Conducting Vulnerability Assessments

Exercise Workbook

Developed by the

FSPCA

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

This *Exercise Workbook* was created to assist participants in the Food Safety Preventive Controls Alliance's Intentional Adulteration *Conducting Vulnerability Assessments* course to provide practice exercises in an attempt to reinforce learning.

All exercises and examples are hypothetical.

Version 1.0 – 2019

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Lesson 1: An Overview of Food Defense Measures

Exercise: "Identifying Food Defense Terms"

Directions: Take 5 minutes to complete the Food Defense Terms Worksheet below. Read the food defense term written in the left column. Match the term with its definition in the right column. When everyone has completed the worksheet, the Instructor will facilitate a 5-minute review/discussion.

Term		Definition
Actionable Process Step	1	A person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required . . . as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.
Food Defense	2	A systematic assessment of points, steps or procedures to identify and rank vulnerabilities to intentional adulteration.
Intentional Adulteration	3	An activity related to manufacturing, processing, packing, or holding of a food product.
Point, Step, or Procedure	4	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.
Qualified Individual	5	The susceptibility of a point, step, or procedure in a facility's food process to intentional adulteration.
Significant Vulnerability	6	The effort to protect food from intentional acts of adulteration where there is an intent to cause wide scale public health harm.
Vulnerability	7	The deliberate contamination of food with a biological, chemical, radiological, or physical agent by an individual or group of individuals with the intent to cause wide scale public health harm.
Vulnerability Assessment (VA)	8	A vulnerability in a food process that, if exploited, could be expected to cause wide scale public harm.

Lesson 2: Vulnerability Assessment Preliminary Steps

Lesson 2 Notes:

Lesson 3: Considering Inherent Characteristics

Lesson 3 Notes:

Lesson 3: Considering Inherent Characteristics (continued)

Exercise: "Inherent Characteristics"

Directions: Take 5 minutes to fill out the Inherent Characteristics Worksheet below. Read the description of the activity or procedure written in the left column. Use a check mark to indicate whether you think the activity would be considered an "inherent characteristic" (Yes) or (No). When everyone has completed the worksheet, the Instructor will facilitate a 10-minute review/discussion. **Remember to ask the question:** "Absent the characteristic described, would the process step function?"

Inherent Characteristics Worksheet For each activity below, check (Yes) or (No) in response to the question: "Is the activity an inherent characteristic"?		
Activity	**Yes**	**No**
Using an enclosed pumping system	☐	☐
Implementing equipment swabbing procedures	☐	☐
Integrated/required safety mechanisms on equipment access points	☐	☐
More than one employee is required for the process step operation	☐	☐
Management requires use of a buddy system in the cold storage room for worker safety concerns	☐	☐
Performing visual quality assurance inspections	☐	☐
Using a pressurized vessel	☐	☐
Using senior personnel at a specific process step for quality reasons	☐	☐

Lesson 4: Considering an Inside Attacker

Lesson 4 Notes:

Lesson 5: Element 1: Evaluating Potential Public Health Impact

Lesson 5 Notes:

Lesson 5: Element 1: Evaluating Potential Public Health Impact (continued)

Exercise: Element 1: Calculating Potential Public Health Impact

Total time: 35 minutes

- Complete *Worksheet 1-D: Calculating Volume of Food at Risk*: 5 minutes
- Report out conclusions: 5 minutes
- Facilitated review/discussion: 5 minutes
- Complete *Worksheet 1-E: Calculating Potential Public Health Impact using a Representative Contaminant*: 10 minutes
- Report out conclusions: 5 minutes
- Facilitated review/discussion: 5 minutes

Resources:

- Example Flow Diagram (Exercise Workbook page 9)
- *Table 1. Potential Public Health Impact* (Exercise Workbook page 10)
- *Element 1: Calculating Potential Public Health Impact Exercise Worksheet* and Unit Conversion Information (Exercise Workbook page 11)

