Food Defense - Mitigation Strategies To Protect Food Against Intentional Adulteration

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- Driving force behind our food safety operations in the areas of Good Manufacturing Practice (cGMP) and supplier assurance programs (GFSI), including SQF, BRC and FSSC 22000.

- 45 years of experience in the food industry, while working for national and international companies in quality assurance, product development and auditing. He is an often requested seminar speaker in the areas of GMP, HACCP and HARPC.

- Ph.D. and BSc in Chemistry and an accomplished food safety trainer for numerous food safety manager certification courses

- In addition, he is a GMP/HACCP/HARPC instructor, a Lead Auditor trainer, and is also certified to consult on the Global Food Safety Initiative. He is certified in 21 SQF product categories
Agenda

• Exempted Businesses
• Mitigation Strategies as a part of FSMA
• Contents of a Food Defense Plan
  1. Vulnerability Assessments (Qualified Individuals).
  2. Actionable Process Steps
  3. Focused Mitigation Strategies (Qualified Individuals).
  4. Monitoring
  5. Corrective Actions
  6. Verification
• Recordkeeping
• Effective and Implementation Dates
Exempted Businesses

This requirement applies to all facilities that are required to register with the FDA as a Qualified Business with the exception of the following facilities:

- Farms, except if they produce milk.
- Very small businesses with <$10,000,000 in sales.
- Storage facilities that store packaged food that is not exposed; (Not exempt if they hold liquid in bulk tanks).
- Facilities that re-pack, re-label foods as long as the food is not exposed.
- Alcohol manufacturers.
- Animal Food manufacturers and distributors.
Food Safety Modernization Act (FSMA) 2010

• Title 1 Designed to improve capacity to prevent food safety problems
• Title 2 Designed to improve capacity to detect and respond to food safety problems
• Title 3 Designed to improve the safety of imported food
• Title 4 Includes miscellaneous provisions
**Title 1 Sections** -
*Designed to prevent food safety problems*

- **Section 101**  
  FDA access to your records
- **Section 102**  
  Registration and possible suspension by FDA
- **Section 103**  
  Preventive Controls for Human Foods
- **Section 104**  
  FDA hazard information
- **Section 105**  
  Produce food safety guidelines
- **Section 106**  
  Regulations to prevent intentional adulteration
- **Section 107**  
  Fee assessments by FDA
- **Section 108**  
  National agriculture and food defense strategy
Sec. 103 of the Food Safety Modernization Act describes Preventive Controls for Human Food in the following way:

“The owner, operator, or agent in charge of a facility **shall**, in accordance with this section, evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility, identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 or misbranded under section 403(w), monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice.
cGMPs 21 CFR 117 Subpart C
Hazard Analysis and Risk-Based Preventive Controls

- 117.126 Food Safety Plan
- **117.130 Hazard Analysis**
- 117.135 Preventive Controls
- 117.136 Preventive Controls exemptions
- 117.137 Assurances required for exemption
- 117.39 Recall Plan
- 117.140 Preventive control management components
- 117.145 Monitoring
- 117.150 Corrective actions and corrections
- 117.155 Verification
- 117.160 Validation
- 117.165 Verification of implementation and effectiveness
- 117.170 Reanalysis
- 117.180 Requirements applicable to preventive controls qualified individual and a qualified auditor
- 117.180 Implementation records required for this subpart
117.130(b) Hazard Identification

- Known or reasonably foreseeable hazards can be
  - Naturally occurring hazards;
  - Unintentionally introduced hazards.
  - **Intentionally** introduced hazards for possible economical gain and to also include acts of terrorism.

