

Contains Nonbinding Recommendations

U.S. Food and Drug Administration
Food Defense Self Assessment Tool
for Importers and Filers

Food Importing Operations:

*Mark each item either Y (Yes), N (No), N/A (Not Applicable) or DNK (Do Not Know).

Management

Y N N/A DNK

- Prepare for the possibility of tampering or other malicious, criminal, or terrorist actions
- Assign responsibility for security to knowledgeable individual(s)
- Conduct an initial, confidential assessment of food security procedures and operations
- Have a crisis management strategy to prepare for and respond to tampering and other malicious, criminal, or terrorist actions, both threats and actual events, including identifying, segregating and securing affected product
- Plan for emergency evacuation, including preventing security breaches during evacuation
- Become familiar with the emergency response system in the community
- Make management aware of 24-hour contact information for local, state, and federal police/fire/rescue/health/homeland security agencies
- Make staff aware of who in management they should alert about potential security problems (24-hour contacts)
- Maintain any floor and food flow plan in a secure, off-site location
- Promote food security awareness to encourage all staff to be alert to any signs of tampering or other malicious, criminal, or terrorist actions or areas that may be vulnerable to such actions, and to report any findings to identified management
- Have internal communication system to inform and update staff about relevant security issues
- Have a strategy for communicating with the public

Recall strategy

- Identify the person responsible, and a backup person
- Provide for proper handling and disposition of recalled product
- Identify customer contacts, addresses, and phone numbers

Investigation of suspicious activity

- Investigate threats or information about signs of tampering or other malicious, criminal, or terrorist actions
- Alert appropriate law enforcement and public health authorities about any threats of or suspected tampering or other malicious, criminal, or terrorist actions

Evaluation program

Y N N/A DNK

- Evaluate the lessons learned from past tampering or other malicious, criminal, or terrorist actions and threats
- Review and verify, at least annually, the effectiveness of the security management program, revise the program accordingly
- Perform random food security inspections of all appropriate areas of the facility (including receiving and storage, where applicable) using knowledgeable in-house or third party staff
- Verify that security contractors are doing an appropriate job, when applicable

Human element – staff

Daily work assignments

- Know who is and who should be on premises, and where they should be located, for each shift
- Keep assignment information updated

Identification

- Establish a system of positive identification and recognition that is appropriate to the nature of the workforce, when appropriate
- Collect the uniforms, name tag, or identification badge when a staff member is no longer associated with the establishment

Restricted access

- Identify staff that require unlimited access to all areas of the facility
- Reassess levels of access for all staff periodically
- Limit access so staff enter only those areas or have access to only those segments of the operation necessary for their job functions and only during appropriate work hours, including access to data operating systems for purchasing, storing and distributing imported foods
- Change combinations, rekey locks and/or collect the retired key card when a staff member who is in possession of these is no longer associated with the establishment, and additionally as needed to maintain security

Personal items

- Restrict the type of personal items allowed in non-public areas of the establishment
- Allow in the establishment only those personal use medicines that are necessary for the health of staff and ensure that these personal use medicines are properly labeled and stored away from food handling or storage areas
- Prevent staff from bringing personal items into food preparation or storage areas
- Provide for regular inspection of contents of staff lockers, bags, packages, and vehicles when on company property

Food Defense Self Assessment Tool for Importers and Filers

Training in food security procedures

- | Y | N | N/A | DNK | |
|-----------------------|-----------------------|-----------------------|-----------------------|---|
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Incorporate food security awareness, including information on how to prevent, detect, and respond to tampering or other malicious, criminal, or terrorist actions or threats, into training programs for staff, including seasonal, temporary, contract, and volunteers |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Provide periodic reminders of the importance of security procedures |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Encourage staff participation in security procedures |

Unusual behavior

- | | | | | |
|-----------------------|-----------------------|-----------------------|-----------------------|---|
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Watch for unusual or suspicious behavior by staff |
|-----------------------|-----------------------|-----------------------|-----------------------|---|

Staff health

- | | | | | |
|-----------------------|-----------------------|-----------------------|-----------------------|---|
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Be alert for atypical staff health conditions that staff may voluntarily report and absences that could be an early indicator of tampering or other malicious, criminal, or terrorist actions, and report such conditions to local health authorities |
|-----------------------|-----------------------|-----------------------|-----------------------|---|

Human element -- public

Visitors (Non-Employees)

- | | | | | |
|-----------------------|-----------------------|-----------------------|-----------------------|---|
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Inspect incoming and outgoing vehicles, packages and briefcases for suspicious, inappropriate or unusual items or activity, to the extent practical |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Restrict entry to the establishment |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Ensure that there is a valid reason for the visit before providing access to the facility - beware of unsolicited visitors |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Verify the identity of unknown visitors |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Restrict access to food handling and storage areas (for example, accompany visitors, unless they are otherwise specifically authorized) |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Restrict access to locker rooms |

Facility

Physical security

- | | | | | |
|-----------------------|-----------------------|-----------------------|-----------------------|---|
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Protect perimeter access with fencing or other deterrent, when appropriate |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Secure all doors, windows, roof openings/hatches, vent openings and trailer bodies, to the extent possible |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Use metal or metal-clad exterior doors to the extent possible when the facility is not in operation, except where visibility from public thoroughfares is an intended deterrent |

