

Food Defense Plan Development

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โครงการก้าวข้ามมาตรฐานสู่ความเป็นเลิศการผลิตและโลจิสติกส์

โปรแกรมการจัดการโลจิสติกส์ (นานาชาติ)

วิทยาลัยอุตสาหกรรมการบินนานาชาติ สถาบันเทคโนโลยีพระจอมเกล้าเจ้าคุณทหารลาดกระบัง

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การสอนและให้คำปรึกษาการส่งออกและนำเข้าสินค้าอาหารสหรัฐอเมริกา

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การจดทะเบียนโรงงาน FFR / FCE/ SID กับ U.S. FDA

การจัดทำ Food Safety Plan ตามระเบียบ Preventive Controls for Human Food

การจัดทำ Food Safety Plan ตามระเบียบ Preventive Controls for Animal Food

การดำเนินการตามระเบียบ Produce Safety

การดำเนินการตามระเบียบ Foreign Supplier Verification Programs : FSVP

การจัดทำ Food Defense Plan ตามระเบียบ Mitigation Strategies to Protect Food Against Intentional Adulteration

การจัดทำเอกสารสินค้าอาหารตามกฎหมาย

การแก้ไขปัญหากรณีสินค้าถูกกักหรืออยู่ใน Red List

กฎหมายที่เกี่ยวข้องการส่งออกอาหารไปสหรัฐอเมริกาใน Platform Online (กรณี ไม่ใช่ Personal Consumption)

Requirements for Additional Traceability Records for Certain Foods

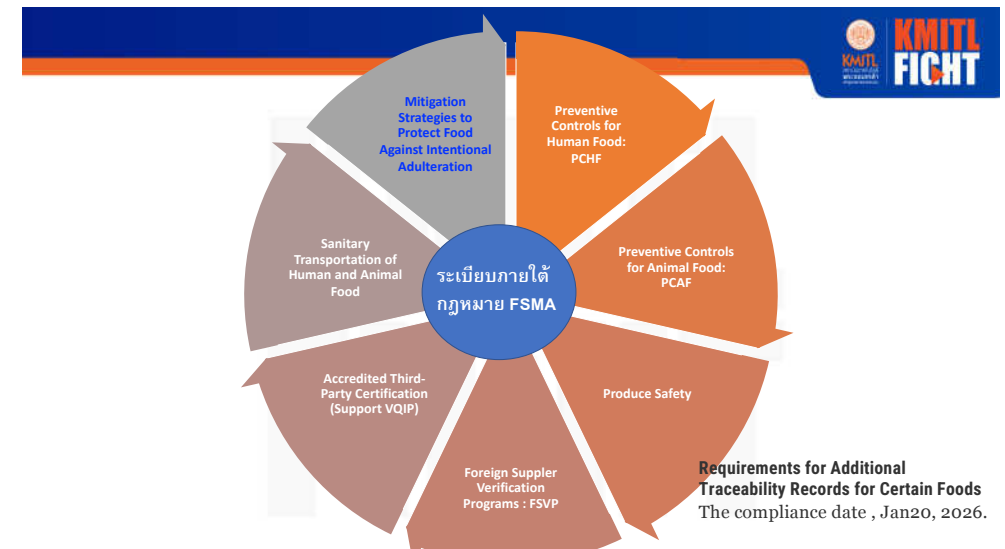
IATA Perishable Air Cargo Logistics

Digitization in Food Safety

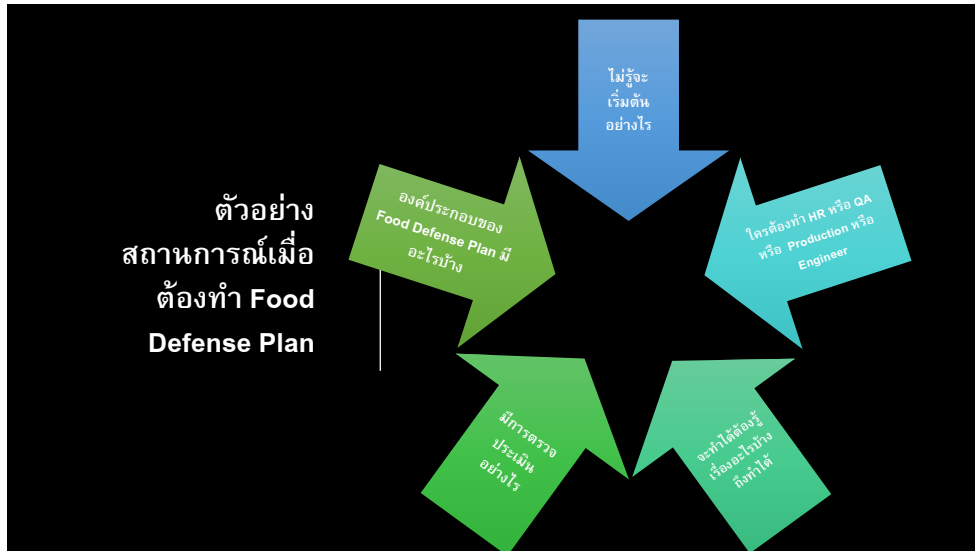
New Era for Food Safety: FDA's Blueprint for the Future