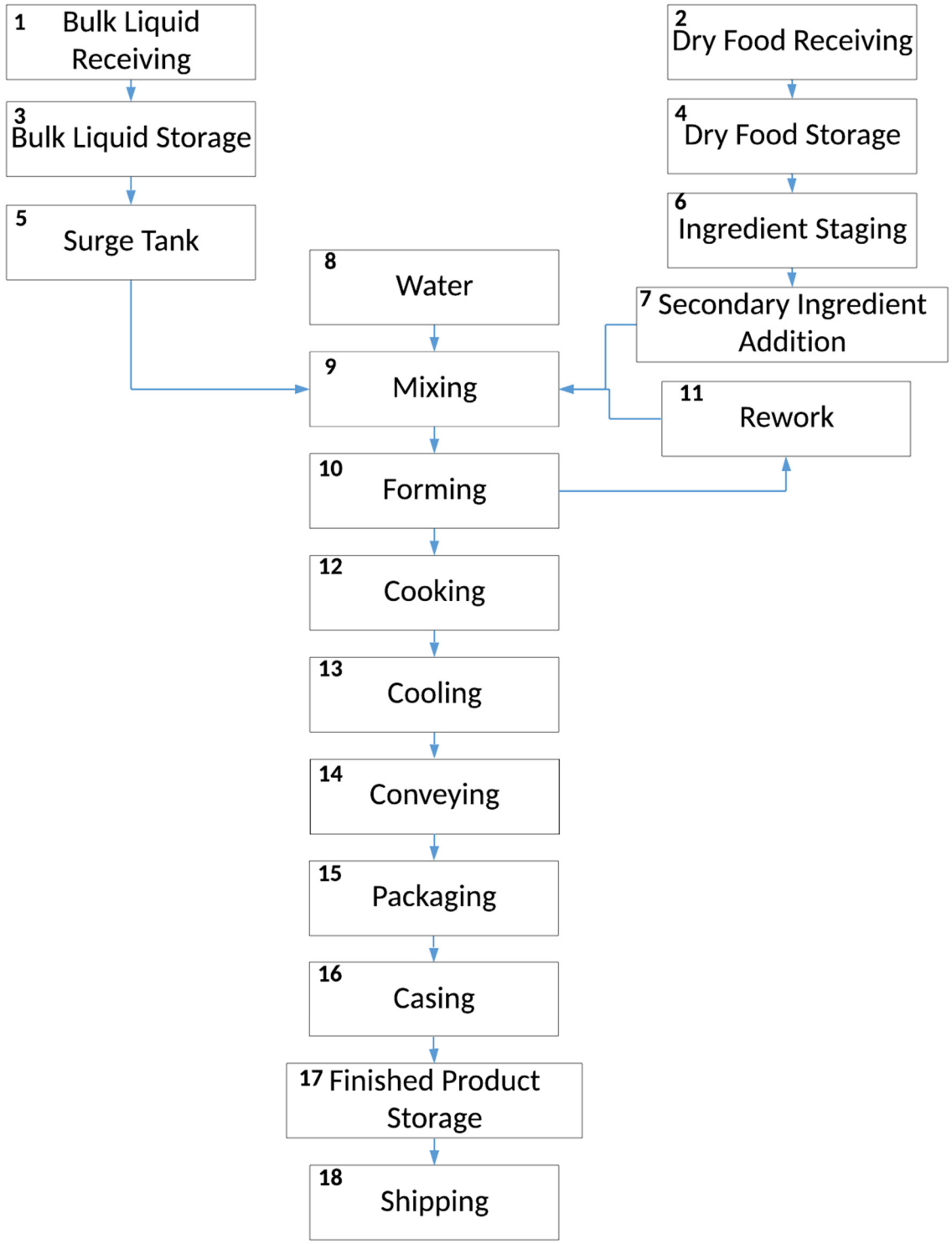
Directions:

1. Calculate public health impact using the volume of food at risk method and document your findings in Worksheet 1-D on the Element 1: Calculating Potential Public Health Impact Exercise Worksheet.
2. ***Remember to use Table 1. Potential Public Health Impact (page 10) to assign a score and pay attention to units—use the conversion information located at the top of the Element 1: Calculating Potential Public Health Impact Exercise Worksheet on page 11.***
3. When everyone has completed the Worksheet 1-D, the Instructor will facilitate a review/discussion before moving on to the representative contaminant method.
4. After additional instruction, calculate the public health impact using the representative contaminant method and document your findings in Worksheet 1-E on the Element 1: Calculating Potential Public Health Impact Exercise Worksheet on page 12.
5. The Instructor will then facilitate a review/discussion for the entire exercise.

