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# Food Defense Awareness for the Intentional Adulteration Rule

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## Course Overview



### **This course is divided into three modules:**

Module 1: Intentional Adulteration and Food Defense Overview

Module 2: Implementation of Food Defense at a Facility

Module 3: Roles and Responsibilities

This food defense awareness training is designed for individuals assigned to work at actionable process steps and their supervisors, and will meet the food defense awareness training requirement (21 CFR 121.4(b)(2)) within the Mitigation Strategies to Protect Food Against Intentional Adulteration rule (IA rule).



## Course Objectives



After completing this course, you will be able to:

1. Explain the importance of food defense.
2. Describe ways to protect food from intentional adulteration.
3. Recognize suspicious activity.
4. Report suspicious activity.



## Welcome to Food Defense Awareness





## Module 1: Intentional Adulteration and Food Defense Overview



### Objectives



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

1. Explain intentional adulteration.
2. Explain food defense.
3. Distinguish food defense from food safety.
4. Explain consequences of intentional adulteration.



## What is Intentional Adulteration of Food?



- What if someone wanted to make people sick on purpose by putting something harmful in the food supply?
- Possible motives to intentionally contaminate food might be:
  - Desire to incite fear and panic
  - Desire to cause wide scale illnesses and death
  - Gain notoriety
- Intentional Adulteration is the deliberate contamination of food with a biological, chemical, radiological, or physical agent with the intent to cause wide scale illnesses and deaths.



## What is Intentional Adulteration?



### IA Rule Fact Sheet

- [Click here to learn more about the IA rule.](#)



- Intentional adulteration is a crime.
- Congress mandated that FDA take steps to protect the public from intentional adulteration.
- FDA issued the IA rule to protect food against intentional adulteration.



## What is Food Defense?



### Definitions:

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



- **Food Defense** is the effort to protect food from acts of intentional adulteration intended to cause wide scale public health harm.
  - Wide scale public health harm means many illnesses and even deaths.
- Efforts include measures to reduce or eliminate the possibility that an intentional adulteration event would occur.
- The IA rule requires covered food facilities to put in place the most important food defense measures through development and implementation of a food defense plan.



## Food Defense Plan and Vulnerability Assessment



- Food defense plans contain many food defense measures, and begin with a vulnerability assessment to identify **significant vulnerabilities** at points, steps, or procedures in a process.
- A vulnerability assessment must consider:
  - Potential public health impact if a contaminant were added.
  - Degree of physical access to the product.
  - Ability of an attacker to successfully contaminate the product.
- Must consider the possibility of an inside attacker.



## Actionable Process Steps and Mitigation Strategies



- The points, steps, or procedures where significant vulnerabilities are identified are called **actionable process steps**.
- Mitigation strategies to reduce or prevent the significant vulnerability must be chosen and implemented.
- More information about the food defense plan, actionable process steps, and mitigation strategies will be discussed in the next module.
- Writing a food defense plan, conducting a vulnerability assessment, and identifying mitigation strategies must be done by a **qualified individual**.



## How is Food Defense Different from Food Safety?



## Why Should I Care About Food Defense?



- Intentional adulteration can result in catastrophic public health consequences. It may also cause:
  - Public panic
  - Disruption of trade hurting the economy
  - Company closures and associated loss of jobs



## Intentional Adulteration Has Already Occurred!



- In December of 2013, frozen food in Japan was intentionally contaminated with pesticides resulting in thousands of sick people. This intentional adulteration resulted in at least:
  - 2,843 reports of foodborne illness
  - 6.4 million packages of food recalled





## Food Defense is Important!



- Food defense measures are designed to reduce or eliminate the vulnerability to intentional adulteration.
- Food defense measures can prevent illnesses, protect your company, and protect your job.



## IA and Food Defense Overview Summary



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

- In this module, you learned to:
  1. Explain intentional adulteration.
  2. Explain food defense.
  3. Distinguish food defense from food safety.
  4. Explain consequences of intentional adulteration.
- Now let's see what you remember about what you just learned.



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## Module 2: Implementation of Food Defense at a Facility



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### Objectives



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

1. Explain the importance of a food defense plan.
2. Describe actionable process steps.
3. Explain mitigation strategies.
4. Recognize the importance of training.



