

**Mitigation Strategies to Protect Food  
Against Intentional Adulteration: What  
You Need to Know About the FDA  
Regulation:  
Guidance for Industry  
Small Entity Compliance Guide**

*Additional copies are available from:  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5001 Campus Drive  
College Park, MD 20740  
(Tel) 240-402-1700  
<http://www.fda.gov/FoodGuidances>*

You may submit either electronic or written comments regarding this guidance at any time. Submit electronic comments to <http://www.regulations.gov>. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2013-N-1425 listed in the notice of availability that publishes in the *Federal Register*.

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
August 2017**

## **TABLE OF CONTENTS**

I.	INTRODUCTION .....	4
A.	Purpose of this Compliance Guide .....	5
B.	Key Requirements.....	5
II.	WHO MUST COMPLY WITH THE RULE? .....	6
A.	Definitions.....	6
B.	Who is exempt from the requirements for the IA Rule?.....	7
C.	Do I have to comply with the requirements of the IA rule if I am not required to register with the FDA?.....	9
D.	Am I exempted from the rule if my firm is a very small business?.....	9
III.	WHEN DO I HAVE TO COMPLY WITH THE RULE?.....	9
IV.	FOOD DEFENSE MEASURES .....	10
A.	Food Defense Plan .....	10
1.	What contents are required in a written food defense plan? .....	10
2.	Who must sign the food defense plan?.....	10
B.	Vulnerability assessment to identify significant vulnerabilities and actionable process steps.....	10
1.	What is a vulnerability assessment?.....	10
2.	What are actionable process steps? .....	11
3.	How do I conduct a vulnerability assessment? .....	11
4.	What are the ways to conduct a vulnerability assessment to identify actionable process steps? .....	11
5.	What training requirements are there for the individual(s) conducting a vulnerability assessment?.....	11
C.	Mitigation Strategies for Actionable Process Steps.....	11
1.	What are mitigation strategies?.....	12
2.	When am I required to identify and implement mitigation strategies? .....	12

*Contains Nonbinding Recommendations*

3. What training requirements are there for the individual(s) identifying and writing explanations of mitigation strategies? .....	12
4. What do I have to do once the mitigation strategies are in place? .....	12
D. Mitigation Strategies Management Components.....	12
E. Reanalysis .....	15
1. When must I conduct a reanalysis of the food defense plan? .....	15
2. Are there other conditions that would require a reanalysis of the food defense plan or sections of the food defense plan? .....	16
3. Do I have to make any changes to the food defense plan as a result of the reanalysis? .....	16
V. RECORDS REQUIREMENTS .....	16
A. What records am I required to make and keep?.....	16
B. What specific information must I include in my records?.....	17
C. What are requirements for records?.....	18
D. Do records have to be in electronic format? .....	18
E. Can I enter information on required records at the end of the day or the end of the week? .....	18
F. How long must I retain my records?.....	18
G. Can I store my records offsite? .....	19
H. Do I have to make required records available to FDA officials? .....	19
I. If FDA collects or copies my records, including the food defense plan, are they protected from public disclosure? .....	19
J. Can I use existing records to meet the records requirements of the IA rule? .....	19
VI. EDUCATION, TRAINING, AND QUALIFICATIONS.....	19
VII. DEFINITIONS (21 CFR 121.3) .....	21

# Mitigation Strategies to Protect Food Against Intentional Adulteration: What You Need to Know About the FDA Regulation: Guidance for Industry<sup>1</sup> Small Entity Compliance Guide

This guidance represents the Food and Drug Administration’s (FDA or Agency) current thinking on this topic. It does not establish any rights for any person and does not bind FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance using the contact information on the title page.

## I. INTRODUCTION

**The FDA Food Safety Modernization Act (FSMA)** directs the Food and Drug Administration (FDA) as the food regulatory agency of the U.S. Department of Health and Human Services to better protect public health by, among other things, adopting a modern, preventive, and risk-based approach to food safety regulation. On May 27, 2016, FDA published in the *Federal Register* a final rule, *Mitigation Strategies to Protect Food Against Intentional Adulteration* (IA rule) (81 FR 34165), that creates new requirements for the production of food by registered food facilities to protect the food supply against intentional adulteration. The final rule became effective on July 26, 2016. Compliance dates are staggered – see “WHEN DO I HAVE TO COMPLY WITH THE RULE?”

