



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

September 10, 2004

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

**Re Docket No. 2004N-0230, CFSAN, Food; Current Good
Manufacturing Practice (GMP) Regulations; Request for Comments, Federal
Register 40312; July 2, 2004**

Dear Sir or Madam:

The International Dairy Foods Association (IDFA) recognizes the U.S. Food and Drug Administration's (FDA) interest in reviewing the food Good Manufacturing Practices (GMP) regulations located in 21 CFR 110, considering they have been in place without substantial change since 1986. However, the current regulations were well written, broadly based, flexible and have provided important guidance to the food processing industry for almost twenty years. Food GMPs are used by dairy plants to develop company and plant specific industry GMP training and operational programs.

These recommendations are submitted on behalf of IDFA and its constituent organizations, the Milk Industry Foundation, the International Ice Cream Association, and the National Cheese Institute. The approximately 500 member companies of these associations operate more than 650 processing and manufacturing plants, which account for 85% of all dairy products produced and consumed in the United States.

IDFA compliments FDA for the participatory process that solicited dairy industry involvement through three public meetings and the opportunity to comment on food GMP revisions found in 21 CFR 110 without any limitations or restrictions. We were had hoped that an extension of the closing date (September 10, 2004) for comments would be granted to fully engage our membership, conduct a more thorough review of the scientific, regulatory and food industry information, evaluate the impact of revisions on our members, and develop a more creative set of recommendations. With the current time limitation of September 10, we are hopeful that the comments and recommendations listed below can assist you in arriving at food GMP revisions that positively impact the already excellent food safety record of the U.S. dairy industry, without creating unnecessary regulatory burdens.

I. General Perspectives:

Broad-based: The current food GMP's strength is its broad-based language. The most effective sections of 21 CFR 110 include those parts of B, C and D which are written in general terms so they are applicable to the entire food industry. More recent documents such as the Codex Code of Practice General Principles of Food Hygiene, last amended in 1999, and the Codex Code of Hygienic Practice for Milk and Milk Products adopted in 2004 also use this broad principle-driven approach as opposed to specific narrowly defined requirements.

Revision of the food GMPs to include specific details identifying numerical limitations such as product shelf life or processing and storage temperatures for some or all food products moves away from the broad-based "principles" approach. Setting numerical limits creates a technically difficult, scientifically challengeable and highly debatable section of the GMPs (110.80(b)(3)) that has been traditionally left to the food processor. Dairy processing plants develop shelf life for their products using scientific studies, in-house challenge studies and experience, which varies from plant to plant and product to product. Any specific guidance by FDA on shelf life related to food safety in the food GMPs should be advisory and general. Specific details of a food safety nature can be addressed in other documents or through references to other documents, such as that developed by National Advisory Committee on Microbiological Criteria for Food (NACMCF) on "Safety-based" code dating.

Flexible: The advantage of the wording chosen for the current food GMPs is flexibility for both state and federal regulators for regulatory oversight, as well as for implementation by the dairy industry. Terms found in the current food GMPs such as "adequately maintained," "in a manner," "where appropriate," "necessary precautions," "proper precautions," "adequate controls," "properly storing," "any effective means," provide important flexibility and have contributed to the effective life of this regulation. This approach also allows the current food GMPs to apply to the entire U.S. food industry. Maintaining flexibility also allows for development and implementation of new technologies without the need to continually revise regulations. IDFA and its members strongly support the continuation of this flexible style in any revisions of the food GMPs.

Areas where the GMPs are least flexible, such as the specific temperature requirements (Part 110.80 (b)(3)(i) on maintaining refrigerated foods at 45° F or below, and Part 110.80 (b)(3)(iii) on keeping hot foods at 140° F or above), do not allow for the application of new scientific information, adjustment for emerging pathogens, or new toxicological information. In a similar fashion, mandating specific transportation, handling, processing and storage temperatures that are applicable to all food products overlooks a variety of factors such as water activity, pH, bacteriocidal and bacteriostatic properties, processing times, processing equipment, and intended end use that need to be evaluated to arrive at appropriate temperatures. It would be preferable for the GMPs to be more flexible and contain general statements about temperature control, such as "adequate" or "scientifically supported" for control of common pathogens. Specific temperature controls are a way of life for the dairy industry, addressed in other regulatory documents (Pasteurized Milk Ordinance - PMO) and should not be included in the food GMPs. Additional details should be addressed in other guidance documents that are food and industry-specific.

II Currently Regulatory Environment:

General Foods: The revision of the food GMPs must be done in the context of all of the other federal and state laws and regulations that now apply and overlap regarding the production, processing, distribution and sale of food products in the U.S. These include the recently updated Food, Drug and Cosmetic Act, the Public Health Services Act, FDA guidance documents such as the Juice Hazard Guidance, FDA Sprout Guidance, and the Frozen Dessert Guidance as well as the 3-A Sanitary Standards and Practices for the hygienic design of dairy equipment.

Dairy Foods: The National Conference on Interstate Milk Shipments' (NCIMS) PMO contains extensive requirements for the production and processing of Grade "A" dairy foods. Many of these very specific requirements (see attached dairy plant inspection sheets) provide details addressed in a more general way by the food GMPs. Also, states have in place very detailed laws and regulations that address the production and processing of non-Grade "A" dairy foods, with GMP-like sections that are very specific. Additionally, the U.S. Department of Agriculture's Agricultural Marketing Service administers a Plant Survey and Dairy Product Grading program that establishes operational requirements in minute detail for dairy plants producing butter, cheese and dry milk products for sale to the government. These USDA requirements are widely implemented by this segment of the U.S. dairy industry, are required by non-government buyers of these products, and have become the de facto production and processing requirements for this part of the dairy industry. We believe that the current GMPs, with most of the sections using the word "shall," provides sufficient direction to effectively address most food safety concerns today.

III. Records Access versus Records Existence:

All prudent dairy manufacturers maintain records to document adherence to internal GMP and food safety programs. The industry has consistently been willing to volunteer records to FDA when it has been demonstrated that a public health issue exists. With this representing the dairy industry's cooperative attitude, it is important to understand that the Federal Food, Drug, and Cosmetic Act (FDCA), the authority for the food GMP regulations, does not extend FDA authority to inspection of food company records except under specific and limited circumstances. In the absence of congressionally-delegated records inspection authority, FDA may not create such authority for itself through the vehicle of revising the GMP regulations. Section 704(a) of the FDCA provides that FDA's authority to inspect the factory, warehouse, establishment, or vehicle of a food manufacturer or processor is limited to "all pertinent equipment, finished and unfinished materials, containers, and labeling therein." By its plain language, the statute does not extend this authority to the inspection of the records of such food facilities. It is therefore clear that Congress intended to allow records inspection authority only in the limited and enumerated fields, and meant to withhold such authority for inspection of food facilities. The FDCA grants FDA the authority to inspect food company records in a few other limited circumstances that are not applicable to the GMP context. Section 703 allows FDA to inspect records that document the interstate shipment of food. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 added Section 414(a), which authorizes food records inspection where FDA has "a reasonable belief that an article of food is adulterated

and presents a threat of serious adverse health consequences or death,” and Section 801(d)(3)(A)(iv), authorizing records inspection relating to “import for export.” The details of this additional but limited records access by FDA remain uncertain until FDA has completed and published these in the Federal Register. Again, these limited, specific grants of records inspection authority further demonstrate that FDA is not authorized to inspect records of food companies in other contexts.

