

Contains Nonbinding Recommendations
 U.S. Food and Drug Administration
 Food Defense Self Assessment Tool for
 Dairy Farms, Bulk Milk Transporters, Bulk Milk
 Transfer Stations and Fluid Milk Processors

Dairy Establishment Operations:

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

Y N N/A DNK

Management

Y N N/A DNK

- Conduct an initial assessment of the adequacy of food security procedures and operations
- Develop 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
- Develop a product recall strategy
- Provide training in 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 report any findings to management.
- Provide appropriate supervision to all staff with access to vulnerable areas of the facility, including cleaning, maintenance and quality control staff, seasonal, temporary, contract, and volunteer staff, and especially, new staff.
- Conduct routine security checks of the raw and pasteurized milk storage, vitamin supplement receiving and storage, and milk processing and packaging areas of the facility, for signs of tampering or malicious, criminal or terrorist actions or areas that may be vulnerable to such actions.
- Alert appropriate law enforcement and public health authorities about any threats of or suspected tampering or other malicious, criminal or terrorist actions.
- Review, at least annually, the effectiveness of the food security plan, use knowledgeable in-house or third party staff, and revise the program accordingly

Human element

- Obtain and verify work references, addresses and phone numbers of all staff with access to raw and pasteurized milk storage, vitamin supplement receiving and storage, and milk processing and packaging areas of the facility, including cleaning, maintenance and quality control staff, seasonal, temporary, contract, and volunteer staff.
- Have a criminal background check performed by local law enforcement or by a contract service provider for the above listed staff, except if such staff are under direct supervision when they access the above listed areas.
- Limit access to raw and pasteurized milk storage, vitamin supplement receiving and storage, and milk processing and packaging areas of the facility to those staff that need to enter because of their job functions and only during appropriate work hours.
- Prevent staff from bringing personal items into raw and pasteurized milk storage, vitamin supplement receiving and storage, and milk processing and packaging areas of the facility.
- 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
- Accompany all visitors.

Facility

- Secure all doors, windows, roof openings/hatches, vent openings, ventilation systems, utility rooms, loft areas, trailer bodies, tanker trucks, and bulk storage tanks, to the extent possible.
- Inspect bulk unloading equipment and pumps in the receiving area before use.
- Monitoring the security of the premises.
- Lock or seal, with serially numbered seals, all entrances to the milk house or all entry ports on the bulk milk tank from the until the time it is emptied, except when it is under direct, visual supervision

Operations

Vitamin supplements and laboratory supplies

- Use only known, appropriately licensed or permitted (where applicable) sources for vitamin supplements.
- Establish delivery schedules for vitamin supplements, not accepting unexplained, unscheduled deliveries or drivers, and investigating delayed or missed shipments.
- Supervise off-loading of incoming vitamin supplements, laboratory reagents and positive controls, 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.
- Investigate shipping documents with suspicious alterations.
- Inspect incoming vitamin supplements for signs of tampering, contamination or damage or "counterfeiting"
- Store vitamin supplements, laboratory reagents, and positive controls in a secure location.
- Keep track of vitamin supplements, laboratory reagents and positive controls and investigate any missing or extra stock outside a predetermined normal range of variability.

Labeling

- Store product labels in a secure location and destroy outdated or discarded labels

Raw Milk

- Accept only those incoming tanker loads of raw milk for which all openings were either locked or sealed, with a serially numbered seal, from the time the tanker was last washed until the load is delivered. Exception may be provided for incoming loads for which a thorough investigation demonstrates that there is a verified, reasonable explanation for a deviation. Seals or locks need not be in place during those times that the tanker was under the direct, visual supervision of the driver.

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Y N N/A DNK

- Use only known, reputable transportation companies
- Establish delivery schedules for raw milk, not accepting unexplained, unscheduled deliveries or drivers, and investigating delayed or missed shipments.
- Supervise off-loading of incoming milk.
- Reconcile the amount received with the amount listed on the shipping documents.
- Verify that operators of bulk milk transfer stations that supply raw milk adhere to the preventive measures listed in this checklist
- Lock or seal, with a serially numbered seals, every tanker from the time it is last washed until the time the load of milk is delivered to the bulk milk transfer station or fluid milk processing facility. Seals or locks need not be in place during those times that the tanker is under the direct, visual supervision of the driver.

If a dairy farm, bulk milk transporter, bulk milk transfer station or fluid milk processor 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.