

Food Defense Plan

Objective: to develop a comprehensive program that will minimize the potential for intentional contamination of a specific food product/facility.

Food Defense: Basic Guidelines for Administration

	YES	NO	N/A
Has a Food Defense Plan been developed for and implemented in your facility? http://www.fsis.usda.gov/PDF/Food_Defense_Plan.pdf http://www.cfsan.fda.gov/~dms/secguid6.html			
<i>Is the plan a written document?</i>			
<i>Is the plan specific for your facility?</i>			
<i>Are copies of the plan securely stored?</i>			
<i>Is the plan reviewed at least annually?</i>			
<i>When was the last update/review?</i>			
During development, did you consider the vulnerability of each process/product to chemical, biological and physical agent introduction? http://www.cfsan.fda.gov/~dms/vltcarv.html			
Have you ranked the vulnerability of the various points in the plant, process or product?			
Does senior management provide strong support for security and defense efforts? <i>How is this displayed and encouraged (e.g., food defense training, signs, defense measures, incentive programs, reporting mechanisms for anonymous tips)?</i>			
Has responsibility for security management been established?			
<i>How many people are involved?</i>			
<i>Have their roles been specified?</i>			
Do employees in supervisory positions have an understanding of the importance of their role in the Food Defense Plan?			
<i>Has a schedule for training and refresher training been established?</i>			
<i>Are supervisors of vulnerable areas aware that these areas are vulnerable?</i>			
<i>Do vulnerable areas have increased supervision?</i>			

Notes/comments/explanation/rationale:

Personnel

Objective(s): to know and understand employees and to foster commitment to food safety and defense.

Food Defense: Basic Hiring/Employment and Training Practices

	YES	NO	N/A
Are background investigations conducted on all new employees?			
• <i>criminal checks?</i> • <i>drug screen?</i> • <i>credit checks?</i> • <i>proof of identity (e.g., drivers license, greencard, work permit, SSN, etc.)</i> • <i>reference checks (personal and professional)?</i> • <i>prior employment verification?</i>			
Have you conducted background checks on employees hired before 9/11/01?			
Are contracted service providers (e.g. cleaning crews, pest control, temporary employees, plant guards) required to perform background checks on their workers?			
Are uniforms provided/required for employees in the plant?			
<i>Are uniforms laundered commercially or in the premises?</i>			
<i>Have uniform pockets been considered as a food defense risk?</i>			
<i>Are uniforms stored in locked lockers?</i>			
<i>Are all uniforms accounted for when an employee ceases working?</i>			
Are personal items (medicines, packages, bags, etc.) restricted from entry to the facility?			
<i>If not, are they stored within a defined area of the facility?</i>			
Are employee owned vehicles parked on the premises of the processing facility?			
<i>If so, are they ever inspected?</i>			
Are cleaning and maintenance staff, contract workers, temporary employees, and new staff provided sufficient supervision?			
<i>Do these workers have a supervisor employed directly by the plant?</i>			
<i>Does a plant employee accompany these workers?</i>			
Has food defense awareness training been conducted for employees?			
http://www.cfsan.fda.gov/~dms/alert.html			
http://www.cfsan.fda.gov/~dms/alerttoc.html			
http://www.cfsan.fda.gov/~comm/vltdef.html			
http://www.fsis.usda.gov/News_&_Events/Food_Security_Awareness_Training/index.asp			
What is the frequency and extent of this training?			

Is this training specified in the Food Defense Plan?

Has food defense awareness training been conducted for contracted service providers before they begin working in the facility?

Is a supplier guarantee in place to document such training?

Added Hiring/Employment Safeguards

- ❖ Foster high employee morale and encourage employee involvement in reporting suspicious or unusual activity to their supervisor/management.
- ❖ Provide economic incentives for personnel to use products made in the facility.
- ❖ Provide ALERT cards to employees.

Notes/comments/explanation/rationale:

Perimeter Security

Objective: to decrease the possibility of unwanted access and/or successful attack on the production facility in question.

Food Defense: Basic Perimeter Control Practices

	YES	NO	N/A
Is perimeter access restricted to employees, contracted personnel and documented visitors?			
Is perimeter protection in place? http://www.cfsan.fda.gov/~dms/secguid6.html http://www.fsis.usda.gov/PDF/Securityguide.pdf			
Does such protection include:			
fencing with limited access?			
gated fencing?			
gate control?			
guards?			
<i>Do they patrol?</i>			
<i>Do they respond to unauthorized entry?</i>			
signs?			
lighting?			
intrusion detection systems?			
<i>Are there response procedures specified in the plan in the event the system is tripped?</i>			
outbuilding controls?			
On this site, are there any buildings or operations outside the perimeter which may need securing (e.g., storage, maintenance equipment, packaging material, etc.)?			

Added Perimeter Control Safeguards

- ❖ Install surveillance cameras that allow view of complete perimeter.
- ❖ Install watch towers that allow for human surveillance of complete perimeter.
- ❖ Use a single-point of access for entire perimeter.
- ❖ Inspect incoming/outgoing vehicles.

Notes/comments/explanation/rationale:

Facility Security

Objective: to limit access to the facility in question so as to inhibit potential delivery of a harmful agent.

Food Defense: Basic Facility Security Practices

	YES	NO	N/A
Are facility access control measures implemented?			
<i>intrusion detection systems?</i>			
<i>card- or code-based access systems?</i>			
<i>closed-circuit monitors?</i>			
<i>secured doors?</i>			
<i>secured windows?</i>			
<i>locks?</i>			
<i>raw material inspections?</i>			
<i>dock controls?</i>			
<i>turnstiles?</i>			
Is access to vulnerable parts of the process restricted to certain employees by the use of key cards, color uniforms etc.?			
Do parcels and mail arrive in designated areas only?			
<i>Are they subject to inspections?</i>			
<i>Are procedures established in the plan for handling suspicious items?</i>			
Are critical utility and communication equipment adequately protected?			
Is there a system for securing computer and process controls (e.g., passwords)?			
Is access to computers that control processing denied once employment of the operator terminates?			
Do computers or surveillance cameras monitor activity in the facility?			
Is bulk-unloading equipment (e.g. pipes, augers, conveyor belts, hoses) secured when not in use?			
<i>Is it inspected before use?</i>			
Are all keys accounted for at all times?			
<i>Is someone identified to control the distribution and logging of keys?</i>			
<i>Are keys stamped "do not copy"?</i>			
<i>Are keys surrendered upon termination of employment?</i>			
<i>Do you assess the need to change locks after termination of employment?</i>			
Are keycards deactivated after termination of employment?			
Does the management team know (recognize) all employees?			
Is the number of employee entrances limited?			

Are employees required to use keycards or other access control devices to enter the facility?

Are identification badges returned when employment terminates?

Are they deactivated?

Are ID badges required of contractors and visitors?

If so, are they different from each other (e.g., different color)?

Are contractor and visitor badges returned upon exit?

Are reception, production and office space areas arranged and controlled so that unescorted visitors are easily noticed and prevented from unauthorized access to the facility?

Is a visitor sign-in log maintained and monitored?

Must visitors sign out as well?

Is a valid reason for visiting required and verified?

Is proof of identity required prior to allowing entry?

Are unsolicited visits allowed? (Are appointments required?)

Are visitors escorted?

Are there areas that are off-limits to visitors?

Is a contractor/service provider sign-in log maintained and monitored?

Must contractors sign out as well?

Is proof of identity required prior to allowing entry?

Is a valid reason for visiting required and verified?

Are unsolicited visits allowed?

Are contracted service providers accompanied?

Are they given color coded badges or other items to distinguish them in the plant?

Is access to the plant by contract providers limited?

Added Safeguards

- ❖ Implement designated/assigned work areas for employees.
- ❖ Minimize the number of entrances to sensitive areas.
- ❖ Restrict access to food handling/storage areas and locker rooms.
- ❖ Use finger print or retina scan to provide controlled entrance.
- ❖ If relying on identification badges, implement a process to ensure valid use, e.g. legitimate access, no substitutions.
- ❖ Post security guards in the plant.

Notes/comments/explanation/rationale:

Receiving/Transporting/Shipping of Inbound Materials

Objective: to accept only expected materials and provide for control of such materials.

Food Defense: Basic Receiving/Transportation/Shipping Practices

	YES	NO	N/A
Do drivers undergo background checks?			
<i>Does the driver have restricted access to the receiving/shipping dock(s) only?</i>			
<i>Is there a separate waiting area including restroom for drivers?</i>			
<i>Are only known/approved transportation contractors used?</i>			
Are drop sites (where trucks are parked and a different driver takes over) secured?			
<i>Do drivers verify seals upon taking custody of the truck or trailer?</i>			
Do drivers adhere to established delivery schedules?			
Are bulk ingredient transports inspected for abnormalities prior to unloading?			
Are there in-bound material inspections?			
Are seals/ID tags/locks in place and inspected?			
<i>Do you have a policy in place if they are not?</i>			
<i>Are seal numbers verified?</i>			
<i>Are seals and locks stored in a secured place?</i>			
<i>Is there a procedure outlining actions to be taken if a seal or lock is missing?</i>			
Is loading/unloading of shipments supervised?			
<i>Are procedures for handling suspect material specified in the plan?</i>			
Are vehicles visually inspected for abnormal/unusual conditions prior to loading and unloading?			
Are shipments verified against an invoice and bill of lading?			
<i>Are lot numbers verified and/or recorded?</i>			
Is off site storage secure?			
Is there a system of traceability?			
http://www.cfsan.fda.gov/~dms/fsbtbook.html			
http://www.cfsan.fda.gov/~dms/recguid4.html			

Added Safeguards

- ❖ Authenticate incoming packages and labels.

Notes/comments/explanation/rationale:

Ingredients, Packaging, and Finished Products

Objective: to ensure acceptance of only high quality and safe materials.

Food Defense: Basic Ingredients, Packaging, and Finished Product Practices

	YES	NO	N/A
Are only known/approved suppliers used?			
<i>Do you have an approval process for suppliers?</i>			
<i>Is the number of approved suppliers limited?</i>			
<i>Are suppliers required to have Food Defense Plans in place?</i>			
<i>Does your company verify the supplier's Food Defense Plans?</i>			
Are lot numbers of incoming ingredients and food contact packaging materials verified and/or recorded?			
Are incoming packages of raw materials visually inspected for abnormalities?			
<i>Is visual inspection sufficient?</i>			
<i>Are damaged bags, containers, or shipments rejected?</i>			
<i>If so, how is the material disposed of?</i>			
Is the process water source well or municipal water?			
<i>If well, is the well secured?</i>			
<i>If water storage is used, is it secured?</i>			
Is the ingredient storage area secured?			
<i>Is access restricted?</i>			
Do you use minor ingredients that are mixed uniformly into large batches?			
<i>Are they secured?</i>			
<i>Is use reconciled to document inventory control?</i>			
Is access to packaging materials and labels controlled?			
Are all finished products lot coded to identify day of production, time and plant?			
Is there a secured area for cleaning agents, pesticides, fumigants, maintenance oils, etc.?			
<i>Is this separate from food ingredient area storage?</i>			
<i>Do you have a list of all pesticides, cleaning products, laboratory reagents, and other potentially hazardous materials used in the plant?</i>			
<i>Have MSDSs for these materials, been reviewed for acute toxicity levels?</i>			

Added Safeguards

- ❖ Maintain minimum inventory.
- ❖ Implement a sequential numbering system for all raw materials, seals and tags.
- ❖ Add surveillance cameras to the storage areas around ingredients and packaging materials.

Notes/comments/explanation/rationale:

Process Security

Objective: to eliminate or reduce (to a non-deadly level) the impact of a potential intentional contamination of the product in question.

Food Defense: Basic Process Security Practices

	YES	NO	N/A
Has a vulnerability assessment of the process been conducted? http://www.cfsan.fda.gov/~dms/vltcarv.html			
Have preventative actions been taken to reduce the vulnerability of specific points in the process?			
Are critical areas in the process monitored or supervised?			
Do computers or surveillance cameras monitor activity in vulnerable processing areas?			
Is access to vulnerable areas restricted via keycard or other measure?			
Do you prohibit carrying non-work related/personal items into the production area?			
<i>Are lockers provided for storage of personal items?</i>			
Are process changes reviewed for vulnerability prior to implementation?			
Are SOPs in place for process verification?			
Are maintenance worker's toolboxes inspected?			

Added Safeguards

- ❖ Restrict access to vulnerable points to essential employees only.
- ❖ Modify processing parameters to inactivate or minimize to the extent possible the impact of specific agents to which your process and product may be susceptible.
- ❖ Become familiar with threat agents as identified by CDC and FDA <http://www.bt.cdc.gov/>

Notes/comments/explanation/rationale:

Transportation Security

Objective: to ensure secure transport of finished product.

Food Defense: Basic Transportation Security Practices

	YES	NO	N/A
Are outbound shipments secured? http://www.fsis.usda.gov/PDF/Transportation_Security_Guidelines.pdf http://www.cfsan.fda.gov/~dms/secguid6.html <i>Is there a record of the seal number/tag on the bill of lading or other documents?</i>			
Are finished product transportation/delivery vehicles secured when not in use?			
Are you able to trace incoming materials from your facility back to the point of distribution?			
Are you able to trace finished product from your facility to the next point of distribution? <i>Once product is on the truck, can it be traced?</i> <i>Is there a product retrieval system in place?</i>			

Notes/comments/explanation/rationale:

Crisis Management

Objective: to effectively manage and recover from a crisis should it occur.

Food Defense: Basic Crisis Management Practices

	YES	NO	N/A
Has a coordinated response plan for food defense emergencies been developed?			
<i>Have roles of staff involved in the plan been identified?</i>			
<i>Who, within the company and/or facility, is the key authority according to the plan?</i>			
<i>How have these individuals been trained?</i>			
<i>Has an alternate chain of command been established?</i>			
Have safety/defense partnerships been established with local, state and federal law enforcement agencies, other public safety and health agencies and surrounding community leaders? ¹			
<i>If so, who maintains contact and contact information for these individuals?</i>			
<i>When was this information last updated?</i>			
<i>Are these individuals identified in the defense plan?</i>			
If needed, is there a plan for emergency shut down in place?			
<i>Who has the authority to initiate an emergency shut down?</i>			
<i>Have the individual(s) responsible for notifying authorities and the public, if needed, been identified?</i>			
<i>Are the criteria for initiating a shut down specified?</i>			
<i>Are procedures in place for securing the facility following shut-down?</i>			
Is there a plan for emergency evacuation in place?			
<i>Who has the authority to initiate an emergency evacuation?</i>			
<i>Does the plan specify how employees are accounted for in the event of an evacuation?</i>			
<i>Is there a specified offsite meeting place?</i>			
<i>Is there an established emergency contact for employees?</i>			
Are mechanisms in place for employees to identify and refer suspicious incidents or site security breaches?			
<i>Does the plan direct how to handle these situations?</i>			
<i>Have point person(s) been identified for incident identification and reporting?</i>			
<i>Have they been trained?</i>			
<i>Are all staff made aware of reporting procedures, including who to contact?</i>			

¹ Note, those contacted in a food defense emergency may be different than those contacted for food safety issues

Are there any incentives for reporting these incidents?

Has a recall strategy been established?

<http://www.cfsan.fda.gov/~lrd/recall2.html>

http://www.fda.gov/ora/compliance_ref/recalls/ggp_recall.htm

Is a written recall plan in place?

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=7>

Are the criteria for initiating a recall specified?

Have you conducted a product traceability exercise from ingredients through finished product (including packaging materials)?

Have persons responsible for implementing the recall strategy been identified and fully informed of responsibilities?

Have you conducted a mock recall exercise?

Are procedures in place for determining the proper handling and disposition of recalled product?

http://www.fsis.usda.gov/PDF/Disposal_Decontamination_Guidelines.pdf

Does the plan specify how consumers are to be informed regarding disposition of contaminated materials?

Has a mitigation/recovery assessment been conducted?

Have alternative ingredient suppliers been identified to produce your product?

Have alternative locations been identified to produce your product?

Added Safeguards

- ❖ Ensure ALL employees (CEO/President to temporary employee, etc.) know and understand their role in the Food Defense Plan.
- ❖ Run effectiveness checks to validate your Food Defense Plan.
- ❖ Perform unannounced food security inspections.
- ❖ Establish alternate/back-up communication systems/devices.

Notes/comments/explanation/rationale: