



## Food Defense Plan Lesson

1. Policy
  - 1.1. The supplier has documented and implemented a plan to assure the security of the site and the product from damage or adulteration from sabotage or terrorist-like incident.
  - 1.2. Establish site security/food defense measures to prevent intentional harm to people, products, and processes, as well as associated losses.
2. Procedures
  - 2.1. Food Defense Protocol
    - 2.1.1. The site prepares, implement, and maintain a food defense protocol that outlines the methods, responsibilities, and criteria for preventing food adulteration caused by deliberate acts of sabotage.
    - 2.1.2. Identify how the site limits access to designated areas of the operation to only appropriately authorized employees.
    - 2.1.3. The facility conducts a documented Food Defense Evaluation that considers all aspects of the physical facility and the manufacturing process. The potential of food fraud is also considered in this evaluation. Refer to *Food Defense Plan Challenge*
    - 2.1.4. The site implements step to protect sensitive processing points from intentional contamination.
    - 2.1.5. Ensure the secure storage and transportation of materials, packaging, equipment, hazardous chemicals, and finished product.
    - 2.1.6. Specific areas of the program that may be addressed include:
      - 2.1.6.1. Employee identification
        - 2.1.6.1.1. A system of positive identification of employees has been established and is enforced.
        - 2.1.6.1.2. Uniforms, name tags, or identification badges are collected from employees prior to the termination of employment
        - 2.1.6.1.3. A minimum level of background checks is established for all employees
        - 2.1.6.1.4. Identification and management of unusual occurrences
        - 2.1.6.1.5. Ensure that only authorized personnel are allowed in the facility or in restricted areas
      - 2.1.7. Visitor, contractor, tour access
        - 2.1.7.1. Implement a check-in/check-out procedure at security or reception areas that includes verification of proper identification, screening equipment, and relinquishment of prohibited items
        - 2.1.7.2. Maintaining a visitor's log. Refer to *Visitors Log Sheet*.
        - 2.1.7.3. Implement a visitor policy which requires proper identification, escorts, and adherence to rules regarding restricted access.
        - 2.1.7.4. Implement a policy for acceptance of goods, mail, and packages that includes proper documentation review, screening procedures, and chain-of-custody when appropriate.
        - 2.1.7.5. Implement a policy for scheduling deliveries, maintenance, and service.
      - 2.1.8. Physical security of the site (e.g., secured doors, windows, outside storage areas)
        - 2.1.8.1. Lock all buildings when not in use.
        - 2.1.8.2. Restrict access to keys.
        - 2.1.8.3. Use locks, fencing, gates or other physical barriers at perimeters, entry/exit points, locations, and operations to restrict access.
        - 2.1.8.4. Routine security checks of the premises are performed for signs of tampering, criminal or terrorist action.

- 2.1.8.5. Use personnel (e.g., guards, supervisors, trusted employees) to monitor perimeters, entry/exit points, locations, and operations.
- 2.1.8.6. Install self-locking doors and/or alarms on emergency exits
- 2.1.8.7. Use surveillance equipment (e.g., cameras) and/or alarms to monitor perimeters, entry/exit points, locations, and operations.
- 2.1.9. Signage
  - 2.1.9.1. Restricted areas are clearly marked.
  - 2.1.9.2. Use signage at perimeters, entry/exit points, locations, and operations to designate restricted areas.
- 2.1.10. Perimeter lighting
  - 2.1.10.1. The facility has an emergency lighting system.
- 2.1.11. Secure chemical storage
  - 2.1.11.1. Secure all chemicals and verify inventory on a scheduled basis. Refer to *Chemical Inventory Log*
  - 2.1.11.2. Hazardous chemicals stored in a restricted area away from operations.
  - 2.1.11.3. Chemicals are properly labeled
- 2.1.12. Restricted access to sensitive areas of processing.
- 2.1.13. Secure storage of incoming materials, packaging, and equipment not in use
  - 2.1.13.1. The receiving of incoming materials is supervised
  - 2.1.13.2. Unauthorized deliveries are not accepted
  - 2.1.13.3. Secure access to all storage areas. Lock doors or install an alarm.
  - 2.1.13.4. Maintain an access log of who has entered the storage area and when the personnel did enter that storage area.
  - 2.1.13.5. Control access to labels and packaging materials to prevent theft and misuse
  - 2.1.13.6. Security assessment of off-site storage.
- 2.1.14. Secure storage and transportation of finished product
  - 2.1.14.1. Outgoing shipments are locked or sealed.
- 2.1.15. Tamper proof or tamper evident packaging
  - 2.1.15.1. Inspect product returned to the facility for tampering.
  - 2.1.15.2. Store product labels in a secure location and destroy outdated or discarded labels.
- 2.1.16. Food security inspections are conducted to measure effectiveness of the program and ensure buildings and grounds are secure.
- 2.1.17. Protection of air, gas, and water supplies
  - 2.1.17.1. Secure water, air, and gas supplies and supply lines.
  - 2.1.17.2. Limit access to storage and handling facilities and controls for airflow, water, electricity, and refrigeration.
- 2.1.18. Protection of process control systems
- 2.1.19. Protection of environmental control systems
- 2.1.20. Protection of sensitive data systems and the data (e.g., formulations, specifications, business information),
  - 2.1.20.1. Implement a policy for protection of sensitive information (e.g., computers, food defense plans, schematics) and periodically modify instituted security measures such as passwords, keys, access cards, and codes
  - 2.1.20.2. Implement a policy to restrict access to locations, equipment and operations and periodically modify instituted security measures such as passwords, keys, access cards, and codes
- 2.1.21. New and existing employees are screened to ensure they are appropriate for employment in a food facility.
- 2.1.22. Employee training programs are established to address food security issues. This includes:



- 2.1.22.1. Awareness for possible tampering occurrences in mail, incoming materials, and finished products
  - 2.1.22.2. Reporting requirements for unusual occurrences, observed behavior or unrecognized people in the facility.
  - 2.1.22.3. Temporary (unscreened) employees only work in areas with pre-packed, coded and labeled product and do not have direct access to unprotected product.
  - 2.1.22.4. Temporary workers are always supervised when on site.
  - 2.1.23. The site assesses the vulnerability of incoming shipments and take appropriate actions such as:
    - 2.1.23.1. Inspect vehicles and incoming product for evidence of tampering
    - 2.1.23.2. Require incoming vehicles to be locked or sealed
    - 2.1.23.3. Match seal numbers to shipping documents at receiving
  - 2.1.24. The site assesses the vulnerability of finished product packaging and use tamper evident packaging where possible.
  - 2.1.25. The transportation systems being used to deliver products are reviewed to ensure food security is maintained from pick-up to delivery, including locking or sealing outgoing vehicles.
  - 2.1.26. There is proof that the facility is registered with the relevant authorities.
- 2.2. Frequency
- 2.2.1. This plan is reviewed, at minimum, on an annual basis.
  - 2.2.2. Conduct a reanalysis of the food defense plan as a whole, or the applicable portion of the food defense plan:
    - 2.2.2.1. 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
    - 2.2.2.2. Whenever there is new information about potential vulnerabilities associated with the food operation or facility
    - 2.2.2.3. Whenever a mitigation strategy, a combination of mitigation strategies, or the food defense plan as a whole is not properly implemented
    - 2.2.2.4. 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.
    - 2.2.2.5. Before any change in activities (including any change in mitigation strategy) at the facility is operative
    - 2.2.2.6. When necessary, within 90-calendar days after production
    - 2.2.2.7. 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.

### 3. Responsibility

- 3.1. All Personnel
  - 3.1.1. Shall adhere to this policy.
- 3.2. Preventative Control Qualified Individual (PCQI)
  - 3.2.1. Visually inspect areas for compliance with this policy.
  - 3.2.2. Oversee (Verify) compliance of procedure.
  - 3.2.3. Ensure personnel is trained on this policy and procedures.
  - 3.2.4. Monitor and take corrective action to ensure compliance with this policy.
- 3.3. Supervisors / Department Heads / Team Leaders
  - 3.3.1. Ensure (inspect) and verify this policy and procedure is adhered to.
  - 3.3.2. Take corrective action to ensure compliance with this policy.
- 3.4. Quality Personnel



- 3.4.1. Replacement of all laboratory glass containers with plastic containers if possible and avoid using glass instruments in processing areas.
  - 3.4.2. Validate training and adherence to policy and procedure.
  - 3.4.3. Monitor and document non-conformance observation is also known as discrepancy using Corrective and Preventive Action Form.
  - 3.4.4. Document control, records, and archive.
4. Corrective Action
    - 4.1. Replace any broken parts of equipment or missing items used in the facility.
    - 4.2. Re-train personnel on this policy that is/are involved in the situation
  5. Review – Quality
    - 5.1. Responsibilities for food defense has been assigned to a senior management representative.
    - 5.2. A food defense plan is in place that identifies the actions required to prevent a serious incident.
    - 5.3. The food defense plan identifies methods to protect sensitive processing points.
    - 5.4. The food defense plan identifies methods to provide authorized access to products and facilities.
    - 5.5. The food defense plan identifies methods to secure storage of raw materials, packing materials, finished product, and hazardous chemicals.
    - 5.6. The food defense plan identifies methods to record and control access to the premises by employees, contractors, and visitors.
    - 5.7. Access points to secured/restricted areas for controlled raw materials, sensitive processing points, hazardous chemicals, etc. are restricted.
    - 5.8. Entry and controlled access points such as guard shacks, reception, production areas, physical security of the site including windows, doors, etc.
    - 5.9. Tamper-proof or tamper-evident packaging.
    - 5.10. Secure storage and transportation of raw materials, packaging, equipment not in use, and storage and transportation of the finished product.

## 6. History

Revision No.:	Revision Date:	Description of Change:	Originator / Author Name:	Title / Department:
0	20220908	Original	Arnel Ryan	PCQI / Compliance

### Requirements:

- (1) The trainee has read or received a verbal translation of all or part of the policy, procedure, method, and or SOP for which they are being trained.
- (2) The trainee has demonstrated the task they are to perform or the procedure for which they are being trained as required.
- (3) The trainee has demonstrated the ability to perform the task with acceptable proficiency and with minimal supervision as required.