FOOD DEFENSE PLAN ESSENTIALS
Intentional Adulteration Rule Training

Participant Manual

FDPI Materials

FOOD DEFENSE PLAN ESSENTIALS
Intentional Adulteration Rule Training

Brought to you by

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

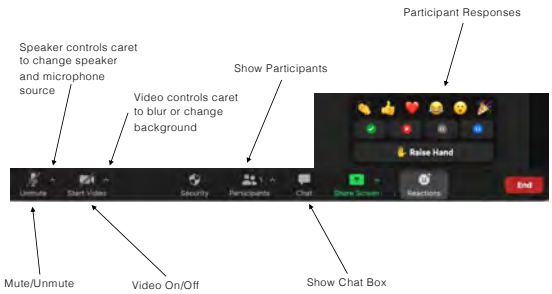
FOOD DEFENSE PLAN ESSENTIALS
Intentional Adulteration Rule Training

November 29 – December 1, 2022

Lead Instructor	Assistant Instructor
Jennifer van de Ligt, PhD Senior Consultant ToxStrategies	Deb Freedman, PhD Director Food Protection and Defense Institute A Homeland Security Center of Excellence

1

Zoom Features



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2

As we get started

In the Chat 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

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Preface: Course Introduction

CONDUCTING VULNERABILITY ASSESSMENTS

5

Welcome to the Intentional Adulteration *Conducting Vulnerability Assessments* Course!

6

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

7

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

8

Disclosure

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;

c) The FSPCA cannot provide legal advice;

d) 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;

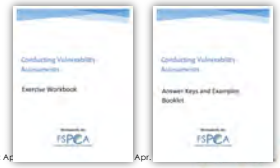
e) Following the FSPCA curriculum does not ensure compliance with FDA's regulations or any other law or legal requirement; and

f) 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

9

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

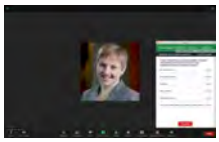
Appendix	Name	Page #
1	IA Rule and Summary	A1-1
2	FDA Key Activity Types (KAT) Report and KAT Descriptions	A2-1
3	Vulnerability Assessment Resources	A3-1
4	Technical Assistance and Resources	A4-1
5	VA Definitions, Acronyms, and Other Terms	A5-1

11

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	• 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	• Any stakeholder interested in learning more about the IA rule requirements • This course is not associated with any IA rule training requirement

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

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13

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	• Food professionals conducting VAs using the KAT Method **ONLY**
Conducting Vulnerability Assessments[2, 3]	Instructor-Led Training	• Food professionals conducting VAs using the 3 fundamental elements approach
Identification and Explanation of Mitigation Strategies[2]	Online Training	• Food professionals identifying mitigation strategies to implement at actionable process steps
Food Defense Plan Preparation and Reanalysis[2]	Online Training	• Food professionals preparing the Food Defense Plan (FDP) and conducting reanalysis activities

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

14

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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15

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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16

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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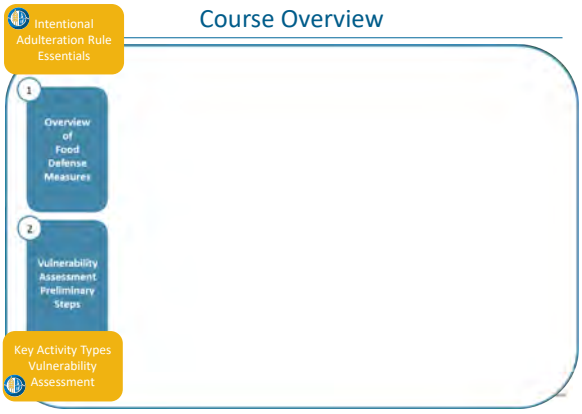
17

17

Course Overview



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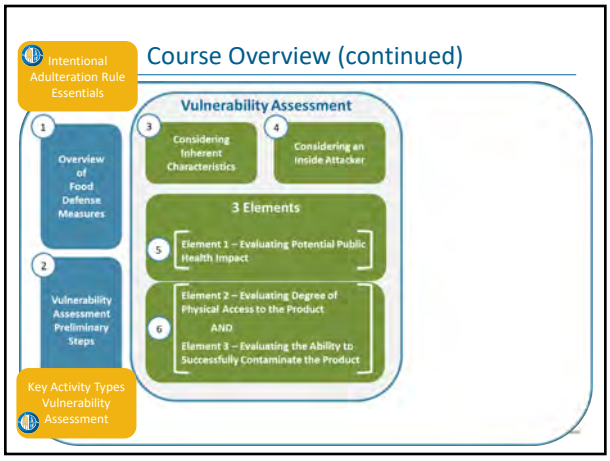

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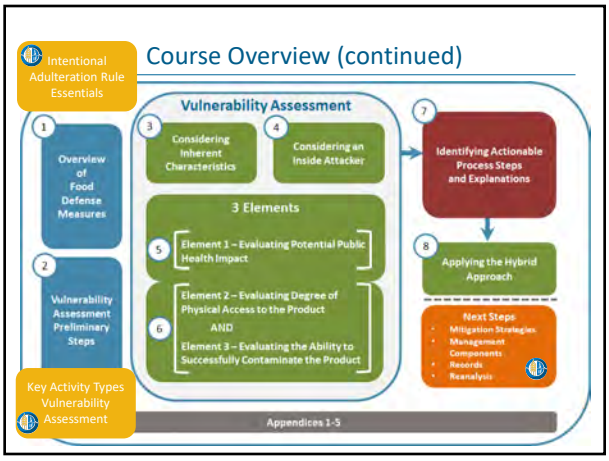

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FSPCA Contact Information

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

21

22

Course Agenda

AM	Welcome, Introductions, and Sign-In
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

23

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

24

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

3

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

4

FOOD PROTECTION

Food Safety
Unintentional Adulteration

VS

Food Defense
Intentional Adulteration

5

Intelligent Adversary

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

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Food Defense Threat Triangle