- As the FDA has also identified that an employee’s possible deliberate act of contamination of your products is a risk then you need to also address this possibility and hence mitigate the risk in your Food Defense program.
Under Sec. 106 of the Food Safety Modernization Act the FDA has determined that Processors and Distributors, where applicable to the latter, need to use a HACCP approach to determine the

- **Nature of the types of hazards for which measures should be taken to mitigate the hazard.**
- **To do this you need to perform a Vulnerability Assessment of your premises, products and processes.**
Possible Deliberate Contamination sources

• FDA has identified 3 types of deliberate acts of contamination
  – Acts of Terrorism
  – Disgruntled employees, consumers or competitors
  – Economically motivated adulteration (i.e. melamine).

FDA in discussions with the intelligence community has identified the inside attacker as the greatest threat. The following are cases where this has happened and hence support this fact.
December 1996, Berlin, Wisconsin

- The organochlorine pesticide chlordane was intentionally added to livestock carcasses taken to a rendering plant. The contaminated carcasses were mixed into livestock feed that was distributed to more than 4,000 farms, mostly dairy operations, in a four-state area.

- The perpetrator then sent letters to customers notifying them of the contamination, resulting in recalls of cheese, butter and ice cream. Product disposal cost more than $4 million. In addition, 4,000 tons of feed and 500,000 pounds of contaminated fat had to be destroyed. The cost to the feed producer targeted in the incident was over $250 million. The event economically impacted the affected farms, local feed companies, processors and others in the food supply chain.

- A competitor of the targeted facility was charged for this criminal contamination. Apparently the competitor’s wife had had a romantic involvement with someone at the targeted facility.

- The Wisconsin secretary of agriculture referred to the incident as an act of domestic terrorism.
On January 3, 2003, the Michigan Department of Agriculture's (MDA) Food and Dairy Division and the U.S. Department of Agriculture (USDA) were notified by a supermarket of a planned recall of approximately 1,700 pounds of ground beef because of customer complaints of illness after eating the product.

On January 10, the supermarket notified MDA that their laboratory had determined that the contaminant in the ground beef returned by customers with reported illness was nicotine.

Approximately 100 persons were affected and a person at the supermarket was arrested and charged with deliberately poisoning the ground beef.
2012 Needles placed in sandwiches

• On July 17th a Delta flight from Amsterdam to the USA was found to have been catered with sandwiches that contained sewing needles.
• Nobody was seriously injured but potential was worrying.
• On August 3rd Air Canada flight reported a needle in a sandwich on flight from Victoria to Toronto.
December 2013 Japan

- A contract employee at Aquilfoods in Japan deliberately adulterated several frozen foods using Malathion
- 2843 people got sick
- 6.4 million packages of frozen seafood were recalled
Possible breach of food defense leads to recall of chicken products -- June 18, 2016.

- Minnesota’s GNP Company, based in Cold Spring, late Saturday recalled approximately 55,608 pounds of chicken products that may be contaminated with extraneous materials, according to the U.S. Department of Agriculture’s Food Safety and Inspection Service (FSIS).

- The company discovered sand and black soil was turning up in some of the products, and reported it to FSIS. No one has reported any adverse reactions to the contaminated products. GNP Company and local law enforcement are investigating how the sand and soil got into the chicken products.
You must prepare, or have prepared, and implement a written food defense plan.

The written food defense plan must include:

- (1) The written vulnerability assessment, including required explanations, to identify significant vulnerabilities and actionable process steps as required by § 121.130(c);
- (2) The written mitigation strategies, including required explanations, as required by § 121.135(b);
- (3) The written procedures for the food defense monitoring of the implementation of the mitigation strategies as required by § 121.140(a);
- (4) The written procedures for food defense corrective actions as required by § 121.145(a)(1); and
- (5) The written procedures for food defense verification as required by § 121.150(b).

- (c) Records. The food defense plan required by this section is a record that is subject to the requirements of subpart D of this part.
Step 1. Prepare a Food Defense Program

- The first step in preparing a Food Defense Program is to perform a **Vulnerability Assessment**
You must conduct or have conducted a vulnerability assessment for each type of food manufactured, processed, packed, or held at your facility using appropriate methods to evaluate each point, step, or procedure in your food operation to identify significant vulnerabilities and actionable process steps.

