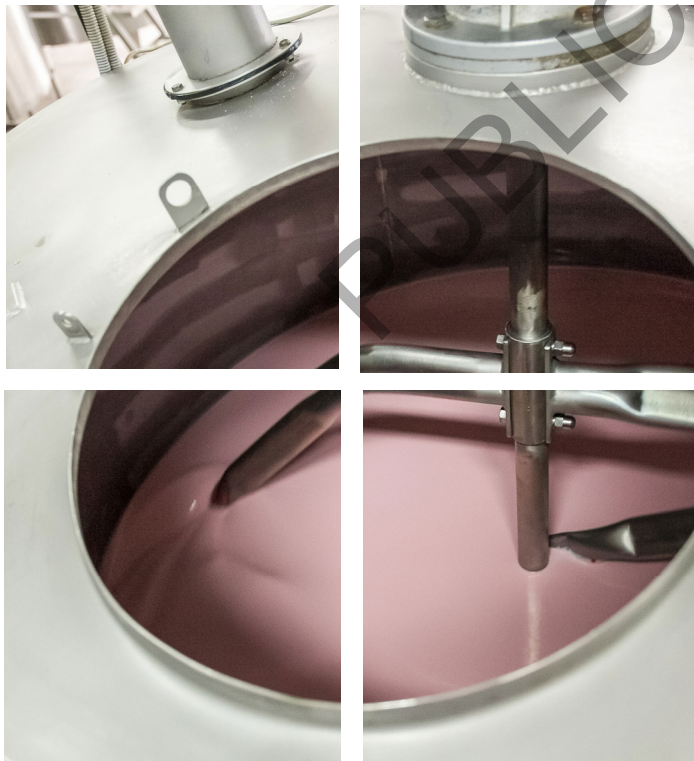




# FSPCA Conducting Vulnerability Assessments

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Version 1.0 – 2019



# Participant Manual

**FSPCA INTENTIONAL ADULTERATION CONDUCTING VULNERABILITY ASSESSMENTS  
TRAINING CURRICULUM**

**Version 1.0 – 2019**

**Copyright Notice**

The Intentional Adulteration Conducting Vulnerability Assessments training curriculum was developed by the Food Safety Preventive Controls Alliance (FSPCA).

The FSPCA is a broad-based public-private alliance of key industry, academia and government stakeholders.

It was established in late 2011 by grants from U.S. Food and Drug Administration (FDA) to Illinois Institute of Technology's Institute for Food Safety and Health (IIT IFSH) (U01FD003801, U19FD005322, U01FD005661).

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# FSPCA CONDUCTING VULNERABILITY ASSESSMENTS *TRAINING CURRICULUM*

Version 1.0 – 2019

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The information provided by the FSPCA will vary in applicability to each facility. It is not possible for the FSPCA training curriculum to address every situation. Facilities should implement the mitigation strategies, including conducting vulnerability assessments, that will function best within their individual operations. FSPCA materials do not outline the only approach to conducting vulnerability assessments. Facilities can follow any approach that satisfies the requirements of the applicable statutes and regulations related to FSMA. The information provided by FSPCA does not create binding obligations for the Food and Drug Administration or industry.

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FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

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## Intentional Adulteration Conducting Vulnerability Assessments Training

The Food Safety Preventive Controls Alliance developed this Conducting Vulnerability Assessments training curriculum in support of FDA's *Mitigation Strategies to Protect Food Against Intentional Adulteration* regulation. For the most current course information, please consult: <http://www.iit.edu/ifsh/alliance/>



This publication was developed by the Food Safety Preventive Controls Alliance (FSPCA) and was supported, in part, by a grant from the Food and Drug Administration to the Illinois Institute of Technology's Institute for Food Safety and Health. The views expressed herein do not necessarily reflect the views of these organizations. Direct all inquiries to the FSPCA to [fspca@iit.edu](mailto:fspca@iit.edu)

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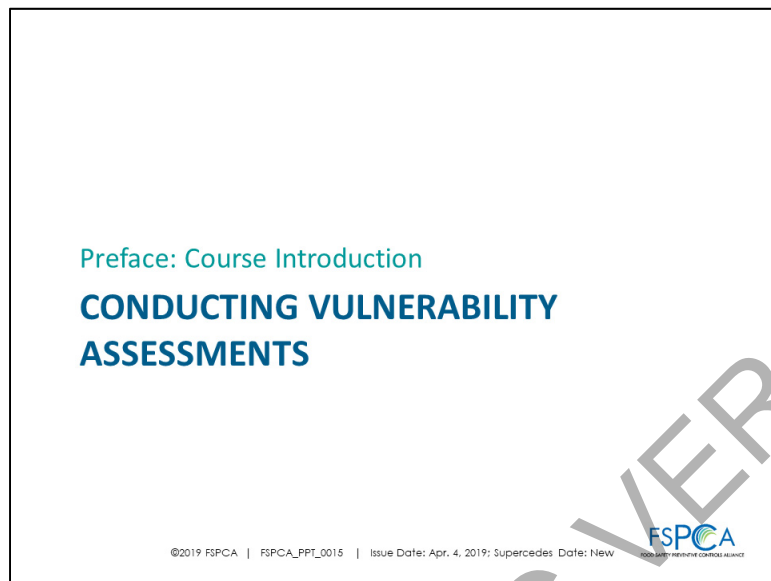
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# PREFACE. Introduction to Conducting Vulnerability Assessments Course

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## Welcome and Introductions



This course will focus on explaining how to conduct a vulnerability assessment (VA) as a requirement of the “Mitigation Strategies to Protect Food Against Intentional Adulteration” regulation, or what we

call the “IA rule” for short, and how facilities can comply with those requirements. The course materials include all slides, lesson content, resource materials and exercises. The materials are yours to keep, so please feel free to take notes in your manual as you go along.

**Goal:** Participants will be able to conduct a vulnerability assessment using the three fundamental elements.

### **Learning Objectives:**

By the end of this course, participants will be able to:

1. Explain the importance of food defense.
2. Explain vulnerability assessment preliminary steps.
3. Explain inherent characteristics.
4. Recognize the importance of considering an inside attacker during a VA.
5. Calculate potential public health impact.
6. Evaluate degree of physical access to the product and the ability of an attacker to successfully contaminate the product.
7. Evaluate vulnerability assessment data.
8. Apply the hybrid approach.

This goal of the course is for participants to be able to conduct a vulnerability assessment using the three fundamental elements, which we will talk more about in Lesson 1.

The overall objectives of the course are to help you understand the importance of food defense, explain the vulnerability assessment preliminary steps, explain inherent characteristics, recognize the importance of considering an inside attacker, and determine how to estimate the potential public health impact while conducting the VA.

Additionally, the course will help you to understand and evaluate degree of physical access to the product, the ability of an attacker to successfully contaminate the product, and how to evaluate vulnerability assessment data. The course will also explain the hybrid approach and next steps once the VA is complete.


## Housekeeping

**Housekeeping**

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- Restrooms
- In case of emergency
- Computer/phones
- Breaks/lunch
- Full attendance is required to receive certificate (sign-in sheet)
- Discussion is encouraged; respect different perspectives
- Purpose is not to debate the rule

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## Food Safety Preventive Controls Alliance (FSPCA)

**Food Safety Preventive Controls Alliance (FSPCA)**

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- Background:
  - FDA recognized the need to assist the regulated industry to comply with the Food Safety Modernization Act (FSMA)
  - Food Safety Preventive Controls Alliance (FSPCA) is a public/private partnership funded by FDA
  - FSPCA's mission is to develop training curricula, outreach programs, and technical assistance to assist the regulated industry in complying with FSMA

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The Food Safety Preventive Controls Alliance (FSPCA) was established in 2011 as part of a grant from the Food and Drug Administration (FDA) to the Illinois Institute of Technology's Institute of Food Safety and Health. The purpose of this broad-based alliance is to develop and maintain a cost-effective education and training program to assist the food industry with understanding and achieving compliance with certain aspects of the Food Safety Modernization Act (FSMA).

FSPCA’s mission is to support safe food production by developing a standardized curriculum and technical educational materials on FSMA regulations and providing technical assistance outreach to the food industry.


## Disclosure

**Disclosure**

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Although I attended the FSPCA Intentional Adulteration Lead Instructor training:




- a) Lead Instructors are not certified, licensed, accredited, qualified, registered, sanctioned, authorized, recognized, endorsed, or approved by the FSPCA;
- b) I do not represent, speak for, or act on behalf of the FSPCA;
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It should be noted that the instructors of this course have attended the FSPCA Lead Instructor training, but:

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## FSPCA IA Rule Training Courses

FSPCA IA Rule Training Courses		
FSPCA Training Course	Delivery Method	Intended Audience
Food Defense Awareness <sup>1</sup>	 Online Training	<ul style="list-style-type: none"> <li>Food workers at actionable process steps (e.g., front line food workers)</li> <li>Supervisors of food workers at actionable process steps</li> </ul>
Overview of IA Rule	 Online Training	<ul style="list-style-type: none"> <li>Any stakeholder interested in learning more about the IA rule requirements</li> <li>This course is not associated with any IA rule training requirement</li> </ul>
Conducting Vulnerability Assessments (VAs) using Key Activity Types (KAT) <sup>2</sup>	 Online Training	<ul style="list-style-type: none"> <li>Food professionals conducting VAs using the KAT Method <b>ONLY</b></li> </ul>

<sup>1</sup>Satisfies requirement in § 121.4(b)(2)  
<sup>2</sup>These courses are "Standardized Curriculum Recognized by FDA" and satisfy the training requirements in § 121.4 of the IA Rule.

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)). The "FSPCA Food Defense Awareness for the IA Rule" was collaboratively developed by FDA and FSPCA and satisfies this requirement. FDA and FSPCA have also developed the "FSPCA Overview of the Intentional Adulteration Rule (IA Rule)" training. The course is optional and not required for compliance with the IA Rule, but the information within the training will assist food facilities that are required to comply with the IA Rule, and other stakeholders, to have a more in-depth understanding of the requirements in the IA Rule.

## FSPCA IA Rule Training Courses (continued)

FSPCA IA Rule Training Courses (continued)		
FSPCA Training Course	Delivery Method	Intended Audience
Conducting Vulnerability Assessments <sup>2, 3</sup>	 Instructor-Led Training	<ul style="list-style-type: none"> <li>Food professionals conducting VAs using the 3 fundamental elements approach</li> </ul>
Identification and Explanation of Mitigation Strategies <sup>2</sup>	 Online Training	<ul style="list-style-type: none"> <li>Food professionals identifying mitigation strategies to implement at actionable process steps</li> </ul>
Food Defense Plan Preparation and Reanalysis <sup>2</sup>	 Online Training	<ul style="list-style-type: none"> <li>Food professionals preparing the Food Defense Plan (FDP) and conducting reanalysis activities</li> </ul>

<sup>2</sup>These courses are "Standardized Curriculum Recognized by FDA" and satisfy the training requirements in § 121.4 of the IA Rule.  
<sup>3</sup>This 1-day course must be taught by trained FSPCA VA Lead Instructors.

The “Conducting Vulnerability Assessments (VAs) using Key Activity Types (KATs)” is a training course targeted towards food professionals using FDA’s Key Activity Type (KAT) method to conduct their facility’s vulnerability assessment (VA). By successfully completing the KAT course, the learner will have satisfied the training requirement to conduct a VA using the KAT method only. The KAT VA course is an online course.

The “Conducting Vulnerability Assessments” course is this current, in-person course. The “Identification and Explanation of Mitigation Strategies” course is intended for those QIs who are responsible for identifying mitigation strategies to implement at actionable process steps and is an online course. The “Food Defense Plan Preparation and Reanalysis” course is intended for the QI who is either preparing the food defense plan or conducting reanalysis and is also an online course.



## FSPCA Vulnerability Assessments (VA) Curriculum

### FSPCA Intentional Adulteration (IA) Conducting Vulnerability Assessments (VA) Curriculum

- This curriculum (course) was designed by regulatory, academic, and industry professionals and developed with funding from FDA as part of the FSPCA
- Individuals conducting or overseeing the conduct of a VA are required to have successfully completed training or be otherwise qualified through job experience to conduct the activities (21 CFR 121.4(c)(2))
- The Key Activity Types (KAT) course is a recommended prerequisite for taking this course
- Successfully completing this course will satisfy the IA rule training requirement for an individual conducting VAs (21 CFR 121.4(c)(2))
- Completing this course will NOT qualify you to conduct any other activities within the IA rule. To be qualified to undertake any other activities, you must take additional training as specified by 21 CFR 121.4 or be otherwise qualified

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This curriculum was designed by regulatory, academic, and industry professionals and developed with funding from FDA as part of the FSPCA. While FDA assisted in the preparation of the course materials, the materials have been written and produced by the Alliance and are not official FDA materials.

The “Mitigation Strategies to Protect Food Against Intentional Adulteration” regulation requires specific training and qualifications in order to conduct or oversee the conduct of a vulnerability assessment (21 CFR 121.4(c)). This course satisfies that training requirement. One of the recommended prerequisites for taking this course is the Key Activity Types (KATs) course, which can be accessed on the FSPCA website.

This course will NOT qualify you to undertake any other activities within the IA rule. To be qualified to undertake any other activities, you must take additional training as specified by 21 CFR 121.4.

#### Key Point:


By "other activities", we are referring to 1) The preparation of the food defense plan; 2) the identification and explanation of mitigation strategies; and 3) Reanalysis.

## Purpose of the Course

**Purpose of the Course**

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To learn how to conduct vulnerability assessments using the three fundamental elements outlined in the IA rule

  
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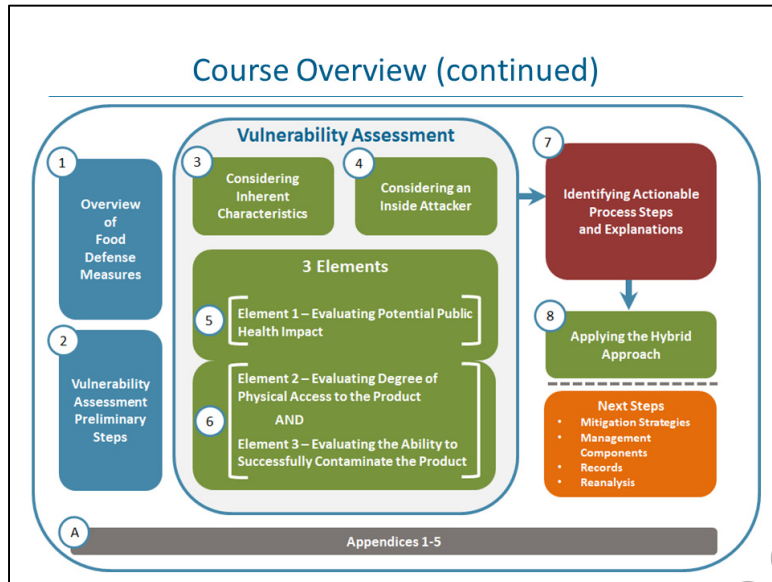
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This course will provide participants with the information and skills necessary to conduct a vulnerability assessment that considers the three fundamental elements outlined in the IA rule. In addition, participants will understand the IA rule's requirements generally, the importance of considering an inside attacker, helpful preliminary steps, how to apply the hybrid approach, and next steps required for completion of the food defense plan.

This regulation is one of a number of regulations and guidance that implement the provisions of the 2011 Food Safety Modernization Act, which focuses on prevention, including intentional contamination, inspection and compliance, and response, imports, and enhanced partnerships.

This course, specifically, is designed for food professionals tasked with conducting a vulnerability assessment.

## Course Overview



## Course Materials

Course Materials

- Agenda
- Participant Workbook, which includes:
  - Course PowerPoints and associated text
  - Appendices
- Exercise Workbook
- Answer Keys and Examples Booklet

Three booklets are shown: 'Participant Manual', 'Exercise Workbook', and 'Answer Keys and Examples Booklet'. Each booklet cover features the FSPCA logo and the title 'Conducting Vulnerability Assessments'.

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The Conducting Vulnerability Assessments training materials include an agenda (located at the end of the Preface), a Participant Manual, an Exercise Workbook, and an Answer Keys and Examples Booklet.

The Participant Manual and Exercise Workbook are yours to keep. Become familiar with them and use them as a reference. The manual contains references, tables, and other vulnerability assessment resources that can help you when conducting a vulnerability assessment and other resources to help you locate basic information. The Exercise Workbook contains pages for you to take notes on the

course lessons, as well as the exercise worksheets and additional information you may need to complete the exercises. Make as many notes and marks in the manual and workbook as needed to assist you in creating an understanding of conducting a VA. The Answer Keys and Examples Booklet contains the exercise answer keys, two completed VA documentation examples, and a hybrid approach documentation example, and will be provided to you once all of the exercises have been completed (Lesson 7).

### Preview of Appendices

Appendix	Name	Page #
1	IA Rule and Summary	A1-1
2	FDA Key Activity Types (KAT) Report and KAT Descriptions	A2-1
3	Vulnerability Assessment Resources	A3-1
4	Technical Assistance and Resources	A4-1
5	VA Definitions, Acronyms, and Other Terms	A5-1

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Throughout this course, there are resources you may want to refer to in the back of the manual. Appendix 1 includes the codified text of the IA rule and a summary of the rule. Appendix 2 includes the KAT descriptions and KAT report. Appendix 3 has the worksheets from FDA’s guidance and other vulnerability assessment resources. Appendix 4 includes technical assistance and other resource information. There are many definitions that you need to understand, which can be found in Appendix 5.


## FSPCA Contact Information

**FSPCA Contact Information**

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If you have any questions,  
please contact the FSPCA at  
**fspca@iit.edu**  
or visit the FSPCA website at  
**http://www.iit.edu/ifsh/alliance**  
for resources on FSVP and information on FSPCA activities,  
including FSPCA's Technical Assistance Network, visit  
**https://www.ifsh.iit.edu/fspca/fspca-technical-assistance-  
network**

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If you have questions, you can contact the Food Safety Preventive Controls Alliance at FSPCA@iit.edu or visit the website at the address listed on the slide. This website has a number of training resources on the IA rule and FSPCA activities. Of course, FDA's website contains all the IA regulation and related documents at FDA.gov.

### Resources:

FDA's Technical Assistance Network (TAN) is available to answer regulatory or rule interpretation questions. TAN can be accessed at:  
<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>

FSPCA's Technical Assistance Network is available to answer scientific/technical questions:  
<https://www.ifsh.iit.edu/fspca/fspca-technical-assistance-network>

For more information about FSPCA, FSPCA's Technical Assistance Network and other resources see Appendix 4.

**Key Point:**

The examples in this course, including any worksheets or sample explanations, are for training purposes only. You may take a different approach to conducting a VA as long as the approach satisfies the rule requirements. We will cover more information on this topic in later lessons.

## Participant Course Agenda

The participant course agenda is intended to be covered as a 1-day (8 hour) course, which includes frequent opportunities for review and classroom exercises designed to provide learning opportunities to thoroughly understand conducting a VA. The time allotted to each section will vary based on the audience and level of familiarity with the IA rule and conducting a VA. A typical agenda appears on the next page.

Exercises and scenarios will keep you engaged and be helpful for the entire class by raising issues and questions that might not otherwise come up.

Please do not be shy about asking questions throughout the course. If you do not understand something, it is likely that others in the class do not as well. There will be an opportunity for questions at the end of each lesson but raise your hand to interrupt if a concept is fuzzy or you need clarification. To get the most out of this course, you will want to participate through sharing examples with others, marking up your manual, and asking questions.

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**AGENDA**

**Participants must attend the entire course to receive a certificate**

**Sign-in, Book Distribution, Coffee**

**Welcome, Introductions**

Preface Introduction to the *Conducting Vulnerability Assessments* Course

Lesson 1 An Overview of Food Defense Measures  
 Exercise: Identifying Food Defense Terms

Lesson 2 Vulnerability Assessment Preliminary Steps

**Break**

Lesson 3 Considering Inherent Characteristics  
 Exercise: Inherent Characteristics

Lesson 4 Considering an Inside Attacker

Lesson 5 Element 1: Evaluating Potential Public Health Impact  
 Exercise: Element 1: Calculating Potential Public Health Impact

**Lunch**

Lesson 6 Element 2: Evaluating the Degree of Physical Access to the Product, and Element 3: Evaluating the Ability of an Attacker to Successfully Contaminate the Product  
 Exercise: Element 2: Evaluating the Degree of Physical Access and Element 3: Evaluating the Ability of an Attacker to Successfully Contaminate the Product

**Break**

Lesson 7 Analyzing Results to Identify Actionable Process Steps  
 Exercise: Analyzing Results

Lesson 8 Applying the Hybrid Approach

**Questions, Closing Remarks, and Course Evaluations/Certificates**

**End of Course**

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# LESSON 1. Introduction to Vulnerability Assessments

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Food defense measures are the actions put in place to reduce or eliminate the potential for an intentional attack on our food supply. The first lesson in this training provides some background to review the concepts of intentional adulteration, food defense and the requirements of the FSMA rule, “Mitigation Strategies to Protect Food Against Intentional Adulteration” (21 CFR Part 121). As mentioned in the Preface, we call it the IA rule for short and will refer to it as the “IA rule” throughout this course.

**Goal:** Participants will be able to explain background information necessary to conduct a vulnerability assessment and the importance of food defense.

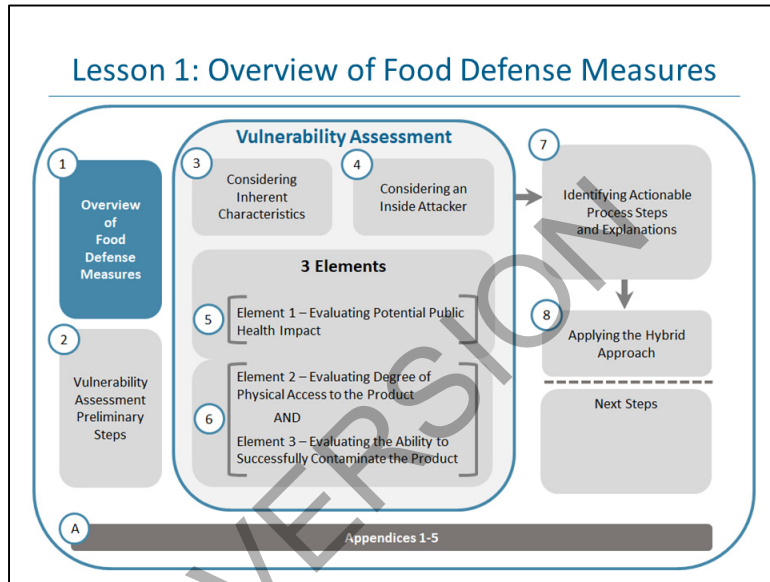
### **Learning Objectives:**

By the end of this lesson, participants will be able to:

1. Recognize CARVER + Shock method.
2. Explain Key Activity Types (KATs).
3. Define food defense.
4. Explain the general requirements of the intentional adulteration rule.
5. List the contents of a food defense plan.
6. Describe a vulnerability assessment.
7. Define significant vulnerability.
8. Define actionable process step.

9. Explain the vulnerability assessment requirements in the intentional adulteration rule.
10. Explain the training/qualifications required for a vulnerability assessment.

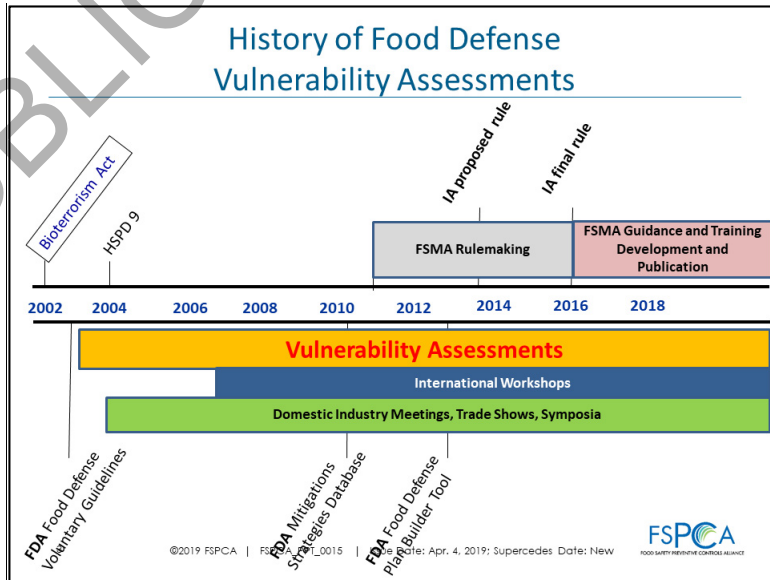
### Lesson 1: Overview of Food Defense Measures



### History of Food Defense Vulnerability Assessments

**Resources:**

For more information on the results from the FDA food defense vulnerability assessments, the *FDA Key Activity Types (KAT) Report* is available in Appendix 2 or can be accessed at the following link: <http://wayback.archive-it.org/7993/20170111073929/http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm347023.htm>



The U.S. Department of Health and Human Services, Food and Drug Administration (FDA) and the U.S. Department of Agriculture are the sector leads for Food and Agriculture in the United States. Homeland Security Presidential Directive #9 was signed by President Bush in

January of 2004 and instructed FDA, in partnership with other agencies, to determine the vulnerabilities that are present within the food system. In response to this directive, FDA and its partners conducted vulnerability assessments on a variety of food commodity systems, distributions and networks.

### Examples of Products Assessed

#### Examples of Products Assessed

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<ul style="list-style-type: none"> <li>• Animal feed</li> <li>• Apple juice</li> <li>• Baby food (jarred)</li> <li>• Bakery</li> <li>• Bottled water</li> <li>• Breaded fish &amp; RTE seafood</li> <li>• Breakfast cereal</li> <li>• Chocolate</li> <li>• Coffee shop</li> <li>• Concessions and catering</li> <li>• Deli salads</li> <li>• Export grain elevator - corn</li> <li>• Fast food restaurant</li> <li>• Flour</li> </ul>	<ul style="list-style-type: none"> <li>• Fluid milk</li> <li>• Frozen pizza</li> <li>• Grocery store - rotisserie chicken</li> <li>• High fructose corn syrup</li> <li>• Ice cream</li> <li>• Infant formula (powder)</li> <li>• Lettuce (bagged)</li> <li>• Pet food</li> <li>• Refrigerated food distribution - lettuce</li> <li>• Retail milk</li> <li>• Transportation (orange juice/milk)</li> <li>• Yogurt</li> </ul>
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Over the years FDA has conducted vulnerability assessments on a wide variety of commodities and systems.

### History of Food Defense Vulnerability Assessments (continued)

#### History of Food Defense Vulnerability Assessments (continued)

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- FDA’s VAs formed the foundation of FDA’s food defense program, including:
  - Food Defense Plan Builder
  - Food Defense Mitigation Strategies Database (FDMSD)
  - Other tools and resources
- FDA issued the IA Final Rule which identifies vulnerability assessments as a component of the required Food Defense Plan (issued May 2016)

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**Key Point:**

The Food Defense Plan Builder and Food Defense Mitigations Strategies Database can be found at <https://www.fda.gov/food/fooddefense/>

The vulnerability assessments that FDA conducted formed the foundational food defense programs that have been evolving since 2004. For example, the Food Defense Plan Builder is a user-friendly software program designed to assist owners and operators of food facilities with developing personalized food defense plans for their facilities. This user-friendly tool harnesses existing FDA tools, guidance, and resources for food defense into one single application. FDA's foundational food defense programs also included the identification of protective measures, otherwise known as mitigation strategies. The Food Defense Mitigation Strategies Database (FDMSD) is a tool designed to assist owners, operators or agents in charge of companies that produce, process, store, package, distribute, and/or transport food with identifying preventive measures to protect the food against intentional adulteration. These programs are the scientific underpinning of everything food defense related the FDA has done since, including the structure and design of the IA rule.

### What Is the CARVER + Shock Method?

#### Key Point:

The CARVER + Shock method was foundational for FDA's food defense vulnerability assessment program; however, it does not satisfy all of the vulnerability requirements of the IA rule.

#### What Is the "CARVER + Shock" Method?

- A method that simplifies and standardizes the process of evaluating a food operation's susceptibility to acts of IA
- The seven "CARVER + Shock" factors:
  - Assess different aspects of overall vulnerability
  - Provide a relative risk ranking for each processing step in a facility to qualify IA vulnerability

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FDA used the CARVER + Shock method to conduct its vulnerability assessments. CARVER + Shock provided a relative risk ranking of vulnerability within the system being analyzed. Knowing that all process steps have some underlying level of vulnerability associated with them, the CARVER + Shock method differentiated those vulnerabilities from those that are considered significant vulnerabilities.