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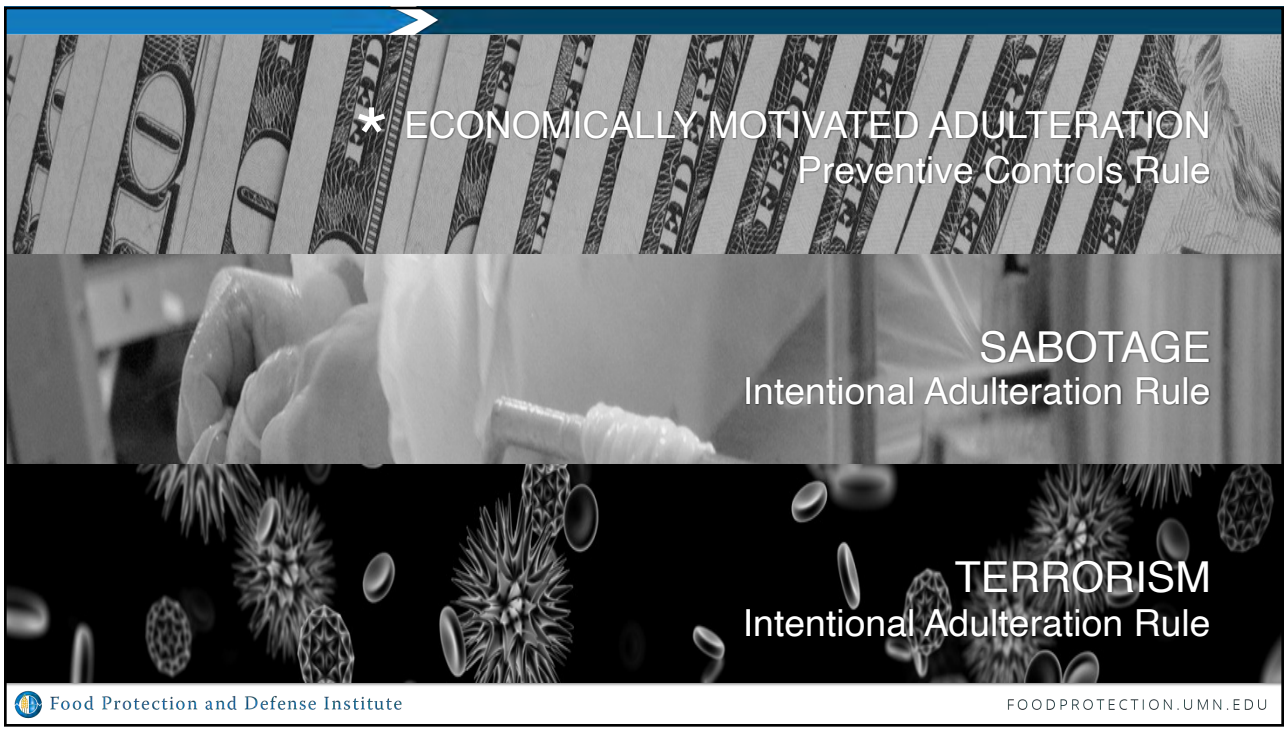

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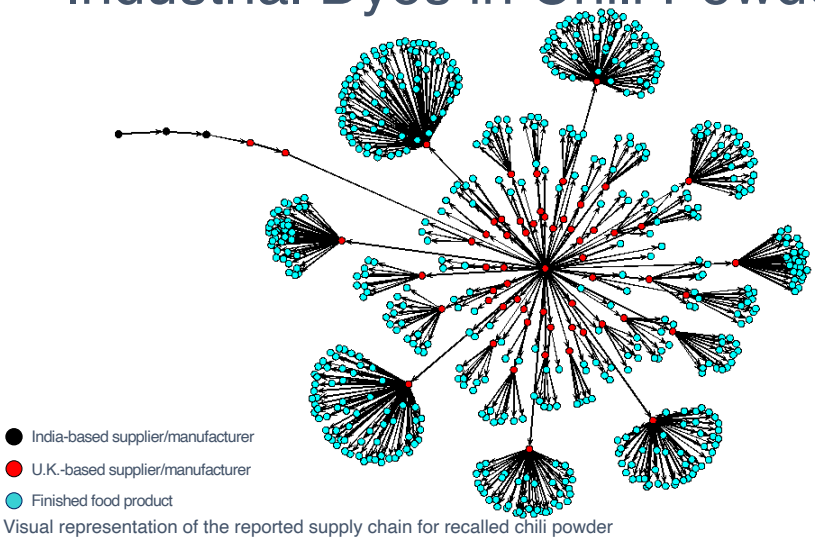
Industrial Dyes in Chili Powder



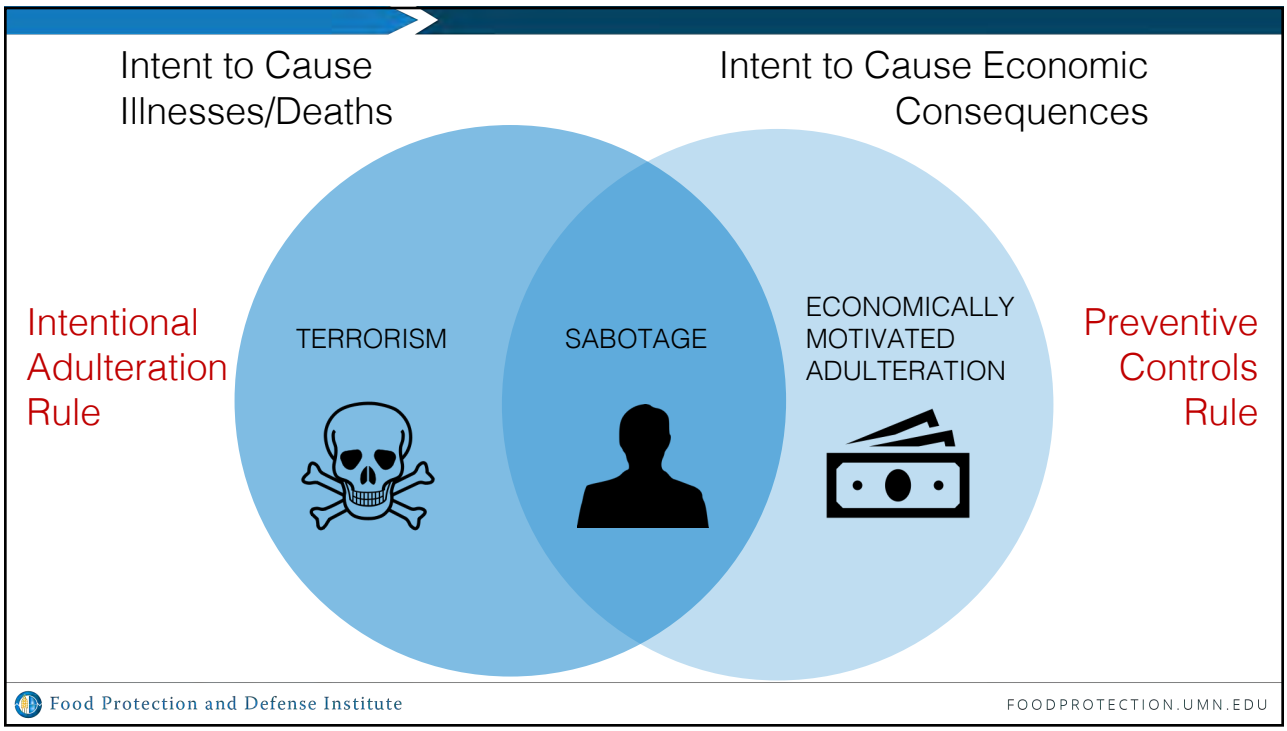
Visual representation of the reported supply chain for recalled chili powder