## Where Should Food Defense Measures Be Implemented?



Production

- There are multiple places where someone wanting to cause public health harm can access the food supply.
- The most vulnerable steps must be determined and measures must be taken to protect those steps.
- The IA rule requires certain facilities to implement food defense measures.



## Where Should Food Defense Measures be Implemented? (continued)



- Your facility's vulnerability assessment will identify the most vulnerable points in your facility.
  - These are called actionable process steps.
- Mitigation strategies must be implemented at actionable process steps.



## Actionable Process Steps and Mitigation Strategies



- Actionable process steps and associated mitigation strategies are facility specific.



## Actionable Process Step Example:



- There is a reasonable opportunity for an inside attacker to contaminate the food without detection at this mixing step because access is unrestricted.
- That makes this step an actionable process step.



## What Could We Do to Protect This?



- **Mitigation strategies** are identified and implemented to reduce or eliminate the vulnerabilities that have been identified at this step. For example, such mitigation strategies could:

- Restrict mixer operation, cleaning, and maintenance to authorized personnel.
- Increase visibility around the mixing operation.
- Assign operators in teams (e.g., buddy system).



## Where Should Food Defense Measures be Implemented?



- Mitigation strategies at actionable process steps make it harder or even impossible for someone, including an inside attacker, to intentionally contaminate the food supply.
- The food defense plan contains:
  - A vulnerability assessment that identifies actionable process steps
  - Mitigation strategies
  - Procedures to ensure that the mitigation strategies are being properly implemented



## Food Defense Awareness Training



- All employees working at actionable process steps and their supervisors must take food defense awareness training.
- Food defense relies on you knowing what to do and following the plan for your facility.



## Importance of Training



- The IA rule further requires you to receive training on the proper implementation of mitigation strategies at your actionable process step(s).





## Congratulations! You have now completed Module 2.

- In this module, you learned to:
  1. Explain the importance of a food defense plan.
  2. Describe actionable process steps.
  3. Explain mitigation strategies.
  4. Recognize the importance of training.
- Now let's see what you remember about what you just learned!

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## Module 3: Roles and Responsibilities

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## Objectives



After completing this module, you will be able to:

1. Explain the various roles in food defense awareness.
2. Recognize your role in preventing intentional adulteration.
3. Give examples of suspicious activity.
4. Report suspicious activities to the appropriate person.



## Food Defense Responsibilities



- Food defense requires diligence from many people and entities

- Regulators
- Industry
- Consumers
- And You!





## Roles in Food Defense



### Industry

Industry is responsible for compliance with the IA rule:

- Developing and implementing a food defense plan
- Ensuring individuals are properly qualified to do their job

### Regulators

FDA and other regulators are responsible for:

- Ensuring that industry is complying with regulations for producing safe food
- Inspections to ensure that covered facilities have a food defense plan



## Your Role in Food Defense



## If Not You, Then Who?



- You are also responsible for recognizing when something is wrong or suspicious.
- You know your work area...
- If it's out of place or just plain wrong, report it!



## Food Defense in Action!



- You may know your work area best!
- Is anything out of place?
- Does anyone seem to be acting unusually?
  - Even if it's a co-worker—if you think it's odd, better to mention it to management!



## Suspicious Events and Activities

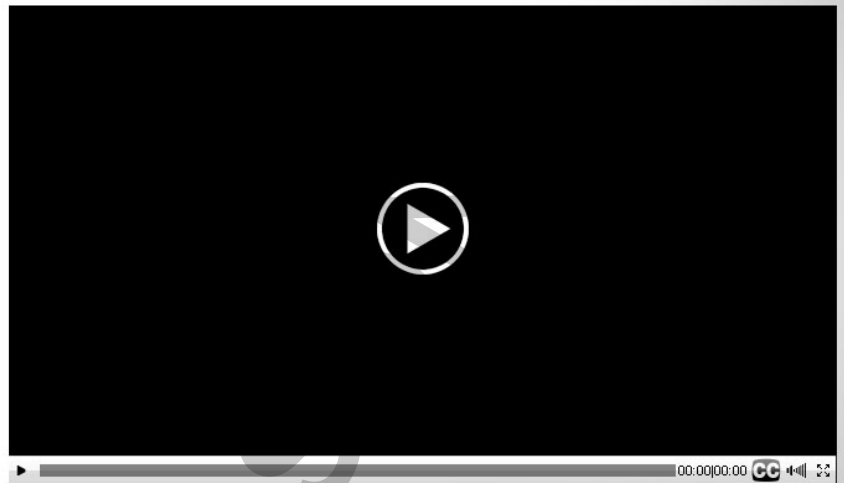


Unsecured Areas

Unescorted Visitors

Unusual Behavior

Abnormal Changes



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## Roles and Responsibilities Summary



- We can't list all suspicious events or activities, as all facilities are unique.
- When it is your facility and your work area, you should know what is out of place.
- Report suspicious events to management.



## Roles and Responsibilities Summary



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

- In this module, you learned to:
  1. Explain the various roles in food defense awareness.
  2. Recognize your role in preventing intentional adulteration.
  3. Give examples of suspicious activity.
  4. Report suspicious activities to the appropriate person.
- Now let's see what you remember about what you just learned!

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## Course Summary



**Congratulations! You have now completed the Food Defense Awareness course.**

- You should now be able to:
  1. Explain the importance of food defense.
  2. Describe ways to protect food from intentional adulteration.
  3. Recognize suspicious activity.
  4. Report suspicious activity.

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## Food Defense Awareness Reminders



- Most importantly, you now know how vital you are to food defense.
  - Stay alert!
  - Report anything unusual!
  - You may be the food supply's first line of defense.



### Congratulations!



- You have successfully met the food defense awareness training requirement of the IA rule (21 CFR 121.4(b)(2)).
- Don't forget to follow up with management to learn how to properly implement mitigation strategies and where to report suspicious activity!
- In order to print your Food Defense Awareness certificate of completion, visit [lms.ifpti.org](https://lms.ifpti.org), click "Transcript" from the drop down menu, and click "Print Certificate" under the "Food Defense Awareness" course.
- Click the "exit" button at the top right corner of this window to close.



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## Course Overview Transcript

Welcome to the Food Defense Awareness for the Intentional Adulteration Rule online course. This training will provide an overview of food defense, and is divided into three modules. Module 1 will provide an overview of "Intentional Adulteration and Food Defense," module 2 will discuss "Implementation of Food Defense at a Facility," and module 3 will discuss "Roles and Responsibilities."

This food defense awareness training is designed for individuals assigned to work at actionable process steps and their supervisors, and will meet the food defense awareness training requirement (21 CFR 121.4(b)(2)) within the Mitigation Strategies to Protect Food Against Intentional Adulteration rule (IA rule).

## Course Objectives Transcript

After completing this course, you will be able to:

1. Explain the importance of food defense.
2. Describe ways to protect food from intentional adulteration.
3. Recognize suspicious activity.
4. Report suspicious activity.

## Course Objectives Transcript

Safe and healthy food is what most people expect, but what if someone wanted to make people sick through food – on purpose?

Since the events of September 11, 2001 and other incidents that followed, there has been growing concern about attacks that could take place on the food supply. This course will introduce you to food defense and also discuss food defense in the context of FDA's Food Safety Modernization Act rule: Mitigation Strategies to Protect Food Against Intentional Adulteration (21 CFR Part 121), which is referred to as the IA rule for short. If you would like to see the full text of the IA rule, click on the "resources" tab at the top right corner of this window. Completing this training or a similar training on food defense awareness is required by this rule for all employees assigned to actionable process steps and their supervisors and is a great step towards protecting food from intentional adulteration.

Module 1: Intentional Adulteration and Food Defense Overview

## Title Transcript

Module 1: Intentional Adulteration and Food Defense Overview

## Objectives Transcript

After completing this module, you will be able to:

1. Explain intentional adulteration.
2. Explain food defense.
3. Distinguish food defense from food safety.
4. Explain consequences of intentional adulteration.

## What is Intentional Adulteration of Food? Transcript

Why would someone want to make people sick on purpose? People or groups could be motivated to intentionally adulterate food for many reasons, ranging from a desire to incite fear and panic, to causing illnesses and deaths. Intentional adulteration is the deliberate contamination of food with a biological, chemical, radiological, or physical agent with the intent to cause wide scale illnesses and deaths. Malicious individuals, including terrorists, may see intentional adulteration as an opportunity to hurt the public and gain notoriety to further their cause.