## CARVER + Shock Method's Seven Factors

**CARVER + Shock Method's Seven Factors**

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1. **C**RITICALITY: Public health and economic impacts to achieve the attacker's intent
2. **A**CCESSIBILITY: Physical access to the food
3. **R**ECUPERABILITY: Ability of the system to recover from the attack
4. **V**ULNERABILITY: Ease of accomplishing the attack
5. **E**FFECT: Amount of direct loss from the attack
6. **R**ECOGNIZABILITY: Ease of identifying a process step  
+
7. **S**HOCK: Psychological effects of an attack

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The term “CARVER” is an acronym for seven different factors that are considered during the analysis. These factors attempt to understand different characteristics of the vulnerability at that process step. The ‘C’ stands for criticality, which is the public health and economic impact if someone were to contaminate the food at that step. The ‘A’ stands for accessibility, which deals with the physical access to the food at that step. The ‘R’ stands for recuperability, which is the ability of the system to recover from an attack. The ‘V’ stands for vulnerability, meaning how easy is it for someone to accomplish an attack at that step. The ‘E’ stands for effect, which is a larger macro-level analysis addressing the market loss associated with an attack. For example, would you still be able to go to the grocery store and buy that commodity on the shelf or would it then be in short supply? The second ‘R’ stands for recognizability, which examines how easy it is to identify a process step, how easy it is to understand how to attack that step, and what strategies would be needed to successfully contaminate the food at that step. In addition to the CARVER acronym, the word “Shock” addresses society’s psychological response to an attack.

## CARVER + Shock Method's Factors Used in the IA Rule

**CARVER + Shock Method's Factors  
Used in the IA Rule**

---

1. **CRITICALITY:** Public health and economic impacts to achieve the attacker's intent
2. **ACCESSIBILITY:** Physical access to the food
3. **RECUPERABILITY:** Ability of the system to recover from the attack
4. **VULNERABILITY:** Ease of accomplishing the attack
5. **EFFECT:** Amount of direct loss from the attack
6. **RECOGNIZABILITY:** Ease of identifying a process step  
+
7. **SHOCK:** Psychological effects of an attack

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The FDA-conducted vulnerability assessments resulted in classified reports of the vulnerabilities that FDA identified. Classified means that FDA is unable to share the reports with people who don't have the appropriate security clearance and a need to know the information. Because of this, FDA was limited in how it could convey the lessons learned to stakeholders. To address this, FDA did an assessment to find out what the CARVER + Shock methodology had revealed about common vulnerabilities in the food system to ascertain what information could be shared with industry and other stakeholders. FDA found that three factors of the assessment were the main contributors to the vulnerability at process steps. Those three factors were criticality, accessibility, and vulnerability. For example, if one process step had a score of 16 and one process step had a score of 32, FDA found that the differentiation between those scores were primarily found in the scoring of these three factors. These three factors are also where facilities can exercise active control to mitigate the significant vulnerabilities. Fortunately, where FDA found the driving forces of vulnerability are also where facilities can make decisions and take actions to mitigate those vulnerabilities.



## Lessons Learned: CARVER + Shock's Three Factors and the Three Fundamental Elements

**Lessons Learned: CARVER + Shock's Three Factors and the Three Fundamental Elements**

- What was learned has been incorporated into the IA rule requirements and translates to the required three elements of the VA in the IA rule

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### Key Point:

Reminder- the IA rule vulnerability assessment must include an evaluation of the potential public health impact (e.g., severity and scale) if a contaminant were added (Element 1); the degree of physical access to the product (Element 2) and the ability of an attacker to successfully contaminate the product (Element 3) (21 CFR 121.130(a)).

The IA rule builds on these findings to set minimum standards for how facilities are required to conduct vulnerability assessments. The three driving factors of vulnerability determined by the CARVER + Shock assessment are now the three fundamental elements of a VA and these elements must be considered in a VA conducted under the IA rule. Element 1 maps directly to criticality, Element 2 maps to accessibility and Element 3 maps directly to the vulnerability factor.

## Lessons Learned: Processing Steps and Common Vulnerabilities

**Lessons Learned: Processing Steps and Common Vulnerabilities**

- Statistical evaluation of FDA's VA program also showed:
  - Certain processing steps repeatedly ranked high across VAs, regardless of the food product
  - Common vulnerabilities can be organized into generalized activity groups (i.e., Key Activity Types)

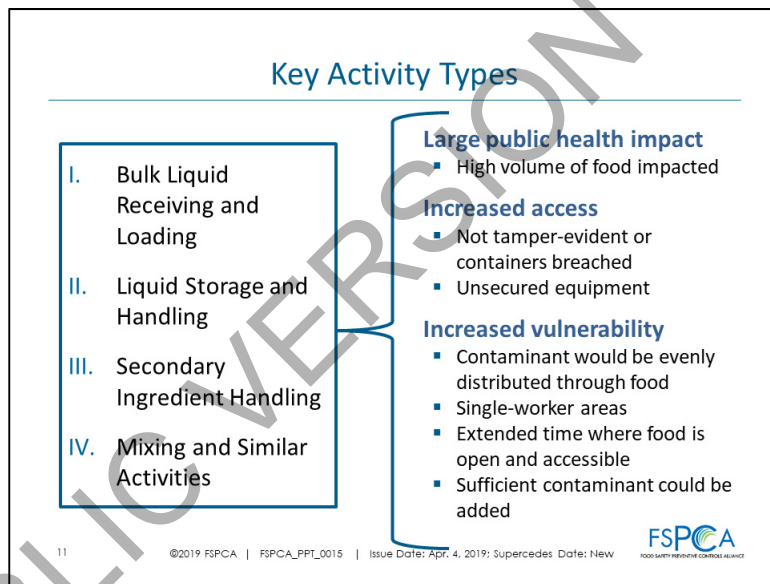
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Armed with hundreds of pages of data on vulnerability in the food system, FDA began a statistical evaluation across a wide variety of food processes to determine if there were characteristics or commonalities in the food system where conditions exist that elevate vulnerability, and if these conditions were consistent across various food processing environments. This analysis concluded that process steps that consistently rank high in vulnerability can generally be classified into certain groups of activities. These are called Key Activity Types.

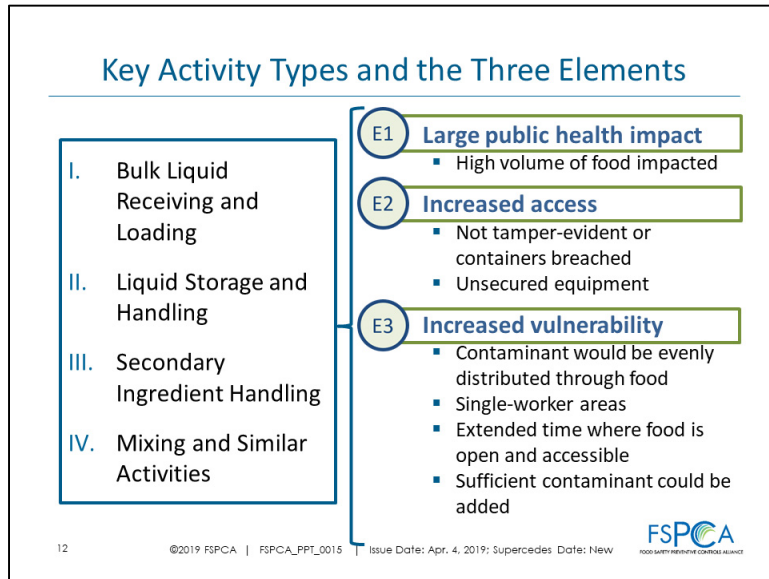
### Key Activity Types

**Resources:**  
 For a description of the KATs, please see KAT Descriptions, located in Appendix 2 of this manual, as well as FDA guidance.



The four Key Activity Types identified are: 1) Bulk liquid receiving and loading, 2) Liquid storage and handling, 3) Secondary ingredient handling, and 4) Mixing and similar activities. The process steps where these activities were taking place consistently ranked high in the various vulnerability assessments performed. When analyzing the individual process steps and evaluating the notes that were captured during these VAs, these activities most commonly exhibited conditions that were indicative of elevated vulnerability.

## Key Activity Types and the Three Elements



One commonality was a high volume of food being produced at that step leading to a large public health impact if an attack were to happen at that step. Also, these steps commonly had increased accessibility, like open vats or extended times where food is accessible. And lastly, there was increased vulnerability at these steps either due to low human observation, the presence of mixing or agitation, and the ease with which an attacker could add sufficient agent without being caught in the act. Again, these three categories link back to the three elements required for a VA in the IA rule.

## Introduction to Intentional Adulteration

### Introduction to Intentional Adulteration

- Intentional adulteration is 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.
- FDA issued a final regulation, Mitigation Strategies to Protect Food Against Intentional Adulteration (21 CFR Part 121), which requires covered facilities to identify and protect their most vulnerable points against intentional adulteration.

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Intentional adulteration is 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. There is a distinction here between our classical understanding of food safety and unintentional contamination versus the deliberate acts of an intentional adulteration. The Food Safety Modernization Act, which President Obama signed in 2011, directed FDA to promulgate a regulation that dealt with preventing intentional adulteration. FDA issued a proposed rule in December of 2013 and received public comment back on that proposed rule. A final rule was issued in May of 2016 entitled “Mitigation Strategies to Protect Food Against Intentional Adulteration.” The focus of the IA rule is to prevent acts of intentional adulteration. Acts of disgruntled employees, consumers, and competitors are generally intended to attack the reputation of a company, and economically motivated adulteration (EMA) is intended to obtain economic gain. In the spectrum of risk associated with intentional adulteration of food, attacks intended to cause wide scale public health harm to humans are ranked as the highest risk. Therefore, the IA rule is focused on addressing those acts and not acts of disgruntled employees, consumers, or competitors, or acts of EMA.


## Food Defense Definition

**Food Defense Definition**

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**Definition: Food Defense**  
 The effort to protect food from intentional acts of adulteration where there is an intent to cause wide scale public health harm. (21 CFR 121.3)

- Efforts include measures taken to reduce or eliminate the possibility that an intentional adulteration event would occur

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In the context of intentional adulteration, the term food defense has been established and used for many years. The IA rule defines food defense as “those efforts to protect food from intentional acts of adulteration where the intent is to cause wide scale public health harm.” Food defense measures include various efforts that can be put in place to protect food from intentional adulteration, but this course will focus on the general requirements of the IA rule and specifically the requirement for facilities to conduct a vulnerability assessment.

## Why is the IA Rule so Important?

Why is the IA Rule so Important?

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- Intentional adulteration has the potential to cause:

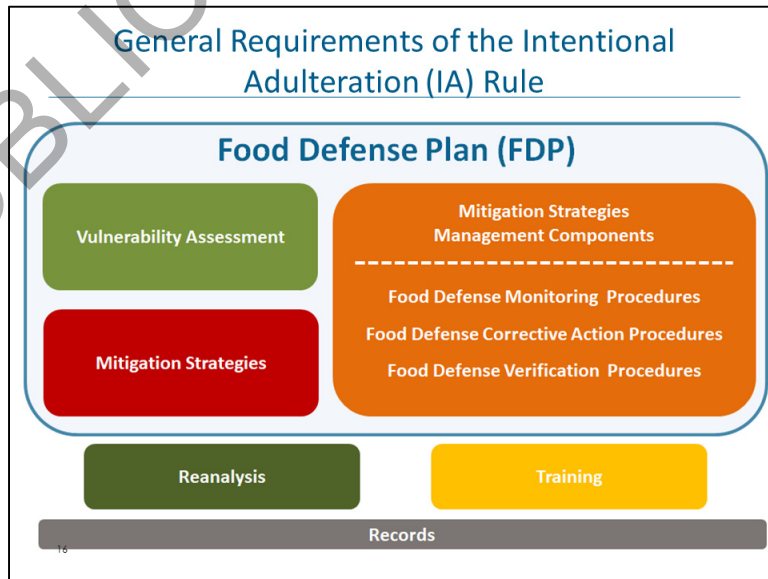
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In the following lessons, specific exercises will help you understand the potential public health consequences of an intentional adulteration event. As seen with food safety outbreaks, the economic impact on a food company can be devastating from a single event.

## General Requirements of the Intentional Adulteration (IA) Rule

**📖 Resources:**

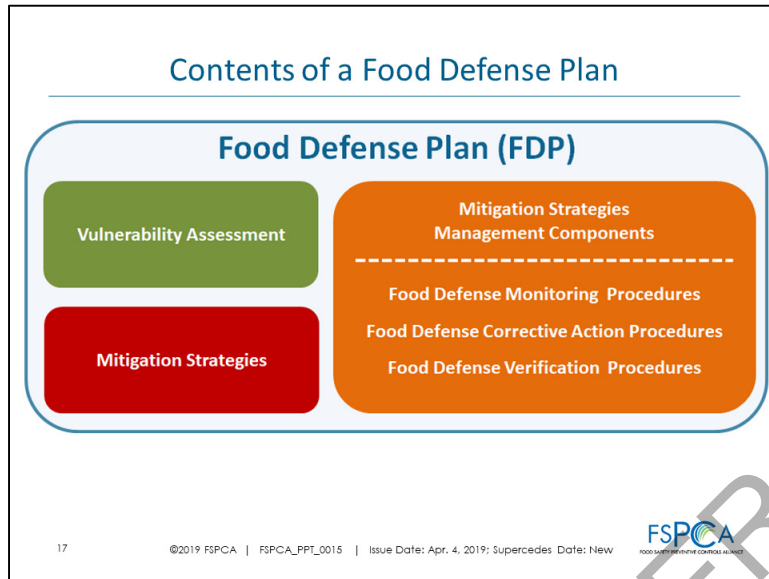
The full text of the IA rule can be found in Appendix 1, which includes a definitions section (21 CFR 121.3).



The general requirements of the IA rule include the development of a food defense plan, general and targeted training requirements based on an individual's food defense responsibilities, recordkeeping requirements, and food defense plan reanalysis requirements. This course will not cover recordkeeping or reanalysis requirements in

detail but will explain those requirements as they pertain to the vulnerability assessment.

## Contents of a Food Defense Plan



A food defense plan must contain a vulnerability assessment to identify actionable process steps, which leads to the identification and explanation of mitigation strategies. The next three requirements start to look a lot like common food safety systems such as hazard analysis and critical control point (HACCP) or preventive controls including monitoring, corrective actions and verification procedures—what we refer to as management components. These management components as required in the IA rule have some distinct differences from how they are typically used in food safety systems, which is why they are termed food defense monitoring, food defense corrective actions, and food defense verification. The focus of the course today will be on the vulnerability assessment (VA) requirement.

## Vulnerability Assessment Requirements

**Vulnerability Assessment Requirements**

**What are the Vulnerability Assessment Requirements?**

See 121.130 in Appendix 1

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The IA rule requires that the VA, at a minimum, must consider for each point, step, or procedure what are termed the three fundamental elements. Element 1 is the potential public health impact if a contaminant were successfully added to the product at that step. Element 2 is the degree of physical access to the product at that step. Element 3 is the ability of an attacker to successfully contaminate the product at that step. In other words, if an attacker has already reached the product, how easy would it be for that individual to contaminate the food. This course will go over each of the three elements in detail.

You must conduct a vulnerability assessment for each type of food produced at your facility. The results of the VA must be documented in the food defense plan.

Each point, step, or procedures requires an explanation for why it was or was not identified as an actionable process step. The explanations will link back to the scores documented for each of the three elements (public health impact, accessibility, and ability to successfully contaminate the product) and will describe how you arrived at those scores. How to score each element will be discussed in later modules. For now, it is important to realize that these explanations are very important for describing why a step is or is not significantly vulnerable and will be useful for identifying mitigation strategies that will address the reasons why the step is significantly vulnerable. The VA is not only conducted so that you are aware of where your significantly vulnerabilities exist, but so you can determine how best to protect the food at these points. The explanations are crucial to determine the best strategies for protection. These explanations will also help when your VA needs to be updated or re-evaluated to satisfy any food defense plan reanalysis requirements because the



explanations provide baseline knowledge about how the step was vulnerable and any changes to that point, step, or procedure can be compared to the original assessment and updated to capture the new state of vulnerability.

## What Is a Vulnerability Assessment?

### What Is a Vulnerability Assessment?

- A vulnerability assessment (VA) is a systematic assessment of points, steps or procedures to identify and rank vulnerabilities to intentional adulteration
- A point, step, or procedure is an activity related to manufacturing, processing, packing, or holding of a food product

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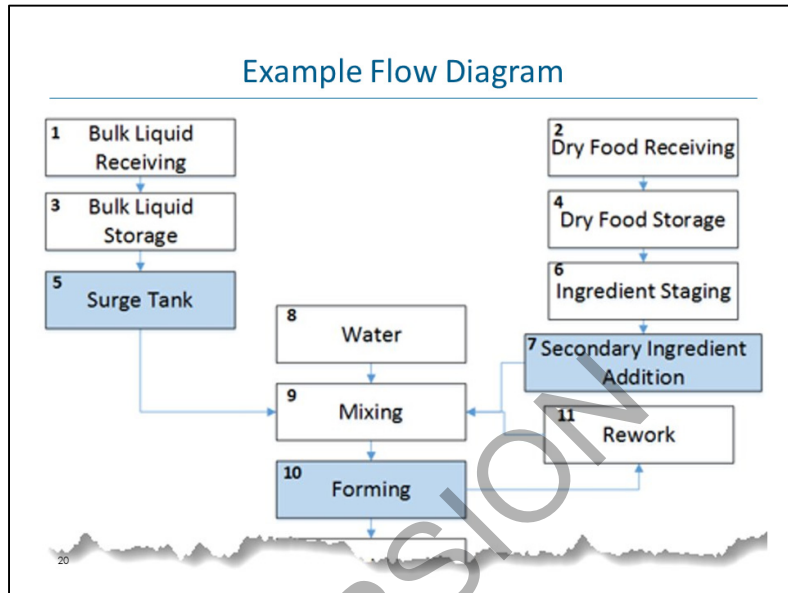
### Key Point:

Points, steps, or procedures do not include businesses processes or other procedures that are not part of your food operation.

A vulnerability assessment is a systematic assessment of points, steps or procedures to identify and rank vulnerabilities to intentional adulteration. It is a prioritization mechanism that differentiates vulnerabilities from significant vulnerabilities. This prioritization allows facilities to focus resources at those points, steps, or procedures that are determined to have the highest risk for intentional adulteration.

A point, step, or procedure is an activity related to manufacturing, processing, packing, or holding of a food product. The VA does not include an assessment of points, steps, or procedures that are not directly related to the production of food, for example, mail handling procedures, human resources procedures, emergency evacuation procedures, utilities, etc.

### Example Flow Diagram



All the steps seen on this flow diagram should be considered in doing your VA. We will be focusing on three specific steps in future exercises (those highlighted in the slide above).

### Significant Vulnerabilities

#### Significant Vulnerabilities

- The goal of the VA is to identify those points at highest risk by distinguishing *vulnerabilities* from *significant vulnerabilities* and identifying actionable process steps (APSs)

**What are Significant Vulnerabilities?**

See 121.3 in Appendix 1

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100 years of history. One food. One mission.

Most process steps have some level of vulnerability associated with them, but the goal of the VA is to distinguish which vulnerabilities would be characterized as “significant vulnerabilities.” A significant vulnerability is defined as a vulnerability in a food process that, if exploited, could be expected to cause wide scale public health harm.

Each point, step, or procedure in your food process will be evaluated to assess its vulnerability score, and then process steps will be ranked to determine which have significant vulnerabilities and would be identified as actionable process steps.

### Actionable Process Step (APS) Definition

Actionable Process Step (APS)


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What is an Actionable Process Step?

See 121.3 in Appendix 1

- APSs are points that are considered most vulnerable to intentional adulteration

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An actionable process step is defined as 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. Actionable process steps are the steps in your facility that would be considered the most vulnerable to intentional adulteration and therefore will need mitigation strategies to reduce or eliminate the significant vulnerability.

## Training/Qualifications Required to Perform a Vulnerability Assessment


### Training/Qualifications Required to Perform a Vulnerability Assessment

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**Definition: Qualified Individual**

A person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required . . . as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment. (21 CFR 121.3)

- Individuals conducting or overseeing the conduct of a VA must:
  - Be a “qualified individual” and
  - Successfully complete training equivalent to a standardized curriculum recognized as adequate FDA, or be otherwise qualified through job experience
    - **This course satisfies this training requirement**

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As mentioned in the Preface, there are specific training and qualification requirements in order to conduct or oversee the conduct of the vulnerability assessment. A qualified individual as defined in the IA rule is a person who has the education, training, or experience (or combination thereof) necessary to perform an activity as appropriate to the individuals assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment. In addition to being a qualified individual, the individual must also complete training that is considered equivalent to the standardized curriculum recognized as adequate by FDA, or be otherwise qualified through job experience. This course satisfies that training requirement.

## Lesson 1: Questions


Lesson 1: Questions

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**Thank you for your attention**

**Questions?**

**Next:** Identifying Food Defense Terms Exercise

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If you have any questions regarding the concepts we just went over, feel free to ask them.

## Lesson 1 Exercise: Identifying Food Defense Terms

Lesson 1 Exercise: Identifying Food Defense Terms

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- Total time: 10 minutes
  - Complete the worksheet: 5 minutes
  - Facilitated review/discussion: 5 minutes
- Instructions:
  - Take 5 minutes to complete the Identifying Food Defense Terms Worksheet (see Exercise Workbook, page 3)
  - Read the food defense terms in the left column of the worksheet and the definitions in the right column of the worksheet.
  - Draw a line to connect each term with its definition. There is only one answer per term.
  - When everyone has completed the worksheet, the Instructor will facilitate a 5-minute review/discussion.

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The Identifying Food Defense Terms worksheet is in the Exercise Workbook (see page 3). The Instructor will review the instructions and then you can complete the exercise. Once everyone has completed the worksheet, the instructor will facilitate a short review/discussion.

PUBLIC VERSION

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PUBLIC VERSION

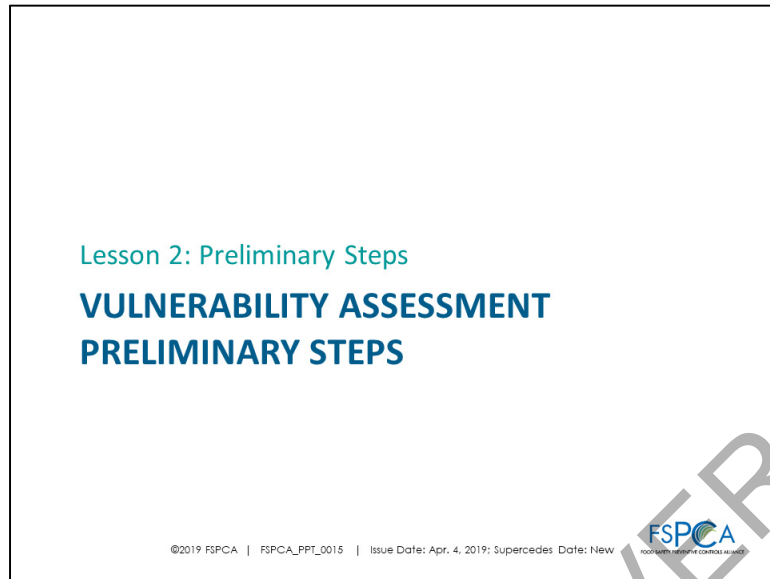
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PUBLIC VERSION



# LESSON 2. Vulnerability Assessment Preliminary Steps

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This lesson provides ideas for some preliminary steps that will help you prepare for your vulnerability assessment. The items in this lesson are not required by the IA rule but are useful when you're preparing for and organizing your vulnerability assessment.

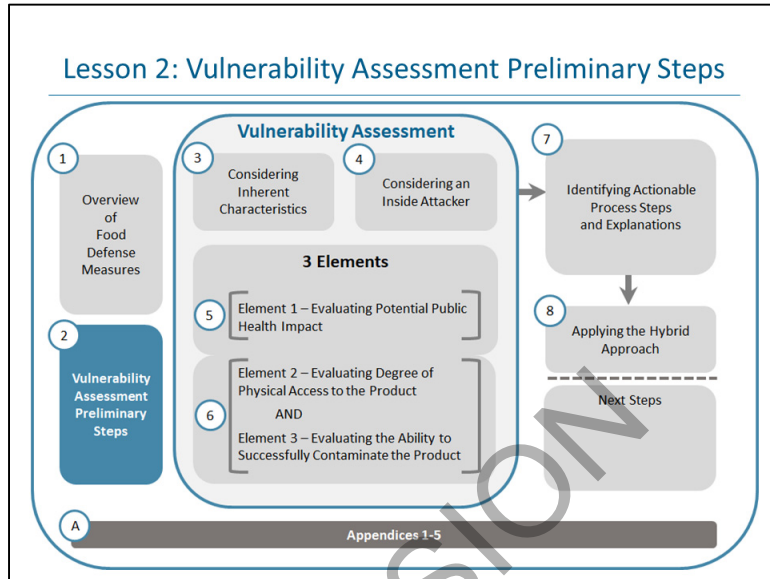
**Goal:** Participants will be able to explain vulnerability assessment preliminary steps.

**Learning Objectives:**

By the end of this lesson, participants will be able to:

1. Group similar processes.
2. Identify a food defense team.
3. Describe product under evaluation.
4. Identify a process flow diagram.
5. Describe process steps under evaluation.

## Lesson 2: Vulnerability Assessment Preliminary Steps



### Preliminary Steps to Conducting a VA

**Key Point:**

The preliminary steps are not required, but useful steps to prepare for your VA, and most of these items probably exist in your facility for other purposes such as your food safety plan or your Hazard Analysis and Critical Control Point (HACCP) plan.

#### Preliminary Steps to Conducting a VA

- Preliminary steps are not required, but may be useful
- Gather information about products, processes, and operations prior to starting the development of the FDP to facilitate efficiency and organization
- Preliminary steps include:
  - Assembling a food defense team
  - Describing the product
  - Developing a process flow diagram
  - Describing the process steps
- Some of these items may already exist at your facility



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The purpose of these preliminary steps is to gather as much information about the products, processes, and operations as possible prior to starting the VA. A thorough understanding of the food operation you are evaluating facilitates efficiency and organization during the assessment. Preliminary steps can include many things, but the ones that are most useful are:

1. Assembling a food defense team;
2. Describing the product under evaluation;

3. Developing, or in most cases identifying, a process flow diagram that have your production processes; and
4. Describing the process steps under evaluation.

These are not required, but useful steps to prepare for your VA, and most of these items probably exist in your facility for other purposes such as your food safety plan or your Hazard Analysis Critical Control Point (HACCP) plan.

### Grouping Similar Processes

#### Grouping Similar Processes

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- Similar or like products using similar processes within one facility can be grouped and assessed together
  - Identify any differences between grouped products

**Examples**

- Different flavored fruit juices using the same processing line
- Cereals of different flavors using similar processes
- Yogurts with different inclusions (e.g., strawberries, blueberries)
- Multiple production lines in the same environment using the same types of equipment

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It can be beneficial to consider how like products can be grouped together before moving into the preliminary steps. The IA rule preamble states that like products that use similar processes can be grouped and assessed together as one group. If there are any differences in the products or processes these identified differences should be noted and evaluated. Examples of products that could be grouped include different flavored fruit juices that use the same processing line but have a variety of flavors. Another example would be if you are processing yogurts that have different inclusions such as strawberries or blueberries, or cereals with and without marshmallows. There is no reason for you to conduct multiple separate VAs if you are manufacturing several products that only have minor variations in their process operation. These like products using similar processes can be grouped together into one vulnerability assessment as long as any differences in the process flow are assessed and documented as well.

## Step 1. Assemble a Food Defense Team

### Step 1. Assemble a Food Defense Team

- A food defense qualified individual is required to conduct a vulnerability assessment
- Facilities have the option to build a multidisciplinary food defense team



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The first recommendation for preliminary steps is to assemble a food defense team. Your vulnerability assessment must be conducted by a food defense qualified individual, but it is recommended to include members from various areas of your facility on your food defense team. A multi-disciplinary team of individuals assessing the vulnerabilities helps ensure appropriate technical knowledge contributed to the assessment and reduces the risk of missing key information.

