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# Key Activity Types

Click to Begin

## Course Description



This training course is targeted towards food professionals using FDA's Key Activity Type (KAT) method to conduct their facility's vulnerability assessment (VA). The VA is a required part of the facility's food defense plan mandated under FDA's Mitigation Strategies to Protect Food Against Intentional Adulteration (IA) rule. By successfully completing this course, the learner will have satisfied the training requirement to conduct a VA using the KAT method.



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## Disclaimer



Please note that this course satisfies the training requirement to conduct a VA using the KAT method ONLY. Any deviation from the KAT method described in this course will necessitate that the individual take a vulnerability assessment training recognized as adequate by the FDA, or be otherwise qualified through job experience to conduct a VA using another VA methodology. See the Resources tab for information about other available trainings.

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## Course Modules



### This course is divided into four modules:

- Module 1: Food Defense Overview and Introduction to the Intentional Adulteration Final Rule
- Module 2: Introduction to the Key Activity Type Vulnerability Assessment Method
- Module 3: Preparing to Use the Key Activity Type Method
- Module 4: Using the Key Activity Type Method

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## Course Objectives



**After completing this course, you will be able to:**

1. Explain the importance of food defense.
2. Understand the basic requirements of FDA's intentional adulteration rule.
3. Identify why using the key activity type method is an appropriate method of conducting a vulnerability assessment.
4. Describe each of the key activity types.
5. Perform preparatory steps to use the key activity type method for conducting a vulnerability assessment.
6. Conduct a vulnerability assessment using key activity types.

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## **Module 1: Food Defense Overview and Introduction to the Intentional Adulteration Final Rule**

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## Objectives



Welcome to Module 1: Food Defense Overview and Introduction to the Intentional Adulteration Final Rule

### After completing this module, you will be able to:

1. Explain food defense.
2. Explain the general requirements of the Intentional Adulteration rule.
3. Describe the contents of a food defense plan.
4. Explain the vulnerability assessment requirements.
5. Define significant vulnerabilities.
6. Define actionable process steps.
7. Explain the training and qualifications required to conduct vulnerability assessments.

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## What is Intentional Adulteration?



- Intentional adulteration is 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.
- FDA issued a final regulation, Mitigation Strategies to Protect Food Against Intentional Adulteration (21 CFR Part 121), which requires covered facilities to identify and protect their most vulnerable points against intentional adulteration.

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## What is Food Defense?



- Food defense is the effort to protect food from intentional acts of adulteration intended to cause wide scale public health harm.
- These efforts include measures taken to significantly minimize or prevent an intentional adulteration event.
- The IA rule requires covered facilities to develop and implement a food defense plan. This is a fundamental step towards an effective food defense program.

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## Why is Food Defense Important?



- Intentional adulteration of the food supply can result in wide scale public health harm including severe illness and death.
- Other potential impacts can include public loss of confidence in the food supply, damage to a company's reputation, and job losses.
- Malicious individuals, including terrorists, may see this as an opportunity to harm the public and further their cause.
- The primary purpose of the food defense plan is to prevent intentional adulteration.

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## General Requirements of the IA Rule



### Definitions:

During this course, you will see certain words underlined in bolded blue. Click on these words to read their definitions.



- Food defense plan, which includes:
  - Vulnerability assessment to identify **actionable process steps (APSs)**.
  - Identification and implementation of mitigation strategies.
  - **Mitigation strategies** management components:
    - Food defense monitoring
    - Food defense corrective actions
    - Food defense verification
- Reanalysis:
  - Reanalysis is required at certain times and under certain conditions.
- Training
- Records


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## For More Information on the IA Rule Requirements



### IA Rule Fact Sheet

- Click here to learn more about the IA rule.



### Additional Resources:

- [IA rule](#)
- [FDA IA rule Fact Sheet](#)
- [IA Rule Overview Requirements Online Course](#)

FDA AT A GLANCE



THE FUTURE IS NOW

**KEY REQUIREMENTS:**  
**FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration**

The FDA Food Safety Modernization Act (FSMA) final rule is aimed at preventing intentional adulteration from acts intended to cause wide-scale harm to public health, including acts of terrorism targeting the food supply. Such acts, while not likely to occur, could cause death, economic devastation of the food industry.

**KEY PROVISIONS**

While this is the first time that companies are required to create a food defense plan, the FDA has taken an approach similar to Hazard Analysis Critical Control Point (HACCP), an approach adopted by the industry.


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## Requirements of the VA



- A VA is a systematic assessment of points, steps, or procedures to identify and rank **vulnerabilities** to intentional adulteration.
- The goal of the VA is to:
  - Distinguish vulnerabilities from **significant vulnerabilities**.
  - Identify APSs.
- Each facility must conduct a VA for each type of food produced.
  - Similar products and processes may be grouped together and assessed as one.

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## Requirements of the VA (continued)



- VAs must consider, for each point, step, or procedure, the following three elements, at a minimum:
  - The potential public health impact if a contaminant were successfully added to the product at that step.
  - The degree of physical access to the product.
  - The ability of an attacker to successfully contaminate the product.
    - These will be referred to as "the three fundamental elements" or "the three elements."
- The KAT method is considered an appropriate method to conduct a VA. This will be described in detail in upcoming modules.

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## Requirements of the VA (continued)



- When conducting a vulnerability assessment, the IA rule requires the consideration of an inside attacker.
- An inside attacker should be assumed to have:
  - 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.
  - The intent to cause wide scale public health harm.


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## Requirements of the VA (continued)



- Regardless of the outcome, the VA must be written and must include an explanation as to why each point, step, or procedure either was or was not identified as an APS.

### 1. Worksheet 1-C: Vulnerability Assessment Analysis Summary

PRODUCT(S): \_\_\_\_\_  
 FACILITY NAME: \_\_\_\_\_  
 ADDRESS: \_\_\_\_\_  
 SIGNED DATE: \_\_\_\_\_

(1) #	(2) Process Step	(3) Process Description	(4) Vulnerability Assessment Method	(5) Explanation	(6) Actionable Process Step


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## Significant Vulnerabilities and APSs



- A **significant vulnerability** is a vulnerability in a food process that, if exploited, could be expected to cause wide scale public health harm.
- **APSs** are points, steps, or procedures in a food process where a significant vulnerability exists.
  - A point, step, or procedure refers to any activity related to manufacturing, processing, packing, or holding of a food product.
- Another way to think about APSs is that once a facility conducts a VA these are the steps that are identified as most vulnerable to intentional adulteration.