## What is Intentional Adulteration? Transcript

Intentional adulteration is a criminal act that can have devastating consequences. That's why Congress mandated that FDA take steps to protect the public from intentional adulteration. FDA issued the IA rule, which says that covered food facilities must identify and protect their most vulnerable points against intentional adulteration.

## What is Food Defense? Transcript

Food defense is the effort to protect food from acts of intentional adulteration intended to cause wide scale public health harm.

These efforts include measures 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 the IA rule requires covered food facilities to institute the most important food defense measures through the development and implementation of a food defense plan.

## What is a Food Defense Plan? Transcript

Food defense plans contain many food defense measures, but begin with a vulnerability assessment to identify significant vulnerabilities at a point, step, or procedure. A point, step, or procedure is an activity related to manufacturing, processing, packing, or holding of a food product. The IA rule defines a **Significant Vulnerability** as a vulnerability that, if exploited, could reasonably be expected to cause wide scale public health harm. A significant vulnerability is identified by a vulnerability assessment conducted by a qualified individual, that includes consideration of the following: (1) Potential public health impact (e.g., severity and scale) if a contaminant were added, (2) degree of physical access to the product, and (3) ability of an attacker to successfully contaminate the product. The assessment must consider the possibility of an inside attacker.

## What is an Actionable Process Step? Transcript

Points, steps, or procedures that are identified as having these significant vulnerabilities are called actionable process steps. The IA rule defines **Actionable Process Steps** as 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.

After that, measures to reduce or prevent the significant vulnerability must be chosen and implemented. These are called mitigation strategies. More information about the food defense plan, actionable process steps, and mitigation strategies will be discussed in the next module. It is important to note that you must be a qualified individual with specialized training or experience to develop the food defense plan, conduct a vulnerability assessment, or choose appropriate mitigation strategies. **A Qualified Individual** is a person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required under subpart C of this part, as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

## How is Food Defense Different from Food Safety? Transcript

Food defense is similar to food safety in that both involve efforts to minimize or prevent adulteration of the food supply, but there are also important differences between food safety and food defense.

Food safety measures protect against unintentional adulteration that may be reasonably foreseeable. For instance, we know that eggs may be susceptible to unintentional *Salmonella* contamination, so pasteurization steps and cooking suggestions are incorporated based on this anticipated hazard.

Food defense is a little different. Food defense, in contrast, protects against contaminants **intentionally** introduced into the food with the intent to cause harm. Intentional acts may be more difficult to anticipate. Food safety measures may not provide safeguards against an intentional contaminant. That's why food defense measures to prevent **intentional** adulteration are critical.

## Why Should I Care About Food Defense? Transcript

You may be wondering why food defense measures are important. In addition to wide scale illnesses and deaths, intentional adulteration can also cause widespread public fear and undermine public confidence in our food supply. An attack on our food might force recalls and company closures, putting all their employees out of work. That would be really hard on our economy but could also result in job loss, which could hurt your family!

## Intentional Adulteration has already occurred! Transcript

Unfortunately, intentional adulteration has already occurred. In December 2013, a contract employee at a food facility in Japan intentionally adulterated several frozen foods with a pesticide. Japanese authorities believe the assailant brought the chemical contaminant to the plant and added it to frozen foods during the manufacturing process. This intentional adulteration resulted in at least 2,843 foodborne illness reports and 6.4 million packages of various frozen foods recalled.

## Food Defense is Important! Transcript

The primary purpose of food defense is to prevent intentional adulteration. A successful intentional adulteration event can result in illnesses, deaths, and psychological and economic damage that can extend far beyond the point of the adulteration. And that is why food defense is so very important!

## IA and Food Defense Overview Summary Transcript

In this module, you learned to:

1. Explain intentional adulteration.
2. Explain food defense.
3. Distinguish food defense from food safety.
4. Explain consequences of intentional adulteration.

Now let's see what you remember about what you just learned!

## Objectives Transcript

Module 2: Implementation of Food Defense at a Facility

## Objectives Transcript

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

1. Explain the importance of a food defense plan.
2. Describe actionable process steps.
3. Explain mitigation strategies.
4. Recognize the importance of training.

## Where Should Food Defense Measures Be Implemented? Transcript

There are multiple points in the food supply chain where it is possible to intentionally contaminate food. The steps that are most vulnerable must be determined and measures must be taken to protect those steps. While FDA encourages diligence in food defense at all stages of the farm-to-fork production chain, the IA rule specifically requires food defense measures at facilities.