IDFA does not support expanding processing records access through modifications to the food GMPs. It is certainly understood that food companies are expected to maintain records to document their own adherence to GMPs; however, the statute does not authorize access to these same records by FDA investigators. Of course, as stated previously, where a public health issue has been identified with one of our products, our members have always cooperated with FDA and have provided agency inspectors with reasonable access to company records on a voluntary basis. We have every reason to expect that practice to continue.

IV. GMPs versus HACCP

The role of GMPs in industry HACCP programs is to provide part of the foundation prior to development of the hazard analysis and HACCP plan. GMPs serve as one of the building blocks of HACCP, but are different. Included in the GMPs are good sanitation practices (GSPs). IDFA members believe that the opportunity to revise and update the food GMPs should not be used as an indirect path toward hybridizing GMPs into a HACCP-like regulation. GMPs have been a recognized part of the federal food safety regulations for many years prior to any mandatory HACCP program. They should continue to stand separate from HACCP.

In order to retain this important position and prevent confusion between GMPs and HACCP, the GMPs should not utilize HACCP terms, i.e. sanitary standard operating procedures (SSOPs), critical control points, critical limits, deviations, corrective actions, verification and validation, since they have very specific meanings and should not be diluted or misconstrued in the context of GMPs. Additionally, the inclusion of the term, “universal preventative controls - UPCs” is unnecessary and confusing in an attempt to bridge the gap between GMPs and HACCP.

The current food GMPs under Part 110.3 list a definition of “critical control point” that is quite different from the NACMCF definition. Because the NACMCF definition was not available in 1986 when the GMPs were last revised, it is important that this conflict be corrected. Our recommendation is to change the GMP definition of “critical control point” to a definition for “control point” reading as follows;

“Control point means a point in a food process where there is a likelihood that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.”

Removing critical control point terminology from the revised GMPs will also require changing the reference in 110.80 b13(iv) to “control points.”

V. Industry Training on GMPs

General: The current GMPs in 110.109(c) outline recommendations on training personnel responsible for identifying sanitation failures or food contamination to “provide a level of competency necessary for the production of sanitary and safe food.” Other references in this section speak to “adequate training in proper food handling techniques and food-protection principles.”

GMP and Recall Report References to Training: The report identified deficient employee training as the most common of the top ten food safety problems. It is clear that most of the other nine have some direct or indirect “root cause” connection to training by the food industry. The Recall Report identified 1146 recalls from 1999-2003 that occurred because of a GMP-related problem (including labeling problems). The Recall Report further identifies ineffective employee training as being associated with 32% of the recalls and failure to follow established SOPs for processing with 26%, likely rooted in training. The ineffective use of sanitation principles (8% of recalls) could also be the result of improper or inadequate training. Based on this information, it would appear that appropriate training could reduce the number of recalls.

Of the top ten food safety problems identified by the GMP Report, all are specified by “shall” in the GMP regulation, except for training which is a “should.” Further, the top five commonly mentioned preventive controls for these problems list training in seven of the ten (deficient employee training, poor plant and equipment sanitation, difficult-to-clean equipment, post-process contamination at manufacturing plant, contamination during processing, poor employee hygiene, incorrect labeling or packaging). Again, the importance of training in addressing food safety and sanitation issues is clearly identified.

Dairy Industry Practices: The dairy processing industry already incorporates extensive training for employees at the production level, as well as supervisory personnel, on GMPs. The general approach is for all new employees to undergo in-plant GMP training, with required updates at least annually for all employees. Additional training, based on mandates in the revised GMP could be helpful as long as the determination of compliance by FDA of industry GMP training programs was based on performance outcomes, not certificates, frequency, or other arbitrary determinations.

The existing food GMPs address environmental controls in 21 CFR 110.20 Plant and Grounds, 110.35 Sanitary Operations, and 110.37 Sanitary Facilities and Controls. However, considerable progress in advancing public health protection has been accomplished in the last two decades through the adoption of environmental monitoring techniques to eliminate pathogens of concern from the post-processing environment of ready to eat (RTE) foods. IDFA supports the implementation of environmental monitoring programs that are designed to meet the individual characteristics of a manufacturer’s RTE processing facility. These programs must be flexible enough to be designed to meet the unique properties of a product, process, or plant. The dairy industry focuses on a number of pathogens of concern such as *Salmonella* or *Listeria monocytogenes*. IDFA believes dairy manufacturers should conduct environmental monitoring to evaluate the effectiveness of cleaning and sanitation practices, find potential sources of contamination, and provide data that leads to effective corrective actions. Industry should have

the flexibility to select the appropriate target organism, sampling frequency and site selection that is adequate to protect public health.

Recommendations: IDFA therefore recommends that 21 CFR 110.10 (c) have the “should” references to training be revised to “shall.” In addition, the term “competency” in (c) should be replaced with “knowledge” since “competency” begs the need to challenge and evaluate, whereas “knowledge” is a simple measure of “knowing” or “not knowing.” The true measure of effective training is whether the end food product is safe and unadulterated, not on how many training sessions an employee has attended or how often an employee has been trained. If there is any doubt regarding the safety of the food, only then should the adequacy of the training or knowledge of the employee be evaluated. Conversely, a determination of inadequate training does not directly indicate a food safety problem.

VI. Allergen Control Program:

FDA Recall Report: The Recall Report identified 1146 GMP-related recalls from 1999-2003, with 65% of these recalls involving labeling problems and 34% involving undeclared allergenic ingredients. Although it is not known to what extent inadequate training played a role in these labeling and allergen-related recalls, it is likely that training in allergen control that included guidance on proper labeling could reduce such incidents.

Existing GMP Language: Allergens are not specifically mentioned in the food GMPs, but as contaminants, they are addressed in many sections including 110.40 (food contact surfaces protected from contamination), 110.80 (b)(5) (protect from contamination), 110.80(b)(1)0 (protect from contamination during processing), 110.80b12 (specific products protect from contamination), 110.80(b)(12)(iv) (physical protection from contamination), 110.80(b)(13) (filling, assembling and packaging protection from contamination), and 110.80(b)(13)(iv) (physical protection from contamination). These sections do not mention allergens but include it in the context that allergenic substances are contaminants if introduced in the processing of products that does not identify the allergen on the label.

