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FSPCA Overview of the Intentional Adulteration Rule (IA Rule)




<http://www.fda.gov/fsma>

FDA FOOD SAFETY
MODERNIZATION ACT

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Helpful Tips:

- When you see text that is **bold, blue and underlined** during this course, you can click on it to read more information about that topic.
- You can click on the  button found in the top right corner of this course at any time to access the full IA rule
- Click on the  button to see a transcript of the slide audio
- Click on the  button turn voice over autoplay on or off
- Be sure to enable browser window pop-ups ALWAYS for this course

Background

Mitigation Strategies to Protect Food Against Intentional Adulteration

- Proposed on December 24, 2013
- Public comments: More than 200 for the original proposal
- Final rule publication date: May 27, 2016



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What Does the IA Rule Do?

- Establishes requirements to prevent or significantly minimize acts intended to cause wide-scale public health harm
- Uses a HACCP-type approach, with important differences from the Preventive Controls for Human Food rule
- Is risk-based and flexible



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Who is Covered by the IA Rule?

- In general, facilities required to register with FDA under sec. 415 of the FD&C Act
 - Not farms or retail food establishments
- Facilities that manufacture, process, pack, or hold human food
- Applies to domestic and imported food
- Some exemptions and modified requirements apply



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External Links & Resources

- [Click here to read about the modified requirements for VSBs](#)

Very Small Business Exemption

- The rule does not apply to [very small businesses \(VSBs\)](#)
 - Averaging less than \$10,000,000 per year, in both sales of human food plus the market value of human food manufactured, processed, packed, or held without sale, e.g., held for a fee
- VSBs are required to provide for official review, upon request, documentation sufficient to show that the facility qualifies for this exemption



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Other Exemptions

- Holding of food, except holding of food in liquid storage tanks
- Packing, repacking, labeling, or relabeling of food where the container that directly contacts the food remains intact
- Activities of a farm subject to the Produce Safety Rule
- Manufacturing, processing, packing, or holding food for animals



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External Links & Resources

- You can find more information about the last exemption in the preamble of the IA rule. You can access the full text of the rule by clicking on the IA Rule button at the top right corner of this course.
- [Click here for more information about any of the exemptions within the IA rule](#)

Other Exemptions (continued)

- Alcoholic beverages at certain facilities (under [two specified conditions](#))
- On-farm manufacturing/processing, packing, or holding by a [small or very small business](#) of eggs (in-shell, other than Raw Agricultural Commodities) or certain types of game meats, if such activities are the only activities conducted by the business subject to section 418 of the FD&C Act



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External Links & Resources

- [Click here to view the Food Defense Plan section of the rule](#)

What is Required?

- Food defense plan
 - Vulnerability assessment (VA)
 - Mitigation strategies
 - Procedures for food defense monitoring
 - Procedures for food defense corrective actions
 - Procedures for food defense verification
- Records
- Training



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Key Terms

- [Actionable Process Step](#)
- [Mitigation Strategies](#)
- [Significant Vulnerability](#)



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External Links & Resources

- [Click here to view the Vulnerability Assessment section of the rule](#)

Food Defense Plan — Vulnerability Assessment

- Identification of actionable process steps
- For each point, step, or procedure, a facility must consider, at a minimum:
 - Potential public health impact
 - Degree of physical access to product
 - Ability of an attacker to successfully contaminate the product



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Food Defense Plan — Vulnerability Assessment

- Must consider the possibility of an inside attacker
- Outcome of assessment must be written



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Vulnerability Assessment Methodology

- Flexible methodology as long as the three elements as well as the inside attacker are considered for each point, step, or procedure
- Must be a **qualified individual** with specific training to conduct a VA
- The Key Activity Types method is considered an appropriate method to conduct a VA
 - Bulk liquid receiving and loading
 - Liquid storage and handling
 - Secondary ingredient handling
 - Mixing and similar activities