## Where Should Food Defense Measures Be Implemented? Transcript 2

Covered food facilities must conduct vulnerability assessments to identify their most vulnerable points in the food production process. Remember from module 1 that these points are referred to as “actionable process steps.” The assessment results in a list of actionable process steps where a significant vulnerability to intentional adulteration exists and where mitigation strategies must be applied.

## Actionable Process Steps and Mitigation Strategies Transcript

There are many different factors involved in both identifying actionable process steps and choosing appropriate mitigation strategies. Actionable process steps and mitigation strategies are facility specific. Just like your facility is unique in its processes and set up, so are its actionable process steps and chosen mitigation strategies. Let's go through an example.

## Actionable Process Step Example Transcript

During a vulnerability assessment, management noted this mixing step allowed unrestricted access to the mixer and a reasonable opportunity for an inside attacker to contaminate the food without detection. An inside attacker is someone who has legitimate access to the facility (for example an employee, contractor, or visitor) and has a basic understanding of the facility's operation and the food being produced. It was also noted that if a successful intentional adulteration were to occur at this step, it could potentially lead to wide spread illness or even death. Based on these conclusions, this step is considered an actionable process step.

## What Could We Do To Protect This? Transcript

Mitigation strategies must now be identified and implemented to reduce or eliminate the vulnerabilities that have been identified at this step. Mitigation Strategies are defined 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.

In this example, mitigation strategies that could be used to reduce this vulnerability are: restricting the operation, cleaning, and maintenance of the mixer to authorized personnel only; maximizing the visibility of the mixing operation to allow a clear view of this step; or assigning operators in such a way that no one is alone while the mixer is in operation.



## Where Should Food Defense Measures be Implemented? Transcript

The chosen mitigation strategies make sense for this example. Your facility may choose other reasonable mitigation strategies. The point is, the mitigation strategies are making it harder or even impossible for someone, including an inside attacker, to intentionally contaminate the food supply.

The food defense plan is important because it contains the vulnerability assessment, the actionable process steps, and the mitigation strategies. It also contains procedures to ensure that the mitigation strategies are being properly implemented.

## Food Defense Awareness Training Transcript

Increasing awareness about food defense is another very important aspect of protection. Because of this, people assigned to actionable process steps and their supervisors are required to take food defense awareness training. The food defense plan is only valuable if people assigned to actionable process steps and their supervisors understand the importance of the plan, and are aware of their responsibility to implement the mitigation strategies outlined in the plan. That means you!

## Food Defense Training Transcript

In addition to the food defense awareness training requirement, the IA rule further requires you to have proper training on the implementation of mitigation strategies at actionable process steps. Individuals working at these process steps, as well as their supervisors, must be qualified through education, training, or experience (or a combination thereof) to implement the mitigation strategy, or combination of strategies, at each actionable process step. This training may require facility-specific information for proper implementation of the mitigation strategy or strategies and, therefore, will need to be developed and administered on the job.

## Implementation of Food Defense at a Facility Summary Transcript

In this module, you learned to:

1. Explain the importance of a food defense plan.
2. Describe actionable process steps.
3. Explain mitigation strategies.
4. Recognize the importance of training.

Now let's see what you remember about what you just learned!

## Title Transcript

Module 3: Roles and Responsibilities

## Objectives

After completing this module, you will be able to:

1. Explain the various roles in food defense awareness.
2. Recognize your role in preventing intentional adulteration.
3. Give examples of suspicious activity.
4. Report suspicious activities to the appropriate person.

## Food Defense Responsibilities Transcript

Responsibility for protecting food from intentional adulteration lies with regulators, industry, consumers and especially you! Everyone plays a role in protecting food from intentional adulteration to actively being aware and reporting suspicious behaviors will make it much harder for anyone to use the food supply to hurt others. Let's review roles and responsibilities in a bit more detail.

## Roles in Food Defense Transcript

In order to produce safe food for consumers, industry plays a leading role in protecting food from intentional adulteration.

The role of the FDA and other regulators is to ensure that industry is complying with various rules and regulations for producing safe food. This includes conducting inspections to ensure that facilities are following their food defense plans.

