.

Note that the explanation accompanying the decision as to whether a point, step, or procedure is an actionable process step can inform the selection of mitigation strategies. For example, if the explanation for identifying the primary ingredient storage tank as an actionable process step is that an unsecured access hatch with unrestricted access created a significant vulnerability, this suggests that an appropriate mitigation strategy is likely to address the accessibility of the hatch.

There may be instances when a facility determines that it does not have any actionable process steps. The facility is still required to document its finding that none of the points, steps, or procedures in their facility are actionable process steps and include a written explanation of the conclusion. (21 CFR 121.130(c)). The documentation must be a part of the written FDP (21 CFR 121.126(b)(1)), and the facility must conduct a reanalysis when required by 21 CFR 121.157.

H. Identifying Actionable Process Steps Using the Hybrid Approach: Combining the Key Activity Types and the Three Fundamental Elements [New March 2019]

In addition to conducting a VA using the KATs (See Section 2.E) or the three fundamental elements (See Sections 2.F and 2.G), a facility may use a hybrid approach. The hybrid approach allows you to use the strengths of both the KAT and three elements methods. In the hybrid approach, a facility first assesses each point, step, or procedure to identify steps that fit within any of the four key activity types. Then, rather than concluding the VA with those steps identified as the actionable process steps, the facility uses the three elements to conduct a more in-depth evaluation of some of the steps. A facility may choose to conduct a more in-depth evaluation of those process steps that, while fitting within the KATs, may have factors present at the step (e.g., inherent characteristics) that would further inform the analysis as to whether a significant vulnerability exists. The hybrid approach combines the speed of KATs with the in-depth analysis of the three fundamental elements. Using the hybrid approach, a facility can conduct its vulnerability assessment faster than if evaluating the three fundamental elements at all of its steps and may possibly identify fewer actionable process steps than if using the KAT method alone.

Appendix 4 of this guidance includes an example that illustrates use of the hybrid approach by a manufacturer of fictional almond cranberry energy bars at a fictional facility. In this example, the facility begins its vulnerability assessment by using KATs to quickly identify its steps at highest risk. The facility identifies five of its fifteen steps as fitting within KATs (See Figure 2c-2, steps 3-7). The facility determines that steps 4 and 5 fit within the KATs of “Mixing and Similar Activities” and “Liquid Storage and Handling” but identifies factors present at these steps that warrant further analysis using the three elements.

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The facility determines that an inherent characteristic of step 4, “Mix and Warm Syrup,” is that it is completely enclosed. The facility determines that this factor will further inform the analysis of this step, so the facility uses the three elements. The facility assigns Element 2 a score of 1. The facility then determines that because this mixer is not accessible, there is no significant vulnerability, and it is not an actionable process step.

The facility determines that step 5, “Cool Syrup,” has factors that will further inform whether there is a significant vulnerability and considers the three elements. Element 1 is scored as 5 because the potential number of deaths, if a contaminant were added at this point, is estimated to be 900. Element 2 is scored as 3 (“Hardly Accessible”) because there is limited physical access to the cooling tank. Element 3 is scored as 3 based on a moderately low ease of attack because it would be difficult for an attacker to bring enough of a representative contaminant into the area and have sufficient time to get the contaminant into the tank. Based on a total score of 11, the facility concludes that the cooling step does not have a significant vulnerability and is not an actionable process step.

In addition, the facility identifies steps 3, 6, and 7 as actionable process steps using the KAT method because they fit within the KATs of “Liquid Storage and Handling” and “Secondary Ingredient Handling,” and “Mixing and Similar Activities,” respectively. The facility does not further evaluate these steps using the three elements because it determines no additional factors are present that would inform the analysis of the existence of a significant vulnerability.

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. See Chapter 2, Section F.1.b. for more information on inherent characteristics.

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

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strategy sufficiently minimizes or prevents the significant vulnerability associated with the 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

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volume of food being processed and thus would not identify strategies designed to address 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

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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 VA⁸. 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

⁸ 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. See Chapter 2, Section F.1.b. for more information on inherent characteristics.

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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. See Chapter 8 for more information on training for workers and supervisors working at actionable process steps.

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 where ingredients are staged, in an accessible manner, overnight. This procedure may be

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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.

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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:

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- 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

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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

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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

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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.

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- 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

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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

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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 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

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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.

3. Scenario 3

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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. 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.

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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.

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**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

(1) #	(2) Actionable Process Step	(3) Mitigation Strategy	(4) Explanation
	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.

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**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.

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(1) #	(2) Actionable Process Step	(3) Mitigation Strategy	(4) Explanation
	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.

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**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.

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**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	<p>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.</p>	<p>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.</p>

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

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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.

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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)

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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.

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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

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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 Appendix 1 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

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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.

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**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

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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

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(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
	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

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	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
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**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

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**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

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(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
		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.			

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

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

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Chapter 7: Reanalysis (coming soon)

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**Chapter 8:
Education, Training, or Experience [New March 2019]**

The guidance provided in this chapter is intended to help you understand the education, training, and experience required for individuals who perform certain activities under the IA rule. Requirements for education, training, and experience are applicable to the following personnel:

- Individuals who perform activities required under subpart C (Food Defense Measures);
- Individuals assigned to actionable process steps;
- Individuals performing or overseeing four specific activities (food defense qualified individuals); and
- Supervisors.

Although the requirements vary depending on the nature and significance of the food defense activity, many activities require that the person performing the activity be a “qualified individual.” A “qualified individual” is a person who has the education, training, or experience (or a combination of these) necessary to perform an activity required under subpart C, as it relates to their assigned duties. (21 CFR 121.3). Education and training can include in-house instruction and instruction by outside entities, such as educational institutions, associations, and consultants. Experience can include both job-related and non-job-related experience relevant to the individual’s assigned duties. For example, you may determine that the experience an individual gained writing corrective action records for another program, such as HACCP, coupled with training on the IA rule’s requirements for food defense corrective action records, is sufficient to enable the individual to adequately document food defense corrective actions records. Alternatively, you may determine that the individual needs some additional training to supplement that experience because that individual is unaware of the IA rule requirements for food defense corrective action records.

A qualified individual may be, but is not required to be, an employee of your facility. (21 CFR 121.3). To identify individuals with the necessary background to perform a particular activity, you should assess the activity to which you intend to assign the individual in relation to an individual’s current level of education, training, and experience. You should ensure that each individual has the necessary education, training, and experience, or combination of these, to properly perform the relevant activity. Some individuals may require additional education, training, or experience to be qualified to perform an activity. For example, an individual who has been operating a mixer in your facility prior to the implementation of a food defense plan would not need additional training or education on proper operation of the mixer but may require additional training regarding the new mitigation strategy that requires the lid of the mixer to be locked while the mixer is in operation because this mitigation strategy is a new requirement based on the food defense plan

A. Individuals Who Perform Activities Required by Subpart C

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An individual who performs any of the activities required under subpart C of the rule must satisfy the requirements to be considered a “qualified individual.” As discussed above, a “qualified individual” is a person who has the education, training, or experience (or a combination of these) necessary to perform an activity required under subpart C, as it relates to their assigned duties. For example, food defense monitoring is required by subpart C. (21 CFR 121.140). Therefore, an individual doing food defense monitoring must be a qualified individual. We expect that many individuals doing food defense monitoring will be qualified through in-house training, on-the-job training, or have experience in food safety monitoring that can be coupled with in-house or on-the-job training for food defense monitoring.

B. Individuals Assigned to an Actionable Process Step

Similar to an individual who performs activities required by subpart C, an individual assigned to an actionable process step must be a “qualified individual.” (21 CFR 121.4(b)(1)). In addition, an individual assigned to an actionable process step must receive training in food defense awareness. (21 CFR 121.4(b)(2)). Food defense awareness training should describe food defense and explain why it is important. Food defense awareness training should also provide information about what to do if an employee notices any suspicious individuals or activities. Food defense awareness training can take place at any location and in any format. Facilities can do their own training or rely on training offered through other sources. One option is to use the online course “FSPCA Food Defense Awareness for the IA Rule” that was collaboratively developed by FDA and the Food Safety Preventive Controls Alliance (FSPCA). This training was designed specifically to satisfy the requirement in 21 CFR 121.4(b) and can be accessed at the FSPCA website.

The diligence of employees to recognize and report suspicious activities is an important factor in ensuring the protection of food from intentional adulteration. Although not all employees are required to have food defense awareness training, you should consider increasing general awareness of food defense throughout your facility. For example, you might incorporate food defense awareness training into routine facility communications, such as brochures, staff meetings, or payroll stuffers. You should encourage all employees to report unusual or suspicious individuals or activities to management.

