International Dairy Foods Association
Milk Industry Foundation
National Cheese Institute
International Ice Cream Association

March 15, 2002

Docket No. 01D-0583

Dockets Management Branch (HFA-305)
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Dear Sir/Madam:

These comments are made on behalf of the International Dairy Foods Association (IDFA). IDFA is America's leading trade association representing the dairy industry. IDFA's approximately 600 member companies manufacture the entire range of dairy products and include processors, manufacturers, marketers, distributors, and suppliers. IDFA consists of three constituent organizations, the Milk Industry Foundation, the International Ice Cream Association, and the National Cheese Institute. Member companies in these groups account for 85 percent of the dairy products consumed in the United States.

IDFA is committed to leading the dairy processing industry on issues related to food security. In early October 2001, IDFA formed a Biosecurity Working Group composed of dairy industry leaders. With the assistance of the Working Group, IDFA has assumed a leadership role in developing guidance security documents for milk tankers and dairy processing plants. IDFA's Voluntary Guidance for Sealing Raw Milk Tankers provides a step-by-step protocol to protect milk from unauthorized access during pick-up and delivery of milk. Our Biosecurity in the Dairy Plant provides detailed suggestions to enhance the security of a dairy processing plant. Both of these documents are included with this letter. Informal surveys of the industry show that our members have enthusiastically embraced IDFA's guidance documents with a high percentage implementing our suggestions. In addition, IDFA's recent workshop on dairy biosecurity was well-attended and revealed a high level of enthusiasm within the industry for implementing new measures to further increase the protection of dairy ingredients and products. Further, IDFA prepared a Biosecurity Handbook that contains a wealth of information on biosecurity in the dairy industry. This book is now in the hands of many of our member companies.

IDFA also supports FDA's recent leadership in the area of food biosecurity. IDFA has utilized FDA's expertise in a number of areas and has distributed FDA's food biosecurity guidance documents to our member companies. In turn, they have submitted suggestions to improve the effectiveness of the advice found in the documents. This letter summarized those suggestions.

FDA requested comments in two specific areas. This letter will address those areas first.

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Tamper-Evident Packaging – Although tamper-evident packaging is effective in preventing intentional contamination of individual packages, it would do little to prevent a terrorist event. The dairy industry's efforts and IDFA's guidance documents focus on upstream points in the process where bulk ingredients are collected, transported, stored, or processed. and provide advice on how to protect them from an intentional act of contamination. We suggest that FDA continue its focus on food security guidance for food processors on the importance of securing upstream ingredients rather than downstream packaging.

Product and Ingredient Trace-back – IDFA believes it is critically important for companies to maintain appropriate processing records. These records are important if it becomes necessary to recreate the processing history of a particular product. Further, IDFA believes that a dairy processor should be able to identify the immediate source of a particular ingredient or product as well as the party that bought or took control of the item. In other words, a company involved in the production of dairy products should be able to trace one step back and one step forward. When each party involved in the production of a food product does this it becomes possible to construct a chain of possession useful in identifying where possible adulteration took place. In addition, processing records should be kept by the processor for the entire time that the product is offered for sale to the public.

IDFA supports the recommendations in the FDA guidance documents. We are also pleased that FDA made the guidance voluntary rather than mandatory. This is important, as each business in the food production chain is faced with a unique set of circumstances that require flexibility. The voluntary nature of the guidance allows each company to adjust their security measures to provide maximum protection for their products. IDFA has consulted with numerous member companies to provide advice on food security and has found that such flexibility is essential to success.

Very truly,

Cary Frye

Cary Frye

Vice President, Regulatory Affairs

International Dairy Foods Association
Milk Industry Foundation
National Cheese Institute
International Ice Cream Association

Voluntary Guidelines for Sealing Raw Milk Tankers

The International Dairy Foods Association and the National Milk Producers Federation have developed milk tanker sealing guidelines to ensure dairy products are protected and to prevent safe milk from being unnecessarily destroyed. These voluntary guidelines are provided as general advice. Individual companies may choose to modify these guidelines to increase the level of security according to their specific needs and circumstances.

The proposal detailed below is a series of procedures designed to reduce the risk of deliberate contamination of raw milk during the various steps employed in the collection and delivery of raw milk to the processing plant. The ultimate goal is to have all openings on milk tankers sealed at all times, except when the tanker is being loaded, unloaded, washed, or is in the immediate control of the driver. Seals should be numbered and recorded to provide a chain of custody for each delivery of milk.

