FOOD DEFENSE PLAN ESSENTIALS
Intentional Adulteration Rule Training

Food Defense Plan Exercise

Food Protection and Defense Institute
A Homeland Security Center of Excellence

FOOD DEFENSE PLAN TRAINING EXERCISE[1]

Background

The Food and Drug Administration (FDA) published the Food Safety Modernization Act (FSMA) final rule "Mitigation Strategies to Protect Food Against Intentional Adulteration" (IA Rule) in May 2016. The IA Rule "applies to the owner, operator, or agent in charge of a domestic or foreign food facility that manufactures/processes, packs, or holds food for consumption in the United States and is required to register under Section 415 of the Federal Food, Drug, and Cosmetic Act," unless an exemption applies.[2] The IA Rule is focused on addressing intentional adulteration in the context of a potential inside attacker. The IA rule requires food manufacturing facilities to have a written food defense plan that incorporates a vulnerability assessment, includes mitigation strategies, and delineates food defense monitoring, corrective actions, and verification procedures to be followed (21 CFR 121.126).

[1] The FPDI Food Defense Plan Training Exercise is an assessment tool developed by the Regents of the University of Minnesota on behalf of its Food Protection and Defense Institute (FPDI), a Department of Homeland Security Science & Technology Emeritus Center of Excellence. The FDPI Food Defense Plan Training Exercise is intended to assist food facilities in understanding how to prepare a food defense plan including vulnerability assessment and identification and explanation of mitigation strategies and mitigation strategy management components.

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[2] See 21 CFR 121.5 for exemptions

PRODUCT INFORMATION

Product Name	Insert full name of the specific product including designations to differentiate from similar products
Product Description	Insert a brief description of product
Ingredients	Insert ingredients within the product
Intended Use/ Customers	Describe the intended use of the product. Key considerations include direct to consumer or an in ingredient for further processing.
Serving Size (the serving size a consumer would experience)	Describe the typical serving size of the product as it would be consumed.
Process Flow Diagram	Insert a process flow diagram or a reference to an accompanying process flow diagram.
Specific points, steps, or procedures	1. Describe a specific point, step, or procedure to assess throughout the remainder of class 2. Describe a second specific point, step, or procedure 3. Describe a third specific point, step, or procedure Be sure to include the amount of product from that step that would be in a final serving food that would be consumed.
Notes	

FOOD DEFENSE PLAN ESSENTIALS
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Food Defense Plan Exercise

Key Activity Type Exercise

PRACTICE EXERCISE: KEY ACTIVITY TYPES VULNERABILITY ASSESSMENT

PRACTICE EXERCISE: KEY ACTIVITY TYPES VULNERABILITY ASSESSMENT	
Process Step	Non-peanut ingredient storage
Process Description	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	
☐ Liquid Storage and Handling	
☐ Secondary Ingredient Handling	
☐ Mixing and Similar Activities	

Step 2: 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] (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)

PRACTICE EXERCISE: KEY ACTIVITY TYPES VULNERABILITY ASSESSMENT

PRACTICE EXERCISE: KEY ACTIVITY TYPES VULNERABILITY ASSESSMENT	
Process Step	Non-peanut ingredient storage #2
Process Description	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 2: 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] (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)

PRACTICE EXERCISE: KEY ACTIVITY TYPES VULNERABILITY ASSESSMENT

PRACTICE EXERCISE: KEY ACTIVITY TYPES VULNERABILITY ASSESSMENT	
Process Step	Roasting
Process Description	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 2: 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] (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)

PRACTICE EXERCISE: KEY ACTIVITY TYPES VULNERABILITY ASSESSMENT

PRACTICE EXERCISE: KEY ACTIVITY TYPES VULNERABILITY ASSESSMENT	
Process Step	Grinding
Process Description	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 2: 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] (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)

PRACTICE EXERCISE: KEY ACTIVITY TYPES VULNERABILITY ASSESSMENT

PRACTICE EXERCISE: KEY ACTIVITY TYPES VULNERABILITY ASSESSMENT	
Process Step	Surge Tank
Process Description	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 2: 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] (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)

PRACTICE EXERCISE: KEY ACTIVITY TYPES VULNERABILITY ASSESSMENT

PRACTICE EXERCISE: KEY ACTIVITY TYPES VULNERABILITY ASSESSMENT	
Process Step	Secondary Ingredient Addition
Process Description	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 2: 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] (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)

PRACTICE EXERCISE: KEY ACTIVITY TYPES VULNERABILITY ASSESSMENT

PRACTICE EXERCISE: KEY ACTIVITY TYPES VULNERABILITY ASSESSMENT	
Process Step	Forming
Process Description	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 2: 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] (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)

PRACTICE EXERCISE: KEY ACTIVITY TYPES VULNERABILITY ASSESSMENT

PRACTICE EXERCISE: KEY ACTIVITY TYPES VULNERABILITY ASSESSMENT	
Process Step	Rework
Process Description	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 2: 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] (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)

PRACTICE EXERCISE: KEY ACTIVITY TYPES VULNERABILITY ASSESSMENT

PRACTICE EXERCISE: KEY ACTIVITY TYPES VULNERABILITY ASSESSMENT	
Process Step	Your process step
Process Description	

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 2: 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] (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)

PRACTICE EXERCISE: KEY ACTIVITY TYPES VULNERABILITY ASSESSMENT

PRACTICE EXERCISE: KEY ACTIVITY TYPES VULNERABILITY ASSESSMENT	
Process Step	Roasting #2
Process Description	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)	☐ 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 2: 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] (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)

FOOD DEFENSE PLAN ESSENTIALS
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Food Defense Plan Exercise

Forming – Hybrid Method

PRACTICE EXERCISE: HYBRID METHOD – FORMING

PRACTICE EXERCISE: KEY ACTIVITY TYPES VULNERABILITY ASSESSMENT	
Process Step	Forming
Process Description	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 2: 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] (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)

FOOD DEFENSE PLAN ESSENTIALS
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Food Defense Plan Exercise

Surge Tank – Hybrid Method

PRACTICE EXERCISE: HYBRID METHOD – SURGE TANK

Vulnerability Assessment Worksheet

(Complete a worksheet for each point, step, or procedure related to manufacturing, processing, packing, or holding the food product identified.)

Process Step	Surge Tank
Process Description	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)

- ☐ 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 2: Inherent Characteristics Analysis

Does this point, step, or procedure contain any inherent characteristics that might decrease its vulnerability?

☐ NO inherent characteristics are present, this point, step, or procedure is an Actionable Process Step because it aligns with a Key Activity Type and contains no inherent characteristics to mitigate its vulnerability (Proceed to Step 4: Actionable Process Step Determination)

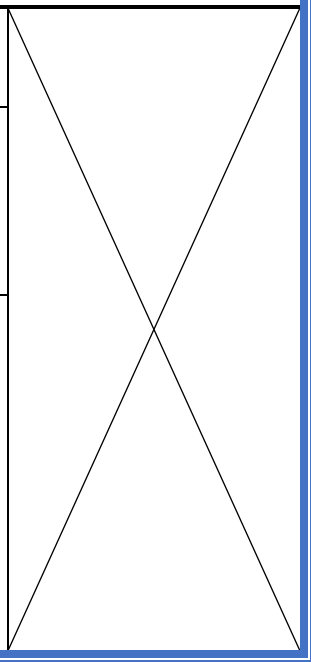
☒ YES, this point, step, or procedure contains inherent characteristics that may mitigate its vulnerability and should be evaluated with the VA Fundamental Element Analysis (Proceed to Step 3: VA Fundamental Element Analysis)

Rationale

Provide an explanation of inherent characteristics

An easy way to determine an inherent characteristic is to evaluate if the step would not function if it was absent

If the characteristics requires management, it is not inherent



PRACTICE EXERCISE: HYBRID METHOD – SURGE TANK

VA Fundamental Element Analysis Worksheet[3]

(Complete if Step 2 of the Vulnerability Assessment indicates that a point, step, or procedure aligns with a Key Activity Type AND has inherent characteristics that may mitigate the step's vulnerability)

Process Step	Insert name of process step

Element 1: Potential public health impact if a contaminant were added – Volume of Food at Risk Approach

Batch Size (align units of measure)	**Amount of Product in Final Serving** (align units of measure)	**Servings per Batch** (batch size multiplied by amount of product in final serving)	**Table 1 Score**	**Representative Contaminant Dose Needed per Serving** (FDA provided value)	**Amount of Representative Contaminant Needed per Batch** (servings per batch multiplied by representative contaminant needed – use in Element 3)
100 gal	4 fl oz	3,200	8	40 mg/serving	0.28 lbs

Rationale	Provide descriptions for any assumptions used for batch size, amount of product in final serving, measurement unit conversions, and if any factors are used to modify servings per batch

Element 2: Degree of physical access to the product	**Table 2 Score**	**Rationale**
	1	The inherent characteristic of the surge tank is fully enclosed making it inaccessible.

Element 3: Ability of an attacker to successfully contaminate the product	**Table 3 Score**	**Rationale**
	1	An inside attacker would not have access to the food at this step because the tank is fully enclosed.

Total Score (add Fundamental Element scores)	NA	

[3] The March 2019 Revised Draft Guidance for Mitigation Strategies to Protect Food Against Intentional Adulteration provides details on methods to evaluate and determine ratings for each of the three fundamental Vulnerability Assessment elements (Chapter 2 Section F). It also provides a Band of Determination which may be used to assist in determination of actionable process steps. It may be helpful to rank order all the fundamental element vulnerability assessments to determine if there is a break where noticeable separation in scores occurs.

PRACTICE EXERCISE: HYBRID METHOD – SURGE TANK

Step 3: Fundamental Element Analysis (Use the Fundamental Element Analysis Worksheet (Step 3b))

Element 1 Public Health Impact	Element 2 Degree of Access	Element 3 Ability to Successfully Contaminate	Total Score
8	1	1	NA

Interpretation of scores

Score ≥26	Score 14 - 25[4]	Score ≤13
significant vulnerabilities will exist when each of the elements are highly scored, i.e., when a process step sum score is greater than or equal to 26	significant vulnerabilities may or may not exist given the nature of the vulnerability at the process step (Refer to Draft Guidance for further information)	significant vulnerabilities will not exist when each of the elements score low, i.e., when a process step sum score is less than or equal to 13

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)	**Explanation** Explain the reasons for assigning the scores above including mention of the specific vulnerabilities and any mitigating inherent characteristics			☐ 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)
	☐ This point, step, or procedure is an Actionable Process Step because it aligns with a Key Activity Type and does not contain inherent characteristics sufficient to mitigate its vulnerability (Proceed to Mitigation Strategies Worksheet)	☐ Use the Band of Determination Guidance to determine if this point, step, or procedure is an Actionable Process Step and include explanation	☒ Although this point, step, or procedure align with Key Activity Type [insert which one/s] it is **not** an Actionable Process Step because [insert explanation] (Evaluation complete, no mitigation strategies or management components are necessary)	
Key Activity Types	Hybrid Approach with Fundamental Element Analysis			Key Activity Types

[4] The March 2019 Revised Draft Guidance for Mitigation Strategies to Protect Food Against Intentional Adulteration provides details on methods to evaluate and determine ratings for each of the three fundamental Vulnerability Assessment elements (Chapter 2 Section F). It also provides a Band of Determination which may be used to assist in determination of actionable process steps. It may be helpful to rank order all the fundamental element vulnerability assessments to determine if there is a break where noticeable separation in scores occurs.

FOOD DEFENSE PLAN ESSENTIALS
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Food Defense Plan Exercise

Secondary Ingredient Addition – Hybrid Method

PRACTICE EXERCISE: HYBRID METHOD – SECONDARY INGREDIENT ADDITION

Vulnerability Assessment Worksheet

(Complete a worksheet for each point, step, or procedure related to manufacturing, processing, packing, or holding the food product identified.)

Process Step	Secondary Ingredient Addition
Process Description	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)

- ☐ 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 2: Inherent Characteristics Analysis

Does this point, step, or procedure contain any inherent characteristics that might decrease its vulnerability?

☒ NO inherent characteristics are present, this point, step, or procedure is an Actionable Process Step because it aligns with a Key Activity Type and contains no inherent characteristics to mitigate its vulnerability (Proceed to Step 4: Actionable Process Step Determination)

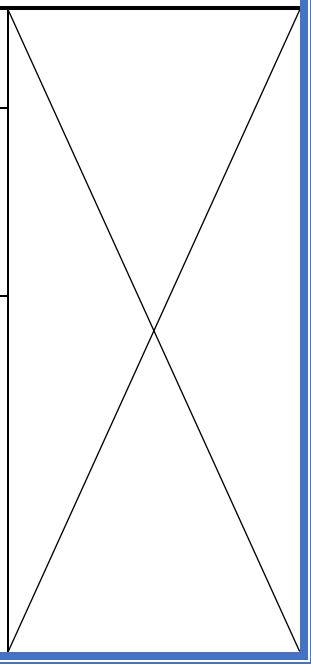
☐ YES, this point, step, or procedure contains inherent characteristics that may mitigate its vulnerability and should be evaluated with the VA Fundamental Element Analysis (Proceed to Step 3: VA Fundamental Element Analysis)

Rationale

Provide an explanation of inherent characteristics

An easy way to determine an inherent characteristic is to evaluate if the step would not function if it was absent

If the characteristics requires management, it is not inherent



PRACTICE EXERCISE: HYBRID METHOD – SECONDARY INGREDIENT ADDITION

Step 3: Fundamental Element Analysis (Use the Fundamental Element Analysis Worksheet (Step 3b))

	Element 1 Public Health Impact	Element 2 Degree of Access	Element 3 Ability to Successfully Contaminate	Total Score	
	Score from 3b	Score from 3b	Score from 3b	Score from 3b	
	Interpretation of scores				
	Score ≥26 significant vulnerabilities will exist when each of the elements are highly scored, i.e., when a process step sum score is greater than or equal to 26	**Score 14 - 25**[5] significant vulnerabilities may or may not exist given the nature of the vulnerability at the process step (Refer to Draft Guidance for further information)	**Score ≤13** significant vulnerabilities will not exist when each of the elements score low, i.e., when a process step sum score is less than or equal to 13		

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)	**Explanation** Explain the reasons for assigning the scores above including mention of the specific vulnerabilities and any mitigating inherent characteristics			☐ 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)
	☐ This point, step, or procedure is an Actionable Process Step because it aligns with a Key Activity Type and does not contain inherent characteristics sufficient to mitigate its vulnerability (Proceed to Mitigation Strategies Worksheet)	☐ Use the Band of Determination Guidance to determine if this point, step, or procedure is an Actionable Process Step and include explanation	☐ Although this point, step, or procedure align with Key Activity Type [insert which one/s] it is **not** an Actionable Process Step because [insert explanation] (Evaluation complete, no mitigation strategies or management components are necessary)	
Key Activity Types	Hybrid Approach with Fundamental Element Analysis			Key Activity Types

[5] The March 2019 Revised Draft Guidance for Mitigation Strategies to Protect Food Against Intentional Adulteration provides details on methods to evaluate and determine ratings for each of the three fundamental Vulnerability Assessment elements (Chapter 2 Section F). It also provides a Band of Determination which may be used to assist in determination of actionable process steps. It may be helpful to rank order all the fundamental element vulnerability assessments to determine if there is a break where noticeable separation in scores occurs.

PRACTICE EXERCISE: HYBRID METHOD – SECONDARY INGREDIENT ADDITION

Mitigation Strategies and Management Components Worksheet[6]	
Process Step	Insert name of process step
Mitigation Strategy(ies) (Identify and explain mitigation strategies for each actionable process step for the food product identified.)	Insert a brief description of the mitigation strategy(ies)
Explanation	Insert a brief explanation of how the mitigation strategy(ies) minimize or prevent significant vulnerabilities

[6] Example for each of these may be found in the FDA 2019 Draft Guidance Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry and 2020 Supplemental Draft Guidance Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry.