Allergen Labeling: The Nutritional Labeling and Education Act of 1990 and its subsequent regulations already require all ingredients to be identified on a food product ingredient statement. In addition, the recently passed Food Allergen Labeling and Consumer Protection Act of 2004 strengthens allergen labeling requirements to clearly identify in common terms to consumers the presence of any of the eight primary allergens in all food products.

Industry Practice and Guidance: IDFA has an entire manual that has been distributed to members on allergen management and good handling practices. The Food Allergy Issues Alliance guidance was developed by the food industry as a training tool for proper identification and labeling of allergens in food products. Milk is one of the primary eight allergens and the main ingredient in all dairy products made by IDFA members. Since dairy plants, particularly ice cream processors, commonly handle a number of food ingredients, i.e. milk, eggs, tree nuts, peanuts, etc. that are part of the “big 8 allergens,” they already have extensive allergen control programs in place that address handling, storage, use, processing schedules and labeling.

Recommendations: IDFA recommends 110.80 be revised to include a separate section requiring an allergen control program for those processing plants that handle any of the eight common allergens. The allergen control plan should address the following:

- Training of processing and supervisory personnel;
- Separation of allergic ingredients during storage and processing;
- Cleaning and Sanitation of processing equipment;
- Scheduling of production runs to enhance physical separation and time separation.;
- Reworking ingredients and finished products;
- Product label review; and
- Supplier control program for ingredients and packaging.

The evaluation of an food plant's allergen control program by FDA investigators must be performance based by observing ingredient storage, equipment cleaning and sanitizing, processing runs and asking questions of plant management. It should not be based on review of plant processing records or the written allergen control program, unless voluntarily supplied by the food processor.

VII. Documenting Sanitation Procedures:

Dairy Industry Practices: The U.S. dairy industry primarily uses automated cleaning and sanitizing (CIP cleaning) of processing equipment with computer controlled and sensor-monitored addition of cleaning and sanitizing chemicals. In addition, there is extensive use of a pre-startup checklist to assure the processing equipment has been properly cleaned and sanitized before use. Since the last revision of the food GMPs, industry has implemented many of the components of the Grade "A" PMO such as proper equipment design and monitoring of sanitizing chemical strength. Additionally, the following sanitation practices have also received emphasis: computerized and electronic monitoring instrumentation for processing and cleanup; increased attention to processing plant environmental cleaning and sanitizing; use of dedicated cleaning systems for raw and finished processing equipment, respectively; new monitoring tools to evaluate the effectiveness of environmental and processing equipment cleaning; employee traffic control plans; and management of visitors and construction zones. Dairy plants already have these kinds of programs in place and would describe them to any FDA investigator.

The dairy industry utilizes its expertise as well as that of suppliers of the chemical cleaners and sanitizers to insure that the automated and manual systems adequately clean and sanitize processing equipment and environmental surfaces. The protocol, chemical strengths, and duration of cleaning, sanitizing and rinse cycles are equipment, plant and product specific. There is little information to demonstrate that this system is the cause for product safety problems

Recommendations: IDFA recommends that Part 110.80 be revised to use the word "should" for all food manufacturers to develop and maintain "written cleaning and sanitation procedures" for processing equipment and the processing environment that focuses on food safety. We also recommend that the terminology, "Sanitation Standard Operating Procedures (SSOPs)" be dropped from any part of the food GMPs because of the strong likelihood of confusion with the eight required SSOPs in the Juice HACCP regulation and all the associated Agency guidance. Essential to complying with GMP requirements is the need for manufacturers to adequately train

their employees on cleaning and sanitation practices, documentation of their effectiveness, and updating procedures as necessary based on process or equipment changes.

The evaluation of written cleaning and sanitation procedures by FDA investigators must be performance based by observing the cleaning and sanitizing operations in the plant, observing the cleanliness of the equipment surfaces, and asking questions of plant management. It can not be based on review of plant processing records, CIP and manual cleaning records, or the written cleaning and sanitizing procedures, unless voluntarily supplied by the food processor.

IDFA does not support the addition of equipment cleaning validation to the existing food GMPs since validation is a term linked to HACCP and implies extensive and thorough scientific studies, when effective equipment cleaning and sanitizing can be easily demonstrated through chemical supplier experience as well as pre-startup monitoring by the processing plant. Problems can be rapidly identified and corrected without the need for extensive scientific or academic studies. More importantly, real time validation test kits for proving equipment cleaning and sanitizing effectiveness have not received formal FDA evaluation or acceptance. Validation of equipment cleaning from the standpoint of allergen control is hampered at this time by rapid detection kits with variable sensitivities, allergens without test kits, and a lack of FDA evaluation and acceptance of these kits.

VIII. Environmental Monitoring Control Program

Existing Regulatory Environmental References: The existing food GMPs address environmental controls in 21 CFR Subpart B, 110.20 Plant and Grounds, 110.35 Sanitary Operations, and 110.37 Sanitary Facilities and Controls. These sections provide detailed guidance on processing plant exterior and interior environmental requirements. The PMO also has significant details on environmental requirements (see attached inspection sheet) that all Grade “A” dairy plants must meet. The draft guidance on listeria in ready-to-eat (RTE) foods also contains environmental guidance.

Dairy Industry Practices: Considerable progress has been made in the area of environmental management in processing plants in the last two decades through the adoption of environmental monitoring techniques to detect and eliminate pathogens. The design, engineering, construction and remodeling of dairy plants removes many of the causes for environmental contamination problems that were common twenty years ago when the GMPs were last revised. The main focus of concern for dairy processors is managing the post-processing environment since most dairy products are RTE foods. Dairy plants routinely monitor the post-pasteurization environment through routine cleaning procedures, microbiological swabbing of surfaces and through selection of easily cleanable environmental surfaces (walls, floors, ceilings, etc.). Although construction is not a GMP requirement, the dairy industry has demonstrated responsibility and expertise in using these tools to maintain environmental hygiene in processing plants.

Recommendations: IDFA supports the revision of 110.35 so plants “should” have a “written environmental control program for post-processing/packaging areas in plants processing RTE foods.” The details of this written program need to be left to the food processor since each environmental monitoring program must be designed to meet the individual characteristics of a

manufacturer's RTE processing facility. These programs must be "adequate" and flexible enough to be designed to meet the unique properties of a product, process, or plant. It would be appropriate to identify within the written environmental monitoring program pathogen(s) of concern such as *Salmonella* or *Listeria monocytogenes* or indicator organism. IDFA believes dairy manufacturers should voluntarily conduct environmental monitoring to evaluate the effectiveness of cleaning and sanitation practices, identify potential sources of contamination, and document environmental monitoring activities. Details of environmental monitoring, such as target organism(s), sampling frequency and location should be left to the industry, based on familiarity with their facility, process and product.