## Your Role in Food Defense Transcript

Your role in food defense is extremely important! Because you are working at an actionable process step, or supervising those workers, **you** are required to take food defense awareness training and to ensure the proper implementation of the mitigation strategies at that step.

There are many possible mitigation strategies that you may come across, but here are a few examples:

- Locking the hatch to the silo if that is where you work, or
- Using your identification card to access your restricted work area, or
- Making sure that you have someone working with you at all times at your actionable process steps.

Since mitigation strategies are put in place to significantly reduce the likelihood of a successful intentional adulteration, it is extremely important that they are implemented properly.

## If Not You, Then Who? Transcript

Think about it. You may have the most knowledge about your work station. For example, if your job routinely involves preparation and staging of ingredients for processing, who is in a better position to notice that something suspicious may have occurred? Maybe one of the mitigation strategies at this step is that you must visually inspect the ingredients and their containers prior to use to ensure that the containers remain intact and the ingredient appearance is normal. Since you are the person doing these things on a regular basis, you play a critical role in recognizing when something appears wrong. If you see something unusual or suspicious, it is your responsibility to report the incident. Your role in protecting the food supply against intentional adulteration is important. Your attentiveness and vigilance are key to the success of the food defense plan!

## Food Defense in Action! Transcript

Let's look at food defense in action. Much of your facility's food defense plan relies on your awareness of your surroundings. Because you work at an actionable process step, or supervise someone who does, you have the experience and knowledge to implement mitigation strategies. You are uniquely positioned to report when something is out of place or when someone is acting suspiciously. This could include suspicious individuals or suspicious activities. In some cases, a suspicious individual could be a colleague or employee.

Any attempt to get around a mitigation strategy should raise a red flag in your mind. Unusual interest in accessing the food supply from or near your workstation should make you suspicious. Let's look at some other things that you should report.

## Suspicious Events and Activities Transcript

Do you pay attention to what's going on around you at work? Would you recognize suspicious activity? Here are some things to look out for.

If you see these things, you should report them. As the old saying goes – better safe than sorry! Select each tab to see a description of each suspicious activity. Select each tab to learn more about each situation.

## What is going on here? Transcript

What's going on here? Brenda, the supervisor, is clearly concerned about some suspicious activities she is visually observing. Can you find everything she is concerned about?

PUBLIC VERSION

## What is going on here? Picture 2 Transcript

Did you see all the things glowing on this image? In each of these cases, Brenda should have been immediately informed. These are suspicious and concerning activities that should have been reported to management.

## What is going on here? Summary Transcript

Because every facility is unique, the situations that spark your food defense knowledge will also be unique. These were but a few suspicious situations in which your vigilance and awareness of food defense measures can help prevent a disaster. These situations should immediately prompt your reporting procedures. Find out today what the reporting procedures are at your facility and identify the individual that you will need to inform about a potential suspicious situation.

## Roles and Responsibilities Summary Transcript

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

- In this module, you learned to:
  1. Explain the various roles in food defense awareness.
  2. Recognize your role in preventing intentional adulteration.
  3. Give examples of suspicious activity.
  4. Report suspicious activities to the appropriate person.
- Now let's see what you remember about what you just learned.



## Course Summary Transcript

We're coming to the end of our time together. By now you should be able to:

1. Explain the importance of food defense.
2. Describe ways to protect food from intentional adulteration.
3. Recognize suspicious activity.
4. Report suspicious activity.

## Food Defense Awareness Reminders Transcript

Most importantly, you've learned how vital you are in protecting food from acts intended to cause wide scale public health harm. As the eyes and ears at actionable process steps, your vigilance may be the food supply's first line of defense.

## Completion Transcript

- Congratulations!
- You have successfully met the food defense awareness training requirement of the IA rule (21 CFR 121.4(b)(2)).
- Don't forget to follow up with management to learn how to properly implement mitigation strategies and where to report suspicious activity!
- In order to print your Food Defense Awareness certificate of completion, visit [lms.ifpti.org](https://lms.ifpti.org), click "Transcript" from the drop down menu, and click "Print Certificate" under the "Food Defense Awareness" course.

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[https://collaboration.fda.gov/intentional\\_adulteration\\_v1/](https://collaboration.fda.gov/intentional_adulteration_v1/)
- FDA's website to access the IA Rule  
<https://www.fda.gov/food/guidanceregulation/fsma/ucm378628.htm>
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