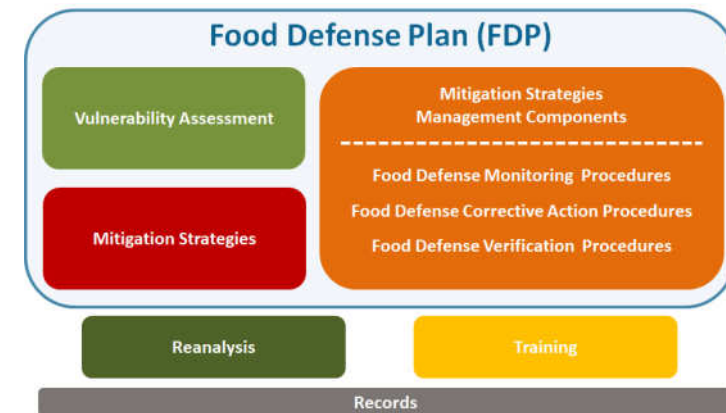
History of Food Defense Vulnerability Assessments



Requirements for Additional Traceability Records for Certain Foods
The compliance date , Jan20, 2026.



General Requirements of the Intentional Adulteration (IA) Rule



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Source: FSPCA Conducting Vulnerability Assessments Manual

Inherent Characteristics: Examples



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

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Source: FSPCA Conducting Vulnerability Assessments Manual

Inside Attacker



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

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Source: FSPCA Conducting Vulnerability Assessments Manual

Assumptions Regarding an Inside Attacker



- **Legitimate access to the facility** (e.g., an employee, contractor, driver, authorized visitor, etc.);
- **A basic understanding of facility operations and the food product(s) under production;**
- **The ability to acquire and deploy a contaminant that is:**
 - highly lethal,
 - capable of withstanding the food production process, and
 - undetectable via simple observation if added to food; and
- **The intent to cause wide scale public health harm**



Source: FSPCA Conducting Vulnerability Assessments Manual

Preliminary Steps



- Assembling a food defense team
- Describing the product
- Developing a process flow diagram
- Describing the process steps



Source: FSPCA Conducting Vulnerability Assessments Manual

Step 1. Assemble a Food Defense Team



- Team approach:
- Individuals with different specialties and experiences:



Source: FSPCA Conducting Vulnerability Assessments Manual

Step 2. Describe Product Under Evaluation



- Product name
- Product description
- Ingredients
- Intended use
- Intended consumers
- Storage and distribution
- Serving size
- Any other details that may be helpful for understanding the product

Sample Almond, Cranberry Energy Bar Product Description	
Product Name(s)	Almond, Cranberry Energy Bar
Product Description, including Important Food Safety Characteristics	This product is a ready-to-eat energy bar packed in a pouch for on-the-go eating. The bar is made of almonds, cranberries, and other ingredients. It is a healthy snack that provides energy and is suitable for consumption by adults and children.
Ingredients	Almonds, cranberries, other ingredients
Packaging Used	Individual pouches, 100g net weight
Intended Use	Ready-to-eat snack
Intended Consumers	General consumers
Shelf Life	One year
Labeling Instructions	None
Storage and Distribution	Almonds, not to exceed 100g

Source: Food Safety Prevention Controls Alliance (FSPCA) Product Description for Illustration purposes only.

Source: FSPCA Conducting Vulnerability Assessments Manual

Step 3. Develop a Process Flow Diagram

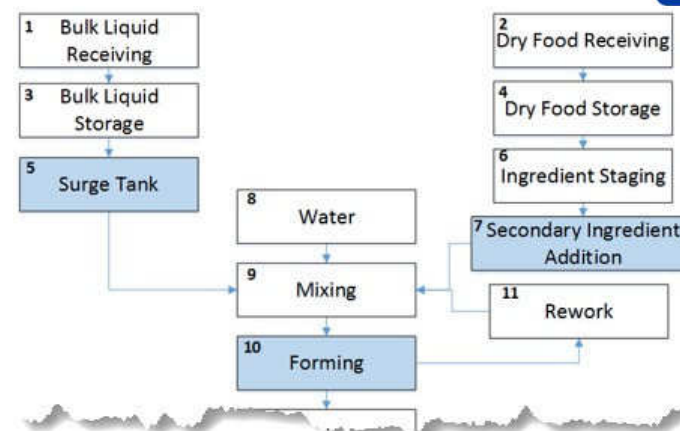


- Flow diagrams provide
 - Include all the process steps within the facility's control
 - Include reworked product, by-product, and diverted product, if applicable
- Process flow diagrams may already exist at your facility

