

Contains Nonbinding Recommendations
 U.S. Food and Drug Administration
 Food Defense Self Assessment Tool for
 Cosmetic Processors and Transporters of Cosmetics

Cosmetics Establishment 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 assessment of cosmetics security procedures and operations
 - Have a security 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
 - Maintain any floor or flow plan in a secure, off-site location
 - 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)
 - Promote cosmetics 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 reporting any findings to identified management
 - Have an 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 & 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 cosmetics security inspections of all appropriate areas of the facility (include receiving and warehousing areas) use 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 information updated

Identification

- Establish a system of positive identification and recognition, 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 necessary for their job functions and only during appropriate work hours
- Change combinations, rekeying locks and/or collecting the retired key card when a staff member is no longer associated with the establishment, and additionally as needed to maintain security

Personal items

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

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Training in cosmetics security procedures

- | Y | N | N/A | DNK | |
|-----------------------|-----------------------|-----------------------|-----------------------|---|
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Incorporate cosmetics 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 volunteer staff |
| <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 - the public

Visitors (Non-Employees)

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|-----------------------|-----------------------|-----------------------|-----------------------|---|
| <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 cosmetics manufacturing and storage areas |
| <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, ventilation systems, utility rooms, loft areas, trailer bodies, tanker trucks, railcars, and bulk storage tanks for liquids, solids, and compressed gases, 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 |

- | Y | N | N/A | DNK | |
|-----------------------|-----------------------|-----------------------|-----------------------|---|
| <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"/> | Secure bulk unloading equipment when not in use and inspecting the equipment before use |
| <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, including emergency lighting, where appropriate, to facilitate detection of suspicious or unusual activities |
| <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 cosmetics manufacturing storage areas and utilities, where practical |

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

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|-----------------------|-----------------------|-----------------------|-----------------------|---|
| <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 |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Store poisonous and toxic chemicals as far away from cosmetics manufacturing and storage areas as practical |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Limit access to and secure storage areas for poisonous and toxic chemicals |
| <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 keeping 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 alerting appropriate law enforcement and public health agencies about unresolved problems, when appropriate |

Operations

Incoming materials and contract operations

- | | | | | |
|-----------------------|-----------------------|-----------------------|-----------------------|---|
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Use only known, appropriately licensed or permitted (where applicable) contract manufacturing and packaging operators and sources for all incoming materials including ingredients, compressed gas, packaging, labels, and materials for research and development |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Take steps to ensure that suppliers, contract operators, and transporters practice appropriate cosmetics security measures |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Authenticate labeling and packaging configuration and product coding/expiration dating systems (where applicable) for incoming materials in advance of receipt of shipment, especially for new products |

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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 the transporter 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 investigate 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 materials including ingredients compressed gas, packaging, labels, product returns, and materials for research and development for signs of tampering, contamination, or damage or "counterfeiting", when appropriate
- Evaluate the utility of testing incoming ingredients, compressed gas, packaging, labels, product returns, and materials for research and development for detecting tampering or other malicious, criminal or terrorist action
- Reject suspect cosmetics or cosmetic ingredients
- Alert appropriate law enforcement and 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 rework products that minimizes their potential for being compromised or to compromise the security of other products
- Keep track of incoming materials and materials in use including ingredients, compressed gas, packaging, labels salvage products, rework products, and product returns

Y N N/A DNK

- Investigate missing or extra stock or other irregularities outside a normal range of variability and report unresolved problems to local appropriate enforcement and public health authorities when appropriate
- Store product labels in a secure location and destroying outdated or discarded product labels
- Minimize reuse of containers, shipping packages, cartons, etc., where practical

Finished products

- Ensure that contract warehousing and shipping operations (vehicles and vessels) practice appropriate security measures
- Perform random inspection of storage facilities, vehicles, and vessels
- Evaluate the utility of finished product testing for detecting, tampering or other malicious, criminal, or terrorist action
- Request locked and/or sealed vehicles/containers/railcars and provide the seal number to the requesting that the transporter have the capability to verify the location of the load at any time
- Establish scheduled pickups, and not accepting unexplained, unscheduled pickups
- Keep track of finished product
- 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
- Advise sales staff to be on the lookout for counterfeit products and to alert management if any problems are detected

Access to computer systems

- Restrict access to computer process control systems and critical 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 and procedures for backing up critical computer-based data systems
- Validate the computer security system

If a cosmetic 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.