



**U.S. Food and Drug Administration**

Department of  
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**CENTER FOR FOOD SAFETY AND APPLIED NUTRITION**

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## **Guidance for Industry**

# **Dairy Farms, Bulk Milk Transporters, Bulk Milk Transfer Stations and Fluid Milk Processors Food Security Preventive Measures Guidance**

## **FINAL GUIDANCE**

Comments regarding this document may be submitted at any time to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

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**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
July 2003**

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## **Guidance for Industry**

# **Dairy Farms, Bulk Milk Transporters, Bulk Milk**

# Transfer Stations and Fluid Milk Processors Food Security Preventive Measures Guidance

This guidance represents FDA's current thinking on the kinds of measures that operators of dairy farms, bulk milk transportation operations, bulk milk transfer stations, and fluid milk processing facilities may take to minimize the risk that fluid milk under their control will be subject to tampering or other malicious, criminal, or terrorist actions. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

## Purpose, Scope and Limitations:

This guidance is designed as an aid to operators of dairy farms, bulk milk transportation operations, bulk milk transfer stations and fluid milk processing facilities. It identifies the kinds of preventive measures operators of these establishments may take to minimize the risk that fluid milk under their control will be subject to tampering or other malicious, criminal, or terrorist actions. Operators of these establishments are encouraged to review their current procedures and controls in light of the potential for tampering or other malicious, criminal, or terrorist actions and make appropriate improvements.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Not all of the guidance contained in this document may be appropriate or practical for every dairy farm, bulk milk transportation operation, bulk milk transfer station, or fluid milk processing facility. FDA recommends that operators of these establishments review the guidance in each section that relates to a component of their operation, and assess which preventive measures are suitable. FDA further recommends that operators consider the goal of the preventive measure, assess whether the goal is relevant to their operation, and, if it is, design an approach that is both efficient and effective to accomplish the goal under their conditions of operation.

Additional food security guidance that may also be applicable to operators of these establishments is contained in an FDA guidance document entitled, "Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance." This document is available at: <http://www.cfsan.fda.gov/~dms/secguid6.html>.

## **Management**

FDA recommends that operators of dairy farms, bulk milk transportation operations, bulk milk transfer stations and fluid milk processing facilities consider:

- Conducting an initial assessment of the adequacy of food security procedures and operations, which we recommend be kept confidential.
- Developing 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.
- Developing a product recall strategy
- Providing 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. The training may also encourage staff to be alert to the presence of unidentified or unknown individuals or individuals that are in areas to which they are not designated access, and to directly question such individuals or report them to management
- Providing appropriate supervision to 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, and especially, new staff. The supervision may include watching for unusual or suspicious behavior by staff (e.g., staff who, without an identifiable purpose, stay unusually late after the end of their shift, arrive unusually early, access files/information/areas of the facility outside of the areas of their responsibility; remove documents from the facility; ask questions on sensitive subjects; bring cameras to work)
- Conducting 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.
- Alerting appropriate law enforcement and public health authorities about any threats of or suspected tampering or other malicious, criminal or terrorist actions. FDA may be contacted through its 24-hour emergency number, 301-443-1240, or through a local FDA District Office. FDA District Office telephone numbers are listed at: [http://www.fda.gov/ora/inspect\\_ref/iom/iomradir.html](http://www.fda.gov/ora/inspect_ref/iom/iomradir.html).
- Reviewing, at least annually, the effectiveness of the food security plan, using knowledgeable in-house or third party staff, and revising the program accordingly, which we recommend be kept confidential.

## Human element

FDA recommends that operators of dairy farms, bulk milk transportation operations, bulk milk transfer stations and fluid milk processing facilities consider:

- Obtaining and verifying 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.
- Having 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.
- Limiting 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.
- Preventing staff from bringing personal items (e.g., lunch containers, purses) into raw and pasteurized milk storage, vitamin supplement receiving and storage, and milk processing and packaging areas of the facility.
- Being 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 (e.g., an unusual number of staff who work in the same part of the facility reporting similar symptoms within a short time frame), and reporting such conditions to local health authorities
- Accompanying all visitors.

## **Facility**

FDA recommends that operators of dairy farms, bulk milk transportation operations, bulk milk transfer stations and fluid milk processing facilities consider:

- Securing doors (including freight loading doors, when not in use and not being monitored, and emergency exits), windows, roof openings/hatches, vent openings, ventilation systems, utility rooms, loft areas, trailer bodies, tanker trucks, and bulk storage tanks, to the extent possible.
- Inspecting bulk unloading equipment and pumps in the receiving area before use.
- Monitoring the security of the premises.

FDA further recommends that operators of dairy farms consider:

- Locking or sealing, with serially numbered seals, all entrances to the milk house or all entry ports

on the bulk milk tank from the time the bulk milk tank is washed until the time it is emptied, except when it is under direct, visual supervision (Remember to first make arrangements with the State regulatory agency that will ensure that the regulatory agency, rating agency and FDA continue to have ready access to the milk house and milking operation for routine inspections, Grade "A" IMS ratings and FDA check ratings, when applicable).

## **Operations**

### Vitamin supplements and laboratory supplies

FDA recommends that operators of fluid milk processing facilities consider:

- Using only known, appropriately licensed or permitted (where applicable) sources for vitamin supplements.
- Establishing delivery schedules for vitamin supplements, not accepting unexplained, unscheduled deliveries or drivers, and investigating delayed or missed shipments.
- Supervising off-loading of incoming vitamin supplements, laboratory reagents and positive controls, including off-hour deliveries.
- Reconciling the product and amount received with the product and amount ordered and the product and amount listed on the invoice and shipping documents.
- Investigating shipping documents with suspicious alterations.
- Inspecting incoming vitamin supplements for signs of tampering, contamination or damage (e.g., abnormal powders, liquids, stains, or odors, evidence of resealing) or “counterfeiting” (e.g., inappropriate or mismatched product identity, labeling, product lot coding or specifications).
- Storing vitamin supplements, laboratory reagents, and positive controls in a secure location.
- Keep track of vitamin supplements, laboratory reagents and positive controls and investigating any missing or extra stock outside a predetermined normal range of variability.

### Labeling

FDA recommends that operators of fluid milk processing facilities consider:

- Storing product labels in a secure location and destroying outdated or discarded labels

### Raw milk

FDA recommends that operators of bulk milk transfer stations and fluid milk processing facilities consider:

- Accepting 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.
- Using only known, reputable transportation companies
- Establishing delivery schedules for raw milk, not accepting unexplained, unscheduled deliveries or drivers, and investigating delayed or missed shipments. We recommend that driver identification include the name of the transportation company.
- Supervising off-loading of incoming milk.
- Reconciling the amount received with the amount listed on the shipping documents.
- Verifying that operators of bulk milk transfer stations that supply raw milk adhere to the preventive measures listed in this guidance.

FDA recommends that operators of bulk milk transportation operations consider:

- Locking or sealing, 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.

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