

FOOD DEFENSE PLAN ESSENTIALS

Intentional Adulteration Rule Training



Participant Manual

FDPI Materials

FOOD DEFENSE PLAN ESSENTIALS

Intentional Adulteration Rule Training



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ToxStrategies

In collaboration with



Food Protection and Defense Institute
A Homeland Security Center of Excellence

FOOD DEFENSE PLAN ESSENTIALS

Intentional Adulteration Rule Training



Lesson 1 – 1

Welcome and IAVA Preface

FOOD DEFENSE PLAN ESSENTIALS Intentional Adulteration Rule Training

November 29 – December 1, 2022

Lead Instructor

Jennifer van de Ligt, PhD
Senior Consultant

ToxStrategies

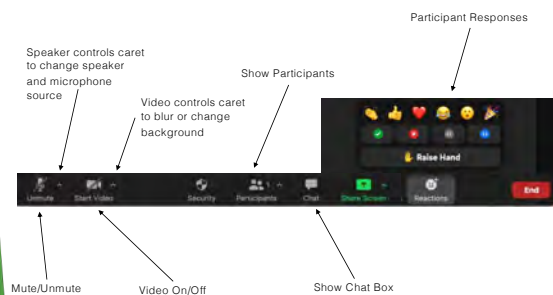
Assistant Instructor

Deb Freedman, PhD
Director

Food Protection and Defense Institute
A Homeland Security Center of Excellence




Zoom Features



As we get started

In the  provide (located at bottom of ZOOM window)

- Your 
- Company you work for
- Progress on food defense planning
- How you plan to use the learning from this course

FOOD DEFENSE PLAN ESSENTIALS



Intentional Adulteration Rule Overview



Preface: Course Introduction CONDUCTING VULNERABILITY ASSESSMENTS



Preface: Course Introduction

CONDUCTING VULNERABILITY ASSESSMENTS

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Welcome to the Intentional Adulteration Conducting Vulnerability Assessments Course!

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Housekeeping

- 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)

- 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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Disclosure

Although I attended the FSPCA Intentional Adulteration Lead Instructor training:

- Lead Instructors are not certified, licensed, accredited, qualified, registered, sanctioned, authorized, recognized, endorsed, or approved by the FSPCA;
- I do not represent, speak for, or act on behalf of the FSPCA;
- The FSPCA cannot provide legal advice;
- The FSPCA does not guarantee the accuracy, adequacy, completeness or availability of any information provided and is not responsible for any errors or omissions or for any results obtained from the use of such information;
- Following the FSPCA curriculum does not ensure compliance with FDA's regulations or any other law or legal requirement; and
- The FSPCA gives no express or implied warranties, including but not limited to, any warranties of merchantability or fitness for a particular purpose or use

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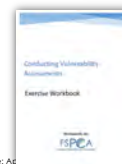
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Course Materials

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



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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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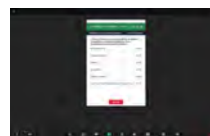
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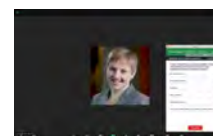
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Entrance Poll

Polls will launch in the middle of your Zoom window



You may drag them to a better location



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FSPCA IA Rule Training Courses

| FSPCA Training Course | Delivery Method | Intended Audience |
|-------------------------------------|-----------------|---|
| Food Defense Awareness ¹ | Online Training | <ul style="list-style-type: none"> Food workers at actionable process steps (e.g., front line food workers) Supervisors of food workers at actionable process steps |
| Overview of IA Rule | Online Training | <ul style="list-style-type: none"> Any stakeholder interested in learning more about the IA rule requirements This course is not associated with any IA rule training requirement |

¹Satisfies requirement in § 121.4(b)(2)

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FSPCA IA Rule Training Courses (continued)

| FSPCA Training Course | Delivery Method | Intended Audience |
|--|-------------------------|---|
| Conducting Vulnerability Assessments (VAs) Using Key Activity Types (KAT) ² | Online Training | <ul style="list-style-type: none"> Food professionals conducting VAs using the KAT Method ONLY |
| Conducting Vulnerability Assessments ^{2,3} | Instructor-Led Training | <ul style="list-style-type: none"> Food professionals conducting VAs using the 3 fundamental elements approach |
| Identification and Explanation of Mitigation Strategies ² | Online Training | <ul style="list-style-type: none"> Food professionals identifying mitigation strategies to implement at actionable process steps |
| Food Defense Plan Preparation and Reanalysis ² | Online Training | <ul style="list-style-type: none"> Food professionals preparing the Food Defense Plan (FDP) and conducting reanalysis activities |

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

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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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Purpose of the Course

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

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Course Topics

Qualified individuals must do or oversee these roles (21 CFR 121.4)

Intentional Adulteration Rule Basics

- Food Defense Awareness
- Understanding Food Defense Threat Motivations
- Understanding Food Defense Threat Capabilities
- Intentional Adulteration Rule Overview

Building Food Defense Plans

- Vulnerability Assessments
 - Key Activity Types
 - Fundamental Element Evaluation
 - Hybrid Analysis
- Mitigation Strategies Identification and Explanation
- Mitigation Strategies Management Components
- Plan Reanalysis

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Course Overview

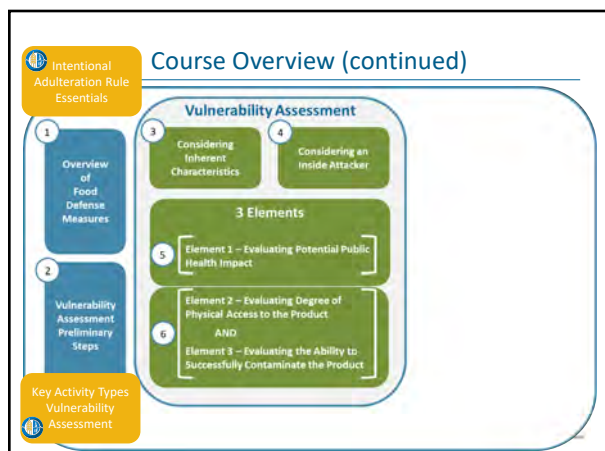
Intentional Adulteration Rule Essentials

1 Overview of Food Defense Measures

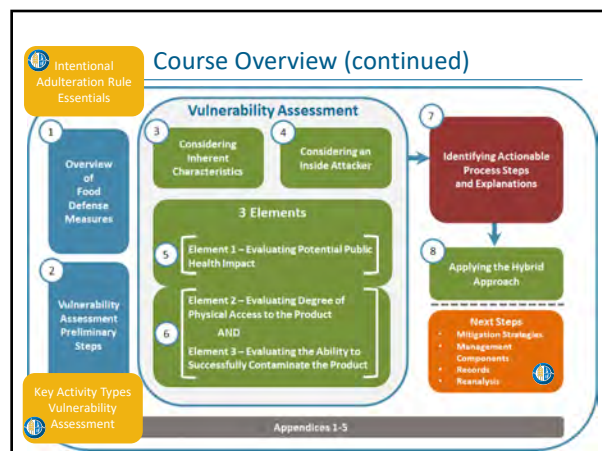
2 Vulnerability Assessment Preliminary Steps

Key Activity Types Vulnerability Assessment

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FSPCA Contact Information

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 IA VA 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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QUESTIONS?

22

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Course Agenda

| AM | Welcome, Introductions, and Sign-In |
|----------|--|
| Preface | Introduction to the <i>Conducting Vulnerability Assessments</i> 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 |

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Course Agenda (continued)

| PM | Welcome back! |
|----------|---|
| 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 to the Product 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 |
| | End of Course |

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FOOD DEFENSE PLAN ESSENTIALS

Intentional Adulteration Rule Training



Lesson 1 – 2

Intentional Adulteration Rule Basics



FOOD DEFENSE PLAN ESSENTIALS



Intentional Adulteration Rule Overview

1

FOOD SECURITY

“When all people at all times have access to sufficient, safe, nutritious food to maintain a healthy and active life.”

World Health Organization



2

FOOD SAFETY

SYSTEM RELIABILITY

Reducing Exposure To Natural Hazards/Errors/Failures

- Regular incidents
- Standard processes exist to keep food safe
- Regulation exists
- Globally recognized



FOOD DEFENSE

SYSTEM RESILIENCY

Reducing The Impact Of System Attacks

- Not always called food defense; called tampering
- Do not have standard practices
- Regulation is new
- Not globally recognized





FOOD PROTECTION

Food Safety
Unintentional Adulteration

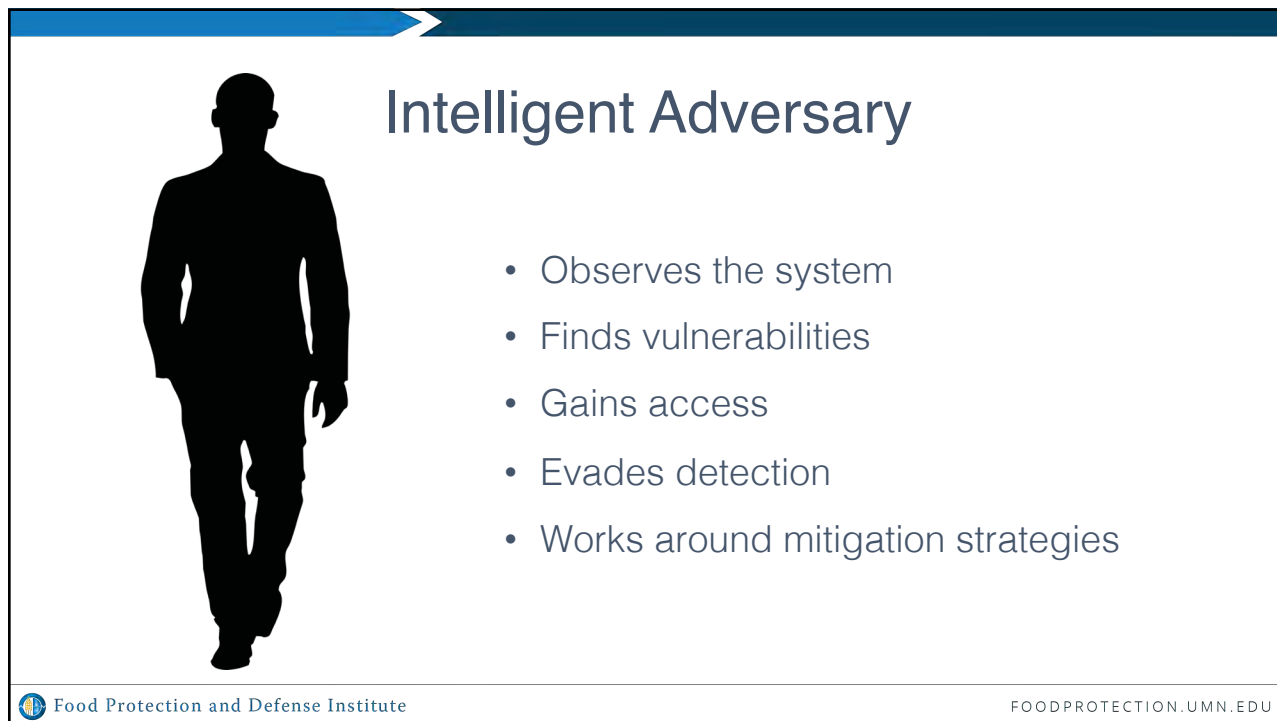
VS

Food Defense
Intentional Adulteration

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Intelligent Adversary

- Observes the system
- Finds vulnerabilities
- Gains access
- Evades detection
- Works around mitigation strategies

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Food Defense Threat Triangle