(a) Appropriate methods must include, at a minimum, an evaluation of:

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.

(b) *Inside attacker.* The assessment must consider the possibility of an inside attacker.
121.130 Vulnerability assessment requirements to identify significant vulnerabilities and actionable process steps

(c) Written vulnerability assessment

- Regardless of the outcome, the vulnerability assessment must be written and must include an explanation as to why each point, step, or procedure either was or was not identified as an actionable process step.
121.3. Qualified Individual

- *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.
121.4. Qualifications of individuals who perform activities

- (a) **Applicability.** You must ensure that each individual who performs activities required under subpart C of this part is a qualified individual as that term is defined in § 121.3.

- (b) **Qualifications of individuals assigned to an actionable process step.**

  Each individual assigned to an actionable process step (including temporary and seasonal personnel) or in the supervision thereof must:

  - (1) Be a qualified individual as that term is defined in § 121.3—*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; and

  - (2) Receive training in food defense awareness.
A Qualified Individual 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 the activities.

Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum.
e) *Records*. Training required by paragraphs (b)(2) and (c)(2) of this section must be documented in records, and must:

1. Include the date of training, the type of training, and the persons trained; and

2. Be established and maintained in accordance with the requirements of subpart D of this part.
Are you ready for these new Food Defense requirements?

- Yes I believe so
- Not yet, but we have started the process
- Not yet, we need to get a Food Defense Management person trained
- Not yet, Food Defense Training for our team is required
Foods considered harder to contaminate

Examples of where contamination would be easier to detect hence lower risk for deliberate contamination.

- Shell Eggs
- Most Whole Produce and Vegetables (Apples have however had needles and razor blades placed in them)
- Game Meats (Whole or Cut but not ground or shredded)
- Peanuts and Tree Nuts (Raw, In-Shell)
- Sugar Cane and Sugar Beets
FDA has determined that the presence of one or more of these key activity types at a process step (e.g., manufacturing, processing, packing, or holding of food) indicates a significant vulnerability under section 418 of the FD&C Act and that the food is at high risk of intentional adulteration caused by acts of terrorism under section 420 of the FD&C Act.

- Bulk liquid receiving and loading;
- Liquid storage and handling;
- Secondary ingredient handling; and
- Mixing and similar activities.
Ingredient and product handling vulnerabilities

- Ingredient weighing rooms
- Pre-mix areas
- Adding rework back to products
- Returned products
Mixing and similar exposed product areas

- Mix kettles
- Blending operations
- Grinding operations
- Open processing points
Mixing and similar exposed product areas
Other possible vulnerable areas

- Unsealed trailers, railcars, tankers allowing access to tamper with products.
- Unlocked doors into your facility allowing easy access to products.
- Unlocked windows on street level allowing access to your facility.
- Inlets into building for receiving liquids including water, if latter is from an unprotected well.
Definition of an Actionable Process Step

- **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.
Step 2. Actionable Process steps

A Facility can identify their actionable process steps using one of two procedures.

• The FDA-identified key activity types (CARVER and Shock), OR
• By conducting their own facility-specific vulnerability assessments
FDA CARVER Program

- Criticality
- Accessibility
- Recuperability
- Vulnerability
- Effect
- Recognizability
FDA SHOCK Program

SHOCK

Added to CARVER program to assess the combined health, economic and psychological impacts of an attack within the food industry.
121.135. *Mitigation strategies for actionable process steps*

(a) You must identify and implement mitigation strategies at each actionable process step to provide assurances that the significant vulnerability at each step will be significantly minimized or prevented and the food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act. For each mitigation strategy implemented at each actionable process step, you must include a written explanation of how the mitigation strategy sufficiently minimizes or prevents the significant vulnerability associated with the actionable process step.