PRACTICE EXERCISE: HYBRID METHOD – SECONDARY INGREDIENT ADDITION

Management Components (Complete management components for each mitigation strategy identified)	
Monitoring Procedure and Frequency (Who, What, How, and How Often)	Insert a brief explanation of how the mitigation strategy(ies) will be monitored. Include what will be monitored, how it will be monitored, how often it will be monitored, and who will monitor it.
Corrective Action Procedures	Written predetermined corrective actions in your FDP provide a "how-to" guide that describes the steps to take when a mitigation strategy is not properly implemented and enables you to act quickly and appropriately. Written food defense corrective actions procedures do not need to address every possible way a mitigation strategy may be improperly implemented but should address circumstances where improper implementation is most likely to occur.
Verification Procedures	Food defense verification activities must include, as appropriate to the nature of the mitigation strategy and its role in the facility's food defense system: 1) Verification that food defense monitoring is being conducted; 2) Verification appropriate decisions about food defense corrective actions are being made; 3) Verification that mitigation strategies are properly implemented and are significantly minimizing or preventing the significant vulnerabilities; and 4) Verification of reanalysis

PRACTICE EXERCISE: HYBRID METHOD – SECONDARY INGREDIENT ADDITION

Records (Identify records for each management component identified)	
Monitoring Records	Insert a brief explanation of food defense monitoring records that will be kept for each mitigation strategy. In some cases, exception records may be appropriate.
Corrective Action Records	Insert a brief explanation of food defense corrective action records that will be kept for each mitigation strategy. In some cases, exception records may be appropriate.
Verification Records	Insert a brief explanation of food defense verification records that will be kept for each mitigation strategy. In some cases, exception records may be appropriate.

Attach any additional documentation or explanation as necessary to support the Food Defense Plan.

FOOD DEFENSE PLAN ESSENTIALS
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Food Defense Plan Exercise

Rework – Hybrid Method

PRACTICE EXERCISE: HYBRID METHOD – REWORK

Vulnerability Assessment Worksheet

(Complete a worksheet for each point, step, or procedure related to manufacturing, processing, packing, or holding the food product identified.)

Process Step	Rework
Process Description	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 2: Inherent Characteristics Analysis

Does this point, step, or procedure contain any inherent characteristics that might decrease its vulnerability?

☒ NO inherent characteristics are present, this point, step, or procedure is an Actionable Process Step because it aligns with a Key Activity Type and contains no inherent characteristics to mitigate its vulnerability (Proceed to Step 4: Actionable Process Step Determination)

☐ YES, this point, step, or procedure contains inherent characteristics that may mitigate its vulnerability and should be evaluated with the VA Fundamental Element Analysis (Proceed to Step 3: VA Fundamental Element Analysis)

Rationale

Provide an explanation of inherent characteristics

An easy way to determine an inherent characteristic is to evaluate if the step would not function if it was absent

If the characteristics requires management, it is not inherent

PRACTICE EXERCISE: HYBRID METHOD – REWORK

Step 3: Fundamental Element Analysis (Use the Fundamental Element Analysis Worksheet (Step 3b))

Element 1 Public Health Impact	Element 2 Degree of Access	Element 3 Ability to Successfully Contaminate	Total Score
Score from 3b	Score from 3b	Score from 3b	Score from 3b

Interpretation of scores

Score ≥26	Score 14 - 25[7]	Score ≤13
significant vulnerabilities will exist when each of the elements are highly scored, i.e., when a process step sum score is greater than or equal to 26	significant vulnerabilities may or may not exist given the nature of the vulnerability at the process step (Refer to Draft Guidance for further information)	significant vulnerabilities will not exist when each of the elements score low, i.e., when a process step sum score is less than or equal to 13

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)	**Explanation** Explain the reasons for assigning the scores above including mention of the specific vulnerabilities and any mitigating inherent characteristics			☐ 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)
	☐ This point, step, or procedure is an Actionable Process Step because it aligns with a Key Activity Type and does not contain inherent characteristics sufficient to mitigate its vulnerability (Proceed to Mitigation Strategies Worksheet)	☐ Use the Band of Determination Guidance to determine if this point, step, or procedure is an Actionable Process Step and include explanation	☐ Although this point, step, or procedure align with Key Activity Type [insert which one/s] it is **not** an Actionable Process Step because [insert explanation] (Evaluation complete, no mitigation strategies or management components are necessary)	

Key Activity Types	Hybrid Approach with Fundamental Element Analysis	Key Activity Types

[7] The March 2019 Revised Draft Guidance for Mitigation Strategies to Protect Food Against Intentional Adulteration provides details on methods to evaluate and determine ratings for each of the three fundamental Vulnerability Assessment elements (Chapter 2 Section F). It also provides a Band of Determination which may be used to assist in determination of actionable process steps. It may be helpful to rank order all the fundamental element vulnerability assessments to determine if there is a break where noticeable separation in scores occurs.