We have prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121, as amended by

---

<sup>1</sup> This guidance has been prepared by the Office of Analytics and Outreach in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

## *Contains Nonbinding Recommendations*

Public Law 110-28). This guidance document is intended to assist small entities in complying with the rule set forth in 21 CFR 121 concerning Mitigation Strategies to Protect Food Against Intentional Adulteration. The rule is binding and has the full force and effect of law.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

### **A. Purpose of this Compliance Guide**

This guide was developed to inform domestic and foreign food facilities about the IA rule and how to comply with it. It contains important information that may affect your firm.

### **B. Key Requirements**

Covered facilities must develop and implement a food defense plan that includes an analysis of vulnerabilities and implementation of mitigation strategies.

1. The rule requires a written food defense plan for all covered facilities unless an exemption applies (21 CFR 121.5). The written plan must include (21 CFR 121.126):
  - A vulnerability assessment to identify significant vulnerabilities and actionable process steps, and associated explanations
  - Mitigation strategies and associated explanations
  - Procedures for food defense monitoring
  - Procedures for food defense corrective actions
  - Procedures for food defense verification
2. The rule requires training for certain personnel. See “EDUCATION, TRAINING, AND QUALIFICATIONS” section (21 CFR 121.4)
3. The rule requires covered facilities to maintain the food defense plan as a record as well as records for training, food defense monitoring, food defense corrective actions, and food defense verification. (21 CFR 121.126(c), 121.140(c), 121.145(b), and 121.150(c))
4. The rule requires reanalysis of the food defense plan. (21 CFR 121.157)

*Contains Nonbinding Recommendations*

## **II. WHO MUST COMPLY WITH THE RULE?**

The requirements of this rule apply to facilities – either in the U.S. or any other country – that are required to register with FDA as food facilities because they manufacture/process, pack, or hold human food for consumption in the U.S. (21 CFR 121.1)

### **A. Definitions**

The IA rule uses a number of terms in very specific ways. A full list of these terms appears in this guide on page 21. The terms defined here and in the section entitled “Who is exempt from the requirements for Mitigation Strategies to Protect Food Against Intentional Adulteration?” will help you determine if your business is subject to the rule. (21 CFR 121.3)

Table 1--Key Terms Used in Part 121

<b>Term</b>	<b>Definition</b>
Facility	Any establishment, structure, or structures under one ownership at one general physical location, or a mobile facility traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the U.S.
Manufacturing/Processing	Making food from one or more ingredients, or creating, preparing, treating, modifying or manipulating food, including food crops or ingredients.
Packing	Placing food into a container other than a container that directly contacts the food and that the consumer receives, including incidental activities to ensure the safe or effective packing of that food such as sorting, culling, grading, and weighing or conveying.
Holding	Storage of food, including activities ensuring the safe or effective storage of a food such as fumigating food during storage, and drying/dehydrating raw agricultural commodities (when the drying/dehydrating does not create a distinct commodity, e.g., drying/dehydrating hay or alfalfa). Holding also includes activities necessary for the distribution of food such as blending of a raw agricultural commodity or breaking down pallets.

***Contains Nonbinding Recommendations***

Mixed-type facility	An establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.
---------------------	---

**B. Who is exempt from the requirements for the IA Rule?**

Table 2--Exemptions for Part 121

<b>Exemption</b>	<b>Conditions</b>
Very small businesses (21 CFR 121.5(a))	A business (including any subsidiaries and affiliates) averaging less than \$10,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee). (21 CFR 121.3)
Holding of food, except the holding of food in liquid storage tanks (21 CFR 121.5(b))	Holding of food in liquid storage tanks is subject to the IA rule. See DEFINITIONS, page 21 for the definition of holding.
Packing, re-packing, labeling, or re-labeling of food where the container that directly contacts the food remains intact (21 CFR 121.5(c))	See DEFINITIONS, page 21 for the definition of packing.
Activities of a farm that are subject to Standards for Produce Safety, section 419 of the Federal Food, Drug, & Cosmetic Act	See FDA’s Produce Safety Rule for a description of these activities  <a href="https://www.federalregister.gov/articles/2015/11/27/2015-28159/standards-for-the-growing-">https://www.federalregister.gov/articles/2015/11/27/2015-28159/standards-for-the-growing-</a>

