



Company Name:

Company Location:

Billing Account No:

Audit Date:

Scope*	Req. No.	Requirement	DOC	Rating	Evidence
Food Defense Plan					
FD	1.1.1	The facility must have and implement a written food defense plan. The facility must keep documentation and records of the plan's implementation.	Policy, Record		
FD	1.1.2	The written food defense plan must include: <ul style="list-style-type: none"> - The written vulnerability assessment; - The written mitigation strategies; - The written procedures for the food defense monitoring of the implementation of the mitigation strategies; - The written procedures for food defense corrective actions; and - The written procedures for food defense verification. 	Policy, Record		
Personnel Qualifications and Training					
FD	1.2.1	All facility personnel must receive training in food defense awareness (as new employee and annually).	Record		

USDA, AMS, SCP, SCI Audit Checklist

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		<p>All personnel who perform activities associated with food defense procedures must:</p> <ul style="list-style-type: none"> - Be, or be under the supervision of, a qualified individual to perform their assigned duties, and <p>Receive externally provided training on the principles of food defense or have experience that prepares them for the assigned task.</p>			
FD	1.2.2	<p>Individuals assigned the following tasks must be qualified individuals:</p> <ul style="list-style-type: none"> - Preparation of the food defense plan; - Completion of a vulnerability assessment; - Identification and explanation of the mitigation strategies; and - Reanalysis of the food defense plan. <p>These individuals must receive externally provided training, specific to the task that they are assigned.</p> <p>Approved courses for a qualified individual are available on the Food Safety Preventive Controls Alliance website, https://www.ifsh.iit.edu/fspca/courses/intentional-adulteration</p> <p>Training records must be maintained for the qualified individuals.</p>	Record		
FD	1.2.3	Responsibility for ensuring compliance by individuals with the food defense requirements	Record		

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		must be clearly assigned to supervisory personnel with a combination of education, training, and experience necessary to supervise the activities.			
		Vulnerability Assessment			
FD	1.3.1	<p>The facility must conduct or have conducted a vulnerability assessment for each type of food manufactured, processed, packed, or held at the facility to identify significant vulnerabilities and actionable process steps. Appropriate methods must include, at a minimum, an evaluation of:</p> <ul style="list-style-type: none"> - The potential public health impact (e.g., severity and scale) if a contaminant were added; - The degree of physical access to the product; and - The ability of an attacker to successfully contaminate the product. 			
FD	1.3.2	The vulnerability assessment must consider the possibility of an inside attacker.			
FD	1.3.3	The vulnerability assessment must be documented.	Record		
		Mitigation Strategies			
FD	1.4.1	The facility must identify and implement mitigation strategies at each actionable process step and include a written explanation of how the mitigation strategy sufficiently minimizes or prevents the significant vulnerability.	Record		

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FD	1.4.2	Mitigation strategies and accompanying explanations must be written.	Record		
FD	1.4.3	Mitigation strategies must be subject to monitoring, corrective actions, and verification activities.			
FD	1.4.3.1	The facility must establish and implement written procedures for the monitoring of mitigation strategies. The monitoring activities must be documented.	Policy, Record		
FD	1.4.3.2	If mitigation strategies are not properly implemented, the facility must establish and implement corrective action procedures. The corrective action must describe the steps to be taken to ensure that appropriate action is taken to correct and prevent identified problems. The corrective and preventive actions must be documented as records.	Policy, Record		
FD	1.4.3.3	The facility must establish and implement written procedures to verify that: <ul style="list-style-type: none"> - Food defense monitoring is being conducted; - Appropriate decisions about food defense corrective actions are being made; - Mitigation strategies are properly implemented and are significantly minimizing or preventing the significant vulnerabilities; and - Reanalysis of the food defense plan has occurred as required. 	Policy, Record		

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		<p>The verification activities must include:</p> <ul style="list-style-type: none"> - Review of the food defense monitoring and food defense corrective actions records within appropriate timeframes; and - Other activities appropriate for verification of proper implementation of mitigation strategies. <p>The verification activities must be documented as records.</p>			
Food Defense Plan Reanalysis					
FD	1.5.1	The facility must conduct a reanalysis of the food defense plan as a whole at least once every 3 years.	Policy		
FD	1.5.2	<p>The facility must conduct a reanalysis of the food defense plan as a whole, or the applicable portion of the plan, whenever:</p> <ul style="list-style-type: none"> - 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; - New information is available about potential vulnerabilities associated with the food operation or facility; - The facility has found that a mitigation strategy, a combination of mitigation 	Policy		

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		strategies, or the food defense plan as a whole is not properly implemented; and - 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.			
FD	1.5.3	The reanalysis of the food defense plan must be completed prior to any change in activities, within 90 days of the start of associated production, or later with written justification.	Policy		
FD	1.5.4	The facility must revise the written food defense plan if a significant change in the activities conducted at the facility creates a reasonable potential for a new vulnerability or a significant increase in a previously identified vulnerability or document the basis for the conclusion that no revisions are needed.	Policy		
		Records			
FD	1.6.1	Food defense records must: <ul style="list-style-type: none"> - Be kept as original records, true copies, 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 	Record		

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		<ul style="list-style-type: none"> - Be as detailed as necessary to provide history of work performed. 			
FD	1.6.2	<p>Records must include:</p> <ul style="list-style-type: none"> - 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 - Where appropriate, the identity of the product and the lot code, if any. 	Record		
FD	1.6.3	<p>The food defense plan must be signed and dated by the owner, operator, or agent in charge of the facility when it is first completed, and when modified.</p>	Record		
FD	1.6.4	<p>Food defense records:</p> <ul style="list-style-type: none"> - Must be retained at the facility for at least 2 years after the date they were prepared or after their use is discontinued. - 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. The food defense plan must remain onsite. 	Record		

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		- If the plant or 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 plant or facility upon request.			

*Scope Indicators:

- CC – Cold Chain
- FD – Food Defense
- FD – Current Good Manufacturing Practices
- HACCP – Hazard Analysis Critical Control Points
- LAF – Low Acid Canned Food
- LMF – Low Moisture Food
- PC – Preventive Controls
- QMS – Quality Management System
- ST – Sanitary Transport
- TR – Traceability
- USDA/USAID – USDA and USAID Contract Requirements for International Procurement