Lesson 5: Element 1: Evaluating Potential Public Health Impact (continued)

Exercise: Element 1: Calculating Potential Public Health Impact (continued)

Example Process Flow Diagram



Lesson 5: Element 1: Evaluating Potential Public Health Impact (continued)

Exercise: Element 1: Calculating Potential Public Health Impact (continued)

Table 1. Potential Public Health Impact	
Description	**Score**
Potential public health impact over 10,000 (acute illnesses, deaths, or both), or over 10,000 servings at risk.	10
Potential public health impact between 1,001 – 10,000 (acute illnesses, deaths, or both), or 1,001 – 10,000 servings at risk.	8
Potential public health impact between 100 and 1000 (acute illnesses, deaths, or both), or 100 – 1000 servings at risk.	5
Potential public health impact between 1 - 99 (acute illnesses, deaths, or both), or between 1 – 99 servings at risk.	3
No potential public health impact (i.e., no illnesses or deaths) or no servings at risk.	1

Lesson 5: Element 1: Evaluating Potential Public Health Impact (continued)

Exercise: Element 1: Calculating Potential Public Health Impact (continued)

Useful Conversions:

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

Element 1: Calculating Potential Public Health Impact Exercise Worksheet Worksheet 1-D: Calculating Volume of Food at Risk					
A **Process Step**	**B** **Batch Size**	**C** **Amount of Product (Ingredient) in Final Serving**	**D** **Servings per Batch** **B ÷ C**	**E** **Score from Table 1**	**F** **Notes**
Bulk Liquid Receiving (example)	***5,000 gal***	***4 fl oz***	***160,000***	***10***	
Surge Tank	100 gal	4 fl oz			
Secondary Ingredient Addition	1,000 lbs	1 oz			
Forming	300 lbs	4 oz			

Lesson 5: Element 1: Evaluating Potential Public Health Impact (continued)

Exercise: Element 1: Calculating Potential Public Health Impact (continued)

Useful Conversions:

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

Element 1: Calculating Potential Public Health Impact Exercise Worksheet

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

Element 1 Calculations Using Representative Contaminant								Element 3 Calculations	
A Process Step	B Batch Size	C Amount of Product (Ingredient) in Final Serving	D Servings per Batch B÷C	E Mortality Rate of Contaminant *(FDA provided value = 50%)*	F Number of Potential Deaths D x E	G Score from Table 1	H Notes	I Representative Contaminant Dose Needed per Serving *(FDA provided value = 40 milligrams)*	J Amount of Representative Contaminant Needed per Batch D x I
Bulk Liquid Receiving (example)	***5,000 gal***	***4 fl oz***	***160,000***	***50%***	***80,000***	***10***		***40 mg/serving***	***6,400,000 mg or 14 lbs***
Surge Tank	100 gal	4 fl oz		50%				40 mg/serving	
Secondary Ingredient Addition	1,000 lbs	1 oz		50%				40 mg/serving	
Forming	300 lbs	4 oz		50%				40 mg/serving	

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

Lesson 6 Notes:

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

Total time: 70 minutes

- Complete worksheet: 30 minutes
- Report out conclusions: 15 minutes
- Facilitated review/discussion: 25 minutes

Resources:

- *Example Process Flow Diagram* (page 9)
- *Example Process Step Descriptions* (pages 15-16)
- *Table 2. Degree of Physical Access to the Product* (page 17)
- *Table 3. The Ability of an Attacker to Successfully Contaminate the Product* (pages 18-20)
- *Element 2: Evaluating Degree of Physical Access to the Product and Element 3: Evaluating the Ability of an attacker to Successfully Contaminate the Product Exercise Worksheet* (page 21)

Directions:

1. Read the process step descriptions for each assigned process step (Step 5- Surge Tank, Step 7- Secondary Ingredient Addition, and Step 10- Forming) and scoring table descriptions.
2. Using the resources noted above, determine the score for Elements 2 and 3 for each assigned process step.
3. With the score, provide your supporting rationale. Please see the example provided for Step 2 (Bulk Liquid Receiving) as a guide.
4. Once you have completed scoring Elements 2 and 3 and writing your supporting rationales, the Instructor will call upon you to report out.
5. After everyone has reported out their results, the Instructor will lead a whole group review/discussion.

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

Exercise: Element 2: Evaluating Degree of Physical Access to the Product and Element 3: Evaluating the Ability of an Attacker to Successfully Contaminate the Product (continued)