The evaluation of a sufficient environmental control program by FDA investigators must be performance based by observing the construction and cleanliness of the post-processing/packaging areas, cleaning procedures, and asking questions of plant management. It can not be based on review of plant processing records, environmental monitoring records, or the written environmental control program, unless voluntarily supplied by the food processor.

IX. Transportation and Product Distribution GMPs

Current Regulations: The Sanitary Food Transportation Act of 1990 contains important requirements on directing and controlling transport of foods, food ingredients and food additives. This Act gives the Secretary of Transportation broad powers to control the construction of transport vehicles, their use, prior cargos, inspection, enforcement and application of penalties. In addition, Section 110.8 ("shall" item) of the food GMPs and the Pasteurized Milk Ordinance already address dairy product transportation requirements including product temperatures, sanitation, cleaning and construction requirements. In addition, requirements for bills of lading containing information on origin, identity, volume, temperature, regulatory agency responsible, seal numbers, etc are addressed.

Recommendations: IDFA does not support the revision of the food GMPS to address transportation issues since this is already addressed for the dairy industry through a number of existing regulations. In addition, transportation issues are not a significant problem, based on the Eastern Research Group (ERG) data and causes of recalls. Transportation issues related to food security are being addressed in other federal laws and regulations and the food GMPS should not be expanded beyond its primary goal of food safety.

X. Application to Imported Foods:

The primary purpose for revising the current food GMPs is to improve public health for the U.S. consumer. Since the effectiveness of the current food GMPs has been proven over time, we encourage FDA to commit more resources toward food GMP application to foreign food production and processing plants. The U.S. dairy industry has developed effective internal GMP programs based on 21 CFR 110 and its enforcement by state and federal regulatory officials. We do not believe this important food safety guidance has been applied equally to imported dairy products, which are consumed in increasing amounts by U.S. consumers. It is very important for FDA to address this application and enforcement imbalance if there is a true commitment to the importance of food GMPs and their role in safe food and public health.

We have included in our comments specific responses to FDA questions listed below.

Q. In general, do the current good manufacturing practice regulations (part 110) need to be revised or otherwise modernized? If yes, please describe generally the shortcomings of the current regulations.

IDFA would support the limited revision of food GMP regulations in 21 CFR Part 110 as detailed in our comments above, but encourage FDA to work with the food processing industry to conduct a more thorough evaluation of current food industry standard manufacturing practices, beyond the anecdotal information already gathered, in order to establish a baseline from which the revision of the food GMPs can proceed.

1. Which practices specified in current part 110 are most effective at preventing each type of food hazard? Which practices are least effective at such prevention?

The most effective sections of 21 CFR 110 include those parts of B, C and D which are written in general terms, are broad-based and provide flexibility so they are applicable to the entire food industry. In addition, those parts of the GMPs that have been validated by recent FDA risk assessments are also of significant value. Conversely, the areas where the GMP's are least effective are where they are too prescriptive, such as the specific temperature requirements (Part 110.80 (b)(3)(i) on maintaining refrigerated foods at 45° F or below, and Part 110.80 (b)(3)(iii) on keeping hot foods at 140° F or above) or where the GMPs contain requirements not supported by FDA risk assessments. It would be preferable for the GMPs to contain general statements about temperature control, such as "adequate" or "scientifically supported" for control of common pathogens and leave specific temperature recommendations to product-specific guidance documents.

2. In today's food manufacturing environment, what conditions, practices, or other factors are the principal contributors to each type of food hazard?

For the dairy industry, the most challenging factors to manage are personnel training, post-pasteurization contamination, environmental pathogens, and allergen control. Through sound internal training, GMP, operational and environmental controls, all can be managed to assure a safe food product. Language barriers are also a contributor to food hazards that did not exist to the same degree twenty years ago versus today in food processing. The language barrier inhibits training and the ability to read directions, instructions and other printed operational material. The development by FDA of a universal food processing symbol program would significantly reduce the language barrier problem.

3. If the CGMP regulations were revised, which type or types of food hazards could be most readily prevented through CGMP-type controls?

GMP's can manage hazards and the frequency and likelihood of occurrence, but GMPs cannot control hazards. GMPs are best suited for managing chemical and physical hazards and have some effect on microbiological hazard. The dairy industry clearly uses programs in addition to GMPs to adequately control microbiological hazards.

4. Are there preventive controls, in addition to those set out in part 110, needed to reduce, control, or eliminate each of the three types of food hazards? If yes, please identify the specific hazard and the particular controls, that would reduce, control, or eliminate the hazard.

As noted above, microbiological hazards in foods regulated by FDA are difficult to completely manage through the application of GMPs. It is necessary, particularly in ready-to-eat (RTE) foods, that processing controls such as pasteurization ultimately control microbiological hazards. See our recommendations above to identify specific preventative controls that can be used to reduce, control or eliminate physical, biological and chemical hazards.

5. What concepts or underlying principles should guide FDA's adoption of newer preventive controls?

It is important that any additions to the current food GMPs be broad-based, applicable to all foods and allow for industry flexibility in the details of implementation. Specific details such as time, temperature, pH, water activity, salt or sugar content, use of bacteriocidal or bacteriostatic ingredients, preservatives, allergen presence and other measures to assure food safety should be left to guidance documents for specific foods. FDA should also gather from the food processing industry "best practices" and analyze those prior to advancing any changes in the current GMPs.

6. How should the effectiveness of preventive controls for each of the three types of hazards be most accurately measured?

IDFA recommends the development of a universal GMP inspection checklist for FDA field investigators and standardized GMP training in order to obtain more consistent interpretation of the food GMP regulations. Once this has been accomplished, then a tracking and measurement system can be developed, knowing that the data being tracked is "apples to apples" as opposed to tracking information from field reports that originate from non-standardized field staff.

Another tracking system that FDA can use would measure effectiveness through tracking the classification of inspections and other adverse action reporting from the FDA field staff and compliance offices. These include tracking the annual number of investigations falling into the No Action Indicated (NAI), Voluntary Action Indicated (VAI), or Official Action Indicated (OAI). This can be the primary barometer, with comparisons made annually to determine the percentage of firms that fall into each category and the change in percentage in each category. Other information that could be tracked include the number of warning letters issued annually based on GMP violations and the percentage compared to the total number of inspections conducted annually.

Because of the way that FDA classifies recalls in broad terms, it is difficult to build a tracking system that would provide accurate and meaningful data. If FDA would revamp and standardize the information captured regarding recalls, then it might be possible to use recalls as not the only tool, but an additional tool for feedback into the effectiveness of revised GMP controls.