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## Mitigation Strategies



- Mitigation strategies must be identified and implemented at APSs.
- Mitigation strategies are measures that are designed to reduce or eliminate significant vulnerabilities at APSs.

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## Training and Qualifications Required for the VA



### For More Information

- For information on "Vulnerability Assessment" training, click on the "Resources" tab above

- Individuals conducting the VA must:
  - be a **qualified individual** (QI), and
  - successfully complete VA training received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience.
- As noted earlier, this training will ONLY qualify you to conduct a VA using the KAT method.

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## Module 1 Summary



### Congratulations! You have now completed Module 1.

Let's review what you have learned before you move on to the knowledge checks.

In this module, you learned to:

1. Explain food defense.
2. Explain the general requirements of the Intentional Adulteration rule.
3. Describe the contents of the food defense plan.
4. Explain the vulnerability assessment requirements.
5. Define significant vulnerabilities.
6. Define actionable process steps.
7. Explain the training/qualifications required to conduct vulnerability assessments.

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## Module 2: Introduction to the Key Activity Type Vulnerability Assessment Method

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### Objectives



#### Welcome to Module 2: “Introduction to the Key Activity Type Vulnerability Assessment Method”

#### After completing this module, you will be able to:

1. Summarize the origins of the key activity types.
2. Recognize why using key activity types is an appropriate method to conduct a vulnerability assessment.
3. Describe bulk liquid receiving and loading.
4. Describe liquid storage and handling.
5. Describe secondary ingredient handling.
6. Describe mixing and similar activities.

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## KAT Method Background



- Since 2004, FDA has conducted VAs and identified mitigation strategies to protect the food system from acts of intentional adulteration under the authority and direction of Homeland Security Presidential Directive-9 (HSPD-9).
- FDA has conducted numerous food defense VAs on a wide variety of foods and processes with industry, academia, and other government partners.
- This VA research forms the foundation of FDA's food defense program and informed the development of the IA rule.
- Over the course of FDA conducting VAs, trends of vulnerable points were identified, which led to the identification of the KATs.

Sources: *Homeland Security Presidential Directive-9 (HSPD-9)*, issued Jan 2004; *VA public summary documents*.

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## KAT Method Background (continued)



In response to the passage of the Food Safety Modernization Act (FSMA), FDA analyzed the VA data and found:

- Certain general activities that frequently occur in food processing operations consistently ranked as the most vulnerable, regardless of the commodity being assessed. These became the KATs.
- A particular food is generally not more inherently vulnerable than other foods to intentional adulteration.
- The main drivers of vulnerability are the processing steps and procedures that are used as food is moved from farm to table.

Sources: *Food Safety Modernization Act (FSMA)*, issued Jan 2011; *VA public summary documents*.

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## KAT Method Background (continued)



- From the results of the analysis, FDA concluded that four groups of processing steps consistently scored highly in the VAs.
- These four groups of processing steps were identified as the KATs.
- At the conclusion of this analysis, FDA produced a detailed report on the development of the Key Activity Types. You can access a link to this report in Resources above.

**Bulk Liquid Receiving and Loading**



**Liquid Storage and Handling**



**Secondary Ingredient Handling**



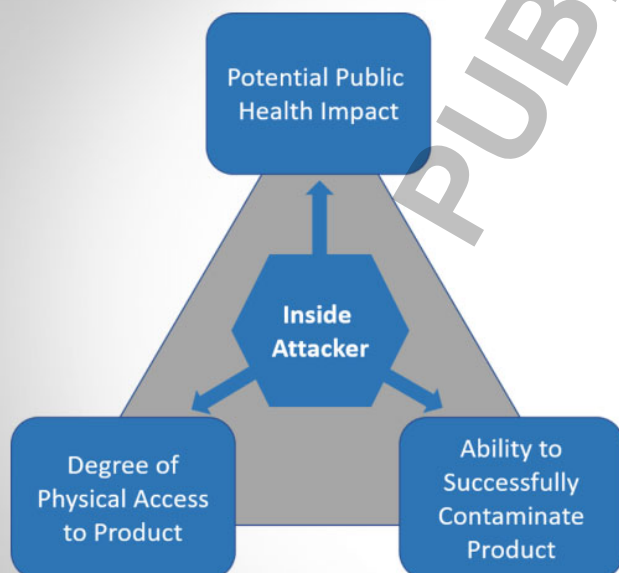
**Mixing and Similar Activities**



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## Why KAT is an Appropriate Method



- FDA's VAs included the consideration of the three required elements and the possibility of an inside attacker as an underlying consideration in the evaluation of all three elements.



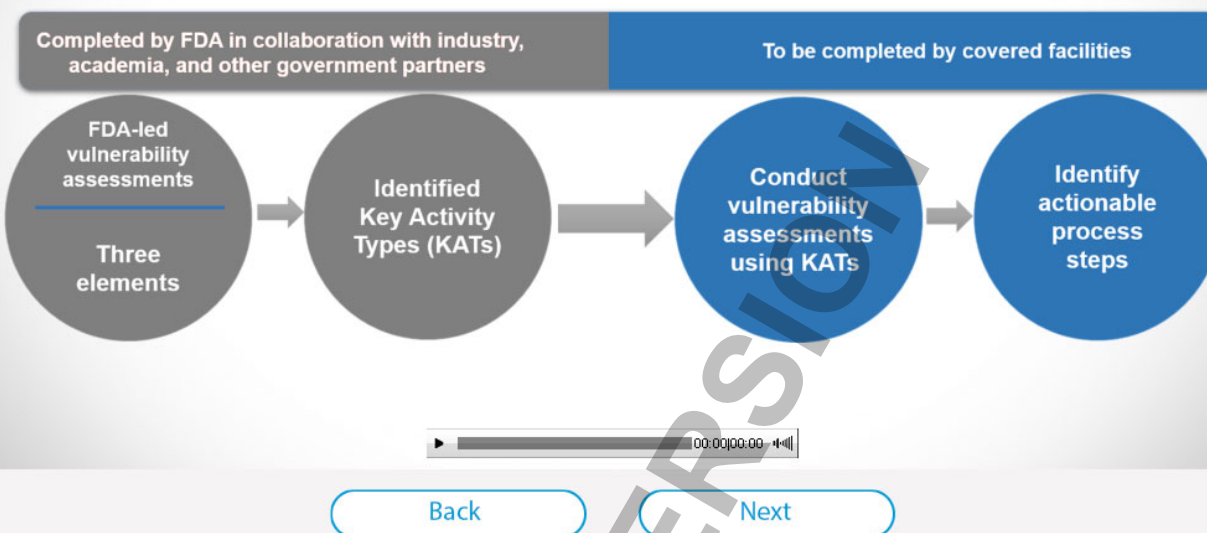
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## Why KAT Is an Appropriate Method (continued)



- Using KATs are an efficient, science-based approach that companies may use to identify APSs.