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Source: FSPCA Conducting Vulnerability Assessments Manual

Example Process Flow Diagram



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Source: FSPCA Conducting Vulnerability Assessments Manual

Step 4. Describe Process Steps Under Evaluation



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

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Source: FSPCA Conducting Vulnerability Assessments Manual

Contents of a Food Defense Plan



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Source: FSPCA Conducting Vulnerability Assessments Manual

Common vulnerabilities can be organized into generalized activity groups

- I. Bulk Liquid Receiving and Loading
- II. Liquid Storage and Handling
- III. Secondary Ingredient Handling
- IV. Mixing and Similar Activities

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Source: FSPCA Conducting Vulnerability Assessments Manual

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

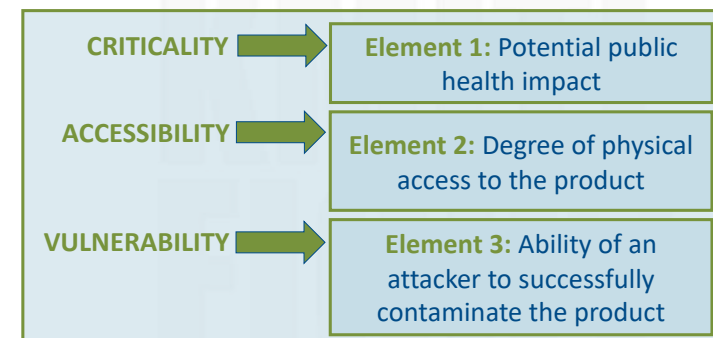
18

Source: FSPCA Conducting Vulnerability Assessments Manual

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Source: FSPCA Conducting Vulnerability Assessments Manual



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Source: FSPCA Conducting Vulnerability Assessments Manual

Key Activity Types



- I. Bulk Liquid Receiving and Loading
- II. Liquid Storage and Handling
- III. Secondary Ingredient Handling
- IV. Mixing and Similar Activities

Large public health impact

- High volume of food impacted

Increased access

- Not tamper-evident or containers breached
- Unsecured equipment

Increased vulnerability

- Contaminant would be evenly distributed through food
- Single-worker areas
- Extended time where food is open and accessible
- Sufficient contaminant could be added

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Source: FSPCA Conducting Vulnerability Assessments Manual

Vulnerability Assessments: Key Activity Types & Three Elements



- I. Bulk Liquid Receiving and Loading
- II. Liquid Storage and Handling
- III. Secondary Ingredient Handling
- IV. Mixing and Similar Activities

E1 Large public health impact

- High volume of food impacted

E2 Increased access

- Not tamper-evident or containers breached
- Unsecured equipment

E3 Increased vulnerability

- Contaminant would be evenly distributed through food
- Single-worker areas
- Extended time where food is open and accessible
- Sufficient contaminant could be added

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Source: FSPCA Conducting Vulnerability Assessments Manual

Element 1 – Evaluating Potential Public Health Impact



Element 1 – Evaluating Potential Public Health Impact

Evaluate Element 1 Using:

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

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Source: FSPCA Conducting Vulnerability Assessments Manual

Potential Public Health Impact Scoring Table



Table 1. Potential Public Health Impact

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

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Source: FSPCA Conducting Vulnerability Assessments Manual

Volume of Food at Risk



Evaluate Element 1 Using:

1. Volume of Food at Risk

OR

2. Representative Contaminant

OR

3. Contaminant-Specific Analysis

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Source: FSPCA Conducting Vulnerability Assessments Manual

Calculating Volume of Food at Risk



Calculating Volume of Food at Risk

A Process Step	B Batch Size	C Amount of product (ingredient) in final serving	D Servings per Batch $B \div C$	E Score from Table 1	F Notes
Ingredient storage tank					

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Source: FSPCA Conducting Vulnerability Assessments Manual

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



Worksheet 1-D: Calculating Volume of Food at Risk

A Process Step	B Batch Size	C Amount of product (ingredient) in final serving	D Servings per Batch $B \div C$	E Score from Table 1	F Notes
Ingredient storage tank	50,000 gallons	1 cup	800,000	10	16 cups/gallon

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

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Source: FSPCA Conducting Vulnerability Assessments Manual

Element 2: Evaluating Degree of Physical Access



Element 2 – Evaluating Degree of
Physical Access to the Product

AND

Element 3 – Evaluating the Ability
to Successfully Contaminate
the Product

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Source: FSPCA Conducting Vulnerability Assessments Manual

Physical Barriers



- Can an attacker get to the food?

- Physical barriers can reduce or eliminate access to the food at the point, step, or procedure under evaluation

- Some examples include shields, pressurized or enclosed systems, inward

opening hatches, equipment safety features (e.g., safety guards)



Source: FSPCA Conducting Vulnerability Assessments Manual

Scoring Degree of Physical Access to the Product



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

Description	Score
Easily Accessible. <ul style="list-style-type: none"> • 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. <ul style="list-style-type: none"> • 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.	5

Source: FSPCA Conducting Vulnerability Assessments Manual

Element 3: Ability to Successfully Contaminate the Products



Element 2 – Evaluating Degree of Physical Access to the Product

AND

Element 3 – Evaluating the Ability to Successfully Contaminate the Product

Source: FSPCA Conducting Vulnerability Assessments Manual

Evaluate the Ability to Successfully Contaminate



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

Important Considerations

Time and visibility	Suspicious activity	Uniform mixing	Quantity of contaminant
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Source: FSPCA Conducting Vulnerability Assessments Manual

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

Description	Score
Highest Ease of Successful Contamination. <ul style="list-style-type: none"> • 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. <p>The process is seldom observed, and an inside attacker would work with little to no time limitations.</p>	8

Source: FSPCA Conducting Vulnerability Assessments Manual

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Applying the Hybrid Approach

Facilities have the flexibility to use a hybrid approach, which combines:

1. The three fundamental elements with
2. The KAT method

Source: FSPCA Conducting Vulnerability Assessments Manual

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Applying the Hybrid Approach

- Step 1:** Assess each step for alignment with any KATs
- Step 2:** Use the three elements to conduct a more in-depth evaluation of some of the steps
- Step 3:** Determine if any of the steps identified as fitting within KATs are not APSs based on the three elements evaluation

Source: FSPCA Conducting Vulnerability Assessments Manual

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

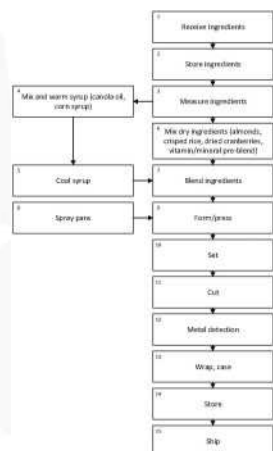
Source: FSPCA Conducting Vulnerability Assessments Manual

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Cold Pressed Almond Cranberry Energy Bar



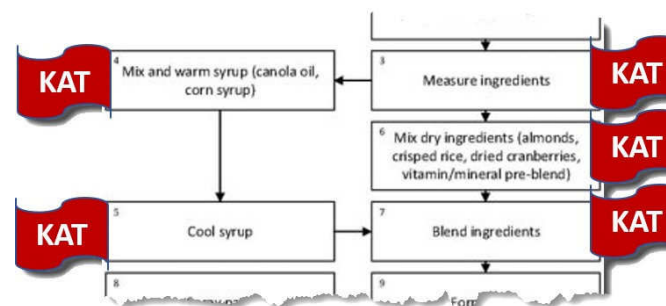
A full-page diagram for viewing is in your Participant Manual



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Source: FSPCA Conducting Vulnerability Assessments Manual

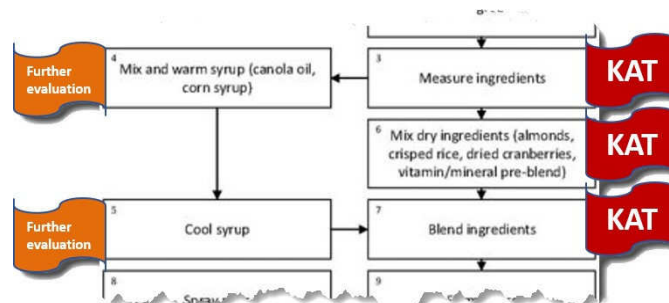
Process Steps that Aligned with KATs



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Source: FSPCA Conducting Vulnerability Assessments Manual

Process Steps Further Evaluated Using the 3 Elements



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Source: FSPCA Conducting Vulnerability Assessments Manual

Process Steps Further Evaluated Using the 3 Elements (continued)



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

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

Cool Syrup – KAT (Liquid Storage and Handling)

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

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Source: FSPCA Conducting Vulnerability Assessments Manual

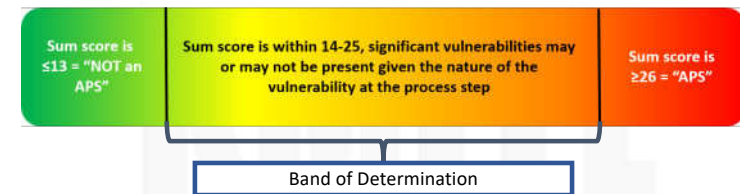
Actional Process Steps (APSs)



- 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.

Source: FSPCA Conducting Vulnerability Assessments Manual

Using Sum Scores to Identify Actional Process Steps (APSs)



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

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Source: FSPCA Conducting Vulnerability Assessments Manual

Explaining Your Decisions



Example Decision Explanations		
Process Step	Explanation	APS or Not an APS
A	The public health impact is high. Open and accessible ingredients are available to an inside attacker. No inherent characteristics limit access, and ingredients are unobserved for extended times.	APS
B	This step is significantly vulnerable because the score ≥ 26 .	APS
C	No significant vulnerability is present since Element 2 = 1	Not an APS
D	Access is difficult. An attack at this step would adulterate individual packages, and not result in wide scale public health harm.	Not an APS

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Source: FSPCA Conducting Vulnerability Assessments Manual

Documenting the Vulnerability Assessment



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

(1) #	(2) Process Step	(3) Process Step Description	(4) Element 1: Score and Rationale	(5) Element 2: Score and Rationale	(6) Element 3: Score and Rationale	(7) Sum	(8) Explanation	(9) Actionable Process Step

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Source: FSPCA Conducting Vulnerability Assessments Manual



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- | (1)
| (2)
Process Step | (4)
Element 1: Score and Rationale | (5)
Element 2: Score and Rationale | (6)
Element 3: Score and Rationale | (7)
Sum | (8)
Explanation | (9)
Actionable Process Step |
|----------|---------------------|---|--|---|------------|--|--------------------------------|
| 4 | Mix and Warm Syrup | Not assessed because Element 2 score = 1. | Score = 1
Because of inherent characteristics, there is no access at this step. The mixer is enclosed for worker safety reasons and accessing the tank would require special tools and disassembling equipment. | Not assessed because Element 2 score = 1. | N/A | While this step fits within the KAT "Mixing and Similar Activities," no significant vulnerability is present because this step has no means of physical access | No |

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Source: FSPCA Conducting Vulnerability Assessments Manual



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- | (1)
| (2)
Process Step | (4)
Element 1: Score and Rationale | (5)
Element 2: Score and Rationale | (6)
Element 3: Score and Rationale | (7)
Sum | (8)
Explanation | (9)
Actionable Process Step |
|----------|---------------------|--|--|---|------------|--|--------------------------------|
| 5 | Cool Syrup | Score = 5
Using a representative contaminant, the cooling tank holds enough liquid ingredient to generate a potential public health impact of 900 deaths. | Score = 3
Because of inherent characteristics, there is limited access at this step. The cooling tank is enclosed, and access is only possible when product is not in the tank. | Score = 3
Using a representative contaminant, it would be difficult to bring enough contaminant into the area and have sufficient time to get the contaminant into the tank. | 11 | While this step fits within the KAT "Liquid Storage and Handling," no significant vulnerability is present because score < 14. | No |

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Source: FSPCA Conducting Vulnerability Assessments Manual



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Source: FSPCA Conducting Vulnerability Assessments Manual



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FIGHT
AGAINST
CORRUPTION

Current Challenges



- การมอบหมายผู้รับผิดชอบ Food Defense Plan ที่เหมาะสม
- การประเมินภาวะเสี่ยง (Vulnerability Assessments) ควรใช้วิธีไหนดี
- การเขียนอธิบายการตัดสินใจให้ระดับคะแนนที่เชื่อมโยงกับ Inherent และ Inside Attackers
- เข้าใจวิธีการประเมินแล้วแต่ยังทำ Food Defense Plan ไม่ได้
- การกำหนด Mitigation Strategies ที่เหมาะสม
- การกำหนดวิธีการ Monitoring ที่เหมาะสม
- การเขียนอธิบายรายละเอียด Food Defense Plan และบันทึก
- อื่นๆ

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โครงการก้าวข้ามมาตรฐานสู่ความเป็นเลิศการผลิตและโลจิสติกส์

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