*Contains Nonbinding Recommendations*

<b>Exemption</b>	<b>Conditions</b>
(21 CFR 121.5(d))	<a href="#"><u>harvesting-packing-and-holding-of-produce-for-human-consumption</u></a>
<p>Alcoholic beverages regulated by the Alcohol and Tobacco Tax and Trade Bureau (TTB) of the U.S. Treasury Department</p> <p>(21 CFR 121.5(e))</p>	<p>Exemption for alcoholic beverages must meet the following two conditions:</p> <ol style="list-style-type: none"> <li>1) Under the Federal Alcohol Administration Act (27 U.S.C. 201 <i>et seq.</i>) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 <i>et seq.</i>) the facility is required to obtain a permit from, register with, or obtain approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States, or is a foreign facility of a type that would require such a permit, registration, or approval if it were a domestic facility;</li> <li>2) Under section 415 of the Federal Food, Drug, and Cosmetic Act the facility is required to register as a facility because it is engaged in manufacturing, processing, packing, or holding one or more alcoholic beverages.</li> </ol> <p>Additionally, this exemption applies to food at these facilities that is not an alcoholic beverage, if such food is in prepackaged form that prevents any direct human contact with such food and it constitutes not more than 5 percent of the overall sales of the facility.</p>
<p>Manufacturing, processing, packing, or holding of food for animals other than man</p> <p>(21 CFR 121.5(f))</p>	<p>If a facility manufactures, processes, packs, or holds food for both humans and animals, the activities related to human food would be covered under this rule.</p>
<p>On-farm manufacturing, processing, packing, or holding of the following foods on a farm mixed-type facility, when conducted by a small</p>	<p>See DEFINITIONS, page 21 for definition of mixed-type facility.</p>



***Contains Nonbinding Recommendations***

<b>Exemption</b>	<b>Conditions</b>
<p>or very small business if such activities are the only activities conducted by the business subject to section 418 of the FD&amp;C Act:</p> <ol style="list-style-type: none"> <li>1. Eggs (in-shell, other than raw agricultural commodities, e.g., pasteurized);</li> <li>2. Game Meats (whole or cut, not ground or shredded, without secondary ingredients)</li> </ol> <p>(21 CFR 121.5(g))</p>	

**C. Do I have to comply with the requirements of the IA rule if I am not required to register with the FDA?**

No. This rule would not apply to you. (21 CFR 121.1)

**D. Am I exempted from the rule if my firm is a very small business?**

You are exempt from the requirements of the IA rule if your firm is a very small business. However, you would be required to provide, upon request, documentation sufficient to show that your facility meets this exemption.

**III. WHEN DO I HAVE TO COMPLY WITH THE RULE?**

We encourage you to comply with the IA rule as soon as possible. However, we are not requiring you to comply with the IA rule right away. As shown in the table below, the amount of time we are allowing you to comply with the IA rule depends on your particular business.

Table 3--Compliance Dates for IA Rule Based on Size of Business

<b>Size of Business</b>	<b>Compliance Date</b>
Very small businesses (see definition in Table 2)	July 26, 2021
Small businesses, i.e., a business (including any subsidiaries and affiliates) with fewer than 500 full-	July 27, 2020

## *Contains Nonbinding Recommendations*

time equivalent employees	
Other businesses that do not qualify for exemptions	July 26, 2019

### **IV. FOOD DEFENSE MEASURES**

#### **A. Food Defense Plan**

##### **1. What contents are required in a written food defense plan?**

A food defense plan must include (21 CFR 121.126(b) and 121.310):

- Information adequate to identify the facility (e.g., the name and, when necessary, location of the facility)
- Vulnerability assessment to identify significant vulnerabilities and actionable process steps and associated explanations
- Mitigation strategies and associated explanations
- Food defense monitoring procedures
- Food defense corrective action procedures
- Food defense verification procedures
- Appropriate signature(s)

##### **2. Who must sign the food defense plan?**

The owner, operator, or agent in charge of the facility must sign and date the food defense plan upon initial completion of the plan and whenever there are any modifications made to the food defense plan. (21 CFR 121.310)

#### **B. Vulnerability assessment to identify significant vulnerabilities and actionable process steps**

You (the owner, operator, or agent in charge of the facility) must conduct, or have conducted, a vulnerability assessment to identify any actionable process steps in your facility. For each point, step, or procedure, you must provide a written explanation as to why that point, step, or procedure was or was not identified as an actionable process step. (21 CFR 121.130)

##### **1. What is a vulnerability assessment?**

## *Contains Nonbinding Recommendations*

A vulnerability assessment is an evaluation of each point, step, or procedure in your food operation to identify significant vulnerabilities and actionable process steps.

### **2. What are actionable process steps?**

An actionable process step is 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. (21 CFR 121.3) Actionable process steps are identified during a vulnerability assessment and are facility and process-specific.

### **3. How do I conduct a vulnerability assessment?**

When conducting a vulnerability assessment the three elements that must be evaluated at each point, step, or procedure include (21 CFR 121.130(a)):

- (1) The potential public health impact (e.g., severity and scale) if a contaminant were added;
- (2) The degree of physical access to the product; and
- (3) The ability of an attacker to successfully contaminate the product.

Additional factors may also be evaluated in the vulnerability assessment, but at a minimum, these three elements must be included in the vulnerability assessment for each point, step, or procedure. The assessment must also consider the possibility of an inside attacker. (21 CFR 121.130(b)) For each point, step or procedure, you must also provide an explanation as to why that point, step, or procedure was or was not identified as an actionable process step. (21 CFR 121.130(c))

### **4. What are the ways to conduct a vulnerability assessment to identify actionable process steps?**

FDA does not prescribe or require a specific methodology for conducting vulnerability assessments. Facilities have the option to choose the methodology for conducting a vulnerability assessment to identify significant vulnerabilities and actionable process steps. The main requirement is that vulnerability assessments include an evaluation of the three elements identified above, and consider the possibility of an inside attacker.

### **5. What training requirements are there for the individual(s) conducting a vulnerability assessment?**

See the EDUCATION, TRAINING, AND QUALIFICATIONS section for details on training requirements.

## **C. Mitigation Strategies for Actionable Process Steps**

## *Contains Nonbinding Recommendations*

### **1. What are mitigation strategies?**

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 consistent with the current scientific understanding of food defense at the time of the analysis. (21 CFR 121.3)

### **2. When am I required to identify and implement mitigation strategies?**

You must identify and implement mitigation strategies for each actionable process step identified during the vulnerability assessment. In addition, you must include a written explanation for how each strategy significantly minimizes or prevents the significant vulnerability at that actionable process step. FDA provides facilities with the flexibility to determine their own appropriate mitigation strategies. (21 CFR 121.135)

### **3. What training requirements are there for the individual(s) identifying and writing explanations of mitigation strategies?**

See the EDUCATION, TRAINING, AND QUALIFICATIONS section for details on training requirements.

### **4. What do I have to do once the mitigation strategies are in place?**

Once you have identified and implemented the mitigation strategies, you are required to conduct activities for food defense monitoring, food defense corrective actions, and food defense verification. (21 CFR 121.138) See MITIGATION STRATEGIES MANAGEMENT COMPONENTS section.

## **D. Mitigation Strategies Management Components**

The rule provides flexibility in the steps needed to ensure that mitigation strategies are properly implemented and to correct problems that may arise. These procedures must be written in the food defense plan, and are designed to provide assurance that mitigation strategies are consistently performed and properly implemented. Mitigation strategies are subject to the following mitigation strategies management components as appropriate to ensure the proper implementation of the mitigation strategies, taking into account the nature of each mitigation strategy and its role in the facility's food defense system (21 CFR 121.138):

- Food defense monitoring;
- Food defense corrective actions; and
- Food defense verification.

Table 4—Mitigation Strategies Management Components

*Contains Nonbinding Recommendations*

<b>Function</b>	<b>Explanation</b>
<p>Food Defense Monitoring (21 CFR 121.140)</p>	<p>For each mitigation strategy, you must establish and implement written procedures for monitoring as appropriate to the nature of the mitigation strategy and its role in the facility’s food defense system. Food defense monitoring is conducting a planned sequence of observations or measurements to assess whether mitigation strategies are operating as intended. (21 CFR 121.3)</p> <p>You must monitor the mitigation strategies with adequate frequency to provide assurances that they are consistently performed. FDA does not specify any specific monitoring frequencies for mitigation strategies.</p> <p><b>Records:</b> All food defense monitoring activities must be documented in records and are subject to verification requirements and records review. Records may be affirmative records, or exception records. See RECORDS REQUIREMENTS section for more details on specific requirements. (21 CFR 121.140(c)(1))</p>
<p>Food Defense Corrective Actions (21 CFR 121.145)</p>	<p>For each mitigation strategy, you must establish and implement written procedures for corrective actions as appropriate to the nature of the actionable process step and the nature of the mitigation strategy. You must establish and implement written food defense corrective action procedures that must be taken if the mitigation strategies are not properly implemented. Food defense corrective action procedures must describe the steps to be taken to ensure that:</p> <ul style="list-style-type: none"> <li>• Appropriate action is taken to identify and correct a problem that has occurred with implementation of a mitigation strategy; and</li> <li>• Appropriate action is taken, when necessary, to reduce the likelihood that the problem will reoccur.</li> </ul> <p><b>Records:</b> All food defense corrective actions taken must be documented in records and are subject to verification requirements and records review. (21 CFR 121.145(b))</p>

*Contains Nonbinding Recommendations*

<b>Function</b>	<b>Explanation</b>
	See RECORDS REQUIREMENTS section for more details on specific requirements for records.
Food Defense Verification (21 CFR 121.150)	<p>Food defense verification is the application of methods, procedures, and other evaluations, in addition to food defense monitoring, to determine whether a mitigation strategy or combination of mitigation strategies is or has been operating as intended according to the food defense plan. (21 CFR 121.3)</p> <p>For each mitigation strategy, you must establish and implement procedures for food defense verification. Food defense verification activities must include, as appropriate to the nature of the mitigation strategy and its role in the facility's food defense system:</p> <ul style="list-style-type: none"> <li>• Verification that food defense monitoring is being conducted as required (21 CFR 121.150(a)(1));</li> <li>• Verification that appropriate decisions about food defense corrective actions are being made as required (21 CFR 121.150(a)(2));</li> <li>• Verification that mitigation strategies are properly implemented and are significantly minimizing or preventing the significant vulnerabilities (21 CFR 121.150(a)(3)); and</li> <li>• Verification of reanalysis in accordance with 21 CFR 121.157 (21 CFR 121.150(a)(4))</li> </ul> <p>To verify that mitigation strategies are properly implemented and are significantly minimizing or preventing the significant vulnerabilities, you must conduct activities that include the following, as appropriate to the facility, the food, and the nature of the mitigation strategy and its role in the facility's food defense system:</p> <ul style="list-style-type: none"> <li>• Review of the food defense monitoring and food defense corrective actions records within appropriate timeframes to ensure that the records</li> </ul>

***Contains Nonbinding Recommendations***

<b>Function</b>	<b>Explanation</b>
	<p>are complete, the activities reflected in the records occurred in accordance with the food defense plan, the mitigation strategies are properly implemented, and appropriate decisions were made about food defense corrective actions (21 CFR 121.150(a)(3)(i)); and</p> <ul style="list-style-type: none"> <li>• Other activities appropriate for verification of proper implementation of mitigation strategies (21 CFR 121.150(a)(3)(ii))</li> </ul> <p>If you are conducting verification through other activities for verification of proper implementation of mitigation strategies according to 21 CFR 121.150(a)(3)(ii), you must establish and implement written procedures, including the frequency for which they are to be performed. (21 CFR 121.150(b))</p> <p><b>Records:</b> All verification activities conducted must be documented in records. (21 CFR 121.150(c)) See RECORDS REQUIREMENTS section for more details on specific requirements for records.</p>

**E. Reanalysis**

**1. When must I conduct a reanalysis of the food defense plan?**

At a minimum, you must conduct a reanalysis of the entire food defense plan at least once every 3 years. (21 CFR 121.157(a))

In addition, you must complete reanalysis of the entire food defense plan or the applicable portions of the plan (21 CFR 121.157(c)):

- Before any change in activities (including any change in mitigation strategy) at the facility is operative;
- When necessary within 90-calendar days after production; and
- Within a reasonable timeframe, providing a written justification is prepared for a timeframe that exceeds 90 days after production of the applicable food first begins.

## *Contains Nonbinding Recommendations*

### **2. Are there other conditions that would require a reanalysis of the food defense plan or sections of the food defense plan?**

You must also conduct a reanalysis of the entire food defense plan or on the applicable section of the food defense plan:

- Whenever a significant change made in the activities conducted at your facility creates a reasonable potential for a new vulnerability or a significant increase in a previously identified vulnerability. (21 CFR 121.157(b)(1))
- Whenever you become aware of new information about potential vulnerabilities associated with the food operation or facility. (21 CFR 121.157(b)(2))
- Whenever you find that a mitigation strategy, a combination of mitigation strategies, or the food defense plan as a whole is not properly implemented. (21 CFR 121.157(b)(3))
- Whenever FDA requires reanalysis to respond to new vulnerabilities, credible threats to the food supply, and developments in scientific understanding including, as appropriate, results from the Department of Homeland Security biological, chemical, radiological, or other terrorism risk assessment. (21 CFR 121.157(b)(4))

### **3. Do I have to make any changes to the food defense plan as a result of the reanalysis?**

You must revise the written food defense plan if a significant change in the activities conducted at your facility creates a reasonable potential for a new vulnerability or a significant increase in a previously identified vulnerability. If after reanalysis it is determined that no changes are needed, you must document the basis for the conclusion that no revisions are needed. (21 CFR 121.157(d))

## **V. RECORDS REQUIREMENTS**

### **A. What records am I required to make and keep?**

You are required to make and keep the records shown in the table below.

Table 5—Records that must be kept

<b>Required Records</b>	<b>Description</b>
Food defense plan, including:	The food defense plan is a record that is



***Contains Nonbinding Recommendations***

<ul style="list-style-type: none"> <li>• Vulnerability assessment, including explanations</li> <li>• Mitigation strategies, including explanations</li> <li>• Food defense monitoring procedures</li> <li>• Food defense corrective action procedures</li> <li>• Food defense verification procedures (21 CFR 121.126(c))</li> </ul>	<p>subject to all of the records requirements described in this section, unless otherwise noted.</p> <p>The owner, operator, or agent in charge of the facility must sign and date the food defense plan upon initial completion of the plan and whenever there are any modifications made to the food defense plan.</p>
<p>Records documenting food defense monitoring of the mitigation strategies (21 CFR 121.140(c))</p>	<p>Monitoring records may be affirmative records demonstrating the mitigation strategy is functioning as intended. Exception records, demonstrating the mitigation strategy is not functioning as intended, may be adequate in some circumstances.</p>
<p>Records documenting food defense corrective actions taken (21 CFR 121.145(b))</p>	
<p>Records documenting food defense verification activities (21 CFR 121.150(c))</p>	
<p>Records documenting required training (21 CFR 121.4)</p>	<p>Training records must:</p> <ol style="list-style-type: none"> <li>(1) Include the date of training, the type of training, and the persons trained; and</li> <li>(2) Be established and maintained in accordance with other records requirements.</li> </ol>

**B. What specific information must I include in my records?**

Records must include (21 CFR 121.305):

- Information adequate to identify the facility (e.g., the name, and when necessary, the location of the facility);
- The date and, when appropriate, the time of the activity documented;
- The signature or initials of the person performing the activity; and

## *Contains Nonbinding Recommendations*

- Where appropriate, the identity of the product and the lot code, if any.

### **C. What are requirements for records?**

Records must (21 CFR 121.305):

- Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records;
- Contain the actual values and observations obtained during food defense monitoring;
- Be accurate, indelible, and legible;
- Be created concurrently with performance of the activity documented; and
- Be as detailed as necessary to provide history of work performed.

### **D. Do records have to be in electronic format?**

Records do not have to be in electronic format.

Records that are established or maintained for the IA rule that meet the definition of electronic records in 21 CFR 11.3(b)(6) are exempt from the requirements of 21 CFR part 11. However, records that satisfy the requirements of 21 CFR 121, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11. (21 CFR 121.305(g))

### **E. Can I enter information on required records at the end of the day or the end of the week?**

Records must be created concurrently with performance of the activity documented.  
(21 CFR 121.305(d))

### **F. How long must I retain my records?**

Records are required to be retained for at least 2 years after they were prepared. Food defense plans must be retained for 2 years after they have stopped being used.

Records that a facility relies on during the 3-year period preceding the applicable calendar year to support its status as exempt as a very small business must be retained at the facility as long as necessary to support the status of a facility as a very small business during the applicable calendar year. (21 CFR 121.315) A very small business must, upon request, provide for official review documentation sufficient to show that the facility meets this exemption. Such documentation must be retained for 2 years.(21 CFR 121.5(a)).

## *Contains Nonbinding Recommendations*

### **G. Can I store my records offsite?**

Except for the food defense plan, offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. The food defense plan must always be on site. Electronic records are considered onsite if they are accessible from an onsite location. If the facility is closed for a prolonged period, the food defense plan may be transferred to some other reasonably accessible location but must be returned to the facility within 24 hours for official review upon request. (21 CFR 121.315)

### **H. Do I have to make required records available to FDA officials?**

Yes. You must have all records required by this rule available for official review and copying at the request of FDA. FDA will copy records on a case-by-case basis as necessary and appropriate. (21 CFR 121.320)

### **I. If FDA collects or copies my records, including the food defense plan, are they protected from public disclosure?**

Records collected or copied by FDA, including the food defense plan, will be protected from public disclosure to the extent allowable under 21 CFR Part 20. (21 CFR 121.325)

### **J. Can I use existing records to meet the records requirements of the IA rule?**

Yes. You may use existing records kept for other purposes (e.g., records that are kept to comply with other Federal, State, or local regulations or for any other reason) to meet the requirements of this rule if they contain all of the required information and satisfy the requirements of this rule. Existing records may be supplemented as necessary to include all of the required information. In addition, records do not need to be kept in one set of records. If existing records contain some of the required information, any new information required may be kept either separately or combined with the existing records. (21 CFR 121.330)

## **VI. EDUCATION, TRAINING, AND QUALIFICATIONS**

### **1. What qualifications and/or training do I need to perform the activities within the IA rule?**

An individual performing activities required subpart C of this rule must be a qualified individual. A qualified individual is a person who has the education, training, or experience (or a combination thereof) necessary to perform an activity within the IA rule, as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an

***Contains Nonbinding Recommendations***

employee of the facility. Additionally, certain activities within the IA rule have specific training requirements as detailed in the chart below. (21 CFR 121.4)

Table 6—Education, training, and qualification requirements

<b>Assigned Duties</b>	<b>Education, Training, and Qualification Requirements</b>
Individuals assigned to an actionable process step (including temporary and seasonal personnel)	<ul style="list-style-type: none"> <li>• Must be a qualified individual, i.e., have the appropriate education, training, or experience (or a combination thereof) necessary to properly implement the mitigation strategy or combination of mitigation strategies at the actionable process step (21 CFR 121.4(b)(1)); and</li> <li>• Must receive training in food defense awareness (21 CFR 121.4(b)(2))</li> </ul>
Supervisors of those individuals assigned to an actionable process step (including temporary and seasonal personnel)	<ul style="list-style-type: none"> <li>• Must be a qualified individual, i.e., have the appropriate education, training, or experience (or a combination thereof) necessary to properly implement the mitigation strategy or combination of mitigation strategies at the actionable process step (21 CFR 121.4(b)(1));</li> <li>• Must receive training in food defense awareness (21 CFR 121.4(b)(2)); and</li> <li>•</li> </ul>
Supervisor responsible for ensuring compliance with Part 121	<ul style="list-style-type: none"> <li>• Must have a combination of education, training, and experience necessary to supervise the activities (21 CFR 121.4(d))</li> </ul>
<p>Individual(s) conducting or overseeing:</p> <ul style="list-style-type: none"> <li>• the preparation of the food defense plan,</li> <li>• the vulnerability assessment,</li> <li>• the identification and explanation of mitigation strategies, and</li> <li>• reanalysis</li> </ul> <p>This individual may be, but is not required to be, an employee of the facility.</p>	<ul style="list-style-type: none"> <li>• Must be a qualified individual, i.e., have the education, training, or experience (or a combination thereof) necessary to properly perform the activities (21 CFR 121.4(c)(1)); and</li> <li>• Must have successfully completed training for the specific function at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to conduct these activities (21 CFR 121.4(c)(2)).</li> </ul>

## *Contains Nonbinding Recommendations*

	Note that the requirements can be satisfied by either the individual conducting a specified activity or the individual overseeing that activity.
--	--

**Records:** Training activities must be documented in records. Records must include the date of training, the type of training, and the persons trained. (21 CFR 121.4(e)) See RECORDS REQUIREMENTS section for more details on specific requirements for records.

## **VII. DEFINITIONS (21 CFR 121.3)**

*Actionable process step* means 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.

*Adequate* means that which is needed to accomplish the intended purpose in keeping with good public health practices.

*Affiliate* means any facility that controls, is controlled by, or is under common control with another facility.

*Calendar day* means every day as shown on the calendar.

*Contaminant* means, for purposes of this part, any biological, chemical, physical, or radiological agent that may be added to food to intentionally cause illness, injury, or death.

*Facility* means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of CFR Title 21, chapter 1, part 1, subpart H.

*Farm* means farm as defined in § 21 CFR 1.227.

*FDA* means the Food and Drug Administration.

*Food* means: (1) Articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article, and includes raw materials and ingredients.

*Food defense* means, for purposes of this part, the effort to protect food from intentional acts of adulteration where there is an intent to cause wide scale public health harm.

## *Contains Nonbinding Recommendations*

*Food defense monitoring* means to conduct a planned sequence of observations or measurements to assess whether mitigation strategies are operating as intended.

*Food defense verification* means the application of methods, procedures, and other evaluations, in addition to food defense monitoring, to determine whether a mitigation strategy or combination of mitigation strategies is or has been operating as intended according to the food defense plan.

*Full-time equivalent employee* is a term used to represent the number of employees of a business entity for the purpose of determining whether the business qualifies as a small business. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (i.e., 40 hours x 52 weeks). If the result is not a whole number, round down to the next lowest whole number.

*Holding* means storage of food and also includes activities performed incidental to storage of food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

*Manufacturing/processing* means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

*Mitigation strategies* mean those 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.

*Mixed-type facility* means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type

## *Contains Nonbinding Recommendations*

facility,” which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

*Packing* means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

*Qualified individual* means 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.

*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.

*Significantly minimize* means to reduce to an acceptable level, including to eliminate.

*Small business* means, for purposes of this part, a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees.

*Subsidiary* means any company which is owned or controlled directly or indirectly by another company.

*Very small business* means, for purposes of this part, a business (including any subsidiaries and affiliates) averaging less than \$10,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee).

*Vulnerability* means the susceptibility of a point, step, or procedure in a facility’s food process to intentional adulteration.

*You* means, for purposes of this part, the owner, operator, or agent in charge of a facility.