## Bulk Liquid Receiving and Loading



- Bulk liquid receiving refers to the inbound movement of liquid ingredients into a facility for its use in the food production process.
  - Bulk liquid loading refers to the outbound shipping of liquid intermediate or finished liquid product from a facility onto a transport vehicle for further processing or use.
  - Bulk liquid receiving and loading leads to a high probability of ingredient mixing and thus an even dispersal of a potential contaminant throughout the liquid.
- These steps include large volumes of liquid and frequent worker access to the liquid and/or handling equipment such as hoses.
  - Activities that do not fall under this KAT include the receiving or loading of sealed jugs, drums, jars, and totes.



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## Liquid Storage and Handling



- Liquid storage and handling refers to a step when a bulk or non-bulk liquid is contained in storage tanks or silos or in holding, surge, metering, or other types of intermediate processing tanks.
- Liquid storage refers to any storage silo or tank where liquid product may be stored prior to introduction into the product stream or prior to loading for outbound shipping.
- Bulk or non-bulk tanks can be used to store liquid ingredients, hold liquid product for sample testing and other quality control activity, or to control flow rates of liquid ingredients or product through the production system.
- Handling tanks also include tanks or totes where the tamper-evident seals are opened and the container itself is used for holding.
- At these steps, there is a high probability of mixing due to agitation which would likely cause even dispersion of a contaminant and likely application to a large amount of servings.

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## Secondary Ingredient Handling



- Includes any point, step, or procedure where dry or liquid secondary ingredients (e.g., inclusions, minor ingredients, processing aids, and food additives, etc.) are manipulated by human contact prior to or during addition to the product stream:
  - [Staging](#)
  - [Preparation](#)
  - [Addition](#)
  - [Rework](#)

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## Secondary Ingredient Handling (continued)



- Includes the storage of partially used, open containers of secondary ingredients where the tamper-evident packaging has been breached.
- Does not include computer metering or automatic weighing, sizing, batching, or measuring so long as the process does not require the active involvement of a person.
- These activities are generally open, accessible points at which a contaminant may be added, then distributed into a larger volume of the main product flow.

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## Mixing and Similar Activities



A point, step, or procedure where the primary purpose or result is:

- mixing (i.e., to blend a powder, dough, or liquid ingredient together).
- homogenizing (i.e., to reduce the particle size of an ingredient and disperse it throughout a liquid).
- grinding (i.e., to reduce the particle size of a solid ingredient or mass to a smaller granularity).
- coating (i.e., to layer a powder or liquid onto the surface of a product, such as a batter, breading, glazing, or flavoring).

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## Mixing and Similar Activities (continued)



- Frequently includes use of equipment such as mixers, homogenizers, blenders, cascade-style breaders and other cascade-style applicators where unused coating is continuously recycled and reapplied, mills, grinders, and pulverizers.
- Successfully added contaminants at this step would generally be evenly dispersed throughout product.
- Accessibility through access ports, lids, in-feed conveyors, flumes etc.

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## Module 2 Summary



### **Congratulations! You have now completed Module 2.**

Let's review what you have learned before you move on to the knowledge checks.

In this module, you learned to:

1. Summarize the origins of the key activity type.
2. Recognize why using key activity type is an appropriate method to conduct a vulnerability assessment.
3. Describe bulk liquid receiving and loading.
4. Describe liquid storage and handling.
5. Describe secondary ingredient handling.
6. Describe mixing and similar activities.

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## Module 3: Preparing to Use the Key Activity Type Method

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### Objectives



#### Welcome to Module 3: “Preparing to Use the Key Activity Type Method”

#### After completing this module, you will be able to:

1. Assembling a food defense team.
2. Describing the product under evaluation.
3. Developing a process flow diagram.
4. Describing the process steps under evaluation.
5. Grouping similar products.

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## Introduction to Preliminary Steps



- Preliminary steps will help you prepare, organize, and conduct your VA using the KATs in an efficient way. They are:
  - Assembling your food defense team
  - Describing the product under evaluation
  - Developing a process flow diagram
  - Describing the process steps under evaluation
  - Grouping similar products
- These preliminary steps are not required by the IA rule, but you may find them helpful.
- Facilities may find that they have already completed some or all of these preliminary steps for other purposes, which may be leveraged to maximize efficiency and reduce duplicate efforts.

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## Assemble the Food Defense Team



- Your food defense team may include your QI(s) and people with expertise in day-to-day operations of your facility.
- Facilities have the flexibility to determine the composition/size of the food defense team.
  - At a minimum, you must have a QI.
- Having a multi-disciplinary food defense team is recommended, but not required.

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## Describe Product Under Evaluation



- A product description helps team members understand characteristics of the product that may impact food defense, for example, whether or not it has tamper-evident seals.
  - See the sample Almond, Cranberry Energy Bar Product Description on the right-hand side of the screen.
  - Feel free to use any product descriptions you already have.

<b>Product Name(s)</b>	<b>Almond, Cranberry Energy Bar</b>
<b>Product Description, including Important Food Safety Characteristics</b>	This product is a ready to eat energy bar packed in a pouch for on-the-go eating. The low water activity makes the product shelf stable. Processing involves dry mixing and forming with no process lethality step.  Water activity $\leq 0.65$
<b>Ingredients</b>	Corn syrup, blanched/slivered almonds, crisped rice, dried cranberries, canola oil, pan release agent (soy lecithin), vitamin and mineral pre-blend
<b>Packaging Used</b>	Metalized polyethylene film, individual retail package with label
<b>Intended Use</b>	Ready-to-eat bars
<b>Intended Consumers</b>	General consumption
<b>Shelf Life</b>	One year
<b>Labeling Instructions</b>	None
<b>Storage and Distribution</b>	Ambient, not to exceed 90°F

FDA. (2017). *Food safety: It's especially important for at-risk groups*. Retrieved from <https://www.fda.gov/food/foodborneillnesscontaminants/peopleatrisk/ucm352830.htm>

Sources:  
Food Safety Preventive Controls Alliance (FSPCA), Product Description for illustrative purposes only.