## Step 1. Assemble a Food Defense Team (continued)

### Step 1. Assemble a Food Defense Team (continued)

- Team approach:
  - Helps identify key food defense considerations
  - Encourages ownership of the plan
- Individuals with different specialties and experiences:
  - Provide knowledge of daily operations
  - Include quality assurance (QA), production, maintenance, security, etc., as applicable



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Including individuals with different specialties and experiences such as QA, maintenance, security, etc., provides your assessment with diverse knowledge of the daily operations of the facility and different perspectives with respect to vulnerability.

## Step 2. Describe Product Under Evaluation

### Step 2. Describe Product Under Evaluation

- Check to see if product descriptions already exist at your facility
- Descriptions could include:
  - Product name
  - Product description
  - Ingredients
  - Intended use
  - Intended consumers
  - Storage and distribution
  - Serving size
  - Any other details that may be helpful for understanding the product
- One product description can be used for products that are similar in nature or use the same or similar equipment, as long as variations are noted

Product Name(s)	Almond, Cranberry Energy Bar
Product Description, including Important Food Safety Characteristics	This product is a ready to eat energy bar packed in a pouch for package retailing. The low water activity makes the product shelf stable. Processing involves dry mixing and forming with no process lethality step.
Ingredients	Water activity <0.05 Corn syrup, blanched/roasted almonds, crisped rice, dried cranberries, vanilla oil, pear release agent (oil lecithin), vitamins and mineral premix
Packaging Used	Individual polyethylene film, individual retail package with label
Intended Use	Ready-to-eat bars
Intended Consumers	General consumption
Shelf Life	One year
Labeling Instructions	None
Storage and Distribution	Ambient, not to exceed 90°F

Source: Food Safety Preventive Controls Alliance (FSPCA), Product Description for illustrative purposes only.

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**Key Point:**

Serving size may not be part of your existing descriptions of your food products but can be helpful in determining the score for Element 1: Evaluating potential public health impact.

The second step is to describe the product under evaluation. You probably already have product descriptions that exist at your facility, and you can leverage your existing documents as much as possible. Product descriptions could include the product name, ingredients, finished product serving size, storage and distribution practices, or any other details that may be helpful for understanding the nature of the product. If some of the products that you manufacture are similar, you do not need to have individual product descriptions. For example, if you manufacture products that are essentially the same constitution with just some variations in ingredients or additives, one product description could be written for those products and the variations, such as different flavors, could be added to the description.

### Step 3. Develop a Process Flow Diagram

#### Step 3. Develop a Process Flow Diagram

- Flow diagrams provide a clear, simple description of the steps involved in the processing of your food product (or grouped products) in their respective order
  - Include all the process steps within the facility's control
  - Include reworked product, by-product, and diverted product, if applicable
- Process flow diagrams may already exist at your facility

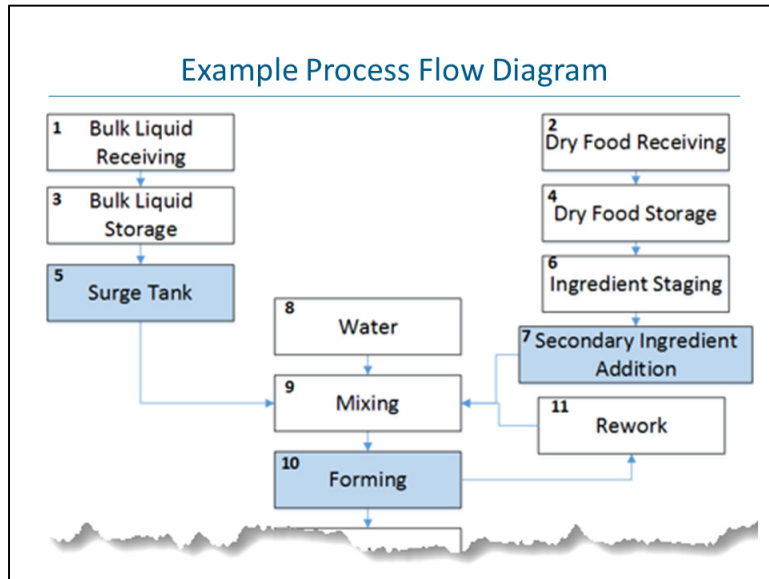
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The third recommended step is to develop a process flow diagram or use one that you already have at your facility. Flow diagrams are helpful because they provide a clear, simple, organized diagram of the steps involved in the process in the appropriate order. Visualizing the flow is important for understanding potential vulnerabilities. A process flow diagram should include all of the process steps within the facility that are part of the food processing operation from receiving to storage and distribution, including reworked product, diverted product, etc. You do not need to include in your VA processes that are not part of the food operation, such as mail handling procedures, human resources procedures, utilities, and processing aids that do not come in contact with or are not incorporated into the food.

### Example Process Flow Diagram




**Resources:**  
 There is a full-page version of the Example Process Flow Diagram in the Exercise workbook, page 9.

Here is an example of part of a process flow diagram. This particular process flow diagram will be used throughout the course as a tool to assist you with learning how to conduct a vulnerability assessment. The flow diagram depicts a fictional food that does not represent any actual food on the market, but the process flow may be similar to some processes at your facility. You may want to walk the production floor to verify the steps in your flow diagram.

### Step 4. Describe Process Steps Under Evaluation

**Step 4. Describe Process Steps Under Evaluation**

- Process descriptions explain what happens at each point, step, or procedure
- Process step descriptions may be helpful when:
  - Identifying mitigation strategies, and
  - developing mitigation strategy management component procedures
- Leverage existing documents

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The fourth preliminary step recommended is to describe the process steps under evaluation. Process step descriptions provide details

about what happens at each point, step, or procedure under evaluation. These descriptions contain more detail than the process flow diagram, such as how many people are at the step when it is operating, what equipment is used during this operation, what is the nature of the food at this step, how it is handled, etc. Describing the process helps to identify attributes that you may need to consider during your vulnerability assessment, including inherent characteristics. A process step description is useful in the vulnerability assessment because it informs your scoring of the three elements at the step. A process step description can also be helpful later when considering, identifying, and explaining mitigation strategies for actionable process steps. Other documents at your facility may be used in place of a process description such as a recipes or work instructions. You may find that those existing documents are sufficient as is, or you may decide to add more detail for the purposes of informing your VA.

**Lesson 2: Questions**

Lesson 2: Questions

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**Thank you for your attention**

Questions?

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If you have any questions regarding the concepts we just went over, feel free to ask them.

**Notes:**

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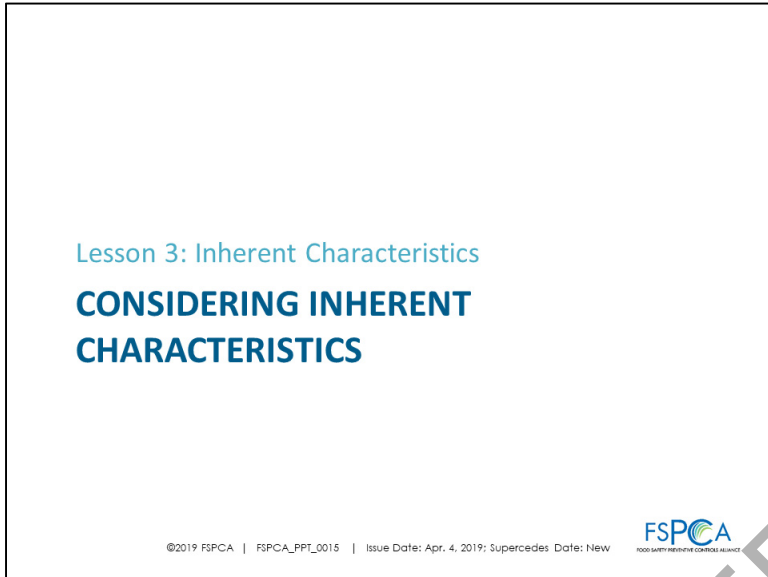
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# LESSON 3. Inherent Characteristics

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By the end of this lesson you will be able to explain inherent characteristics and activities that are not inherent and differentiate between those two concepts.

**Goal:** Participants will be able to explain inherent characteristics.

**Learning Objectives:**

By the end of this lesson, participants will be able to:

1. Explain inherent characteristics.
2. Explain activities that are not inherent.
3. Differentiate between inherent characteristics and those that are not inherent.




into the equipment or part of the process step environment and operation. For these reasons, inherent characteristics may have an impact on vulnerability at that step and should be considered when performing a vulnerability assessment.

### Inherent Characteristics: Examples

#### Inherent Characteristics: Examples

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- Required presence of employees in the immediate area
- Design of the room
- Type and nature of equipment used
- Nature of the processing
- Nature of the food being processed
- Equipment safety features

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**Key Point:**

This is not an exhaustive list of inherent characteristics.

Inherent characteristics may include the required presence of employees in the immediate area, the design of the room, the location and type of equipment used, the nature of the processing, the nature of the food being processed, and equipment safety features. Let's take some time to look at these examples in more detail.

## Inherent Characteristics: Examples (continued)

### Inherent Characteristics: Examples (continued)

- Required presence of employees in the immediate area:
  - A process step that can function **only** when there are multiple people 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
  - 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



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The presence of employees at a process step can be an inherent characteristic in some instances. One example of this scenario is a process step that would require two workers for the process step to properly function. For example, if you need two people to align product before it goes into a piece of equipment and if two people weren't present the equipment will jam, that would be considered inherent to that process step. By contrast, this would not be an inherent characteristic if there is a policy for two workers to be at a step, but the step could function if one worker stepped away or was absent. A second example of an inherent characteristic would be if a step requires two workers to perform specific functions at the same step, and if one those workers were absent, then the line would stop completely because the product was not able to continue to be processed.

## Inherent Characteristics: Examples (continued)

### Inherent Characteristics: Examples (continued)

- Type and nature of equipment used:
  - 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
  - A process step that is pressurized so that access would result in noticeable ejection of the food or cause bodily harm



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Sometimes the type or nature of the equipment is an inherent characteristic. For example, your facility may use a pasteurizer that is completely enclosed and if it were opened, the pasteurization would stop and would be easily noticed by other workers. Another example is if your facility has a liquid food storage tank that is pressurized. Access to that tank would be very difficult, and the liquid food would be ejected from the tank if it were accessed.

## Inherent Characteristics: Examples (continued)

### Inherent Characteristics: Examples (continued)

- Nature of the processing:
  - 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)
  - 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



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The nature of the processing itself may be an inherent characteristic. For example, if your product was on a very fast-moving belt, it would be

difficult for an attacker to stand at that belt and add enough contaminant to cause wide scale public health harm. Another example is if you have a final product being conveyed to another location for packaging, addition of a contaminant at that step would not be mixed into other product and would not cause wide scale public health harm.

### Inherent Characteristics: Examples (continued)

#### Inherent Characteristics: Examples (continued)

- Nature of the food being processed:
  - Whether the food is solid or liquid



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Sometimes the nature of the food itself help inform inherent characteristics at specific processing steps. Liquid foods may have a higher vulnerability than solid foods to intentional adulteration because they may be more likely to be agitated or mixed, which would effectively mix a contaminant into the food if it were added.



## Examples of Practices That Are Not Inherent Characteristics, But Could Be Existing Measures

### Examples of Practices That Are Not Inherent Characteristics, But Could Be Used as Mitigation Strategies

- Positioning a person of specific seniority or experience at a particular process step for quality reasons
- Preventing delivery drivers from entering the facility
- Requiring workers in specific areas or with specific responsibilities to wear specially colored uniforms or caps
- Reviewing shipping documentation and verifying the presence of seals on transport conveyances

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Some points, steps or procedures have practices that are put in place for one reason or another but are not inherent to the operation of that process step. These existing measures may be something that you put in place for quality control reasons, worker safety, asset or inventory control, or other reasons, but they are not built into the equipment. An existing measure requires you to make a decision to implement that measure and continue to do so on an ongoing basis. The process step could technically function without the existing measure and therefore may be altered or changed more frequently than an inherent characteristic. These measures may or may not have practices in place to ensure their implementation.

Existing measures shouldn't be considered for their effect on the vulnerability at that step, because of their non-inherent nature. These existing measures are better evaluated when identifying and explaining mitigation strategies because these measures may provide a level of protection against intentional adulteration and therefore may be used as mitigation strategies. The training designed for individuals responsible for identifying and explaining mitigation strategies goes into this concept in much more detail. This training does not qualify you to identify and explain mitigation strategies, but it is important for you to understand the ways in which inherent characteristics and existing measures are considered.

One example of a practice that is not an inherent characteristic is the practice of positioning a person of specific seniority or experience at a particular process step for quality reasons. The process would continue to operate if someone with less seniority is placed at that process step, therefore it would not be an inherent characteristic. Another example is

the practice of preventing delivery drivers from entering the facility. This is a facility policy decision that has no bearing on the proper functioning of process steps. There are ways that this practice could serve as a potential mitigation strategy. Another example is if a facility institutes procedures for reviewing shipping documentation and verifying the presence of seals on incoming product as a matter of routine good manufacturing processes (GMPs). This practice would also be considered as an existing measure rather than an inherent characteristic and could potentially be used as part of a mitigation strategy.

In summary, inherent characteristics are considered during a VA because they are so integral to a process step's operation that they should be part of the nature of the vulnerability at that process step that you are assessing. Existing measures can be identified during the VA, but they shouldn't be evaluated in your scoring of vulnerability because they could potentially change or be altered, resulting in a change in the nature of the vulnerability at that step. Existing measures are more appropriate for consideration when identifying and explaining mitigation strategies, because if they are providing a level of protection then they may be written into the food defense plan as mitigation strategies and would require management component procedures to ensure they are consistently implemented and providing the protection intended.

### Lesson 3: Questions


Lesson 3: Questions

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**Thank you for your attention**

**Questions?**

**Next: Inherent Characteristics Exercise**

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If you have any questions regarding the concepts we just went over, feel free to ask them. Next, we are going to complete the Inherent Characteristics Exercise.

## Lesson 3 Exercise: Inherent Characteristics

### Lesson 3 Exercise: Inherent Characteristics

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- Total time: 15 minutes
  - Complete the worksheet: 5 minutes
  - Facilitated review/discussion: 10 minutes
- Instructions:
  - Take 5 minutes to complete the Inherent Characteristics Worksheet (see Exercise Workbook, page 5)
  - Read the description of the activity or procedure written in the left column
  - Use a check mark to indicate whether you think the activity or procedure would be considered an "inherent characteristic" or not
  - When everyone has completed the worksheet, the instructor will facilitate a 10-minute review/discussion

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The Inherent Characteristics Worksheet is in the Exercise Workbook (see page 5). The instructor will review the instructions and then you can complete the worksheet. Once everyone has completed the worksheet, the instructor will facilitate a short review/discussion.

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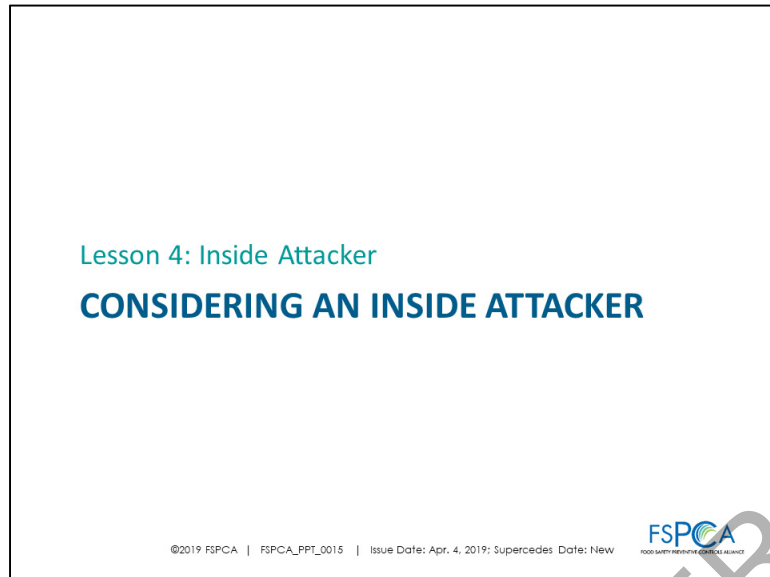
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# LESSON 4. Inside Attacker

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Prior to going into detail of the three elements required in the VA, it is important to discuss the overarching consideration of the inside attacker.

**Goal:** Participants will be able to recognize the importance of considering an inside attacker during a VA.

**Learning Objectives:**

By the end of this lesson, participants will be able to:

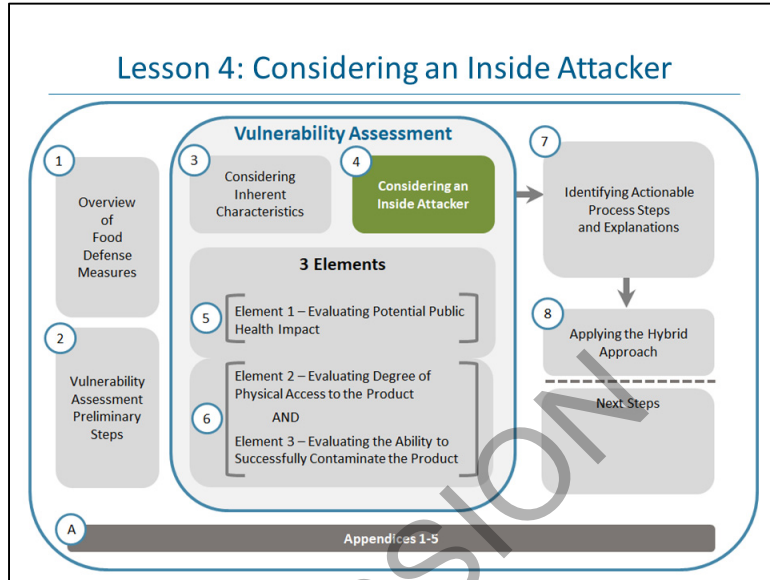
1. Describe an inside attacker.
2. Recognize the importance of considering an inside attacker during a VA.

## Lesson 4: Considering an Inside Attacker

**Key Point:**

Remember, the three elements are:

1. Element 1: Potential Public Health Impact,
2. Element 2: Degree of Physical Access to the Product, and
3. Element 3: The Ability of an Attacker to Successfully Contaminate the Product.



## Considering an Inside Attacker

**Considering an Inside Attacker**

**Vulnerability assessments must consider the possibility of an inside attacker (21 CFR 121.130(b))**

- You should think of the possibility of an inside attacker as an overarching principle that:
  - Informs the decision-making for the evaluation of each of the 3 required elements of a VA, and
  - Is NOT a separate decision point

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The concept of an inside attacker is an overarching principle that must be considered during the conduct of a vulnerability assessment, but the way an inside attacker could affect the vulnerability can change from process step to process step.

When thinking through the possibility of an insider attacker, you should 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), but also consider the ability



of these individuals to move freely throughout the facility, and the personnel in the area around each point, step, or procedure (e.g., multiple workers in a well trafficked area or a single worker in an isolated area) being evaluated. If a process step is generally accessible to any person working in 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. When considering an inside attacker at an isolated or single worker area, including those who have responsibilities associated with the process step (i.e., are stationed at the process step as a part of their job function), you should include these individuals as potential inside attackers. If your VA determines that a significant vulnerability is present when these individuals are potential inside attackers, then you should identify these area as Actionable Process Steps and then identify mitigation strategies.

The possibility of an inside attacker will factor into each of the three required elements of the VA but will have particular influence over Element 2 when you are evaluating accessibility, and Element 3 when you are determining the ability of an attacker to successfully contaminate the product.

The concept of an inside attacker helps to eliminate the thinking that just because you locked your exterior doors and have security at the front of the building that you don't have any vulnerabilities. You must consider the possibility that an inside attacker could be at that process step under evaluation.

### Why Must an Inside Attacker be Considered During the VA?

#### Why Must an Inside Attacker be Considered During the VA?


- Based on years of collaboration with the law enforcement and the intelligence community,
  - it is widely recognized that the inside attacker poses the highest risk for intentional adulteration of food
- Many instances of intentional adulteration in recent years were carried out by an inside attacker
- The VA must be conducted based on the assumption that an inside attacker is possible

FDA is not an intelligence agency, therefore they must rely on the expertise and judgment that they receive from the intelligence community. Over the course of more than a decade, the intelligence community has consistently informed FDA that the inside attacker represents the highest risk for intentional adulteration of food. Consequently, since the inception of FDA's food defense program, all FDA-led vulnerability assessments have focused on a scenario involving an inside attacker. The highest risk is not the individual who has broken into a facility to contaminate the food, it is the inside attacker who has already gained legitimate access. The intelligence community gathers this information based on the traffic that they see, past instances that have occurred, and other sources. That is why it is required that the VA must consider the actions of an inside attacker.

### Assumptions Regarding an Inside Attacker

Assumptions Regarding 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, etc.);
  - **A basic understanding of facility 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**



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There are four characteristics that should be assumed when considering an inside attacker. The first is that an inside attacker is an individual that has been granted legitimate access to the facility (such as an employee, contractor, driver, authorized visitor, etc.). Second, this individual would have a basic understanding of facility operations and the food products under production. This refers to a basic understanding of the production process such as a knowledge of the types of equipment being used or a general knowledge of how the food flows through the operation. The inside attacker may not have in-depth knowledge of the process itself but rather a high-level understanding of operations. The third attribute of an inside attacker is 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 it were to be added to the food. For example, simple observation may include noticing that the food

has changed color or texture. The fourth characteristic is the assumption that the intent of an inside attacker would be to cause wide scale public health harm. An inside attacker wants to use their access and their basic knowledge of the food or process to successfully contaminate the food and cause illness and death to as many people as possible.

### Inside Attacker Case Study – Derby Terror Plot

Inside Attacker Case Study – Derby Terror Plot

January 2018 – "UK Derby Terror Plot: The Online Casanova and His Lover"

- An individual used counterfeit identification to gain employment at a major manufacturer of ready-meals in the U.K. His girlfriend, a pharmacist, helped him to devise a plan to poison the food using ricin.

Source: <http://www.bbc.com/news/uk-42370025>

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**Key Point:**

The ricin plan was abandoned in favor of a bomb, and the whole plan was eventually intercepted by law enforcement, but this circumstance illustrates how someone with legitimate access to a food facility could cause wide scale public health harm.

The potential public health impact if an inside attacker was to successfully contaminate food could be catastrophic. Two case studies will be discussed to assist with conceptualizing this fact. The first case is from January 2018 and involved a plan to contaminate food inside a food manufacturing facility. An individual in the United Kingdom falsified documents to gain employment at a food manufacturing facility that was producing ready-to-eat foods. He was an ISIS (a terrorist organization) sympathizer and his girlfriend/accomplice had a pharmacy background. They devised several attack plots, one of which was to produce ricin and contaminate the food at his processing facility. Ultimately, they settled on a plot to use a bomb instead and were apprehended before the plot could be executed. Although their intentional adulteration plan was intercepted, this is an example of a case of someone who is an insider using their position in a food manufacturing facility to try to hurt people with a lethal substance. If the outcome were different, this could have resulted in wide scale public health harm.

## Inside Attacker Case Study – Japan Malathion

### Key Point:

While the intent of this disgruntled worker was only to harm the company, this illustrates how devastating the consequences would be if his intent was to cause wide scale public health harm, which is what the IA rule is designed to address.

### Inside Attacker Case Study – Japan Malathion

#### December 2013 – "Toshiki Abe arrested for poisoning frozen food in Japan"

- A contract food worker at a frozen food facility in Japan intentionally contaminated food with malathion, resulting in
  - 2,843 reports of foodborne illness, and
  - 6.4 million packages of food recalled

Source:

<https://www.news.com.au/world/toshiki-abe-arrested-for-poisoning-frozen-in-japan/news-story/1116b75a5e147c273de8ae4c38144b2b>

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The next example took place in late 2013 and involved foods contaminated with a pesticide called malathion. A long-term contracted employee at a frozen foods manufacturing facility in Japan used malathion to contaminate the food where he had access. His responsibilities included adding together ingredients to make dough. His actions led to 6.4 million packages of foods being recalled and at least 2,843 reported illnesses. The attacker used a relatively nontoxic contaminant, but if he had chosen a more lethal agent it could easily have resulted in thousands of deaths. Even though it appears this individual was a disgruntled employee and was not intending to cause wide scale public health harm, it demonstrates that inside attackers have a great potential for harm. This employee was an insider who had been in the facility for some time, had access to the food at a vulnerable point, and had an opportunity to successfully contaminate the food. In addition, several workers noted that the facility had a policy that prohibited personal items from being brought onto the production floor but thought the policy was likely not being properly supported with management oversight or training to ensure the policy was operating as intended.

## Points to Consider

Points to Consider

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- When considering the possibility of an inside attacker while conducting a VA, some points to consider at the process step include:
  - Times when the step is unobserved
  - Areas that are obscured from the view
  - Multiple workers
  - Movement of workers
  - Solitary workers

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### Key Point:

A solitary worker may seem like it would reduce vulnerability since only one person can access that step, but when you consider whether that solitary person could be the inside attacker you may come out with a different conclusion on vulnerability.

The inside attacker must be considered for each step under evaluation as a part of the step itself and the surrounding environment. A few questions that may be helpful when considering an inside attacker include: Are there lengthy periods of time where there is limited observation of food at the step under evaluation? For example, do people set up the equipment to run and then take care of other duties leaving the food unobserved? Are there times when a worker may step away from the process step? Are there times when surrounding staff fluctuates by shift or during particular periods of processing (e.g., the equipment is not being used). Are there process steps that are obscured by facility design or other obstructions that allow an inside attacker to adulterate the food without being caught in the act? Or conversely, are there multiple workers in the area so that even if an inside attacker was present there is a high likelihood that their actions would be noticed? Can workers move freely throughout the facility making it difficult to determine if someone is in an area that they do not belong? Or are there procedures in place that would make traversing impossible, such as rules about not going from raw to finished, or procedures implemented that would make an intruder stand out and be noticed? Are there steps where only solitary workers are stationed? If the solitary worker at that step is the inside attacker, how will that affect your evaluation of the vulnerability at that step?

Each process step has its own unique circumstances and it is not possible to list them all; therefore, the concept of an inside attacker needs to be evaluated in the context of the step under evaluation and its surrounding environment.



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# LESSON 5. Element 1

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Lesson 5: Element 1

## EVALUATING POTENTIAL PUBLIC HEALTH IMPACT

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### Key Point:

Remember, the three elements are:

1. Element 1: Potential Public Health Impact,
2. Element 2: Degree of Physical Access to the Product, and
3. Element 3: The Ability of an Attacker to Successfully Contaminate the Product.

The VA requires, at minimum, that three fundamental elements be considered for each point, step, or procedure under evaluation, as well as the overarching concept of the inside attacker. We will go through each of the three elements individually:

- Element 1: Potential Public Health Impact,
- Element 2: Degree of Physical Access to the Product, and
- Element 3: Ability of an attacker to Successfully Contaminate the Product.

This lesson will describe how to evaluate and score Element 1: Potential Public Health Impact.

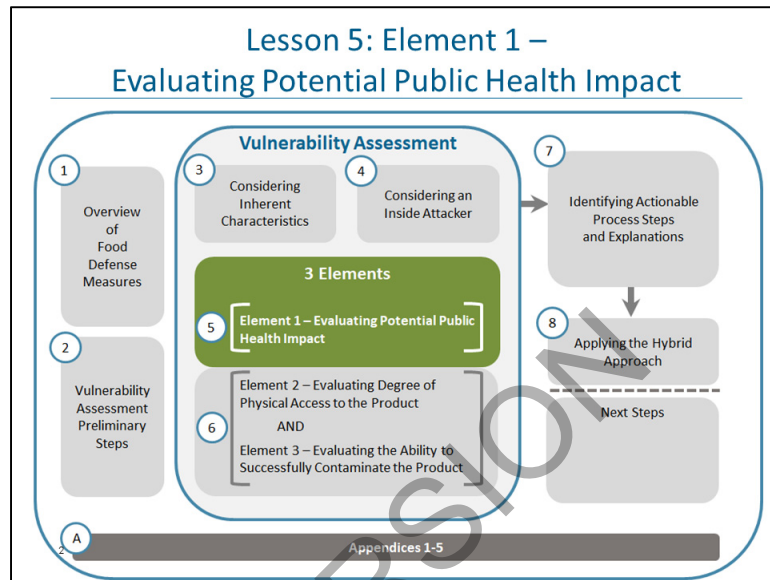
**Goal:** For each point, step or procedure, participants will be able to calculate potential public health impact.

### Learning Objectives:

By the end of this lesson, participants will be able to:

1. Describe public health impact.
2. Describe approaches used to calculate potential public health impact.
3. Calculate the potential public health impact using volume of food at risk.
4. Calculate the potential public health impact using the representative contaminant approach.
5. Score potential public health impact.

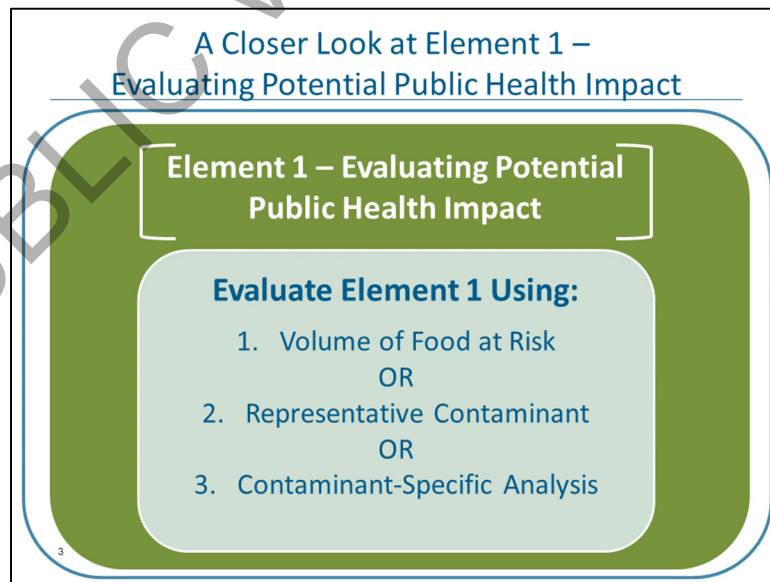
## Lesson 5: Element 1 – Evaluating Potential Public Health Impact



### A Closer Look at Element 1- Evaluating Potential Public Health Impact

**Resources:**

Table 1. Potential Public Health Impact is available in Appendix 3, page A3-3 and in the Exercise Workbook, page 10.



This lesson will discuss two methods in detail that are used to calculate public health impact. Both start with a formula to determine how much food is at risk at the step under evaluation and then extrapolate how many illnesses or deaths could result if a contaminant were added at that step. The first is an evaluation of the volume of food at risk. We will also discuss how to consider a representative contaminant in a more involved analysis. The concept of a third method called the contaminant-specific

method will be introduced but not discussed in detail, but this approach is similar to the representative contaminant method.

## Element 1: Potential Public Health Impact

### Element 1: Potential Public Health Impact

- Requires you to determine what the public health impact would be if an attacker successfully contaminated the food at the point, step, or procedure under evaluation
- Directly relates to the scale of a potential intentional adulteration event
- Estimates how many casualties are possible if a contaminant were added at the point under evaluation
- Is calculated for every process step under evaluation

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Public health impact refers to the potential result of a contamination on consumers. The IA rule is risk-based and aims to protect the most vulnerable points in food production operations where there could be a large public health impact if the food were intentionally contaminated. Public health impact estimates the number of servings of food being processed at the process step and extrapolates the number of consumers that would be affected if a contaminant were added to the food at that step. The public health impact score takes into account the severity and scale of illnesses or deaths based on the characteristics of the point, step, or procedure under evaluation. The degree of public health impact is calculated for every process step under evaluation in order to take into account how the characteristics of each process step may impact potential public health impact.

For example, packaging steps typically have a lower degree of public health impact because servings are frequently already parsed out. Therefore, a contamination would affect a lower number of consumers since an attacker would be attempting to contaminate individual servings. Conversely, a bulk storage tank of an ingredient would have a high score for public health impact because that contaminated product could impact thousands of servings.

## Potential Public Health Impact Scoring Table

Potential Public Health Impact Scoring Table	
• Table 1. Potential Public Health Impact	
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

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Once the number of servings at risk, illnesses or deaths has been calculated, then Table 1 can be used to arrive at a score ranging from 1 to 10. A score of 1 means that there are no potential illnesses or deaths if a contaminant were added at the step under evaluation, therefore there is no public health impact. A score of 10 means that there is a risk of over 10,000 servings at risk, or potentially over 10,000 illnesses or deaths would be expected if a contaminant were added at the step under evaluation. Therefore, this step would be the highest risk of potential public health impact. A score of 3 would be used for a step where potentially 1-99 servings were at risk or 1-99 illnesses or deaths are expected, a score of 5 would be used for a step where between 100 and 1,000 servings/people were at risk, and a score of 8 would be used for a step where between 1,001 and 10,000 servings/people were at risk if a contaminant was added.

## Volume of Food at Risk Approach

1. Volume of Food at Risk

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**Evaluate Element 1 Using:**

1. Volume of Food at Risk

OR

2. Representative Contaminant

OR

3. Contaminant-Specific Analysis


The first approach to evaluate potential public health impact we will be covering is the volume of food at risk approach.

## Volume of Food at Risk Approach (continued)

Volume of Food at Risk Approach

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- Answers the question: How many servings would be affected if a contaminant were added at the step under evaluation?
- Calculates the volume of food at risk at each process step to arrive at servings at risk
- Extrapolates the potential public health impact without the scientifically rigorous examination of a specific contaminant
- Can be used for batch steps or steps where product is under a continuous flow

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The volume of food at risk method is a method for establishing potential public health impact by calculating the total volume of food at risk at a process step and then extrapolating the public health impact by calculating how many servings this volume of food would generate. This is a simple method that provides the number of servings at a step that would be used to compare to Table 1 to get a score. This method can be used to ultimately determine how many servings could be contaminated

at a process step where product is in batch format. This method can also be used for a step where product may be flowing or moving.

## Worksheet 1-D

### Resources:


A blank Worksheet 1-D can be found in Appendix 3, page A3-9, and in the Exercise Workbook page 11.

As noted earlier, Table 1 can be found in Appendix 3, page A3-3, and in the Exercise Workbook, page 10.

**Worksheet 1-D**

**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 $B \div C$	E Score from Table 1	F Notes
Ingredient storage tank					

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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.

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 (see Exercise Workbook page 10) associated with the servings per batch from Column D in this worksheet.
- F. **Notes:** Provide any information that would assist review of this VA, such as how batch size was calculated.

### Example Calculation Using the Volume of Food at Risk Approach for a Batch Processing Step

**Example Calculation Using the Volume of Food at Risk Approach for a Batch Processing Step**

**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 <small>B ÷ C</small>	E Score from Table 1	F Notes
Ingredient storage tank	50,000 gallons	1 cup	800,000	10	16 cups/gallon

- This 50,000 gallon primary ingredient liquid storage tank would generate 800,000 one cup servings
- 50,000 gallons (16 cups per 1 gallon)= 800,000 cups
- 800,00 cups ÷ 1 cup serving= 800,000 servings
- The facility would consider all 800,000 servings as being at risk

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**Key Point:**

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.

An example of the calculation for volume of food at risk is provided for an ingredient storage tank. Column A of the chart identifies the process step by name and column B lists the batch size at this step, which is 50,000 gallons. Column C lists the amount of ingredient (from this step) in the final product as 1 cup. You will need to convert gallon units to cups to arrive at the number for Column D, Servings per Batch. There are 16 cups in a gallon, transforming batch size (Column B) to 800,000 cups. Column D would result in 800,000/1, which equals 800,000 servings at risk at this step.

Using Table 1 this would result in a score of 10 for public health impact since there are greater than 10,000 servings at risk. Since 800,000 servings are at risk, there is a very high potential public health impact if a contamination were to happen at this step. In the upcoming example exercise, you will have the opportunity to fill out the information in this

chart using an example process step, perform the calculations and arrive at a score.

### Example Calculation Using the Volume of Food at Risk Approach for a Continuous Flow Process Step

**Key Point:**

If you have a continuous flow process, you would have to evaluate how much product you think is at risk at a certain point in time that an attacker might be able to introduce an adulterant. For this example, it was assumed that someone could be at the process step for no more than 3 minutes, which helped inform how many pounds of food product were at risk.

**Example Calculation Using the Volume of Food at Risk Approach for a Continuous Flow Process Step**

**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 $B \div C$	E Score from Table 1	F Notes
Generic Process Step	900 lbs	4 oz	3,600	8	16 oz/lb

- The facility determines that a person would have no more than 3 minutes at the access point to introduce a contaminant
- The flow rate of food is 300 lbs per min for 3 min = 900 lbs of product is at risk
- This 900 lbs continuous flow "batch" would generate 3,600 4 oz Servings
- 900 lbs. (16 oz/1 lb)= 14,400 oz ÷ 4 oz per serving= 3,600 servings
- The facility would conclude that 3,600 servings are at risk at this step

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Another example of this calculation is provided for a generic process step where the product is continuously flowing. Since this is not a step where the product is held in batch format, the flow rate of the food and the estimated time that someone would/could stand at that step must be factored in to estimate the batch size at this step. In this example, it is estimated that the food is passing by this step at a rate of 300 pounds/minute, and someone could stand at the access point to this process step for no more than 3 minutes. Therefore, the batch size at this step is 900 pounds (Column B). Column C lists the amount of ingredient (from this step) in the final product is also 4 ounces. You will need to convert pound units to ounces to arrive at the number for Column D, Servings per Batch. There are 16 ounces in a pound, transforming batch size (Column B) to 14,400 ounces. Column D would result in 14,400/4, which equals 3,600 servings at risk at this step.

Using Table 1 this would result in a score of 8 for public health impact since the servings at risk are between 1,001 and 10,000. You would be expected to fill out the information in this chart, perform the calculations and arrive at a score.



## Lesson 5 Exercise: Element 1: Calculating Public Health Impact Using the Volume of Food at Risk Approach

### Lesson 5 Exercise: Element 1: Calculating Potential Public Health Impact Using the Volume of Food at Risk Approach

- Total time: 15 minutes
  - Complete the worksheet: 5 minutes
  - Report out conclusions: 5 minutes
  - Facilitated review/discussion: 5 minutes
- Instructions:
  - Calculate potential public health impact using the *Element 1: Calculating Potential Public Health Impact Exercise Worksheet 1-D* and other resources (see your Exercise Workbook, pages 8-12 for details)
  - Use ONLY the volume of food at risk method
  - **Remember to use:** *Table 1. Potential Public Health Impact* to assign a score (see Exercise Workbook, page 10)
  - **Pay attention to units:** Use conversion information located at the top of the worksheet, page 11

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The Element 1: Calculating Potential Public Health Impact Exercise instructions and a list of resources you will need, along with the Element 1 Exercise Worksheet 1-D are in the Exercise Workbook (see pages 8-12). The instructor will review the instructions and then you can complete the worksheet. Once everyone has completed the worksheet, the Instructor will facilitate a report out of conclusions and short review/discussion.

## Representative Contaminant Approach

2. Representative Contaminant Approach

**Evaluate Element 1 Using:**

1. Volume of Food at Risk
- OR
2. Representative Contaminant
- OR
3. Contaminant-Specific Analysis

The second approach to evaluate potential public health impact we will be covering is the representative contaminant approach.


## Representative Contaminant Approach (continued)

### Key Point:

LD50 is the amount of contaminant sufficient to kill 50% of an exposed population. Using the LD50 value is an accepted scientific method and is one way to measure the acute poisoning potential (acute toxicity) of a contaminant.

Representative Contaminant Approach

- Starts with estimating public health impact by calculating servings at risk, and then
  - Factors in a lethal dose (LD50) of a representative contaminant
  - LD50 is derived from a compilation of potential contaminants that are highly lethal and able to survive the production process
  - Does not reflect an actual contaminant, but a combination of characteristics from actual contaminants
  - FDA's representative contaminant dose = 40 mg per serving


  
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The representative contaminant method goes one step further than the volume of food at risk method. It calculates the servings at risk and then multiplies that by the lethal dose derived from a compilation of potential contaminants. This approach uses an unnamed representative contaminant that has been derived from an amalgam of characteristics from a wide data set of actual contaminants. FDA has provided a value


of dose per serving that a person would have to consume in order for 50% of the consuming population to die as a result. This is known as a Lethal Dose 50, or LD50. Using the LD50 is one way to measure the acute poisoning potential (acute toxicity) of a contaminant. LD50 data is a reliable toxicity indicator because it accounts for variations such as size of the exposed subjects within a general population.

### Representative Contaminant Approach (continued)

**Representative Contaminant Approach**  
(continued)

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- Has a higher degree of specificity compared to the volume of food at risk method because it incorporates data from actual contaminants
- Can inform evaluation of Element 3, i.e., the ability of an attacker to successfully contaminate the product at this step, since this calculates the amount of contaminant needed

  
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The representative contaminant method provides a higher degree of specificity compared to the volume of food at risk method because it incorporates data from actual contaminants and takes into account how the contaminant may affect the consumer. Additionally, the representative contaminant method provides data that can be used in your evaluation of Element 3, the ability to successfully contaminate the product. The representative contaminant method provides you with an amount of contaminant (volume of agent) needed to successfully adulterate the product at the step under evaluation.

## Worksheet 1-E

**Resources:**

Blank Worksheet 1-E can be found in Appendix 3, page A3-11, and in the Exercise Workbook, page 12.

Worksheet 1-E									
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 (FDA provided value = 50%)	Number of Potential Deaths D x E	Score from Table 1	Notes	Representative Contaminant Dose Needed per Serving (FDA provided value = 40 milligrams)	Amount of Representative Contaminant Needed per Batch D x I
Generic Process Step				50%				40 mg/serving	

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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 through D, please see descriptions provided on page 5-6 and 5-7.

**E. Mortality Rate of Representative Contaminant:** An LD50 value is used 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. 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.

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

**I. Representative Contaminant Dose Needed per Serving:** A value of 40 milligrams per serving is used. FDA derived this dose value, in consultation with 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. This was converted 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.

**Example Calculation of the Public Health Impact Using the Representative Contaminant Approach**

**Example Calculation of the Potential Public Health Impact Using the Representative Contaminant Approach**

**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 (FDA provided value = 50%)	Number of Potential Deaths: D x E	Score from Table 1	Notes	Representative Contaminant Dose Needed per Serving (FDA provided value = 40 milligrams)	Amount of Representative Contaminant Needed per Batch D x I
Generic Process Step	300 lbs	1 oz	4,800	50%	2,400	8		40 mg/serving	192,000 mg or 0.42 lb



An example of calculating public health impact using the representative contaminant method is provided. This chart is similar to the volume of food at risk chart, but contains columns E, F, I, and J which were not present in the volume of food at risk calculation chart. You would be expected to fill out the information in this chart, however FDA will be providing the information for columns E and I. You would then perform the calculations and arrive at a score. You will still need batch size, serving size and amount of servings per batch. The FDA-provided LD50 is a static number for Column E (Mortality Rate of Contaminant). The number of illnesses/deaths is calculated in Column F by multiplying your number of servings times

50%. In this example, there were 4800 exposures multiplied by 50% brings it to 2,400 illnesses/deaths to be recorded in Column F. Using Table 1, 2,400 illnesses result in a public health impact score of 8 in Column G.

Additionally, this chart has Columns I and J. These columns calculate the amount of contaminant that would be required to add to the batch to achieve the number of illnesses/deaths in Column F. The number recorded in Column J is not used to score Element 1: Public health impact but is calculated in this chart to be considered when scoring Element 3: Ability of an attacker to successfully contaminate the product. This will be discussed in more detail in Lesson 6, but this number helps to provide an idea of how much contaminant must be brought into the facility and added at this step. This can be helpful in understanding the ability of an attacker to successfully contaminate the product.

The amount of contaminant may be so large that it is not feasible for someone to successfully carry out the contamination. For example, if 100 pounds of contaminant were required to be added at a step, that feasibility will assist with determining the score for the ability to successfully contaminate the product. Conversely, if only 1 gram of contaminant were needed, this would be easier for an attacker to conceal and contaminate without being caught in the act.

## Lesson 5 Exercise: Element 1: Calculating Public Health Impact Using the Representative Contaminant Approach

### Lesson 5 Exercise: Element 1: Calculating Potential Public Health Impact Using the Representative Contaminant Approach

- Total time: 20 minutes
  - Complete worksheet: 10 minutes
  - Report out conclusions: 5 minutes
  - Facilitated review/discussion: 5 minutes
- Instructions:
  - Calculate potential public health impact using the *Element 1: Calculating Potential Public Health Impact Exercise Worksheet 1-E* and other resources (see your Exercise Workbook, pages 8-12 for details)
  - Use Worksheet 1-E and the representative contaminant method
  - **Remember to use:** *Table 1. Potential Public Health Impact* to assign a score (see Exercise Workbook, page 10)
  - **Pay attention to units:** Use conversion information located at the top of the worksheet, page 12

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The Element 1: Calculating Potential Public Health Impact Exercise instructions and a list of resources you will need, along with the

Element 1 Exercise Worksheet 1-E are in the Exercise Workbook (see pages 8-12). The instructor will review the instructions and then you can complete the worksheet. Once everyone has completed the worksheet, the Instructor will facilitate a report out of conclusions and short review/discussion.

### Contaminant-Specific Approach

3. Contaminant-Specific Approach

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**Evaluate Element 1 Using:**

1. Volume of Food at Risk  
OR
2. Representative Contaminant  
OR
3. Contaminant-Specific Analysis

**Key Point:**

FDA’s experience has been that the contaminant-specific analyses, conducted with adequate scientific rigor, are some of the most complex and resource-intensive components of vulnerability assessments. Moreover, in many cases, the limited information in the public domain to support contaminant-specific analyses may make this level of analysis particularly challenging. Additionally, individual facilities may find it challenging to remain up-to-date on the threat landscape regarding certain contaminants, which may change quite rapidly. For these reasons, we encourage you to carefully weigh the benefits and drawbacks before undertaking contaminant-specific analyses and recommend you first explore the ‘contaminant agnostic’ methods previously outlined (i.e., the Key Activity Types, Volume of Food at Risk, and Representative Contaminant) that do not rely on an in-depth knowledge of a wide array of potential contaminants.


The third approach to evaluate potential public health impact we will be briefly covering is the contaminant-specific approach.

### Contaminant-Specific Approach (continued)

Contaminant-Specific Approach

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- Calculation is performed the same as the representative contaminant method, but
  - data from actual contaminants would be used
- Allows for the highest degree of specificity, but
  - the list of contaminants goes far beyond common food safety hazards
- Qualified individual conducting the VA is responsible for conducting research into specific contaminants to complete this approach

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The contaminant-specific method is foundationally the same as the representative contaminant method, except for this approach FDA will not be providing the numbers for Column E – Mortality rate of contaminant, or Column I – Contaminant dose required per serving. To use this method, you would perform appropriate research and use data from actual contaminants that could be used to adulterate the product and use those numbers for Columns E and I. This method provides you with a higher degree of specificity as the other methods introduced, but requires extensive research, preparation, knowledge, and scientific information to successfully evaluate a wide variety of potentially relevant contaminants. This would be the responsibility of the qualified individual conducting the VA to ensure that appropriate research is performed and applied to use this method successfully. 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.

### What Contaminants Should be Considered?

**Key Point:**

Facilities should refer to guidance on types of contaminants to be considered, specifically guidance related to radiological and physical contaminants. The agents considered should be representative of all possible agents.

For column E, 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. For column H, provide an estimated contaminant dose per serving derived from oral toxic dose information found in scientific literature.

#### What Contaminants Should be Considered?

- Biological, chemical, radiological, or physical contaminants that if ingested could cause wide scale public health harm
- Numerous potential contaminants that could be used in an attack on food
  - FDA will NOT be providing a list
- Worksheet 1-E below could be used for every contaminant evaluated
  - You would be responsible for providing the values for columns E and I

Element 1 Calculations								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	Number of Potential Deaths D x E	Score from Table 1	Notes	Contaminant Dose Needed per Serving	Amount of Contaminant Needed per Batch D x I
Process Step									

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If you choose to use the contaminant specific method you would be required to determine the appropriate values for the specific contaminant that you are evaluating, and there are numerous biological, chemical, radiological and physical contaminants that should be evaluated. FDA will NOT be providing a list of contaminants to evaluate; therefore, it will be up to facilities to decide which to use. Worksheet 1-E could be used for each point, step, or procedure under evaluation, also evaluating all applicable contaminants that may be used to adulterate your product.



## Choosing an Approach Method for Calculating Potential Public Health Impact

Choosing an Approach Method for Calculating Potential Public Health Impact		
	Pros	Cons
Volume of food at risk	<ul style="list-style-type: none"> <li>Simple calculations based on information readily available</li> </ul>	<ul style="list-style-type: none"> <li>May overestimate number of deaths</li> </ul>
Representative Contaminant	<ul style="list-style-type: none"> <li>More accurately estimates number of deaths</li> </ul>	<ul style="list-style-type: none"> <li>No ability to identify process considerations to neutralize specific contaminants</li> </ul>
Contaminant-Specific	<ul style="list-style-type: none"> <li>Highest degree of specificity for estimating number of deaths</li> </ul>	<ul style="list-style-type: none"> <li>Requires extensive knowledge of a wide variety of contaminants and difficult to stay up to date on evolving threat landscape</li> </ul>

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In summary, calculating public health impact scores for each point, step, or procedure can be performed in a few different ways. There are pros and cons to each of the methods described in this lesson.

The volume of food at risk method provides very simple calculations based on information that is readily available at your facility. However, this method does not take into account the nature of the contaminant or how it will affect consumers, so it may overestimate the number of illnesses or deaths.

The representative contaminant method also involves simple calculations and takes into account the nature of a representative contaminant, which was derived from data from various sources and reflects an amalgam of characteristics from actual contaminants. Because of this, the representative contaminant method will more accurately represent the number of illnesses or deaths and also provides a calculated amount of contaminant needed which is helpful when evaluating Element 3. The representative contaminant method does not enable the consideration of the unique characteristics of specific agents, which means that you are not able to consider how specific contaminants may or may not be affected by the process. However, since the representative contaminant is derived from a compendium of potential contaminants, the representative contaminant approach generates more precise results than simply using the volume of food at risk, while not requiring the research and expertise needed to consider specific contaminants.

The contaminant specific method has the highest degree of specificity because it allows for each contaminant to be evaluated individually

and can take into consideration all the survival and denaturation considerations of the contaminant and how the production process can factor into those determinations, but this is the most labor-intensive method. It requires extensive knowledge of agent characteristics and behaviors and FDA will not be providing this information. Additionally, in order to evaluate the impact of different types of potential contaminants, multiple calculations would be required for each process step under evaluation. You would be required to defend your estimates with the data and information used to make your determinations. Additionally, agent information and threat landscapes can change over time and you would need to stay current on these issues and perform additional calculations if new and emerging threats are brought to light.


### Additional Considerations for Public Health Impact

**Additional Considerations for  
Public Health Impact**

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- You have the flexibility to consider additional factors in your evaluation if you have enough information to do so and you incorporate them into the analysis appropriately
  - End use of the food
  - Consumer packaging
- You can use your own worksheets or adapt the examples shown to incorporate these items
- Your written rationales should detail how these additional considerations factored into your score

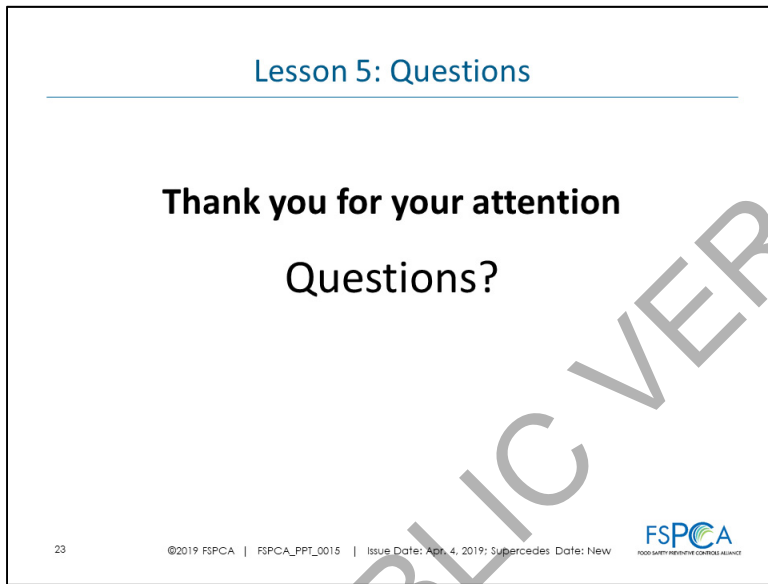
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After performing the public health impact calculations using the methods described, you also have the flexibility to incorporate additional factors that may be relevant and have an effect on your potential public health impact score. For example, if you are processing breakfast cereal and you estimate 10,000 servings are at risk using the volume of food at risk method, you may be able to reduce that number based on distribution units and customers per unit. If your cereal contains 12 servings per box and those are typically consumed in a single household with an average family size of 3.5 you can divide 10,000 by 12 to get the 833 boxes at risk, and then multiply that by 3.5 people consuming those boxes, you can arrive at an estimate of 2917 for numbers of illnesses/deaths (these numbers are provided for example purposes only and do not represent actual servings of cereal or typical household number).

If you have done enough research on subjects such as food velocity, market turnover, servings per distribution unit, etc., you may be able to arrive at a public health impact estimate that is more accurate than the volume of food at risk method or the representative contaminant method. For any additional factors you use to evaluate public health impact, you would need to explain how the additional factors were evaluated, what real world data was used to support your evaluation, and how they were used to determine your public health impact score. The written rationale would need to be sufficient to explain your conclusions.

**Lesson 5: Questions**



If you have any questions regarding the concepts we just went over, feel free to ask them.

**Notes:**

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PUBLIC VERSION

# Placeholder for Blank Colored Insert-Front

PUBLIC VERSION

**Placeholder for  
Blank Colored Insert-Back**

PUBLIC VERSION

# LESSON 6. Element 2 and Element 3

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Lesson 6: Elements 2 and 3

## EVALUATING DEGREE OF PHYSICAL ACCESS TO THE PRODUCT AND EVALUATING THE ABILITY TO SUCCESSFULLY CONTAMINATE THE PRODUCT

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### Key Point:

Remember, the three elements are:

1. Element 1: Potential Public Health Impact,
2. Element 2: Degree of Physical Access to the Product, and
3. Element 3: The Ability of an Attacker to Successfully Contaminate the Product.

Continuing with the three fundamental elements, this lesson will describe how to evaluate and score Element 2: The degree of physical access to the product, and Element 3, which considers the concept of once the attacker gets to the product, how easy or difficult it is for them to successfully contaminate the product.

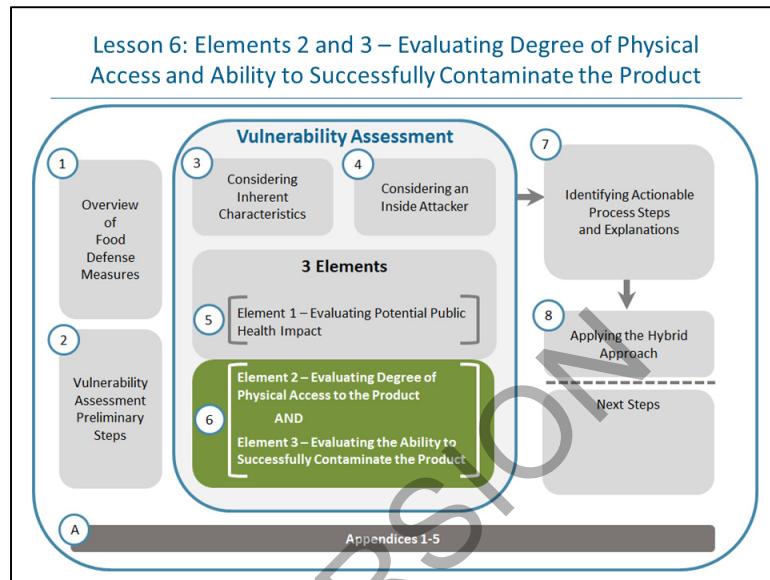
**Goal:** For each point, step, or procedure, participants will be able to evaluate the degree of physical access to the product and the ability to successfully contaminate the product.

### Learning objectives:

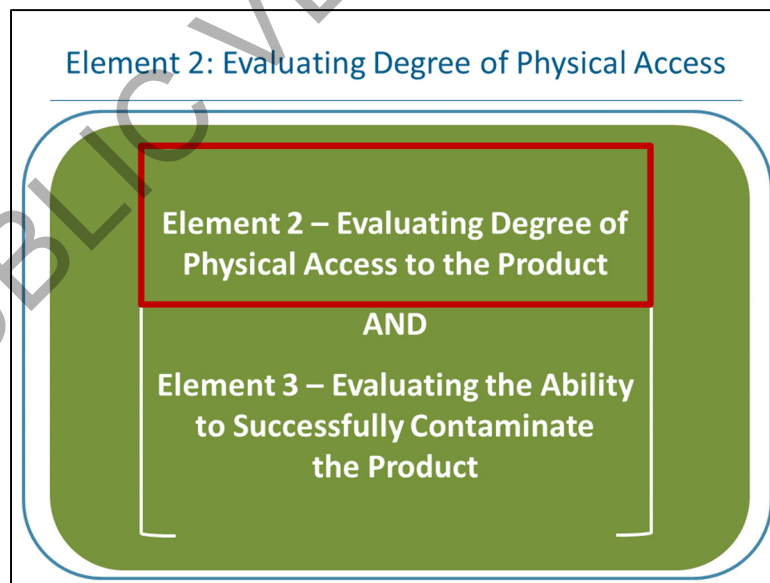
By the end of this lesson, participants will be able to:

1. Evaluate the degree of physical access to the food product.
2. Score degree of physical access to the product.
3. Evaluate the ability of an attacker to successfully contaminate the product.
4. Score the ability of a successful contamination.

## Lesson 6: Elements 2 and 3 – Evaluating Degree of Physical Access and Ability to Successfully Contaminate the Product



### Element 2: Evaluating Degree of Physical Access



First, we'll focus on Element 2 – Evaluating degree of physical access to the product.



## Considering the Degree of Physical Access to the Product

### Considering the Degree of Physical Access to the Product

- Focuses on the physical accessibility of the food at the process step under evaluation
  - Can an insider attacker get to the food?
  - Are there inherent characteristics that would impact access to the product?

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Evaluating the degree of physical access to the product means to determine if an attacker can get to the product at the point, step, or procedure under evaluation. Meaning, could an attacker actually touch the product at that step?

Are there inherent characteristics that would impact access to the product, such as physical barriers or space limitations that would prevent access? Is the product in an open vat, or is it covered, enclosed, or in sealed packages? Is the food being handled or moved in an inaccessible manner like in enclosed piping or in an elevated tank with no means of access, or is it a waist-high conveyor belt with multiple points that an attacker could access the food?

For this evaluation, you must assume the attacker could be an insider who already has access to the facility and/or this step.

## Physical Barriers

### Key Point:

When evaluating the degree of physical access, facilities should consider inherent characteristics, which are described as those conditions, activities, practices, or characteristics that are integral to the operation of a process point, step or procedure. In other words, they are present as crucial to the operation of the process step.

### Physical Barriers

- Can an attacker get to the food?
  - Physical barriers can reduce or eliminate access to the food at the point, step, or procedure under evaluation
- Some examples include shields, pressurized or enclosed systems, inward opening hatches, equipment safety features (e.g., safety guards)



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When evaluating physical barriers that reduce or eliminate access to the food at the step under evaluation, remember to determine whether those barriers are inherent characteristics or not. Some examples of physical barriers that reduce access to the product and should be factored into your degree of physical access evaluation because they are inherent include permanently attached shields, inward opening hatches that will not open due to the pressure of the product inside, or fully enclosed systems.

Other examples of inherent characteristics of the equipment and the surrounding environment that would prevent access include safety features that are part of the design of equipment, such as safety barriers that cover blades, heating elements, or other hazardous situations that would cause injury if accessed. Another inherent characteristic to consider would be whether tools are needed to gain access and whether the use of these tools would be obvious and noticed.

## Scoring Degree of Physical Access to the Product

### Scoring Degree of Physical Access to the Product

- Evaluate using a scoring table (Table 2)
- Written rationale for scores are recommended

Description	Score
<b>Easily Accessible.</b> <ul style="list-style-type: none"> <li>• Inside attacker has access to the product (e.g., attacker can physically touch the product).</li> <li>• 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).</li> <li>• Product is open and unsecured by packaging, equipment, or other physical access barriers.</li> <li>• Product is handled, staged, or moved in an easily accessible manner.</li> </ul>	10
<b>Accessible.</b> <ul style="list-style-type: none"> <li>• 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).</li> <li>• Product is in equipment that can be accessed without tools or specialized supplies.</li> <li>• 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.</li> </ul>	8
<b>Partially Accessible.</b>	5

Since this element does not have mathematical calculations associated with determining a score, it relies more on your judgement and evaluation than scoring for Element 1 did. Table 2 provides some examples of characteristics that you may consider when scoring the degree of physical access. For example, Table 2 suggests a score of 1 if the food is not accessible at the process step under evaluation. This means an attacker has no access to the product at this step or inherent characteristics are present that make accessing the food impossible at this step. A score of 3 is considered “hardly accessible” because there are inherent characteristics that make access to the product at this step very difficult, such as requiring tools for access, enclosed systems or shields are present, or the area surrounding this step has physical space constraints limiting human access. A score of 5 is considered “partially accessible” meaning there is access, but it would be somewhat difficult for an attacker to reach the product at this step. A score of 8 means that the product is accessible at this step because there are no inherent characteristics limiting access and no obvious circumstances that would make access at this step difficult. A score of 10 means that the food is “easily accessible” at this step because it is in an open environment with no physical barriers or other inherent characteristics limiting access. Written rationales for why you chose the score are recommended to explain thought processes. Those rationales can be based on the description of the score in the Table 2. or supplemented with other information that you factored in to the score for degree of physical access. Your vulnerability assessment must include a written explanation as to why each point, step, or procedure overall was or was not identified as an actionable process step, so individual rationales can be useful in writing that explanation.

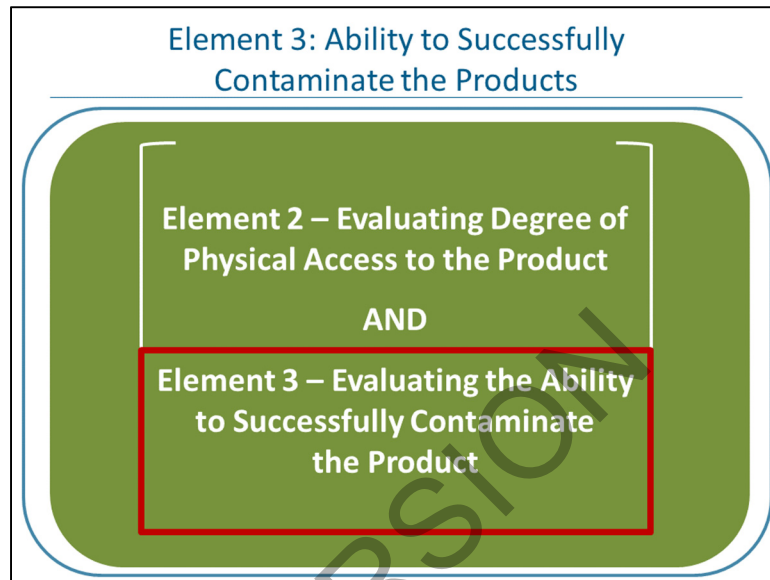
#### Key Point:

*Table 2. Degree of Physical Access to the Product* provides some example considerations when determining the scores but does NOT represent all the factors that you may encounter when evaluating physical access. Your written rationales should detail why you chose the score for the process step under evaluation and can be based on the descriptions of the score in this table.

#### Resources:

*Table 2. Degree of Physical Access to the Product* is available in Appendix 3 (page A3-5) and in the Exercise Workbook (page 17).

### Element 3: Evaluating the Ability to Successfully Contaminate the Product



Now, we'll focus on Element 3 – Evaluating the ability to successfully contaminate the product.

#### What Is Successful Contamination?

##### Key Point:

When we say, "successful contamination," we are assuming that the attacker has successfully accessed the food product.

##### What Is Successful Contamination?

- We are using the word "success" from an attacker's perspective
- A successful contamination means that the attacker is able to introduce a contaminant into the food in such a way that it will reach the consumer and cause wide scale public health harm

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It may seem awkward to talk about success in the context of a contamination, but Element 3, the ability of an attacker to successfully contaminate the product, is approaching "success" from the perspective of the attacker. From this perspective, success would mean that they


introduced a contaminant into the food that could reasonably be expected to cause wide scale public health harm.

## Evaluate the Ability to Successfully Contaminate

**Evaluate the Ability to Successfully Contaminate**

- Once an attacker gets to the process step, can they successfully contaminate the product?

Important Considerations			
Time and visibility	Suspicious activity	Uniform mixing	Quantity of contaminant

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The evaluation of Element 3 takes into consideration factors that would contribute to or deter from a successful contamination and answers the key question: once an attacker gets to the product, can they adulterate it? A few overarching concepts come into play during this evaluation:

1. Would the attacker have enough time to contaminate the food without being observed?
2. Would the attacker have to engage in suspicious activity that would be noticeable to others?
3. Will the product be mixed in a way that will result in the contaminant being homogenously distributed throughout the food?
4. Can a sufficient amount of contaminant be added at this step based on volume of food and the nature of access?

## Questions to Consider

Questions to Consider

- **Time and Visibility**
  - How easy is it for the attacker to introduce a contaminant?
  - Are there inherent characteristics to consider?
    - Are multiple people required at this step that could be visual observers?
    - Is the step permanently located in a highly visible area or an isolated part of the facility?
- **Suspicious Activity**
  - Would the attacker be forced to conduct suspicious or highly irregular activities?
  - Alarms/automatic shutdown that activate when equipment is accessed?



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Time and visibility play a role in the evaluation of the ability of an attacker to successfully contaminate the food. The slide includes some helpful questions for you to consider when performing the evaluation. For example, how easy is it for the attacker to introduce a contaminant? Are multiple people required at this step that could be visual observers, making this an inherent characteristic to consider? For instance, is it a line where there are multiple people working side by side sorting products, which would limit the ability of someone to introduce a contaminant without being observed? Or, is the step located in a highly visible area based on facility design, so observation is high? Conversely, is the step located in an isolated part of the facility or obscured by equipment or materials, providing an attacker with time and privacy to contaminate the food without being caught in the act?



You should consider whether an attacker has to do something very suspicious or highly irregular in order to introduce a contaminant. For example, if an attacker had to drag a ladder through the facility to reach the top of an elevated ingredient tank to introduce a contaminant, that would most likely be observed and stopped. Additionally, consider if equipment alarms or automatic shutdowns would be triggered if equipment was accessed, thereby limiting the likelihood of a successful attack.


## Questions to Consider (continued)

Questions to Consider (continued)

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- **Mixing**
  - Will the contaminant be thoroughly mixed at this process step or a subsequent step?
  
- **Quantity of Contaminant**
  - Can a sufficient amount of contaminant be added at this step based on volume of food?
  - Will downstream dilution or concentration affect the contaminant?



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### Key Point:

**Reminder:** The quantity of contaminant needed for a successful contamination is determined when calculating Element 1, if you used the representative contaminant method.

Mixing is another factor that should be considered when evaluating Element 3. Processing steps that include mixing would evenly distribute the contaminant into the food, making the food at these steps more susceptible to a successful contamination, and impacting a maximum number of servings. Steps such as secondary ingredient addition or mixing in which a contaminant could be evenly distributed throughout the product are very common in food production and should be closely evaluated.

Another factor that should be taken into consideration is line speed. For example, you may have product moving through a continuous process, and there may be access to that product (as determined in your Element 2 evaluation), but what is the ability to actually contaminate a large amount of servings if it is moving on a conveyor at a high speed and not subsequently mixed? Keep in mind the attacker will need to be able to introduce a quantity of contaminant within enough servings that would result in wide scale public health harm. Thinking back to the calculations performed using the representative contaminant method for Element 1, how much contaminant is needed to contaminate the product at this step and achieve the attackers' goal? Can an attacker realistically get that much contaminant into the food at this point without being detected? Finally, there may be instances where downstream dilution or concentration may affect the ability of an attacker to successfully contaminate the product. 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., if a significant amount of liquid was added), may decrease the score you assign to Element 3 at earlier steps because the amount of contaminant is more difficult to introduce in these earlier steps.

### Worksheet 1-E

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 (FDA provided value = 50%)	Number of Potential Deaths D x E	Score from Table 1	Notes	Representative Contaminant Dose Needed per Serving (FDA provided value = 40 milligrams)	Amount of Representative Contaminant Needed per Batch D x I
Generic Process Step	300 lbs	1 oz	4,800	50%	2,400	8		40 mg/serving	192,000 mg or 0.42 lb

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This is worksheet 1-E that was introduced in the previous lesson. You'll notice the table is divided into Elements 1 and 3 calculations. As a reminder, FDA is providing the dose of the representative contaminant needed per serving (column I). This helps you calculate how much total contaminant is needed in order to adulterate the product batch being evaluated. In this example, we have 300 lbs of product as a batch size, which, based on the calculations performed during the Element 1 analysis, would only require 0.42 lbs (192,000 mg) of contaminant in order to achieve wide scale public health harm. Considering that this is an accessible process step, and the actions of the attacker wouldn't be suspicious, this would be an easy amount of contaminant to introduce into the product.



## Scoring the Ability of an Attacker to Successfully Contaminate the Product

### Scoring the Ability of an Attacker to Successfully Contaminate the Product

- Evaluate using a scoring table (See screenshot of Table 3 below)
- Written rationale for scores are recommended

Description	Score
<p><b>Highest Ease of Successful Contamination.</b></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• It is easy to successfully add sufficient volume of contaminant to the food.</li> <li>• Inherent characteristics of the point, step, or procedure (e.g., uniform mixing) would evenly distribute the contaminant into the food.</li> <li>• 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.</li> <li>• 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.</li> <li>• 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.</li> </ul>	10
<p><b>Moderately High Ease of Successful Contamination.</b></p> <p>The process is seldom observed, enabling an inside attacker to work unobserved with</p>	8

#### Resources:

Table 3. The Ability of an Attacker to Successfully Contaminate the Product is available in Appendix 3 (pages A3-7 to A3-8) and in the Exercise Workbook (pages 18-20).

Similar to Elements 1 and 2, you can use Table 3 (see Exercise Workbook, pages 18-20) to assist you with determining your Element 3 score. Element 3 is another area where there is some subjectivity in the evaluation. It is impossible for FDA to foresee every scenario that you may come across, so flexibility is allowed. Written rationales assist with explaining how you arrived at your Element 3 score and provide details that will help you at the end of your VA to determine if a step would be considered an actionable process step.

Table 3 provides you with descriptions of scores to assist with scoring the ability of an attacker to successfully contaminate the food. A score of 1 means there is a “low ease of attack” for reasons such as a large volume of contaminant would be needed and would be easily detected, the process step is under constant supervision, or other inherent characteristics reduce the ability of an attacker to be successful. A score of 3 indicates a “moderately low ease of attack” because the process step is observed most of the time, the attacker would have to perform overtly suspicious activities to contaminate the product, or other characteristics hinder the chances of success. A score of 5 indicates a “moderate ease of attack” meaning that an attacker could potentially be successful but would need to act with some degree of stealth to avoid detection. Another factor to consider is if the contaminant would end up being lost, diluted, or otherwise inactivated at later points in the process. A score of 8 indicates a “moderately high ease of attack,” meaning there is a good likelihood that an attack could be carried out and result in wide scale public health harm. There could be many reasons for this moderately high ease of attack. For example, the amount of contaminant is small and could be brought to the step and introduced into the food without detection, or that the step is

located in a remote area and is often unobserved for long periods of time. Finally, a step with a score of 10 indicates the “highest level of ease of attack”. Steps scoring a 10 would be unobserved, do not require high volumes of contaminant, would result in even distribution of the contaminant at this step or down the line, and/or will not result in denaturation or inactivation of the contaminant prior to the consumption of food. Steps scoring 10 for Element 3 indicate a very high likelihood that once an attacker reaches the step, they could successfully contaminate the product.

### Lesson 6: Questions


Lesson 6: Questions

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**Thank you for your attention**

**Questions?**

**Next: Lessons 6 Exercise: Element 2: Evaluating the Degree of Physical Access to the Product and Element 3: Evaluating the Ability of an Attacker to Successfully Contaminate the Product Worksheet**

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If you have any questions regarding the concepts we just went over, feel free to ask them. Next, we will complete the Lessons 6 Exercise: Element 2: Degree of Physical Access to the Product and Element 3: Evaluating the Ability of an Attacker to Successfully Contaminate the Product Worksheet. This exercise will give you examples that will help these concepts become clearer.

## Lessons 6 Exercise: Element 2 and Element 3

### Lessons 6 Exercise: Element 2 and Element 3 Worksheet

- Total time: 70 minutes
  - Complete worksheet: 30 minutes
  - Report out conclusions: 15 minutes
  - Whole group review/discussion: 25 minutes
- Instructions:
  - Using the following resources, determine the score for Elements 2 and 3 for Step 5 (Surge Tank), Step 7 (Secondary Ingredient Addition), and Step 10 (Forming):
    - *Example Process Flow Diagram* (see Exercise Workbook, page 9)
    - *Example Process Step Descriptions* (see Exercise Workbook, pages 15-16)
    - *Table 2. Degree of Physical Access to the Product* (Exercise Workbook, page 17)
    - *Table 3. The Ability of an Attacker to Successfully Contaminate the Product* (see Exercise Workbook, pages 18-20)
    - *Element 2 and Element 3 Worksheet* (see Exercise Workbook, page 21)
  - With the score, provide your supporting rationale. Please see the example provided for Step 2 (Bulk Liquid Receiving) as a guide
  - Once you have completed scoring Elements 2 and 3 and writing your supporting rationales, the Instructor will call upon you to report out
  - After everyone has reported out their results, the Instructor will lead a whole group review/discussion

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The information on the slide above is included in your Exercise Workbook (see page 14). The instructor will review the resources and instructions and then you can complete the worksheet. Once everyone has completed the worksheet, the instructor will facilitate a short review/discussion.

PUBLIC VERSION

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PUBLIC VERSION

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# LESSON 7. Analyzing Results

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Lesson 7: Analyzing Results

## IDENTIFYING ACTIONABLE PROCESS STEPS

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### Key Point:

Remember, the three elements are:

1. Element 1: Potential Public Health Impact,
2. Element 2: Degree of Physical Access to the Product, and
3. Element 3: The Ability of an Attacker to Successfully Contaminate the Product.

At this point in the VA, all three elements will have been evaluated and scored for every process step. The next step is to compile and analyze those results to determine where significant vulnerabilities are present and which process steps are actionable process steps.

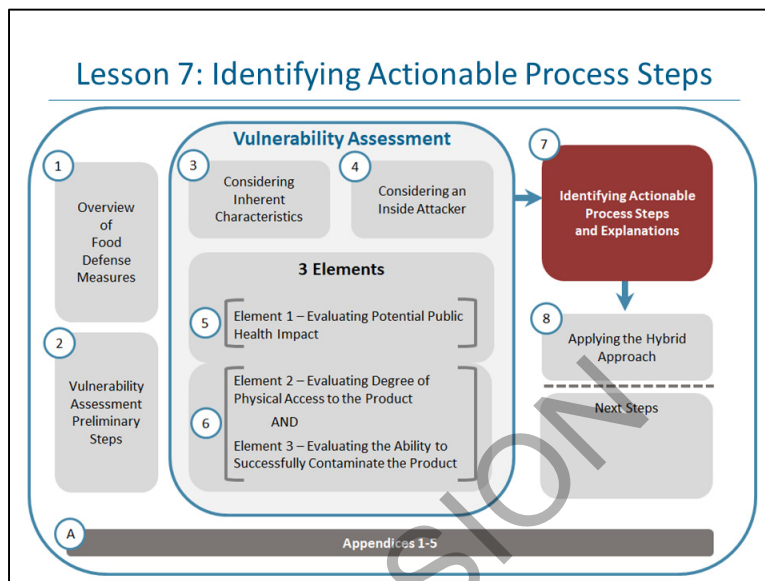
**Goal:** Participants will be able to analyze results from the evaluation of the three elements and identify actionable process steps.

### Learning Objectives:

By the end of this lesson, participants will be able to:

1. Explain the interplay of elements.
2. Compile scores.
3. Prioritize process steps based on scores.
4. Identify actionable process steps.
5. Explain your decisions.
6. Document your vulnerability assessment.

## Lesson 7: Identifying Actionable Process Steps

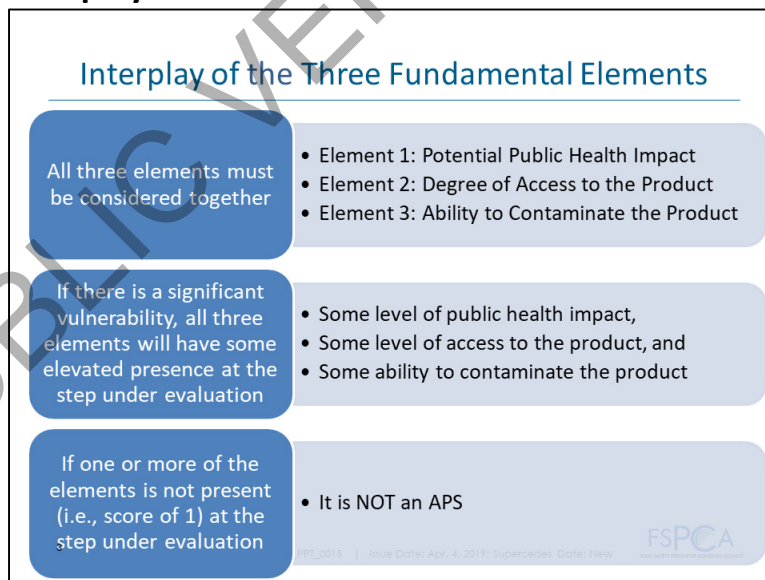


### Key Point:

Just as we noted in Lesson 1, **the goal of the VA is to identify those points, steps, or procedures at highest risk for intentional adulteration by distinguishing vulnerabilities** (a point, step, or procedure that is susceptible to intentional adulteration [21 CFR 121.3]) **from significant vulnerabilities** (“a vulnerability that, if exploited, could reasonably be expected to cause wide scale public health harm” [21 CFR 121.3]).

In food production operations, significant vulnerabilities, by nature, present themselves at particular points, steps, or procedures in the food process. **Actionable process steps or APSs**, are those points, steps, or procedures where significant vulnerabilities exist and “where mitigation strategies can be applied and are essential to significantly minimize or prevent the significant vulnerability” (21 CFR 121.3).

## Interplay of the Three Fundamental Elements



Significant vulnerabilities only exist where the three elements are present to an elevated degree. A significant vulnerability would not exist at a process step where one of the elements was scored as 1. A score of 1 means that the element is not present, therefore, the vulnerability could not be significant, regardless of the presence of the other elements. Conversely, a high score for one element does not automatically result in identification of an actionable process step. For example, a process step could have an estimated potential public health impact of over 10,000 illnesses or deaths (a score of 10), but also either be inaccessible or have a very low ability for an attacker to



successfully contaminate the food. Such a step would not be an actionable process step, regardless of the potential number of 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).

## Compile Scores


### Compile Scores

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- For each process step, sum the scores of the three elements to arrive at a total score per process step
- Review the rationales written for each of the element scores
- Rank order all process steps by their total scores (i.e., sum of the three scores)
  - The steps that were not summed due to one or more of the three elements scoring a 1 would be placed at the bottom of the rank order

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### Key Point:

In your rank ordering, be sure to include the process steps that have lower scores, including the steps that were not summed (because at least one element was scored a 1).

Doing this helps ensure that you have appropriate documentation of each point, step or procedure you evaluated and haven't omitted a process step.

For each point, step, or procedure you will need to add the three element scores together to arrive at a total sum number for each step, which represents the totality of vulnerability present at that process step. Steps where one of the three elements has been scored a 1 do not have to be summed, but you should include them in your listing. After compiling the scores, review each element's rationale, making sure that all three elements have been appropriately considered. Once you have calculated the sum scores for the points, steps, and procedures where each of the three elements scored greater than 1, rank order all process steps by the sum value from highest to lowest. Process steps that were not summed due to one of the element scores being a 1 can be placed at the bottom of the rank order.

### Key Point:

In many cases, there is a group of process steps that have noticeably higher total scores than the majority of other process steps. Historically, FDA has found a separation between highest scoring process steps commonly occurs at or around the top 20-25% of scores. If you see a noticeable separation, this may help you differentiate significantly vulnerable process steps from other process steps.

If you find that there is no noticeable separation, it is up to each facility to make a determination about the actionable nature of a process step based on the rationales written for each element.


## Prioritize Process Steps Based on Scores

### Prioritize Process Steps Based on Scores

Example Rank Order Worksheet	
Process Step	Sum Total Score
Process Step 1	26
Process Step 5	26
Process Step 2	24
Process Step 4	24
Process Step 11	18
Process Step 3	11
Process Step 6	11
Process Step 8	11
Process Step 9	9
Process Step 7	9
Process Step 10	n/a*
Process Step 12	n/a*
Process Step 13	n/a*
Process Step 14	n/a*
Process Step 15	n/a*

- Analyze sum of scores to determine where there may be a noticeable separation of higher scoring process steps

\*For these process steps, one of the elements scored a 1, therefore they are not summed.  
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When your process steps are ranked by sum score, there is typically a group of process steps that have higher sum scores, with other process steps differentiated from this grouping by a noticeable separation in sum score. You should look closely at steps in this highest grouping of sum scores. These steps are most likely significantly vulnerable, and you would identify these process steps as actionable process steps. Historically, FDA has found this grouping of the highest scoring process steps typically 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 smaller number of points, steps, or procedures. However, FDA has found in their experience conducting vulnerability assessments that there is often a break where a noticeable separation between the scores can be observed.

Included here is an example rank order worksheet using generic process step names and hypothetical sum scores that serves to illustrate how the noticeable separation can be identified.

This process of rank ordering and identifying process steps above the noticeable separation is one way to help delineate which process steps are significantly vulnerable and which ones are not.

## Using Sum Scores to Identify APs

### Using Sum Scores to Identify APs

- VAs are facility specific:
  - account for the unique characteristics of each facility and food
  - a single “threshold” for determining significant vulnerability is not appropriate
- The combination of individual element scores that together sum to create a single score may reflect a wide variety of circumstances
- However, there are cases where sum scores are so high or so low that the presence or absence of significant vulnerabilities is apparent

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Regardless of whether your VA exhibits a break in scores or where that break occurs, there are cases where sum scores are so high or so low that the presence or absence of significant vulnerabilities is apparent. However, FDA cannot draw a single score as a threshold for significant vulnerabilities due to the wide diversity of processing environments in the food industry. Vulnerability assessments using the three fundamental elements are specific to a facility and its processes. The sum score may reflect a wide variety of circumstances based on the combination of individual element scores. 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.

## Using Sum Scores to Identify APSs (continued)

### Using Sum Scores to Identify APSs (continued)

- It is possible to determine upper and lower limits for vulnerability and use these to determine if a process step is an APS
- Significant vulnerabilities:
  - are present when each of the elements are highly scored, such as when a process step sum score  $\geq 26$
  - do not exist when each of the elements score low, such as when a process step sum score  $\leq 13$
  - May or may not be present 14-25, explained on next slide

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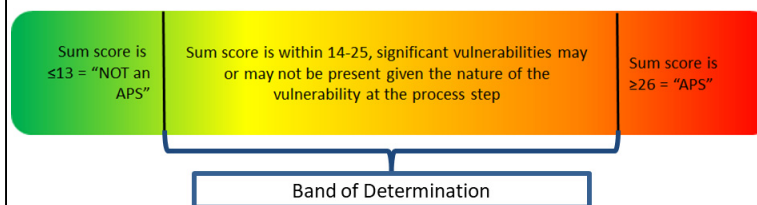
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However, it is possible to determine upper and lower thresholds for vulnerability. Significant vulnerabilities are present when each of the elements are highly scored, such as when a process step sum score is greater than or equal to 26 ( $\geq 26$ ). Similarly, according to FDA guidance, FDA expects that significant vulnerabilities do not exist when each of the elements score low, such as when a process step sum score is less than or equal to 13 ( $\leq 13$ ). These upper and lower limits can help facilitate identification of actionable process steps.

## The Band of Determination

### The Band of Determination



- Naturally, significant vulnerabilities would more commonly exist at the upper range of sum scores in this range, but there is no specific number within this band that indicates that a significant vulnerability is present in all cases

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When a process step sum score is within 14-25, significant vulnerabilities may or may not be present given 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 variability of conditions, the nature and degree of each of the three elements, and how they contribute to the sum scores is such that comparisons between separate facilities is inappropriate and an individual sum score viewed in isolation does not provide enough information as to the presence, or absence, of significant vulnerabilities. Naturally, significant vulnerabilities would more commonly exist at the upper end 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. Within this range, it is imperative that facilities exercise judgement and document decision making as it relates to whether a step is determined to be actionable or not.

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 conclude 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 considers 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, there is no mixing at the step, and 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 contribution 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 might pose a highly accessible target (Element 2 = 10) and the ease of successful contamination may be 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 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 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).

## Identify Actionable Process Steps

### Key Point:

Remember that any process steps that scored a 1 for any of the three elements would not be considered an actionable process step.

### Identify Actionable Process Steps

- Based on the rank order of process steps and the contribution of the three elements on the process step's vulnerability, identify which points, steps, or procedures are actionable process steps
- Process steps where each element score is elevated would typically be identified as actionable process steps

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After determining which process steps are significantly vulnerable based on the rank order of process steps and your consideration of the contribution of the three elements on the process step's vulnerability, you would then identify those as actionable process steps. Actionable process steps carry that term because once that determination is made, further action is necessary to identify and implement mitigation strategies and put into place mitigation strategy management components (food defense monitoring, food defense corrective actions, and food defense verification) in order to make sure that the significant vulnerability present at that step is properly protected.

## Lesson 7 Exercise: Analyzing Results – Part 1

### Lesson 7 Exercise: Analyzing Results – Part 1

- Total time: 5 minutes
- Instructions:
  1. Use the data and decisions from your Element 1 Exercise Worksheet and Elements 2 and 3 Exercise Worksheet to fill in the blanks on the **Analyzing Results Worksheet (see Exercise Workbook, pages 24-30)**:
    - a) Transcribe the scores from your Element 1 Exercise Worksheet and your Combined Elements 2 and 3 Exercise Worksheet into columns (4), (5), and (6) in the *Analyzing Results Worksheet* for the three process steps you have in the exercise (Surge Tank, Secondary Ingredient Addition, and Forming)
    - b) Sum the scores from columns (4), (5), and (6) and enter the sum in column (7)
  2. Use the **Rank Order Worksheet (see Exercise Workbook, page 31)** to place your three process steps in order with the other fifteen steps from highest sum total to lowest.
    - *Remember to place process steps that were not summed due to one or more elements scoring a 1 at the bottom of the Rank Order Worksheet. There will be two extra rows in the worksheet after you have included your three steps.*

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The Analyzing Results Exercise – Part 1 instructions and a list of resources you will need, along with the Analyzing Results Exercise Worksheet and Rank Order Worksheet are in the Exercise Workbook (see pages 24-31). The instructor will review the instructions and then you will complete the worksheet.

## Explanations Requirement

Explanations Requirement

Required by the regulation (21 CFR 121.130(c))

- For each point, step, or procedure under evaluation, you must explain why it was identified as an actionable process step or why it was not

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For each point, step, or procedure under evaluation, you must explain why it was identified as an actionable process step or why it was not. 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.

Your required explanation 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.




## Importance of Explanations

### Importance of Explanations

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- Additionally, explanations are beneficial by:
  - Informing the identification of mitigation strategies
  - Informing monitoring, corrective action, and verification procedures
  - informing the reanalysis of the VA

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When writing explanations, it may be beneficial to consider that they have utility beyond satisfying the written explanation requirement by serving as a stepping stone to completing the next sections of your food defense plan. The detail provided in your explanations can help inform the identification of mitigation strategies. For example, if the explanation for identifying the primary ingredient storage tank as an actionable process step is that an accessible hatch with created a significant vulnerability, this suggests that an appropriate mitigation strategy is likely to address the accessibility of the hatch.

The detail provided in your explanations can also help inform mitigation strategy management components (monitoring, corrective actions, and verification) and, importantly, the reanalysis of the vulnerability assessment.

## Explaining Your Decisions

Explaining Your Decisions		
Example Decision Explanations		
Process Step	Explanation	APS or Not an APS
A	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.	APS
B	This step is significantly vulnerable because the score $\geq$ 26.	APS
C	No significant vulnerability is present since Element 2 = 1	Not an APS
D	Access is difficult. An attack at this step would adulterate individual packages, and not result in wide scale public health harm.	Not an APS

The IA rule requires written explanations as to why a step was or was not identified as an actionable process step, but, as noted earlier, there is flexibility on how to do so and the level of detail necessary. It is recommended that you write your explanations at the end of your analysis because at that point you have the added benefit of seeing all element evaluations together, and you can then summarize your rationales from each of the individual elements. 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 to refer back to this explanation.

Once the explanation is written, it should generally touch on why that significant vulnerability is present at the actionable process step or be able to explain why the process step is not significantly vulnerable. The explanation should provide a summary of or reference back to your rationale for the evaluations from Elements 1, 2, and 3 in sufficient detail to clearly communicate the determination of why the point, step, or procedure is an actionable process step or not.


## Documenting the Vulnerability Assessment

Documenting the Vulnerability Assessment

- Your VA needs to be written and included in the FDP

**Example VA Worksheet**

(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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**Key Point:**

**Reminder:** Worksheets are examples only. As long as all the minimum requirements are documented, your facility has the flexibility to determine how best to capture the results of the VA.

Two different examples of complete VAs will be provided at the end of the course.

This is an example of a VA worksheet that can be used to document the results of your VA. The example worksheet may be used as is, or augmented as necessary, but you also have the flexibility to document your VA in any way you choose as long as it contains all the required information.

**Key Point:**

**Reminder:** If one element was scored a “1,” the other two elements would not need to be evaluated because the step is already determined to be not significantly vulnerable.


## Lesson 7: Questions

Lesson 7: Questions

**Thank you for your attention**

**Questions?**

**Next: Analyzing Results Exercise Part 2**

  
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If you have any questions regarding the concepts we just went over, feel free to ask them. Next, we will complete the Analyzing Results Exercise Part 2.

## Lesson 7 Exercise: Analyzing Results – Part 2

### Lesson 7 Exercise: Analyzing Results – Part 2

- Total time: 30 minutes
  - Individually complete the worksheets and report out: 20 minutes
  - Facilitated review/discussion: 10 minutes
- Instructions:
  1. Identify the band of determination (between 14-25) in your **Rank Order Worksheet** (see **Exercise Workbook, page 31**).
  2. For the three process steps that you have been using in the exercises (surge tank, secondary ingredient addition, and forming), refer back to your rationale for each element score for each process step.
  3. Consider each element's contribution to the overall vulnerability of each process step. Assess whether a significant vulnerability is present. If you believe a significant vulnerability is present, identify the process step as an actionable process step.
  4. Write an explanation in column (8) in the **Analyzing Results Worksheet** (see **Exercise Workbook, pages 24-30**) for why the process step was determined to be an actionable process step, or why it was not. The individual element rationale scores will be helpful with informing the explanation.
  5. Indicate which process steps would be actionable process steps and record (Y) or (N) in column (9) based on your explanations.

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The information on the slide above is included in your Exercise Workbook (see pages 24-31). The instructor will review the resources and instructions and then you can complete the worksheets. Once everyone has completed the worksheets, the instructor will facilitate a short review/discussion.

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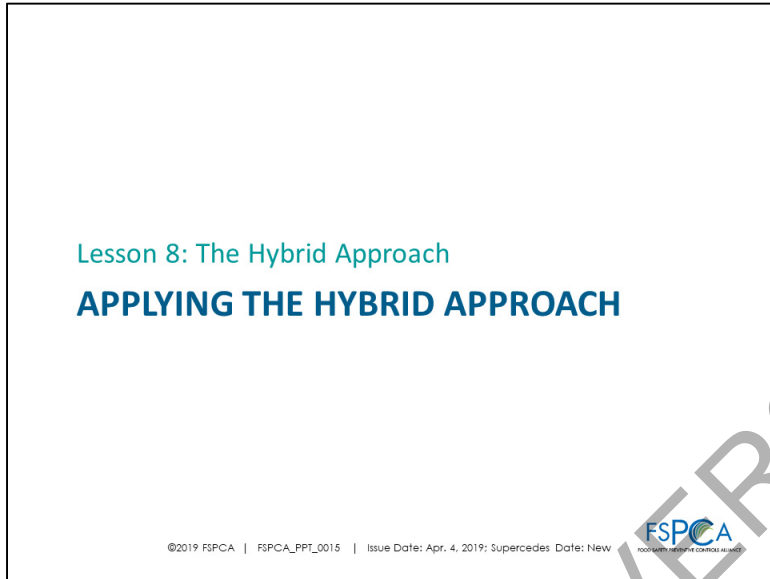
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# LESSON 8. The Hybrid Approach

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You have learned how to conduct a VA by evaluating the three fundamental elements and are familiar with the KAT method. You also have the flexibility to use a combination of the two, which is referred to as the “hybrid approach.”

**Goal:** Participants will understand the benefits of, and how to apply, the hybrid approach.

**Learning Objective:**

By the end of this lesson, participants will be able to:

1. Apply the hybrid approach.

**Key Point:**

Remember, the three elements are:

1. Element 1: Potential Public Health Impact,
2. Element 2: Degree of Physical Access to the Product, and
3. Element 3: The Ability of an Attacker to Successfully Contaminate the Product.

And the four KATs are:

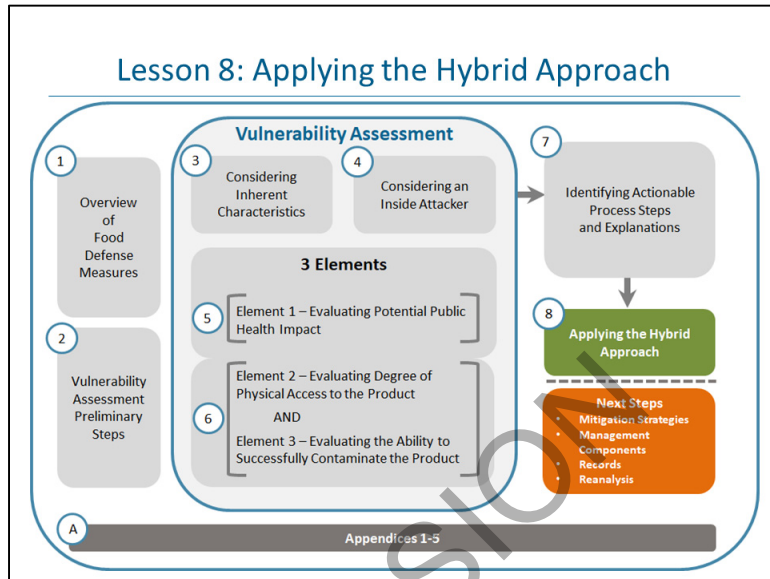
1. Bulk Liquid Receiving and Loading
2. Liquid Storage and Handling
3. Secondary Ingredient handling
4. Mixing and Similar Activities

**Resources:**

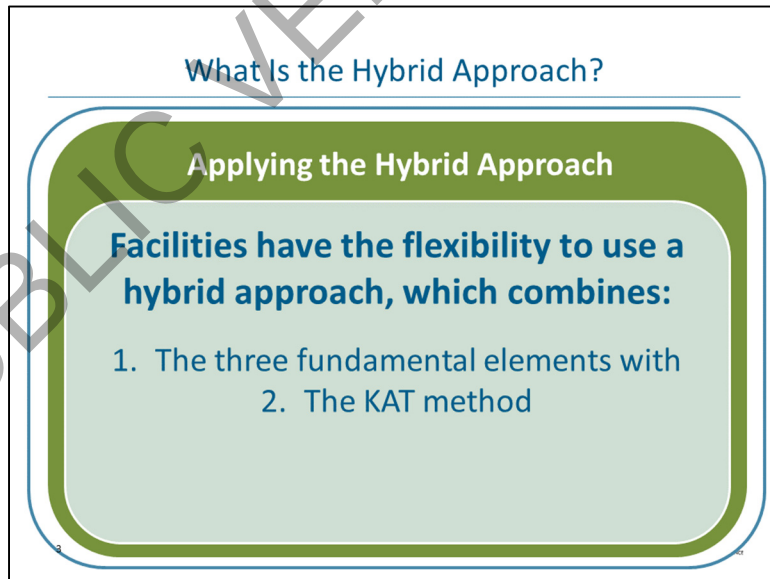
FDA’s Key Activity Types (KAT) Report and KAT Descriptions are located in Appendix 2.



## Lesson 8: The Hybrid Approach

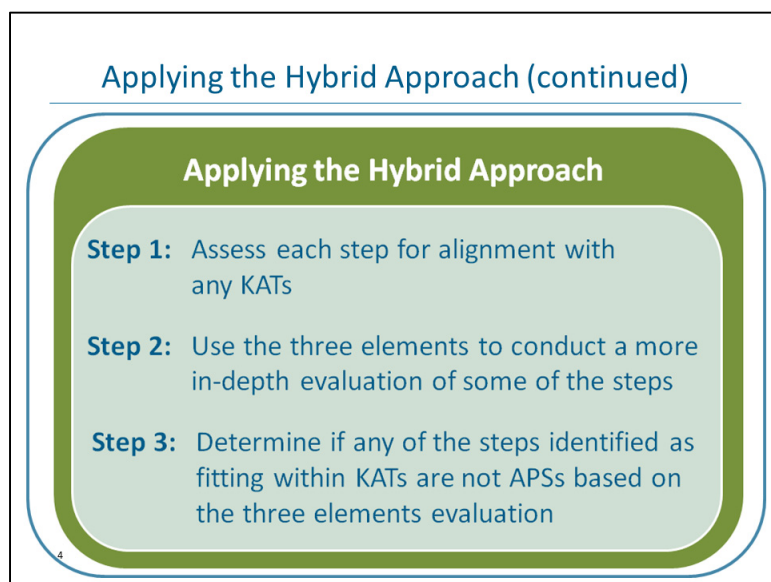


### What is the Hybrid Approach?



The hybrid approach is another method you can use to conduct a VA. The hybrid approach allows you to use the strengths of both the KAT and three elements methods. In the hybrid approach, you can first take advantage of the less resource-intensive KAT method to identify points, steps, or procedures that fit within the KATs. Then, rather than concluding the VA with those steps identified as APSs, you can conduct a more in-depth evaluation of all, or a subset, of those steps using the three elements.

## Applying the Hybrid Approach



**Key Point:**

Facilities always have the option to do an in-depth evaluation of process steps that did not fit within a KAT as well.

**Key Point:**

The hybrid approach does not include a rank order of steps because not all steps are being scored. Written explanations will need to explain the downgrading of any steps that were identified as a KAT but are not identified as APSs.

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. For example, steps that receive a score of 1 on any of the three elements do not have significant vulnerabilities, and therefore even though they may have aligned with a KAT, they are not significantly vulnerable. The facility would then determine if any of the previously identified KATs are in fact not significantly vulnerable based on the three-element evaluation.

Conversely, a facility may choose to reevaluate a step that did not align with a KAT because of potential circumstances surrounding that step that may make it significantly vulnerable and therefore should be identified as an APS.

When using the three elements on selected steps, you can use the scoring categories that were discussed in Lesson 7 in order to determine if they are APSs or not. The requirement for written explanations, also discussed in Lesson 7, applies here as well.

## Benefits of the Hybrid Approach

### Benefits of the Hybrid Approach

- Uses the less resource-intensive KAT method to quickly identify steps that fully align with KATs, steps that don't, and steps that warrant further evaluation
- Allows facilities to conduct an in-depth evaluation on a subset of steps using the three elements
- May lead to the downgrading of a process step identified as an APS using KAT, but was determined to not have a significant vulnerability using the three elements

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There are many benefits to using the hybrid approach. The hybrid approach starts with the cost-effective and efficient KAT method which quickly separates out steps that fully align with KATs and are therefore actionable process steps. Using the KAT method also quickly separates out steps that are not actionable process steps. As we just mentioned, 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. This part of the hybrid approach narrows down the number of steps that are evaluated using the three elements. The hybrid approach also provides the flexibility for facilities to conduct a more in-depth evaluation on a subset of steps based on the circumstances and facility-specific nature of those steps. Allowing for the consideration of specific conditions within the facility may result in the determination that some steps that aligned with the KATs are not actionable process steps. This could reduce the number of APSs in the facility and eliminates the need for mitigation strategies and management components at those downgraded steps. This can save time and resources for the facility.

## Key Activity Types

Key Activity Types

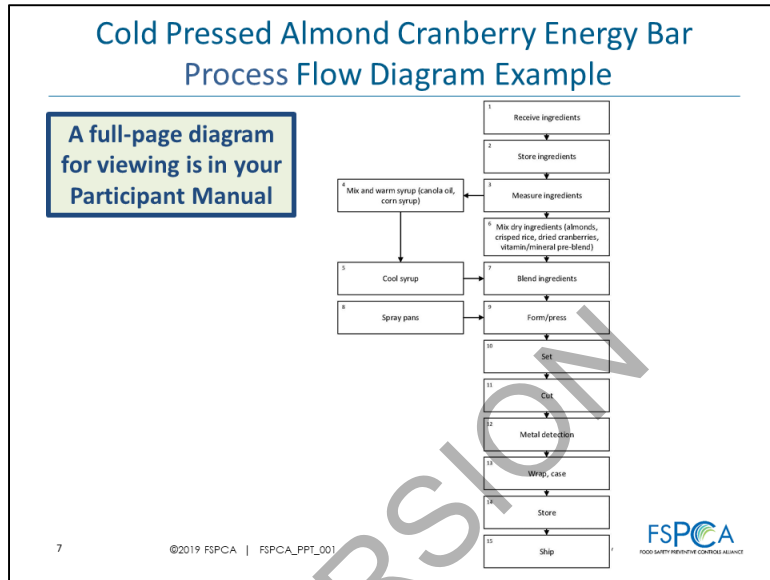
1. Bulk Liquid Receiving and Loading
2. Liquid Storage and Handling
3. Secondary Ingredient Handling
4. Mixing and Similar Activities

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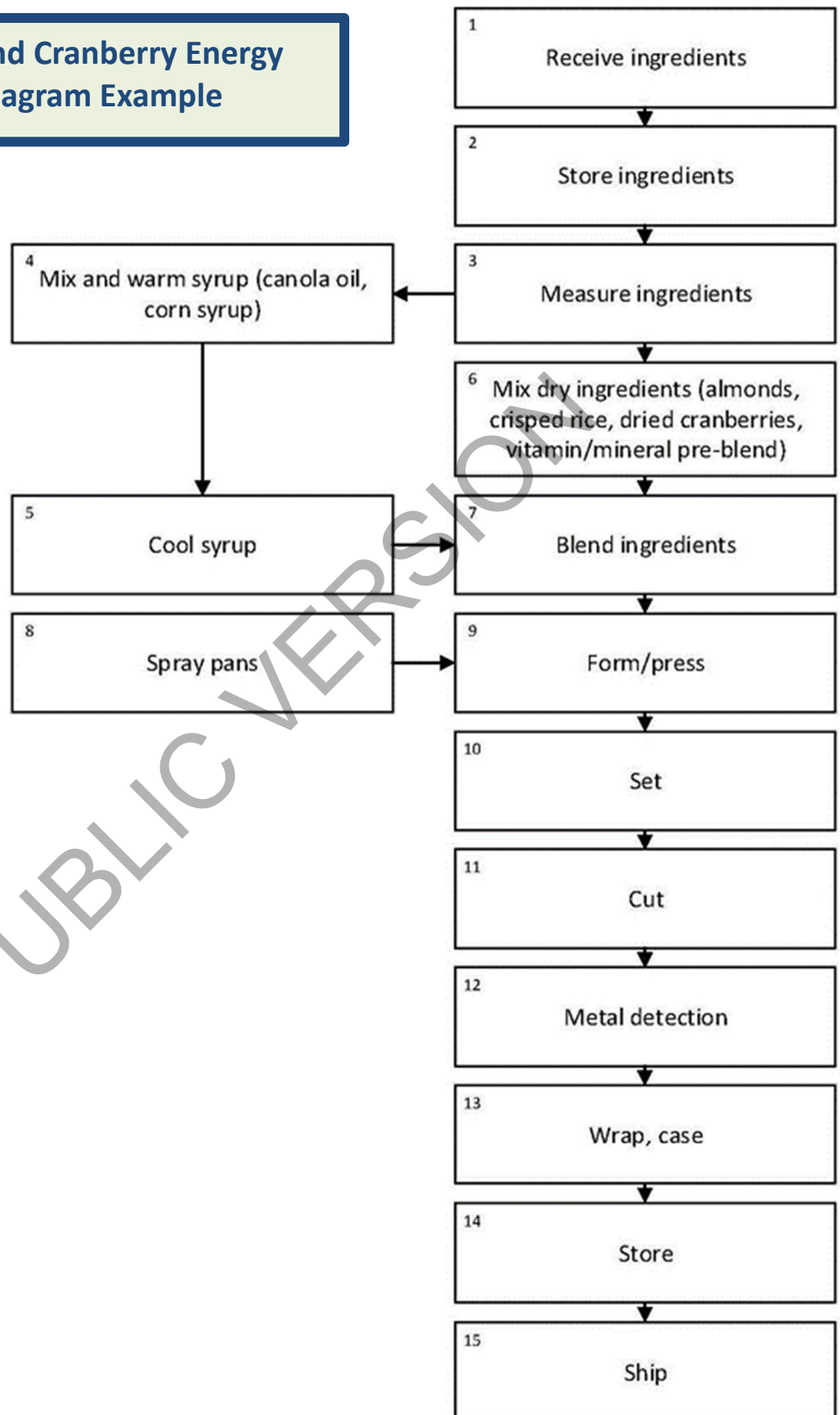
Before getting into an example, let's quickly review the four Key Activity Types: Bulk Liquid Receiving and Loading, Liquid Storage and Handling, Secondary Ingredient Handling, and Mixing and Similar Activities. As mentioned previously in this course, the identification of these KATs came from many years of vulnerability assessment work that FDA did with industry. The KAT training and guidance provides background information that describes these KATs in detail, but over the course of this training you have learned that the drivers of vulnerability have been Element 1 (public health impact), Element 2 (increased access), and Element 3 (ability to successfully contaminate the product). Those are the same drivers of vulnerability that were documented in the four KATs.

### Cold Pressed Almond Cranberry Energy Bar Process Flow Diagram Example

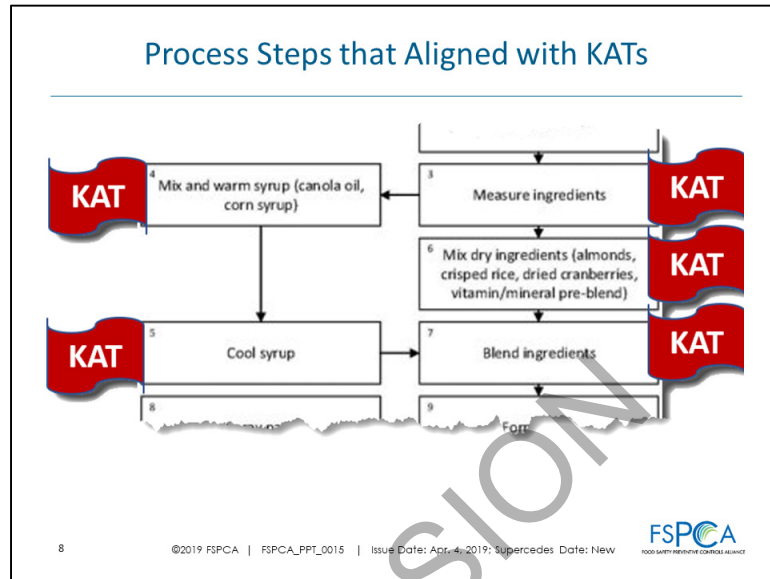


This example flow diagram for a cold pressed almond cranberry energy bar will be used for our hybrid approach example and is enlarged for easier viewing on the next page.

**Cold Pressed Almond Cranberry Energy Bar Process Flow Diagram Example**



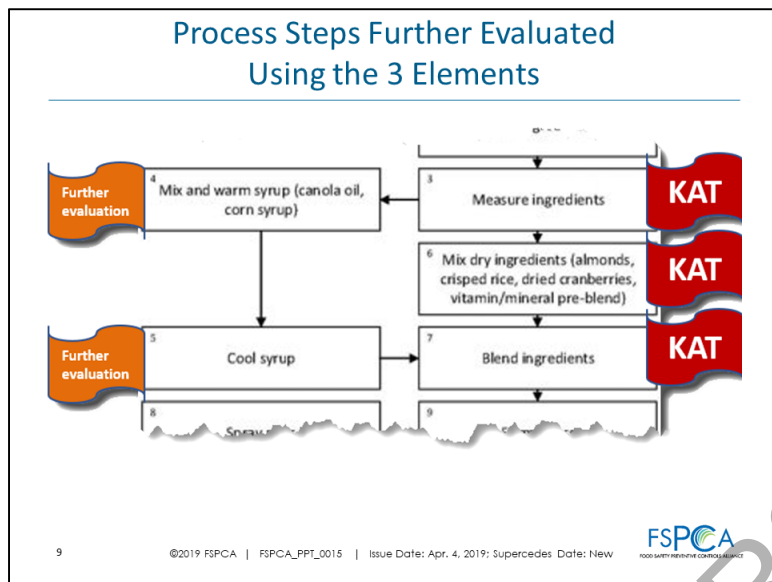
## Process Steps that Aligned with KATs



The first step in the hybrid approach is to evaluate each process step in the flow diagram to determine if it aligns with any of the four KATs. In this scenario, the facility has determined that there are five process steps that have aligned with a KAT. Those steps are:

- Step 3 – Measure Ingredients
- Step 4 – Mix and Warm Syrup
- Step 5 – Cool Syrup
- Step 6 – Mix Dry Ingredients
- Step 7 – Blend Ingredients

### Process Steps Being Further Evaluated Using the 3 Elements



### Process Steps Being Further Evaluated Using the 3 Elements (continued)

Process Steps Further Evaluated Using the 3 Elements (continued)

**Mix and Warm Syrup – KAT  
(Mixing and Similar Activities)**

- **Description:** Corn syrup and canola oil are added to an enclosed jacketed mixer and warmed to 195 to 205°F and blended for 20 minutes to ensure even distribution.

**Cool Syrup – KAT  
(Liquid Storage and Handling)**

- **Description:** The syrup is pumped into a cooling tank and cooled to 120-130°F. The cooling tank is enclosed except for a hatch that is closed when product is in the tank but opened during cleaning and maintenance.

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The facility may opt to stop here and determine these five steps to be their actionable process steps. However, they believe that Step 4 – Mix and Warm Syrup, and Step 5 – Cool Syrup, have inherent characteristics that cause these steps not to have a significant vulnerability. The facility decides to use the hybrid approach and further evaluates Steps 4 and 5 using the three elements.




## Mix and Warm Syrup Being Further Evaluated

**Mix and Warm Syrup Being Further Evaluated**

- Mix and Warm Syrup step aligns with a KAT, but was further evaluated using the three elements

(1) #	(2) Process Step	(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
4	Mix and Warm Syrup	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

- Using the three elements this step was downgraded because there is no physical access at this step

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The facility has chosen to further evaluate Step 4 – Mix and Warm Syrup, because this step in their facility is enclosed and inaccessible. They start with the Element 2 analysis of physical access and arrive at a score of 1 because the mixer is designed to be fully enclosed to protect workers and can only be opened with special tools and disassembling equipment. The score of 1 for Element 2 means that the other elements do not need to be evaluated because this step cannot be significantly vulnerable if it is inaccessible. Therefore, the facility can downgrade this step and document that it is not an actionable process step.

## Cool Syrup Being Further Evaluated

**Cool Syrup Being Further Evaluated**

- Cool Syrup step aligns with a KAT, but was further evaluated using the three elements

(1) #	(2) Process Step	(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
5	Cool Syrup	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 contaminant into the tank.	11	While this step fits within the KAT "Liquid Storage and Handling," no significant vulnerability is present because score < 14.	No

- Using the three elements this step was downgraded because all three element scores are low

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In this example, the Cool Syrup step is not significantly vulnerable because it is a small tank that is enclosed and in plain view of many employees. The facility uses the three elements and arrives at a sum score of 11 for this step.

First, the facility used FDA's representative contaminant method to estimate public health impact. Element 1 scored a 5 because the cooling tank is small and contamination at this step would generate a public health impact of 900 deaths.

The facility then evaluated Element 2 and scored the step a 3 because while the tank cannot be accessed when product is inside, it can be accessed through a hatch when the tank is empty, making it "hardly accessible."