MOTIVATION

CAPABILITY

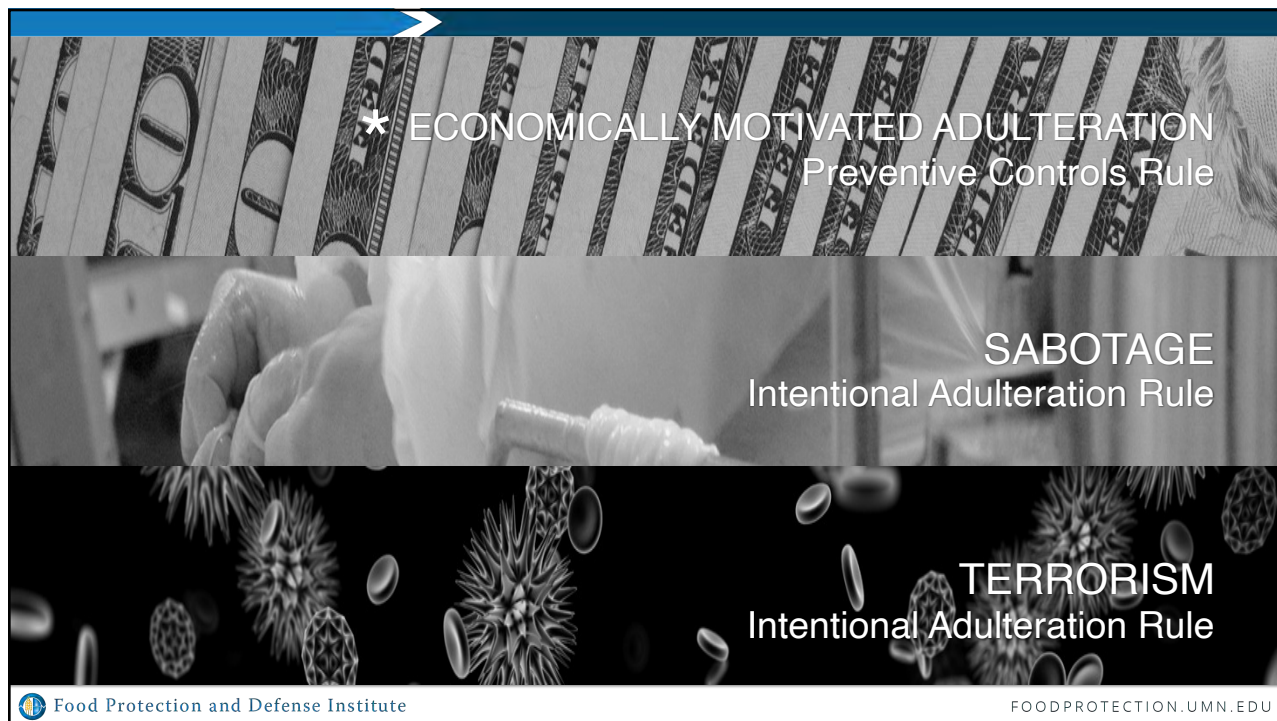
FOOD
DEFENSE
THREAT

VULNERABILITY

7



8



★ ECONOMICALLY MOTIVATED ADULTERATION
Preventive Controls Rule

SABOTAGE
Intentional Adulteration Rule

TERRORISM
Intentional Adulteration Rule

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Melamine in Dairy Products

Several Dairy Firms

China

2008-2009

- Melamine added to milk system-wide
- Melamine artificially increases apparent protein content
- 300,000 illnesses, 6 deaths
- Recalls in 47 countries

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New Zealand 1080 Scandal

Auckland,
New Zealand

2015

- Threatening letters to NZ dairy companies
- Samples of infant formula contaminated
- Environmentalism investigated first
- Perpetrator had competing business
- Perpetrator jailed for 8½ years
- New Zealand lost \$37 million

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Rajneeshee Commune

The Dalles,
Oregon

1984

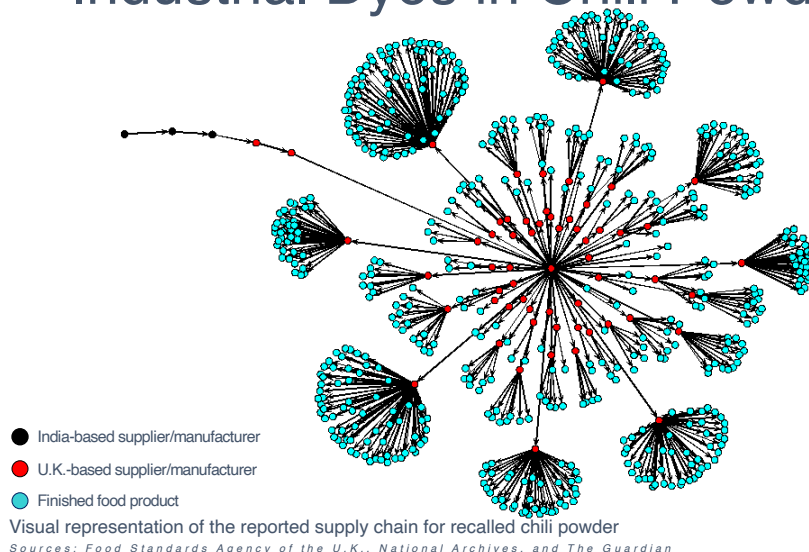
- Poured Salmonella Typhimurium on salad bars
- To incapacitate the public to influence a local election
- Initially investigated as unintentional
- 751 gastroenteritis illnesses
- 45 hospitalizations

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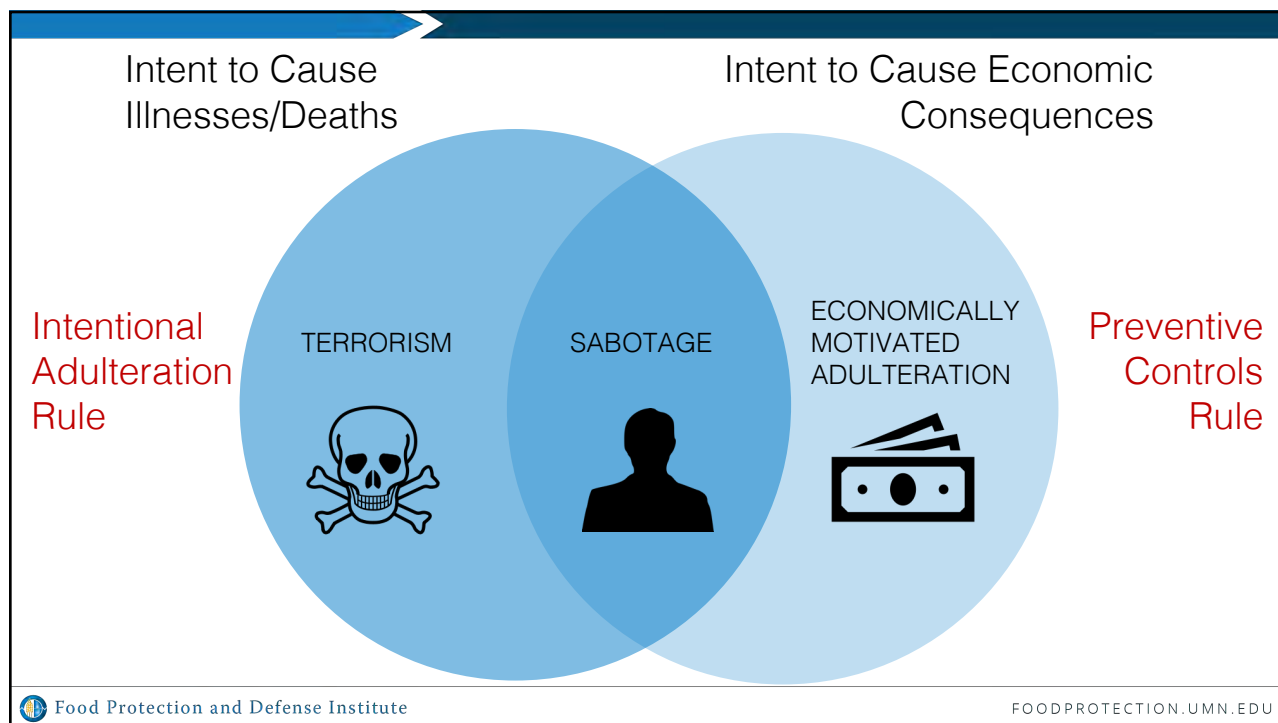
Industrial Dyes in Chili Powder



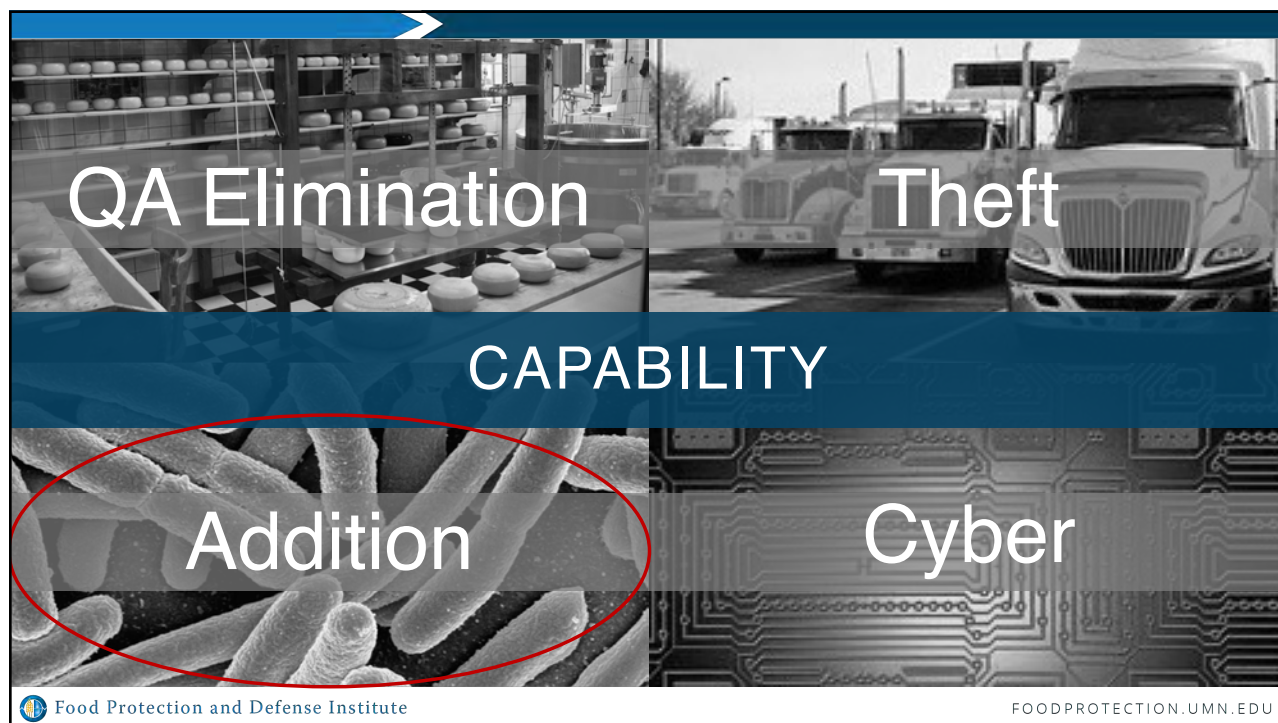
Intentional Adulteration Final Rule

“...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.”