C. Individuals Doing or Overseeing Four Specified Activities (Food Defense Qualified Individuals)

As discussed in Chapter 1, Section B.1, the preparation of the FDP, conduct of a vulnerability assessment, identification and explanation of the mitigation strategies, and reanalysis of the FDP must be performed or overseen by a “food defense qualified individual.” A “food defense qualified individual” must be a qualified individual as defined in 21 CFR 121.3 and have successfully completed training that is considered to be at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to perform those activities. (21 CFR 121.4(c)).

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The FSPCA, in collaboration with FDA, is developing and delivering standardized curriculum training on: the preparation of the FDP; the conduct of a vulnerability assessment, including use of the Key Activity Types method; the identification and explanation of the mitigation strategies; and reanalysis. Information about the curriculum is located on the FSPCA website. Note that your training options for the specific activities described in 21 CFR 121.4(c)(3), are not limited to the curriculum from FSPCA. Any training that is at least equivalent to the standardized curriculum is acceptable. (21 CFR 121.4(c)(2)).

We recognize that many individuals have experience in food defense. It is possible to satisfy the training requirement to perform or oversee the four specified activities based on job experience that has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. (21 CFR 121.4(c)(2)). For example, if an individual has been working on food defense initiatives, including performing vulnerability assessments, in a facility for many years, that experience may render them qualified to conduct a vulnerability assessment if the previously conducted vulnerability assessments included all components required in the IA rule. Similarly, job experience identifying mitigation strategies and writing or conducting a reanalysis of an FDP could qualify an individual to perform those activities without training equivalent to the standardized curriculum.

You have flexibility to determine how many and which people will be food defense qualified individuals at your facility. For example, a facility may have two people with the training required to perform each of the four activities specified at 21 CFR 121.4(c)(3)). These two individuals could together perform each activity or divide responsibility for them. Another facility may have one person trained to prepare the FDP and perform the reanalysis, and a different individual trained to perform the vulnerability assessment and the identification and explanation of mitigation strategies. A third facility may train four people, one person for each of the four activities. A fourth facility may choose to have one person trained to perform all four activities. A fifth may choose to hire consultants to perform some, or all, of these activities because the rule does not require that employees of the facility perform the activities.

We are not establishing minimum standards for competency and do not intend routinely to directly assess the qualifications of persons who function as the food defense qualified individual, whether by their training or by their job experience. Instead, we intend to focus our inspections on the adequacy of the food defense plan. As necessary and appropriate, we will consider whether deficiencies we identify in the food defense plan suggest that the food defense qualified individual may not have adequate training or experience to carry out the assigned functions.

D. Supervisors

A supervisor assigned to an actionable process step must meet the requirements to be a qualified individual and must have food defense awareness training, similar to a non-supervisor assigned to such a step. (21 CFR 121.4(b)). In addition, responsibility for ensuring compliance by individuals with the requirements of part 121 must be clearly assigned to supervisory personnel

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with a combination of education, training, and experience necessary to supervise the activities. (21 CFR 121.4(d)). You may find that you will need multiple individuals to be responsible for ensuring compliance with the IA rule but, in some cases, one individual may be able to perform all the necessary duties to ensure compliance. You should assess the education, training, and experience of your supervisory personnel to determine the provisions of the IA rule for which they are qualified to ensure compliance. For example, a supervisor with education and experience in developing food defense plans may be the best person to supervise this activity. In another example, you may identify a supervisor who has been overseeing monitoring for food safety purposes, and this experience would be useful for supervising food defense monitoring activities for the food defense plan.

Supervisory personnel who are assigned to ensure compliance by individuals with the requirements of this subpart should be able to effectively assess whether individuals are conducting activities in a manner that complies with the IA rule. You should ensure that your supervisory personnel are aware of their role in recognizing and ensuring compliance with the requirements of the IA rule. You should also charge your supervisory personnel with recognizing when individual deviations are recurring, or are widespread among personnel, as either of these occurrences indicate a need to reassess the qualifications of the responsible individuals.

E. Training Frequency

Any individual performing activities that require education, training, or experience should have completed that education, training, or experience prior to undertaking the relevant activities. The IA rule does not include specific retraining frequency requirements; however, in most cases, individuals conducting activities with associated requirements for education, training, and experience should repeat training periodically and as necessary to ensure that they are qualified to perform their duties. For example, employees and supervisors may need retraining if their responsibilities under subpart C change because of changes to the food defense plan from a production change resulting in a modified or new mitigation strategy. Another circumstance that may require retraining is if an individual performing an activity under subpart C is not performing the activity correctly. Also, a corrective action may result in a need for retraining or additional training. For example, if food defense monitoring indicates that certain mitigation strategies are not operating as intended, a component of the corrective action may be to retrain the individuals assigned to implement the mitigation strategy. Forthcoming guidance will include more information about corrective actions.

F. Training Records

Required training must be documented in records and must include the date of training, the type of training, and the persons trained. (21 CFR 121.4(e)). There are many acceptable ways of documenting training, such as using a sign-in sheet provided for a group training or retaining a “certificate of completion” provided to each attendee at the end of a training. Training records

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must be established and maintained in accordance with the records requirements. (21 CFR 121.4(e)).

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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.

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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: _____

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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).

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

PRODUCT NAME(S): _____
COMPANY NAME: _____
FACILITY NAME: _____
ADDRESS: _____

Product Name(s)	
Product Description	
Ingredients	
Intended Use	
Intended Consumers	
Storage and Distribution	

D. Food Defense Plan Vulnerability Assessment [Updated March 2019]⁹

In Chapter 2 of this guidance, we provide guidance on how to conduct a vulnerability assessment [to identify significant vulnerabilities and actionable process steps by using Key Activity Types, by evaluating the three fundamental elements, or a hybrid of both (See Chapter 2, Sections 2.E, 2.F- G, and 2.H, respectively).] 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.E 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.E of this guidance, then you will write “Key Activity Types” in this column. [If you used the three fundamental elements or the hybrid approach, as described in Chapter 2.F-G and H, respectively, of this guidance, then you will write “Three Fundamental Elements” or “Hybrid Approach” 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

⁹ Revisions were made to the text in the introduction and D.1 sections, and denoted by [...].

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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. 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.

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2. Worksheet 1-C: Vulnerability Assessment Analysis Summary

PRODUCT(S): _____

FACILITY NAME: _____

ADDRESS: _____

SIGNED DATE: _____

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

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[New March 2019]

In Chapter 2.F.2.a.i, we provide guidance on how to calculate volume of food at risk to inform your public health impact estimate if you conduct a VA using the three fundamental elements to identify significant vulnerabilities and actionable process steps. The VA must be written (21 CFR 121.126(b)(1)), and Worksheet 1-D can assist you in conducting and documenting your VA. You can use Worksheet 1-D to organize your calculation of volume of food at risk. Regardless of whether you use Worksheet 1-D, we recommend that you include such information in your VA documentation if you use the volume of food at risk method to estimate potential public health impact.

3. How to Fill in Worksheet 1-D: Calculating Volume of Food at Risk

The information included in Worksheet 1-D is explained below, along with recommendations on how to use this information to estimate the volume of food at risk if a contaminant were added to food at a particular point, step, or procedure.

- A. Process Step:** Provide the name of each of the process steps from the process flow diagram or other source.
- B. Batch Size:** Provide an estimate of the amount of product held or processed at the process step. The batch size is usually the volume of the process step's operation (e.g., the volume of food in a mixer or tank, or the amount of product in a constant flow process). For constant flow process steps, batch size is the amount of product you determine an attacker could contaminate, given the time the attacker would have to add a contaminant to a constant flow process and the flow rates of product at that step.
- C. Amount of Product (Ingredient) in Final Serving:** Provide the amount of the product being processed at the step under evaluation in the final consumable serving. For process steps that involve single ingredient products or that occur after all ingredients are added to the product line, this is likely the same as the serving size. For process steps that involve an ingredient, the amount of the ingredient in the final serving would not be the same as the serving itself. For example, the amount of concentrated fruit juice in a final serving of 8 ounces of fruit juice might be 0.8 ounces.

The column is used to calculate the number of finished servings an ingredient may affect if that ingredient were intentionally adulterated. You should consult your finished product formulations to determine the amount of product (ingredient) in final servings.

- D. Servings per Batch:** Divide the value in Column B by the value in Column C. This number is the estimate of the volume of food at risk.

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E. Score from Table 1: Provide the number from the “Score” column in Table 1 (See Chapter 2, Section F.2 of this guidance) associated with the servings per batch from Column D in this worksheet. For example, if Column D in this worksheet shows 3,000 servings per batch, then you would determine that it corresponds to a score of 8 in Table 1. The score from Column E of this worksheet goes into Column 4 (Element 1) in Worksheet 1-F.