Example Process Step Descriptions		
Process Step		**Description**
1	**Bulk Liquid Receiving**	Bulk liquid is received at the receiving bay by tanker trucks. Upon receipt, venting hatches at the top of the vehicle are opened and hoses are attached to the back of the vehicle. Truck drivers may remain in the area but are not permitted to participate in unloading activity. The entire receiving process takes approximately thirty minutes. One truck typically contains 5,000 gallons of liquid ingredient.
2	**Dry Food Receiving**	Packages of secondary ingredients such as seasoning (sugar, spices, baking soda) are received via truck in 50 lb. bags (sugar, spices) and 5lb bags of baking soda on shrink-wrapped pallets. Product is moved directly to storage via forklift.
3	**Bulk Liquid Storage**	Ingredient is pumped from bulk liquid receiving bay into a 50,000-gallon primary ingredient tank. Tank is agitated to prevent separation of the liquid ingredient. Tank has a hatch at the top that is accessible via a ladder from the outside of the building.
4	**Dry Food Storage**	Pallets of dry ingredients are moved into the storage room via forklift from the loading dock. Pallets may be broken down, but bags are not opened in the storage rooms. Partials are not returned into storage.
5	**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.
6	**Ingredient Staging**	Sealed bags of dry ingredients are moved from the storage room to the staging area adjacent to the mixer. Bags are not opened during staging and remain sealed until addition. Partial bags are not used.
7	**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.
8	**Water**	Municipal water is directly pumped into the mixer. The facility does not hold or treat water on-site.

Example Process Step Descriptions	
Process Step	**Description**
9 Mixing	Bags of secondary ingredients are added by hand to the mixer by the mixer operator. Liquid ingredient is pumped directly from the surge tank and computer metered into the mixer. The mixer combines ingredients with water into a uniform mixture. Batch size of the mixer is 2,000 lbs. The mixer is covered by a lid, but the lid is not locked or secured. Mixing takes approximately 30-45 minutes. Mixer operator may not be present at the mixer at all times during operation. Mixer may be unobserved for periods of time.
10 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.
11 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.
12 Cooking	Once formed, squares are conveyed through an enclosed oven where they are baked at 425 degrees Fahrenheit for 10 minutes. Oven is located beside the forming machine with only a small gap between the end of the forming machine and the entrance to the oven. Line capacity of the conveyer is the same as the former (100lbs./min).
13 Cooling	After cooking, the product is immediately conveyed through a cooling tunnel to reduce its temperature to approximately 40°F. Cooling tunnel is enclosed with only access points at its immediate entrance and exit. Product flows through the cooling tunnel at approximately 100 lbs./min.
14 Conveying	Once cooled, product is moved via belt conveyor to the packaging room. The belt is at floor level for approximately 50 feet but then elevates for the remainder of its run to the packager. Product is still moving at 100 lbs./min., but the belt conveyer is much narrower than the conveyer that moves through forming, cooking and cooling that belt speed is much faster.
15 Packaging	Belt conveyer moves product to packaging machine where a computer eye diverter directs 12 squares into each package. Packaging consists of filling a plastic pouch with product and vacuum sealing the pouch. The pouch is then moved automatically into a box which is labeled and then sealed.
16 Casing	12 filled pouches are manually placed in boxes, sealed with tape and labeled for distribution.
17 Finished Product Storage	Boxes are loaded by hand onto a pallet which is moved via hand truck to an automated palletizing machine. Finished product is stored for up to three days in a storage room fully packaged and palletized prior to forklift loading on to outbound trucks.
18 Shipping	Fully loaded pallets are moved via forklift from storage to the loading dock and into outbound trucks.

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

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

Table 2. Degree of Physical Access to the Product	
Description	**Score**
Easily Accessible. • Inside attacker has access to the product (e.g., attacker can physically touch the product). • There are no inherent characteristics that would make access to the product difficult (e.g., enclosed systems, pressurized equipment, railings, equipment safety features, or shields). • Product is open and unsecured by packaging, equipment, or other physical access barriers. • Product is handled, staged, or moved in an easily accessible manner.	10
Accessible. • There are limited inherent characteristics that would make access to the product difficult (e.g., enclosed systems, pressurized equipment, railings, equipment safety features, or shields). • Product is in equipment that can be accessed without tools or specialized supplies. • Access to the food is not difficult (e.g., there are minimal physical space constraints that limit access to food) but may require opening equipment, access points, or non-tamper-evident packaging.	8
Partially Accessible. • Inside attacker has partial access to the product. • There are some inherent characteristics that would make access to the product somewhat difficult (e.g., enclosed systems, pressurized equipment, railings, equipment safety features, or shields).	5
Hardly Accessible. • There are significant inherent characteristics that would make access to the product very difficult (e.g., enclosed systems, pressurized equipment, railings, equipment safety features, or shields). • Product is in equipment that make access difficult without tools or specialized supplies. • Physical space constraints limit access to food being processed or stored.	3
Not Accessible. • Inside attacker has no access to the product (e.g., attacker cannot physically touch the product). • There are significant inherent characteristics that would make access to the product impossible (e.g., enclosed systems, pressurized equipment, railings, equipment safety features, or shields). • Product is enclosed and secured by packaging, equipment, or other physical access barriers. • Product is handled, staged, or moved in an inaccessible manner (e.g., bucket conveyors being moved via elevated track, an elevated ingredient surge tank with no means of access).	1