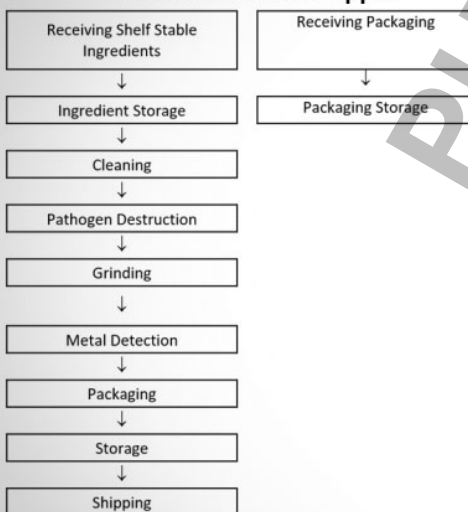
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## Produce a Process Flow Diagram



### Sample Food Processing Flow Diagram for Ground Black Pepper



- You may use an existing flow diagram.
- List or draw a diagram of each point, step, or procedure.
- This should cover all process steps in the food operation that the facility performs from receipt of ingredients through loadout of finished product.
- Processes and procedures that are not part of the food operation do not need to be included in the flow diagram (e.g., utilities).

Source: Food Safety Preventive Controls Alliance (FSPCA), Food Processing Flow Diagram for illustrative purposes only.



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## Describe Process Steps Under Evaluation



### Example of a Process Description

#### Process Description – Plain, Cheese and Cheese Biscuit Omelet

##### Receiving Ingredients and Packaging:

Ingredients and raw materials are purchased from reputable suppliers that comply with internationally recognized food safety and quality systems. For each ingredient, the same brand is used consistently to minimize variation. Ingredients are stored according to manufacturers' recommendations when specified.

- **Receiving packaging:** Corrugated shippers, paperboard trays and plastic wrap are received in bulk. Specifications require food grade material for trays and plastic wrap that is compatible with frozen storage of food products. Labeled cartons are reviewed for conformance with product allergen requirements and ingredients.
- **Receiving shelf stable ingredients:**
  - *Salt:* Received in 10-pound bags from our distributor. Specifications require food grade salt.
  - *Pan release oil:* The pan release oil contains soybean oil, soy lecithin and natural flavor. It is received from our distributor in 10-gallon jugs.

Source: Food Safety Preventive Controls Alliance (FSPCA), Partial Process Description or Narrative for illustrative purposes only.

- Include a description of what each process step entails to explain what happens at each of the process steps listed in the process flow diagram.
- The process step description can serve to inform whether or not the process step aligns with a KAT.


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## Grouping Similar Products and Processes



- VAs of like products can be grouped into similar processes.
  - Identify any differences between grouped products.
- Examples:
  - Different flavored fruit juices using the same processing line.
  - Cereals of different flavors using very similar processes.
  - Yogurts with different inclusions (e.g., strawberries, blueberries).


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## Module 3 Summary



**Congratulations! You have now completed Module 3.**

Let's review what you have learned before you move on to the knowledge checks.

In this module, you learned certain steps that can help you prepare to use the KAT method, including:

1. Assembling a food defense team.
2. Describing the product under evaluation.
3. Developing a process flow diagram.
4. Describing the process steps under evaluation.
5. Grouping similar products.

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## Module 4: Using the Key Activity Type Method

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## Objectives



### Welcome to Module 4: “Using the Key Activity Type Method”

#### After completing this module, you will be able to:

1. Conduct key activity mapping.
2. Identify actionable process steps using the KAT method.
3. Explain your decisions.

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## Conduct Key Activity Mapping to Identify APSs



- Review KAT descriptions.
- Map process steps to KATs:
  - For each process step, determine if it is a KAT.
- Process steps that align with KATs are APSs.
- Process steps that do not align with KATs are not APSs.
- Any deviation from this method will require the individual conducting or overseeing the VA receive training in conducting the VA using an evaluation of the three elements, or be otherwise qualified through job experience.

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## Conduct Key Activity Mapping to Identify APSs (continued)



- Explain why each process step is or is not an APS:
  - For each process step that aligns with a KAT, the written explanation could simply state, “This step aligns with the KAT \_\_\_\_\_ (e.g., ‘This step aligns with the KAT mixing and similar activities’).”
  - For each process step that doesn’t align with a KAT, the written explanation could simply state, “This step does not align with a KAT.”

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## Almond Cranberry Pressed Energy Bar Example Video

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## Module 4 Summary



**Congratulations! You have now completed Module 4.**

Let's review what you have learned before you move on to the knowledge checks.

In this module, you learned to:

1. Conduct key activity mapping.
2. Identify actionable process steps using the key activity type method.
3. Explain your decisions.

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## Course Summary



This concludes the instructional portion of this training course. Lets summarize what you've learned today:

- The KAT method is an acceptable method of conducting your facility's VA.
- The KAT method simplifies the VA process and is less intensive with respect to time, resources, and technical expertise.
- The four KATs and their characteristics.
- The recommended preliminary steps that will help make your VA using the KAT method streamlined and efficient.
- How to identify APSs by recognizing which process steps in your food operation align with the KATs.
- How to explain your decisions of what is and what is not an APS in the context of the KAT method.

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## Key Activity Types Introduction Course Description Transcript

This training course is targeted towards food professionals using FDA's Key Activity Type, or KAT, method to conduct their facility's vulnerability assessment, or VA. The VA is a required part of the facility's food defense plan mandated under FDA's Mitigation Strategies to Protect Food Against Intentional Adulteration, or IA rule. By successfully completing this course, the learner will have satisfied the training requirement to conduct the vulnerability assessment using the KAT method.

## Key Activity Types Introduction Disclaimer Transcript

Please note that this course satisfies the training requirement to conduct a vulnerability assessment using the KAT method ONLY. Any deviation from the KAT method described in this course will necessitate that the individual take a vulnerability assessment training recognized as adequate by the FDA, or be otherwise qualified through job experience to conduct a vulnerability assessment using another vulnerability assessment methodology. See the Resources tab for information about other available trainings.