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External Links & Resources

- [Click here to view the Mitigation Strategies section of the rule](#)

Food Defense Plan — Mitigation Strategies

- Measures to ensure significant vulnerabilities at actionable process steps are significantly minimized or prevented
- Facilities must identify and implement mitigation strategies for each actionable process step
- Must include a written explanation for how the strategy minimizes the vulnerability
- Must be performed by a qualified individual with the appropriate training or experience



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Food Defense Plan — Mitigation Strategy Management Components

- Food defense monitoring
- Food defense corrective actions
- Food defense verification

— As appropriate to ensure the proper implementation of the mitigation strategies, taking into account the nature of the mitigation strategy and its role in the facility's food defense system



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External Links & Resources

- [Click here to view the Monitoring section of the rule](#)

Food Defense Plan — Food Defense Monitoring

- Facilities must have written procedures, including the frequency they are to be performed, for monitoring the mitigation strategies (as appropriate to the nature of the mitigation strategies)
- Monitoring must be documented in records subject to verification



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External Links & Resources

- [Click here to view the Corrective Actions section of the rule](#)

Food Defense Plan — Food Defense Corrective Actions

- Facilities must have written procedures for steps to be taken when mitigation strategies are not properly implemented (as appropriate to the nature of the actionable process step and the nature of the mitigation strategy)
 - Identify and correct a problem
 - Reduce likelihood of recurrence
- Corrective actions must be documented in records subject to verification



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External Links & Resources

- [Click here to view the Verification section of the rule](#)

Food Defense Plan — Food Defense Verification

- Includes (as appropriate to the nature of the mitigation strategy and its role in the facility's food defense system):
 - Verification of monitoring
 - Verification of corrective actions
 - Verification that mitigation strategies are properly implemented through records review or other activities
- Does not include a number of the requirements that food safety verification utilizes, such as validation, calibration, or testing
- Verification must be documented in records



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External Links & Resources

- [Click here to view the Reanalysis section of the rule](#)

Reanalysis of Food Defense Plan

- At least every three years
- Situational triggers:
 - Whenever there is a significant change that creates the potential for a new vulnerability or a significant increase in one previously identified
 - When there is new information about potential vulnerabilities associated with a food operation or facility
 - When a mitigation strategy is found to be not properly implemented
 - Whenever FDA requires reanalysis to respond to new vulnerabilities, credible threats, or developments in scientific understanding



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External Links & Resources

- [Click here to view the Training section of the rule](#)

Training

- All people performing activities for this rule must be qualified individuals
- Individuals working at actionable process steps and their supervisors must also complete:
 - Food defense awareness training
 - Training on the proper implementation of mitigation strategies at their actionable process steps



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External Links & Resources

- [Click here to view the Training section of the rule](#)

Training (continued)

- Individuals performing the following activities: (1) Writing or overseeing the writing of the food defense plan, (2) Performing a vulnerability assessment, (3) Identifying and explaining the mitigation strategies, and (4) Performing a reanalysis of the food defense plan must also:
 - Complete training for these activities at least equivalent to that received from a standardized curriculum recognized as adequate by FDA, or
 - Be otherwise qualified through job experience



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External Links & Resources

- [Click here to view the Records section of rule](#)

Records

- Facilities are required to establish and maintain certain records, including:
 - Food defense plan
 - Food defense monitoring, corrective action, and verification records
 - Documentation related to training of personnel
- Use of existing records



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Compliance Dates

- **Very small businesses***: Five years — 7/26/2021
- **Small businesses**: Four years — 7/27/2020
- **All other businesses**: Three years — 7/26/2019

*Reminder: VSB averages less than \$10,000,000 per year, in both sales of human food plus the market value of human food manufactured, processed, packed, or held without sale



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External Links & Resources

- [Click here to view FDA's "Guidance for Industry: Mitigation Strategies to Protect Food Against Intentional Adulteration - What you Need to Know About the FDA Regulation: Small Entity Compliance Guide"](#)

Guidance to Support the IA Rule

- A small entity compliance guide to assist small and very small businesses to comply with the rule
- Vulnerability assessment
- Mitigation strategies
- Food defense monitoring, corrective actions, and verification
- Recordkeeping



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External Links & Resources

- [Click here to view the Technical Assistance Network website](#)

Training and Technical Assistance — Domestic

- Established the Intentional Adulteration Subcommittee within the Food Safety Preventive Controls Alliance to create training and technical assistance programs
- The FDA FSMA Technical Assistance Network has been established



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Training and Technical Assistance — International

- FDA plans include:
 - Collaborating with the Food Safety Preventive Controls Alliance on capacity building through its International Subcommittee
 - Working with regulatory counterparts and multinational organizations
 - Developing and disseminating outreach, education, and technical materials
 - Establishing training and technical assistance networks



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For More Information

- Website: <http://www.fda.gov/fooddefense>
 - Subscription feature available
- To contact FDA about FSMA and find the online form for submitting questions:
<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>

You have completed the FSPCA Overview of the Intentional Adulteration Rule (IA Rule) course!



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Welcome

Welcome to this overview of FDA's rule "Mitigation Strategies to Protect Food Against Intentional Adulteration." This is one of seven foundational rules of the Food Safety Modernization Act of 2011. To access the full rule at any time during this training, click on the Resources tab located at the top right corner of this screen.

The Food Safety Modernization Act—or FSMA—, the most sweeping reform of our food safety laws in more than 70 years, was signed into law by former President Obama on January 4, 2011. It aims to ensure that the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it. This important piece of legislation mandates a proactive preventive approach to food protection and includes directives to FDA to issue regulations for both food safety and food defense. This course will introduce you to the requirements of a very important rule that addresses protecting the food supply from intentional adulteration. The official title is long, Mitigation Strategies to Protect Food Against Intentional Adulteration, so let's call it the IA rule for short.

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Background

The IA rule was proposed on December 24, 2013 and we received more than 200 comments to the docket on the original proposal. The final rule was published on May 27th, 2016 with an effective date of July 26th in the same year. We will talk about compliance dates for various size businesses a little later in this course.

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What Does the IA Rule Do?

So what is the overarching principle of the IA rule? The IA rule establishes various food defense measures that an owner, operator, or agent in charge of a facility is required to implement in order to protect against the intentional adulteration of food. The purpose of the IA rule is to prevent or significantly minimize intentional acts of food adulteration intended to cause wide scale public health harm. Let's talk about two important components of that statement. The first is "acts intended to cause harm." Here we are focusing on those acts involving a person or group of people that are doing something to food to cause harm to others. The second component is "wide-scale public health harm". In FSMA, congress directed FDA to apply the requirements of this rule only to those points, steps, or procedures in the food system that are at highest risk for intentional adulteration. When we analyzed the spectrum of risk associated with intentional adulteration, wide-scale public health harm causing significant human morbidity and mortality was that of highest risk, and that is how the IA rule is organized and scoped to prevent those acts. The IA rule follows an approach that is similar in a number of ways to the Hazard Analysis Critical Control Point – or HACCP approach, but with some important differences. We'll look at those differences as we come to them a little later on in this course. For now, I'd like to point out one key difference between HACCP and the IA rule: increased flexibility! The IA rule is risk-based and also allows sufficient flexibility for owners, operators, or agents in charge to determine the most reasonable and appropriate food defense measures for their specific facility.

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Who is Covered by the IA Rule?

So, what facilities are covered by this rule? In general, the IA rule applies to facilities that are required to register with FDA under section 415 of the Federal Food, Drug and Cosmetic Act. What we mean here are facilities that manufacture, process, pack, or hold human food for consumption in the United States, whether they are a domestic facility or a foreign facility exporting food to the U.S. You should note that this does not include farms or retail food establishments. There are other exemptions from the IA rule that we will discuss on the next few pages.

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Very Small Business Exemption

The IA rule has an exemption for very small businesses. The main requirements of the rule do not apply to very small businesses, but these entities do have one modified requirement. First, you should know that the IA rule defines a very small business as an entity averaging less than 10 million US dollars per year, averaged over three years, of total sales of human food plus the market value of human food manufactured, processed, packed, or held without sale, for example held for a fee. The only requirement that very small businesses have for this rule is to provide documentation to show that they qualify for this exemption, if requested by FDA.

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Other Exemptions

Now, let's review the other exemptions. Some of the activities that are exempt from the IA rule are:

- Holding of food – except holding of food in liquid storage tanks
- Packing, repacking, labeling or relabeling where the container that directly contacts the food remains intact
- Activities of a farm subject to the Produce Safety Rule. In other words, activities being conducted under FDA's new farm definition and
- Manufacturing, processing, packing, or holding of food for animals.

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Other Exemptions (continued)

The IA rule also exempts alcoholic beverages at a facility that meet two specified conditions. Food that is not an alcoholic beverage at a facility described above is also exempt, provided the food is in prepackaged form that prevents any direct human contact and constitutes not more than 5 percent of the overall sales of the facility.

Finally, the rule exempts on-farm manufacturing, processing, packing, or holding by a small business or very small business of eggs that are in shell, other than raw agricultural commodities such as pasteurized eggs, or certain types of game meats, if such activities are the only activities conducted by the business. It is crucial to note that this last exemption only applies to mixed-type facilities that are also small or very small businesses. This exemption is very detailed, and you can find more information about this in the preamble of the IA rule.

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What is Required?

Let's move on to discussing the requirements of the rule. The rule requires the writing and implementation of a food defense plan. That plan includes five main components and there are records requirements throughout each of those components. The first component of the food defense plan is a vulnerability assessment to identify points in the facility that are most vulnerable. Once this is done, facilities then identify mitigation strategies to reduce or prevent those vulnerabilities. After that, facilities are required to have procedures for food defense monitoring, food defense corrective actions, and food defense verification. There are records requirements for each of those components, as well as specific training requirements for certain individuals.

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Key Terms

Before we move on to talk about the major requirements individually, let's take a moment to understand three key terms we will be using a lot for the rest of this course: actionable process steps, mitigation strategies, and significant vulnerabilities. We do have analogies for these key terms in the food safety arena, but these terms are specific for food defense.

First, actionable process steps are those points, steps, or procedures 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. 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.

Second, mitigation strategies are 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 also consistent with the current scientific understanding of food defense at the time of the analysis. Think of it this way, mitigation strategies are the activities and safeguards put in place to reduce or eliminate an identified vulnerability.

Lastly, a significant vulnerability means 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.

Keeping these terms in mind, let's talk about the first component of the food defense plan.

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Food Defense Plan - Vulnerability Assessment

The first component in developing the food defense plan is to conduct a vulnerability assessment. The goal of the vulnerability assessment is to identify those points at highest risk, or again, what we call actionable process steps. This means that each point, step, or procedure in the food process must be assessed while considering, at a minimum, the following three elements:

- The potential public health impact if a contaminant were successfully added at the point under assessment;
- The degree of physical access to the product, in other words can an attacker access the food stream at this point; and finally
- The ability of an attacker to successfully contaminate the product. For example, would an attacker be able to bring enough contaminant into the facility and then add that contaminant to the food stream at that point without detection?

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Food Defense Plan - Vulnerability Assessment

Importantly, the vulnerability assessment must consider the possibility of an inside attacker when evaluating the three elements. We will again note Congress' direction to FDA to only cover foods at highest risk for this rule. In conducting vulnerability assessments with industry and government partners, including intelligence and law enforcement agencies, we have jointly determined the scenario of highest risk includes an attacker. Facilities must consider how vulnerable their processing steps are to an attack by someone with legitimate inside access to their facility who intends to adulterate the food supply in order to cause wide-scale harm. The vulnerability assessment must be written and must include an explanation of why each point, step, or procedure either was or was not identified as an actionable process step. This written vulnerability assessment becomes a record subject to Subpart D of the IA rule. We'll talk more about this and other records a little later.

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Vulnerability Assessment Methodology

There are many appropriate approaches, but FDA is not requiring any particular vulnerability assessment method, only that an inside attacker and the three elements discussed previously must be considered. FDA recognizes that certain expertise is required for the proper conduct of most vulnerability assessments. This is why it is required that those performing vulnerability assessments be “qualified individuals.” This means that they have the appropriate training, education or experience – or a combination – to properly perform their assigned activities. Qualified individuals will be discussed later in this lesson.

One recognized approach of conducting a vulnerability assessment that has the advantage of being more simplified is using the key activity type method. Over the past 10 to 15 years, government, academia, and industry partners have jointly conducted many vulnerability assessments on a number of food products. When looking at the data from these vulnerability assessments, FDA noticed a pattern. Certain activities consistently ranked higher in vulnerability than other activities, no matter what type of food was being produced. So what we found is that there are no particular foods that are more inherently vulnerable to intentional adulteration compared to other foods. Rather, the main drivers of vulnerability are the processing steps and procedures that we use to produce food. FDA grouped the activities that scored higher in the vulnerability assessments into four general categories of food processing steps or procedures and identified them as key activity types. They are:

- Bulk liquid receiving and loading
- Liquid storage and handling
- Secondary ingredient handling
- Mixing and similar activities

When using the key activity type methodology to conduct a vulnerability assessment, if these types of activities occur in a facility’s process, these steps will be actionable process steps. The key activity type method helps facilities that may have less technical expertise to identify actionable process steps and makes it easier for industry to more quickly identify some of the most vulnerable process steps in any facility. See guidance documents for more information about the key activity types method.

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Food Defense Plan — Mitigation Strategies

The result of a vulnerability assessment will be a list of the facility’s most vulnerable points—its actionable process steps. Now the facility must identify appropriate mitigation strategies at these actionable process steps. Remember that mitigation strategies are those measures put in place to reduce or eliminate the significant vulnerability. Facilities must identify and implement mitigation strategies for each actionable process step. Mitigation strategies are facility-specific. Facilities are in the best position to know which mitigation strategies are appropriate for their particular vulnerabilities, processes, and procedures. The rule reflects this by providing facilities the flexibility to identify the best strategy or combination of strategies needed at each actionable process step. Like all components of the food defense plan, the mitigation strategies must be in written form. The written strategy must include an explanation describing how the identified strategy reduces or prevents the significant vulnerability. Just like conducting a vulnerability assessment, this activity must be performed by a qualified individual with the appropriate training or experience.

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Food Defense Plan — Mitigation Strategy Management Components

The next three components of the food defense plan are food defense monitoring, food defense corrective actions, and food defense verification. Collectively these are called mitigation strategies management components. Together, they form a system to ensure that mitigation strategies are being properly implemented and are in fact reducing significant vulnerabilities. If you've been in the food production business a while, these terms may seem familiar. The HACCP approach mentioned earlier also requires monitoring, corrective actions, and verification, as does the FSMA Preventive Controls Rule for Human Food. The difference between those requirements and the IA rule requirements is directly related to the nature of the hazard you are trying to control. Preventive controls are more likely to be process-oriented, and lend themselves to scientific validation, calibration, and sometimes testing. The nature of mitigation strategies is focused squarely on minimizing and/or preventing intentional adulteration and are put into place to reduce access to the food stream at a particular point, step, or procedure or to prevent or minimize the ability of an attacker to successfully contaminate the food supply at a particular point, step, or procedure. Mitigation strategies, due to their nature, do not necessarily lend themselves to scientific validation, nor are the vast majority of strategies process-oriented. Mitigation strategies management components also lend themselves to being less resource-intensive, in some cases significantly so, compared to management components put in place for food safety. To highlight these differences, and how the system put in place to ensure proper implementation of mitigation strategies is different from HACCP and the PC rule requirements, FDA has qualified these requirements by indicating that for the IA rule, these are called "food defense" monitoring, "food defense" corrective actions, and "food defense" verification. Let's look at each one individually.

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Food Defense Plan — Food Defense Monitoring

For the food defense monitoring requirement, facilities must have written procedures, including the frequency they are to be performed, for monitoring mitigation strategies. This must be incorporated as appropriate to the nature of the mitigation strategy. Monitoring must be documented in records subject to food defense verification. An important difference between food defense monitoring and monitoring for preventive controls emerges due to the nature of the two activities. For preventive controls and food safety activities, constant monitoring may be more appropriate for some things such as time and temperature control. That is not the case for food defense monitoring. For example, if the mitigation strategy was a lock on a liquid storage silo, we would not expect the facility to constantly monitor that lock. A more appropriate method for monitoring may be monitoring the lock at the end of the silo's cleaning cycle, such as every 48 hours. We also encourage viewers to look into exception record reporting as a way to save on resources. More information about exception records is provided in later in this course.

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Food Defense Plan — Food Defense Corrective Actions

For food defense corrective actions, facilities must have written procedures for corrective actions or previously determined steps to be taken when mitigation strategies are not properly implemented. These corrective action procedures take into consideration the nature of the actionable process step, as well as the nature of the mitigation strategy. Two important pieces to note here are that facilities must identify and correct problems with mitigation strategies, as well as reduce the likelihood the problem will recur. For food defense corrective actions, the intent is for facilities to think through the one or two most likely, and common sense, issues that may arise with a mitigation strategy, and have written corrective actions in place, if needed. Corrective action procedures must be documented in records subject to food defense verification.

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Food Defense Plan — Food Defense Verification

The third management component is food defense verification.

Food defense verification accomplishes three things:

1. It ensures that monitoring is being accomplished as planned,
2. That appropriate decisions about corrective actions are being made, and
3. That mitigation strategies are properly implemented, through records review of food defense monitoring records and food defense corrective action records or other activities.

Verification procedures are performed as appropriate to the nature of the mitigation strategy and its role in the facility's food defense system, and the procedures and their frequencies must be documented in the food defense plan. Food defense verification does not include a number of the requirements that food safety verification requires, such as validation, calibration, or testing. Performance of verification activities also must be documented in accordance with records requirements.

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Reanalysis of Food Defense Plan

The food defense plan is a dynamic document, subject to reanalysis and changes to make sure that it remains up-to-date and relevant. The IA rule requires that a facility must perform a reanalysis of the food defense plan at least once every three years in its entirety. There are also four situations that would trigger a reanalysis of the entire food defense plan or applicable portions of the plan. The first trigger is when a significant change of activities at the facility creates the potential for a new vulnerability or a significant increase in the likelihood or severity of an identified vulnerability. The second trigger is when new information has come to light about a potential vulnerability associated with a food operation or facility. The third trigger is when a mitigation strategy, combination of strategies, or the food defense plan as a whole is found not to have been properly implemented. The last trigger is whenever FDA requires a reanalysis to respond to new vulnerabilities, credible threats, or developments in scientific understanding related to intentional adulteration.

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Training

Now let's talk a little bit about training. The IA rule requires all individuals who are performing activities under the rule to be qualified to perform those functions. Remember, a qualified individual is a person who has the education, training, or experience (or a combination thereof) necessary to perform their assigned activities. In addition, workers assigned to actionable process steps and their supervisors must complete food defense awareness training. People in these positions are on the front line of food defense and are responsible for implementing mitigation strategies or supervising these activities. Because of that, these individuals also need training on the proper implementation of the mitigation strategies at their actionable process step.

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Training (continued)

The rule also requires individuals that are:

(1) Writing or overseeing the writing of the food defense plan, (2) Performing a vulnerability assessment, (3) Identifying and explaining the mitigation strategies, or (4) Performing a reanalysis of the food defense plan to be a qualified individual and to have successfully completed training at least equivalent to that received from a standardized curriculum recognized as adequate by the FDA or be otherwise qualified through job experience. FDA has been working through the Intentional Adulteration Subcommittee of the Food Safety Preventive Controls Alliance to develop the standardized curriculum training for these activities.

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Records

Let's take a moment now and review the recordkeeping requirements associated with the IA rule. IA rule records include the food defense plan itself, food defense monitoring records—whether they are affirmative records or exception records, corrective action and verification records, as well as reanalysis activity records and training documentation. Training records must include the date of training, the type of training, and the persons trained. As mentioned earlier, records supporting a very small business' exempt status must be kept at the facility, for as long as the facility will be claiming the exemption, and made available if a regulator requests it. We know that some facilities have been involved in food defense for a number of years, and may have records related to these activities already in place. Some of these existing records may count towards compliance with the requirements of the IA rule. Individuals responsible for records should be sure to read through the requirements and compare them to the records they have already created to ensure existing records meet these requirements.

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Compliance Dates

As with other FSMA rules, the IA rule has staggered compliance dates – based on the size of the business. Very small businesses, which as a reminder only have the modified requirement to prove that they are under the \$10 million threshold, must comply by July 26th of the year 2021. Small businesses, which we define as businesses employing fewer than 500 full-time equivalent employees, must be fully compliant with the rule by July 27th of the year 2020. Finally, all other businesses covered by the rule must comply by July 26th of the year 2019.

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Guidance to Support the IA Rule

FDA guidance is planned for many of the topics covered in this course, and may be available to you now. A small entity compliance guide was released in August of 2017 to assist small and very small businesses with complying with this rule. Other guidance covers vulnerability assessments and how to properly conduct them, how to identify and implement mitigation strategies, what food defense monitoring, food defense corrective actions, and food defense verification procedures look like, and how to comply with record keeping requirements.

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Training and Technical Assistance — Domestic

As previously mentioned, the FDA is working through the Intentional Adulteration subcommittee within the Food Safety Preventive Controls Alliance to develop and update trainings to assist with IA rule compliance. Also, the Technical Assistance Network, or TAN, has been established to help facilities better understand and comply with FSMA rules. FDA has received and responded to numerous FSMA-related questions through the TAN, including questions related to this rule. FDA encourages those with questions to submit their inquiries to the TAN.

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Training and Technical Assistance — International

The international aspects of training and technical assistance will build on the domestic activities we just covered. FDA will continue to collaborate with the Food Safety Preventive Controls Alliance on capacity building through its International Subcommittee and will work with regulatory counterparts and multi-national organizations. FDA will also develop and disseminate education, outreach, and technical materials, and finally, will establish training and technical assistance networks.

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For More Information

I want to thank you for your interest in the intentional adulteration rule and your attention during this course. For more information please visit the FDA website at www.fda.gov/Fooddefense. Additional resources pertaining to the IA rule are located in the Resources tab located at the top right corner of this course.

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Resources

Resources

Help

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- Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration
<https://www.regulations.gov/document?D=FDA-2013-N-1425-0146>
- Guidance for Industry: Mitigation Strategies to Protect Food Against Intentional Adulteration - What You Need to Know About the FDA Regulation: Small Entity Compliance Guide
<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm562216.htm>
- FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration Fact Sheet
<https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM503566.pdf>
- FDA's website for Technical Assistance for all FSMA rules
<https://www.fda.gov/food/guidanceregulation/fsma/ucm459719.htm>
- FDA's website for Food Defense Tools and Resources
<https://www.fda.gov/Food/FoodDefense/default.htm>
- Other FSPCA IA Subcommittee Trainings
<https://www.ifsh.iit.edu/fspca/courses/intentional-adulteration>

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