Sources: Food Standards Agency of the U.K., National Archives, and The Guardian

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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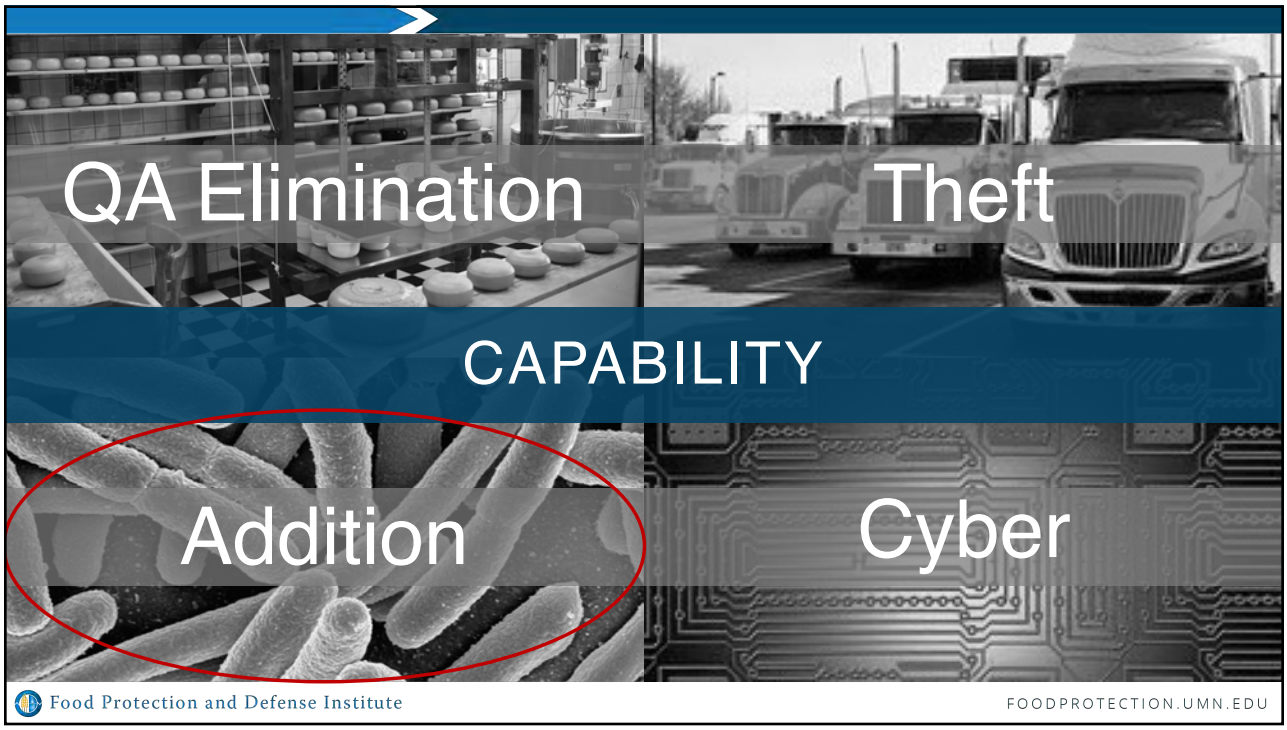

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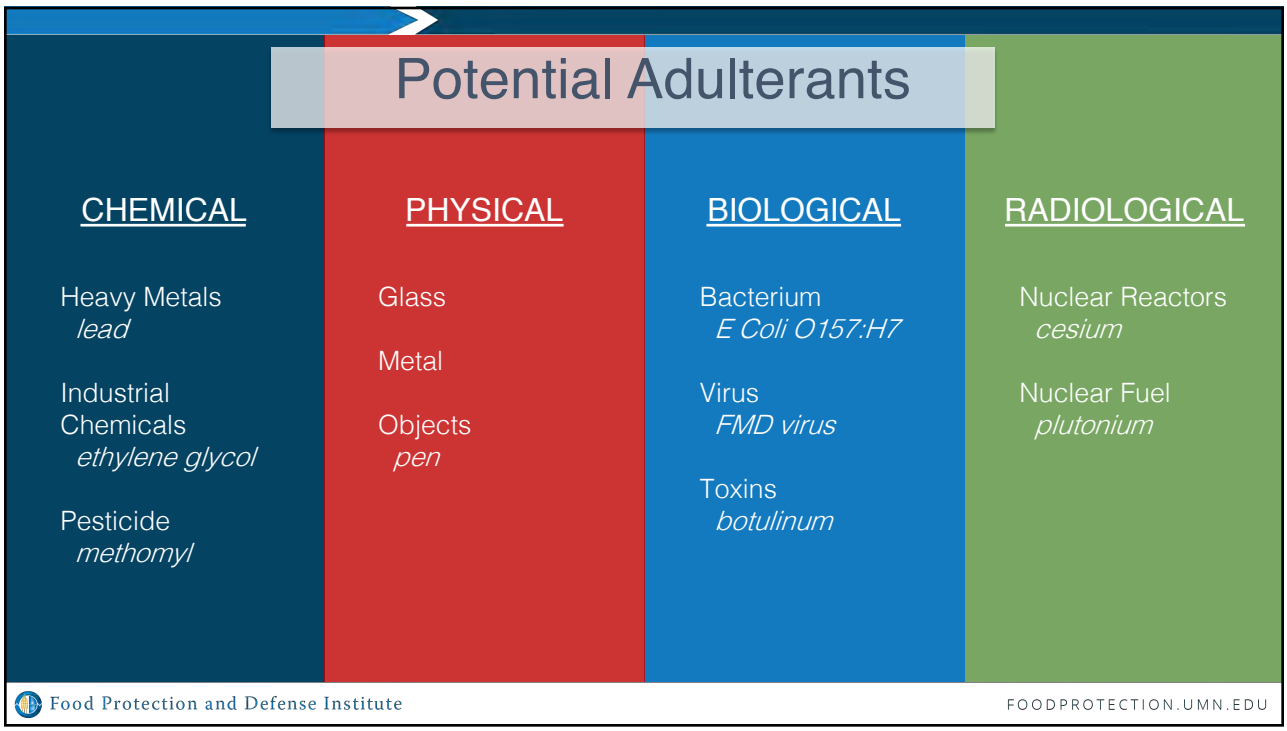

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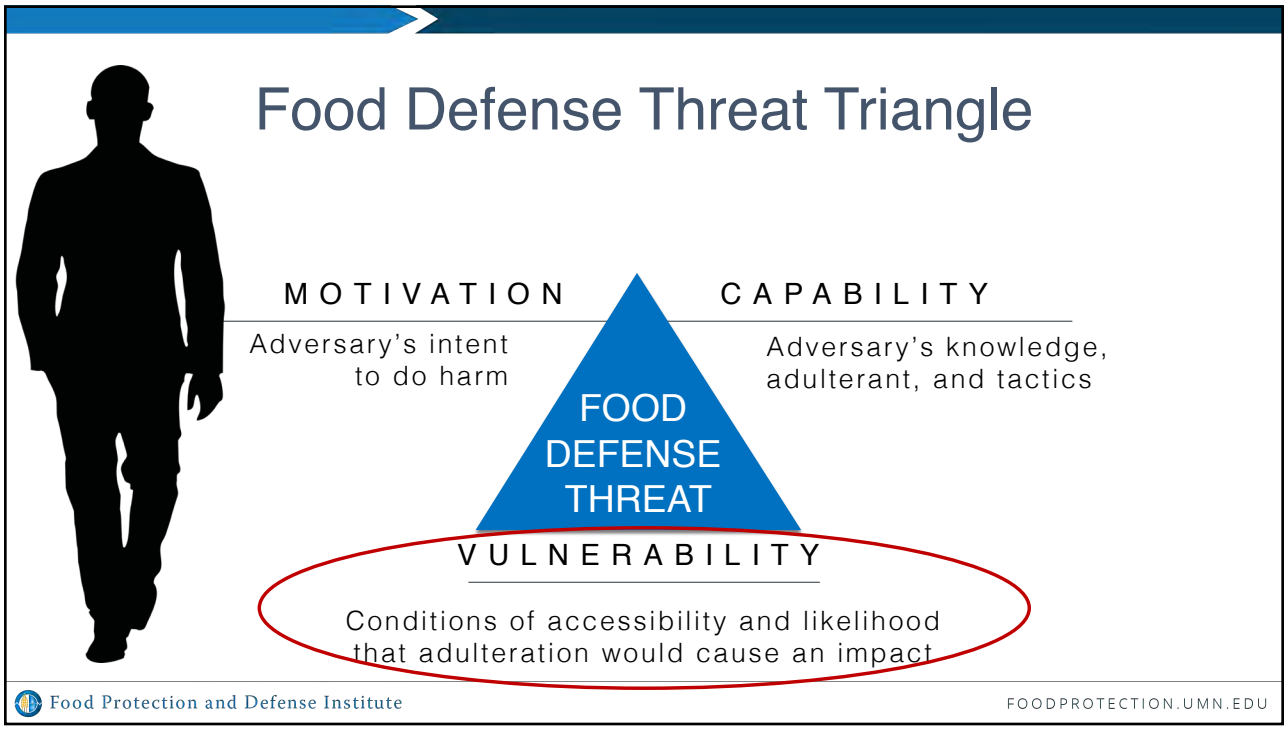