7. In today's manufacturing environment, what are the principal contributors to the presence of undeclared allergens in food? For example, do labeling errors or cross-contamination contribute? Which preventive controls could help reduce, control, or eliminate the presence of undeclared allergens in food?

IDFA believes that in the dairy processing industry, the primary cause of undeclared allergens in dairy products is the result of improper labeling. For the reasons identified above (VI.), we believe that through the addition of an allergen control program that includes employee training, this issue will be adequately addressed.

Unfortunately, human error, even in the most rigorously monitored allergen control programs does occur and added regulations will not eliminate it. Therefore, the processing industry must make every attempt to design their processing runs to reduce or eliminate human error related allergen problems.

8. Are there existing quality systems or standards (such as international standards) that FDA should consider as part of the agency's exploration of food CGMP modernization? Please identify these systems or standards and explain what their consideration might contribute to this effort?

As described in #1 above, the Codex Code of Practice General Principles of Food Hygiene, last amended in 1999 and the Codex Code of Hygienic Practice for Milk and Milk Products adopted in 2004 provide good examples of how to incorporate new flexibility into the existing food GMPs. Other quality or standards systems that the dairy industry is using include 3-A Sanitary Standards and Practice for the Design of Processing Equipment, World Class Manufacturing, Six Sigma and Lean Manufacturing, which all have some components related to operational safety and efficiency. Due to the diversity of the food industry and products produced, GMP revisions to address equipment design and construction should only be addressed in very broad terms, not in specific "dos" and "do nots."

9. There is broad variation within the food manufacturing and processing industry, including variations in size of establishments, the nature of the food produced, the degree to which the food is processed, and the vulnerability of a particular operation to physical, chemical, or microbial hazards. How, if at all, should the CGMP regulations be revised to take into account such variation? For example, should there be different sets of preventive controls for identifiable segments of the food industry, such as different storage temperature limits?

IDFA members are generally large dairy processing companies, but range to very small facilities that operate only on a limited basis. We do not believe that safe food should be dependent on the size of the processing facility. Food GMPs should apply equally to all parts of the food processing industry and to all size operations. If FDA feels there is need for more specific direction to a particular segment of the food industry, the agency should work directly with that industry segment to develop guidance applicable to them.

Additionally, a proposal for reduced lot size volumes for all foods as a solution to reduce recall sizes and improve product traceability is flawed. Limitations in lot sizes will result in limitations in production runs and increase the number of product change-overs. It has been documented in the dairy industry that potential food hazard conditions are magnified and their likelihood of occurrence is increased during product change-overs. Minimizing lot size for many food industries would significantly increase the potential for product mishandling, mislabeling, and increased micro contamination during change-over activities.

10. There are a number of measures, procedures, and programs that help to ensure that preventive controls are carried out adequately. These include the following items:

- **Training programs for managers and/or workers;**
- **Audit programs;**
- **Written records, e.g., batch records, sanitation records;**
- **Validation of control measures;**
- **Written sanitation standard operating procedures;**
- **Food label review and control programs;**
- **Testing of incoming raw materials, in-process materials, or finished products.**

Which (if any) of these should be required practices for food manufacturers and why? Which (if any) of these should be recommended practices for food manufacturers and processors and why?

As explained in detail in our comments above, IDFA supports some additional language in the existing food GMPs to address employee training, allergens, written sanitation programs and written environmental control programs, but all of the other specific items mentioned above are either being already carried out effectively by the dairy processing industry or add time and cost without any certainty of added assurance of food safety. See our comment for the rationale for this statement. The flexibility of industry driven preventative controls has worked well in the dairy industry and is philosophically consistent with the concept that primary responsibility for food safety lies with the food processor. Additionally, some of the items above are already addressed by other state and federal regulations so the issue is not one of adding more requirements such as those listed above, but of utilizing the extensive amount of guidance FDA already has made available along with more effective enforcement by FDA district investigators and their state counterparts. Also, the effective application of each varies so much from company to company and from product area to product area that trying to bring them under a single, prescriptive regulatory scheme is simply not desirable or feasible.

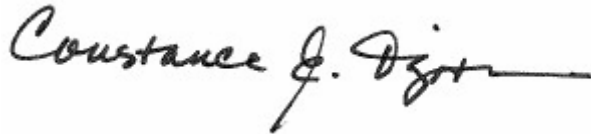
11. Are there preventive controls in addition to those already set out in part 110 for food distributors, wholesalers, and warehouses that are needed to help ensure the safe and sanitary holding of food. If yes, please identify the controls by hazard and sector of the industry.

We believe that improved enforcement of the current food GMP's in these sectors of the industry adequately covers these areas.

IDFA looks forward to continuing its cooperative working relationship with CFSAN and FDA, by strongly encouraging additional opportunities for comment on draft language to update the

food GMPs found in 21 CFR 110. Further, IDFA would like to discuss further the process to finalize any changes to these important federal regulations that may have a significant operational and economic impact on the U.S. dairy industry.

Respectfully submitted,

A handwritten signature in black ink that reads "Constance E. Tipton" followed by a horizontal line.