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

Exercise: Element 2: Evaluating Degree of Physical Access to the Product and Element 3: Evaluating the Ability of an Attacker to Successfully Contaminate the Product Worksheet (continued)

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

Description	Score
Highest Ease of Successful Contamination. • The process step is in an isolated area, or obscured from view, enabling an inside attacker to work unobserved with little or no time limitations. • It is easy to successfully add sufficient volume of contaminant to the food. • Inherent characteristics of the point, step, or procedure (e.g., uniform mixing) would evenly distribute the contaminant into the food. • It is highly unlikely the inside attacker would be detected adding a contaminant to the food; an attacker would need to act with little to no stealth to introduce the contaminant. • There are no, or few, workers in the area, and it is highly unlikely that they would notice a contamination attempt by an inside attacker. • There is a low likelihood of the contaminant being removed (e.g., by washing, screening, vibration), diluted, or neutralized at this or later points, steps, or procedures in the process.	10
Moderately High Ease of Successful Contamination. • The process step is seldom observed, enabling an inside attacker to work unobserved with minor time limitations. • It would be relatively easy for an inside attacker to successfully add a contaminant in sufficient volume. • It is unlikely the inside attacker would be detected adding a contaminant to the food; an inside attacker would need to act with minimal stealth to introduce the contaminant. • There are few workers in the area, and it is unlikely that they would notice a contamination attempt by an inside attacker. • Mixing, or agitation, is present but the contaminant may not be evenly distributed throughout the food because of inherent characteristics of the point, step, or procedure. • There is a moderately low likelihood of the contaminant being removed (e.g., by washing, screening, vibration), diluted, or neutralized at this or later points, steps, or procedures in the process.	8

Table 3. The Ability of an Attacker to Successfully Contaminate the Product	
Description	**Score**
Moderate Ease of Successful Contamination. • The process step is observed about half of the time, or semi-obscured from view; an inside attacker would be under time limitations. • It would be somewhat difficult for an inside attacker to successfully add a contaminant in sufficient volume without being detected. • An inside attacker only would be able to add a reasonably small volume of contaminant (e.g., what can be carried in a pocket) without being detected. • It is moderately likely the inside attacker would be detected adding a contaminant to the food; an inside attacker would need to act with some degree of stealth, irregular, or suspicious activity to introduce the contaminant. • There is no intended mixing or agitation of the product, but processing conditions may distribute the contaminant into the surrounding food because of inherent characteristics of the point, step, or procedure. • There is a moderate likelihood of the contaminant being removed (e.g., by washing, screening, vibration), diluted, or neutralized at this or later points in the process.	5
Moderately Low Ease of Successful Contamination. • The process step is observed more than half of the time; an inside attacker would be under relatively strict time limitations. • It would be difficult for an inside attacker to successfully add a contaminant in sufficient volume without being detected. • It is highly likely the inside attacker would be detected adding a contaminant to the food; an inside attacker would have to conduct suspicious or irregular activities to contaminate the product. • There are some, or many, workers in the area, and it is highly likely that they would notice a contamination attempt by an inside attacker. • Mixing or agitation is not present, and the contaminant would not be effectively distributed into surrounding food because of inherent characteristics of the point, step, or procedure. • There is a high chance that the contaminant would be removed (e.g., by washing, screening, vibration), diluted, or neutralized at this or later points in the process.	3

Table 3. The Ability of an Attacker to Successfully Contaminate the Product	
Description	**Score**
Lowest Ease of Successful Contamination. • The process step is under constant observation, or the view of the step is unobscured, preventing an inside attacker from adding a contaminant without being detected. • It is extremely likely the inside attacker would be detected adding a contaminant to the food due to the need to conduct highly irregular or suspicious activities to contaminate the food; successful introduction of a contaminant at the point, step, or procedure is extremely difficult or impossible. • There are numerous workers in the immediate area that would notice a contamination attempt by an inside attacker. • An inside attacker would need to add a large volume of contaminant without being detected. • The contaminant likely would be removed (e.g., by washing, screening, vibration), diluted, or neutralized at this or later points in the process. • Other inherent characteristics of the point, step, or procedure (e.g., multiple workers are required to be present for the step to function; positive airflow would prevent introduction of a contaminant; product is moving at a high rate of speed; introduction of a contaminant would result in human injury such as burns, cuts, or lacerations) significantly reduce the ability of an inside attacker to contaminate the product.	1

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

Exercise: Element 2: Evaluating Degree of Physical Access to the Product and Element 3: Evaluating the Ability of an Attacker to Successfully Contaminate the Product Worksheet (continued)

Element 2 and Element 3 Exercise Worksheet			
(1) #	**(2) Process Step**	**(5) Element 2: Score and Rationale**	**(6) Element 3: Score and Rationale**
1	***Bulk Liquid Receiving (example)***	*Score = 8* *Vent and sampling hatches are opened before unloading. Hoses are accessible when not in use. Open hatches provide a means of access to the food. This area is accessible by anyone already in the facility.*	*Score = 8* *When multiple trucks are in the receiving bay (which is not uncommon), it is difficult for other workers in the area to observe opening of vent hatches and hooking-up of hoses. A contaminant added to either the vent or the hose itself would mix with the food during unloading and pumping to the storage tank.*
5	**Surge Tank**		
7	**Secondary Ingredient Addition**		
10	**Forming**		

Lesson 7: Analyzing Results to Identify Actionable Process Steps

Lesson 7 Notes:

Lesson 7: Analyzing Results to Identify Actionable Process Steps (continued)

Exercise: Analyzing Results

Total time: 35 minutes

- Individually complete worksheets (Part One): 5 minutes
- Individually complete worksheets and report out (Part Two): 20 minutes
- Facilitated review/discussion: 10 minutes

Resources:

- *Example Process Flow Diagram* (page 9)
- *Example Process Step Descriptions* (pages 15-16)
- Your completed *Element 1 Exercise Worksheet* (page 11)
- Your completed *Element 2 and Element 3 Exercise Worksheet* (page 21)
- *Analyzing Results Exercise Worksheet* (pages 24-30)
- *Rank Order Exercise Worksheet* (page 31)

Directions – Part 1:

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

Directions – Part 2:

1. Identify the band of determination (between 14-25) in your *Rank Order Exercise Worksheet*.
2. For the three process steps that you have been using in the exercises (surge tank, secondary ingredient addition, and forming), refer back to your rationale for each element score for each process step.
3. Consider each element's contribution to the overall vulnerability of each process step. Assess whether a significant vulnerability is present. If you believe a significant vulnerability is present, identify the process step as an actionable process step.
4. Write an explanation in column (8) in the *Analyzing Results Worksheet* for why the process step was determined to be an actionable process step, or why it was not. The individual element rationale scores will be helpful with informing the explanation.
5. Indicate which process steps would be actionable process steps and record (Y) or (N) in column (9) based on your explanations.
6. Once you have completed the worksheets and have identified whether the process step is an actionable process step or not, the Instructor will call upon you to report out.
7. After everyone has reported out their results, the Instructor will lead a whole group review/discussion.

Lesson 7: Analyzing Results to Identify Actionable Process Steps (continued)

Exercise: Analyzing Results (continued)

Analyzing Results Exercise Worksheet							
(1) #	(2) Process Step	(4) Element 1: Score and Rationale	(5) Element 2: Score and Rationale	(6) Element 3: Score and Rationale	(7) Sum	(8) Explanation	(9) Actionable Process Step
1	Bulk Liquid Receiving	Score = 10	Score = 8	Score = 8	26	This step is significantly vulnerable. If successfully contaminated, it is anticipated that the result would be a very large public health impact. An intentional contamination by an insider at this step would not be prevented by any inherent characteristics of this step. Observation of this process is low since the design of the receiving bay presents visual obstructions.	Yes
2	Dry Food Receiving	Score = 5	Score = 3	Score = 3	11	This step is not significantly vulnerable. Contamination at this step would result in 400 potential deaths, however the product here is wrapped in multiple layers of packaging or wrapping and generally not accessible (i.e., hardly accessible). Pallets are moving quickly via forklift to storage and under constant observation of the forklift operator, but a pallet may sometimes be left in the receiving area for a short time if quality testing is performed. An attacker would have to conduct irregular/suspicious activities to contaminate a bag on a pallet that is being held in the receiving area. Surrounding workers would make it highly likely that an inside attacker attempting to introduce a contaminant into a bag would be detected, even if the attacker were the quality control manager taking samples. It would	No

Analyzing Results Exercise Worksheet							
(1) #	(2) Process Step	(4) Element 1: Score and Rationale	(5) Element 2: Score and Rationale	(6) Element 3: Score and Rationale	(7) Sum	(8) Explanation	(9) Actionable Process Step
						be difficult to introduce a contaminant into the small tear in the bag used for QC testing without significantly deviating from the established normal sampling process and engaging in suspicious behavior.	
3	Bulk Liquid Storage	Score = 10	Score = 8	Score = 8	26	This step is significantly vulnerable. Tanks are accessible when empty. Since tanks are in an isolated part of the facility, a contaminant added after cleaning may not be detected prior to food being reintroduced into the tank. Anyone with legitimate access to the facility has access to the tanks.	Yes
4	Dry Food Storage	Score = 5 Three contaminated bags would generate approximately 600 potential deaths.	Score = 3	Score = 3	11	This step is not significantly vulnerable. Bags of ingredients are still sealed and any attempt to access would likely leave indications of tampering. When stored on the shelves, it is difficult to physically access the bags because the pallets are shrink-wrapped. There may be cases where a single pallet has been stored on the floor. An attacker could potentially access the top 3 bags on the pallet, but this would likely result in evidence of tampering. It would be difficult for an inside attacker to introduce enough contaminant into a bag in a way that would not be readily identified as suspicious. The attacker would have to remove some ingredient from the bag to introduce sufficient volumes of contaminant. There is a high chance any attempt to introduce a contaminant to the bags would be detected. This is not	No

Analyzing Results Exercise Worksheet							
(1) #	(2) Process Step	(4) Element 1: Score and Rationale	(5) Element 2: Score and Rationale	(6) Element 3: Score and Rationale	(7) Sum	(8) Explanation	(9) Actionable Process Step
						scored as a 1 because we consider that the inside attacker could successfully introduce a contaminant if given enough time.	
5	**Surge Tank**						
6	Ingredient Staging	Score = 5 Contamination of 3 bags would generate approximately 600 deaths.	Score = 3	Score = 3	11	Sealed bags of dry ingredients present significant access limitations. It would be difficult for an attacker, including an insider, to introduce enough contaminant into a bag in a way that would not be readily identified as suspicious. The attacker would have to remove some ingredient from the bag in order to introduce sufficient volumes of contaminant. There is a high chance any attempt to introduce a contaminant to the bags would be detected. This is not scored as a 1 because we consider that the attacker could have enough time to attempt to introduce a contaminant.	No

Analyzing Results Exercise Worksheet							
(1) #	(2) Process Step	(4) Element 1: Score and Rationale	(5) Element 2: Score and Rationale	(6) Element 3: Score and Rationale	(7) Sum	(8) Explanation	(9) Actionable Process Step
7	**Secondary Ingredient Addition**						
8	Water	Not assessed since Element 2 score = 1.	Score = 1	Not assessed since Element 2 = 1.	n/a	No significant vulnerability is present since Element 2 = 1. The water system is fully enclosed and pressurized (inherent characteristics). Therefore, this step is not accessible.	No
9	Mixing	Score = 8 Using FDA's representative contaminant, this will result in 8000 potential deaths (using LD50 contaminant dose/serving).	Score = 8	Score = 8	24	The mixer has a lid that is unsecured and the mixer operator periodically opens the lid to check on the status of mixing. The mixer is on the primary production floor and anyone already in the facility can enter the area. It would be relatively easy for an inside attacker to introduce a contaminant to the product during mixing either during the introduction of minor ingredients or during the mixing stage. The mixer operator is not constantly in the area, and there are times when the mixer area is not under observation.	Yes

Analyzing Results Exercise Worksheet							
(1) #	(2) Process Step	(4) Element 1: Score and Rationale	(5) Element 2: Score and Rationale	(6) Element 3: Score and Rationale	(7) Sum	(8) Explanation	(9) Actionable Process Step
10	**Forming**						
11	Rework	Score = 8 One mixing batch would potentially yield 4000 deaths.	Score = 8	Score = 8	24	Rework product is easily accessible because it is staged in bins with no inherent characteristics to limit access since the lids are not sealed and are easily opened. It would be relatively easy for an insider to add a sufficient volume of contaminant to the rework product. The attacker would have to act with minimal stealth to select a time when a mixer operator was not in the room to introduce a contaminant, which can be up to 6 hours per shift.	Yes
12	Cooking	Not assessed since scores for Elements 2 and 3 = 1.	Score = 1	Score = 1 .	n/a	Due to inherent characteristics, there is no access at this step. Cooker is enclosed for worker safety reasons. Serious injury would result if any attempt to adulterate the food at his point were attempted.	No
13	Cooling	Score = 3 See element 1 calculations	Score = 3	Score = 3	9	There is a space between the cooker and the cooler where access to the conveyed food is possible, but physical space limitations would make introduction of a contaminant difficult. Removing the access panel to access the food within the cooling tunnel would require specialized tools and time to work. There is no mixing of the product.	No