Element 3 scored a 3 because a large amount of contaminant would be required at this step, in order to achieve a significant public health impact. Additionally, the tank is located in an area where many employees can see it, making it hard for an attacker to have enough time to introduce a contaminant into the tank without being caught in the act.

To downgrade this step, the facility should provide a detailed explanation for how they can determine this step is not an actionable process step based only on the rationales and scores for each of the elements. This could be based on that for this example, the public health impact and the ability to successfully contaminate the product are both moderately low and this step is hardly accessible. Since all three elements scored low at this step it would not be considered an actionable process step. The facility would write an explanation to this effect that captures the information that justifies this conclusion. In


addition, FDA expects 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. Since the sum score for the cooling step is 11, that would fall into this range. As seen on the slide, another example explanation could be, "While this step fits within the KAT "Liquid Storage and Handling," no significant vulnerability is present because score < 14."

## Documenting the Hybrid Approach in the VA

Documenting the Hybrid Approach in the VA

For each point, step, or procedure under evaluation, you must explain why it was identified as an actionable process step or why it was not

- Process steps that aligned or did not align with a KAT should be clearly identified
- Process steps that were further evaluated using the three elements should be clearly identified
- Conclusions as to a process step's status (i.e., whether it is an APS or not) using the hybrid approach must include an explanation similar to those discussed in Lesson 7.

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The hybrid approach must be documented and must include all the required information detailed in the IA rule. Process steps that aligned with a KAT and those that did not should be clearly identified, and it should be clearly written which steps were further evaluated using the three elements approach. The conclusions reached at the end of the hybrid approach as to whether a process step is an actionable process step or not must include an explanation, similar to the explanations requirements discussed in Lesson 7. Rationales for each of the element scores are very helpful when making these determinations and writing explanations.

Facilities have the flexibility to document the hybrid approach in any format, but one example of how this can be done is provided in the *Answer Keys and Examples Booklet* for your reference.


## Lesson 8: Questions

Lesson 8: Questions

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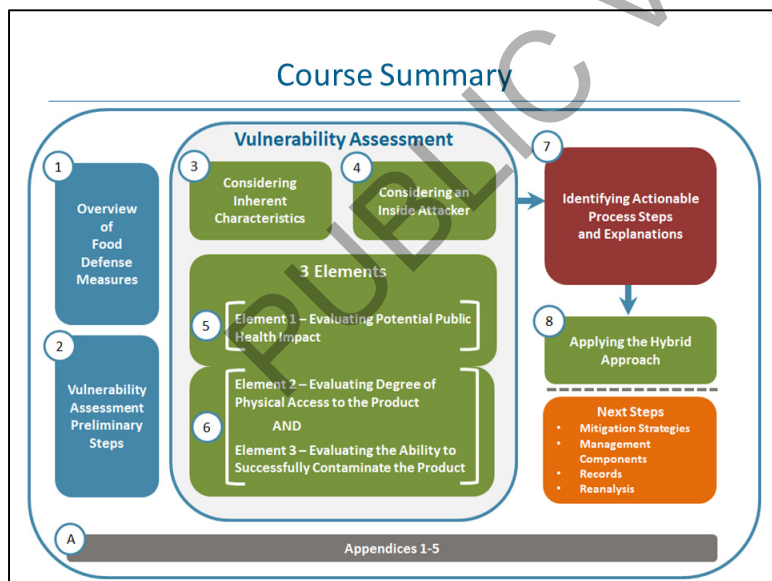
Thank you for your attention

Questions?

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If you have any questions regarding the concepts we just went over, feel free to ask them.

## Course Summary



In summary, we've walked through all the steps of conducting a vulnerability assessment, including the voluntary preliminary steps, considering inherent characteristics, considering the actions of an inside attacker, and an in-depth examination of each of the three elements. The overarching goal of this process was to distinguish vulnerabilities from significant vulnerabilities. The rule requires facilities to identify actionable process steps where those significant

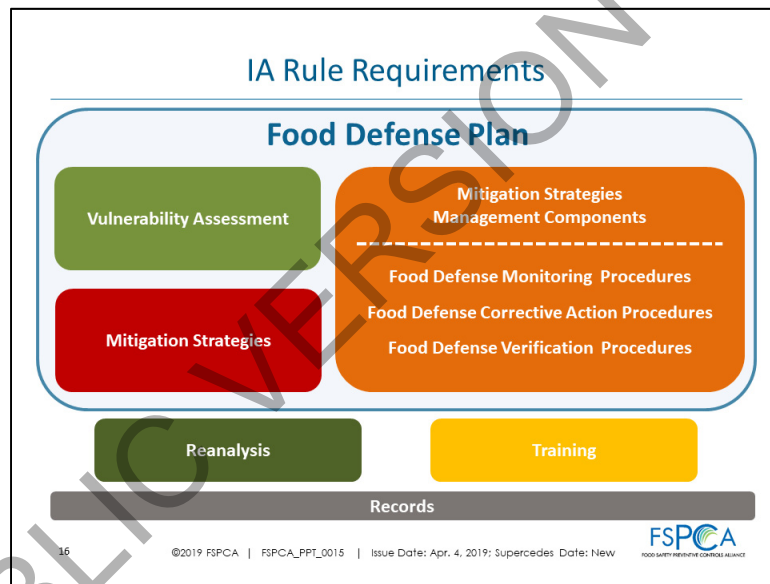
vulnerabilities exist. Finally, we just finished our discussion of the hybrid approach, which combines the Key Activity Type method with an analysis that further evaluates selected points, steps, or procedures using a method that incorporates the three elements.

Actionable process steps are “actionable” because they require, under the IA rule, further action to significantly minimize or prevent the significant vulnerability present at that step. We’d like to conclude this training with a brief overview of these next steps that will make up the other required components of the food defense plan.

## IA Rule Requirements

### Key Point:

**Reminder:** This training does not qualify you to perform activities other than conducting a vulnerability assessment using the three elements and hybrid approaches.



The rule requires the writing and implementation of a food defense plan. That plan includes five main components and there are records requirements throughout each of those components. The first component, and the subject of this training, is a vulnerability assessment to identify points in the facility that are most vulnerable. Once this is done, facilities then identify mitigation strategies to reduce or prevent those vulnerabilities. After that, facilities are required to have procedures for food defense monitoring, food defense corrective actions, and food defense verification. These three requirements work as a system to ensure strategies are reducing vulnerabilities. There are records requirements for each of those components, as well as specific training requirements for certain individuals.

Finally, the IA rule requires reanalysis of some or all of the food defense plan under specific circumstances. As the QI for conducting vulnerability assessments at your facility, you may be called upon by



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# APPENDIX 1: IA Rule and Summary

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<b>Title of Document</b>	<b>Page</b>
21 CFR Parts 11, and 121	A1-3
<i>Mitigation Strategies to Protect Food Against Intentional Adulteration or IA Rule</i>	
FDA Summary from FDA Website	A1-11

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**Retrieved from U.S. Office of the Federal Register website at:**

<https://www.federalregister.gov/documents/2016/05/27/2016-12373/mitigation-strategies-to-protect-food-against-intentional-adulteration>

The codified portion of the final VA rule follows a lengthy preamble that responds to the issues raised in comments that were submitted to the proposed VA rule and the supplemental proposal. The preamble is not presented below, but can be found at the website above. The preamble explains what FDA did and why, so it is useful as guidance on many aspects of the final rule. Only the codified portion of the rule, i.e., the portion that is now incorporated in Title 21 of the Code of Federal Regulations, is presented below.

**Summary from the Federal Register:**

The Food and Drug Administration (FDA or we) is issuing this final rule to require domestic and foreign food facilities that are required to register under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to address hazards that may be introduced with the intention to cause wide scale public health harm. These food facilities are required to conduct a vulnerability assessment to identify significant vulnerabilities and actionable process steps and implement mitigation strategies to significantly minimize or prevent significant vulnerabilities identified at actionable process steps in a food operation. FDA is issuing these requirements as part of our implementation of the FDA Food Safety Modernization Act (FSMA).

**List of Subjects:***21 CFR Part 11*

Administrative practice and procedure, Computer technology, Reporting and recordkeeping requirements.

*21 CFR Part 121*

Food packaging, Foods. Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR Chapter 1 is amended as follows.

**34218 Federal Register / Vol. 81, No. 103 / Friday, May 27, 2016 / Rules and Regulations**

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**PART 11—ELECTRONIC RECORDS;****ELECTRONIC SIGNATURES****■ 1. The authority citation for part 11 continues to read as follows:**

**Authority:** 21 U.S.C. 321–393; 42 U.S.C. 262.

**■ 2. In § 11.1, add paragraph (o) to read as follows:****§ 11.1 Scope.**

\*\*\*\*\*

(o) This part does not apply to records required to be established or maintained

**34219 Federal Register / Vol. 81, No. 103 / Friday, May 27, 2016 / Rules and Regulations**

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by part 121 of this chapter. Records that satisfy the requirements of part 121 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

**■ 3. Add part 121 to read as follows:**

**PART 121—MITIGATION STRATEGIES TO PROTECT FOOD AGAINST INTENTIONAL ADULTERATION**

Sec.

**Subpart A—General Provisions**

121.1 Applicability.

121.3 Definitions.

121.4 Qualifications of individuals who perform activities under subpart C of this part.

121.5 Exemptions.

**Subpart B—Reserved****Subpart C—Food Defense Measures**

121.126 Food defense plan.

121.130 Vulnerability assessment to identify significant vulnerabilities and actionable process steps.

121.135 Mitigation strategies for actionable process steps.

121.138 Mitigation strategies management components.

121.140 Food defense monitoring.

121.145 Food defense corrective actions.

121.150 Food defense verification.

121.157 Reanalysis.

**Subpart D—Requirements Applying to Records That Must Be Established and Maintained**

121.301 Records subject to the requirements of this subpart.

121.305 General requirements applying to records.

121.310 Additional requirements applying to the food defense plan.

121.315 Requirements for record retention.

121.320 Requirements for official review.

121.325 Public disclosure.

121.330 Use of existing records.

**Subpart E—Compliance****121.401 Compliance.**

Authority: 21 U.S.C. 331, 342, 350g, 350(i), 371, 374.

**Subpart A—General Provisions****§ 121.1 Applicability.**

This part 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 Federal Food, Drug, and Cosmetic Act, unless one of the exemptions in § 121.5 applies.

**§ 121.3 Definitions.**

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act are applicable to such terms when used in this part. The following definitions also apply:

*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 Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of this chapter.

*Farm* means farm as defined in § 1.227 of this chapter.

*FDA* means the Food and Drug Administration.

*Food* means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

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

**34219 Federal Register / Vol. 81, No. 103 / Friday, May 27, 2016 / Rules and Regulations (continued)**

*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 × 52 weeks). If the result is not a whole number, round down to the next lowest whole number.

*Holding* means storage of food and also includes activities performed incidental to storage of food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets) but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic 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 Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a “farm

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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 Federal Food, Drug, and Cosmetic Act.

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

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

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

*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.

#### § 121.4 Qualifications of individuals who perform activities under subpart C of this part.

(a) Applicability. You must ensure that each individual who performs activities required under subpart C of this part is a qualified individual as that term is defined in § 121.3.

(b) Qualifications of individuals assigned to an actionable process step. Each individual assigned to an actionable process step (including temporary and seasonal personnel) or in the supervision thereof must:

(1) Be a qualified individual as that term is defined in § 121.3—i.e., have the appropriate education, training, or experience (or a combination thereof) necessary to properly implement the mitigation strategy or combination of mitigation strategies at the actionable process step; and

(2) Receive training in food defense awareness.

(c) Qualifications of individuals for certain activities described in paragraph (c)(3) of this section. Each individual assigned to certain activities described in paragraph (c)(3) of this section must:

(1) Be a qualified individual as that term is defined in § 121.3—i.e., have the appropriate education, training, or experience (or a combination thereof) necessary to properly perform the activities; and

(2) Have successfully completed training for the specific function 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 the standardized curriculum. This individual may be, but is not required to be, an employee of the facility.

(3) One or more qualified individuals must do or oversee:

(i) The preparation of the food defense plan as required in § 121.126;

(ii) The conduct of a vulnerability assessment as required in § 121.130;

(iii) The identification and explanation of the mitigation strategies as required in § 121.135; and

(iv) Reanalysis as required in § 121.157.

(d) Additional qualifications of supervisory personnel. Responsibility for ensuring compliance by individuals with the requirements of this part must be clearly assigned to supervisory personnel with a combination of education, training, and experience necessary to supervise the activities under this subpart.

(e) Records. Training required by paragraphs (b)(2) and (c)(2) of this section must be documented in records, and must:

(1) Include the date of training, the type of training, and the persons trained; and

(2) Be established and maintained in accordance with the requirements of subpart D of this part.

#### § 121.5 Exemptions.

(a) This part does not apply to a very small business, except that a very small business must, upon request, provide for official review documentation sufficient to show that the facility meets this exemption. Such documentation must be retained for 2 years.

(b) This part does not apply to the holding of food, except the holding of food in liquid storage tanks.

(c) This part does not apply to the packing, re-packing, labeling, or relabeling of food where the container that directly contacts the food remains intact.

(d) This part does not apply to activities of a farm that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety).

(e)(1) This part does not apply with respect to alcoholic beverages at a facility that meets the following two conditions:

(i) 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

(ii) Under section 415 of the Federal Food, Drug, and Cosmetic 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.

(2) This part does not apply with respect to food that is not an alcoholic beverage at a facility described in paragraph (e)(1) of this section, provided such food:

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- (i) Is in prepackaged form that prevents any direct human contact with such food; and
- (ii) Constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.
- (f) This part does not apply to the manufacturing, processing, packing, or holding of food for animals other than man.
- (g) This part does 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 Federal Food, Drug, and Cosmetic Act.
  - (1) Eggs (in-shell, other than raw agricultural commodities, e.g., pasteurized); and
  - (2) Game meats (whole or cut, not ground or shredded, without secondary ingredients).

**Subpart B—Reserved****Subpart C—Food Defense Measures****§ 121.126 Food defense plan.**

- (a) *Requirement for a food defense plan.* You must prepare, or have prepared, and implement a written food defense plan.
- (b) *Contents of a food defense plan.* The written food defense plan must include:
  - (1) The written vulnerability assessment, including required explanations, to identify significant vulnerabilities and actionable process steps as required by § 121.130(c);
  - (2) The written mitigation strategies, including required explanations, as required by § 121.135(b);
  - (3) The written procedures for the food defense monitoring of the implementation of the mitigation strategies as required by § 121.140(a);
  - (4) The written procedures for food defense corrective actions as required by § 121.145(a)(1); and
  - (5) The written procedures for food defense verification as required by § 121.150(b).
- (c) *Records.* The food defense plan required by this section is a record that is subject to the requirements of subpart D of this part.

**§ 121.130 Vulnerability assessment to identify significant vulnerabilities and actionable process steps.**

- (a) *Requirement for a vulnerability assessment.* 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. Appropriate methods must include, at a minimum, an evaluation of:
  - (1) The potential public health impact (e.g., severity and scale) if a contaminant were added;
  - (2) The degree of physical access to the product; and
  - (3) The ability of an attacker to successfully contaminate the product.
- (b) *Inside attacker.* The assessment must consider the possibility of an inside attacker.
- (c) *Written vulnerability assessment.* Regardless of the outcome, the vulnerability assessment must be written and must include an explanation as to why each point, step, or procedure either was or was not identified as an actionable process step.

**§ 121.135 Mitigation strategies for actionable process steps.**

- (a) 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 Federal Food, Drug, and Cosmetic Act. For each mitigation strategy implemented at each actionable process step, you must include a written explanation of how the mitigation strategy sufficiently minimizes or prevents the significant vulnerability associated with the actionable process step.
- (b) Mitigation strategies and accompanying explanations must be written.

**§ 121.138 Mitigation strategies management components.**

Mitigation strategies required under § 121.135 are subject to the following mitigation strategies management components as appropriate to ensure the proper implementation of the mitigation strategies, taking into account the nature of each such mitigation strategy and its role in the facility's food defense system:

- (a) Food defense monitoring in accordance with § 121.140;
- (b) Food defense corrective actions in accordance with § 121.145; and

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(c) Food defense verification in accordance with § 121.150.

**§ 121.140 Food defense monitoring.**

As appropriate to the nature of the mitigation strategy and its role in the facility's food defense system:

(a) *Written procedures.* 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.

(b) *Food defense monitoring.* You must monitor the mitigation strategies with adequate frequency to provide assurances that they are consistently performed.

(c) *Records*—(1) Requirement to document food defense monitoring. You must document the monitoring of mitigation strategies in accordance with this section in records that are subject to verification in accordance with § 121.150(a)(1) and records review in accordance with § 121.150(a)(3)(i).

(2) *Exception records.* Records may be affirmative records demonstrating the mitigation strategy is functioning as intended. Exception records demonstrating the mitigation strategy is not functioning as intended may be adequate in some circumstances.

**§ 121.145 Food defense corrective actions.**

(a) *Food defense corrective action procedures.* As appropriate to the nature of the actionable process step and the nature of the mitigation strategy:

(1) You must establish and implement written food defense corrective action procedures that must be taken if mitigation strategies are not properly implemented.

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(2) The food defense corrective action procedures must describe the steps to be taken to ensure that:

(i) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a mitigation strategy; and

(ii) Appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur.

(b) *Records.* All food defense corrective actions taken in accordance with this section must be documented in records that are subject to food defense verification in accordance with § 121.150(a)(2) and records review in accordance with § 121.150(a)(3)(i).

**§ 121.150 Food defense verification.**

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

(1) Verification that food defense monitoring is being conducted as required by § 121.138 (and in accordance with § 121.140);

(2) Verification that appropriate decisions about food defense corrective actions are being made as required by § 121.138 (and in accordance with § 121.145); (3) Verification that mitigation strategies are properly implemented and are significantly minimizing or preventing the significant vulnerabilities. To do so, you must conduct activities that include the following, as appropriate to the facility, the food, and the nature of the mitigation strategy and its role in the facility's food defense system:

(i) Review of the food defense monitoring and food defense corrective actions records within appropriate timeframes to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food defense plan, the mitigation strategies are properly implemented, and appropriate decisions were made about food defense corrective actions; and

(ii) Other activities appropriate for verification of proper implementation of mitigation strategies; and

(4) Verification of reanalysis in accordance with § 121.157.

(b) *Written procedures.* You must establish and implement written procedures, including the frequency for which they are to be performed, for verification activities conducted according to § 121.150(a)(3)(ii).

(c) *Documentation.* All verification activities conducted in accordance with this section must be documented in records.

**§ 121.157 Reanalysis.**

(a) You must conduct a reanalysis of the food defense plan, as a whole at least once every 3 years;

(b) You must conduct a reanalysis of the food defense plan as a whole, or the applicable portion of the food defense plan:

(1) Whenever a significant change made in the activities conducted at your facility creates a reasonable potential for a new vulnerability or a significant increase in a previously identified vulnerability;

(2) Whenever you become aware of new information about potential vulnerabilities associated with the food operation or facility;



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(3) Whenever you find that a mitigation strategy, a combination of mitigation strategies, or the food defense plan as a whole is not properly implemented; and

(4) Whenever FDA requires reanalysis to respond to new vulnerabilities, credible threats to the food supply, and developments in scientific understanding including, as appropriate, results from the Department of Homeland Security biological, chemical, radiological, or other terrorism risk assessment.

(c) You must complete such reanalysis required by paragraphs (a) and (b) of this section and implement any additional mitigation strategies needed to address the significant vulnerabilities identified, if any:

(1) Before any change in activities (including any change in mitigation strategy) at the facility is operative;

(2) When necessary within 90-calendar days after production; and

(3) Within a reasonable timeframe, providing a written justification is prepared for a timeframe that exceeds 90 days after production of the applicable food first begins.

(d) You must revise the written food defense plan if a significant change in the activities conducted at your facility creates a reasonable potential for a new vulnerability or a significant increase in a previously identified vulnerability or document the basis for the conclusion that no revisions are needed.

#### **Subpart D—Requirements Applying to Records That Must Be Established and Maintained**

##### **§ 121.301 Records subject to the requirements of this subpart.**

(a) Except as provided by paragraph

(b) of this section, all records required by subpart C of this part are subject to all requirements of this subpart.

(b) The requirements of § 121.310 apply only to the written food defense plan.

##### **§ 121.305 General requirements applying to records.**

Records must:

(a) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records;

(b) Contain the actual values and observations obtained during food defense monitoring;

(c) Be accurate, indelible, and legible;

(d) Be created concurrently with performance of the activity documented;

(e) Be as detailed as necessary to provide history of work performed; and

(f) Include:

(1) Information adequate to identify the facility (e.g., the name, and when necessary, the location of the facility);

(2) The date and, when appropriate, the time of the activity documented;

(3) The signature or initials of the person performing the activity; and

(4) Where appropriate, the identity of the product and the lot code, if any.

(g) Records that are established or maintained to satisfy the requirements of this part and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.

##### **§ 121.310 Additional requirements applying to the food defense plan.**

The owner, operator, or agent in charge of the facility must sign and date the food defense plan:

(a) Upon initial completion; and

(b) Upon any modification.

##### **§ 121.315 Requirements for record retention.**

(a)(1) All records required by this part must be retained at the facility for at least 2 years after the date they were prepared.

(2) Records that a facility relies on during the 3-year period preceding the applicable calendar year to support its status as exempt as a very small business must be retained at the facility as long as necessary to support the status of a facility as a very small business during the applicable calendar year.

(b) The food defense plan must be retained for at least 2 years after its use is discontinued.

(c) Except for the food defense plan, offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. The food defense plan must remain onsite. Electronic records are considered to be onsite if they are accessible from an onsite location.

(d) If the facility is closed for a prolonged period, the food defense plan may be transferred to some other reasonably accessible location but must be returned to the facility within 24 hours for official review upon request.

##### **§ 121.320 Requirements for official review.**

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All records required by this part must be made promptly available to a duly authorized representative of the Secretary of Health and Human Services for official review and copying upon oral or written request.

**§ 121.325 Public disclosure.**

Records required by this part will be protected from public disclosure to the extent allowable under part 20 of this chapter.

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**§ 121.330 Use of existing records.**

(a) Existing records (e.g., records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this subpart. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this subpart.

(b) The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing records.

**Subpart E—Compliance**

**§ 121.401 Compliance.**

(a) The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is required to comply with, and is not in compliance with, section 418 of the Federal Food, Drug, and Cosmetic Act or subparts C or D of this part is a prohibited act under section 301(uu) of the Federal Food, Drug, and Cosmetic Act.

(b) The failure to comply with section 420 of the Federal Food, Drug, and Cosmetic Act or subparts C or D of this part is a prohibited act under section 301(ww) of the Federal Food, Drug, and Cosmetic Act.

Dated: May 20, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-12373 Filed 5-26-16; 8:45 am]

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<https://www.fda.gov/food/guidanceregulation/fsma/ucm378628.htm>

## FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration

[Imports under the FSMA Main Page](#)

View the Final Rule Contents in [Docket Folder FDA-2013-N-1425](#) starting May 27, 2016.

Below is a fact sheet provided by FDA.

In this fact sheet:

- [Who is Covered?](#)
- [Key Provisions](#)
- [Compliance Dates](#)
- [Exemptions](#)
- [Assistance to Industry](#)

### Introduction

The FDA Food Safety Modernization Act (FSMA) final rule is aimed at preventing intentional adulteration from acts intended to cause wide-scale harm to public health, including acts of terrorism targeting the food supply. Such acts, while not likely to occur, could cause illness, death, economic disruption of the food supply absent mitigation strategies.

Rather than targeting specific foods or hazards, this rule requires mitigation (risk-reducing) strategies for processes in certain registered food facilities.

The proposed rule was issued in December 2013. The changes in the final rule are largely designed to provide either more information, where stakeholders requested it, or greater flexibility for food facilities in determining how they will assess their facilities, implement mitigation strategies, and ensure that the mitigation strategies are working as intended.

In developing the rule, FDA interacted with the intelligence community and considered vulnerability assessments conducted in collaboration with the food industry.

While acts of intentional adulteration may many other forms, including acts of disgruntled employees or economically motivated adulteration, the goal of this rule is to prevent acts intended to cause wide-scale harm. Economic adulteration is addressed in the final preventive controls rules for human and animal foods.

## Who is Covered?

With some exceptions listed below, this rule applies to both domestic and foreign companies that are required to register with the FDA as food facilities under the Federal Food, Drug, and Cosmetic (FD&C) Act.

This rule is designed to primarily cover large companies whose products reach many people, exempting smaller companies. There are 3,400 covered firms that operate 9,800 food facilities.

It does not cover farms.

## Key Provisions

While this is the first time that companies are required to create a food defense plan, the FDA has taken an approach similar to Hazard Analysis Critical Control Point (HACCP) system, an approach adopted by industry for the identification, evaluation and control of food safety hazards. The FSMA rules advance and strengthen those safeguards.

Each covered facility is required to prepare and implement a food defense plan. This written plan must identify vulnerabilities and actionable process steps, mitigation strategies, and procedures for food defense monitoring, corrective actions and verification. A reanalysis is required every three years or when certain criteria are met, including mitigation strategies that are determined to be improperly implemented.

**Vulnerability assessment:** This is the identification of vulnerabilities and actionable process steps for each type of food manufactured, processed, packed or held at the food facility. For each point, step, or procedure in the facility's process, these elements must be evaluated:

- The severity and scale of the potential impact on public health. This would include such considerations as the volume of product, the number of servings, the number of exposures, how fast the food moves through the distribution system, potential agents of concern and the infectious/lethal dose of each; and the possible number of illnesses and deaths.
- The degree of physical access to the product. Things to be considered would include the presence of such physical barriers as gates, railings, doors, lids, seals and shields.
- The ability to successfully contaminate the product.

**Mitigation strategies:** These should be identified and implemented at each actionable process step to provide assurances that vulnerabilities will be minimized or prevented. The mitigation strategies must be tailored to the facility and its procedures.

- The final rule removes the distinction between "broad" and "focused" mitigation strategies. The original proposal only required "focused" mitigation strategies because "broad" mitigation strategies, such as a fence around the entire facility, did not protect specific points from being attacked by an insider.
- The final rule recognizes that a mitigation strategy, applied in a directed and appropriate way to protect the actionable process step from an insider attack, would sufficiently minimize the risk of intentional adulteration.

**Mitigation strategy management components:** Steps must be taken to ensure the proper implementation of each mitigation strategy. In each of these areas of food defense, the facilities are

given more flexibility in the final rule to establish the actions most appropriate to their operation and product.

- **Monitoring:** Establishing and implementing procedures, including the frequency with which they are to be performed, for monitoring the mitigation strategies.
- **Corrective actions:** The response if mitigation strategies are not properly implemented.
- **Verification:** Verification activities would ensure that monitoring is being conducted and appropriate decisions about corrective actions are being made.

**Training and recordkeeping:** Facilities must ensure that personnel assigned to the vulnerable areas receive appropriate training; facilities must maintain records for food defense monitoring, corrective actions, and verification activities.

## Compliance Dates

This rule is a first of its kind, so education and outreach is critical. Additionally, FDA recognizes that many of the food facilities covered by this rule will also be meeting the requirements of other FSMA rules. Therefore, FDA is providing a longer timeline in the final rule for facilities to comply with the intentional adulteration rule.

- **Very Small Businesses**—a business (including any subsidiaries and affiliates) averaging less than \$10,000,000, adjusted for inflation, per year, during the three-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). These businesses would have to comply with modified requirements within five years after the publication of the final rule.
- **Small Businesses**—a business employing fewer than 500 persons would have to comply four years after the publication of the final rule.
- **Other Businesses**—a business that is not small or very small and does not qualify for exemptions would have to comply three years after the publication of the final rule.

## Exemptions

- A very small business. While exempt, the business would be required to provide to FDA, upon request, documentation to demonstrate that the business is very small.
- The holding of food, except the holding of food in liquid storage tanks
- The packing, re-packing, labeling or re-labeling of food where the container that directly contacts the food remains intact
- Activities that fall within the definition of “farm”
- Manufacturing, processing, packing, or holding of food for animals
- Alcoholic beverages under certain conditions
- On-farm manufacturing, processing, packing, or holding by a small or very small business of certain foods identified as having low-risk production practices. The exemption applies if such activities are the only activities conducted by the business subject to the rule. These foods include certain types of eggs, and certain types of game meats.

## Assistance to Industry

FDA has established an Intentional Adulteration Subcommittee with the Food Safety Preventive Controls Alliance to develop food defense training resources for industry and regulators alike.