Constance E. Tipton
President & CEO

cc: D. Zink, CFSAN
C. Hough, IDFA
C. Frye, IDFA
A. Sayler, IDFA

Department of Health and Human Services Public Health Service Food and Drug Administration	MILK PLANT INSPECTION REPORT (Includes Receiving Stations, Transfer Stations, and Bulk Tank Cleaning Facilities)	INSPECTING AGENCY
NAME AND LOCATION OF PLANT		POUNDS SOLD DAILY Milk _____ Other Milk Products _____ Total _____ Permit No. _____
Inspection of your plant today showed violations existing in the items checked below. You are further notified that this inspection sheet serves as notification of the intent to suspend your permit if the violations noted are not in compliance at the time of the next inspection. (See sections 3 and 5 of the Grade "A" Pasteurized Milk Ordinance.)		
1. FLOORS: Smooth, impervious; no pools; good repair; trapped drains (a) _____ 2. WALLS AND CEILINGS: Smooth; washable; light-colored; good repair (a) _____ 3. DOORS AND WINDOWS: All outer openings effectively protected against entry of flies and rodents (a) _____ Outer doors self-closing; screen doors open outward (b) _____ 4. LIGHTING AND VENTILATION: Adequate in all rooms (a) _____ Well ventilated to preclude odors and condensation; filtered air with pressure systems (b) _____ 5. SEPARATE ROOMS: Separate rooms as required; adequate size (a) _____ No direct opening to bars or living quarters (b) _____ Storage tanks properly vented (c) _____ 6. TOILET FACILITIES: Complies with local ordinances (a) _____ No direct opening to processing rooms; self-closing doors (b) _____ Clean; well-lighted and ventilated; proper facilities (c) _____ Sewage and other liquid wastes disposed of in sanitary manner (d) _____ 7. WATER SUPPLY: Constructed and operated in accordance with Ordinance (a) _____ No direct or indirect connection between safe and unsafe water (b) _____ Condensing water and vacuum water in compliance with Ordinance requirements (c) _____ Complies with bacteriological Standards (d) _____ 8. HAND-WASHING FACILITIES: Located and equipped as required; clean and in good repair; improper facilities not used (a) _____ 9. MILK PLANT CLEANLINESS: Heat; clean; no evidence of insects or rodents; trash properly handled (a) _____ No unnecessary equipment (b) _____ 10. SANITARY PIPING: Smooth; impervious, corrosion-resistant, non-toxic, easily cleanable materials; good repair; accessible for inspection (a) _____ Mechanically cleaned lines meet Ordinance specs. (b) _____ Pasteurized products conducted in sanitary piping, except as permitted by Ordinance (c) _____ 11. CONSTRUCTION AND REPAIR OF CONTAINERS AND EQUIPMENT: Smooth, impervious, corrosion-resistant, non-toxic, easily cleanable materials; good repair; accessible for inspection (a) _____ Self-draining; strainers of approved design (b) _____ Approved single-service articles; not reused (c) _____ 12. CLEANING AND SANITIZING OF CONTAINERS/ EQUIPMENT: Containers, utensils, and equipment effectively cleaned ... (a) _____ Mechanical cleaning requirements of Ordinance in compliance; records complete (b) _____ Approved sanitization process applied prior to use of product-contact surfaces (c) _____ Required efficiency tests in compliance (d) _____ Multi-use plastic containers in compliance (e) _____	13. STORAGE OF CLEANED CONTAINERS AND EQUIPMENT: Stored to assure drainage and protected from contamination (a) _____ 14. STORAGE OF SINGLE-SERVICE ARTICLES: Received, stored and handled in a sanitary manner; paperboard containers not reused except as permitted by the Ordinance (a) _____ 15a. PROTECTION FROM CONTAMINATION: Operations conducted and located so as to preclude contamination of milk, milk products, ingredients, containers, equipment, and utensils (a) _____ Air and steam used to process products in compliance with Ordinance (b) _____ Approved pesticides, safely used (c) _____ 15b. CROSS CONNECTIONS: No direct connections between pasteurized and raw milk or milk products (a) _____ Overflow, spilled and leaked products or ingredients discarded (b) _____ No direct connections between milk or milk products and cleaning and/or sanitizing solutions (c) _____ 16a. PASTEURIZATION-BATCH: (1) INDICATING AND RECORDING THERMOMETERS: Comply with Ordinance Specifications (a) _____ (2) TIME AND TEMPERATURE CONTROLS : Adequate agitation throughout holding; agitator sufficiently submerged (a) _____ Each pasteurizer equipped with indicating and recording thermometer; bulb submerged (b) _____ Recording thermometer reads no higher than indicating thermometer (c) _____ Product held minimum pasteurization temperature continuously for 30 minutes, plus filling time if product preheated before entering vat, plus emptying time, if cooling is begun after opening outlet (d) _____ No product added after holding begun (e) _____ Airspace above product maintained at not less than 5.0° F higher than minimum required pasteurization temperature during holding (f) _____ Approved airspace thermometer; bulb not less than 1 inch above product level (g) _____ Inlet and outlet valves and connections in compliance with Ordinance (h) _____ 16b. PASTEURIZATION-HIGH TEMPERATURE: (1) INDICATING AND RECORDING THERMOMETERS: Comply with Ordinance specifications (a) _____ (2) TIME AND TEMPERATURE CONTROLS: Flow-diversion device complies with Ordinance requirements (a) _____ Recorder controller complies with Ordinance requirements (b) _____ Holding tube complies with Ordinance requirements (c) _____ Flow promoting devices comply with Ordinance requirements (d) _____ (3) ADULTERATION CONTROLS: Satisfactory means to prevent adulteration with added water (a) _____ 16c. ASEPTIC PROCESSING: (1) INDICATING AND RECORDING THERMOMETERS: Comply with Ordinance Specifications (a) _____	(2) TIME AND TEMPERATURE CONTROLS: Flow-diversion device complies with Ordinance requirements (a) _____ Recorder controller complies with Ordinance requirements (b) _____ Holding tube complies with Ordinance requirements (c) _____ Flow promoting devices comply with Ordinance requirements (d) _____ (3) ADULTERATION CONTROLS: Satisfactory means to prevent adulteration with added water (a) _____ 16d. REGENERATIVE HEATING: Pasteurized or aseptic product in regenerator automatically under greater pressure than raw product in regenerator at all times (a) _____ Accurate pressure gauges installed as required; booster pump properly identified and isolated (b) _____ Regenerator pressures meet Ordinance Requirements (c) _____ 16e. RECORDING CHARTS: Batch pasteurizer charts comply with applicable Ordinance Requirements (a) _____ HTST & HST pasteurizer charts comply with applicable Ordinance Requirements (b) _____ Aseptic charts comply with applicable Ordinance Requirements (c) _____ 17. COOLING OF MILK: Raw milk maintained at 45° F or less until processed (a) _____ Pasteurized milk and milk products, except those to be cultured, cooled immediately to 45° F or less in approved equipment; all milk and milk products stored thereat until delivered (b) _____ Approved thermometer properly located in all refrigeration rooms and storage tanks (c) _____ Recirculated cooling water from safe source and properly protected; complies with bacteriological standards (d) _____ 18. BOTTLING AND PACKAGING: Performed in a plant where contents finally pasteurized ... (a) _____ Performed in a sanitary manner by approved mechanical equipment (b) _____ Aseptic filling in compliance (c) _____ 19. CAPPING: Capping and/or closing performed in sanitary manner by approved mechanical Equipment (a) _____ Imperfectly capped/closed products properly handled (b) _____ Caps and/or closures comply with Ordinance (c) _____ 20. PERSONNEL CLEANLINESS: Hands washed clean before performing plant functions; re-washed when contaminated (a) _____ Clean outer garments and hair covering worn (b) _____ No use of tobacco in processing areas (c) _____ 21. VEHICLES: Vehicles clean; constructed to protect milk (a) _____ No contaminating substances transported (b) _____ 22. SURROUNDINGS: Heat and clean; free of pooled water, harborage, and breeding areas (a) _____ Tank enclosing areas properly constructed (b) _____ Approved pesticides, used properly (c) _____
REMARKS		
DATE	SANITARIAN	
1. A receiving station shall comply with Items 1 to 15, inclusive, and 17, 20, and 22. Separation requirements of Item 5 do not apply. 2. A transfer station shall comply with items 1, 4, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 20, 22 and as climatic and operating conditions require, applicable provisions of Items 2 and 3. In every case, overhead protection shall be required. 3. Facilities for the cleaning and sanitizing of bulk transport tanks shall comply with the same requirements for transfer stations.		
NOTE - Item numbers correspond to required sanitation items for Grade "A" pasteurized milk in the <i>Grade "A" Pasteurized Milk Ordinance</i> .		

