



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

August 30, 2010

Division of Dockets Management (HFA-305)  
Food and Drug Administration (FDA)  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Re: Docket No. FDA-2010-N-0013  
Implementation of Sanitary Food Transportation Act of 2005 –  
Advance Notice of Proposed Rulemaking, 75 Fed. Reg. 22713 (April  
30, 2010).**

Dear Sir/Madam:

The International Dairy Foods Association (IDFA) represents the \$110-billion a year dairy manufacturing and marketing industries and their suppliers, with a membership of 550 companies. IDFA is comprised of three constituent organizations: the Milk Industry Foundation (MIF), the National Cheese Institute (NCI) and the International Ice Cream Association (IICA). IDFA's 220 dairy processing members run more than 600 plant operations, and range from large multi-national organizations to single-plant companies. Together they represent more than 85% of the milk, cultured products, cheese and frozen desserts produced and marketed in the United States. IDFA can be found online at [www.idfa.org](http://www.idfa.org).

IDFA is pleased that FDA has issued an advance notice of proposed rulemaking (ANPR) on the implementation of the Sanitary Food Transportation Act of 2005. The dairy industry has substantial experience in this area and we are happy to share our insight and experience with FDA to assist in the development of appropriate standards and/or practices.

#### Preliminary Matters

At the outset, IDFA would like to clarify a point raised in the ANPR concerning the 1994 salmonella outbreak associated with ice cream mix. The ice cream mix incident, although unfortunate, is one that is highly unlikely to reoccur. In fact it has not reoccurred in the 16 years since. The reason for this is that IDFA, the National Food Processors Association and the FDA took immediate steps to educate the industry in order to prevent cross contamination. We have attached a copy of our member

communication, dated October 20, 1994 with these comments, though the gist of the communication can be summarized in the three statements below:

- 1) The most effective means to ensure product safety is to pasteurize the product at the plant of final packaging;
- 2) In the event that pasteurization (or equivalent treatment) does not occur at the plant of final packaging, incoming ingredients should not, under any circumstances, be transported in tankers which are used to haul raw eggs, a food which may serve to cross-contaminate the finished product; and
- 3) All companies should review their transportation practices to eliminate possible sources of cross contamination between ready-to-eat food products and products that could contain pathogenic organisms.

Since the collaborative industry-government efforts successfully resolved the ice cream problem identified in the ANPR, IDFA urges FDA to explore what other successful preventative measures--industry practices or regulatory changes, for example--may have been put in place following the other incidents identified in the ANPR. We suspect that both industry and government have learned from past mistakes and have implemented sensible practices to mitigate past mistakes.

In the ANPR, FDA mentioned that the Michigan State Police uncovered 22 incidents of illegal and unsafe food transportation. IDFA believes the operative word is *illegal*. Black's Law Dictionary defines illegal as being *forbidden by law*. Forbidden by law is a fairly clear and strong expression. Issuing a regulation or rule on top of something that is already forbidden by law would seem to offer no additional protection. We find the reference to the incident involving raw poultry dripping juices onto produce particularly reprehensible and disturbing. Clearly, the individuals responsible should not be in the business of transporting or handling food at all. In these cases, full enforcement of existing rules and criminal statutes is the appropriate treatment.

#### Dairy Industry Transportation Overview

Dairy products have been produced for thousands of years while beneficially contributing essential nutrients to the diets of billions of people around the world. While dairy products were originally procured locally, technology has changed the industry into one that is truly global and heavily dependent on all forms of transportation. The vast majority of transportation though occurs via over-the-road-trucks. Raw milk is typically transported in heavily insulated bulk tankers that contain up to 5000 gallons of milk. Finished products are shipped via refrigerated 18-wheelers and smaller route trucks. Deviations from established temperature requirements can harm product quality which could reflect badly against a brand owner in a highly competitive marketplace, so dairy companies take refrigeration and transportation issues seriously.

Each year the US dairy industry transports approximately 4.5 million tanker loads of raw milk to processing facilities. These facilities pasteurize the raw milk and make it into a variety of dairy products including fluid milk, yogurt, ice cream, various cheeses and other products. Those finished products are transported in a variety trucks, rail cars and even ocean-bound ships. While we cannot put a precise number on those outbound finished goods shipments, we suspect they exceed the inbound raw shipments. Using simple rounding, we believe it is fair to estimate that there are 10-plus million raw and processed dairy product shipments a year. In FDA's review of past incidents, only one incident involving dairy was identified in the 30-plus year timeframe referenced and, as noted above, that situation has been remedied. The reason for the good food sanitary transportation record is centered on a rigorous, industry-specific regulatory regimen called the National Conference on Interstate Milk Shipments (NCIMS) that was created largely through a collaborative process involving the FDA, state regulatory agencies and the dairy industry.

### History of NCIMS

United States Public Health Service (USPHS) activities in the area of milk sanitation began at the turn of the 20th century with studies on the role of milk in the spread of disease. These studies led to the conclusion that effective public health control of milkborne disease required the application of sanitation measures throughout the production, handling, pasteurization, and distribution of milk and milk products. These early studies were followed by research to identify and evaluate sanitary measures which might be used to control disease, including studies that led to the improvement of the pasteurization process.

To assist states and municipalities in initiating and maintaining effective programs for the prevention of milkborne disease, in 1924 the USPHS developed a model regulation known as the *Standard Milk Ordinance* for voluntary adoption by state and local Milk Control Agencies. To provide for the uniform interpretation of this *Ordinance*, an accompanying *Code* was published in 1927, which provided administrative and technical details as to satisfactory compliance. This model milk regulation, now titled the *Grade "A" Pasteurized Milk Ordinance* (Grade "A" PMO) incorporates the provisions governing the processing, packaging, and sale of Grade "A" milk and milk products, including buttermilk and buttermilk products, whey and whey products, and condensed and dry milk products and incorporates new knowledge into public health practice.

The USPHS/FDA alone did not produce the *Grade "A" PMO*, it was developed with the assistance of Milk Regulatory and Rating Agencies at every level of Federal, state, and local Government, including both health and agriculture departments; all segments of the dairy industry, including producers, milk plant operators, equipment manufacturers, and associations; many educational and research institutions; and with helpful comments from many individual sanitarians and others. The USPHS/FDA's recommended *Grade "A" PMO* is the basic standard used in the voluntary Cooperative State-USPHS/FDA Program for the certification of Interstate Milk Shipments, a program participated in by all fifty (50) States, the District of Columbia and U.S. Trust Territories.

The NCIMS, in accordance with the Memorandum of Understanding with the Food and Drug Administration (FDA), has at its biennial conferences recommended changes and modifications to the *Grade "A" PMO*. The *Grade "A" PMO* is incorporated by reference in federal specifications for procurement of milk and milk products; is used as the sanitary regulation for milk and milk products served on interstate carriers; and is recognized by the public health agencies, the milk industry, and many others as the national standard for milk sanitation. The *Grade "A" PMO* adopted and uniformly applied will continue to provide effective public health protection without being unduly burdensome to either regulatory agencies or the dairy industry. It represents a "grass-roots" consensus of current knowledge and experiences and as such represents a practical and equitable milk sanitation standard for the nation. It is important to note that amendments to the *Grade "A" PMO* are undertaken biennially at the Conference to keep the regulations up to date with new technology and food safety information.

#### PMO Transportation Highlight

The PMO has an extensive list of requirements that apply to milk transportation. IDFA recommends that FDA review the most current version of the PMO in its entirety to identify all relevant portions. Of particular relevance is Item 21p - Vehicles, which states:

*All vehicles used for the transportation of pasteurized milk and milk products shall be constructed and operated so that the milk and milk products are maintained at 7°C (45°F) or less and are protected from contamination. Milk tank cars, milk tank trucks, and portable shipping bins shall not be used to transport or contain any substances that may be toxic or harmful to humans.*

The PMO states that Item 21p is satisfied when:

- 1. All vehicles are kept clean.*
- 2. Material that is capable of contaminating milk or milk products is not transported with milk or milk products.*
- 3. Milk and milk products, except dry milk products, are maintained at 7 degrees C (45 degrees F) or less.*
- 4. The operation of milk tank cars and shipping bins comply with the following provisions:*
  - a. Milk and milk products shall be conducted to and from tank cars or shipping bins only through sanitary conveying equipment. Such equipment shall be capped or otherwise protected when not in use.*
  - b. Inlets and outlets of shipping bins shall be provided with tight-fitting dust caps or covers.*