General Guidelines

1. After a milk tanker is unloaded and washed, the wash station/plant seals all potential points of access to the interior of the tank with an appropriate sealing device such as a plastic tie or wire with a pressed metal seal. Each seal should have an identification number for tracability purposes. Access points that require sealing include inlet/outlet valves, manhole cover, vent tube, CIP connections, and any other point at which one could access the inside of the tank.

2. After washing of the tanker and installation of seals, each seal is inspected and its number is recorded in an appropriate place. For example, numbers may be recorded on the wash tag, on the manifest, or on a log specifically carried by the driver for this purpose. The instrument used to record seal numbers will be referred to in this document as the "seal record."

3. If wash tags are used as the seal record, they should be printed with unique identifiers (company logo, plant I.D. number, etc.). Wash tags should be accounted for and kept in a secure place by receiving personnel as required by the PMO.

4. When the driver is preparing to leave on his collection route, he checks to verify that the numbers on the seals correspond to the numbers that were entered in the seal record. If the numbers match, the driver writes his initials on the seal record.

5. If at any time the driver finds that a seal has been broken without his knowledge or that a seal is missing, he should immediately notify the plant or cooperative.

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6. When the tanker arrives at the first farm pickup, the driver checks all seals to be sure that none are broken. The driver then breaks and removes the seals on the rear door and the outlet valve. The numbers on the broken seals are recorded.

7. Any time the tanker is not under direct supervision of the driver, all openings on the tanker are secured with a seal or lock.

8. At the last farm pickup the driver attaches a numbered seal to the inlet/outlet valve, the rear door, or any other point of access that has been opened. The seal numbers are recorded in the seal record. A padlock may be used instead of a seal to secure the rear door.

9. When the tanker arrives at the receiving plant, authorized receiving personnel compares the numbers on all seals to the numbers in the seal record. It is recommended that the receiving plant maintain a seal verification log.

10. If the seal numbers match, the milk is unloaded.

11. If any seals do not correspond to the seal verification entries, or if any seal is inexplicably broken, the receiving plant does not unload the milk until a further investigation reveals the cause.

12. If a tanker delivers milk to a receiving plant more than once a day and is not washed until the last load is delivered, the procedure outlined above is utilized each time the tanker exits the plant. At the end of the day, after the plant has unloaded and washed the tanker, those points of access listed above are sealed, with the seal numbers entered on the seal record. The cycle for the tanker begins again the following day or the next scheduled use.

BIOSECURITY IN THE DAIRY PLANT
IDFA's guidance document for the dairy industry

This guidance document was prepared by the International Dairy Foods Association (IDFA) to help you evaluate the security and integrity of your operations in dealing with a deliberate act of tampering - however unlikely. Our industry has long dealt with issues of food pathogens and inadvertent adulteration; we now need to review our systems with a new perspective.

Each plant has its own handling protocols, physical lay-out and employee policies. Therefore, this document is not all-inclusive, but should help you review your operations to see if changes are needed. Please use this paper to stimulate your thinking and planning. IDFA urges all members to seek consultation from experts to address any specific issues of concern in your plant.

*We have laid out areas to consider in order **of** milk and other materials entering your facilities, through to the distribution offinished product.*

I. Incoming Materials

In general, start by considering the milk, food ingredients, packaging, chemicals and other materials that come into your plant facility and warehouses, and ensure that these product streams are secure, and that materials are stored in a secure place.

A. Milk Tankers

- Consider the security of your tanker trucks that transport milk, cream and other liquid bulk products. Consider their movement from farm to farm, or plant to plant, as well as parking and off-hours holding, and unloading and cleaning for re-use. Is the truck secure from tampering at all times?
- Trucks should not be left unlocked and unattended, whether full or empty.
- Regardless of where the truck is parked (within view or out of sight) nobody should have access to the inside of the tanker unless they are unloading or cleaning it.
- Consider ways to tag or lock the bulk area of your trucks for tamper-resistance or tamper-evidence at each step of the journey.
- Raw milk suppliers should provide information on driver identification, driver background checks and measures taken to assure that potential food safety issues are addressed and controlled.
- Your receiving people should be able to identify the truck driver, to be sure that he is who he says he is. This could be as simple as having the driver register with your office and confirmed with a phone call. A picture I.D. can be used for verification.
- Discuss these issues with your hauler and maintenance staff to determine the easiest and most effective way to accomplish these important precautions.

B. Other Incoming Materials

- Consider the trucks that carry all of your supplies to your plant - packaging, ingredients, etc. - and apply the same consideration for these trucks as the milk tankers

above. Consider a tagging system with your suppliers that ensures these materials have not been tampered with in-transit.

- Compile documentation from ingredient and packaging suppliers on their safety and security programs.
- Reconcile the amount of ingredient received with the amount ordered and the amount listed on the invoice and shipping documents.
- Supervise off-loading of incoming ingredients, compressed gas, packaging, labels, salvage products, rework products, and product returns.
- Keep inventory of ingredients, packaging, labels, salvage products, rework products, and product returns.
- Investigate missing or extra stock or other irregularities outside a pre-determined normal range of variability and report any unresolved problems to local law enforcement.
- Destroy outdated or discarded product labels to prevent product counterfeiting.
- Some liquid bulk ingredients are pumped into the plant through inlets on the outside of the plant. These should be secure.
- Bagged dry ingredients (nonfat dry milk, spices, etc.) should be in bags that show no evidence of tampering. Half-full bags should have the name of the operator who last used it and the date it was last used written on the bag. Half-full bags should be stored in a secure place.
- If your water supply is from a public works facility, check with city officials to find out what security measures they have in place. If you use a private well, secure it.
- Consider the storage of your ammonia and other chemicals, and ensure that these materials are secure.

C. Security in the Receiving Bay

- The receiving bay can be a point of vulnerability. If your bay is big enough, the roll-down door should be closed after trucks are inside and positioned for unloading. If the bay is not big enough to do this, or if your bay has no door, you should train your receiving operators to watch for anyone who tries to get into the receiving area.
- The door leading into the plant should have a keypad or some other device that restricts entry.
- Pumps and other equipment in the receiving area should be secured from tampering. Sample plugs (the in-line rubber device used to pull samples) should be installed in a protected location where they can be observed.

II. General Plant Security

Consider the perimeter of your facility, entrance and egress to your plant and warehouses, access to all storage areas, and security of key areas within the plant.

A. Plant Perimeter/Interior Security

- Consider the perimeter of your plant. Do you have appropriate fencing, gates and/or surveillance to deter trespassers?
- Is outside lighting adequate?
- Security plans should be in place for weekends and holidays.
- Secure access to air intake points for the facility, to the extent possible (e.g. fences, sensors, guards, video surveillance).

- Routinely examine air intake points for physical integrity.
- Restrict Access to areas where chemicals (e.g. ammonia, sanitizers pesticides, etc.) are stored and make sure a supervisor monitors who goes in and out.
- Ladders on outdoor silos should be locked so that nobody can get to the top hatch. All points that allow access to the inside of the silo should be locked or somehow secured.
- All doors and windows that allow access to the plant need to be secured. Most windows and some doors can be locked more-or-less permanently. Other doors need a keypad or some other security device to restrict entry. *Be careful to keep within the fire code.*
- If you have doors that are not necessary, shut them permanently. Again, remember the fire code.
- Computer access to production records should be password protected.
- Eliminate computer access to past employees immediately upon voluntary or involuntary termination.
- Establish a system of tracability of computer transactions.
. Review adequacy of procedures for backing up critical computer-based data systems.
- Some silo bays have doors that allow access both from the plant and from the outside. It is very important to put keypads on all of these doors.

B. Processing Areas

- Maintain the safety and security of processing equipment through cleaning records, employee traffic and access control.
. Limit access to sensitive areas of your operation. For example, areas on the processing floor that have bulk holding tanks (silos, staging tanks, etc.) should have restricted access, if possible. Painted lines on the floor may be useful to identify such areas.
. Be sure that procedures and documentation for processing rework are in place and followed.
- Laboratory reagents should remain in the lab except when needed for sampling, etc.

III. Personnel

Consider all personnel movements within your plant, and in and out of your plant, including management of temporary employees and guests. Communicate with your people: Remember that your plant employees are your first (and best) line of defense against intentional contamination of your products. Enlist them in helping identify any suspicious people in or around the plant. If you have just 50 employees, you will have 50 sets of eyes and ears looking out for the safety of your products 24 hours a day, seven days a week.

A. Employee Access

- Consider performing citizenship, immigration status and criminal background checks on all employees.
- Review your hiring procedures: check the references for any new employees, and make background checks as appropriate.
- If an outside hiring source is used, verify that their recruitment methods are acceptable.
- Train all employees in your security procedures (including temporary workers) and enforce these policies.

• Change combinations and or collect the retired key card when an employee is terminated, either voluntarily or involuntarily, and additionally as needed to maintain security.
• Prohibit personal items (e.g. lunch containers, purses) in food handling areas (e.g. eliminate pockets from uniforms).
• Establish policy and provide for inspection of contents of employee lockers (e.g. metal mesh lockers, company-provided locks), bags, and vehicles when on company property.
• Consider color coding employee clothing so that it is easy to spot if people are in a restricted area. This might be particularly helpful with temporary employees who might not be allowed near certain areas.
. Casual laborers should be restricted to designated areas. This is important, as you often do not have background information on these people. Put one of your better Production Managers in charge of these temporary workers.
• Be aware of unusual behavior by plant personnel such as arriving early or leaving late, accessing restricted files or removing files.
• Storage facilities for employees (e.g.lockers) should be secured with company owned locks. Company procedures should permit access to these areas.
• Account for all keys to the facility.

B. Visitors and Vendors/General Surveillance

• Review or establish a sign-in procedure for visitors. Any vendors and other visitors should sign in and have an escort during their time in the plant. If a vendor representative is unfamiliar to you, call the vendor to verify that they are who they say they are. Visitors should present a photo I.D.
• Consider requiring visitors, temporary employees and vendors to wear identifying clothing during their time in the plant.
• Security cameras positioned at strategic points around the plant and monitored at a central location can provide excellent protection against intruders.
• If you don't currently have one, consider an electronic security system that requires a magnetic card for entry.

IV. Distribution

A. Final Product Distribution

. When a truck carrying your products has multiple stops, the truck should be sealed with a tamper-evident device until the first stop, and locked when the driver is away.
• Truck drivers who distribute your product should be enlisted to watch for suspicious activity around the truck during stops.
• Ensure that public storage warehousing and shipping (vehicles and vessels) practice appropriate security measures (e.g. include requirements in contracts and audits).
• Perform random inspection of storage facilities, vehicles, and vessels.
• Advise sales staff to be on the lookout for counterfeit products during visits to customers and report any problems to management.
• Maintain records of product distribution, including product code (i.e. lot number) and consignee.

V. Crisis Planning

A. Planning/Authorities

. Have a crisis plan in place for your facility.
. Have tested recall programs in place in all plants in the event of a recall.
. Maintain floor and flow plan in secure, off-site location with local fire officials.
. Discuss emergency plans with police/fire/rescue officials so that their questions about the physical facility and materials/chemicals stored in it can be answered.
. Designate an emergency management coordinator and back-up for each processing plant, available 24/7. This person would be responsible for receiving any emergency or safety concerns, documenting their receipt, making contact with the corporate offices, determining the significance of the information, and notifying IDFA and the government agencies, as necessary.
. Educate your employees as appropriate on your plan, and on the need for vigilance in food operations.
. Contact your local police and let them know that you have implemented security plans. Meet with a local law enforcement representative on site and show him your plans.
. Make sure the local police and fire department have contact phone numbers for your facility so that you can be contacted 24 hours a day, 7 days a week. Be sure that your employees have phone numbers for the police, sheriff and fire department in case they need to report an incident.
. Designate and train a media spokesperson.
. Prepare generic press statements and background information.
. Annually review and test the effectiveness of procedures and plans (e.g. mock criminal, terrorist or tampering events, mock recall) and revise accordingly. Use third party or in-house security expert.
. The Food and Drug Administration (FDA) has an emergency operations telephone number you can call in case of an incident. The number is (301) 443-1240. Keep this number close by.
. IDFA's emergency contact is Dr. Gordon Brown at 202-220-3524 or 202-841-0887 (cell phone); or Allen Sayler at 202-220-3544 or 202-841-1029 (cell phone).

If you have additional questions about plant biosecurity, call Gordon Brown at (202) 220-3524.