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	MANUFACTURING PLANT INSPECTION REPORT <i>(Single-Service Milk Containers)</i>	INSPECTING AGENCY
NAME AND LOCATION OF PLANT		
<p>1. FLOORS: Smooth; impervious; in good repair Joints between walls and floors tight Floor drains properly trapped</p> <p>2. WALLS AND CEILINGS: In production areas--smooth, cleanable, light colored In production areas--good repair</p> <p>3. DOORS AND WINDOWS: All outside openings protected against entrance of insects, dust, and airborne contamination Outer doors tight, self-closing</p> <p>4. LIGHTING AND VENTILATION: Adequate light in all rooms--20-foot candles in production areas and 5-foot candles in storage areas Ventilation sufficient to prevent excessive odors and condensation Pressure ventilation systems filtered</p> <p>5. SEPARATE ROOMS: Fabrication rooms separate from non-processing areas Regrinding conducted in separated room(s)</p> <p>6. TOILET FACILITIES/SEWAGE DISPOSAL: Disposal of waste in compliance with local regulations All plumbing complies with State and local plumbing codes Self-closing doors on toilet rooms Clean; in good repair Adequate light and ventilation Proper handwashing facilities Windows effectively screened Employee handwashing signs posted Eating/food storage prohibited</p> <p>7. WATER SUPPLY: Safe; sanitary quality; complies with bacteriological and construction requirements No direct or indirect connection between safe and unsafe water Water supply sampled annually</p> <p>8. HANDWASHING FACILITIES: Hot and cold or warm running water, soap, individual towels or air dryers provided Clean; convenient to fabricating areas</p> <p>9. PLANT CLEANLINESS: Floors, walls, ceiling, overhead beams, fixtures of all rooms clean</p>	<p>Plant interior free of evidence of insects, rodents and birds</p> <p>Machines and appurtenances clean</p> <p>10. LOCKERS AND LUNCHROOMS: Separated from plant operation; self-closing doors Eating/storage of food prohibited in fabricating and storage rooms Locker and lunchrooms clean Covered, impervious trash containers provided Handwashing facilities provided Employee handwashing signs posted</p> <p>11. DISPOSAL OF WASTES: Refuse in plant properly stored in covered containers Refuse containers properly identified Refuse stored outside plant</p> <p>12. PERSONNEL CLEANLINESS: Clean hands Clean garments; hair restraints No person with inadequately treated wounds or lesions working in processing areas Tobacco use in authorized areas only</p> <p>13. PROTECTION FROM CONTAMINATION: Product contact surfaces protected Air directed at product contact surfaces in compliance Pesticides approved; safely used</p> <p>14. STORAGE OF MATERIALS AND FINISHED PRODUCTS: Elevated off the floor and away from wall Single service articles in process protected from contamination Stored in clean, dry place, protected from splash, insects, and dust Containers and closures stored in original cartons and sealed until used; partially used cartons resealed during storage Containers for reuse materials are covered, clean and identified</p> <p>15. FABRICATING, PROCESSING AND Contact surfaces clean Materials in process protected from contamination; overhead shields Fasteners, guides hangers, supports and baffles properly constructed; makeshift devices not used</p>	<p>Container contact surfaces properly constructed; in good repair</p> <p>Wax coating applied properly; wax temperature maintained</p> <p>Grinders, shredders and similar equipment properly installed; protected from contamination</p> <p>Resin storage facilities properly filtered; air tubes covered</p> <p>16. EQUIPMENT AND MATERIALS FOR CONSTRUCTION OF CONTAINERS AND CLOSURES: Equipment thoroughly cleaned after use of non-food-grade materials Plastic sheeting, laminated paper, metal, and paper board blanks from approved source Sanitary lubricants used on contact surface Proper separation of raw and non-food-grade materials Containers or materials for containers not used if on floor</p> <p>17. WAXES, ADHESIVES, AND INKS: Properly stored in covered containers Materials not in use properly stored Nontoxic; impart no flavor or odor Transfer containers clean; identified</p> <p>18. HANDLING OF CONTAINERS AND EQUIPMENT: Handling of product contact surfaces minimal</p> <p>19. WRAPPING AND SHIPPING: Single service articles protected from contamination prior to use Packaged contents protected Transportation vehicles clean; in good repair Paper board containers, wrappers and dividers not reused Packaging materials in compliance</p> <p>20. IDENTIFICATION AND RECORDS: Plant identification on outer wrapping Required bacteriological tests on file All materials and components in compliance; records on file</p> <p>21. SURROUNDINGS Surroundings neat and clean and free of breeding areas Driveways graded; no standing water</p>
REMARKS:		
DATE	SANITARIAN	
NOTE: This form has been developed for use with the Grade A Pasteurized Milk Ordinance/Recommendations of the U.S. Public Health Service		