*c. Facilities shall be provided for the adequate washing and sanitizing of shipping bins, piping, and accessories at all milk plants receiving or shipping milk or milk products in shipping bins.*

*d. Shipping bins shall be cleaned at the receiving milk plant immediately after being emptied. The clean shipping bins shall be sanitized at the shipping milk plant before loading. Milk tank trucks, which must make more than one trip while unloading a tank car, need not be cleaned and sanitized after each time they are emptied.*

*e. Piping connections and pumps used with shipping bins shall be cleaned and sanitized after each use.*

*5. The doors of tank cars and covers of shipping bins are sealed with a metal seal immediately after loading. The seal shall remain unbroken until the contents are delivered to the consignee. Contents of the tank car or shipping bin shall be labeled as prescribed in Section 4 by means of a tag attached to the tank car or shipping bin.*

*6. Vehicles have fully enclosed bodies with well-fitted, solid doors.*

In addition to Item 21p, the PMO contains Appendix B: MILK SAMPLING, HAULING AND TRANSPORTATION which has extensive requirements, a portion of which are provided below:

#### ***IV. MILK TANK TRUCK PERMITTING AND INSPECTION***

*Milk tank trucks shall be evaluated annually using the requirements established in Sections 3 and 5 of this Ordinance using FORM FDA 2399b-MILK TANK TRUCK INSPECTION REPORT. (Refer to Appendix M.)*

***PERMITTING:*** *Each milk tank truck shall bear a permit for the purpose of transporting milk and milk products. (Refer to Section 3 of this Ordinance.) The permit shall be issued to the owner of each milk tank truck by an authorized Regulatory Agency. The permit identification and State issuing the permit shall be displayed on the milk tank truck. It is recommended that this permit be renewed each year pending satisfactory completion of an inspection as outlined in the following INSPECTION Section.*

***RECIPROCITY:*** *Each permit shall be recognized by other Regulatory Agencies under the reciprocal agreements of the NCIMS and supporting documents of this Ordinance. A milk tank truck need only bear one (1) permit from an appropriate Regulatory Agency. A milk tank truck may be inspected at any time when deemed appropriate by the Regulatory Agency. Absent proof of a current permit and current inspection, when the milk*

*tank truck is inspected by a Regulatory Agency other than the permitting agency, an inspection fee may be charged to the owner of the milk tank truck. This is necessary to allow a milk tank truck to pickup and deliver in several jurisdictions without the need for more than one (1) permit. A Regulatory Agency may have the option of inspecting any milk tank truck at any time when milk and milk products are transported in or out of a particular jurisdiction. It is the responsibility of the milk tank truck owner or operator to maintain a current proof of inspection to avoid a re-inspection fee. Disputes concerning reciprocal agreements on milk tank truck inspection between Regulatory Agencies may be tendered to the Chair of the NCIMS or the Chair's designee for resolution.*

***INSPECTION:*** *Each milk tank truck shall be inspected at least once each year by a Regulatory Agency. (Refer to Section 5 of this Ordinance.) A copy of the current inspection report shall accompany the milk tank truck at all times, or the tank shall bear an affixed label, which identifies the Regulatory Agency with the month and year of inspection. The affixed label shall be located near the tank outlet valve. When significant defects or violations are encountered by a Regulatory Agency, a copy of the report shall be forwarded to the permitting agency and also carried on the milk tank truck until the violations are corrected. Milk tank truck inspections shall be conducted in a suitable location, i.e., a dairy plant, receiving or transfer station or milk tank truck cleaning facility. Inspections may not require entry of confined spaces as defined by the Occupational Safety and Health Administration (OSHA) standards. When significant cleaning, construction or repair defects are noted the milk tank truck shall be removed from service until proper confined entry safety requirements can be satisfied to determine cleaning or repairs needed. Cleaning or repairs may be verified by a qualified individual to the satisfaction of the Regulatory Agency. Inspection reports completed by Regulatory Agencies other than the permitting agency shall be forwarded to the permitting agency for verification of annual inspection as required in the **PERMITTING** Section of this Appendix. The permitting agency may use these reports to satisfy permit requirements.*

***MILK TANK TRUCK STANDARDS:*** *All Items of FORM FDA 2399b-MILK TANK TRUCK INSPECTION REPORT fall into the categories of "Compliance", "Non-Compliance" or "Not Applicable" (NA) as determined during the inspection. The following Items relate to FORM FDA 2399b: (Refer to Appendix M.)*

***1. Samples and Sampling Equipment:*** *(When provided) a. Sample containers shall be stored to preclude contamination. b. The sample box shall be in good repair and kept clean. c. Sample transfer instrument shall be cleaned and sanitized to insure that proper samples are collected. d. The sample transfer instrument container is provided and adequate means*

for maintaining sanitizer solutions is on hand. e. The samples are properly stored to preclude contamination. f. The sample storage compartment shall be clean. g. Samples are maintained at an acceptable temperature 0°C-4.4°C (32°F-40°F) and a temperature control sample is provided. h. An approved thermometer is available for use by the sampler. The accuracy of the thermometer is checked each six (6) months with the results and date recorded on the carrying case.

**2. Product Temperature 7° C (45°F) or Less:** a. The product temperature must meet all the requirements of Section 7, Items 18r and 17p- Cooling of Milk, of this Ordinance. b. Product that remains in external transfer systems that exceeds 7°C (45°F) is discarded. This includes pumps, hoses, air elimination equipment or metering systems.

**3. Equipment Construction, Cleaning, Sanitizing and Repair:** Items a. through l. on FORM FDA 2399b shall be evaluated according to the following criteria: a. **Construction and Repair Requirements:** (1) The milk tank truck and all appurtenances shall meet applicable requirements of Section 7, Item 10p-Sanitary Piping and Item 11p-Construction and Repair of Containers and Equipment, of this Ordinance. Equipment manufactured in conformity with 3-A Sanitary Standards, complies with sanitary design and construction requirements of this Ordinance. (2) The interior of the milk tank trucks shall be constructed of smooth, non-absorbent, corrosion-resistant, non-toxic material; and it shall be maintained in good repair. (3) The appurtenances of the milk tank truck includes aseptic samplers, if applicable, hoses, pumps and fittings, shall be constructed of smooth, non-toxic cleanable material; and shall be maintained in good repair. Where flexibility is required, the fluid transfer system shall be free draining and so supported to maintain uniform slope and alignment. They shall be easily disassembled and accessible for inspection. (4) The cabinet portion(s) of the tank, used for the storage of appurtenances and sampling equipment, where applicable, shall be constructed to preclude contamination by dust, dirt; be clean; and in good repair. (5) The milk tank truck dome lid assembly, vent and dust cover shall be designed to protect the tank and milk from contamination. 137 b. **Cleaning and Sanitizing Requirements:** (1) The milk tank truck and all of its appurtenances shall be cleaned and sanitized in accordance with applicable requirements of Section 7, Item 12p-Cleaning and Sanitizing of Containers and Equipment, of this Ordinance. (2) The milk tank truck shall be cleaned and sanitized prior to its first use. When the time elapsed after cleaning and sanitizing, and before its first use, exceeds ninety-six (96) hours the tank must be re-sanitized. (3) It is allowable to pickup multiple loads continuously within a twenty-four (24) hour period, provided the milk tank truck is washed after each day's used.

**4. Exterior Condition of Tank:** *The exterior of the milk tank truck is properly constructed and in good repair. Defects and damage that would adversely affect products contained in the milk tank truck are pointed out on FORM FDA 2399b-MILK TANK TRUCK INSPECTION REPORT and corrective actions are prescribed. Cleanliness of the milk tank truck exterior is evaluated with consideration for existing weather and environmental conditions.*