(b) Mitigation strategies and accompanying explanations must be written.
Possible Focused Mitigation Strategies—Bulk Products

- Establish check-in and shipment verification procedures, such as checking seals and associated documentation
- Restrict movement of delivery drivers if allowed into the facility
- Secure transfer hoses in locked cabinets
- Install locks on tanks inside and outside
- Restrict access to bulk tanks to only key individuals
- Cameras
**Suggested Focused Mitigation Strategies – General**

- Always ensure a clear line of sight to actionable process steps (e.g., store stacks of pallets in less obstructive location).
- Reduce staging time of ingredients and in-process products including rework.
- Avoid employees working in rooms on their own with exposed products/ingredients.
- Retrofit equipment to reduce accessibility (e.g., install lids on open mixers).
Possible Focused Mitigation Strategies – In-process Products

- Supervisors
- Cameras
- Restricting employee flow
- Locked doors from outside
- Restricted Visitor movement
- Equipment covers
- Peer observations
Mitigation strategies required under § 121.135 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 such mitigation strategy and its role in the facility’s food defense system:

(a) Food defense monitoring in accordance with § 121.140;
(b) Food defense corrective actions in accordance with § 121.145; and
(c) Food defense verification in accordance with § 121.150.
Step 4. Monitoring of Mitigation Strategies (121.140)

As appropriate to the nature of the mitigation strategy and its role in the facility’s food defense system:

- (a) Written procedures. You must establish and implement written procedures, including the frequency with which they are to be performed, for food defense monitoring of the mitigation strategies.

- (b) Food defense monitoring. You must monitor the mitigation strategies with adequate frequency to provide assurances that they are consistently performed.

- (c) Records—
  1. Requirement to document food defense monitoring. You must document the monitoring of mitigation strategies in accordance with this section in records that are subject to verification in accordance with § 121.150(a)(1) and records review in accordance with § 121.150(a)(3)(i).
Step 4. Monitoring of Mitigation Strategies (121.140)

• (2) Exception records.

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.
(a) Food defense corrective action procedures.

As appropriate to the nature of the actionable process step and the nature of the mitigation strategy:

• (1) You must establish and implement written food defense corrective action procedures that must be taken if mitigation strategies are not properly implemented.

• (2) The food defense corrective action procedures must describe the steps to be taken to ensure that:
  – (i) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a mitigation strategy; and
  – (ii) Appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur.
(b) *Records.* All food defense corrective actions taken in accordance with this section must be documented in records that are subject to food defense verification in accordance with § 121.150(a)(2) and records review in accordance with § 121.150(a)(3)(i).
(a) **Food defense verification activities.**

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:

- (1) Verification that food defense monitoring is being conducted as required by § 121.138 (and in accordance with § 121.140);
- (2) Verification that appropriate decisions about food defense corrective actions are being made as required by § 121.138 (and in accordance with § 121.145);
Step 6. Verification Procedures (121.150)

(3) Verification that mitigation strategies are properly implemented and are significantly minimizing or preventing the significant vulnerabilities. To do so, 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:

• (i) Review of the food defense monitoring and food defense corrective actions records within appropriate timeframes to ensure that the records 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; and

• (ii) Other activities appropriate for verification of proper implementation of mitigation strategies; and
(4) Verification of reanalysis in accordance with § 121.157. (b) **Written procedures.**

You must establish and implement written procedures, including the frequency for which they are to be performed, for verification activities conducted according to § 121.150(a)(3)(ii).
121.305 General requirements applying to records

Records must:

a) 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;

b) Contain the actual values and observations obtained during food defense monitoring;

c) Be accurate, indelible, and legible;

d) Be created concurrently with performance of the activity documented;
121.305 General requirements applying to records

(e) Be as detailed as necessary to provide history of work performed; and
(f) Include:
   – (1) Information adequate to identify the facility (e.g., the name, and when necessary, the location of the facility);
   – (2) The date and, when appropriate, the time of the activity documented;
   – (3) The signature or initials of the person performing the activity; and
   – (4) Where appropriate, the identity of the product and the lot code, if any.
Steps to implement an effective Food Defense Program

- Ensure that personnel and supervisors assigned to actionable process steps receive appropriate training in food defense awareness and their respective responsibilities in implementing focused mitigation strategies.

- Establish and maintain certain records, including
  - the written food defense plan;
  - written identification of actionable process steps and the assessment leading to that identification;
  - written focused mitigation strategies;
  - written procedures for monitoring and corrective actions;
  - verification;
  - documentation related to training of personnel.
Steps to implement an effective Food Defense Program

1. Identify and implement focused mitigation strategies at each actionable process step to provide assurances that the significant vulnerability at each step will be significantly minimized or prevented and that the food manufactured, processed, packed, or held by such facility will not be adulterated.

2. Establish and implement procedures, including the frequency with which they are to be performed, for monitoring the focused mitigation strategies.

3. Establish and implement corrective action procedures that must be taken if focused mitigation strategies are not properly implemented.

4. Verify that monitoring is being conducted and appropriate decisions about corrective actions are being made; verify that the focused mitigation strategies are consistently implemented and are effectively and significantly minimizing or preventing the significant vulnerabilities; and conduct a reanalysis of the food defense plan.
What is your biggest challenge?

• Shortage of time
• Our culture is to trust people
• We feel these requirements are intrusive
§ 121.157. Reanalysis

a) You must conduct a reanalysis of the food defense plan, as a whole at least once every 3 years;

b) You must conduct a reanalysis of the food defense plan as a whole, or the applicable portion of the food defense plan:

(1) 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;
§ 121.157. Reanalysis

(2) Whenever you become aware of new information about potential vulnerabilities associated with the food operation or facility;

(3) Whenever you find that a mitigation strategy, a combination of mitigation strategies, or the food defense plan as a whole is not properly implemented; and
§ 121.157. Reanalysis

(4) 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.
§ 121.157. Reanalysis

(c) You must complete such reanalysis required by paragraphs (a) and (b) of this section and implement any additional mitigation strategies needed to address the significant vulnerabilities identified, if any:

(1) Before any change in activities (including any change in mitigation strategy) at the facility is operative;

(2) When necessary within 90-calendar days after production; and

(3) 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.
§ 121.157. Reanalysis

(d) 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 or document the basis for the conclusion that no revisions are needed.
§ 121.315 Requirements for record retention

(a)

(1) All records required by this part must be retained at the facility for at least 2 years after the date they were prepared.

(2) 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.

(b) The food defense plan must be retained for at least 2 years after its use is discontinued.
(c) 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 remain onsite.

   Electronic records are considered to be onsite if they are accessible from an onsite location.

(d) 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.
§ 121.310 Additional requirements applying to the food defense plan

The owner, operator, or agent in charge of the facility must sign and date the food defense plan:

• (a) Upon initial completion; and
• (b) Upon any modification.
Effective and Compliance Dates

- Effective date is July 26, 2016
- Compliance dates are:
  - Large businesses have 3 years
  - Small businesses (<500 FTE Employees) have 4 years
  - Very small businesses (<$10 million sales) have 5 years to prove they are exempt
SAI Global was founded in 1922
Largest registrar in North America, 14,000+ sites / 60,000+ globally
Both local and global resources: 500 Auditors within North America and 1,600 Globally
Deliver audits by global accreditation bodies such as JASANZ and ANAB
Accredited to deliver audits and certify organizations against a wide range of international standards
We have a deep global footprint with over 2000 employees in 29 countries across Europe, the Americas and Asia-Pacific
Provide a number of training options including public courses, online and in-house
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| • SQF       | • Global GAP Standards  
• Global Aquaculture Alliance  
• BAP Standards  
• ASC Standards  
• ASC Chain of Custody | • SQF  
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