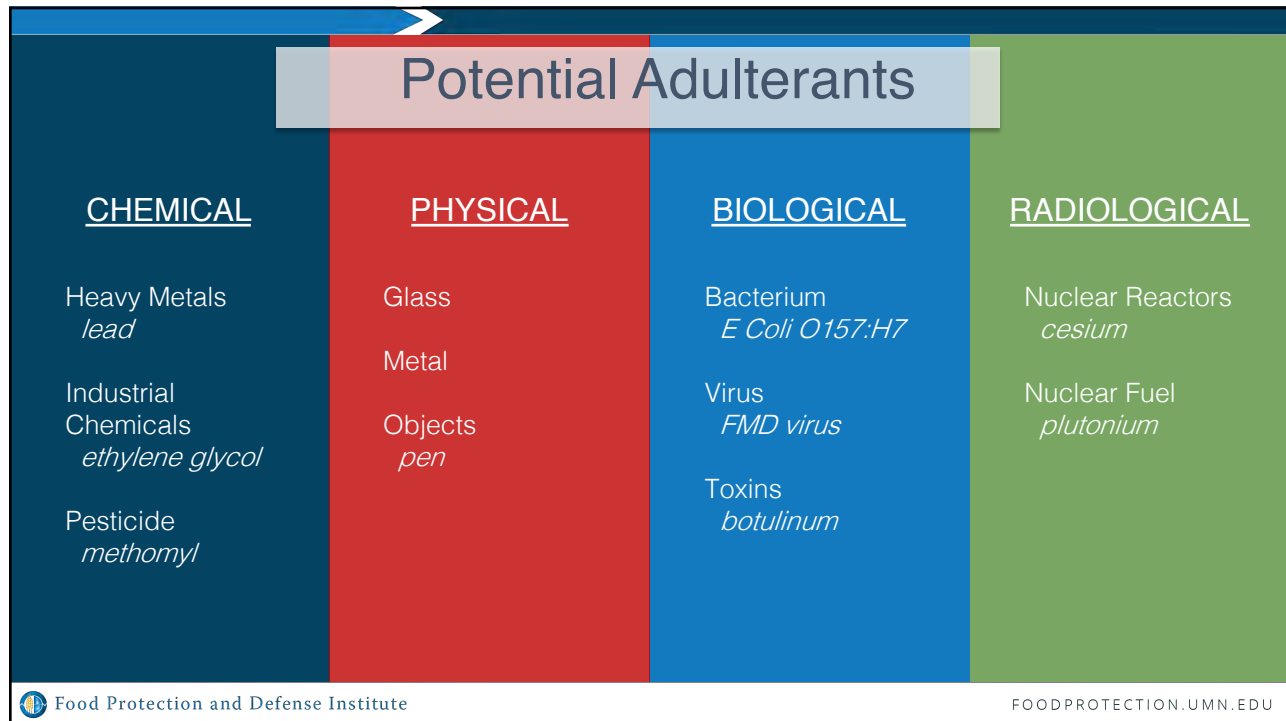
<https://www.fda.gov/food/guidanceregulation/fsma/ucm378628.htm>



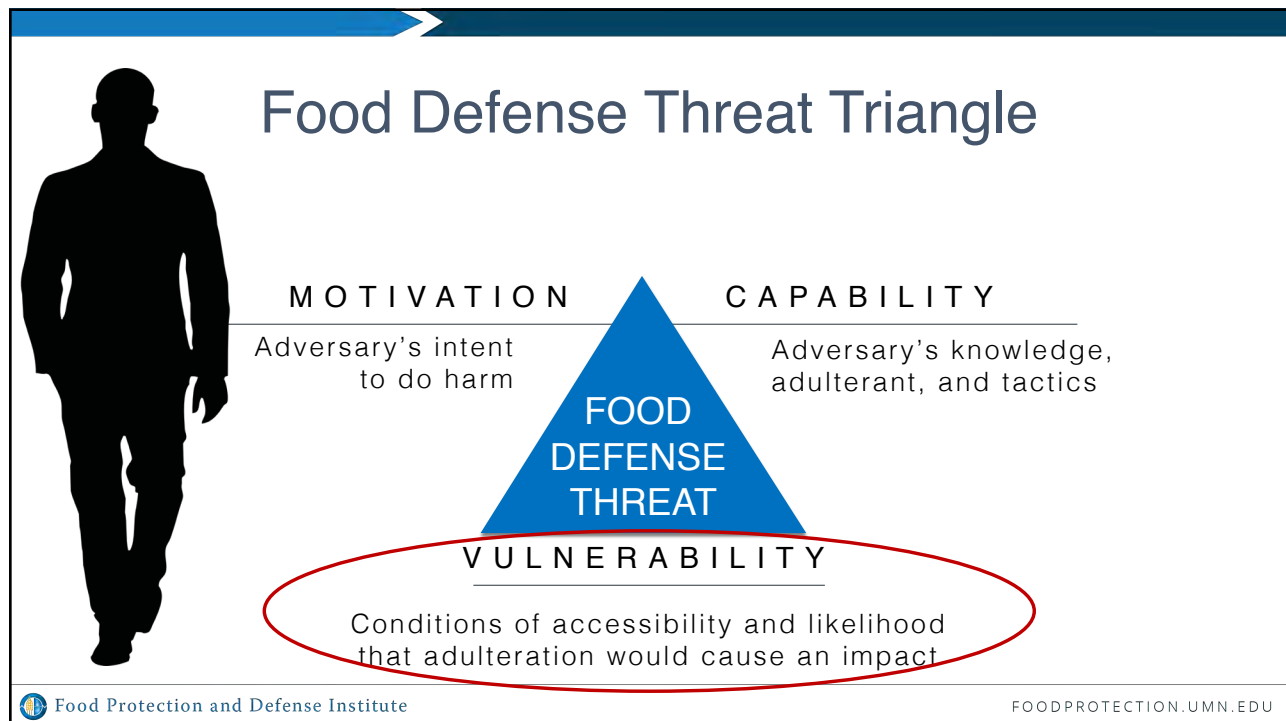
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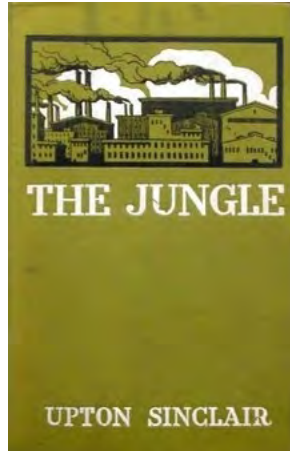


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The Jungle



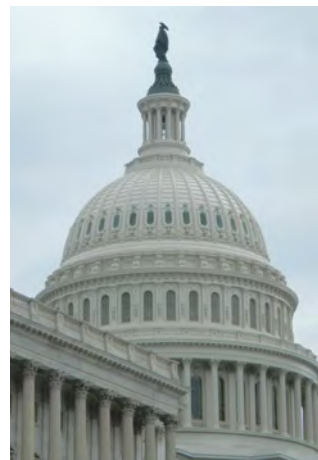
1906

Portrays egregious working conditions in meat packing facilities

Meat Inspection Act
Pure Food and Drug Act

Food Safety Modernization Act

- Passed in 2011
- Most sweeping reform of food safety laws in more than 70 years
- Aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it

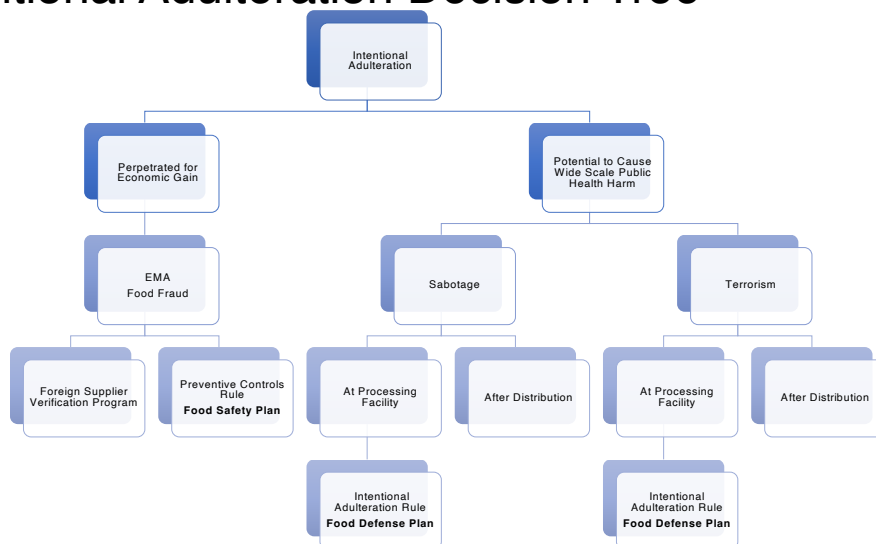


FSMA Rules

| | |
|---|-----------------|
| Preventive Controls for Human Foods | September 2015 |
| Preventive Controls for Animal Foods | September 2015 |
| Standards for Produce Safety | November 2015 |
| Foreign Supplier Verification | November 2015 |
| Accreditation of Third Party Certification | November 2015 |
| Sanitary Transportation of Human and Animal Food | April 2016 |
| Mitigation Strategies to Protect Food Against Intentional Adulteration | May 2016 |

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Intentional Adulteration Decision Tree



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What does the IA rule do?

New Requirements

- Establishes requirements to prevent or significantly minimize acts intended to cause wide-scale public health harm

Vulnerability Assessment

- Uses a HACCP-type approach
 - with important differences from the Preventive Controls for Human Food rule
- Is risk-based and flexible

Who is covered?

FDA-Regulated Facilities

- Facilities that manufacture, process, pack or hold human food
- In general, facilities required to register with FDA under sec. 415 FD&C Act
 - Not farms or retail food establishments

Domestic and Imported

- Applies to domestic and imported food

Exemptions

- Some exemptions and modified requirements apply

Compliance Dates

Very Small Businesses

- July 26, 2021

Small businesses

- A business with fewer than 500 full-time equivalent employees
- July 27, 2020

All other businesses:

- July 26, 2019

Quick Check Inspections are occurring

Full Inspections anticipated in mid-2020s

Guidance

Draft Guidance

Part 1 – June 2018

Key Activity Types vulnerability assessment method, mitigation strategies, monitoring

Part 2 – March 2019

Fundamental Element Analysis vulnerability assessment method

Supplemental Draft Guidance

Part 3 – February 2020

Corrective actions, verification, reanalysis, and recordkeeping

What is required?

Food Defense Plan

Records

Training

Reanalysis

FOOD DEFENSE PLAN

- Vulnerability assessment
- Mitigation strategies
- Monitoring procedures
- Corrective actions
- Verification procedures

Key Terms

Actionable Process Steps

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.

Mitigation Strategies

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.

Quick Check

- Please complete our Knowledge Check poll

QUESTIONS?



FOOD DEFENSE PLAN ESSENTIALS

Intentional Adulteration Rule Training



Lesson 1 – 3

Overview Food Defense Measures

FOOD DEFENSE PLAN ESSENTIALS

Intentional Adulteration Rule Training



Lesson 1 – 4

Preliminary Steps

FOOD DEFENSE PLAN ESSENTIALS

Intentional Adulteration Rule Training



Lesson 1 – 5

Key Activity Type Vulnerability Assessments



FOOD DEFENSE PLAN ESSENTIALS

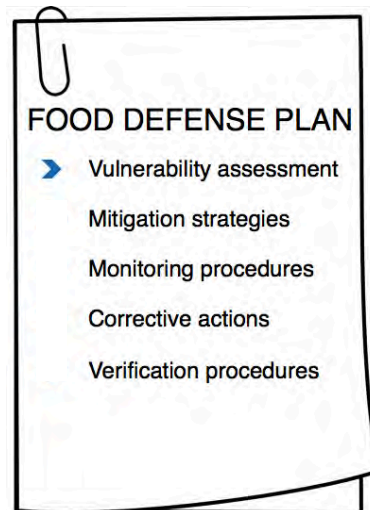


Food Defense Plans: Vulnerability Assessment

1

Vulnerability Assessment

- Identification of those points at highest risk
i.e., actionable process steps
- For each point, step, or procedure, a facility must consider, at a minimum:
 - Potential public health impact
 - Degree of physical access to product
 - Ability of an attacker to successfully contaminate the product
- Must consider the possibility of an inside attacker



2

Key Activity Types



Bulk Liquid
Receiving or
Loading



Liquid
Storage and
Handling



Secondary
Ingredient
Handling



Mixing and
Similar
Activities

Easiest method of vulnerability assessment

3



Bulk liquid
receiving or
loading

- Bulk liquid receiving at the facility from an inbound conveyance
 - opening the inbound transport vehicle,
 - opening of venting hatches or other access points,
 - attaching any pumping equipment or hoses, and
 - unloading of the bulk liquid
- Bulk liquid loading into an outbound conveyance
 - opening the outbound transport vehicle,
 - attaching any pumping equipment or hoses, and
 - opening any venting hatches at the facility