**5. Wash and Sanitize Record:** *a. The bulk milk hauler/sampler shall be responsible for assuring that the milk tank truck has been properly cleaned and sanitized at a permitted milk plant, receiving station, transfer station, or milk tank truck cleaning facility. A milk tank truck without proper cleaning and sanitizing documentation shall not be loaded or unloaded until the proper cleaning and sanitization can be verified. b. A cleaning and sanitizing tag shall be affixed to the outlet valve of the milk tank truck until the milk tank truck is next washed and sanitized. When the milk tank truck is washed and sanitized, the previous cleaning and sanitizing tag shall be removed and stored at the location where the milk tank truck was washed for a period of not less than fifteen (15) days. c. The following information shall be recorded on the cleaning and sanitization tag: (1) Identification of the milk tank truck. (2) Date and time (optionally, in military time (24 hour clock)) of day the milk tank truck was cleaned and sanitized. (3) Location where the milk tank truck was cleaned and sanitized. (4) Signature or initials of the person who cleaned and sanitized the milk tank truck. d. The maintenance of all information on the cleaning and sanitizing tag shall be the responsibility of the bulk milk hauler/sampler or the milk tank truck operator. e. State will submit to the NCIMS Executive Secretary an updated list of all currently permitted non-IMS listed milk tank truck cleaning facilities. The list is to be submitted for publication on the NCIMS or other easily accessible web site.*

**6. Location of Last Cleaning/Sanitizing:** *The location of the last cleaning and sanitizing shall be verified by the Regulatory Agency during any milk tank truck inspection and recorded on the Milk Tank Truck Inspection Form.*

**7. Labeling:** *The maintenance of all pertinent information on all shipping documents, shipping invoices, bills of lading or weight tickets is the responsibility of the bulk milk hauler/sampler. A milk tank truck transporting raw, heat-treated or pasteurized milk and milk products to a milk plant from another milk plant, receiving station or transfer station is required to be marked with the name and address of the milk plant or hauler and the milk tank truck shall be under a proper seal. All shipping documents must contain the following information as outlined in Section 4- Labeling, of this Ordinance: 138 a. Shipper's name, address and permit number. Each milk tank truck load of milk shall include the IMS BTU*

*identification number(s) or the IMS Listed Milk Plant Number, for farm groups listed with a milk plant, on the farm weight ticket or manifest; b. Permit identification of the hauler, if not an employee of the shipper; c. Point of origin of shipment; d. Milk tank truck identification number; e. Name of product; f. Weight of product; g. Temperature of product when loaded; h. Date of shipment; i. Name of supervising Regulatory Agency at the point of origin of shipment; j. Whether the contents are raw, pasteurized, or in the case of cream, lowfat or skim milk, whether it has been heat-treated; k. Seal number on inlet, outlet, wash connections and vents; and l. Grade of product. All information contained on the above described documents shall be verified by the Regulatory Agency and recorded on the appropriate inspection sheet for any bulk milk tank trucks under inspection.*

**8. Vehicle and Milk Tank Truck Properly Identified:** *It shall be the responsibility of the milk tank truck owner or operator to insure the proper and legible identification of the milk tank truck(s) in their possession.*

**9. Previous Inspection Sheet or Affixed Label Available:** *When a milk tank truck transports milk and milk products from one (1) regulatory jurisdiction to another it is not necessary to inspect each milk tank truck upon each arrival. Milk tank truck owners and operators shall carry proof of annual inspection from a recognized Regulatory Agency. A milk tank truck may be inspected at any time or at the discretion of any Regulatory Agency responsible for the milk supply.*

**10. Sample Chain-of-Custody:** *When samples for official laboratory analysis are transported by any individual where the sample chain-of-custody must be established, the driver may be required to carry a valid permit or shall be evaluated biennially for the collection of samples for official laboratory analysis. The criteria from Section I-Evaluation of Bulk Milk Hauler/ Sampler Procedures, Item 7-Sampling Responsibilities of this Appendix will be used as the basis for the evaluation. As an alternative, a sample case sealed as required by the Regulatory Agency may be accepted.*

As indicated above, this is a small sample of a very complex, detailed set a requirements that are applied to the dairy industry. Provisions were developed in a collaborative fashion with regulators from federal, state, and local entities as well as with input from the industry, its trade associations and other knowledgeable parties. We believe the program works as well as it does because it was created to address specific concerns about a specific product with considerable deliberation and input from all stakeholders. Again, we strongly encourage FDA to thoroughly review the entire PMO and remain mindful of the effort and process that went into its creation.

### Regulation Beyond the PMO

IDFA, FDA, the States and industry are pleased with the PMO's success and believe it is working well for the dairy industry. The PMO's focus, however, is on a subset of dairy products with a particular focus on raw milk. FDA obligations with respect to the Sanitary Food Transportation Act of 2005 go well beyond the subject matter of milk and milk products. We believe our mutual experiences with the PMO should provide insight for FDA as it moves forward.

Based on IDFA's reading of the ANPR, there appears to be interest in the area of dedicated equipment and for seeking out specific prohibitions. IDFA would like to point out that despite having comprehensive and detailed transportation requirements for milk and dairy products, neither raw milk tankers, nor finished product transportation vehicles, have mandatory dedication requirements. For example, there is NO express provision which states that a raw milk tanker must be exclusively used to haul raw milk. Nor is there an express prohibition that a raw milk tanker cannot haul pesticides, irradiated products, chemicals, poisons, etc. Instead there is a simple premise "*Milk tank cars, milk tank trucks, and portable shipping bins shall not be used to transport or contain any substances that may be toxic or harmful to humans.*" For the millions of dairy transportation shipment instances that occur each year, that simple language appears to work well for the dairy industry.

The appropriate focus on food transportation safety should be the prevention or elimination cross contamination issues. How one accomplishes this depends on a number of factors. It is highly unlikely that a reasonable, economically affordable one-size-fits-all regulation could be created. In addition, FDA should understand that companies consider factors that go beyond food safety and address food quality issues. For example, shipping butter and onions in close proximity in the same truck would not generally present a food safety issue. It could, however, result in off flavors due to the strong odors that come from onions. The two might otherwise be compatible, but particular product attributes may dictate otherwise. The incompatibilities are by no means limited to butter and onions. We have been told that mint or menthol products could easily cause problems when shipped with other food products. To further complicate matters though, even with these examples there are no absolutes, a great deal depends on the attributes of the food and its packaging. Clearly there are barriers that could be utilized to keep onion or mint flavors out of other products and these barriers could either be deployed to cover the emission receiving or emitting product. The appropriate strategy for food safety, or quality, is to specifically consider all cross contamination risks and the product attributes.

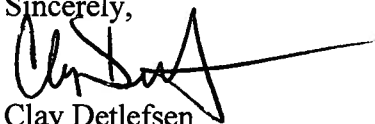
We note some interest in the issue of transporting non-food products with food products in the same vehicle. While it may be easy or tempting to issue a blanket ban on shipping non-food products with food products, we think such an action is unnecessary and ill-conceived. In addition, it would be extremely costly. Further, the reality is that we can think of no instance in which food is shipped or transported without some non-food products in close proximity. For example, the transport vehicles themselves are comprised of paint, metal, wood, plastics and numerous secondary non-food packaging materials. Some of these have undoubtedly been treated with, consist of or contain non-food chemicals or materials. Beyond that, there are endless examples of food contacting

non-food items without any risk of cross contamination-- in retail operations for example. We wonder if it makes any sense to separate or segregate food from non-food items when we know that in subsequent handling the two will be brought together once again. To elaborate, at grocery stores food products are displayed in non-food item containers, placed into non-dedicated shopping carts by consumers who ultimately transport them home in a non-dedicated, non-food item vehicle. In this day of supercenters, one can only begin to imagine all the combinations of non-food and food products that come into contact with each other. Despite this fact, we are not aware of any contamination instances that have occurred as a result.

From IDFA's perspective, the regulatory process cannot take shortcuts. The best rules and regulations are made not on the basis of absolute prohibitions, but through extensive collaboration between federal, state, local and industry partners which reflect all aspects of the products and packaging attributes and the totality of circumstances under which the foods are transported. When the government and the private sector take the time to properly identify problems and work together to solve them, the results are superior. Generally speaking, IDFA believes that the United States as a nation has a very good record of safe and sanitary food transportation; there are only isolated instances of unsafe practices which are in most cases already illegal or prohibited by the Food Drug and Cosmetic Act. Where the practice is illegal or prohibited, additional regulations are unwarranted and will do little to eliminate problem. In essence, where bad actors disregard the rules to everyone's detriment, the existing rules must be enforced.

IDFA appreciates the opportunity FDA has provided with this comment period and looks forward to working with FDA throughout its rulemaking process on this issue.

Sincerely,

A handwritten signature in black ink, appearing to read 'Clay Detlefsen', with a long horizontal stroke extending to the right.