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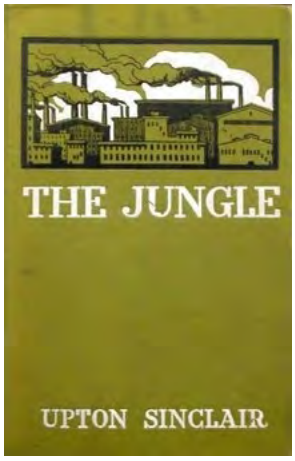
The Jungle



1906

Portrays egregious working conditions in meat packing facilities

Meat Inspection Act

Pure Food and Drug Act

Food Safety Modernization Act

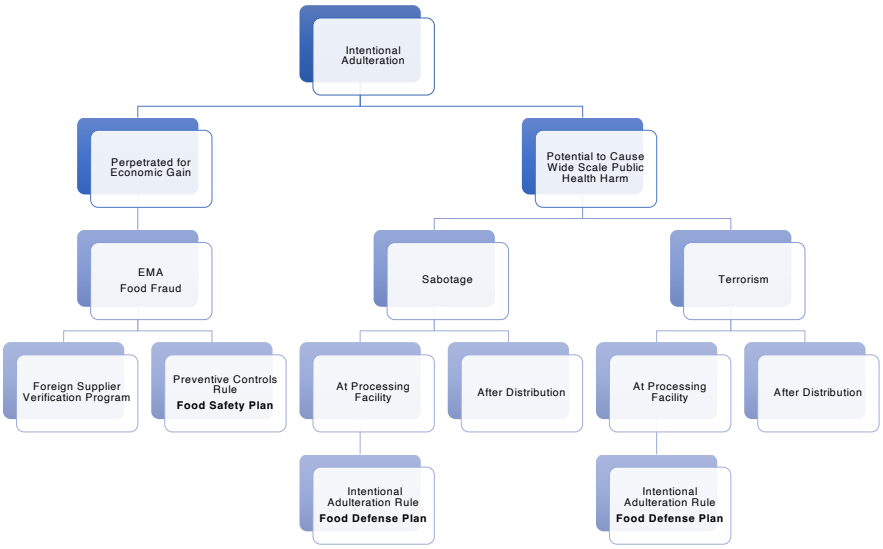
- Passed in 2011
- Most sweeping reform of food safety laws in more than 70 years
- Aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it

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**

21

Intentional Adulteration Decision Tree



22

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

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

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

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Lesson 1 – 4

Preliminary Steps

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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

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

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

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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

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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

☐ This point, step, or procedure fits within the following Key Activity Types (Select all that apply)	☐ This point, step, or procedure does **not** fit within any of the Key Activity Types (Proceed to Step 4: Actionable Process Step Determination)
☐ Bulk Liquid Receiving and Loading	
☐ Liquid Storage and Handling	
☐ Secondary Ingredient Handling	
☐ Mixing and Similar Activities	

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.

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.

Step 1: Key Activity Types Method

☐ This point, step, or procedure fits within the following Key Activity Types (Select all that apply)	☐ This point, step, or procedure does **not** fit within any of the Key Activity Types (Proceed to Step 4: Actionable Process Step Determination)
☐ Bulk Liquid Receiving and Loading	
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☐ Secondary Ingredient Handling	
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2019. FDA. Revised Draft Guidance Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry.

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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.

Step 1: Key Activity Types Method

☐ This point, step, or procedure fits within the following Key Activity Types (Select all that apply)	☐ This point, step, or procedure does **not** fit within any of the Key Activity Types (Proceed to Step 4: Actionable Process Step Determination)
☐ Bulk Liquid Receiving and Loading	
☐ Liquid Storage and Handling	
☐ Secondary Ingredient Handling	
☐ Mixing and Similar Activities	

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

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)	☐ This point, step, or procedure does **not** fit within any of the Key Activity Types (Proceed to Step 4: Actionable Process Step Determination)
☐ Bulk Liquid Receiving and Loading	
☐ Liquid Storage and Handling	
☐ Secondary Ingredient Handling	
☐ Mixing and Similar Activities	

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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11

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)	☐ This point, step, or procedure does **not** fit within any of the Key Activity Types (Proceed to Step 4: Actionable Process Step Determination)
☐ Bulk Liquid Receiving and Loading	
☐ Liquid Storage and Handling	
☐ Secondary Ingredient Handling	
☐ Mixing and Similar Activities	

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.

Step 1: Key Activity Types Method

☐ This point, step, or procedure fits within the following Key Activity Types (Select all that apply)	☐ This point, step, or procedure does **not** fit within any of the Key Activity Types (Proceed to Step 4: Actionable Process Step Determination)
☐ Bulk Liquid Receiving and Loading	
☐ Liquid Storage and Handling	
☐ Secondary Ingredient Handling	
☐ Mixing and Similar Activities	

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.

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.

Step 1: Key Activity Types Method

☐ This point, step, or procedure fits within the following Key Activity Types (Select all that apply)	☐ This point, step, or procedure does **not** fit within any of the Key Activity Types (Proceed to Step 4: Actionable Process Step Determination)
☐ Bulk Liquid Receiving and Loading	
☐ Liquid Storage and Handling	
☐ Secondary Ingredient Handling	
☐ Mixing and Similar Activities	

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.

Key Activity Type Practice

Forming

Once mixed, the mixture is emptied onto a conveyer, 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 conveyer as it moves through the former. Line capacity of the conveyer 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)	☐ This point, step, or procedure does **not** fit within any of the Key Activity Types (Proceed to Step 4: Actionable Process Step Determination)
☐ Bulk Liquid Receiving and Loading	
☐ Liquid Storage and Handling	
☐ Secondary Ingredient Handling	
☐ Mixing and Similar Activities	

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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15

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)	☐ This point, step, or procedure does **not** fit within any of the Key Activity Types (Proceed to Step 4: Actionable Process Step Determination)
☐ Bulk Liquid Receiving and Loading	
☐ Liquid Storage and Handling	
☐ Secondary Ingredient Handling	
☐ Mixing and Similar Activities	

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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16

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.

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

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

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

FOOD DEFENSE PLAN ESSENTIALS
Intentional Adulteration Rule Training

Day 2 – 2

Inside Attacker

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

FOOD DEFENSE PLAN ESSENTIALS
Intentional Adulteration Rule Training

Day 2 – 3

IAVA Element 1

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

FOOD DEFENSE PLAN ESSENTIALS
Intentional Adulteration Rule Training

Day 2 – 4

IAVA Element 2 & 3

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

FOOD DEFENSE PLAN ESSENTIALS
Intentional Adulteration Rule Training

Day 3 – 1

Analyzing Results

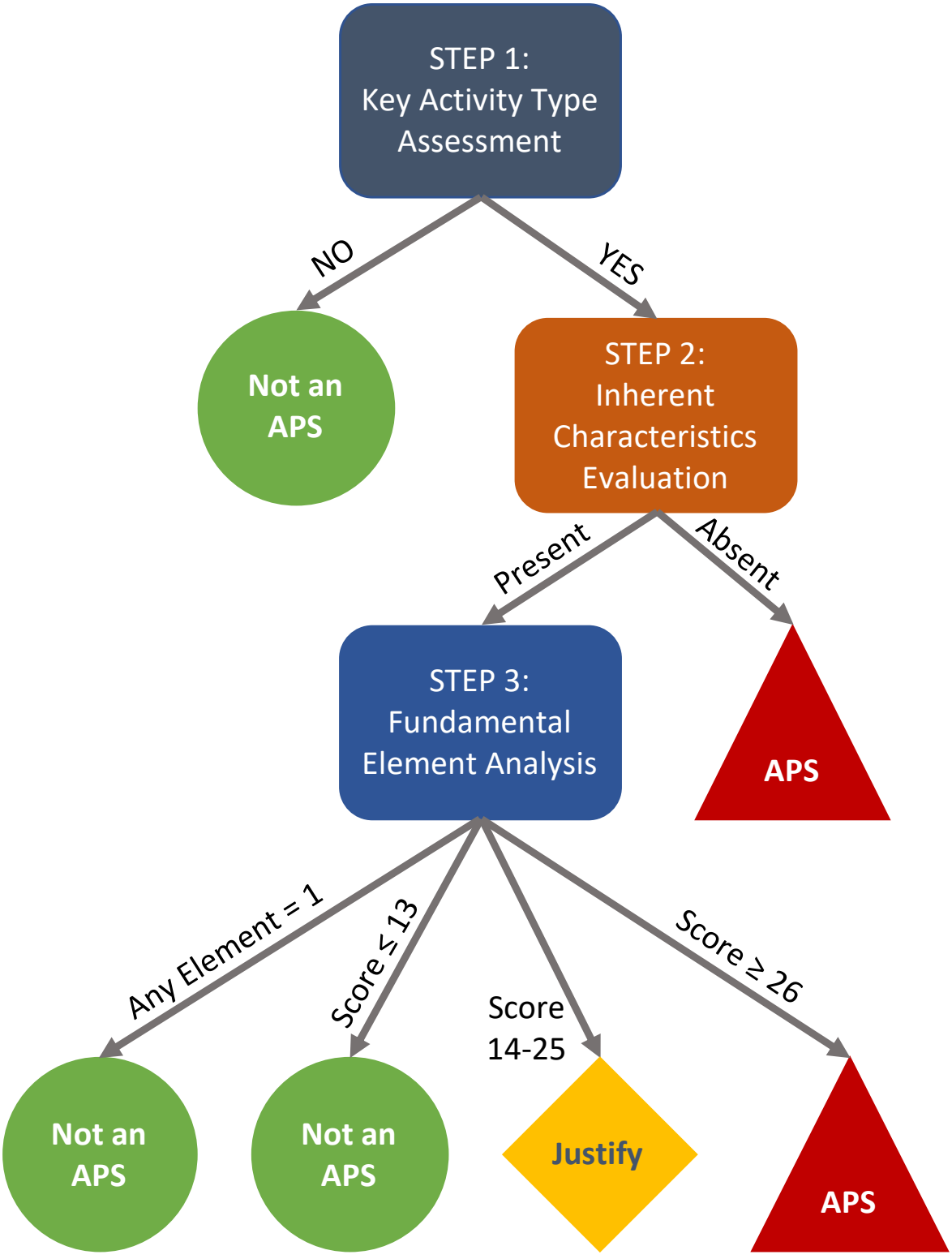
FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

FOOD DEFENSE PLAN ESSENTIALS
Intentional Adulteration Rule Training

Day 3 – 2

Hybrid Method

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE



FOOD DEFENSE PLAN ESSENTIALS
Intentional Adulteration Rule Training

Lesson 3 – 3

Mitigation Strategies

FOOD DEFENSE PLAN ESSENTIALS

Food Defense Plans: Mitigation Strategies

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1

OVERARCHING STRATEGIES

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2

OUTSIDE SECURITY

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

INSIDE SECURITY

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

PEOPLE

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

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5

LOGISTICS, PRODUCTION, STORAGE

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

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6

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)

8

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).

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

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 ... ments
- Pr... of 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		

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

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.

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

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

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.
Reduci Inside Contan		

- 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.

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	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.	

- Peer monitoring
- Altering existing inspection
- Increasing ease of observation

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

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 alarm • Sensors • Observing CCTV	
Reducing the Ability of an Inside Attacker to Contaminate the Product ↓ Success		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.

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.

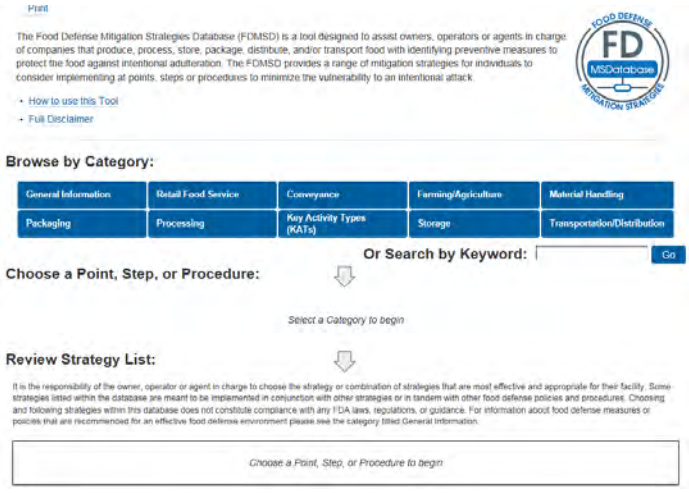
MITIGATION STRATEGIES

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 est… authorized to be… actionable pro… individuals fro… required …	Technology-assisted mitigation strategies generally rely on the … …ysical access …ation of …r detection …nt access …erate the …
Reducing the Ability of an Inside Attacker to Contaminate the Product ↓ Success	Personnel… mitigation… ability of an in… adulterate a produ… strategies that increase observatio… a significantly vulnerable area such that an attacker's actions would be easily detected.	…ility of an …duce a …oduct typically …at would detect an …s actions, alert management of …blem, 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.