4



Liquid storage
and handling

- Storage or holding of liquids (bulk or non-bulk) either in storage tanks or in other tanks at the facility
- Handling, metering, surge, or other types of intermediate processing tanks used to control flow rates of liquid ingredients or product through the production system
- Includes tanks or totes where the tamper-evident seals are opened
- Including when the container itself is used as a storage or handling tank

5



Secondary Ingredient
Handling

- Staging of secondary ingredients
 - moving the ingredient to the production area in advance
- Preparation of secondary ingredients
 - process of measuring, weighing, premixing prior to addition
- Addition of secondary ingredients
 - process of physically adding ingredient directly or into surge or meter
- Rework product
 - removing clean, unadulterated food from processing for reasons other than insanitary conditions or
 - product that has been reconditioned by reprocessing

6



Mixing and similar activities

- Mixing
 - to blend a powder, dough, or liquid ingredient together
- Homogenizing
 - to reduce the particle size of an ingredient and disperse it throughout a liquid
- Grinding
 - to reduce the particle size of a solid ingredient or mass to a smaller granularity
- Coating
 - to layer a powder or liquid onto the surface of a product, such as a batter, breading, glazing, or flavoring

Key Activity Type Practice

Example

Description

The poll will open and cover the screen. You will need to drag it out of the way. After polling, the poll results and the answers will be shared. You will need to drag the poll results out of the way to see the answers.

| Step 1: Key Activity Types Method | |
|--|---|
| <input type="checkbox"/> This point, step, or procedure fits within the following Key Activity Types (Select all that apply) | <input type="checkbox"/> This point, step, or procedure does not fit within any of the Key Activity Types (Proceed to Step 4: Actionable Process Step Determination) |
| <input type="checkbox"/> Bulk Liquid Receiving and Loading | |
| <input type="checkbox"/> Liquid Storage and Handling | |
| <input type="checkbox"/> Secondary Ingredient Handling | |
| <input type="checkbox"/> Mixing and Similar Activities | |

| Step 4: Actionable Process Step Determination | |
|--|---|
| <input type="checkbox"/> This point, step, or procedure is an Actionable Process Step because it aligns with Key Activity Type [insert which one/s] and contains no inherent characteristics to mitigate its vulnerability (Proceed to Mitigation Strategies Worksheet) | <input type="checkbox"/> This point, step, or procedure does not align with any Key Activity Types and is not an Actionable Process Step (Evaluation complete, no mitigation strategies or management components are necessary) |

Key Activity Type Practice

Non-peanut ingredient storage

Sugar, hydrogenated vegetable oil, and salt are received and stored at ambient conditions in an area separate from raw peanuts. Ingredients are stored in tamper-evident sealed containers. These materials are used on a first-in-first-out basis. Open containers of partially used ingredients may be put back into storage for later use.

2019. FDA. Revised Draft Guidance Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry.

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Step 1: Key Activity Types Method

☐ This point, step, or procedure fits within the following Key Activity Types (Select all that apply)

☐ Bulk Liquid Receiving and Loading

☐ Liquid Storage and Handling

☐ Secondary Ingredient Handling

☐ Mixing and Similar Activities

☐ This point, step, or procedure does **not** fit within any of the Key Activity Types (Proceed to Step 4: Actionable Process Step Determination)

Step 4: Actionable Process Step Determination

☐ This point, step, or procedure is an Actionable Process Step because it aligns with Key Activity Type [insert which one/s] and contains no inherent characteristics to mitigate its vulnerability

(Proceed to Mitigation Strategies Worksheet)

☐ This point, step, or procedure does not align with any Key Activity Types and is **not** an Actionable Process Step

(Evaluation complete, no mitigation strategies or management components are necessary)

Key Activity Type Practice

Non-peanut ingredient storage

Sugar, hydrogenated vegetable oil, and salt are received and stored at ambient conditions in an area separate from raw peanuts. Ingredients are stored in tamper-evident sealed containers. These materials are used on a first-in-first-out basis. Partially used ingredients may be put back into storage for later use. When this occurs, these ingredients are placed in in tamper-evident sealed containers.

2019. FDA. Revised Draft Guidance Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry.

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Step 1: Key Activity Types Method

☐ This point, step, or procedure fits within the following Key Activity Types (Select all that apply)

☐ Bulk Liquid Receiving and Loading

☐ Liquid Storage and Handling

☐ Secondary Ingredient Handling

☐ Mixing and Similar Activities

☐ This point, step, or procedure does **not** fit within any of the Key Activity Types (Proceed to Step 4: Actionable Process Step Determination)

Step 4: Actionable Process Step Determination

☐ This point, step, or procedure is an Actionable Process Step because it aligns with Key Activity Type [insert which one/s] and contains no inherent characteristics to mitigate its vulnerability

(Proceed to Mitigation Strategies Worksheet)

☐ This point, step, or procedure does not align with any Key Activity Types and is **not** an Actionable Process Step

(Evaluation complete, no mitigation strategies or management components are necessary)

10

Key Activity Type Practice

Roasting

Raw peanuts are conveyed through a roaster in a continuous process that applies forced heated air uniformly from above and below the peanut bed at a uniform bed depth. No mixing occurs during the roasting process. The roaster is not accessible.

Step 1: Key Activity Types Method

☐ This point, step, or procedure fits within the following Key Activity Types (Select all that apply)

- ☐ Bulk Liquid Receiving and Loading
- ☐ Liquid Storage and Handling
- ☐ Secondary Ingredient Handling
- ☐ Mixing and Similar Activities

☐ This point, step, or procedure does **not** fit within any of the Key Activity Types (Proceed to Step 4: Actionable Process Step Determination)

Step 4: Actionable Process Step Determination

☐ This point, step, or procedure is an Actionable Process Step because it aligns with Key Activity Type [insert which one/s] and contains no inherent characteristics to mitigate its vulnerability
(Proceed to Mitigation Strategies Worksheet)

☐ This point, step, or procedure does not align with any Key Activity Types and is **not** an Actionable Process Step
(Evaluation complete, no mitigation strategies or management components are necessary)

2019. FDA. Revised Draft Guidance Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry.

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Key Activity Type Practice

Grinding

Peanuts are conveyed across a magnet to a grinder where the peanuts are coarse ground to a paste consistency.

Step 1: Key Activity Types Method

☐ This point, step, or procedure fits within the following Key Activity Types (Select all that apply)

- ☐ Bulk Liquid Receiving and Loading
- ☐ Liquid Storage and Handling
- ☐ Secondary Ingredient Handling
- ☐ Mixing and Similar Activities

☐ This point, step, or procedure does **not** fit within any of the Key Activity Types (Proceed to Step 4: Actionable Process Step Determination)

Step 4: Actionable Process Step Determination

☐ This point, step, or procedure is an Actionable Process Step because it aligns with Key Activity Type [insert which one/s] and contains no inherent characteristics to mitigate its vulnerability
(Proceed to Mitigation Strategies Worksheet)

☐ This point, step, or procedure does not align with any Key Activity Types and is **not** an Actionable Process Step
(Evaluation complete, no mitigation strategies or management components are necessary)

2019. FDA. Revised Draft Guidance Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry.

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Key Activity Type Practice

Surge Tank

Liquid ingredient from the bulk liquid storage tank is directly pumped into the surge tank to control flow rates into the mixer. The surge tank is fully enclosed during operations and is only accessible during maintenance when the tank must be disassembled and cleaned. The maintenance process requires a team of 3 technicians to perform. The surge tank is located above and next to the mixer.

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Key Activity Type Practice

Secondary Ingredient Addition

Sealed bags of dry ingredients (e.g. sugar, spices, baking soda) are manually opened and dumped into the mixer. These activities are performed by the mixer operator.

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Step 1: Key Activity Types Method

☐ This point, step, or procedure fits within the following Key Activity Types (Select all that apply)

☐ Bulk Liquid Receiving and Loading

☐ Liquid Storage and Handling

☐ Secondary Ingredient Handling

☐ Mixing and Similar Activities

☐ This point, step, or procedure does **not** fit within any of the Key Activity Types (Proceed to Step 4: Actionable Process Step Determination)

Step 4: Actionable Process Step Determination

☐ This point, step, or procedure is an Actionable Process Step because it aligns with Key Activity Type [insert which one/s] and contains no inherent characteristics to mitigate its vulnerability

(Proceed to Mitigation Strategies Worksheet)

☐ This point, step, or procedure does not align with any Key Activity Types and is **not** an Actionable Process Step

(Evaluation complete, no mitigation strategies or management components are necessary)

Key Activity Type Practice

Forming

Once mixed, the mixture is emptied onto a conveyor, divided and passed under molds where it is pressed from above into 1" squares. Access to the product is only possible from the side of the conveyor as it moves through the former. Line capacity of the conveyor through the former is 100 lbs./min. Trimmings from forming are diverted to a collection tray for reintroduction as rework.

Step 1: Key Activity Types Method

☐ This point, step, or procedure fits within the following Key Activity Types (Select all that apply)

☐ Bulk Liquid Receiving and Loading

☐ Liquid Storage and Handling

☐ Secondary Ingredient Handling

☐ Mixing and Similar Activities

☐ This point, step, or procedure does **not** fit within any of the Key Activity Types (Proceed to Step 4: Actionable Process Step Determination)

Step 4: Actionable Process Step Determination

☐ This point, step, or procedure is an Actionable Process Step because it aligns with Key Activity Type [insert which one/s] and contains no inherent characteristics to mitigate its vulnerability

(Proceed to Mitigation Strategies Worksheet)

☐ This point, step, or procedure does not align with any Key Activity Types and is **not** an Actionable Process Step

(Evaluation complete, no mitigation strategies or management components are necessary)

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Key Activity Type Practice

Rework

Trimmings from the former are taken by the mixer operator. Rework may be generated from the mixing operation or after forming. Rework is manually collected in clean and dry containers, which are labelled with the product name, relevant allergens, and date rework was generated. Rework product can be staged in containers with lids for up to 6 hours prior to addition to the mixer.

Step 1: Key Activity Types Method

☐ This point, step, or procedure fits within the following Key Activity Types (Select all that apply)

☐ Bulk Liquid Receiving and Loading

☐ Liquid Storage and Handling

☐ Secondary Ingredient Handling

☐ Mixing and Similar Activities

☐ This point, step, or procedure does **not** fit within any of the Key Activity Types (Proceed to Step 4: Actionable Process Step Determination)

Step 4: Actionable Process Step Determination

☐ This point, step, or procedure is an Actionable Process Step because it aligns with Key Activity Type [insert which one/s] and contains no inherent characteristics to mitigate its vulnerability

(Proceed to Mitigation Strategies Worksheet)

☐ This point, step, or procedure does not align with any Key Activity Types and is **not** an Actionable Process Step

(Evaluation complete, no mitigation strategies or management components are necessary)

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Key Activity Type Practice

Your Process

Enter a brief description of your process in the chat window and indicate which, if any, key activity types apply

Step 1: Key Activity Types Method

☐ This point, step, or procedure fits within the following Key Activity Types (Select all that apply)

☐ Bulk Liquid Receiving and Loading

☐ Liquid Storage and Handling

☐ Secondary Ingredient Handling

☐ Mixing and Similar Activities

☐ This point, step, or procedure does **not** fit within any of the Key Activity Types (Proceed to Step 4: Actionable Process Step Determination)

Step 4: Actionable Process Step Determination

☐ This point, step, or procedure is an Actionable Process Step because it aligns with Key Activity Type [insert which one/s] and contains no inherent characteristics to mitigate its vulnerability

(Proceed to Mitigation Strategies Worksheet)

☐ This point, step, or procedure does not align with any Key Activity Types and is **not** an Actionable Process Step

(Evaluation complete, no mitigation strategies or management components are necessary)

Key Activity Type Practice

Roasting

Raw peanuts are conveyed through a roaster in a continuous process that applies forced heated air uniformly from above and below the peanut bed at a uniform bed depth. The bed contains agitation bars to gently mix throughout the roasting process. The roaster is not accessible.