Clay Detlefsen  
Vice President & Counsel



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

**FAX FACT #29**  
**October 20, 1994**

**TO: IICA and MIF MEMBERS**

**OUTBREAK FOCUSES ATTENTION ON ICE CREAM**

As you may be aware, there has been a recent incident involving ice cream which has initially been identified as having been contaminated with *Salmonella enteritidis*. Preliminary information obtained during the investigation points to the possible cross-contamination of pasteurized ice cream mix transported to the final packaging plant in tankers which may have also been used to transport raw eggs. *Salmonella enteritidis* is destroyed by pasteurization.

The Associations were contacted by the Commissioner of the Food and Drug Administration (FDA) who requested that IICA and MIF meet and work with them and other food trade groups to prevent similar potential problems in the future. At the meeting, FDA expressed a concern about the potential cross-contamination of any food transported in a bulk tanker with a product that may be a vector for the introduction, transmission, or spread of pathogenic organisms. The Agency also expressed a particular concern about frozen dessert plants which receive pasteurized mix and do not repasteurize in the plant of final packaging.

As a result of the meeting with FDA, which also included the National Food Processors Association, the Associations and the Agency agreed on three points which Commissioner David Kessler intends to convey in a press conference today:

- 1) The most effective means to ensure product safety is to pasteurize the product at the plant of final packaging;
- 2) In the event that pasteurization (or equivalent treatment) does not occur at the plant of final packaging, incoming ingredients should not, under any circumstances, be transported in tankers which are used to haul raw eggs, a food which may serve to cross-contaminate the finished product;
- 3) All companies should review their transportation practices to eliminate possible sources of cross-contamination between ready-to-eat food products and products that could contain pathogenic organisms.

*FDA has indicated they intend to increase surveillance on this issue and staff believes that similar activities could be forthcoming at the state level.* In order to assure FDA, state regulatory agencies, and consumers about the safety of ice cream and ice cream products, the Associations

recommend that all ice cream and ice cream mix manufacturers consider the following recommendations and immediately assess their operations to make certain that these areas do not present potential problems.

### **Transportation of Products and Ingredients in Tankers**

Ice cream and ice cream mix manufacturers should assure that the transportation of ice cream mix and/or ingredients is done in a manner which prevents cross-contamination of products with pathogenic organisms. One of the best ways to prevent potential problems is through the use of dedicated tankers which are used only to transport ice cream mix, milk, or other dairy products. Plants receiving pasteurized ice cream mix should require certification or some other form of guarantee that the tankers are only used for this purpose. No substance capable of contaminating dairy products should be transported in these tankers. Detailed records should be maintained and reviewed by the receiving plant, and should contain, at the minimum, the following information:

- Shipper's name, address, and permit number
- Point of origin of shipment
- Tanker identity number
- Name of product
- Weight of product
- Temperature of product
- Date of shipment and arrival
- Whether the contents are raw or pasteurized
- Integrity of tanker seals

### **Cleaning and Sanitizing Records**

Operators of tankers used to transport ice cream mix products and ingredients must ensure that these vehicles are adequately maintained, cleaned, and sanitized to guarantee that the vehicle itself does not act as a source of pathogenic organisms. Facilities for the cleaning and sanitizing of tankers should be properly equipped for manual and/or mechanical operations. If facilities are not provided on the plant premises, these operations should be performed at a separate tank washing facility. Records should be kept which verify that proper cleaning and sanitizing has been conducted. These tankers should have a tag or record showing the date, time, place, and signature of the person performing the work.

### **Pasteurization in Plant of Final Packaging**

Although the use of dedicated tankers can provide protection from contamination, the most effective way to prevent similar problems is to pasteurize in the plant of final packaging. The Associations recommend that all ice cream mix be pasteurized at the plant of final freezing and packaging to eliminate any pathogenic organisms. Proper pasteurization records should be maintained as to the time and temperature of the pasteurization.

Because of the recent incident, additional regulations could be forthcoming from FDA unless

appropriate precautionary procedures are fully implemented by the industry.

### **HACCP**

The Associations have a number of educational materials to assist companies in preventing problems such as those described above. In addition, IICA has a model HACCP program specifically designed for ice cream and other frozen dessert products. All member companies are strongly encouraged to become familiar with this program.

Technical assistance on all of these matters can be obtained by calling Jerry Kozak, Tom Balmer, Rob Byrne or Kim Carson at 202-737-4332.