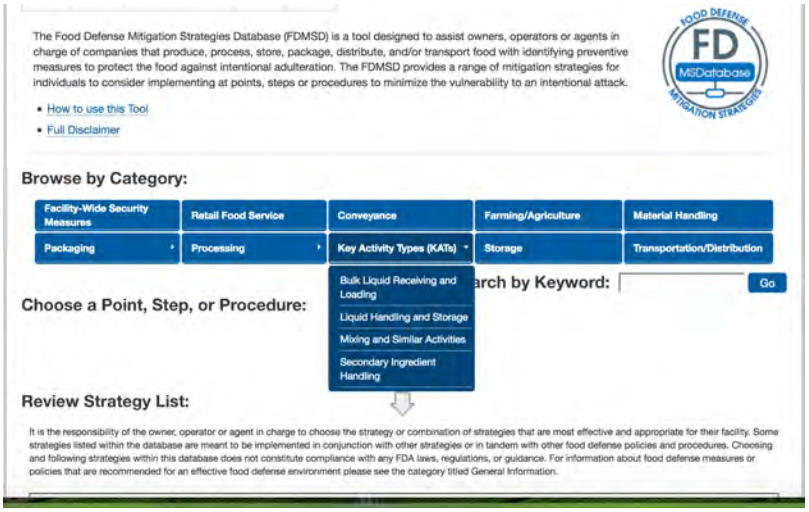
Multiple lower cost mitigation strategies may be as effective as a single more expensive mitigation strategy

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

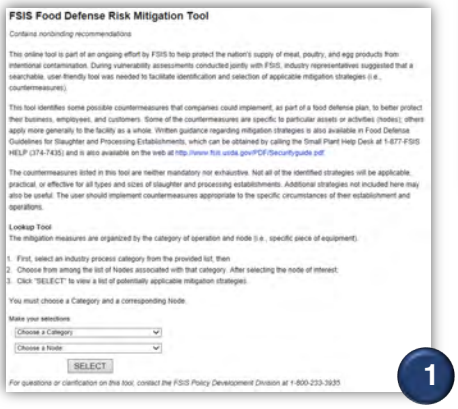
FDA Mitigation Strategies Database



FDA Mitigation Strategies Database



FSIS Risk Mitigation Tool



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

27

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

28

Mitigation Strategies Practice - 1

Liquid ingredient storage tank

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

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

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 several factors 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 tamper-evident seals on inbound shipping conveyances. Match the numbers on the seals with the numbers provided on the shipping documentation from the supplier. If the seals do not match, the load will be rejected to prevent potentially adulterated ingredient from entering the facility.	Using numbered wire or plastic seals to secure hatches, ports, and other access points to the transport conveyance significantly reduces the ability of an attacker to successfully contaminate the product without being detected. Tamper-evident seals will indicate if the product has been interfered with during transport.

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

Mitigation Strategies Practice – 2.b

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 several factors 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 tamper-evident tape on hose ends after capping.	Using tamper-evident tape to seal the hose caps when not in use limits the ability of an attacker to successfully contaminate the product without being detected.

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

31

Mitigation Strategies Practice – 2.c

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 several factors 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 authorized personnel for visual observation of the unloading bay during the opening of the conveyance and the attachment of hoses and pumping equipment.	Having the employee responsible for reviewing shipping documentation visually observe the opening of venting and sampling hatches as well as the hooking up of hoses and pumping equipment significantly reduces the ability of an attacker to introduce a contaminant either to the conveyance via the venting or sampling hatches, or into the hoses prior to unloading without being detected.

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

32

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 significant vulnerability exists when the tank is empty–a person could open the hatch and add a contaminant. Normal facility practice is for a supervisor to conduct a visual check of storage tanks after a cleaning cycle to ensure the cleaning has been conducted as intended. The tank is then accessible and empty for an extended period.	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.	The use of both high intensity flashlights and ultraviolet lights will enable the quality control manager to make a thorough inspection of the tank to ensure no contamination occurred. The hatch is wide enough to provide a clear view of both the walls and floor of the tank, enabling inspection of all surfaces of the tank interior.

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

Mitigation Strategies Practice – 4.a

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 significant physical access to the product as well as a sufficient likelihood that an inside attacker could contaminate the food without detection.	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.	This mitigation strategy significantly reduces the ability of an attacker to enter the area to contaminate the food.

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

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 significant physical access to the product as well as a sufficient likelihood that an inside attacker could contaminate the food without detection.	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.	Restricting this area to only Food Safety Technician Level 3 workers significantly reduces the number of people who are authorized to be in the area and significantly minimizes the vulnerability posed by an attacker, including an inside attacker. Food Safety Technician Level 3 workers in good standing and with more than 4 years of employment have demonstrated their level of responsibility and trustworthiness to work in this highly vulnerable area and to restrict access to the area.

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

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.

Mitigation Strategies Breakout Room 2

Rework

Process Step	Mitigation Strategy	Explanation
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.	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.

Mitigation Strategies Practice Sharing

Your Process

Process Step	Mitigation Strategy	Explanation
Explain your process step and its vulnerabilities	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.

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

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

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.	If lock is not locked, properly engage lock, and retrain employee on proper lock use. If lock is broken, replace lock.	QA technician reviews tank observation records to verify monitoring (weekly), and reviews correction action log (weekly) Review records to verify reanalysis every 3 years and when required by 21 CFR 121.157(b)	Liquid storage tank observations record Corrective actions log Food defense verification log

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

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.

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

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

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

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

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

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

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

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

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				

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

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				

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

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				

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

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

Training

17

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)

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

18

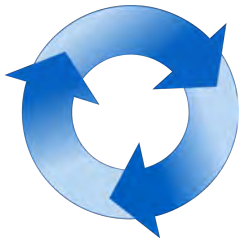
Food Defense Plan Training

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

21



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

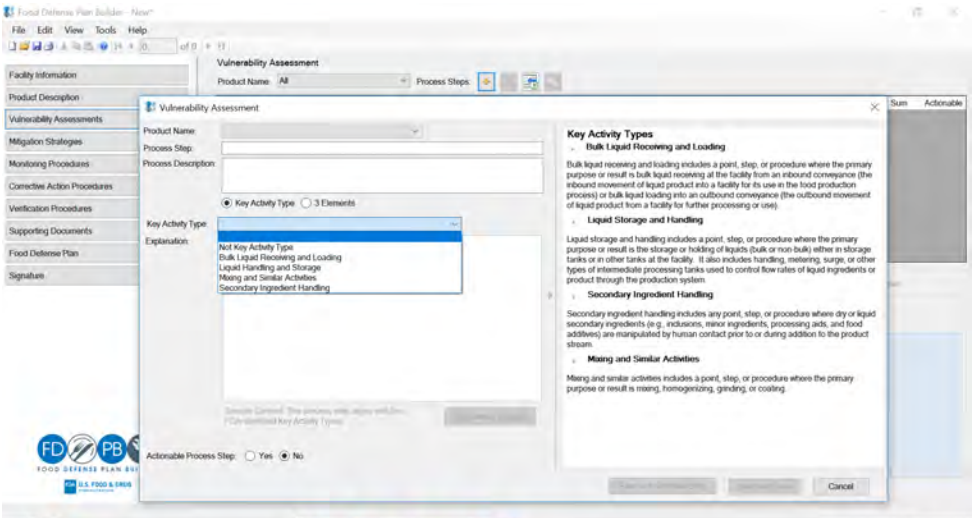
2018. FDA. Draft Guidance Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry.