## Key Activity Types Introduction Course Modules Transcript

This course is divided into four modules, which will cover: an overview of food defense and the Intentional Adulteration rule, an introduction to using the key activity type method as a way to conduct your vulnerability assessment, getting prepared to use the key activity type method, and finally, putting the key activity type method into practice.

## Key Activity Types Course Objectives Transcript

After completing this course, you will be able to:

1. Explain the importance of food defense.
2. Understand the basic requirements of FDA's intentional adulteration rule.
3. Identify why using the key activity type method is an appropriate method of conducting a vulnerability assessment.
4. Describe each of the key activity types.
5. Perform preparatory steps to use the key activity type method for conducting a vulnerability assessment.
6. Conduct a vulnerability assessment using key activity types.

## Module 1 – Welcome and Introduction Transcript

Welcome to Module 1: Food Defense Overview and Introduction to the Intentional Adulteration Final Rule

After completing this module, you will be able to:

1. Explain food defense.
2. Explain the general requirements of the Intentional Adulteration rule.
3. Describe the contents of a food defense plan.
4. Explain the vulnerability assessment requirements.
5. Define significant vulnerabilities.
6. Define actionable process steps.
7. Explain the training and qualifications required to conduct vulnerability assessments.

## What is Intentional Adulteration? Transcript

Intentional adulteration is 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. It is a criminal act that can have devastating results. Therefore, Congress mandated that FDA publish regulations setting forth requirements to protect the public from intentional adulteration of food. FDA has issued a final regulation, Mitigation Strategies to Protect Food Against Intentional Adulteration (21 CFR Part 121), which requires covered facilities to identify and protect their most vulnerable points against intentional adulteration. To keep things simple, this will be referred to as the IA rule.

## What is Food Defense? Transcript

Food defense is the effort to protect food from intentional acts of adulteration intended to cause wide scale public health harm. These efforts include measures taken to reduce or eliminate the possibility that an intentional adulteration event would occur. There are many measures that can be implemented for food defense purposes but one of the most important is a food defense plan. The IA rule requires covered facilities to develop and implement a food defense plan that identifies and implements additional food defense measures at the most vulnerable points within their facilities. We'll talk more about the requirements of the IA rule in later slides.

## Why is Food Defense Important? Transcript

Intentional adulteration of the food supply can result in wide scale public health harm including severe illness and death. In addition to illnesses and deaths, potential impacts include public loss of confidence in the food supply, damage to a company's reputation, and job losses, among others. Malicious individuals, including terrorists, may see this as an opportunity to harm the public and further their cause. Hard as it is to imagine, intentional adulteration has already occurred. In December 2013, there were at least 2,843 mild foodborne illnesses reported and 6.4 million packages of various frozen foods recalled because a contract employee at a food facility intentionally adulterated several frozen foods with a pesticide. This example illustrates why food defense plans are so important—they aim to prevent these potentially devastating events.

## General Requirements of the IA Rule Transcript

The IA rule aims to prevent or significantly minimize intentional acts of food adulteration, including acts of terrorism, intended to cause wide scale public health harm. This is accomplished by requiring that covered facilities develop and implement a food defense plan that includes a vulnerability assessment to identify actionable process steps, or APSs, identification and implementation of mitigation strategies at those actionable process steps, and mitigation strategy management components (food defense monitoring, food defense corrective actions, and food defense verification). Reanalysis of the food defense plan is also required under certain conditions. The IA rule also has records and training requirements.

This training focuses on the first food defense plan component—a vulnerability assessment to identify actionable process steps. Specifically, it covers one possible approach to conducting a vulnerability assessment: the key activity type method.

## For more information on the IA Rule Requirements Transcript

For more detailed information about the rule and its requirements, please visit the following resources: The IA rule link will take you to the full text of the regulation, and the FDA IA rule Fact Sheet provides a brief summary of the rule's provisions, coverage, and exemptions.

Additionally, the Food Safety Preventive Controls Alliance has developed an online course that provides an overview of the IA rule requirements.

## Requirements of the VA Transcript

When conducting a vulnerability assessment, facilities are systematically assessing each step of their food processing operations to identify and rank vulnerabilities to intentional adulteration.

Recognizing that all points, steps, or procedures have some level of vulnerability, the goal of a vulnerability assessment is to identify those points, steps, or procedures that have what the IA rule terms "significant vulnerabilities" or those points which are most vulnerable to an intentional adulteration attack. These points are called actionable process steps. More details on actionable process steps will be covered later in this module.

You must conduct a vulnerability assessment for each type of food produced. However, like products and processes may be grouped together and assessed as a single group. For example, if a facility manufactures yogurt with different fruit flavor add-ins and the processing steps for these lines are the same, the facility may group these food products into one food type (e.g., "yogurt with fruit add-ins") for the vulnerability assessment and consider them together.

## Requirements of the VA (continued) Transcript

This requirement provides significant flexibility. FDA is not specifying a particular methodology for conducting vulnerability assessments. Facilities may choose the vulnerability assessment method of their liking. However, it must consider, for each point, step, or procedure, at a minimum: the potential public health impact if a contaminant were added to the product at that step; the degree of physical access to the product; and the ability of an attacker to successfully contaminate the product.

One appropriate approach of conducting a vulnerability assessment is using the FDA-identified Key Activity Type method, which takes into account these three elements and is the focus of this training. This method will be detailed in subsequent modules.



## Requirements of the VA (continued) Transcript

The IA rule requires a consideration of an inside attacker when conducting a vulnerability assessment.

An inside attacker is someone who has legitimate access to the facility, is knowledgeable about the facility's operations and procedures, and can potentially introduce a contaminant.

Based on years of collaboration with the law enforcement and the intelligence community, it is widely recognized that an inside attacker poses the highest risk for intentional adulteration of food and represents a worst-case scenario. The vulnerability assessment must be conducted based on the assumption that an inside attacker is possible.

## Requirements of the VA (continued) Transcript

Regardless of the outcome, the vulnerability assessment must be written and must include an explanation as to why each point, step, or procedure either was or was not identified as an actionable process step. These written documents must be part of the food defense plan. Here is an example form that can be used to document the vulnerability assessment. Using this specific form is not a requirement; it simply illustrates one possible method of documenting the vulnerability assessment in the food defense plan.