- | Y | N | N/A | DNK | |
|-----------------------|-----------------------|-----------------------|-----------------------|---|
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Secure bulk unloading equipment when not in use and inspect the equipment before use |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Minimize the number of entrances to restricted areas |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Account for all keys to establishment |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Monitor the security of the premises using appropriate methods |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Minimize to the extent practical, places that can be used to temporarily hide intentional contaminants |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Provide adequate interior and exterior lighting, include emergency lighting, where appropriate, to facilitate detection of suspicious or unusual activity |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Implement a system of control vehicles authorized to park on the premises |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Keep parking areas separated from entrances to food storage and processing areas and utilities, where practical |

Storage and use of poisonous and toxic chemicals (for example, cleaning and sanitizing agents, pesticides)

- | | | | | |
|-----------------------|-----------------------|-----------------------|-----------------------|---|
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Limit poisonous and toxic chemicals in the establishment to those that are required for the operation and maintenance of the facility and those that are being held for sale |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Store poisonous and toxic chemicals as far away from food handling and storage areas as practical |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Limit access to and securing storage areas for poisonous and toxic chemicals that are not being held for sale |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Ensure that poisonous and toxic chemicals are properly labeled |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Use pesticides in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Know what poisonous and toxic chemicals should be on the premises and keep track of them |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Investigate missing stock or other irregularities outside a normal range of variation and alert appropriate law enforcement and public health authorities about unresolved problems, when appropriate |

Operations

Incoming products

- | | | | | |
|-----------------------|-----------------------|-----------------------|-----------------------|---|
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Use only known and appropriately licensed or permitted (where applicable) sources for all products |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Take reasonable steps to encourage suppliers, distributors and transporters to practice appropriate food security measures |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Authenticate labeling, packaging configuration, tamper-evident packaging and product coding/expiration dating systems (where applicable) in advance of receipt of shipment, especially for new products |

Food Defense Self Assessment Tool for Importers and Filers

Y N N/A DNK

- Request locked and/or sealed vehicles/containers/railcars, and, if sealed, obtaining the seal number from the supplier, and verify upon receipt, making arrangements to maintain the chain of custody when a seal is broken for inspection by a governmental agency or as a result of multiple deliveries
- Request that transporters have the capability to verify the location of the load at any time, when practical
- Establish delivery schedules, not accepting unexplained, unscheduled deliveries or drivers, and investigating delayed or missed shipments
- Supervise off-loading of incoming materials, including off hour deliveries
- Reconcile the product and amount received with the product and amount ordered and the product and amount listed on the invoice and shipping documents; take into account any sampling performed prior to receipt
- Investigate shipping documents with suspicious alterations
- Inspect incoming products and product returns for signs of tampering, contamination or damage or "counterfeiting", when appropriate
- Inspect incoming products for authenticity, packaging/product integrity, and evidence of unauthorized relabeling/repackaging and verify batch/lot/container codes
- Verify conformance with FDA requirements for products safety, quality, effectiveness, and labeling
- Evaluate the utility of testing incoming products and product returns for detecting tampering or other malicious, criminal, or terrorist action
- Develop and implement procedures for inspecting shipping containers, vehicles
- Investigate damage and loss and alert appropriate authority of discrepancies
- Reject suspect food
- Alert appropriate law enforcement and food public health authorities about evidence of tampering, "counterfeiting" or other malicious, criminal, or terrorist action

Storage

- Have a system for receiving, storing and handling distressed, damaged, returned, and reworked products that minimizes their potential for being compromised or to compromise the security of other products

Y N N/A DNK

- Keep track of incoming products, salvage products, and returned products
- Minimize reuse of containers, shipping packages, cartons, etc., where practical
- Investigate missing or extra stock or other irregularities outside a normal range of variability and report unresolved problems to appropriate law enforcement and public health agencies, when appropriate

Outgoing products

- Ensure that public storage warehousing and shipping (vehicles and vessels) practice appropriate security measures
- Perform random inspection of storage facilities, vehicles, and vessels
- Request locked and/or sealed vehicles/containers/railcars and provide the seal number to the consignee
- Establish scheduled pickups and not accepting unexplained, unscheduled pickups
- Restrict access to distribution process to employees with appropriate clearance
- Request that the transporter have the capability to verify the location of the load at any time
- Advise sales staff to be on the lookout for counterfeit products during visits to customers and notify management if any problems are detected
- Investigate missing or extra stock or other irregularities outside a normal range of variation and alert appropriate law enforcement and public health authorities about unresolved problems, when appropriate

Security of ventilation system (where applicable)

- Secure access to air intake points for the facility, to the extent possible
- Examine air intake points for physical integrity routinely

Access to computer systems

- Restrict access to critical computer data systems to those with appropriate clearance
- Eliminate computer access when a staff member is no longer associated with the establishment
- Establish a system of traceability of computer transactions
- Review the adequacy of virus protection systems and procedures for backing up critical computer based data systems
- Validate and periodically challenging the computer security system and procedures

If a food import establishment operator suspects that any of his/her products that are regulated by the FDA have been subject to tampering, "counterfeiting", or other malicious, criminal, or terrorist action, FDA recommends that he/she notify the FDA 24-hour emergency number at 301-443-1240 or call their local FDA District Office. FDA District Office telephone numbers are listed at: http://www.fda.gov/ora/inspect_ref/iom/iomoradir.html. FDA recommends that the operator also notify local law enforcement and public health agencies.