22

Food Defense Plan Builder v2

23

FDA Food Defense Plan Builder v2



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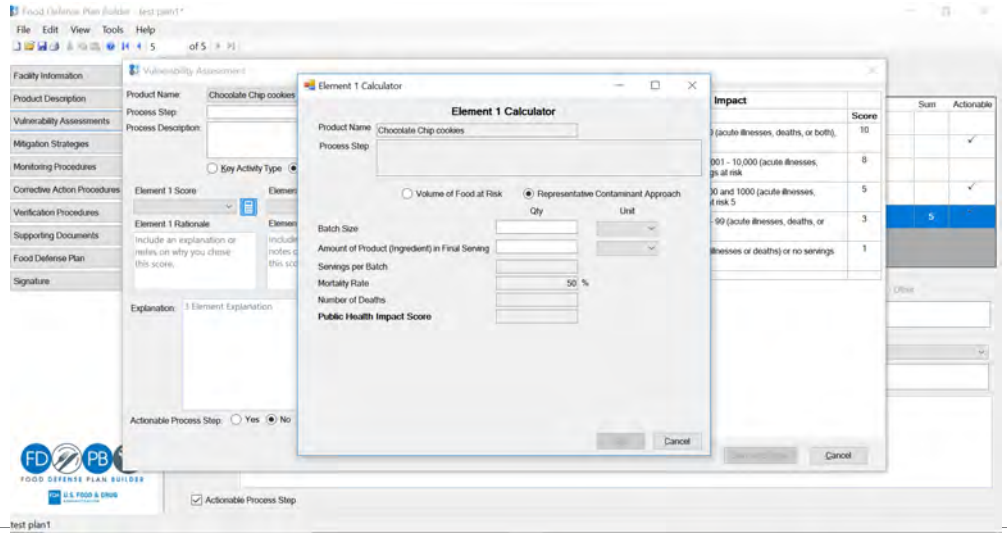
FDA Food Defense Plan Builder v2



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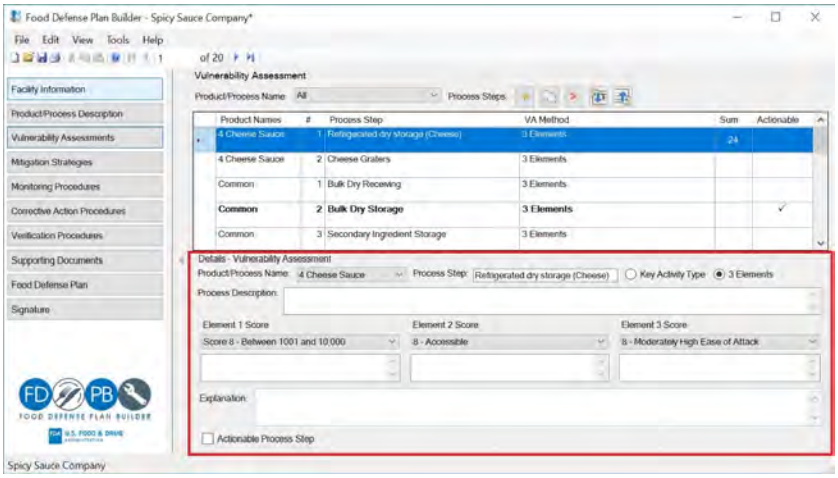

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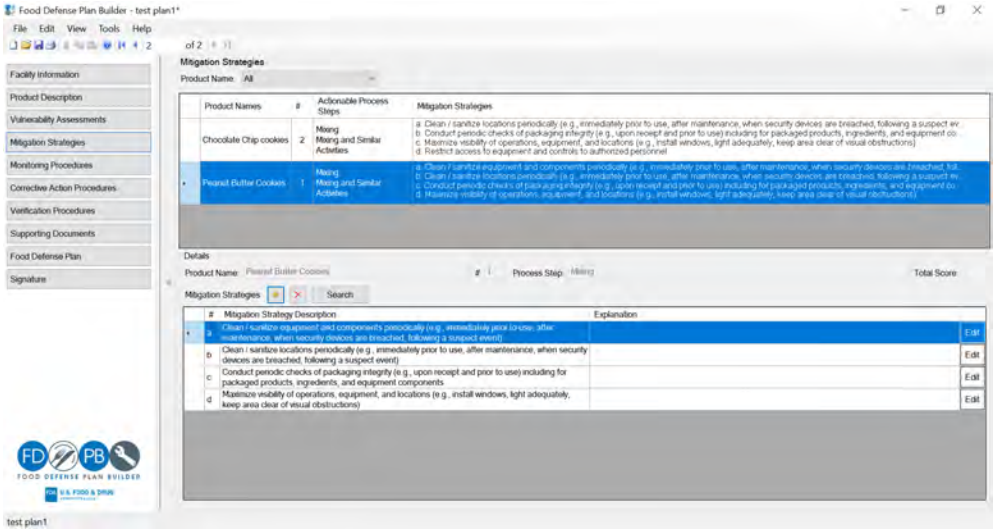
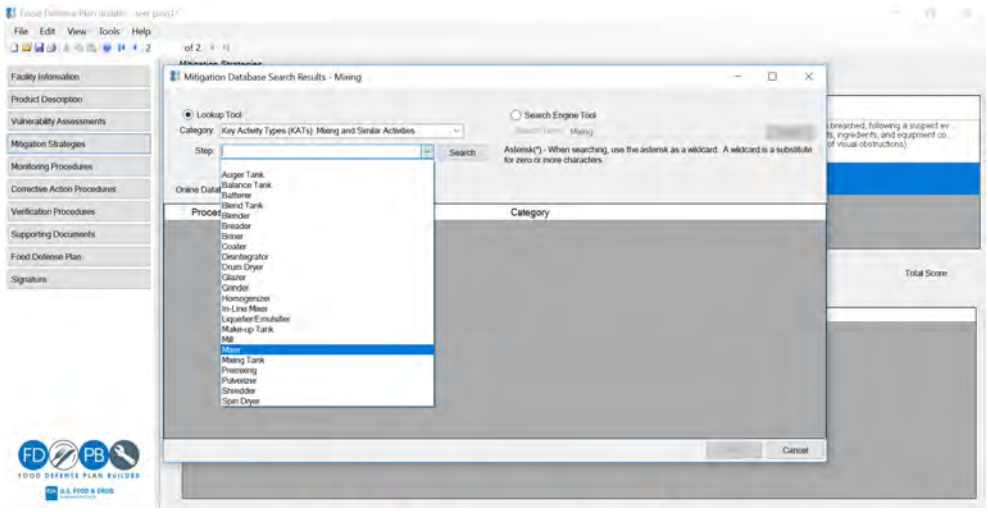
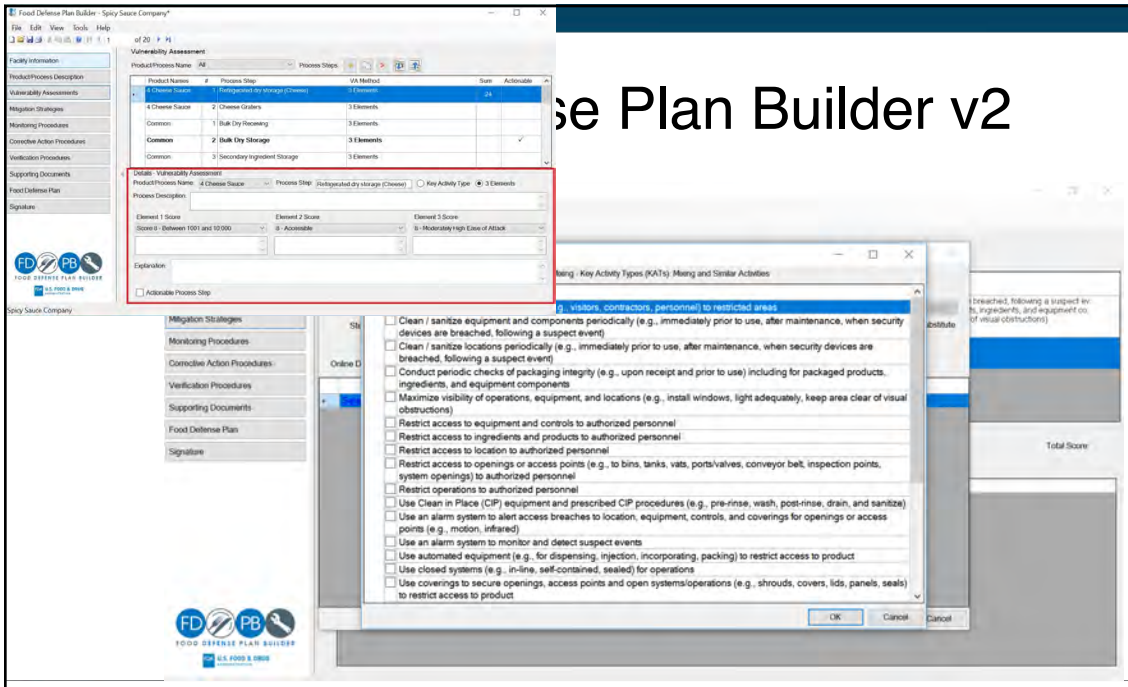