## Significant Vulnerabilities and APSs Transcript

Let's continue on and talk in more detail about two concepts we introduced earlier that make up the outcome of your vulnerability assessment: the identification of significant vulnerabilities and actionable process steps.

FDA uses the term significant vulnerability to describe a vulnerability in a food process that is highly susceptible to intentional adulteration and one that, if exploited, could be expected to cause wide scale public health harm.

Those points, steps, or procedures in a food process where a significant vulnerability exists are called actionable process steps. Another way to think about actionable process steps is that once a facility conducts a vulnerability assessment, these are the steps that are identified as most vulnerable to intentional adulteration.

## Mitigation Strategies Transcript

Mitigation strategies must be applied and are essential to significantly minimize or prevent the significant vulnerability at actionable process steps. The IA rule defines mitigation strategies as "Risk-based, reasonably appropriate measures that a person knowledgeable about food defense would employ to significantly minimize or prevent significant vulnerabilities identified at actionable process steps, and that are consistent with the current scientific understanding of food defense at the time of the analysis."

## Training/Qualifications Required for the VA Transcript

The individual conducting a facility's vulnerability assessment must be a qualified individual, or QI, and successfully complete VA training under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience. In order to be considered qualified, this person must have the education, training, or experience, or a combination thereof, to conduct a vulnerability assessment. It is important to note that this person could be, but does not have to be, an employee of the facility. Outside expertise may be sought.

As mentioned earlier, this training will qualify an individual to conduct a vulnerability assessment using the key activity type method ONLY. A separate training is required for those seeking to be qualified to conduct a vulnerability assessment using other methods.

## Summary Transcript

Congratulations on completing module one. Let's review what you have learned before you move on to the knowledge checks.

In this module you learned to:

1. Explain food defense.
2. Explain the general requirements of the Intentional Adulteration rule.
3. Describe the contents of the food defense plan.
4. Explain the vulnerability assessment requirements.
5. Define significant vulnerabilities.
6. Define actionable process steps.
7. Explain the training and qualifications required to conduct vulnerability assessments.

## Welcome and Introduction Transcript

Welcome to Module 2: "Introduction to the Key Activity Type Vulnerability Assessment Method"

After completing this module, you will be able to:

1. Summarize the origins of the key activity types;
2. Recognize why using key activity types is appropriate method to conduct a vulnerability assessment;
3. Describe bulk liquid receiving and loading;
4. Describe liquid storage and handling;
5. Describe secondary ingredient handling; and
6. Describe mixing and similar activities.

## KAT Method Background Transcript

Let's start here with a quick discussion of how the key activity type method was developed.

As directed by Homeland Security Presidential Directive-9, FDA has, since 2004, conducted numerous vulnerability assessments covering a wide array of food manufacturing settings in collaboration with industry, academia, and other government partners. These activities have formed the foundation of FDA's food defense program, informed the development of the IA rule, and resulted in the identification of trends with regards to vulnerabilities within the food system which led to the development of the key activity type method.

## Module 2 – KAT Method Background (continued) Transcript

In response to the passage of the Food Safety Modernization Act, or FSMA, FDA further analyzed the vulnerability assessment data and found a few key results. Certain general categories of food processing steps or procedures (i.e., the key activity types) consistently ranked high in terms of vulnerability, regardless of the commodity in question. It turned out that particular foods were not inherently more vulnerable to intentional adulteration compared to other foods. Rather, the main drivers of vulnerability to intentional adulteration caused by acts intended to cause wide scale public health harm are the processing steps and procedures that are used as food is moved from farm to table.

## Module 2 – KAT Method Background (continued) Transcript

From the data, FDA and its partners concluded that four groups of processing steps consistently scored high in the vulnerability assessments—these four groups became the key activity types.

They are:

- Bulk Liquid Receiving and Loading;
- Liquid Storage and Handling;
- Secondary Ingredient Handling, and;
- Mixing and Similar Activities.

## Module 2 – Why KATs Are an Appropriate Method Transcript

Because the FDA's vulnerability assessments included consideration of the three elements (the potential public health impact if a contaminant were successfully added to the product; the degree of physical access to the product; and the ability of an attacker to successfully contaminate the product), with the possibility of an inside attacker as an underlying assumption, as is required in the IA rule, the key activity types already have these factors "built in." This is why the key activity types are considered an appropriate method for conducting a vulnerability assessment.

## Why Using KATs Is an Appropriate Method Transcript

The vulnerability assessment requirement under the IA rule was written with a level of flexibility that allows firms to decide which vulnerability assessment method is best for them. Conducting a vulnerability assessment using an evaluation of the three elements, of which there are a number of appropriate methodologies, is one option. Another appropriate approach is using the key activity type method. If the facility uses the key activity type method to conduct a vulnerability assessment it is not required to separately consider the three elements and the inside attacker as FDA already did that work in identifying the key activity types. However, the facility may choose to do so, provided such work is conducted by a qualified individual. Remember that this course does not address conducting a vulnerability assessment by a method that is not the key activity types.

The key activity type approach enables facilities to identify actionable process steps in an efficient way that is consistent with current food defense scientific understanding and that may be less resource intensive than a full vulnerability assessment evaluating the three elements individually.

Now let's move on to a more detailed discussion of the four key activity types.

## Bulk Liquid Receiving and Loading Transcript

Bulk liquid receiving refers to a point, step, or procedure that involves the inbound movement of liquid ingredients into a facility for its use in the food production process. This includes opening the inbound transport vehicle, opening any venting hatches or other access points, attaching pumping equipment or hoses, and unloading the bulk liquid.

Bulk liquid loading refers to the outbound shipping of liquid intermediate or finished liquid product from a facility onto a transport vehicle for further processing or use. This includes opening the outbound transport vehicle, attaching any pumping equipment or hoses, and opening any facility venting hatches.

Examples of products that may be received or loaded in bulk include juices, high fructose corn syrup and other sweeteners, milk, animal fats, syrups, and vegetable oils.

These processing steps are key activity types because there is a high probability of a contaminant, if intentionally added, to be mixed within the liquid due to significant sloshing, movement, or turbulence associated with the receiving or loading activity. These activities involve a large volume of liquid that, if contaminated, could cause wide scale public health harm. In addition, the need for worker activity associated with these processing steps provides access to hoses, the transport vessel, and potentially the product as it is being received or loaded.

Activities that do not fall under this key activity type include the receiving or loading of sealed jugs, drums, jars, and totes. The receiving or loading of these sealed containers are not included in this key activity type regardless of the total volume of liquid received or loaded.

## Liquid Storage and Handling Transcript

Liquid storage and handling refers to a point, step, or procedure in which a bulk or non-bulk liquid is contained in storage tanks or silos or in holding, surge, metering, or other types of intermediate processing tanks. Liquid storage refers to any storage silo or tank where liquid product may be stored prior to introduction into the product stream or prior to loading for outbound shipping. Bulk or non-bulk tanks can be used to store liquid ingredients (e.g., fats, oils, vitamin mixes, and sweeteners), hold liquid product for sample testing and other quality control activity, or to control flow rates of liquid ingredients or product through the production system. Handling tanks also include tanks or totes where the tamper-evident seals are opened and the container itself is used for holding, such as when a drum is opened and a pump is attached directly onto the drum to meter an ingredient into the product line.

These are considered key activity types because if a contaminant were successfully introduced, there is a high probability of the contaminant mixing within the liquid. This could be due to the agitation commonly used to prevent separation within the liquid medium, the mixing or agitation caused as liquid enters or exits the tanks, or the likelihood that liquid ingredients will be metered or applied to a large amount of servings. Access necessary for the introduction of a contaminant is generally available through hatches, sample ports, or container lids.

## Secondary Ingredient Handling Transcript

Secondary ingredient handling refers to a point, step, or procedure in which staging, preparation, addition, or rework occurs and ingredients (either dry or liquid) are manipulated by human contact prior to or during addition to the product stream. Inclusions, minor ingredients, processing aids, and food additives are all examples of secondary ingredients.

Specifically, “staging” refers to the process of opening the tamper-evident packaging of a secondary ingredient and moving the ingredient to the production area in advance of being added into the primary product stream. “Preparation” refers to any act of measuring, weighing, premixing, or otherwise manipulating the ingredient prior to addition to the product stream. “Addition” refers to any act of physically adding ingredient directly into the product stream or into surge or meter hoppers in order to deliver the ingredient into the product stream. “Rework” refers to clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

## Secondary Ingredient Handling (continued) Transcript

This key activity type also includes the storage of partially used, open containers of secondary ingredients where the tamper-evident packaging has been breached.

Computer metering or automatic weighing, sizing, batching, or measuring is not included in this activity so long as the process does not require the active involvement of a person.

Staging, preparation, addition, and rework involving secondary ingredients are key activity types because a contaminant added to a relatively small volume of product would likely be distributed into a larger volume of food within the main product flow. These activities are generally open and accessible and that accessibility is an inherent component of the activity.

Also, mixing frequently occurs immediately after ingredients are staged, prepared and/or added to the product stream. Whereas mixing would homogeneously distribute an agent in a batch, the activities of ingredient staging/preparation/addition provide a point of access to introduce the agent into the product stream.



## Mixing and Similar Activities Transcript

Mixing and similar activities refers to a point, step, or procedure where the primary purpose or result is:

- mixing, i.e., to blend a powder, dough, or liquid ingredient together;
- homogenizing, i.e., to reduce the particle size of an ingredient and disperse it throughout a liquid;
- grinding, i.e., to reduce the particle size of a solid ingredient or mass to a smaller granularity, and;
- coating, i.e., to layer a powder or liquid onto the surface of a product, such as a batter, breading, glazing or flavoring.

## Mixing and Similar Activities (continued) Transcript

Examples of equipment associated with these activities include: mixers, homogenizers, blenders, cascade-style breaders, mills, grinders, and pulverizers.

These are key activity types because a potential contaminant successfully added at one of these steps would generally be readily dispersed throughout the product. Further, access is generally available through access ports or lids.

## Summary Transcript

Congratulations on completing module two. Let's review what you have learned before moving on to the knowledge checks.

In this module you learned to:

1. Summarize the origins of the key activity types.
2. Recognize why using key activity types is an appropriate method to conduct a vulnerability assessment.
3. Describe bulk liquid receiving and loading.
4. Describe liquid storage and handling.
5. Describe secondary ingredient handling.
6. Describe mixing and similar activities.

## Welcome and Introduction Transcript

Welcome to Module 3: "Preparing to Use the Key Activity Type Method."

After completing this module, you will understand certain activities that can help you prepare to use the key activity type method, such as:

1. Assembling a food defense team;
2. Describing the product under evaluation;
3. Developing a process flow diagram;
4. Describing the process steps under evaluation, and;
5. Grouping similar products.

## Introduction to Preliminary Steps Transcript

### Introduction to Preliminary Steps

Preliminary steps will help you prepare, organize, and conduct your vulnerability assessment using the key activity types in an efficient way. They are:

- Assembling your food defense team;
- Describing the product under evaluation;
- Producing a process flow diagram;
- Describing the process steps under evaluation, and;
- Grouping similar products.

These steps are not required by the IA rule but you may find them helpful.

Facilities may find that they have already completed some or all of these preliminary steps for other purposes. For example, you may have process flow diagrams and process descriptions prepared for food safety activities. You may leverage these and all relevant resources already available to you to maximize efficiency and reduce duplicate efforts.

## Assemble the Food Defense Team Transcript

The first preliminary step that is recommended is assembling the food defense team. This group of individuals and their expertise related to the facility's practices, processes, and products will impact the quality and completeness of your vulnerability assessment. It is therefore recommended that facilities gather a food defense team comprised of personnel with a diverse range of expertise in the day-to-day operations of the facility. Facilities have the flexibility to determine the composition and size of the food defense team that best fits their needs and circumstances, but at least one member of the group must be a qualified individual. Multiple team members may not be necessary for some facilities, especially considering the streamlined nature of the key activity type method.

Having a diverse range of skills and expertise represented on the food defense team can help ensure a complete understanding of, and thorough approach to, the vulnerability assessment process. It may be helpful to include individuals from management, production, quality assurance or quality control, security, sanitation, maintenance, laboratories, human resources, purchasing, and other relevant departments, but again, this not required.

## Describe Product Under Evaluation Transcript

The next recommended preliminary step is describing the product under evaluation. Product descriptions will help food defense team members understand the characteristics of the product that may impact food defense, for example, whether or not it has tamper-evident seals. The description should include the full name(s) of the finished product and any other information that may be helpful to those conducting or reviewing the vulnerability assessment.