Step 1: Key Activity Types Method

☐ This point, step, or procedure fits within the following Key Activity Types (Select all that apply)

☐ Bulk Liquid Receiving and Loading

☐ Liquid Storage and Handling

☐ Secondary Ingredient Handling

☐ Mixing and Similar Activities

☐ This point, step, or procedure does **not** fit within any of the Key Activity Types (Proceed to Step 4: Actionable Process Step Determination)

Step 4: Actionable Process Step Determination

☐ This point, step, or procedure is an Actionable Process Step because it aligns with Key Activity Type [insert which one/s] and contains no inherent characteristics to mitigate its vulnerability

(Proceed to Mitigation Strategies Worksheet)

☐ This point, step, or procedure does not align with any Key Activity Types and is **not** an Actionable Process Step

(Evaluation complete, no mitigation strategies or management components are necessary)

Key Activity Types



Bulk Liquid
Receiving or
Loading



Liquid
Storage and
Handling



Secondary
Ingredient
Handling



Mixing and
Similar
Activities

Easiest method of vulnerability assessment

It may identify steps that are not actionable process steps

Fundamental Elements



Evaluating
Potential Public
Health Impact



Evaluating
Degree of
Physical
Access to
the Product



Evaluating the
Ability to
Successfully
Contaminate the
Product

QUESTIONS?



FOOD DEFENSE PLAN ESSENTIALS

Intentional Adulteration Rule Training



Day 2 – 1

Inherent Characteristics

FOOD DEFENSE PLAN ESSENTIALS

Intentional Adulteration Rule Training



Day 2 – 2

Inside Attacker

FOOD DEFENSE PLAN ESSENTIALS

Intentional Adulteration Rule Training



Day 2 – 3

IAVA Element 1

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Intentional Adulteration Rule Training



Day 2 – 4

IAVA Element 2 & 3

FOOD DEFENSE PLAN ESSENTIALS

Intentional Adulteration Rule Training



Day 3 – 1

Analyzing Results

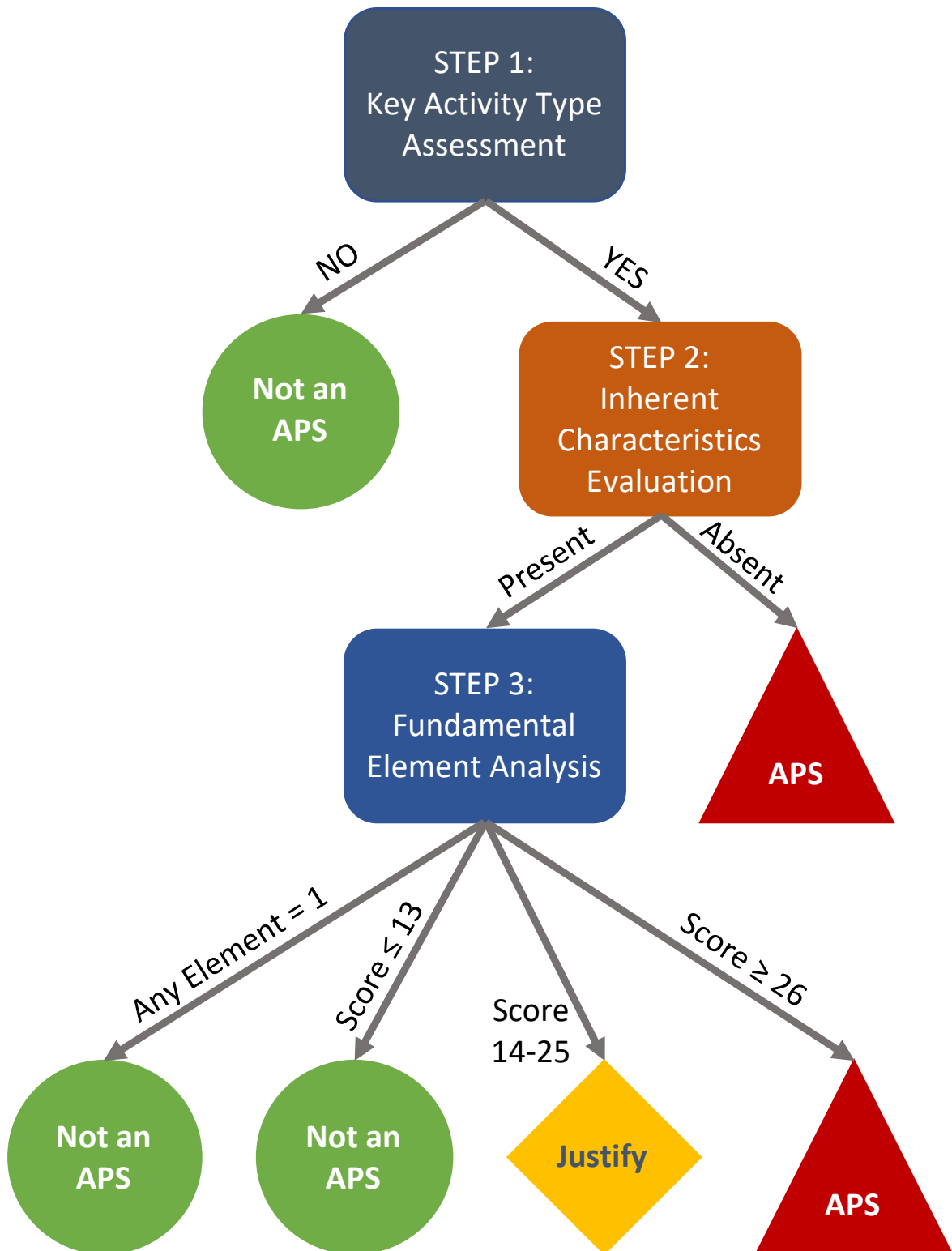
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Intentional Adulteration Rule Training



Day 3 – 2

Hybrid Method



FOOD DEFENSE PLAN ESSENTIALS

Intentional Adulteration Rule Training



Lesson 3 – 3

Mitigation Strategies



FOOD DEFENSE PLAN ESSENTIALS



Food Defense Plans: Mitigation Strategies

1

OVERARCHING STRATEGIES

2

OUTSIDE SECURITY

- Property perimeter (fences, gates, guards)
- Building perimeter (locked and alarmed doors, lighting and surveillance)
- Visitor and employee identification
- Vehicle controls



3

INSIDE SECURITY

- Adequate lighting & security cameras
- Restricted access to sensitive areas
- Protect access to utilities
- Protect cyber systems from internal and external threats



4

PEOPLE

- Background checks for new employees
- Employee training
- Controlled access to the facility and specific departments
- Restriction of personal items in production areas



LOGISTICS, PRODUCTION, STORAGE

- Trusted supplier programs
- Shipping and receiving policies
- Hazardous materials storage
- Warehouse and storage access controls



ACTIONABLE PROCESS STEPS

7

ACTIONABLE PROCESS STEPS

- Identified in Vulnerability Assessment
- May align with Key Activity Types
- Mitigation Strategies Required

21 CFR 121.135 (a)

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MITIGATION STRATEGIES

- Risk based, reasonably appropriate measures employed to significantly minimize or prevent significant vulnerabilities
- Implemented at each Actionable Process Step to sufficiently minimize the risk of intentional adulteration

FDA Mitigation Strategies to Protect Food Against Intentional Adulteration, 81 Fed. Reg. 34165 (May 27, 2016).



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MITIGATION STRATEGIES

- Mitigation Strategies are:
 - Customized to the process step at which they are applied;
 - Tailored to existing facility practices and procedures; and
 - Directed toward the actionable process step's vulnerability, including vulnerability to an inside attacker
 - Facilities have flexibility to identify and implement appropriate strategies

Key Term

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

Public Meeting on the Draft Guidance to Support Compliance with the Intentional Adulteration Rule, April 17, 2019



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MITIGATION STRATEGIES EXAMPLES



Peer
Observation



Access
Control



Tamper Evident
Seals



Inspection

Mitigation strategies should be tailored to the specific vulnerability

More than one may be needed

LOW COST / NO COST

Build on existing systems

Choose based on vulnerabilities

Prevent or physical change

Prioritization

Keep it simple

Should not adversely affect food safety

Decreasing Degree of Access

How can you reduce or eliminate physical access to the product?

Decreasing Ability to Successfully Contaminate

How can you reduce or eliminate the ability of an inside attacker to introduce a contaminate?

How can you improve observation so that actions would be readily evident and, thus, prevented?

How can you make actions implausible or impossible?

Decreasing Public Health Impact

Not commonly considered for mitigation strategies

How could the scale and severity of public health impact be lowered?

MITIGATION STRATEGIES

| 2x2 Matrix Approach | Personnel and Operations-Based Mitigation Strategies | Technology-Assisted Mitigation Strategies |
|--|--|---|
| Minimizing the Accessibility of the Product to an Inside Attacker ↓ Access | | |
| Reducing the Ability of an Inside Attacker to Contaminate the Product ↓ Success | | |

MITIGATION STRATEGIES

| 2x2 Matrix Approach | Personnel and Operations-Based Mitigation Strategies | Technology-Assisted Mitigation Strategies |
|--|--|---|
| Minimizing the Accessibility of the Product to an Inside Attacker ↓ Access | Personnel and operations-based mitigation strategies reduce accessibility by establishing who is authorized to be present at an actionable process step and prohibiting individuals from being there if not required by work function. | |
| Reducing the Ability of an Inside Attacker to Contaminate the Product | | |

Progressive employee vetting such that employees working in less vulnerable areas receive a less intrusive level of vetting than workers at actionable process steps

2018. FDA. Draft Guidance Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry.

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MITIGATION STRATEGIES

| 2x2 Matrix Approach | Personnel and Operations-Based Mitigation Strategies | Technology-Assisted Mitigation Strategies |
|--|--|---|
| Minimizing the Accessibility of the Product to an Inside Attacker ↓ Access | Personnel and operations-based mitigation strategies reduce accessibility by establishing who is authorized to be present at an actionable process step and prohibiting individuals from being there if not required by work function. | |
| Reducing the Ability of an Inside Attacker to Contaminate the Product | | |

Authorize senior or long-term employees, or those who have elevated trust by management to work at a particular actionable process step

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MITIGATION STRATEGIES

| 2x2 Matrix Approach | Personnel and Operations-Based Mitigation Strategies | Technology-Assisted Mitigation Strategies |
|--|---|--|
| Minimizing the Accessibility of the Product to an Inside Attacker ↓ Access | | Technology-assisted mitigation strategies generally rely on the implementation of a physical access barrier or the implementation of tamper-evident seals or other detection mechanisms that would prevent access to someone intending to adulterate the food without leaving detectable evidence. |
| Reducing Inside Contamination | <ul style="list-style-type: none"> • Tamper evident seals • Locking gates or barriers • Blocking access paths • Using automated or enclosed equipment | |

2018. FDA. Draft Guidance Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry.

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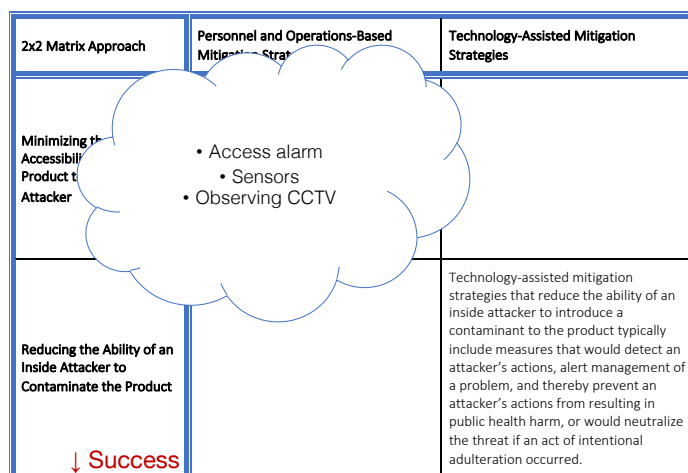
MITIGATION STRATEGIES

| 2x2 Matrix Approach | Personnel and Operations-Based Mitigation Strategies | Technology-Assisted Mitigation Strategies |
|---|---|---|
| Minimizing the Accessibility of the Product to an Inside Attacker | | |
| Reducing the Ability of an Inside Attacker to Contaminate the Product ↓ Success | <p>Personnel and operations-based mitigation strategies that reduce the ability of an inside attacker to adulterate a product typically include strategies that increase observation of a significantly vulnerable area such that an attacker's actions would be easily detected.</p> | <ul style="list-style-type: none"> • Peer monitoring • Altering existing inspection • Increasing ease of observation |