FDA Food Defense Plan Builder v2





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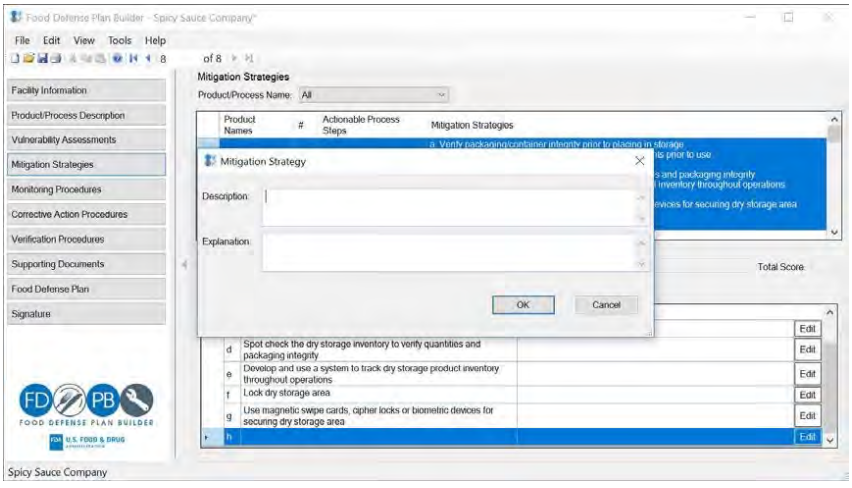

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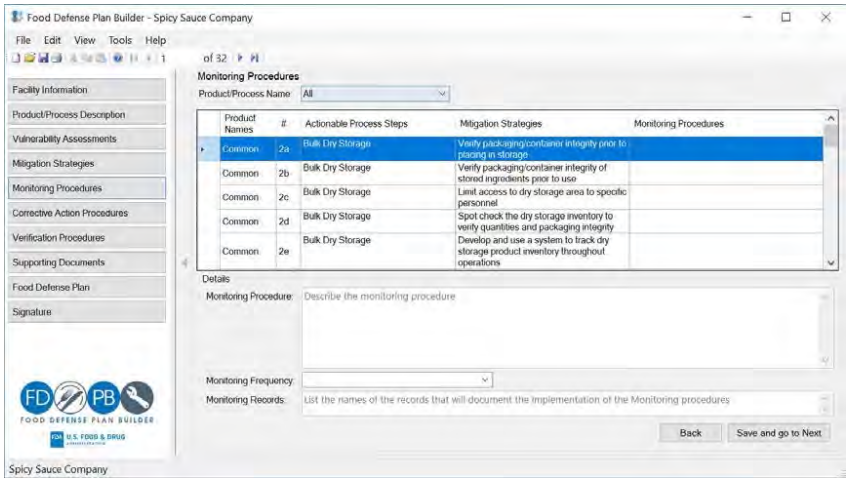


31

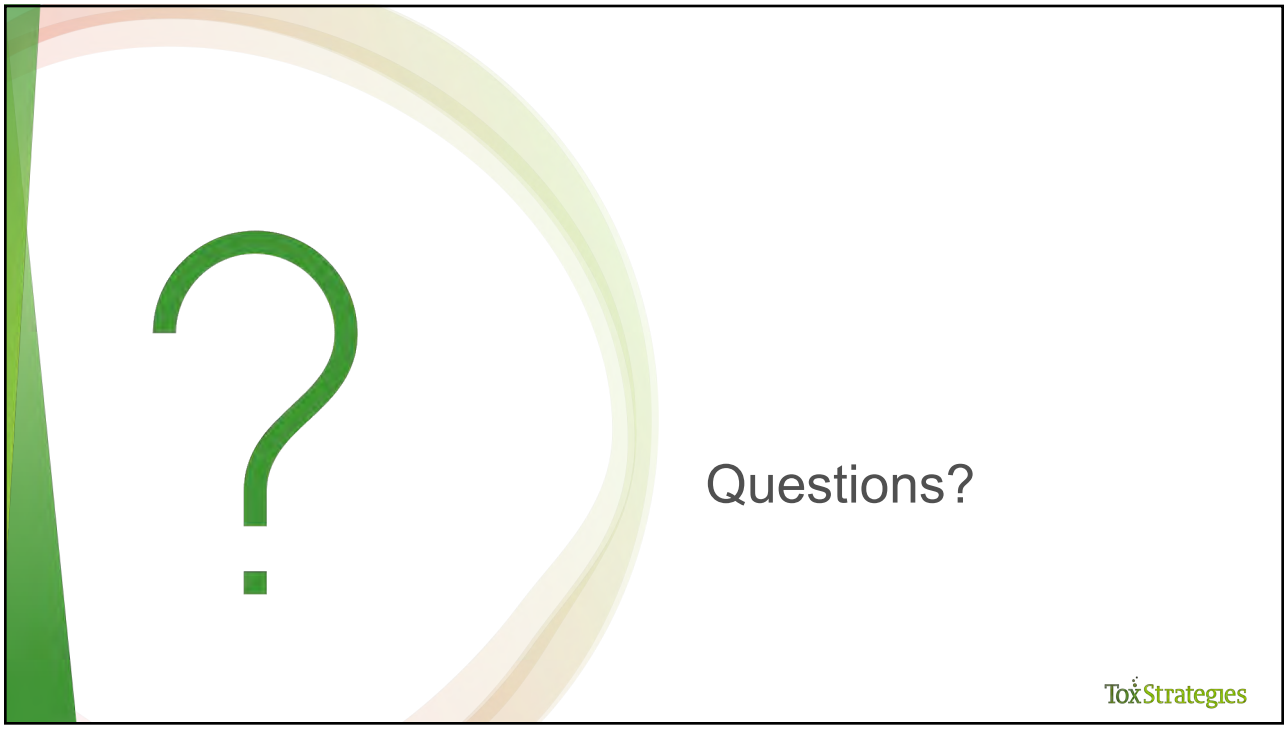
Quick Check

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

32

ToxStrategies

32



33

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

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