PRACTICE EXERCISE: HYBRID METHOD – REWORK

Mitigation Strategies and Management Components Worksheet[8]	
Process Step	Insert name of process step
Mitigation Strategy(ies) (Identify and explain mitigation strategies for each actionable process step for the food product identified.)	Insert a brief description of the mitigation strategy(ies)
Explanation	Insert a brief explanation of how the mitigation strategy(ies) minimize or prevent significant vulnerabilities

[8] Example for each of these may be found in the FDA 2019 Draft Guidance Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry and 2020 Supplemental Draft Guidance Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry.

PRACTICE EXERCISE: HYBRID METHOD – REWORK

Management Components (Complete management components for each mitigation strategy identified)	
Monitoring Procedure and Frequency (Who, What, How, and How Often)	Insert a brief explanation of how the mitigation strategy(ies) will be monitored. Include what will be monitored, how it will be monitored, how often it will be monitored, and who will monitor it.
Corrective Action Procedures	Written predetermined corrective actions in your FDP provide a "how-to" guide that describes the steps to take when a mitigation strategy is not properly implemented and enables you to act quickly and appropriately. Written food defense corrective actions procedures do not need to address every possible way a mitigation strategy may be improperly implemented but should address circumstances where improper implementation is most likely to occur.
Verification Procedures	Food defense verification activities must include, as appropriate to the nature of the mitigation strategy and its role in the facility's food defense system: 5) Verification that food defense monitoring is being conducted; 6) Verification appropriate decisions about food defense corrective actions are being made; 7) Verification that mitigation strategies are properly implemented and are significantly minimizing or preventing the significant vulnerabilities; and 8) Verification of reanalysis

PRACTICE EXERCISE: HYBRID METHOD – REWORK

Records (Identify records for each management component identified)	
Monitoring Records	Insert a brief explanation of food defense monitoring records that will be kept for each mitigation strategy. In some cases, exception records may be appropriate.
Corrective Action Records	Insert a brief explanation of food defense corrective action records that will be kept for each mitigation strategy. In some cases, exception records may be appropriate.
Verification Records	Insert a brief explanation of food defense verification records that will be kept for each mitigation strategy. In some cases, exception records may be appropriate.

Attach any additional documentation or explanation as necessary to support the Food Defense Plan.

FOOD DEFENSE PLAN ESSENTIALS
Intentional Adulteration Rule Training

Food Defense Plan Exercise

Your Process Step – Hybrid Method

PRACTICE EXERCISE: HYBRID METHOD – REWORK

Vulnerability Assessment Worksheet

(Complete a worksheet for each point, step, or procedure related to manufacturing, processing, packing, or holding the food product identified.)

Process Step	Rework
Process Description	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 2: Inherent Characteristics Analysis

Does this point, step, or procedure contain any inherent characteristics that might decrease its vulnerability?

☒ NO inherent characteristics are present, this point, step, or procedure is an Actionable Process Step because it aligns with a Key Activity Type and contains no inherent characteristics to mitigate its vulnerability (Proceed to Step 4: Actionable Process Step Determination)

☐ YES, this point, step, or procedure contains inherent characteristics that may mitigate its vulnerability and should be evaluated with the VA Fundamental Element Analysis (Proceed to Step 3: VA Fundamental Element Analysis)

Rationale

Provide an explanation of inherent characteristics

An easy way to determine an inherent characteristic is to evaluate if the step would not function if it was absent

If the characteristics requires management, it is not inherent

PRACTICE EXERCISE: HYBRID METHOD – YOUR PROCESS STEP

Vulnerability Assessment Worksheet

(Complete a worksheet for each point, step, or procedure related to manufacturing, processing, packing, or holding the food product identified.)

Process Step	Insert name of process step in the production of the product
Process Description	Insert a brief description of the process step. Focus on the physical processes involved – where and how an inside attacker could have access to the product, flow rates, volumes of production, product forms, how the step might disperse a potential adulterant in a larger volume, etc.