2018. FDA. Draft Guidance Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry.

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MITIGATION STRATEGIES



2018. FDA. Draft Guidance Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry.

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MITIGATION STRATEGIES

| 2x2 Matrix Approach | Personnel and Operations-Based Mitigation Strategies | Technology-Assisted Mitigation Strategies |
|--|--|---|
| Minimizing the Accessibility of the Product to an Inside Attacker ↓ Access | Personnel and operations-based mitigation strategies reduce accessibility by establishing who is authorized to be present at an actionable process step and prohibiting individuals from being there if not required by work function. | Technology-assisted mitigation strategies generally rely on the implementation of a physical access barrier or the implementation of tamper-evident seals or other detection mechanisms that would prevent access to someone intending to adulterate the food without leaving detectable evidence. |
| Reducing the Ability of an Inside Attacker to Contaminate the Product ↓ Success | Personnel and operations-based mitigation strategies that reduce the ability of an inside attacker to adulterate a product typically include strategies that increase observation of a significantly vulnerable area such that an attacker's actions would be easily detected. | Technology-assisted mitigation strategies that reduce the ability of an inside attacker to introduce a contaminant to the product typically include measures that would detect an attacker's actions, alert management of a problem, and thereby prevent an attacker's actions from resulting in public health harm, or would neutralize the threat if an act of intentional adulteration occurred. |

2018. FDA. Draft Guidance Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry.

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FDA Mitigation Strategies Database

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. The FDMSD provides a range of mitigation strategies for individuals to consider implementing at points, steps or procedures to minimize the vulnerability to an intentional attack.

• [How to use this Tool](#)
• [Full Disclaimer](#)

Browse by Category:

| | | | | |
|---------------------------------|---------------------|---------------------------|---------------------|-----------------------------|
| Facility-Wide Security Measures | Retail Food Service | Conveyance | Farming/Agriculture | Material Handling |
| Packaging | Processing | Key Activity Types (KATs) | Storage | Transportation/Distribution |

Choose a Point, Step, or Procedure:

Bulk Liquid Receiving and Loading
Liquid Handling and Storage
Mixing and Similar Activities
Secondary Ingredient Handling

Search by Keyword:

Review Strategy List:

It is the responsibility of the owner, operator or agent in charge to choose the strategy or combination of strategies that are most effective and appropriate for their facility. Some strategies listed within the database are meant to be implemented in conjunction with other strategies or in tandem with other food defense policies and procedures. Choosing and following strategies within this database does not constitute compliance with any FDA laws, regulations, or guidance. For information about food defense measures or policies that are recommended for an effective food defense environment please see the category titled General Information.

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FSIS Risk Mitigation Tool

FSIS Food Defense Risk Mitigation Tool
Contains nonbinding recommendations

This online tool is part of an ongoing effort by FSIS to help protect the nation's supply of meat, poultry, and egg products from intentional contamination. During vulnerability assessments conducted jointly with FSIS, industry representatives suggested that a searchable, user-friendly tool was needed to facilitate identification and selection of appropriate mitigation strategies (i.e., countermeasures).

This tool identifies some possible countermeasures that companies could implement, as part of a food defense plan, to better protect their business, employees, and customers. Some of the countermeasures are specific to particular assets or activities (nodes); others apply more generally to the facility as a whole. Written guidance regarding mitigation strategies is also available in Food Defense Guidelines for Slaughter and Processing Establishments, which can be obtained by calling the Small Plant Help Desk at 1-877-FSIS-HELP (374-7435) and is also available on the web at <http://www.fsis.usda.gov/PDF/SecurityGuides.pdf>.

The countermeasures listed in this tool are neither mandatory nor exhaustive. Not all of the identified strategies will be applicable, practical, or effective for all types and sizes of slaughter and processing establishments. Additional strategies not included here may also be useful. The user should implement countermeasures appropriate to the specific circumstances of their establishment and operations.

Lookup Tool
The mitigation measures are organized by the category of operation and node (i.e., specific piece of equipment):

1. First, select an industry process category from the provided list, then
2. Choose from among the list of Nodes associated with that category. After selecting the node of interest,
3. Click "SELECT" to view a list of potentially applicable mitigation strategies.

You must choose a Category and a corresponding Node.

Make your selection:

Choose a Category:

Choose a Node:

For questions or clarification on this tool, contact the FSIS Policy Development Division at 1-800-233-3935

2

FSIS Food Defense Risk Mitigation Tool

Suggested mitigation measures applicable to the selected node are listed below. Some measures may only require a policy change, while others may require your company to install up-front controls to prepare for a higher level of security. The number and extent of the preventive measures that you choose to implement is dependent on an analysis of your vulnerabilities and your determination of the cost-effectiveness of each measure for your organization.

Mitigation Measures for Grinders

- Designate and clearly mark the grinder area as restricted (i.e., authorized employees only).
- Limit access to grinder to authorized employees only. Restrict visitors, guests and other non-employees (e.g., contractors, sales people, and truck drivers) to non-product areas unless accompanied by an authorized employee.
- Monitor the grinder area to confirm that only authorized personnel are present.
- Check that all contractors have had for clearing and maintenance operations have adequate employee screening procedures.
- Use post monitoring when accessing the grinder.
- Consider engineering controls to restrict access to the grinder (e.g., install a lock, secure access points).
- Consider the use of surveillance cameras to monitor grinder operations.

Not all recommendations are applicable to all facilities.

1

3

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Bulk liquid
receiving or
loading

- Keep one operator with transportation at all times (e.g., relay operators, relief driver, peer-monitoring)
- Use electronic access control system to restrict access to location
- Use closed systems
- Use tamper-evident devices (seals, covers, locks to secure access to equipment and products)
- Visually inspect equipment, equipment components, and supplies prior to use and report anomalies

Find more strategies at [FDA Mitigation Strategy Database](#)



Liquid storage
and handling

- Use one-way valves to restrict access to product
- Use an alarm system to detect suspect events
- Use locks to secure location, equipment, and controls when not in use or unattended
- Use personnel identification (e.g., color coded uniforms, badges) to restrict access to location
- Use physical barriers to restrict access to location

Find more strategies at [FDA Mitigation Strategy Database](#)



Secondary Ingredient
Handling

- Conduct periodic checks of packaging integrity
- Maximize visibility of operations, equipment and location
- Use peer monitoring (e.g. buddy system) during operations
- Reduce amount of product and supplies accessible at one time to reduce the impact of contamination
- Document or record addition of ingredients

Find more strategies at [FDA Mitigation Strategy Database](#)

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Mixing and similar
activities

- Use automated equipment to restrict access to product
- Clean, sanitize, and inspect equipment and area periodically (e.g., immediately before use)
- Accompany unauthorized persons to restricted areas
- Use coverings to secure openings, access points, and equipment
- Restrict access to ingredients and products to authorized personnel

Find more strategies at [FDA Mitigation Strategy Database](#)

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Mitigation Strategies Practice - 1

Liquid ingredient storage tank

| Vulnerability Scenario | Mitigation Strategy | Explanation |
|--|--|--|
| A facility identified the <u>primary ingredient storage tank</u> as an actionable process step because it met the definition of a key activity type. The VA identified that an <u>unsecured access hatch at the top of the tank provided unrestricted access</u> to the ingredient in the tank and would enable an attacker to intentionally contaminate the food. | Use a <u>lock</u> to secure access hatch on ingredient storage tank. <u>Keys to the lock</u> are held in the security office and can only be retrieved with good reason and approval from the facility security manager or food defense coordinator. | The lock on the hatch renders the food in the <u>tank inaccessible</u> to an attacker, including an inside attacker, thereby significantly reducing the vulnerability present at this actionable process step. |

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Mitigation Strategies Practice – 2.a

Bulk liquid receiving

| Vulnerability Scenario | Mitigation Strategy | Explanation |
|---|--|---|
| A facility's VA identified the receiving of bulk liquid ingredients as an actionable process step. The facility recognizes that there are <u>several factors</u> in this process that are relevant to the food defense vulnerability of receiving bulk liquid ingredients. The facility determined that multiple mitigation strategies were needed to address the vulnerability. | Use <u>tamper-evident seals</u> on inbound shipping conveyances. Match the numbers on the seals with the numbers provided on the shipping documentation from the supplier. If the <u>seals do not match</u> , the load will be <u>rejected</u> to prevent potentially adulterated ingredient from entering the facility. | Using numbered wire or plastic seals to secure hatches, ports, and other access points to the transport conveyance significantly <u>reduces the ability of an attacker to successfully contaminate</u> the product without being detected. Tamper-evident seals will indicate if the product has been interfered with during transport. |

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Mitigation Strategies Practice – 2.b

Bulk liquid receiving

| Vulnerability Scenario | Mitigation Strategy | Explanation |
|--|--|--|
| <p>A facility's VA identified the receiving of bulk liquid ingredients as an actionable process step. The facility recognizes that there are <u>several factors</u> in this process that are relevant to the food defense vulnerability of receiving bulk liquid ingredients.</p> <p>The facility determined that multiple mitigation strategies were needed to address the vulnerability.</p> | Use <u>tamper-evident tape</u> on hose ends after capping. | Using tamper-evident tape to seal the hose caps when not in use <u>limits the ability of an attacker to successfully contaminate</u> the product without being detected. |

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Mitigation Strategies Practice – 2.c

Bulk liquid receiving

| Vulnerability Scenario | Mitigation Strategy | Explanation |
|--|--|--|
| <p>A facility's VA identified the receiving of bulk liquid ingredients as an actionable process step. The facility recognizes that there are <u>several factors</u> in this process that are relevant to the food defense vulnerability of receiving bulk liquid ingredients.</p> <p>The facility determined that multiple mitigation strategies were needed to address the vulnerability.</p> | Use <u>authorized personnel</u> for <u>visual observation of the unloading bay</u> during the opening of the conveyance and the attachment of hoses and pumping equipment. | Having the employee responsible for reviewing shipping documentation visually observe the opening of venting and sampling hatches as well as the hooking up of hoses and pumping equipment <u>significantly reduces the ability of an attacker to introduce a contaminant</u> either to the conveyance via the venting or sampling hatches, or into the hoses prior to unloading without being detected. |

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Mitigation Strategies Practice - 3

Liquid Storage Tank

| Vulnerability Scenario | Mitigation Strategy | Explanation |
|---|---|---|
| The tank is accessible with an inward opening hatch. When the tank is full, the pressure of the liquid ingredient inside prevents the hatch from being opened, rendering the tank inaccessible. However, a <u>significant vulnerability exists when the tank is empty</u> —a person could open the hatch and add a contaminant. Normal facility practice is for a supervisor to conduct a <u>visual check of storage tanks after a cleaning cycle</u> to ensure the cleaning has been conducted as intended. <u>The tank is then accessible and empty for an extended period.</u> | <u>Inspect tank prior to use.</u> Immediately prior to reintroducing food, the tank will be visually inspected by the quality control manager using high intensity flashlights and ultraviolet lights to ensure that no contaminant has been added to the tank while it was open and accessible after cleaning. | The use of both high intensity flashlights and ultraviolet lights will enable the quality control manager to make a thorough inspection of the tank to <u>ensure no contamination occurred.</u> The hatch is wide enough to provide a clear view of both the walls and floor of the tank, enabling inspection of all surfaces of the tank interior. |