The agency intends to publish guidance documents to provide information relevant to the provisions of the final rule, such as conducting a vulnerability assessment, identifying and implementing mitigation strategies, and writing procedures for food defense monitoring, corrective actions and verification.

In addition, FDA has a number of tools and resources currently available on our website ([www.fda.gov/fooddefense](http://www.fda.gov/fooddefense)) that were developed for our voluntary food defense program.

The [Mitigation Strategies Database](#) is an online, searchable listing of mitigation strategies that can be applied to different steps in a food operation to reduce the risk of intentional adulteration.

The [FDA FSMA Food Safety Technical Assistance Network](#) is already operational and provides a central source of information to support industry understanding and implementation of FSMA. Questions submitted online or by mail will be answered by information specialists or subject matter experts.

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# APPENDIX 2: FDA Key Activity Types (KAT) Report & KAT Descriptions

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KAT Descriptions	A2-11

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Retrieved from FDA website (page last updated 12/05/2016) at:

<http://wayback.archive-it.org/7993/20170111073929/http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm347023.htm>

## Analysis of Results for FDA Food Defense Vulnerability Assessments and Identification of Activity Types

### Archived Content

The content on this page is provided for reference purposes only. This content has not been altered or updated since it was archived.

April 2013

This report is required under [Section 106 of the Food Safety Modernization Act](#). Over the past several years, FDA has conducted vulnerability assessments (VA) on more than 50 products or processes, leading to the identification of processing steps of highest concern, and potential mitigation strategies to reduce vulnerabilities. The current study utilized the results from 25 VAs to determine if a potential “threshold” score for the implementation of mitigation strategies could be identified.

- I. [Executive Summary](#)
- II. [Methodology](#)
- III. [Findings](#)
- IV. [Analysis](#)
- V. [Conclusion](#)

### [APPENDIX A: Activity Type Descriptions](#)

## I. Executive Summary

Section 106 of the Food Safety Modernization Act (FSMA), requires FDA, among other things, to conduct a vulnerability assessment (VA) of the food system. A VA is the process of identifying, quantifying, and prioritizing (or ranking) the vulnerabilities in a system.

From 2005 to 2008, under the [Strategic Partnership Program Agroterrorism \(SPPA\)](#), the U.S. Food and Drug Administration (FDA), along with the United States Department of Agriculture (USDA), Federal Bureau of Investigation (FBI), and Department of Homeland Security (DHS) conducted vulnerability assessments (VAs) on products, processes, or commodities in the food and agriculture sector. In keeping with the requirements of Homeland Security Presidential Directive 9 (HSPD-9), *Defense of*

*Agriculture and Food* as well as the requirement under FSMA, FDA reassessed VAs conducted from 2005 to 2008 and continued this assessment process for products not previously assessed.

To date, FDA has conducted vulnerability assessments on more than 50 products or processes, which has led to the identification of processing steps of highest concern, potential mitigation strategies that may reduce these vulnerabilities, as well as research gaps.

The methodology used to conduct these VAs is called CARVER+Shock. CARVER is an acronym for the following six attributes used to evaluate the attractiveness of a target for attack:

- Criticality – measure of public health and economic impacts of an attack
- Accessibility – ability to physically access and egress from target
- Recuperability – ability of system to recover from an attack
- Vulnerability – ease of accomplishing attack
- Effect – amount of direct loss from an attack as measured by loss in production
- Recognizability – ease of identifying target.

A seventh attribute, “Shock,” was added to the original six attributes to assess the combined health, economic and psychological impacts of an attack within the food industry. CARVER+Shock is a tool that can be used to assess the vulnerabilities within a system or infrastructure. By conducting a CARVER+Shock assessment of a food production facility or process, the user can determine the most vulnerable points in the infrastructure and focus resources on protecting the most susceptible points in the system.

The current study utilized the results from 25 VAs to determine if a potential “threshold” score for the implementation of mitigation strategies could be identified. The analysis of Criticality, Accessibility, and Vulnerability (CAV) scores showed that since CARVER+Shock is a relative risk ranking tool, there is no equivalence between a score value of a processing step in one industry to the same score value for another processing step in a different industry. The data set was then reevaluated to determine what common attributes or activities occurred between processing steps in the data set. Through this review, it was determined that processing steps could be grouped according to the type of activity occurring at a particular point in an operation.

The key activity types in most production environments are:

1. Coating/Mixing/Grinding/Rework
2. Ingredient Staging/Prep/Addition
3. Liquid Receiving/Loading
4. Liquid Storage/Hold/Surge Tanks

By identifying and defining key activity types, a CAV score is no longer needed as a threshold. The activity types and their descriptions can be publicly disseminated, industry can objectively map processing steps into activity types and any mitigation strategies associated with those activity types could be audited.

## II. Methodology

FDA, with support from Battelle Memorial Institute, reviewed the Criticality, Accessibility, and Vulnerability (CAV) scores from 25 vulnerability assessments to determine a potential “threshold” score for the implementation of food defense mitigation strategies. Other CARVER+Shock scoring components (Recuperability, Effect, Recognizability, Shock) were not included. The data set includes scoring results derived from the following vulnerability assessments:

- VAs conducted under the original SPPA initiative when an updated VA was not conducted;
- Updated VA results from a previous SPPA assessment, and;
- New VAs conducted since the conclusion of the SPPA initiative.

The CAV score results for each assessment were reviewed and only included processing steps for further analysis if they were part of the top twenty-five percent of CAV scores within a vulnerability assessment. Where there were ties at the bottom of the quartile, all processing steps with the same score were included. This selection constituted the data set for further analysis and consisted of 141 of the 465 scored processing steps (or approximately 30% of all scored processing steps from 25 assessments).

When the data set is sorted by CAV score, some processing step types repeatedly rise to the top. Forty-seven processing steps had CAV scores of 26 or above (top quartile of the analyzed population). Fourteen of the 47 processing steps involve mixing, grinding, or coating as the primary function, thus resulting in probable homogeneous distribution of a threat agent into the product. Twelve of the 47 processing steps involved the staging, preparation, or addition of minor ingredients. Six of the 47 processing steps involved receiving and five of the 47 processing steps involved storage. The 10 remaining processing steps were an assortment of other activities. When ordering by CAV score, the processing steps where mixing occurs, or secondary ingredients are staged, prepped or added, prove to be critical processing steps in many assessed products. Even though assessment scores are independent from other products/assessments, the high CAV scores in these types of processing steps indicate that attention should be placed on these areas when considering food defense mitigation strategies.

Additionally, when comparing across industries, it was found that 65% of products were assigned a high CAV score of 26 or above (17 of 25 products). It should also be noted that several products had multiple processing steps tied for highest rank. However, for industries where the high CAV score was not 26 or above, the highest scoring processing step(s) in the assessment of these products should still be regarded as highly sensitive within that assessment and should not be considered less risky for intentional contamination.

It was also found that the higher range of CAV scores (26 or above) was dominated by assessments of manufacturing facilities generating processed, consumer-ready foods. This may help in targeting industries where more attention should be focused when considering the development of mitigation strategies.

CAV scores obtained and used in this analysis were generated during the conduct of the assessments with experienced, unbiased facilitators who were highly trained in the CARVER+Shock process. In addition, the CARVER+Shock tool is a relative ranking tool and was never intended to be used to compare disparate industries. Since CARVER+Shock is a relative ranking tool there is no equivalence between a score value of a processing step in one industry to the same score value for another processing step in a different industry. CARVER+Shock and CAV scores can vary between repeat assessments of the same product, as well. During a repeat or update assessment, the relative ranking

may remain the same, but assessments conducted at different times with different participants frequently receive different scores values. This could result in a processing step being scored above a CAV score threshold in one assessment and fall below the threshold in a later reassessment.

Also, when conducting the assessments, the facilitators and participants did not have a financial interest in targeting scores for processing steps. Were a CAV score threshold to be used as a factor for requiring industry to institute mitigation strategies, CAV scores could be manipulated to fall below any threshold. Also, since the CARVER+Shock Software tool was developed to be used by individual companies, answers to the questions with the software tool could be changed to generate lower scores.

The data set was reevaluated to determine what common attributes or activities occurred between processing steps in the data set. A review was conducted of the processing step descriptions and CAV score spreadsheet for all upper quartile scoring processing steps within an assessment. Through this review, it was determined that processing steps could be grouped according to the type of activity occurring at the processing step (e.g. Coating, Mixing, Grinding; Ingredient Prep/Staging/Addition; Liquid Surge/Holding/Storage tanks; Rework; Dry Receiving; etc.). These activities types helped to refine the processing step analysis by focusing on the nature of the activity at the processing step and not the name that processing step has been assigned by either industry assessment participants, or the CARVER+Shock Software tool. A list of four yes/no questions, and the answers to each question for each processing step were included. The processing steps were then ranked first by the number of yes answers to the four questions and secondarily by the CAV score. The questions were developed to identify processing steps which contained characteristics that have consistently resulted in processing steps being assigned a high CAV score. The four questions were as follows:

1. Does mixing occur at or immediately after this processing step?
2. Are minor ingredients added at this processing step?
3. Are minor ingredients involved with this processing step?
4. Are liquids or partially liquid mixtures dealt with at this processing step?

### **III. Findings**

Processing steps which satisfied all or most of the questions above were almost universally assigned high CAV scores. The processing steps that satisfy the questions above resided in the Coating/Mixing/Grinding/Rework activity, the Ingredient Staging/Prep/Addition activity, the Liquid Receiving/Loading Activity, or the Liquid Storage/Hold/Surge Tanks activity. As a result, it was determined that these activity types, when present in a facility, should be given priority consideration for the implementation of food defense mitigation strategies.

As with the previous analysis, when the top quartile of processing steps were organized based on the nature of the activity being performed, it became clear that certain activities in a production process should be given priority consideration for the implementation of food defense mitigation strategies. When sorting by CAV scores, processing steps in the Coating/Mixing/Grinding/Rework activity group and the Ingredient Preparation/Staging/Addition activity group were consistently very highly ranked both within and between assessments. The grouping of various processing step names into these two activity groups only reinforced the importance of what activity occurs at a processing step. In addition, it became apparent that processing steps involving liquid handling carry more risk than handling or storage of other types of ingredients. There was a distinct separation in CAV scores between receiving and storage of liquid vs. dry ingredients. Liquid Receiving/Loading and Liquid Storage/Hold/Surge Tanks activities routinely ranked higher than their counterparts for dry

products. By focusing on activities being conducted, the data provided insight into the processes where mitigation strategies and food defense measures should be focused.

## IV. Analysis

It was necessary to find a solution that would reliably identify processing steps which contain key attributes or characteristics so that mitigating actions can be taken. In seeking such a solution, three requirements must be satisfied in order for the solution to be usable:

1. The solution must be able to be publicly disseminated and thus not contain sensitive information about a commodity, facility, agent, or CARVER+Shock scores.
2. The solution must be able to be assigned in an objective manner.
3. The solution must provide an ability to be verified by audit or inspection.

Once the types of activities which take place at certain processing steps were defined and grouped, it was possible to identify the common factors that caused a processing step to receive the CAV scores assigned. A draft was then developed with the four activity types which most commonly ranked high in the vulnerability assessments conducted. By developing detailed descriptions of the key characteristics of these activities, it would be possible to draft mitigation strategies specific to the processing steps in a production environment which are associated with these activities.

Based on this review, the key activity types in most production environments are:

1. Coating/Mixing/Grinding/Rework
2. Ingredient Staging/Prep/Addition
3. Liquid Receiving/Loading
4. Liquid Storage/Hold/Surge Tanks

Detailed descriptions of these activities are contained in Appendix A. The benefit of focusing on activity types and applying relevant mitigation strategies to those activities rather than establishing a CAV Score threshold is that there is no burden on the industry to attempt to objectively self-score their process. Moreover, there is no burden on FDA or other government agencies to attempt to establish a specific CAV score as the threshold for the implementation of mitigation strategies.

An activity description can be disseminated publicly as the information contained therein is not sensitive. Industry then must only develop a process flow diagram and map their processing steps into activity types; this can be completed objectively as the activity types will have specific characteristics associated with them and processing steps matching these characteristics would be easily identifiable. Mitigation strategies could also be provided to industry members if they have any of the key activity types contained in their production process.

There could also be several tools that could be developed to help the industry understand what mitigation strategies would be most effective and relevant to key processing steps/activities within their process. A “decision tree” with yes/no answers could be developed to help industry members

1) detail and compare a particular processing step in their process against the characteristics of the

activity type and 2) identify potential mitigation strategies which would be most appropriate to reduce the vulnerabilities associated with a particular processing step in their operation.

## **V. Conclusion**

The solution detailed above complies with the three requirements that needed to be satisfied for a successful approach. By identifying and defining key activity types, a CAV score is no longer needed as a threshold. The activity types and their descriptions can be publicly disseminated, industry can objectively map processing steps into activity types and any mitigation strategies associated with those activity types could be audited. Additionally, the processing step/activity type map and any mitigation strategies a facility currently employs could easily be added to existing or future facility registration requirements or food defense plans.

Moreover, tools can be developed by the FDA to assist industry members define and specify the activity conducted at a particular processing step in their process and select effective mitigation strategies unique to their process.

There are tools, such as the CARVER+Shock Vulnerability Assessment Software, that industry members can use to perform a private, custom vulnerability assessment. It is important and worthwhile for industry members to conduct a vulnerability assessment of their production process and facility, so they gain a more comprehensive understanding of the vulnerabilities that exist in their process with regard to intentional contamination of their product. The awareness generated by conducting a vulnerability assessment helps industry members understand the need for mitigation strategies and assists them in identifying where process improvements can be made to reduce the likelihood of intentional contamination. The method detailed above does not seek to undermine or replace existing vulnerability assessment efforts; to the contrary, it complements the vulnerability assessment process by helping industry members understand on a more detailed and comprehensive basis why a processing step in their process should be evaluated more closely and where mitigation strategies would most effectively reduce the likelihood of intentional contamination.

For more information regarding FDA's Food Defense tools and resources, including the Vulnerability Assessment Software and Mitigation Strategies Database, please visit: [www.fda.gov/fooddefense](http://www.fda.gov/fooddefense).

## **APPENDIX A. Activity Type Descriptions**

### **Activity Type I: Coating/Mixing/Grinding/rework**

This activity type refers to any processing step where the primary purpose or result of the processing step is:

- a. Coating: Evenly coat a solid product with a powder or liquid coating, batter, breading, flavoring, or other ingredient or ingredient mixture where any coating ingredients that did not adhere to the product are recycled and used again in the coating process;
- b. Mixing: Homogeneously mix a powder, dough, or liquid ingredient mixture;
- c. Grinding: Reduce the particle size of a solid ingredient to a medium or fine granularity in a manner that would result in widespread mixing of a threat agent among the processed ingredient.
- d. Rework: Means the practice of using previous batches of product in production runs of other products.



The effect of any of these processes is that an agent added to the process would be evenly mixed throughout the product batch and contaminates the total servings produced from the contaminated batch. Processing steps and equipment associated with this activity include but are not limited to: mixer, blender, homogenizer, cascade breeder, mill, grinder, pulverizer, etc.

### **Activity Type II: Ingredient Staging/Preparation/Addition**

This activity type refers to any processing step where ingredients are manipulated prior to or during addition to the product stream by human contact. Computer metering or automatic weighing, sizing, batching, or measuring is not included in this activity so long as the process does not involve the active involvement of a person. Specifically,

- a. Staging is defined as the act of moving ingredient from medium- or long-term storage to the production area *and* any tamper evident packaging is breached.
- b. Preparation is defined as any act of measuring, weighing, premixing, or otherwise manipulating the ingredient prior to addition to the product stream.
- c. Addition covers any act of physically adding ingredient directly into the product stream or into surge/metering hoppers in any way that is not remotely or automatically carried out.

The effect of any of these actions is that ingredients are generally open and accessible at processing steps where ingredient manipulation occurs. Also, mixing frequently occurs immediately after ingredients are staged, prepared and/or added to the product stream. Whereas mixing would homogeneously distribute an agent in a batch, the activities of ingredient staging/preparation/addition provide a point of access to introduce the agent into the product stream.

### **Activity Type III: Bulk Liquid Receiving/Loading**

This activity type refers to any processing step where a liquid ingredient is being received and unloaded at a facility or a liquid intermediate or finished product is being loaded into an outbound shipping transport vehicle. This activity type incorporates the actions of opening the transport vehicle, attaching any pumping equipment or hoses, and opening any venting hatches. The characteristics associated with these activities involving bulk liquid receiving/loading are a high probability of an agent mixing within the liquid due to significant sloshing, movement, and turbulence associated with receiving/loading. Also, the actions of the worker associated with these processing steps provides access to hoses, the transport vessel, and potentially the product as it is being received or loaded.

1. Bulk liquid receiving refers to the inbound shipping of liquid product into a facility for its use in the food production process.
2. Bulk liquid loading refers to the outbound shipping of liquid product from a facility for further processing or use by an end customer/consumer.

### **Activity Type IV: Liquid Storage/Holding/Surge Tanks**

This activity type refers to any processing step where liquid ingredient or intermediate/finished liquid product is stored in either bulk storage tanks or smaller secondary holding tanks or surge tanks. Specifically, liquid storage can be broken down into two broad categories,

- a. Bulk liquid storage refers to any medium-long term storage silo or tank where liquid product may be stored prior to introduction into the product stream or to hold finished product prior to loading for outbound shipping.
- b. Non-bulk liquid holding and surge tanks refer to any storage tanks used to hold product for a short period or surge tanks. Non-bulk tanks can be used to store non-bulk liquid ingredients,

hold liquid product for sample testing and other QC activity, or to control flow rates of liquid ingredients/product through the production system.

Both categories of this activity type can be considered key processing steps because many liquid storage/hold/surge tanks are agitated to prevent any separation or inconsistency within the liquid. Also, many times, tanks are located in isolated parts of the facility where human observation is infrequent. Access hatches may not be locked or alarmed. With regard to surge tanks in the production area, there may not be lids present or locking hatches which would limit accessibility to the liquid ingredient/product.

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## Key Activity Type (KAT) Descriptions

### A. 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., 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.

### 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).

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# APPENDIX 3: Vulnerability Assessment Resources

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Table 1. Potential Public Health Impact	
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 1000 (acute illnesses, deaths, or both), or 100 – 1000 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

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**Table 2. Degree of Physical Access to the Product**

<b>Table 2. Degree of Physical Access to the Product</b>	
<b>Description</b>	<b>Score</b>
<p><b>Easily Accessible.</b></p> <ul style="list-style-type: none"> <li>• Inside attacker has access to the product (e.g., attacker can physically touch the product).</li> <li>• 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).</li> <li>• Product is open and unsecured by packaging, equipment, or other physical access barriers.</li> <li>• Product is handled, staged, or moved in an easily accessible manner.</li> </ul>	10
<p><b>Accessible.</b></p> <ul style="list-style-type: none"> <li>• 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).</li> <li>• Product is in equipment that can be accessed without tools or specialized supplies.</li> <li>• 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.</li> </ul>	8
<p><b>Partially Accessible.</b></p> <ul style="list-style-type: none"> <li>• Inside attacker has partial access to the product.</li> <li>• 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).</li> </ul>	5
<p><b>Hardly Accessible.</b></p> <ul style="list-style-type: none"> <li>• 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).</li> <li>• Product is in equipment that make access difficult without tools or specialized supplies.</li> <li>• Physical space constraints limit access to food being processed or stored.</li> </ul>	3
<p><b>Not Accessible.</b></p> <ul style="list-style-type: none"> <li>• Inside attacker has no access to the product (e.g., attacker cannot physically touch the product).</li> <li>• 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).</li> <li>• Product is enclosed and secured by packaging, equipment, or other physical access barriers.</li> <li>• 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).</li> </ul>	1

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

<b>Table 3. The Ability of an Attacker to Successfully Contaminate the Product</b>	
<b>Description</b>	<b>Score</b>
<p><b>Highest Ease of Successful Contamination.</b></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• It is easy to successfully add sufficient volume of contaminant to the food.</li> <li>• Inherent characteristics of the point, step, or procedure (e.g., uniform mixing) would evenly distribute the contaminant into the food.</li> <li>• 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.</li> <li>• 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.</li> <li>• 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.</li> </ul>	10
<p><b>Moderately High Ease of Successful Contamination.</b></p> <ul style="list-style-type: none"> <li>• The process step is seldom observed, enabling an inside attacker to work unobserved with minor time limitations.</li> <li>• It would be relatively easy for an inside attacker to successfully add a contaminant in sufficient volume.</li> <li>• 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.</li> <li>• There are few workers in the area, and it is unlikely that they would notice a contamination attempt by an inside attacker.</li> <li>• 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.</li> <li>• 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.</li> </ul>	8
<p><b>Moderate Ease of Successful Contamination.</b></p> <ul style="list-style-type: none"> <li>• The process step is observed about half of the time, or semi-obscured from view; an inside attacker would be under time limitations.</li> <li>• It would be somewhat difficult for an inside attacker to successfully add a contaminant in sufficient volume without being detected.</li> <li>• 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.</li> <li>• 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.</li> </ul>	5

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

Description	Score
<ul style="list-style-type: none"> <li>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.</li> <li>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.</li> </ul>	
<p><b>Moderately Low Ease of Successful Contamination.</b></p> <ul style="list-style-type: none"> <li>The process step is observed more than half of the time; an inside attacker would be under relatively strict time limitations.</li> <li>It would be difficult for an inside attacker to successfully add a contaminant in sufficient volume without being detected.</li> <li>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.</li> <li>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.</li> <li>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.</li> <li>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.</li> </ul>	3
<p><b>Lowest Ease of Successful Contamination.</b></p> <ul style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>There are numerous workers in the immediate area that would notice a contamination attempt by an inside attacker.</li> <li>An inside attacker would need to add a large volume of contaminant without being detected.</li> <li>The contaminant likely would be removed (e.g., by washing, screening, vibration), diluted, or neutralized at this or later points in the process.</li> <li>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.</li> </ul>	1



**Useful Conversions:**

- 1 pound= 16 ounces; 1 ounce=28 grams; 1 gram=1000 milligrams;
- 1 gallon=128 fluid ounces; 1 fluid ounce=0.03 liters; 1 liter=1000 cubic centimeters

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 $B \div C$	E Score from Table 1	F Notes

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

**Useful Conversions:**

- 1 pound= 16 ounces; 1 ounce=28 grams; 1 gram=1000 milligrams;
- 1 gallon=128 fluid ounces; 1 fluid ounce=0.03 liters; 1 liter=1000 cubic centimeters

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 (FDA provided value = 50%)	Number of Potential Deaths D x E	Score from Table 1	Notes	Representative Contaminant Dose Needed per Serving (FDA provided value = 40 milligrams)	Amount of Representative Contaminant Needed per Batch D x I

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

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

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

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

Worksheet 1-F: Identifying Actionable Process Steps Using the Three Fundamental Elements								
(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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# APPENDIX 4: Technical Assistance and Resources

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Name of Resource		Location	Purpose
<b>General Resources</b>			
FDA Technical Assistance Network (TAN)		<a href="https://www.fda.gov/food/guidanceregulation/fisma/ucm459719.htm">https://www.fda.gov/food/guidanceregulation/fisma/ucm459719.htm</a>	Answers regulatory questions about FSMA rules and implementation of the rules
FDA Draft Guidance for FSMA Implementation		<a href="http://www.fda.gov/Food/GuidanceRegulation/FSMA/">http://www.fda.gov/Food/GuidanceRegulation/FSMA/</a>	Answers compliance questions related to policy, compliance, and rule interpretation. Non-binding guidance that offers additional information and interpretation on FSMA rules
Food Safety and Preventive Controls Alliance (FSPCA)		<a href="http://www.iit.edu/ifsh/alliance/">http://www.iit.edu/ifsh/alliance/</a>	Answers compliance questions related to policy and compliance. Non-binding guidance that offers additional information on FSMA rules
FSPCA Technical Assistance Network		<a href="https://www.ifsh.iit.edu/fspca/fspca-technical-assistance-network">https://www.ifsh.iit.edu/fspca/fspca-technical-assistance-network</a>	Answers scientific/technical questions related to Preventive Controls and FSVP
FSPCA Courses		<a href="http://www.iit.edu/ifsh/alliance/">http://www.iit.edu/ifsh/alliance/</a>	FSPCA offers courses on Preventive Controls for Human Food, Preventive Controls for Animal Food, FSVP, and Intentional Adulteration
<b>Intentional Adulteration Courses</b>			
FSPCA Intentional Adulteration Courses		<a href="https://www.ifsh.iit.edu/fspca/courses/intentional-adulteration">https://www.ifsh.iit.edu/fspca/courses/intentional-adulteration</a>	(see individual course details below)
Food Defense Awareness for the IA Rule (online)		Same as above	The <i>Food Defense Awareness for the Intentional Adulteration Rule</i> course is designed specifically for those individuals assigned to work at actionable process steps and their supervisors who are required to receive training in food defense awareness (21 CFR 121.4(b)(2)).
IA Rule Overview (online)		Same as above	This training will provide stakeholders with more information about the Food Safety Modernization Act (FSMA) Final Rule on Mitigation Strategies to Protect Food Against Intentional Adulteration (21 CFR Part 121) (IA Rule). This training course is

Name of Resource	Location	Purpose
<p><b>Key Activity Types (KAT)</b> (online)</p>	<p>Same as above</p>	<p>optional and not required for compliance with the IA Rule, but may be useful for food facilities who are required to comply and other stakeholders who have interest in the IA Rule.</p> <p>This training course is targeted towards food professionals using FDA's Key Activity Type (KAT) method to conduct their facility's vulnerability assessment (VA). By successfully completing this course, the learner will have satisfied the training requirement to conduct a VA using the KAT method.</p> <p><b>Note: This course is recommended for participants to take prior to taking the Vulnerability Assessments course. (see below).</b></p>
<p><b>Identification and Explanation of Mitigation Strategies Course</b> (online)</p>	<p>Same as above</p>	<p>The IA rule requires that individuals identifying and explaining the mitigation strategies to successfully complete training for the specific function or be otherwise qualified through job experience to conduct the activities. By successfully completing this course, the learner will have satisfied the training requirement to identify and explain mitigation strategies.</p>
<p><b>Vulnerability Assessments</b> (face-to-face instructor-led)</p>	<p>Same as above</p>	<p>This course will provide participants with the information and skills necessary to conduct a vulnerability assessment that considers the three fundamental elements outlined in the IA rule. This course satisfies the requirement for those individuals that conduct or oversee the conduct of a VA using the three fundamental elements.</p>

Name of Resource		Location	Purpose
			<i>Note: The KAT course (see above) is recommended for participants to take prior to taking the Vulnerability Assessments course.</i>
Food Defense Plan & Plan Reanalysis (online)	Same as above		Description to come
<b>Intentional Adulteration Rule</b>			
Intentional Adulteration (IA) Rule	<a href="https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm378628.htm">https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm378628.htm</a>		Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration
<b>Other Significant FSMA Rules</b>			
Foreign Supplier Verification Programs Rule	<a href="https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm">https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm</a>		Final rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals
PC for Animal Food Rule	<a href="https://www.fda.gov/food/guidanceregulation/fsma/ucm366510.htm">https://www.fda.gov/food/guidanceregulation/fsma/ucm366510.htm</a>		Final rule for the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals
PC for Human Food Rule	<a href="https://www.fda.gov/food/guidanceregulation/fsma/ucm334115.htm">https://www.fda.gov/food/guidanceregulation/fsma/ucm334115.htm</a>		Final rule for the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food
Produce Safety Rule	<a href="https://www.fda.gov/food/guidanceregulation/fsma/ucm334114.htm">https://www.fda.gov/food/guidanceregulation/fsma/ucm334114.htm</a>		Final rule for the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

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# APPENDIX 5: VA Definitions, Acronyms, and Other Terms

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## VA Definitions, Acronyms, and Other Terms:

**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.

**CARVER + Shock** is 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.

**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 Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of this chapter.

**Farm** means farm as defined in § 1.227 of this chapter.

**FDA** means the Food and Drug Administration.

**Food** means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

**Food defense** means, for purposes of this part, 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 plan** 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).

**Food defense qualified individual** is 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** is the result of the implementation of the Food Defense Plan.

**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.

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

**Holding** means storage of food and also includes activities performed incidental to storage of food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes

activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets) but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

**Intentional Adulteration** means 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)** are 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.

**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.

**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 Federal Food, Drug, and Cosmetic Act.

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

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

**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.

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