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 2: Inherent Characteristics Analysis

Does this point, step, or procedure contain any inherent characteristics that might decrease its vulnerability?

☐ NO inherent characteristics are present, this point, step, or procedure is an Actionable Process Step because it aligns with a Key Activity Type and contains no inherent characteristics to mitigate its vulnerability (Proceed to Step 4: Actionable Process Step Determination)

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Rationale

Provide an explanation of inherent characteristics

An easy way to determine an inherent characteristic is to evaluate if the step would not function if it was absent

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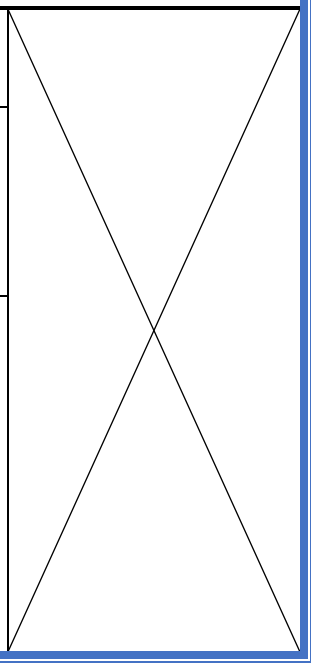

PRACTICE EXERCISE: HYBRID METHOD – YOUR PROCESS STEP

VA Fundamental Element Analysis Worksheet[9]

(Complete if Step 2 of the Vulnerability Assessment indicates that a point, step, or procedure aligns with a Key Activity Type AND has inherent characteristics that may mitigate the step's vulnerability)

Process Step	Insert name of process step

Element 1: Potential public health impact if a contaminant were added – Volume of Food at Risk Approach

Batch Size (align units of measure)	**Amount of Product in Final Serving** (align units of measure)	**Servings per Batch** (batch size multiplied by amount of product in final serving)	**Table 1 Score**	**Representative Contaminant Dose Needed per Serving** (FDA provided value)	**Amount of Representative Contaminant Needed per Batch** (servings per batch multiplied by representative contaminant needed – use in Element 3)
				40 mg/serving	
Rationale			Provide descriptions for any assumptions used for batch size, amount of product in final serving, measurement unit conversions, and if any factors are used to modify servings per batch		

Element 2: Degree of physical access to the product	**Table 2 Score**	**Rationale**
		Provide descriptions for any aspects of the step under evaluation that influences the ability of an inside attacker to physically access the product at that step

Element 3: Ability of an attacker to successfully contaminate the product	**Table 3 Score**	**Rationale**
		Provide descriptions for any aspects of the step under evaluation that influences the ability of an inside attacker successfully contaminate a product at that step without being detected. Considerations could include visibility, unusual actions, etc.

Total Score (add Fundamental Element scores)		

[9] The March 2019 Revised Draft Guidance for Mitigation Strategies to Protect Food Against Intentional Adulteration provides details on methods to evaluate and determine ratings for each of the three fundamental Vulnerability Assessment elements (Chapter 2 Section F). It also provides a Band of Determination which may be used to assist in determination of actionable process steps. It may be helpful to rank order all the fundamental element vulnerability assessments to determine if there is a break where noticeable separation in scores occurs.

PRACTICE EXERCISE: HYBRID METHOD – YOUR PROCESS STEP

Step 3: Fundamental Element Analysis (Use the Fundamental Element Analysis Worksheet (Step 3b))

	Element 1 Public Health Impact	Element 2 Degree of Access	Element 3 Ability to Successfully Contaminate	Total Score	
	Score from 3b	Score from 3b	Score from 3b	Score from 3b	
	Interpretation of scores				
	Score ≥26 significant vulnerabilities will exist when each of the elements are highly scored, i.e., when a process step sum score is greater than or equal to 26	**Score 14 - 25**[10] significant vulnerabilities may or may not exist given the nature of the vulnerability at the process step (Refer to Draft Guidance for further information)	**Score ≤13** significant vulnerabilities will not exist when each of the elements score low, i.e., when a process step sum score is less than or equal to 13		

Step 4: Actionable Process Step Determination

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PRACTICE EXERCISE: HYBRID METHOD – YOUR PROCESS STEP

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PRACTICE EXERCISE: HYBRID METHOD – YOUR PROCESS STEP

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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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