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Mitigation Strategies Practice – 4.a

Breeder

| Vulnerability Scenario | Mitigation Strategy | Explanation |
|--|---|---|
| A facility identifies a process step where a breeding coating is applied to food as an actionable process step. The facility concludes in its vulnerability assessment that the hopper that feeds the breeder at this step allows both <u>significant physical access</u> to the product as well as a sufficient likelihood that an <u>inside attacker could contaminate the food without detection.</u> | <u>Restrict access</u> to authorized personnel. The facility issues these employees special red caps and identifies their job function on their employee identification badges. Employees working at this step will immediately <u>escort out</u> of the area anyone <u>not authorized</u> to be in the area surrounding this step. | This mitigation strategy significantly <u>reduces the ability of an attacker to enter the area</u> to contaminate the food. |

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Mitigation Strategies Practice – 4.b

Breader

| Vulnerability Scenario | Mitigation Strategy | Explanation |
|---|--|---|
| A facility identifies a process step where a breading coating is applied to food as an actionable process step. The facility concludes in its vulnerability assessment that the hopper that feeds the breader at this step allows both <u>significant physical access</u> to the product as well as a sufficient likelihood that an <u>inside attacker could contaminate the food without detection</u> . | Workers authorized to work at the this step will have attained at least the position of <u>"Food Safety Technician Level 3"</u> with at least 4 years of employment and be in good standing with human resources with no pending or previous disciplinary actions. | Restricting this area to only Food Safety Technician Level 3 workers significantly <u>reduces the number of people who are authorized to be in the area</u> and significantly minimizes the vulnerability posed by an attacker, including an inside attacker. Food Safety Technician Level 3 workers in good standing and with more than 4 years of employment have <u>demonstrated their level of responsibility and trustworthiness to work in this highly vulnerable area and to restrict access to the area</u> . |

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Mitigation Strategies Breakout Room 1

Secondary Ingredient Addition

| Process Step | Mitigation Strategy | Explanation |
|---|--|--|
| Sealed bags of dry ingredients (e.g. sugar, spices, baking soda) are manually opened and dumped into the mixer. These activities are performed by the mixer operator. | Identify mitigation strategies for this process step | Explain why the mitigation strategies for this process step reduce the vulnerability |

2019, FDA, Revised Draft Guidance Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry.

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Mitigation Strategies Breakout Room 2

Rework

| Process Step | Mitigation Strategy | Explanation |
|---|---|---|
| <p>Trimnings from the former are taken by the mixer operator. Rework may be generated from the mixing operation or after forming. Rework is manually collected in clean and dry containers, which are labelled with the product name, relevant allergens, and date rework was generated. Rework product can be staged in containers with lids for up to 6 hours prior to addition to the mixer.</p> | <p>Identify mitigation strategies for this process step</p> | <p>Explain why the mitigation strategies for this process step reduce the vulnerability</p> |

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Mitigation Strategies Practice Sharing

Your Process

| Process Step | Mitigation Strategy | Explanation |
|--|---|---|
| <p>Explain your process step and its vulnerabilities</p> | <p>Identify mitigation strategies for this process step</p> | <p>Explain why the mitigation strategies for this process step reduce the vulnerability</p> |

2019, FDA, Revised Draft Guidance Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry.

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QUESTIONS?



FOOD DEFENSE PLAN ESSENTIALS

Intentional Adulteration Rule Training



Lesson 3 – 4

Management Components and Reanalysis



FOOD DEFENSE PLAN ESSENTIALS



Food Defense Plans: Management Components

1

Food Defense Monitoring

• Who, What, How, How Often

- Facility must have written procedures, including the frequency they are to be performed, for monitoring the mitigation strategies (as appropriate to the nature of the mitigation strategies)
- Must be documented in records subject to verification



2

Food Defense Corrective Actions

- **Identify and correct a problem**
- **Reduce likelihood of occurrence**

- Facility must have written procedures for steps to be taken when mitigation strategies are not properly implemented (as appropriate to the nature of the actionable process step and the nature of the mitigation strategy)
- Must be documented in records subject to verification



Food Defense Verification

- **Verification**
 - **of monitoring and corrective actions**
 - **that mitigation strategies are properly implemented**
- Includes (as appropriate to the nature of the mitigation strategy and its role in the facility's food defense system)
- Must be documented in records



Management Component Differences

Preventive Controls

- Process-based
 - Validation,
 - Calibration,
 - Product testing, and
 - Environmental monitoring

More objective

Intentional Adulteration

- More flexible
- Less resource intensive
- Aligned to mitigation strategy
 - Often verified by records review
 - Verification could occur via independent monitoring, visual observation, testing of process (e.g., testing alarms, peer observation, etc.)

More subjective

Management Components Practice - 1

Liquid ingredient storage tank

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

Management Components Practice – 2.a

Bulk liquid receiving

| Mitigation Strategy | Monitoring Procedure | Corrective Action | Verification Procedure | Records |
|---|---|---|---|--|
| Use tamper-evident seals on inbound shipping conveyances. Match the numbers on the seals with the numbers provided on the shipping documentation from the supplier. If the seals do not match, the load will be rejected. | Technician assesses whether the seal is intact and matches seal or documentation numbers upon arrival of the load before hooking up the hose for each delivery. | If seals do not match, are broken, or are missing, the load will be rejected. | Supervisor reviews receiving/delivery paperwork, and reviews corrective actions log (monthly) Review records to verify reanalysis every 3 years and when required by 21 CFR 121.157(b) | Receiving/delivery paperwork that includes additional information to indicate monitoring was completed Food defense corrective actions log Food defense verification log |

2020, FDA. Supplemental Draft Guidance Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry.

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Management Components Practice – 2.b

Bulk liquid receiving

| Mitigation Strategy | Monitoring Procedure | Corrective Action | Verification Procedure | Records |
|---|---|--|--|---|
| Use tamper-evident tape on hose ends after capping. | After daily operations, supply chain supervisor confirms that the hose caps are on and taped. | If caps are broken, replace caps. Clean and flush hose. If tape is ripped, reapply tape. Clean and flush hose. Retrain employee on capping and tape use. | Supervisor reviews monitoring and corrective actions logs (weekly) Review records to verify reanalysis every 3 years and when required by 21 CFR 121.157(b) | Food defense monitoring log Food defense corrective actions log Food defense verification log |

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Management Components Practice – 2.c

Bulk liquid receiving

| Mitigation Strategy | Monitoring Procedure | Corrective Action | Verification Procedure | Records |
|--|---|---|--|---|
| Use authorized personnel for visual observation of the unloading bay during the opening of the conveyance and the attachment of hoses and pumping equipment. | On a periodic basis, (but at least twice weekly), a manager observes whether personnel are visually observing the unloading bay during the opening of the conveyance and the attachment of hoses and pumping equipment. | Retrain employee on observation of the bay. | Senior manager reviews monitoring and corrective actions logs (weekly) Review records to verify reanalysis every 3 years and when required by 21 CFR 121.157(b) | Food defense monitoring log Food defense corrective actions log Food defense verification log |

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Management Components Practice - 3

Liquid storage tank

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

2020, FDA. Supplemental Draft Guidance Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry.

Management Components Practice – 4.a

Breader

| Mitigation Strategy | Monitoring Procedure | Corrective Action | Verification Procedure | Records |
|--|--|---|--|--|
| Restrict access to authorized personnel. The facility issues these employees special red caps and identifies their job function on their employee identification badges. Employees working at this step will immediately escort out of the area anyone not authorized to be in the area surrounding this step. | Employees assigned to this step constantly monitor the area and ensure that only authorized employees (i.e., those wearing special badges and red caps) are in the area. The employees in the area will notify security personnel if an unauthorized person is in the restricted area. The security personnel will use exception records to record when a deviation from the strategy is observed. | Escort unauthorized personnel from restricted area. Immediately retrain employees on identifying authorized personnel and escorting unauthorized personnel out of the area. If red cap or identification badge is missing, provide worker with replacement cap or badge for that day. | Once per month, and on an unannounced, irregular basis, a manager conducts a penetration audit, which consists of sending an employee, who is not wearing the cap or badge, into the area and observing whether the authorized employees adhere to mitigation strategy implementation responsibilities. The audit verifies food defense monitoring is being conducted because it provides the manager the opportunity to observe whether the employees are implementing the monitoring procedure. The audit verifies whether appropriate decisions about corrective actions were made because the manager can observe whether the unauthorized personnel are escorted from the area, and whether immediately retraining of employees occurred. The manager can also observe whether the red cap or identification badge was provided for the day. Review records to verify reanalysis every 3 years and when required by 21 CFR 121.157(b) | Food defense monitoring/ exception records log Food defense corrective actions log Food defense verification log |

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Management Components Practice – 4.b

Breader

| Mitigation Strategy | Monitoring Procedure | Corrective Action | Verification Procedure | Records |
|---|---|---|--|--|
| Workers authorized to work at the this step will have attained at least the position of "Food Safety Technician Level 3" with at least 4 years of employment and be in good standing with human resources with no pending or previous disciplinary actions. | Human resources will coordinate review of employment records once per year to assure authorized personnel continue to meet criteria for the area. Deviations will be recorded by exception records. | Reassignment of employees not meeting criteria for the area. Retraining of human resources and supervisory team for the area on appropriate worker criteria. | Review records to verify reanalysis every 3 years and when required by 21 CFR 121.157(b) | Food defense monitoring/ exception records log Food defense corrective actions log Food defense verification log |

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Management Components Room 1

Secondary Ingredient Addition (Page 13; process described on page 5)

| Mitigation Strategy | Monitoring Procedure | Corrective Action | Verification Procedure | Records |
|--|----------------------|-------------------|------------------------|---------|
| Using the mitigation strategies identified in the previous section, identify monitoring procedures, corrective actions, verification procedures, and records | | | | |

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Management Components Room 2

Rework (Page 14; process described on page 7)

| Mitigation Strategy | Monitoring Procedure | Corrective Action | Verification Procedure | Records |
|--|----------------------|-------------------|------------------------|---------|
| Using the mitigation strategies identified in the previous section, identify monitoring procedures, corrective actions, verification procedures, and records | | | | |

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Management Components Sharing

Your Process (Page 15)

| Mitigation Strategy | Monitoring Procedure | Corrective Action | Verification Procedure | Records |
|---|----------------------|-------------------|------------------------|---------|
| Using the mitigation strategies identified for your process, identify monitoring procedures, corrective actions, verification procedures, and records | | | | |

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Mitigation Strategies Management Components

| | |
|---------------------|--|
| MONITORING: | What, How, Who, and Frequency procedures to check that the mitigation strategy is operating as intended. Document at time of observation. Exception records allowed. |
| CORRECTIVE ACTIONS: | The response if monitoring shows that mitigations strategies are not properly implemented. Document. |
| VERIFICATION: | Ensure that monitoring is being conducted and appropriate decisions about corrective actions are being made. Document. |
| RECORD KEEPING: | Maintain records for food defense plan, vulnerability assessments, mitigation strategies, monitoring, corrective actions, and verification |

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Training

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21 CFR 121.4

Qualified individuals must do or oversee:

- Prepare the food defense plan
- Conduct a vulnerability assessment
- Identify and explain the mitigation strategies
- Reanalysis of the food defense plan

Each individual assigned to an actionable process step, and their supervisor, must:

- Receive food defense awareness training
- Receive training to properly implement the mitigation strategy(ies)

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Food Defense Plan Training

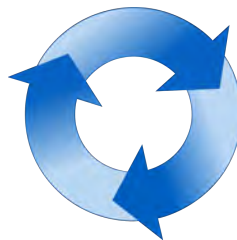
The IA Rule states that the required training and/or on-the-job experience may be met in a variety of ways as long as it provides the individual with knowledge at least equivalent to that received by the FDA standardized curriculum.



Visual Design by Bennett Graham, www.bennettgraham.com

Reanalysis

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21 CFR 121.157

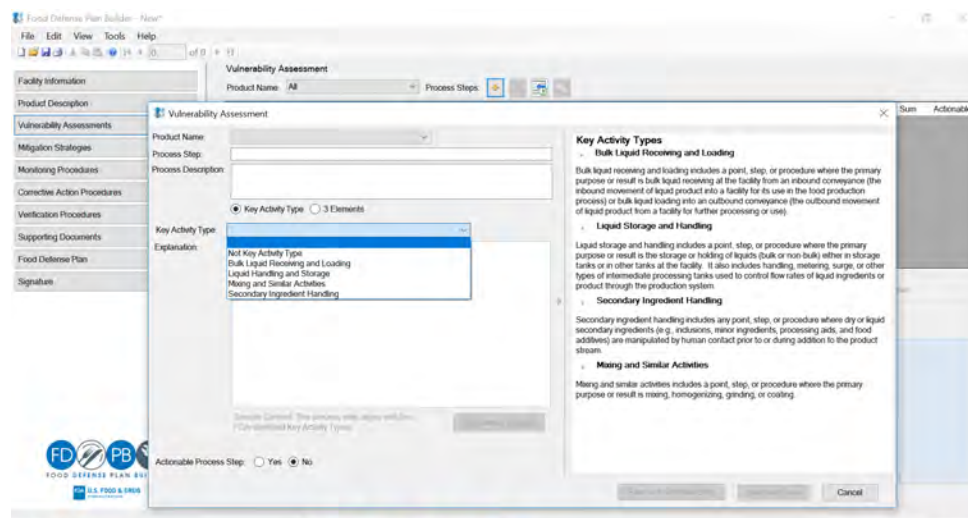
- At least every three years
- Changes affecting vulnerability
- Mitigation strategies ineffective
- New information about vulnerabilities
- Whenever FDA requires
 - new vulnerabilities, credible threats, or developments in scientific understanding

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Food Defense Plan Builder v2

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FDA Food Defense Plan Builder v2



Food Defense Plan Builder - New

File Edit View Tools Help

Facility Information Vulnerability Assessment

Product Name: All Process Steps

Product Description

Vulnerability Assessments

Mitigation Strategies

Monitoring Procedures

Corrective Action Procedures

Verification Procedures

Supporting Documents

Food Defense Plan

Signatures

Vulnerability Assessment

Product Name: [Dropdown]

Process Step: [Text Box]

Process Description: [Text Box]

Key Activity Type

Key Activity Type: [Dropdown]

Explanation:

Not Key Activity Type

Bulk Liquid Receiving and Loading

Liquid Handling and Storage

Mixing and Similar Activities

Secondary Ingredient Handling

Key Activity Types

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) or bulk liquid loading into an outbound conveyance (the outbound movement of liquid product from a facility for further processing or use).

Liquid Storage and Handling

Liquid storage and handling includes a point, step, or procedure where the primary purpose or result is the storage or holding of liquids (bulk or non-bulk) either in storage tanks or in other tanks at the facility. It also includes handling, mixing, surge, or other types of intermediate processing tanks used to control flow rates of liquid ingredients or product through the production system.

Secondary Ingredient Handling

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

Mixing and Similar Activities

Mixing and similar activities includes a point, step, or procedure where the primary purpose or result is mixing, homogenizing, grinding, or coating.

Save (Ctrl+S) The process will save with the... (Ctrl+Shift+S) Save Key Activity Types

Actonable Process Step: ☐ Yes ☒ No

Save Cancel

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File Edit View Tools Help

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Facility Information

Product Description

Process Step

Vulnerability Assessments

Mitigation Strategies

Monitoring Procedures

Corrective Action Procedures

Verification Procedures

Supporting Documents

Food Defense Plan

Signature

Element 1 Score

Element 1 Rationale

Explanation

Actionable Process Step

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FOOD DEFENSE PLAN BUILDER

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Element 1 Calculator

Product Name: Chocolate Chip cookies

Process Step:

☐ Volume of Food at Risk ☒ Representative Contaminant Approach

Qty Unit

Batch Size

Amount of Product (ingredient) in Final Serving

Servings per Batch

Mortality Rate: 50 %

Number of Deaths

Public Health Impact Score

Impact

| Score | Sum | Actionable |
|-------|-----|------------|
| 10 | | |
| 8 | | |
| 5 | | |
| 3 | 5 | |
| 1 | | |

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Vulnerability Assessment

Product/Process Name: All

Process Steps

| Product Names | # | Process Step | VA Method | Sum | Actionable |
|----------------|---|-----------------------------------|------------|-----|------------|
| 4 Cheese Sauce | 1 | Refrigerated dry storage (Cheese) | 3 Elements | 24 | |
| 4 Cheese Sauce | 2 | Cheese Graters | 3 Elements | | |
| Common | 1 | Bulk Dry Receiving | 3 Elements | | |
| Common | 2 | Bulk Dry Storage | 3 Elements | | |
| Common | 3 | Secondary Ingredient Storage | 3 Elements | | |

Details - Vulnerability Assessment

Product/Process Name: 4 Cheese Sauce

Process Step: Refrigerated dry storage (Cheese)

Key Activity Type: ☒ 3 Elements

Process Description:

Element 1 Score: 8 - Between 1001 and 10,000

Element 2 Score: 8 - Accessible

Element 3 Score: 8 - Moderately high Ease of Attack

Explanation:

Actionable Process Step: ☐

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Mitigation Strategies

Product Name: All

| Product Name | # | Actionable Process Steps | Mitigation Strategies |
|------------------------|---|-------------------------------|---|
| Chocolate Chip cookies | 2 | Mixing | <ul style="list-style-type: none"> a. Clean / sanitize locations periodically (e.g., immediately prior to use, after maintenance, when security devices are breached, following a suspect event) b. Conduct periodic checks of packaging integrity (e.g., upon receipt and prior to use) including for packaged products, ingredients, and equipment components c. Maximize visibility of operations, equipment, and locations (e.g., install windows, light adequately, keep area clear of visual obstructions) d. Restrict access to equipment and controls to authorized personnel |
| Peanut Butter Cookies | 1 | Mixing and Similar Activities | <ul style="list-style-type: none"> a. Clean / sanitize equipment and components periodically (e.g., immediately prior to use, after maintenance, when security devices are breached, following a suspect event) b. Clean / sanitize locations periodically (e.g., immediately prior to use, after maintenance, when security devices are breached, following a suspect event) c. Conduct periodic checks of packaging integrity (e.g., upon receipt and prior to use) including for packaged products, ingredients, and equipment components d. Maximize visibility of operations, equipment, and locations (e.g., install windows, light adequately, keep area clear of visual obstructions) |

Details

Product Name: Peanut Butter Cookies

Process Step: Mixing

Total Score

Mitigation Strategies

| # | Mitigation Strategy Description | Explanation | Edit |
|---|---|-------------|------|
| a | Clean / sanitize equipment and components periodically (e.g., immediately prior to use, after maintenance, when security devices are breached, following a suspect event) | | Edit |
| b | Clean / sanitize locations periodically (e.g., immediately prior to use, after maintenance, when security devices are breached, following a suspect event) | | Edit |
| c | Conduct periodic checks of packaging integrity (e.g., upon receipt and prior to use) including for packaged products, ingredients, and equipment components | | Edit |
| d | Maximize visibility of operations, equipment, and locations (e.g., install windows, light adequately, keep area clear of visual obstructions) | | Edit |

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File Edit View Tools Help

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Mitigation Database Search Results - Mixing

Lookup Tool

Category: Key Activity Types (KATs): Mixing and Similar Activities

Search

Search Engine Tool

Search Term: Mixing

Asstestest - When searching, use the asterisk as a wildcard. A wildcard is a substitute for zero or more characters.

Process

- Auger Tank
- Balance Tank
- Batter
- Blend Tank
- Blender
- Boiler
- Cooler
- Degreaser
- Drum Dryer
- Glaze
- Grinder
- Homogenizer
- In-Line Mixer
- Liquefier/Emulsifier
- Make-up Tank
- Mill
- Mixer
- Mixing Tank
- Processor
- Shredder
- Spin Dryer

Category

Total Score

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Food Defense Plan Builder v2

The screenshot displays the 'Food Defense Plan Builder - Spicy Sauce Company' interface. The 'Vulnerability Assessment' section is active, showing a table of process steps and their associated vulnerabilities. A 'Details: Vulnerability Assessment' window is open, showing 'Process Description' and 'Element 1 Score'. A 'Mitigation Strategies' list is also visible, detailing various security measures. The 'Total Score' is shown on the right side of the interface.

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FDA Food Defense Plan Builder v2

The screenshot displays the 'FDA Food Defense Plan Builder - Spicy Sauce Company' interface. The 'Mitigation Strategies' section is active, showing a table of strategies and their descriptions. A 'Total Score' is displayed on the right side of the interface.

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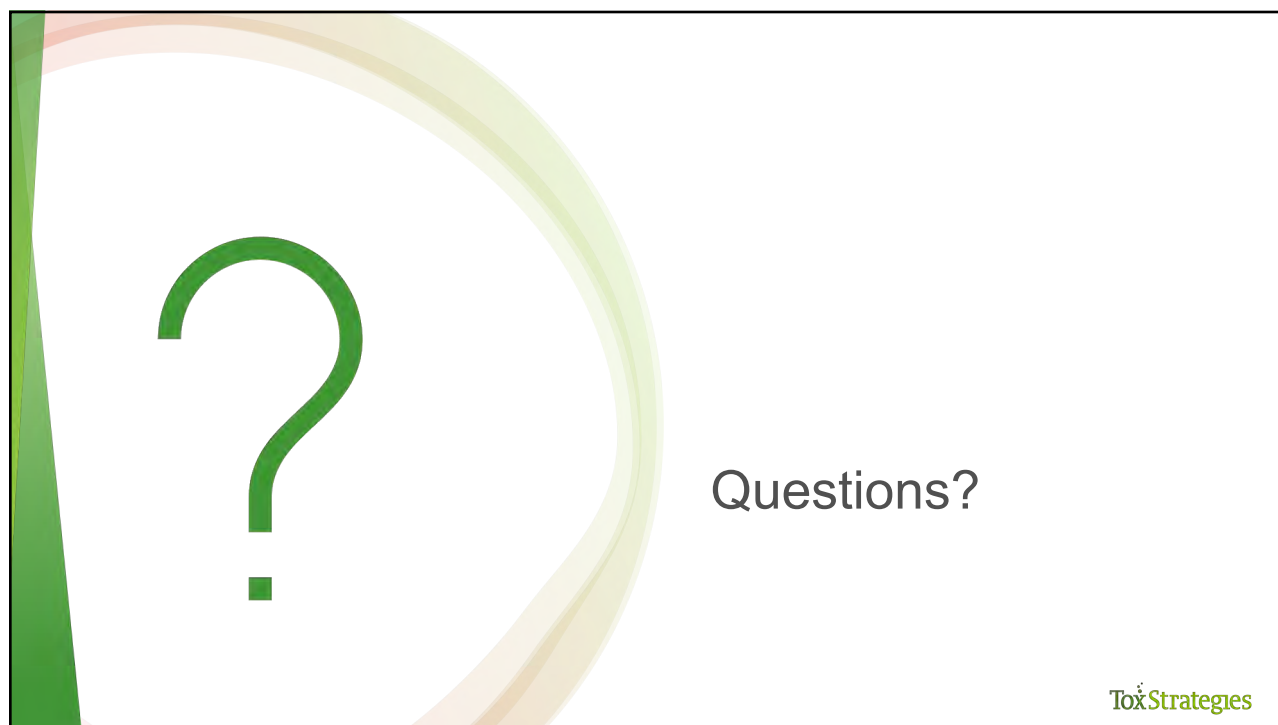
Quick Check

- Please complete our Knowledge Check poll
- For the training forum, chat us what worked well and where we could improve your experience



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FOOD DEFENSE PLAN ESSENTIALS

Intentional Adulteration Rule Training



Thank you for choosing us as
your instruction team and
please let us know how we
can assist you in the future

jvandeligt@toxstrategies.com