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		CONDENSED and DRY - MILK & WHEY PLANT INSPECTION REPORT <i>(Including Bulk Tank Cleaning Facilities)</i>		INSPECTING AGENCY	
NAME AND LOCATION OF PLANT				PRODUCTION PER DAY	
				POUNDS OF GRADE A RAW PRODUCT RECEIVED	
				POUNDS OF GRADE A CONDENSED AND/OR DRY PRODUCTS PRODUCED	
				MAXIMUM CAPACITY OF DRIERS AND PANS	
				PERMIT NUMBER	
<p>Site: Inspection of your plant today showed violations existing in the items checked below. You are further notified that this inspection sheet serves as notification of the intent to suspend your permit if the violations noted are not in compliance at the time of the next inspection. (See Sections 3 and 5 of the Grade A Condensed and Dry Milk Products and Condensed and Dry Whey, Supplement 1 to the Grade A Pasteurized Milk Ordinance - 1978 Recommendations of the U.S. Public Health Service/Food and Drug Administration.)</p>					
<p>1. FLOORS: Smooth; impervious; no pools; good repair; trapped drains (a)-----</p> <p>2. WALLS AND CEILINGS: Smooth; washable; light-colored; good repair (a)-----</p> <p>3. DOORS AND WINDOWS: All outer openings effectively protected against entry of flies and rodents (a)-----</p> <p>Outer doors self-closing; screen doors open outward (b)-----</p> <p>4. LIGHTING AND VENTILATION: Adequate light in all rooms (a)-----</p> <p>Well ventilated to preclude odors and condensation; filtered air with pressure systems (b)-----</p> <p>5. SEPARATE ROOMS: Separate rooms as required; adequate size (a)-----</p> <p>No direct opening to living quarters (b)-----</p> <p>Storage tanks properly vented (c)-----</p> <p>6. TOILET FACILITIES: Complies with local ordinances (a)-----</p> <p>No direct openings to processing rooms; self-closing doors (b)-----</p> <p>Clean; well-lighted and ventilated; proper facilities (c)-----</p> <p>Sewage and other liquid wastes disposed of in a sanitary manner (d)-----</p> <p>7. WATER SUPPLY: Constructed and operated in accordance with Ordinance (a)-----</p> <p>No direct or indirect connection between safe and unsafe water (b)-----</p> <p>Condensing water and vacuum water in compliance with Ordinance requirements (c)-----</p> <p>Reclaimed water complies with Ordinance (d)-----</p> <p>Complies with bacteriological standards (e)-----</p> <p>8. HAND-WASHING FACILITIES: Located and equipped as required; clean and in good repair; improper facilities not used (a)-----</p> <p>9. MILK PLAN CLEANLINESS: Neat; clean; no evidence of insects or rodents; trash properly handled (a)-----</p> <p>No unnecessary equipment (b)-----</p> <p>No excessive product dust (c)-----</p> <p>10. SANITARY PIPING: Smooth, impervious, corrosion-resistant, non-toxic, easily cleanable materials; good repair; accessible for inspection (a)-----</p>	<p>Cleaned-in-Place lines meet Ordinance specifications (b)-----</p> <p>Pasteurized products conducted in sanitary piping (c)-----</p> <p>11. CONSTRUCTION AND REPAIR OF CONTAINERS AND EQUIPMENT: Smooth, impervious, corrosion-resistant, non-toxic, easily cleanable materials; good repair; accessible to inspection (a)-----</p> <p>Self-draining; strainers and sifters of approved design (b)-----</p> <p>Approved single-service article; not reused (c)-----</p> <p>12. CLEANING AND SANITIZING OF CONTAINERS AND EQUIPMENT: Containers, utensils, and equipment effectively cleaned (a)-----</p> <p>Mechanical cleaning requirements of Ordinance in compliance; records complete (b)-----</p> <p>Approved sanitization process applied prior to use of product-contact surfaces (c)-----</p> <p>Required efficiently tests in compliance (d)-----</p> <p>13. STORAGE OF CLEANED CONTAINERS AND EQUIPMENT: Stored to assure drainage and protected from contamination (a)-----</p> <p>14. STORAGE OF SINGLE-SERVICE ARTICLES: Received, stored, and handled in a sanitary manner; paperboard shipping containers not reused (a)-----</p> <p>15. PROTECTION FROM CONTAMINATION: Operations conducted and located so as to preclude contamination of products, ingredients, containers, equipment, and utensils (a)-----</p> <p>Overflow, spilled and leaked products or ingredients discarded (b)-----</p> <p>Air and steam used to process products in compliance with Ordinance (c)-----</p> <p>Approved pesticides; safely used (d)-----</p> <p>16a. PASTEURIZATION--HIGH-TEMPERATURE SHORT-TIME CONTINUOUS FLOW: (1) Indicating and Recording Thermometers: Comply with Ordinance specifications (a)-----</p> <p>(2) Time and Temperature control: Flow diversion device complies with Ordinance requirements; diverted flow line self-draining; stoppage precluded; proper assembly and operation; product held minimum pasteurization temperatures (a)-----</p> <p>Recorder-controller complies with Ordinance requirements; recorder temperature no higher than indicating thermometer temperature; cut-in and cut-out temperature at or above required temperature; setting sealed; no bypass around sensor; sensor located properly (b)-----</p> <p>Holding tube complies with Ordinance requirements; proper design and assembly; no short circuiting; proper slope and supports (c)-----</p>	<p>Flow promoting devices comply with Ordinance requirements; no improper manual switches; maximum speed assures 15-second hold; setting sealed as required; proper location (d)-----</p> <p>16b. PASTEURIZATION -- REGENERATIVE HEATING: Pasteurized products in regenerator automatically under greater pressure than raw products in the regenerator at all times (a)-----</p> <p>Accurate pressure gauges installed as required; booster pump properly identified (b)-----</p> <p>16c. PASTEURIZATION--TEMPERATURE RECORDING CHARTS: HTST pasteurizer charts comply with applicable Ordinance requirements (a)-----</p> <p>17. COOLING Raw and pasteurized products and condensed products cooled to and maintained at required temperatures (a)-----</p> <p>Approved thermometer properly located in all refrigeration rooms and storage tanks (b)-----</p> <p>Recirculated cooling water from safe source and properly protected; complies with bacteriological standards (c)-----</p> <p>18. CONTAINER FILLING: Dry products packaged in new containers (a)-----</p> <p>Performed in sanitary manner by mechanical equipment (b)-----</p> <p>Transportation in sealed containers for further processing and/or packaging (c)-----</p> <p>Stored in sanitary manner (d)-----</p> <p>19. CONTAINER CLOSURE, SEALING AND STORAGE: Closing and sealing performed in sanitary manner by mechanical equipment (a)-----</p> <p>Imperfectly closed products properly handled (b)-----</p> <p>Sanitary closure (c)-----</p> <p>20. PERSONNEL CLEANLINESS: Hands washed clean before performing plant functions; reashed when contaminated (a)-----</p> <p>No use of tobacco in processing area (b)-----</p> <p>Clean outer garments worn (c)-----</p> <p>Clean bootcovers, caps, and coveralls worn when entering dryer (d)-----</p> <p>21. VEHICLES: Vehicles clean; constructed to protect milk (a)-----</p> <p>No contaminating substances transported (b)-----</p> <p>Dry products transported in sanitary manner (c)-----</p> <p>22. SURROUNDINGS: Neat and clean; free of pooled water, harborage, and breeding areas (a)-----</p> <p>Tank unloading areas properly constructed (b)-----</p> <p>Approved pesticides, used properly (c)-----</p>			
REMARKS					
DATE		SANITARIAN			
<p>¹ Facilities for the cleaning and sanitizing of bulk transport tanks shall comply with items 1, 4, 6, 7, 8, 9, 10, 11, 12, 14, 15, 20, 22, and as climatic and operating conditions require, applicable provisions of items 2 and 3. In every case, overhead protection shall be required.</p>					
<p>NOTE: Item numbers correspond to required sanitation items for Grade A Condensed Milk, Dry Milk Products and Dry Whey in the Grade A Condensed and Dry Milk Products and Dry Whey, Supplement 1 to the Grade A Pasteurized Milk Ordinance - 1978 Recommendations of the U.S. Public Health Service/Food and Drug Administration.</p>					