## Produce a Process Flow Diagram Transcript

The next recommended preliminary step is producing a process flow diagram. The purpose of a process flow diagram is to provide a clear outline of the steps involved in the processing of your food product and its associated ingredients as they “flow” from receipt to distribution. This will provide an organizing foundation on which your vulnerability assessment using the key activity types is based.

Existing flow diagrams, for example those used for food safety purposes, may be used.

Processes and procedures that are not part of the food operation (e.g., utilities) do not need to be included in the flow diagram.

## Describe Process Steps Under Evaluation Transcript

Next, it is recommended that the activity at each process step be described. The purpose of a process description is to explain what happens at each of the process steps listed in the process flow diagram. It is helpful to include a description of what each process step entails so that when you are conducting the vulnerability assessment you have the background information you would need to assist you in determining whether or not it aligns with a key activity type.

## Grouping Similar Products and Processes Transcript

Let's conclude the discussion of preliminary steps with grouping similar products or very similar processes. As with the vulnerability assessment discussion earlier, similar food products may be grouped together and assessed as one grouping when conducting a vulnerability assessment using the key activity types. However, any product or process-specific differences must be carefully delineated and noted in the vulnerability assessment, and the facility must clearly identify the specific products included in each vulnerability assessment. This grouping of similar products may help streamline the analysis when facilities are manufacturing similar products using either the same equipment or very similar processes.

## Summary Transcript

Congratulations on completing module three. Let's review what you have learned before you move on to the knowledge checks.

In this module, you learned certain steps that can help you prepare to use the key activity type method, including:

1. Assembling a food defense team;
2. Describing the product under evaluation;
3. Developing a process flow diagram;
4. Describing the process steps under evaluation, and;
5. Grouping similar products.

## Welcome and Introduction Transcript

Welcome to Module 4: "Using the Key Activity Type Method"

After completing this module, you will be able to:

1. Conduct key activity type mapping;
2. Identify actionable process steps using the key activity type method, and;
3. Explain your decisions.

## Conduct Key Activity Mapping to Identify APSs Transcript

Now that you have completed the preliminary steps, you have the resources and preparation needed to move forward with conducting your vulnerability assessment using the key activity type method. As you proceed, it may be helpful to review the four key activity type descriptions so that they are fresh in your mind.

To conduct a vulnerability assessment using the key activity type method, you will assess each point, step, or procedure to determine whether those activities fit within one or more of the key activity types. Process steps that fit within one or more of the key activity types are actionable process steps. Process steps that do not fit within any of the key activity types are not actionable process steps. For example, a step where multiple ingredients are combined and mixed would fit within the "Mixing and Similar Activities" key activity type. This process step would then be identified as an actionable process step. In contrast, the storage of dry ingredients that are sealed with tamper-evident packaging in a storage room would not fit within any of the key activity types, and therefore would not be an actionable process step.

It should be noted again that any deviation from this key activity type method, for example choosing to further evaluate the points, steps, or procedures identified as key activity types to determine whether or not they are actionable process steps using the three elements, what the FDA calls the hybrid approach, will require the individual conducting or overseeing the vulnerability assessment to receive training in conducting vulnerability assessments using the three elements, or be otherwise qualified through job experience.

## Conduct Key Activity Mapping to Identify APSs (continued) Transcript

While identifying actionable process steps using any vulnerability assessment method, including the key activity type method, written explanations are required as to why each point, step, or procedure was or was not identified as an actionable process step. Explanations can be straightforward and simple. For example, if a processing step fits within the Mixing and Similar Activities key activity type, then you should identify that process step as an actionable process step and write an explanation as to why, which could simply be: "This point, step, or procedure fits within the key activity type- Mixing and Similar Activities."

Conversely, for each process step that doesn't align with a key activity type, the written explanation could simply state, "This step does not align with a key activity type."

If a process step aligns with more than one key activity type, the facility could identify them both or the primary one. The result is the same. However, identifying all applicable key activity types in the explanation is recommended because determining the specific key activity types may assist with the identifying the mitigation strategies best suited for that actionable process step.

## KAT Mapping Exercise #1 Instructions

In the following exercises, you will see excerpts from some sample flow diagrams. They have been simplified for training purposes. Your task is to click on each process step and read the accompanying description, then decide whether or not that process step aligns with one of the four KATs: bulk liquid receiving and loading; liquid storage and handling; secondary ingredient handling; mixing and similar activities. Select "Yes" or "No" to respond to the question: Does this process step align with a KAT?

## KAT Mapping Exercise #2 Instructions

As noted in KAT Mapping Exercise 1, your task is to click on each process step and read the accompanying description, then decide whether or not that process step aligns with one of the four KATs: bulk liquid receiving and loading; liquid storage and handling; secondary ingredient handling; mixing and similar activities. Select "Yes" or "No" to respond to the question: Does this process step align with a KAT?



## Summary Transcript

Congratulations on completing module four. Let's review what you have learned before you move on to the knowledge checks.

In this module you learned to:

1. Conduct key activity type mapping;
2. Identify actionable process steps using the key activity type method, and;
3. Explain your decisions.

## Key Activity Types Course Summary Transcript

This concludes the instructional portion of this training course. Before finishing up with a short assessment, let's summarize what you've learned today:

- The key activity type method is an acceptable method of conducting your facility's vulnerability assessment
- The key activity type method simplifies the vulnerability assessment process and is less intensive with respect to time, resources, and technical expertise
- How to describe the four key activity types
- The recommended preliminary steps that will help make your vulnerability assessment using the key activity type method streamlined and efficient
- How to identify actionable process steps by recognizing which process steps in your food operation align with the key activity types
- How to explain your decisions of what is and what is not an actionable process step in the context of the key activity type method

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# Resources

- [Analysis of Results for FDA Food Defense Vulnerability Assessments and Identification of Activity Types](#)
- [FDA Fact Sheet for the IA Rule](#)
- [FDA Technical Assistance Network \(TAN\)](#)
- [FSPCA Intentional Adulteration Training and Materials](#)
- [IA Rule](#)
- [IA Rule Overview Course](#): (In order to access the IA Rule Overview course, You will need to log out first and then click the link on the FSPCA webpage.)

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