F. Notes: Provide any information that would assist review of this VA, such as how batch size was calculated.

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4. Worksheet 1-D: Calculating Volume of Food at Risk

A Process Step	B Batch Size	C Amount of Product (Ingredient) in Final Serving	D Servings per Batch B ÷ C	E Score from Table 1	F Notes

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In Chapter 2.F.2.a.ii, we provide guidance on how to calculate potential public health impact using a representative contaminant, if you conduct a VA using the three fundamental elements to identify significant vulnerabilities and actionable process steps. The VA must be written (21 CFR 121.126(b)(1)), and Worksheet 1-E can assist you in conducting and documenting your VA. You can use Worksheet 1-E to organize your calculation of public health impact using a representative contaminant. Regardless of whether you use Worksheet 1-E, we recommend that you include such information in your VA documentation if you use the representative contaminant method to estimate potential public health impact.

5. How to Fill in Worksheet 1-E: Calculating Potential Public Health Impact using a Representative Contaminant

You can use Worksheet 1-E to organize your potential public health impact estimate using a representative contaminant. Regardless of whether you use Worksheet 1-E, we recommend that you include such information in your VA documentation if you use this method to estimate potential public health impact.

The information included in Worksheet 1-E is explained below, along with recommendations on how to use this information to calculate potential public health impact using a representative contaminant if a contaminant were added to food at a particular point, step, or procedure. For Columns A – D, please see descriptions provided in “How to Fill in Worksheet 1-D: Calculating Volume of Food at Risk.

E. Mortality Rate of Representative Contaminant: We use an LD50 value to calculate the dose needed per serving (See Column I); therefore, the mortality rate value is 50%. The representative contaminant approach relies on this value to estimate potential public health impact.

F. Number of Potential Deaths: Multiply the value of Column D by the value of Column E (D x E).

G. Score from Table 1: Provide the number from the “Score” column in Table 1 (See Chapter 2, Section F.2 of this guidance). Determine into which “Description” from Table 1 the number of potential deaths from Column F in this worksheet fits and then find the corresponding “Score” in Table 1. For example, if Column F in this worksheet shows 3,000 potential deaths, then you would determine it fits into the Table 1 “Description” of “Potential public health impact between 1,001 – 10,000 (acute illness or deaths), or 1,001 – 10,000 servings at risk” which corresponds to a score of 8. The score from column G of this worksheet goes into Column 4 (Element 1) in Worksheet 1-F.

H. Notes: Provide any information that would assist during review of this VA.

I. Representative Contaminant Dose Needed per Serving: We use the value of 40 milligrams per serving. We derived this dose value, in consultation with our interagency governmental partners, from the LD50 data of a compilation of potential contaminants

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that are applicable to food. LD50 is typically expressed in dose per kg body weight. We converted this into a dose per serving value based on a typical adult body weight of 85 kg.

J. Amount of Representative Contaminant Needed per Batch: Multiply the value in Column D by the value in Column I (D x I). This will provide the total amount of contaminant the attacker needs to intentionally adulterate the food at this process step to achieve wide scale public health harm. This estimate informs the amount of the contaminant the attacker needs to carry out the attack, which is a component of Element 3.

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6. Worksheet 1-E: Calculating Potential Public Health Impact Using a Representative Contaminant

Element 1 Calculations using Representative Contaminant								Element 3 Calculations	
A	B	C	D	E	F	G	H	I	J
Process Step	Batch Size	Amount of Product (Ingredient) in Final Serving	Servings per Batch B ÷ C	Mortality Rate of Contaminant (<i>FDA provided value = 50%</i>)	Number of Potential Deaths D x E	Score from Table 1	Notes	Representative Contaminant Dose Needed per Serving (<i>FDA provided value = 40 milligrams</i>)	Amount of Representative Contaminant Needed per Batch D x I

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In Chapter 2.F.2.a.iii, we provide guidance on how to calculate potential public health impact using a contaminant-specific analysis, if you conduct a VA using the three fundamental elements to identify significant vulnerabilities and actionable process steps. The VA must be written (21 CFR 121.126(b)(1)), and Worksheet 1-E can assist you in conducting and documenting your VA. You can use Worksheet 1-E to organize your calculation of public health impact using a contaminant-specific analysis. Regardless of whether you use Worksheet 1-E, we recommend that you include such information in your VA documentation if you use the contaminant-specific analysis method to estimate potential public health impact.

How to Fill in Worksheet 1-E: Calculating Potential Public Health Impact using a Contaminant-Specific Analysis

Calculating potential public health impact using specific contaminants is essentially the same as using the representative public health approach. The calculation should be repeated for each contaminant considered. The contaminant with the largest estimated public health impact should be used to identify the appropriate score from Table 1 in Chapter 2 of this guidance, as this is the estimate that adequately captures the full extent of the potential public health impact. To use Worksheet 1-E in considering individual contaminants, you should use values you have determined are appropriate to the analysis. At a minimum you will need to update the following Columns from Worksheet 1-E:

E. Mortality Rate of Contaminant: Provide the mortality rate for the specific contaminant. If an LD50 value is used to calculate the dose per serving, 50% should be placed in this Mortality Rate column. The mortality rate should be from the same source (e.g., scientific literature) used for the contaminant dose needed per serving calculation.

H. Notes: Provide any information that would assist during review of this VA, such as the source of information for the contaminant under evaluation, including characteristics and toxicity information.

I. Contaminant Dose Needed Per Serving: Provide an estimated contaminant dose per serving derived from oral toxic dose information found in scientific literature. The value is typically reported as the dosage per kilogram of bodyweight, which is then converted to a dose per serving. For example, if a substance has a reported LD50 of 1 mg/kg and you assume a typical adult male weighs 85 kg, then the LD dose is $85 \text{ kg} * 1 \text{ mg/kg} = 85 \text{ mg/serving}$. Only oral routes of exposure should be considered.

Estimating Morbidity for the Contaminant-Specific Analysis

If you perform a contaminant-specific analysis, you could choose to include estimates of acute morbidity (i.e., acute illnesses) and mortality in your Element 1 evaluation. Columns E, I, and J in Worksheet 1-E could be used for morbidity by replacing the mortality-specific information with morbidity-specific information. Morbidity and mortality estimates should then be added

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together, and this sum entered into Column F. The score in Column G will be based on the summed estimate from Column F.

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In Chapter 2, Sections F and G of this guidance, we provide guidance on how to conduct a vulnerability assessment using the three fundamental elements to identify significant vulnerabilities and actionable process steps. The VA must be written (21 CFR 121.126(b)(1)), and Worksheet 1-F can assist you in organizing information related to the three fundamental elements. Regardless of whether you use Worksheet 1-F, we recommend that you include similar information in your VA documentation.

7. How to Fill in Worksheet 1-F: Identifying Significant Vulnerabilities and Actionable Process Steps using the Three Fundamental Elements

The information included in Worksheet 1-F is explained below, along with recommendations on how to use this information to determine actionable process steps using the three fundamental elements.

- (1) **Number (#):** Provide a number for each process step evaluated, e.g., process steps from a process flow diagram.
- (2) **Process Step:** Provide the name of each of the process steps.
- (3) **Process Step Description:** Explain what happens at the process step under evaluation.
- (4) **Element 1: Score and Rationale:** Provide the score that corresponds to the potential public health impact if a contaminant were added at the relevant process step. Also include an explanation or notes on why you chose this score for the process step. See Chapter 2, Section F.2 for possible methods to estimate the public health impact and how to score this element using Table 1.
- (5) **Element 2: Score and Rationale:** Provide the score that corresponds to the degree of physical access to the product at the relevant process step. Also include an explanation or notes on why you chose this score for the process step. See Chapter 2, Section F.3 for a possible method to estimate the degree of physical access to the product and how to score this element using Table 2.
- (6) **Element 3: Score and Rationale:** Provide the score that corresponds to the ability of an attacker to successfully contaminate the product at the relevant process step. Also include an explanation or notes on why you chose this score for the process step. See Chapter 2, Section F.4 for a possible method to estimate the ability of an attacker to successfully contaminate the product and how to score this element using Table 3.
- (7) **Sum:** Calculate the sum of the scores entered in Columns 4 - 6.
- (8) **Explanation:** Explain why you determined that the point, step, or procedure is or is not an actionable process step, based on the evaluation of the three fundamental elements and the rationale as to the element scores.

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- (9) Actionable Process Step:** Indicate “Yes” or “No” regarding whether the process step is an actionable process step. If you organize your vulnerability assessment by using Worksheet 1-C, you would have the same response for this column and Column 6 of that worksheet because both columns indicate whether a step is an actionable process step.

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8. Worksheet 1-F: Identifying Actionable Process Steps Using the Three Fundamental Elements

PRODUCT(S): _____

FACILITY NAME: _____

ADDRESS: _____

DATE SIGNED: _____

(1) #	(2) Process Step	(3) Process Step Description	(4) Element 1: Score and Rationale	(5) Element 2: Score and Rationale	(6) Element 3: Score and Rationale	(7) Sum	(8) Explanation	(9) Actionable Process Step

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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.

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2. Worksheet 1-H: Mitigation Strategies

PRODUCT(S): _____

FACILITY NAME: _____

ADDRESS: _____

SIGNED DATE: _____

(1) #	(2) Actionable Process Step	(3) Mitigation Strategy	(4) Explanation

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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.

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- (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).

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2. Worksheet 1-I: Mitigation Strategies Management Components

PRODUCT(S): _____

FACILITY NAME: _____

ADDRESS: _____

SIGNED DATE: _____

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

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

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

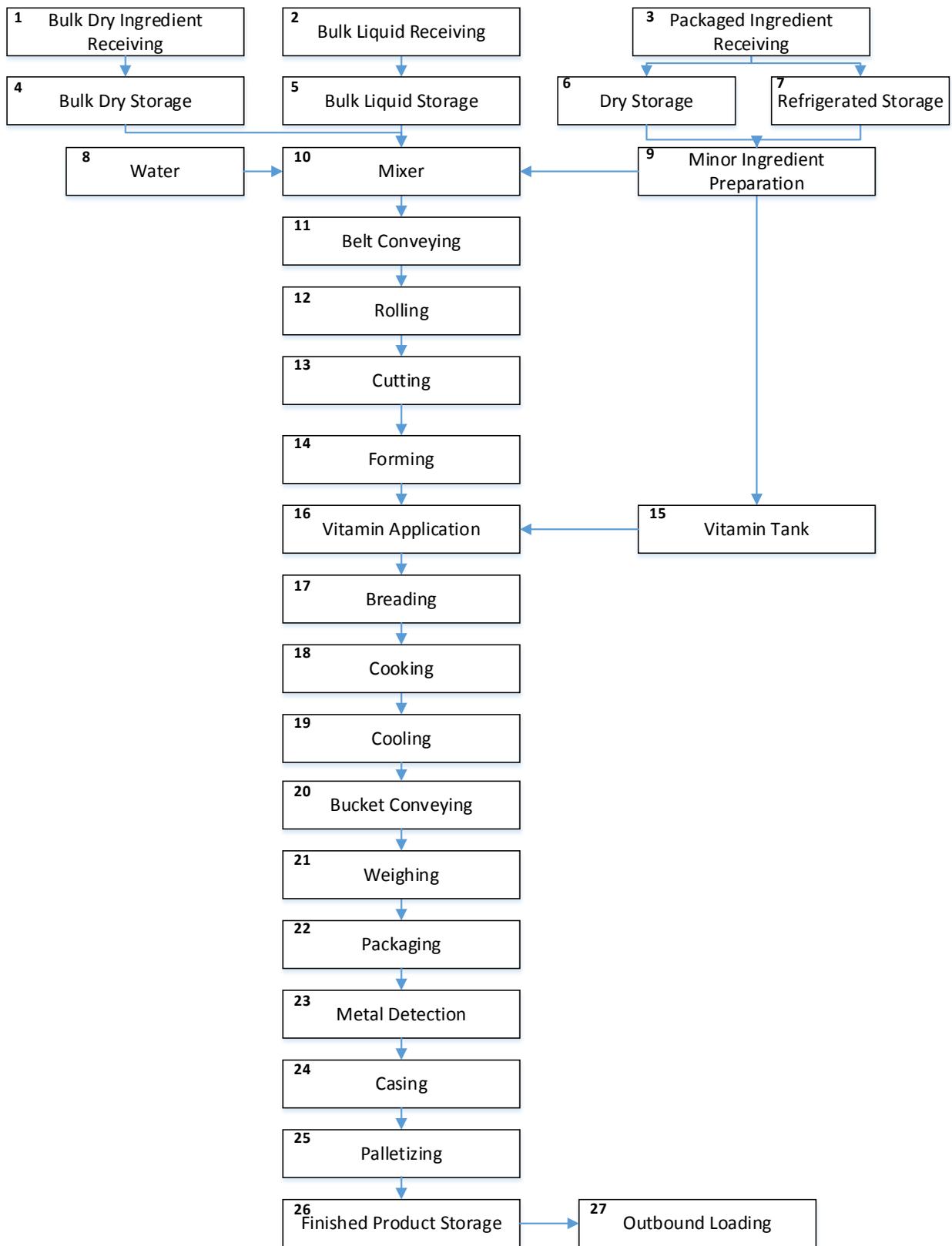
Appendix 4: Vulnerability Assessment Examples [New March 2019]

A. Example of a Vulnerability Assessment Using the Three Fundamental Elements

Figure 2b-1 is a sample process flow diagram for a fictional breaded morsel product. Figure 2b-2 is an example of a VA conducted using the fictional breaded morsel product at a fictional facility. Figure 2b-3 is an example of rank ordering process steps after each element is scored and those scores are summed. Figure 2b-2 illustrates scoring of the fundamental elements using Tables 1-3 in Chapter 2 of this guidance, and demonstrates the flexibility and range of information you can include. For instance, you may choose to include detailed information in your element score and rationale boxes (i.e., Columns 4-6), and only summarize this in the explanation box (Column 8), or you could provide more information in the score and rationale boxes and just reference those in the explanation box. Figure 2b-2 also illustrates a variety of approaches such as footnotes, referencing other worksheets you may have used, referencing previous scoring of identical process steps, and consolidating into a single scoring evaluation different processes that are conducted by integrated equipment (e.g., cutting and forming in this example); you may find these strategies helpful in reducing the time needed to conduct your VA.

You are not required to use the worksheet in Figure 2b-2 or the rank ordering in Figure 2b-3 to organize your VA. How you capture and organize your VA information is up to you; however, your food defense plan must include information required by 21 CFR 121.130.

Figure 2b-1. Three Fundamental Elements VA Example – Breaded Morsel Process Flow Diagram



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Figure 2b-2. Three Fundamental Elements VA Example - Worksheet 1-F – Breaded Morsels

(1) #	(2) Process Step	(3) Process Step Description	(4) Element 1: Score and Rationale	(5) Element 2: Score and Rationale	(6) Element 3: Score and Rationale	(7) Sum	(8) Explanation¹	(9) Actionable Process Step
1	Bulk Dry Ingredient Receiving	<p>Trucks arrive, enter a receiving bay, and dump bulk dry ingredients into a collector where an auger conveyor moves the ingredients into the storage silo.</p> <p>Usually one employee performs unloading activity. The entire receiving process takes approximately fifteen minutes. Facility procedures allow truck drivers to remain in the area, but not to participate in unloading activity.</p>	<p>Score = 10</p> <p>One truck typically contains 50,000 lbs. of bulk dry ingredient. Each serving of the finished product includes 4 oz. of the ingredient. Using FDA's representative contaminant approach, this will result in approximately 200,000 servings. Successful contamination at this process step would result in 100,000 deaths.²</p>	<p>Score = 8</p> <p>This area is accessible from outside the facility when the receiving bay doors are open. Additionally, there is easy access to the collector when the ingredients are being unloaded.</p>	<p>Score = 1</p> <p>The amount of a representative contaminant was determined using Worksheet 1-E.² It is not feasible to introduce the amount of agent required to contaminate the entire batch undetected. The auger conveyor does not mix the ingredient. Any contaminant would be conveyed as a concentrated slug and would not be distributed throughout the product.</p>	N/A ³	No significant vulnerability is present because Element 3 = 1.	No
2	Bulk Liquid Receiving ⁴	<p>Bulk liquid is received at the receiving bay in tanker trucks. Upon receipt, venting hatches at the top of the vehicle are opened and hoses are attached to the back of the vehicle. Facility procedures allow truck drivers to remain in the area but not to participate in unloading activity. The entire receiving process takes</p>	<p>Score = 10</p> <p>Contamination at this process step could result in 80,000 deaths. See Worksheet 1-E for calculations.²</p>	<p>Score = 8</p> <p>Vent and sampling hatches are opened before unloading. Hoses are accessible when not in use. Open hatches provide a means of access to the food. This area is accessible by anyone already in the facility.</p>	<p>Score = 8</p> <p>When multiple trucks are in the receiving bay (which is not uncommon), it is difficult for other workers in the area to observe opening of vent hatches and hooking-up of hoses. A contaminant added to either the vent or the hose itself would mix with the food during</p>	26	This step is significantly vulnerable. If successfully contaminated, it is anticipated that the result would be a very large public health impact. An intentional contamination by an insider at this step	Yes

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		approximately thirty minutes. One truck typically contains 5,000 gallons of liquid ingredient.			unloading and pumping to the storage tank.		would not be prevented by any inherent characteristics of this step. Observation of this process is low since the design of the receiving bay presents visual obstructions. ⁵	
3	Packaged Ingredient Receiving	Packages of secondary ingredients such as seasoning (salt, spices), dehydrated minced onions and garlic, and premixed breading are received via truck in 50 lb. bags on shrink-wrapped pallets. Product is moved directly to storage via forklift.	Score = 5 Bags of seasoning were used as the representative product for this step ⁶ . Due to the movement of the pallets, as described in the Element 3 rationale for this step, it was determined that only 1 bag could potentially be available for contamination (such as if there was a gap in the shrink-wrap). A single 50 lb. bag will generate 800 finished product servings (1 oz. of seasoning/serving). This will result in 400 potential deaths. ²	Score = 3 Product here is wrapped in multiple layers of packaging or wrapping and generally not accessible (i.e., hardly accessible). Only if shrink-wrap has a gap in its coverage would potential access exist for an inside attacker to try and rip or puncture a bag. Even if there was a gap in the wrapping, an inside attacker would need specialized tools to access the food (knives, syringes, or other way to penetrate the packages).	Score = 3 Pallets are moving quickly via forklift to storage and under constant observation of the forklift operator, but a pallet may sometimes be left in the receiving area for a short time if quality testing is performed. An attacker would have to conduct irregular/suspicious activities to contaminate a bag on a pallet that is being held in the receiving area. Surrounding workers would make it highly likely that an inside attacker attempting to introduce a contaminant into a bag would be detected, even if the attacker were the quality control manager taking samples. It would be difficult to introduce a contaminant into the small tear in the bag used for QC testing without significantly deviating from the established normal sampling process and engaging in suspicious behavior.	11	No significant vulnerability is present because score < 14.	No

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4	Bulk Dry Storage	Bulk dry ingredient is stored in large silos and then pneumatically conveyed to the mixer.	Not assessed because Element 3 score = 1 ⁷	Score = 10 Access to the silo is easily achieved from an attached ladder on the side that is accessible from the exterior of the building. A maintenance hatch is at the top of the silo.	Score = 1 It would be extremely difficult, if not impossible, to carry enough contaminant up the silo ladder to introduce into the food. ² No mixing occurs at this step. A contaminant added to the silo would proceed through the system as a concentrated lump but would not be spread across a large number of servings.	N/A	No significant vulnerability is present because Element 3 = 1.	No
5	Bulk Liquid Storage	Bulk liquid is stored in two 10,000 gallon tanks. These two tanks are assessed as one step because they are of the same equipment design, and are located together in an isolated part of the facility. Liquid ingredient is typically held for up to 48 hours prior to processing. Tanks are agitated to prevent separation of the liquid ingredient.	Score = 10 Bulk storage tanks hold enough liquid ingredient to generate a public health impact of well over 10,000 deaths if successfully contaminated. ²	Score = 8 An unsecured hatch at the top of the tank provides access to the food in the tank. An attacker would need to climb a ladder to reach the hatch at the top of the tank.	Score = 8 It would be possible for an attacker to bring enough contaminant into the area to introduce it into the tank without being detected. ² Tanks are agitated so if a contaminant was added to the empty tank, it would be mixed into the food when food is reintroduced.	26	This step is significantly vulnerable because the score > 25.	Yes
6 & 7	Dry Storage Refrigerated Storage	These process steps are being assessed together since the conditions are essentially identical. The only difference is that the refrigerated storage room is chilled to 41 degrees. Pallets from dry and refrigerated receiving are moved into their respective	Score = 5 We believe that because of the way the bags are stored in the shelves, an attacker would only realistically be able to contaminate the food in the 3 bags on the top row of an unwrapped pallet.	Score = 3 Bags of ingredients are still sealed and any attempt to access would likely leave indications of tampering. When stored on the shelves, it is difficult to physically access the bags because the pallets are shrink-wrapped.	Score = 3 It would be difficult for an inside attacker to introduce enough contaminant into a bag in a way that would not be readily identified as suspicious. ² The attacker would have to remove some ingredient from the bag to	11	While the public health impact is approximately 600 potential deaths, there is a moderately low ease of attack at this step. Sealed bags also present significant access limitations to any attacker trying to	No

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		storage rooms. Pallets may be broken down, but bags are not opened in the storage rooms. Partially used bags are not returned into storage.	Three bags would generate approximately 600 potential deaths. ²	There may be cases where a single pallet has been stored on the floor. An attacker could potentially access the top 3 bags on the pallet, but this would likely result in evidence of tampering.	introduce sufficient volumes of contaminant. There is a high chance any attempt to introduce a contaminant to the bags would be detected. This is not scored as a 1 because we consider that the inside attacker could successfully introduce a contaminant if given enough time.		introduce a contaminant. ⁹	
8	Water	Municipal water is pumped directly into the mixer. The facility does not hold or treat water on-site.	Not assessed because Element 2 score = 1.	Score = 1 The water system is fully enclosed and pressurized (inherent characteristics). Therefore, this step is not accessible.	Not assessed because Element 2 score = 1.	N/A	See Element 2 rationale.	No
9	Minor Ingredient Preparation	Dry ingredients (e.g. spices, salt, onions, garlic) are prepared by hand in advance of their introduction to the mixer. The preparation area is in a separate room, but not secured and easily accessible to many employees, including those who are not responsible for ingredient preparation. Tamper-evident bags are opened and ingredients are weighed, measured, and staged for addition to the primary product stream at the mixer. The staged ingredients can sit out for up to two hours before use. These activities	Score = 8 Ingredients are measured and prepped for inclusion into the mixer so at any one time, at least 1 mixer's worth of minor ingredients will be measured and staged-- but it is common for 3-4 mixers' worth to be staged. Four mixer batches were used as a potential target for adulteration to estimate the public health impact. A mixer's worth of minor ingredients would potentially yield 1,600	Score = 10 Minor ingredients are easily accessible because they are staged in open bins with no inherent characteristics to limit access.	Score = 8 Ingredient prep technicians are some of the most senior members of the staff and extremely unlikely to act as an attacker – but unless they are actively prepping the ingredients, the ingredient prep technicians are typically not in the prep room. It would be relatively easy for an insider to add a sufficient volume of contaminant to the staged bins. ² The attacker would have to act with minimal stealth to select a time when an ingredient prep	26	The public health impact is high. Open and accessible ingredients are available to an inside attacker. No inherent characteristics limit access, and ingredients are unobserved for extended times. ⁵	Yes

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		are performed by the ingredient prep technician. There are approximately 4-5 ingredient prep technicians who perform this function during their respective shifts.	deaths and four mixers worth would result in 6,400 deaths. ²		technician was not in the room to introduce a contaminant. Staged minor ingredients may sit for extended times while awaiting inclusion to the mixer.			
10	Mixer	Measured minor ingredients are taken from the ingredient preparation room and added by hand to the mixer. Bulk liquid ingredients are pumped directly from the bulk liquid storage tank and computer-metered into the mixer. Bulk dry ingredients are automatically fed from the dry storage silo into the mixer, also via computerized metering. The mixer combines ingredients with water into a uniform mixture. Batch size of the mixer is 2,000 lbs. Mixing takes approximately 30-45 minutes.	Score = 8 2,000 lbs. of dough is mixed at a time. A finished 12 oz. serving of morsels has 10 oz. of dough. 3,200 finished product servings are present in the mixer per batch. This would result in potentially 1,600 deaths. ²	Score = 8 The mixer has an unsecured lid and the mixer operator periodically opens the lid to check on the status of mixing. The mixer is on the primary production floor and anyone in the facility can enter the area.	Score = 8 It would be relatively easy for an inside attacker to introduce a sufficient volume of contaminant to the product during mixing either during the introduction of minor ingredients or during the mixing stage. ² The mixer operator is not constantly in the area, and there are times when the mixer area is not under observation.	24	The public health impact is 1,600 deaths. Mixer provides elevated levels of access. An insider would be able to introduce a contaminant, but it would require a moderate degree of stealth to do so. The ingredients are mixed at this step so the entire batch would be evenly contaminated.	Yes
11	Belt Conveying	Product is pumped from the mixer onto a flat belt conveyor where it is conveyed to the rollers for flattening. The line speed of the belt conveyor is 100 lbs. per minute. The distance of the belt conveyor is approximately 50 feet, but it is in a highly visible location in an area with many	Score = 5 Given our Element 3 estimation that an inside attacker could stand at this step for three minutes, this period would place 300 lbs. of food at risk, which would generate 480 finished servings. This would result in the	Score = 8 Rollers are open and accessible to any person within the facility. The railing provides a minor amount of separation between the conveyor and worker movement paths. An inside attacker would have to enter the area beyond the	Score = 3 No mixing occurs at this step and the application of a sufficient volume of contaminant would have to occur over an extended period to contaminant many servings. ² Multiple workers in the area can observe the equipment, making it difficult for an inside attacker	16	Despite an elevated degree of access at the conveyors, high levels of observation in the surrounding area mean that an inside attacker would need to act with great stealth to add a contaminant at this step. Any contaminant would be limited to the	No

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		employees with a high degree of observation of the surrounding area. A railing is present to prevent personnel from accidentally bumping into the conveyor.	potential to generate 240 deaths. ²	railing or reach over the railing to introduce a contaminant.	to contaminate the food without being detected. We estimate that an inside attacker would only be able to stand at the conveyor and add a contaminant for three minutes without being detected. Additionally, an inside attacker reaching over or entering the area beyond the railing would be noticeable and suspicious.		surface of the mixture and not be incorporated into the product. Mixing does not occur at this step or subsequent steps.	
12	Rolling	Product is pumped from the mixer onto flat belts and conveyed to a series of rollers to flatten the mixture prior to cutting and forming. The line speed of the belts is approximately 100 lbs./min. of product.	Score = 5 Line speed is the same as process step #11. Element 3 considerations are the same and we conclude that an act of intentional adulteration would be limited to 300 lbs. of food, which has the potential to cause 240 deaths.	Score = 5 Rollers themselves provide only limited space to add a contaminant, but the food is more accessible while on the conveyor before entering the roller. However, worker safety railings surrounding the roller prevent people from inadvertently getting too close to the equipment and possibly getting clothing caught in the rollers. Anyone attempting to access the food here would have to cross over the railing.	Score = 3 Similar to belt conveying, no mixing occurs at this step, and any contaminant would have to be applied to the food over an extended period to contaminate many servings. Multiple workers in the area can observe the equipment, making it difficult for an inside attacker to contaminate the food without being detected. We estimate that an inside attacker would only be able to stand at the rollers for three minutes and introduce a contaminant without being detected.	13	Inherent characteristics of the roller limits physical access to the product, and it would be difficult for an attacker to successfully contaminate the food at this step and achieve wide scale public health harm. ⁹	No
13 & 14	Cutting Forming	The product continues into cutting and forming after flattening. Cutting blades slice the ribbon of product into small squares that are then moved to the former,	Score = 5 Given our Element 3 estimation that an inside attacker would only be able to introduce a	Score = 3 The physical space to introduce a contaminant is very constrained and access is only possible along the	Score = 3 It is unlikely an inside attacker would be able to contaminate the food via the side opening of the machine. While the food is	11	No significant vulnerability is present because score < 14.	No

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		which molds the cut squares into spheres. Line speed is the same as the roller (100 lbs./min.). This is an integrated piece of equipment, so both processes are evaluated as one.	contaminant by attempting to propel it onto the food from the side of the machine, we estimate that only a few servings would be impacted due to the movement of product and the likelihood that only the food closest to the edge of the machine would be potentially exposed to the contaminant. This would result in few deaths. ²	side of the machine where food is visible to workers viewing the status of cutting and forming. There are panels that can be removed during cleaning but access is prevented by worker safety mechanisms that are inherent to the equipment. An alarm will sound and shut down the machine if the safety panels are removed during operations to access the food.	visible from the side opening, it is at a distance from the side of the machine such that an inside attacker could only contaminate the food by propelling a contaminant into the immediate area where cutting and forming occurs. We consider this is an unlikely strategy to intentionally adulterate the food. An attempt likely would be detected given how suspicious this activity is. For these reasons, there is doubt as to the feasibility of successful contaminant introduction at this step.			
15	Vitamin Tank	5 Gallon jugs of vitamin mixture are manually added to the vitamin tank. The tank has a lid that is accessible to fill the tank. The tank has a capacity of 25 gallons. The tank lid at the top is unsecured and is used to add more vitamin mixture. The vitamin tank is adjacent to and elevated above the forming machine, and workers access it via an elevated gangway to fill the tank.	Score = 8 At an application rate of 0.25 fl. oz. vitamin mixture per serving of morsels, 25 gallons of vitamin mix would contaminate 12,800 servings. This would potentially result in 6,400 deaths if an intentional adulteration were successfully attempted at this step. ²	Score = 8 Tank is accessible. The top hatch is not secured. The gangway is not locked or otherwise access-restricted; however, introducing a contaminant would require releasing the lid clasp and opening the lid to access the vitamin mixture.	Score = 8 There are periods when this process step is unobserved and an inside attacker would be able to climb the gangway stairs without being detected. It does not take much time to open the lid, and it would be relatively easy to transport and introduce a sufficient volume of agent. The tank is not agitated, but adding more vitamin mix would serve to distribute the contaminant within the mixture.	24	Large public health impact is possible and vitamin tank is accessible. There are frequent periods where an inside attacker could act without being observed or detected.	Yes
16	Vitamin Application	The vitamin mixture is pumped directly to applicator nozzles within the breading	Not assessed because Element 2 score = 1.	Score = 1 System is pressurized and enclosed (inherent	Not assessed because Element 2 score = 1.	N/A	No significant vulnerability is present because Element 2 = 1.	No

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		equipment. The system is pressurized and enclosed.		characteristics). There is no means of access without completely disassembling the equipment.				
17	Breading ⁸	After application of the vitamin mixture, which also serves as a medium for breading adhesion, the dough spheres are conveyed through a breader where they pass through a curtain of breading, are rotated, and pass through another curtain of breading to achieve complete coverage. Unadhered breading is recycled in a continuous process. Bags of premixed breading are brought from dry storage, opened, and added to the breader's hopper.	Score = 8 500 lbs. of breading (ten 50 lb. bags) are loaded into the hopper and will coat many mixer batches of morsels. If contaminated, this would result in a potential public health impact of 4,000 deaths via 8,000 servings. ²	Score = 10 Breder is easily accessible through the hopper where bags of breading are added to the system. The hopper is uncovered and accessible from floor level. There are no inherent characteristics of this process step that would limit the ability of an insider to contaminate the breading.	Score = 8 The openness of the hopper would enable an inside attacker to easily add sufficient volumes of contaminant into the hopper. During the process of breading a contaminant would be mixed across several batches of product as the breading is recycled for continuous use. An inside attacker would have to use a minor degree of stealth to add a sufficient amount of contaminant without detection. The hopper is partially obscured by the breader, thus creating an impediment to clear observation.	26	See each element rationale. ⁵	Yes
18	Cooking	Once breaded, dough spheres are conveyed through a cooker where they are baked at 425°F for 20 minutes.	Not assessed because scores for Elements 2 and 3 = 1.	Score = 1 Due to inherent characteristics, there is no access at this step. Cooker is enclosed for worker safety reasons. Therefore, due to inherent characteristics, there is no access at this step.	Score = 1 Serious injury would result if any attempt to adulterate the food at this point were attempted.	N/A	No significant vulnerability is present because Elements 2 and 3 = 1.	No

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19	Cooling	After cooking, the product is immediately conveyed through a cooling tunnel to reduce its temperature to approximately 40°F. The cooling tunnel is enclosed with only access points at its immediate entrance and exit. Product flows through the cooling tunnel at approximately 100 lbs./min.	Score = 3 Product flow rate is 100 lbs./min. However, given the time estimation in Element 3, 75 lbs. of food would be impacted by an intentional adulteration at the cooler. Therefore, 60 deaths are possible if product is contaminated at this step. ²	Score = 3 There is a space between the cooker and the cooler where access to the conveyed product is possible, but physical space limitations would make introduction of a contaminant difficult. Removing the access panel to access the food within the cooling tunnel would require specialized tools and time to work.	Score = 3 There is no mixing of the product. An inside attacker would have to stand at the intake or discharge of the cooling tunnel for an extended period while applying the contaminant to the product, which would arouse suspicion. We estimate that an individual would be able to stand at the entrance/exit of the cooling tunnel for less than a minute without being detected.	9	Relatively low public health impact. Step is hardly accessible. Low ease of attack. Minimal timeframes for contaminant introduction and surrounding workers prevent an inside attacker from working unobserved for enough time to contaminate any significant amount of product. ⁹	No
20	Bucket conveying	This is included as a process step in this assessment because it is not assessed as part of another process step's evaluation. Bucket conveyers take discharge morsels from the cooler on an elevated track from the primary production room to the packaging room. Buckets move quickly and carry approximately 15 lbs. of product.	Score = 3 Due to general levels of observation and time constraints noted in Element 3 of this step, we determine it is potentially feasible to contaminate 5 buckets loaded with morsels after they exit the cooler. This would result in potentially 75 lbs. or approximately 100 servings at risk. This would lead to 50 potential deaths if contaminated. ²	Score = 3 Access is only possible immediately after the cooler, but buckets fill quickly and then elevate product away from an inside attacker. Accessing the buckets could very easily cause bodily harm as they move rapidly, and guard rails are present to prevent accidental contact with the buckets. Once filled, buckets are inaccessible as they are moving rapidly on an elevated track.	Score = 3 Timeframes are very short to contaminate the product while each bucket fills as product is discharged from the cooler. Once filled, buckets move very quickly on an elevated track. Mixing does not occur.	9	No significant vulnerability is present because score < 14.	No
21	Weighing	Bucket conveyers deposit the product into a hopper above a carousel-style weighing	Score = 5	Score = 8	Score = 5	18	Even though there is an elevated degree of access, and, once	No

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		machine where morsels are funneled into weigh scales in preparation for packaging. This process is conducted in an elevated area above the packaging equipment, and access to the process step is possible via stairs and a gangway.	The carousel may have, at any given time, approximately 50 lbs. of product that would yield about 200 servings that are at risk. This would cause 100 potential deaths. ² This is the very bottom of the public health impact range for score 5.	The hopper is elevated above the carousel and is not accessible without bringing a ladder up the stairs and onto the gangway. However, the food in the carousel is accessible and open as it is being funneled to the weigh scales.	The volume of contaminant needed is minimal and would be easily concealed. ² However, mixing is not present at this step and any contamination would be concentrated in only a limited number of packages.		accessed, it would be easy to introduce a contaminant to the food, this process step would not generate wide scale public health harm if intentionally adulterated. The small volume of food available coupled with the lack of mixing across many packages result in this step not being an actionable process step.	
22	Packaging	Once weighed, morsels are dropped into an automated packaging machine where individual 24 oz. consumer packages (2 servings per package) are filled. Packaging consists of filling a plastic pouch with product and vacuum sealing the pouch. The pouch is then moved automatically into a box that is labeled and then sealed.	Score = 3 At this point, only individual packages are at risk of adulteration by an inside attacker. At most, an inside attacker accessing the intake of the packager could contaminate only 5 packages, resulting in potentially 3 deaths.	Score = 3 Access is difficult but possible at the point where morsels drop from the weigh scales into the packaging machine. An inside attacker would need to bring a stool or ladder to reach the intake.	Score = 3 As mentioned in Element 1, only individual packages are at risk. There is no mixing. After a short time, the inside attacker's actions would be detected because reaching up into the intake as food is falling into the packager is a safety hazard.	9	Access is difficult. An attack at this step would adulterate individual packages, and not result in wide scale public health harm. ⁹	No
23, 24, 25, 26, 27	Metal Detection, Casing, Palletizing, Finished Product Storage,	Sealed boxes pass under a metal detector, and are automatically placed in cases of 48 boxes. Cases are then sealed for distribution. Cases are then loaded by hand onto a pallet which is moved via	Not assessed because Element 2 score = 1.	Score = 1 Product is in multiple layers of tamper-evident packaging that eliminates access to the food by an inside attacker.	Not assessed because Element 2 score = 1.	N/A	No significant vulnerability is present because Element 2 = 1. These process steps are being grouped together because the product is in the same	No

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	Outbound Loading ¹⁰	hand truck to an automated palletizing machine. Fully packaged and palletized finished product is stored for up to three days in a storage room and then forklift loaded on to outbound trucks.					inaccessible state due to multiple layers of packaging.	
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¹ If the rationale for your determination of the individual element scores explains in sufficient detail why a process step is or is not an actionable process step, you do not need to include an explanation in this column.

² These estimates were generated by completing Worksheet 1-E, described in Chapter 2, Section F.2.a.ii, with the information included in this example. The calculations generating these results are not included in this guidance. Worksheet 1E can also generate estimates for the total amount of contaminant needed, which can inform the evaluation of Element 3.

³ Process steps that receive a score of 1 for any of the three fundamental elements should not go through the summation process since the facility has concluded that one of the three elements is not present at that step.

⁴ This process step is discussed in Chapter 3, Scenario 2 of this guidance.

⁵ This text provides an example for how you could summarize your analysis of the scoring of the three fundamental elements; however, it is not required that you do so in this manner. Alternatively, you could state “This step is significantly vulnerable because the score > 25.” See Chapter 2, Section G.1 for more information on identifying actionable process steps and Section G.2 for more information on written explanations.

⁶ Similar food products can be grouped when conducting VAs. For more information, see Chapter 2, Section A.2 of this guidance.

⁷ Because Element 3 was scored as 1, there is no need to continue to evaluate public health impact because if any of the elements score as 1, then there is no significant vulnerability present. Process step1 in this example has scores for all three elements, and this process step has scores for two elements, for explanatory purposes only.

⁸ This process step is discussed in Chapter 3, Scenario 4 in this guidance.

⁹ This text provides an example for how you could summarize your analysis of the scoring of the three fundamental elements; however, it is not required that you do so in this manner. Alternatively, you could state “This step is not significantly vulnerable because the score < 14.” See Chapter 2, Section G.1 for more information on identifying actionable process steps and Section G.2 for more information on written explanations.

¹⁰ In this example, process steps 23-27 have the same scores and rationale for why these points, steps, or procedures are not actionable process steps. You have the flexibility to combine these steps into one row if you so choose.

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Figure 2b-3. Three Fundamental Elements VA Example – Process Steps Rank Ordered by Sum Score – Breaded Morsels

Rank-ordering process steps by the sum score can assist you in quickly identifying process steps with significant vulnerabilities. Once the scores for the three fundamental elements have been assigned, these scores are added together to give an overall value (i.e., sum) for each point, step, or procedure. Once the facility sums the scores for all of the points, steps, or procedures evaluated in the vulnerability assessment (except for those steps where one or more elements scored a 1), the facility orders the process steps from highest to lowest sum values. The facility should identify steps with sum scores >25 as actionable process steps, and steps with sum scores <14 not as actionable process steps. For steps with scores in the range of 14 – 25, significant vulnerabilities may or may not be present depending on the nature of the vulnerability at the process step under evaluation and the contribution of each of the three elements in each case. The following Figure rank orders the sum scores, and associated information for the process steps of those scores, from Figure 2b-2, Columns 1, 2, and 4-8.

(1) #	(2) Process Step	(4) Element 1 Score	(5) Element 2 Score	(6) Element 3 Score	(7) Sum	(8) Actionable Process Step
2	Bulk Liquid Receiving	10	8	8	26	Yes
5	Bulk Liquid Storage	10	8	8	26	Yes
9	Minor Ingredient Preparation	8	10	8	26	Yes
17	Breading	8	10	8	26	Yes
10	Mixer	8	8	8	24	Yes
15	Vitamin Tank	8	8	8	24	Yes
21	Weighing	5	8	5	18	No
11	Belt Conveying	5	8	3	16	No
12	Rolling	5	5	3	13	No
3	Packaged Ingredient Receiving	5	3	3	11	No

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6	Dry Storage	5	3	3	11	No
7	Refrigerated Storage	5	3	3	11	No
13	Cutting	5	3	3	11	No
14	Forming	5	3	3	11	No
19	Cooling	3	3	3	9	No
20	Bucket Conveying	3	3	3	9	No
22	Packaging	3	3	3	9	No
1	Bulk Dry Ingredient Receiving	10	8	1	N/A *	No
4	Bulk Dry Storage	Not assessed	10	1	N/A	No
8	Water	Not assessed	1	Not assessed	N/A	No
16	Vitamin Application	Not assessed	1	Not assessed	N/A	No
18	Cooking	Not assessed	1	1	N/A	No
23	Metal Detection	Not assessed	1	Not assessed	N/A	No
24	Casing	Not assessed	1	Not assessed	N/A	No
25	Palletizing	Not assessed	1	Not assessed	N/A	No
26	Finished Product Storage	Not assessed	1	Not assessed	N/A	No
27	Outbound Loading	Not assessed	1	Not assessed	N/A	No

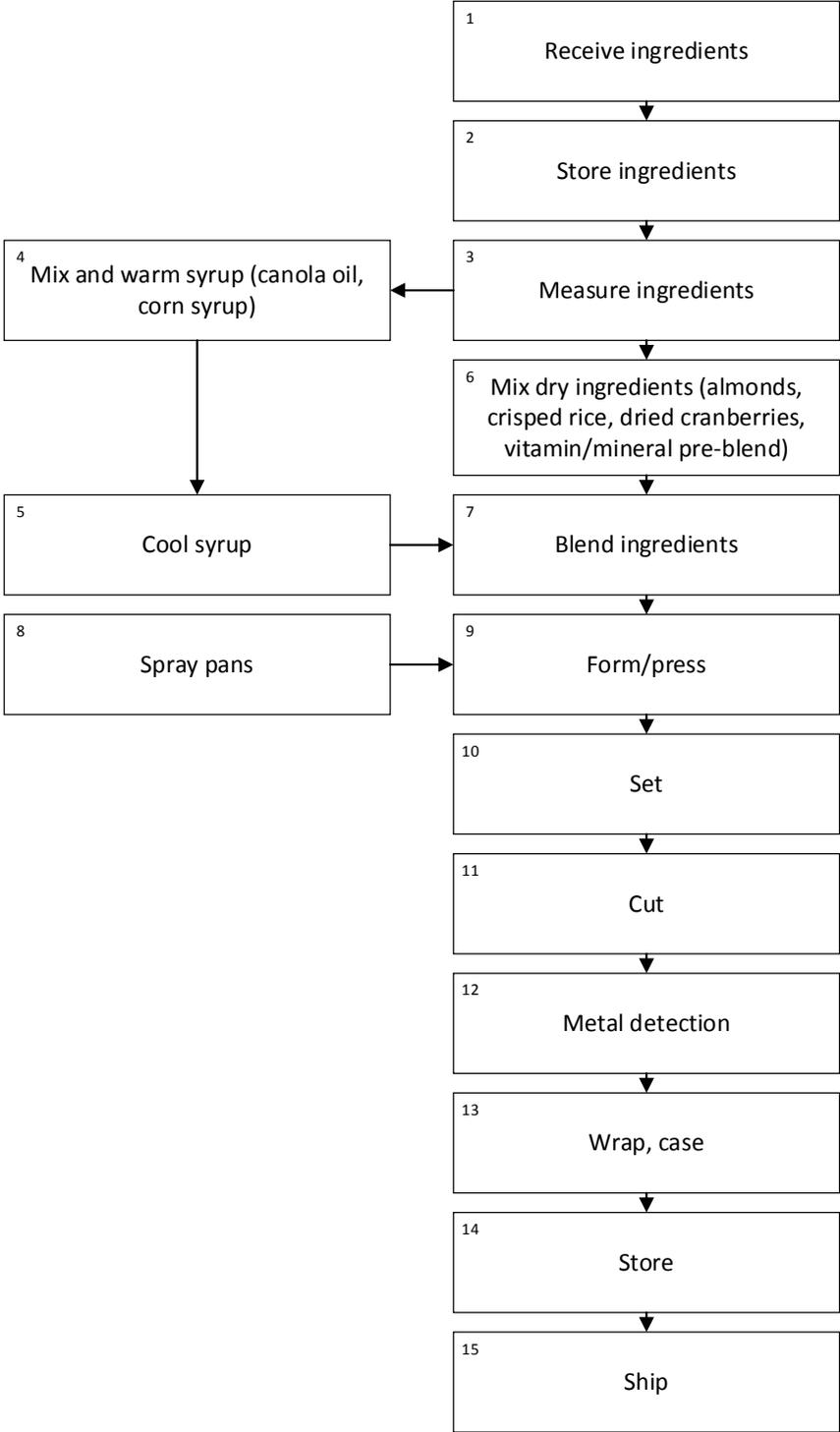
* Process steps with a score of one for any of the three fundamental elements are not actionable process steps.

B. Example of a Vulnerability Assessment Using the Hybrid Approach

Figure 2c-1 is a sample process flow diagram for a fictional cold pressed almond cranberry energy bar. Figure 2c-2 is an example of a VA conducted using the fictional cold pressed almond cranberry energy bar at a fictional facility. Figure 2c-2 is an example of how Worksheet 1-F can be modified to document a vulnerability assessment using the hybrid approach. In Section 2.G.1, we provided a description for how to use this worksheet, and much of that description is applicable when documenting a VA using the hybrid approach. When using Worksheet 1-F for documenting the hybrid approach, you should complete Columns 4 - 7 for steps where the three fundamental elements analysis is used in combination with the KAT analysis; you do not need to complete these columns when the KAT analysis is the only one used for a step.

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Figure 2c-1. Hybrid Approach VA Example- Cold Pressed Almond Cranberry Energy Bar Process Flow Diagram*



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Figure 2c-2. Hybrid Approach VA Example- Worksheet 1-F- Cold Pressed Almond Cranberry Energy Bar

PRODUCT(S): Cold Pressed Almond Cranberry Energy Bar

FACILITY NAME: EB #12345

ADDRESS: 12345 Main Street, Anywhere, USA

SIGNED DATE: May 17, 2018

(1) #	(2) Process Step	(3) Process Step Description	(4) Element 1: Score and Rationale	(5) Element 2: Score and Rationale	(6) Element 3: Score and Rationale	(7) Sum	(8) Explanation	(9) Actionable Process Step
1	Receive Ingredients	Corn syrup – Received in 5 gal. tamper-evident sealed plastic containers Canola oil – Received in 5 gal. tamper-evident sealed plastic containers Almonds, blanched and slivered – Received in 20 lb. bags Crisped rice – Received in 22 lb. bag-in-box Dried cranberries – Received in 25 lb. cases Powdered vitamin/ mineral pre-blend – Vitamins (A, B-mix, C, E) and minerals (Ca, Mg, K, Zn) received in 1 lb. plastic sealed bags, with 10 bags in a box Pan release agent – contains soy lecithin – received in spray cans	NA	NA	NA	NA	Does <u>not</u> fit within any of the KATs.	No
2	Store Ingredients	All ingredients are stored in the dry storage room (temperature kept below 75°F) in the ingredient area, arranged by ingredient code number. All containers are sealed to avoid cross-contact and cross-contamination during storage.	NA	NA	NA	NA	Does <u>not</u> fit within any of the KATs.	No
3	Measure Ingredients	Liquid ingredients are measured and staged in a dedicated room. Ingredients are measured and weighed before being staged in dedicated containers. When needed, liquid ingredients	NA	NA	NA	NA	Fits within the KATs- Liquid Storage and Handling, and Secondary Ingredient Handling.	Yes

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		are directly pumped from the containers into the mixer.						
4	Mix and Warm Syrup	The corn syrup and canola oil mixture is pumped from the ingredient measuring room to the main production floor and into an enclosed jacketed mixer and warmed to 195 - 205°F, and blended for 20 minutes to ensure even distribution.	Not assessed because Element 2 score = 1.	Score = 1 Because of inherent characteristics, there is no access at this step. The mixer is enclosed for worker safety reasons, and accessing the tank would require special tools and disassembling equipment.	Not assessed because Element 2 score = 1.	N/A	While this step fits within the KAT “Mixing and Similar Activities,” no significant vulnerability is present because this step has no means of physical access.	No
5	Cool Syrup	The syrup is pumped into a cooling tank and cooled to 120-130°F. The cooling tank is enclosed except for a hatch that can only be opened when product is not in the tank.	Score = 5 Using a representative contaminant, the cooling tank holds enough liquid ingredient to generate a potential public health impact of 900 deaths.*	Score = 3 Because of inherent characteristics, there is limited access at this step. The cooling tank is enclosed and access is only possible when product is not in the tank.	Score = 3 Using a representative contaminant, it would be difficult to bring enough contaminant into the area and have sufficient time to get the	11	While this step fits within the KAT “Liquid Storage and Handling,” no significant vulnerability is present because score < 14.	No

* These estimates were generated by completing Worksheet 1-E, described in Chapter 2, Section F.2.a.ii, with the information included in this example. The calculations generating these results are not included in this guidance.

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					contaminant into the tank.			
6	Mix Dry Ingredients	Dry ingredients, including almonds, crisped rice, dried cranberries, and the vitamin/mineral pre-blend, are added to a mixer and blended for 30 minutes to ensure even distribution.	NA	NA	NA	NA	Fits within the KAT-Mixing and Similar Activities.	Yes
7	Blend All Ingredients	Mixed dry ingredients are gradually added to the syrup mixer.	NA	NA	NA	NA	Fits within the KAT-Mixing and Similar Activities.	Yes
8	Spray Pans	Pans that have been cleaned and dried are sprayed by hand with a processing aid containing soy lecithin.	NA	NA	NA	NA	Does <u>not</u> fit within any of the KATs.	No
9	Form/Press	The blended mass is dispensed onto pans. The mixture is formed and pressed with rollers to ensure consistent spreading and density.	NA	NA	NA	NA	Does <u>not</u> fit within any of the KATs.	No
10	Set	Pans are placed in cooling racks and moved to setting area where they are cooled to ambient temperature--around 70°F.	NA	NA	NA	NA	Does <u>not</u> fit within any of the KATs.	No
11	Cut	Sheets are cut mechanically in two successive cutting operations, vertically and horizontally (rotary blade, reciprocal blade).	NA	NA	NA	NA	Does <u>not</u> fit within any of the KATs.	No
12	Metal Detection	Cut bars are passed through a calibrated metal detector on the conveyor. Bars that are kicked off during this operation are passed through a more sensitive metal detector. Rejected bars are inspected and sent to waste.	NA	NA	NA	NA	Does <u>not</u> fit within any of the KATs.	No
13	Wrap, Case	Trays containing cut bars are flipped onto wrappers and bars are individually heat sealed and cut. Lot information is printed onto each sealed package. Bars are transferred by hand into cases, with 24 bars/case. Product and lot information is printed on each case. Cases are transferred by hand to pallets, which are sealed in plastic.	NA	NA	NA	NA	Does <u>not</u> fit within any of the KATs.	No
14	Store	Pallets are transferred by fork lift to the warehouse where they are stored under	NA	NA	NA	NA	Does <u>not</u> fit within any of the KATs.	No

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		ambient condition at < 70% RH until shipping.						
15	Ship	Wrapped pallets are loaded into trucks via forklift for outbound distribution.	NA	NA	NA	NA	Does <u>not</u> fit within any of the KATs.	No

NA = Not applicable.

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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.

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