Analyzing Results Exercise Worksheet							
(1) #	(2) Process Step	(4) Element 1: Score and Rationale	(5) Element 2: Score and Rationale	(6) Element 3: Score and Rationale	(7) Sum	(8) Explanation	(9) Actionable Process Step
		for more detail.				An attacker would have to stand at the intake or discharge of the cooler for an extended period of time while applying the contaminant to the food, which would be suspicious. It is estimated that an individual would be able to stand at the entrance/exit of the cooler for less than a minute without being detected. This would likely result in detection of the attack.	
14	Conveying	Score = 3 See element 1 calculations for more detail.	Score = 8	Score = 3	14	Despite there being open access to the conveyor, there would not be a wide scale public health harm if an attack were attempted at this step. For part of its run, the conveyor is open and at ground level. For 50 feet, the conveyor runs at ground level prior to elevating to the ceiling as it moves food to packaging. During the span where the conveyor is at ground level there is a railing barrier that prevents people from inadvertently walking too closely to the belt, rollers, or the food being conveyed. The railing would require anyone attempting to access to food to reach over the railing and may prevent someone from being able to come in contact with the full width of the belt. Additionally, given the speed of the conveyor and the very short time an attacker would have to introduce a contaminant without potentially being detected it would be difficult to introduce enough contaminant to a large enough volume of food to result in wide scale public health harm.	No

Analyzing Results Exercise Worksheet							
(1) #	(2) Process Step	(4) Element 1: Score and Rationale	(5) Element 2: Score and Rationale	(6) Element 3: Score and Rationale	(7) Sum	(8) Explanation	(9) Actionable Process Step
15	Packaging	Score = 3 An attacker accessing the intake of the packager could contaminate only 5 packages.	Score = 3	Score = 3	9	An attack at this step would adulterate individual packages, and not result in wide scale public health harm. Access is difficult but possible at the point where morsels drop from the weigh scales into the packaging machine. An attacker would need to bring a stool or ladder to reach the intake. As mentioned in Element 1, only individual packages are at risk. There is no mixing. After a short time, the attacker's actions would be detected because it is a safety hazard to reach up into the intake as food is falling into the packager.	No
16	Casing	Not assessed since Element 2 score = 1.	Score = 1	Not assessed since Element 2 score = 1.	n/a	No significant vulnerability is present since Element 2 = 1. Product is in multiple layers of tamper-evident packaging that eliminates access to the food to any attacker.	No
17	Finished Product Storage	Not assessed since Element 2 score = 1.	Score = 1	Not assessed since Element 2 score = 1.	n/a	No significant vulnerability is present since Element 2 = 1. Product is in multiple layers of tamper-evident packaging that eliminates access to the food to any attacker.	No
18	Shipping	Not assessed since Element 2 score = 1.	Score = 1	Not assessed since Element 2 score = 1.	n/a	No significant vulnerability is present since Element 2 = 1. Product is in multiple layers of tamper-evident packaging that eliminates access to the food to any attacker.	No

Lesson 7: Analyzing Results to Identify Actionable Process Steps (continued)

Exercise: Analyzing Results (continued)

Directions: Use the **Rank Order Exercise Worksheet** (below) to place your three assigned process steps in order with the other fifteen steps from highest sum total to lowest. Remember to place process steps that were not summed due to one or more elements scoring a 1 at the bottom of the rank order. *There will two extra empty rows in the worksheet after you have included your three steps.*

Rank Order Worksheet		
Process Step #	**Process Step Name**	**Sum Total Score**
1	Bulk Liquid Receiving	26
3	Bulk Liquid Storage	26
9	Mixing	24
11	Rework	24
14	Conveying	14
4	Dry Food Storage	11
6	Ingredient Staging	11
13	Cooling	9
15	Packaging	9
2	Dry Food Receiving	n/a
8	Water	n/a
12	Cooking	n/a
16	Casing	n/a
17	Finished Product Storage	n/a
18	Shipping	n/a

Lesson 8: The Hybrid Approach

Lesson 8 Notes: