



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

August 18, 2006

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

Re: Docket No. 2004n-0230; Food, Current Good Manufacturing Practice Regulations

Dear Sir or Madam:

The following comments are submitted by the International Dairy Foods Association (IDFA). IDFA represents the nation's dairy manufacturing and marketing industries and their suppliers, with a membership of 530 companies representing a \$90-billion a year industry. IDFA is composed 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.

The U.S. dairy industry has effectively used the current food Good Manufacturing Practices (GMPs) for the past 20 years to develop safety assurance programs for dairy products. However, new food safety concerns and technologies have developed that are not addressed in the existing GMPs. Therefore, IDFA and its members support FDA's efforts to update and revise the food GMPs, urging the agency to build on and enhance the existing regulations. The regulatory flexibility in the existing GMPs, that have allowed these regulations to be effective 20 years after implementation, needs to be maintained in any new language. It must be recognized that the food GMPs have to span a wide range of food products and processing technologies with different safety challenges. These variations result in different levels and types of risk. Accordingly, flexibility is crucial as FDA updates the existing GMP language.

These comments address the FDA Working Group's White Paper and attempt to provide suggestions or recommendations where specific questions are raised.

GMP TRAINING:

General Comments on Training:

Food safety training is an essential component of an effective GMP program. Training needs to be applicable to the specific job function. Regulations governing training cannot be prescriptive due to

variations in processes, products, and employee job functions. Processors must be able to establish their own programs without FDA mandating specific approaches. Additionally, IDFA and its members do not believe a government-based or government-supported private accreditation program on food safety training would be appropriate. Such an accreditation program would require scarce government resources to develop, oversee and monitor; would be very general in nature; and would still need food industry enhancements to focus on GMP issues unique to their industry. It would be very difficult to demonstrate that government resources invested in accreditation of food-safety training programs would significantly enhance the food safety system, when other options are available.

Effectiveness of food safety training should be measured by inspection compliance/performance outcomes, not by tests, records of successful completion, certification, or frequency of training. The true measure of effective training is whether the end food product is safe and unadulterated and the employees are practicing safe food handling practices, not the number or frequency of training sessions an employee has attended. If there is 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.

Food safety training must be presented by a person with adequate education, experience and expertise. The training material must be presented in an easily understood format. While there are substantial benefits to general, nonspecific GMP training across all areas, there may be practical limitations, especially in operations with temporary employment or frequent turnover. In all cases, the training should target, at a minimum, those areas that are directly related to the employees' responsibilities and the specific food product they are handling, processing, packaging, storing or distributing.

Training must be conducted for new hires and should be repeated for plant employees at a frequency that will result in attainment of an industry-prescribed level of staff competency. Training should also be available for employees with responsibilities affected by significant changes in regulatory requirements or processing procedures, and whenever employees encounter a significant change in job function.

Specific Comments on Training:

Employers must have a written employee food safety training program in place that addresses the following core elements for production supervisors and staff:

- GMP regulations;
- Principles of food safety (specific to the type of foods processed);
- Proper food handling, storage, and distribution, specific to the type of foods processed;
- Maintenance and sanitation of facilities and equipment;
- Environmental *Listeria monocytogenes* (LM) monitoring;
- Employee hygiene and health;
- Temperature controls specific to the type of food processed;
- Food allergens awareness; and
- Pathogen control.

Employers should maintain documentation of training to include the course outline, date of training, name of individual(s) conducting the training and employees attending the training.

Currently, industry-based, food safety training programs are actually “customized” for each specific audience. As a result, these training programs are effective and can ensure the content and value of industry GMP training. Should FDA choose to develop standardized core training, we suggest that FDA use elements similar to the successful approach used for development of training for the FDA Juice HACCP Regulations in 2001. FDA organized an “alliance” of stakeholders (states, academia and the industry) that worked together to develop and outline critical training elements and then expand that outline into a core curriculum training manual. The core Juice HACCP curriculum acted as a model that was individualized by specific states, academic institutions and processors. An alliance could become an integral part of a GMP training plan. Agreed-upon food-safety curricula could be published by FDA as guidance. Importantly, the alliance concept is consistent with the FDA Working Group’s recommendation to provide numerous sources of training, to enhance availability and to improve the selection of training programs, while maintaining some consistency between them. Having training information that has been developed by an alliance and endorsed by FDA will result in affordable and cost-effective GMP training materials.

RECORDS RETENTION AND ACCESS

General Comments on Records Retention and Access:

IDFA believes that dairy product manufacturers should be expected to maintain records as necessary to achieve and monitor their basic adherence to GMPs. IDFA agrees that it would be reasonable to allow FDA to view general documents that demonstrate the existence of written programs that support compliance with food GMPs. This access, however, should be limited to a general plan (i.e. an outline, template or summary) to indicate a specific plan is in place, but not extend or expand FDA access to the specific plan or records that support the plan. The written general plan will be available to FDA on-site only, and should not be removed or copied.

FDA records access should not extend to any other GMP-related manufacturer records, including but not limited to, specific records documenting plan details, records pertaining to monitoring compliance with GMP elements, monitoring test results, and records regarding corrective actions taken by the manufacturer. Finally, absent specific statutory authority, FDA should not routinely demand access to manufacturer's records.

IDFA also believe there should be no *per se* violations for recordkeeping deficiencies. The remedial focus of the GMP regulations should be on the adequacy of the GMP program itself, not on the records. Therefore, the product would not become adulterated or misbranded solely due to recordkeeping deficiencies. Rather, FDA would need to find the GMP program itself to be deficient (or the underlying product to be adulterated or misbranded) before initiating regulatory action.

The FDA Working Group envisioned that the agency would develop detailed criteria for investigators to use in evaluating these records. According to the White Paper, FDA’s Working Group believes that food processors should maintain a copy of the specific GMP plan at the processing facility and update the plan as necessary whenever required by changes in ingredients, products, processes or labeling. IDFA does not support development of detailed criteria for use in evaluating records because manufacturers should be allowed to determine which records are necessary to achieve adherence to the updated GMPs. This position is consistent with the GMP concept of allowing flexibility for food establishments to tailor their records requirements to their unique needs. IDFA believes that establishing detailed criteria to evaluate such records would run counter to records development flexibility, since the record needs for two different food processing

plants are not the same. Finally, given that FDA's legal authority to access records is limited to instances where they have specific statutory authority, developing detailed regulatory criteria for evaluation of such records would be inappropriate and a waste of resources.

Specific Comments on Records Retention and Access:

1. **Employee Food GMP Training Program:** IDFA believes that manufacturers should maintain and allow FDA access to a general plan (i.e. an outline, template or summary) that indicates a written employee training program on food safety is in place, but not extend or expand FDA access to the specific plan or records that support the plan. Further, these records should cover the general outline and frequency of the training course. However, current law specifically excludes FDA access to personnel records, where employee training information is often maintained. Effectiveness of training should be measured by inspection compliance/performance outcomes, not by test results, records of successful completion, certifications, or frequency of training.
2. **Allergen Monitoring Plan:** IDFA believes that manufacturers should maintain and allow FDA access to a general plan (i.e. an outline, template or summary) that indicates a written allergen monitoring plan is in place, but not extend or expand FDA access to the specific plan or records that support the plan. These records should cover the basics of the written allergen control plan such as: employee training, segregation of food allergens during storage and handling, cleaning procedures, prevention of cross-contact, product label review and supplier control. However, records documenting the specific details of the plan or its implementation should not be accessible by FDA. IDFA believes that a company should be able to maintain records in whatever form and at whatever location it deems appropriate. Voluntarily providing access to a plan template should not be construed as giving FDA authority to approve or disapprove any particular plan.
3. ***Listeria monocytogenes* (LM) Environmental Monitoring Plan:** IDFA believes that manufacturers should maintain and allow FDA access to a general plan (i.e. an outline, template or summary) that indicates a written, scientifically based, LM Environmental Monitoring Plan for foods that support its growth plan is in place, but not extend or expand FDA access to the specific plan or records that support the plan, including but not limited to environmental monitoring results. IDFA believes it is reasonable for a manufacturer to demonstrate to FDA that environmental plans are in place by voluntarily providing FDA access to a template or other general documentation, but does not believe that FDA should routinely have access to such plans or records. In no case should voluntary access to a written LM Environmental Monitoring Plan be interpreted as giving FDA authority to approve or disapprove such plans.
4. **Written Sanitation Procedures:** IDFA believes that manufacturers should maintain and allow FDA access to a general plan (i.e. an outline, template or summary) that indicates a written sanitation program for food contact surfaces of processing equipment and utensils is in place. However, IDFA does not support FDA access to the specific plan or records supporting the written cleaning and sanitation plan for food contact surfaces, including but not limited to, cleaning and sanitation monitoring records or records of corrective actions taken by the manufacturer. IDFA believes it is reasonable for a manufacturer to voluntarily allow FDA to review but not copy a template or other documentation demonstrating that the

facility has a written cleaning and sanitation plan for food contact surfaces. This should not be construed as giving FDA authority to approve or disapprove any particular plan.

SANITATION PRACTICES FOR FOOD CONTACT SURFACES

General Comments on Sanitation Practices:

Good sanitation practices have always served as a foundation for FDA's current GMPs. The existing GMPs are based upon the expectation that food manufacturers will implement comprehensive procedures designed to ensure:

- Food contact surfaces are regularly cleaned and protected from contamination during processing and post-processing operations;
- Employees comply with personal hygiene recommendations compatible with a clean processing environment;
- Compliance is monitored.

Although the practices contemplated by the current GMPs are sound and should continue, the food industry has learned much over the years about the risks of foodborne disease created by inadequate sanitation and cross-contamination in the processing environment, and how those risks can be reduced. GMP regulations should provide the general standards that industry needs to meet, but provide industry flexibility on how it goes about meeting those standards.

Specific Comments on Sanitation Practices:

IDFA supports updating FDA's current GMPs on sanitation practices to reflect current best practices within the dairy industry by adding a requirement that dairy manufacturers have written sanitation procedures for product contact surfaces. The industry should allow FDA access to a general plan (i.e. an outline, template or summary) that indicates a written sanitation program for food contact surfaces of processing equipment and utensils is in place, but not extend or expand FDA access to the specific plan or records that support the plan. Written sanitation procedures should be developed for all food contact surfaces, including utensils. These sanitation procedures should include:

1. Scope;
2. Cleaning and sanitation objective;
3. Equipment systems and utensils included;
4. General description of cleaning and sanitizing systems and procedures, stopping short of detailed step-by-step standard operating procedures (SOPs);
5. Measures to prevent equipment and utensil re-contamination prior to use;
6. Generic cleaning and sanitizing schedules;
7. Cleaning and sanitizing monitoring activities; and
8. Guidelines on appropriate corrective actions if cleaning and sanitizing problems develop.

Food processing facilities vary considerably in size, complexity and scope of operation; no one sanitation approach is appropriate for every facility. More specific details can be developed as "guidelines" for specific industry segments.

LISTERIA MONOCYTOGENES (LM) ENVIRONMENTAL MONITORING PLAN:

General Comments on an LM Environmental Monitoring Plan:

IDFA supports a requirement for a written LM environmental monitoring program for processors of ready-to-eat (RTE) foods that support rapid and progressive growth, but do not support the program extending to product contact surfaces and product. The written program should be science-based, with manufacturers monitoring the production and processing environment to evaluate the effectiveness of its sanitation practices, identify potential microbial harborage sites, and provide guidance on corrective actions. The use of monitoring programs that detect indicator organisms (i.e. listeria species) should be an acceptable alternative to monitoring directly for LM.

It is important that any LM Environmental Monitoring Plan is flexible to address different processing and packaging situations, as well as product parameters for growth of LM. IDFA believes food processors should maintain and allow FDA access to a general plan (i.e. an outline, template or summary) that indicates a written, scientifically based, LM Environmental Monitoring Plan for foods that support its growth is in place, but not extend or expand FDA access to the specific plan or records that support the plan, including but not limited to environmental monitoring results. In no case should voluntary records access be construed as giving FDA authority to approve or disapprove such plans.

IDFA also recognizes that certain foods, because of their composition, characteristics, packaging and handling do not support the growth of LM and should be excluded from this requirement, such as:

1. RTE dairy foods that have been scientifically demonstrated to not support growth of *L. monocytogenes*, including foods that are maintained at temperatures of minus one degree Celsius (-1C) or below, or that have pH values of less than 4.6, or that have water activity values less than 0.92, or that can be demonstrated by other scientifically valid means to not support growth, including the use of antimicrobial substances in formulations.
2. RTE foods that are subject to a process that is lethal for *L. monocytogenes* in the final package (i.e., that are not exposed to the environment after the lethal process) or are not likely to be contaminated from the post-process environment, such as aseptically processed and packaged RTE foods.
3. RTE foods that are exposed to a scientifically validated post-process lethality treatment that is designed to inactivate the levels of *L. monocytogenes* likely to be present on the product before packaging.
4. RTE foods that are designated as non-potentially hazardous food, (non-PHS)/non-time/temperature control for food safety (non-TCS) food in accord with the pH and water activity interaction tables found in the 2005 FDA Pasteurized Milk Ordinance or 2005 Model Food Code.

Specific Comments on an LM Environmental Monitoring Plan:

Manufacturers of RTE foods that are not exempt from having an LM Environmental Monitoring Plan should employ scientifically based programs to monitor the processing environments and verify the effectiveness of their management programs. IDFA recommends that the LM environmental monitoring program address the following:

1. Goal and objective;
2. Purpose: Methods used to identify LM or an indicator organism in the processing environment and prevent potential contamination of the RTE product;
3. Monitoring procedures identifying non-product contact zones;
4. Description of the indicator organism, procedure, frequency, and identifying acceptable sample and testing methodology (e.g. AOAC, BAM, etc.);
5. Definition of what constitutes a confirmed positive test;
6. Training needs for individuals conducting the sampling and/or analyses;
7. Identification of monitoring activities to be used to document effectiveness of the program;
8. Recommendations on verification of monitoring, sampling and testing data, as well as the person responsible for verification; and
9. Description of the corrective actions to be taken, the person responsible for taking the actions, and verification of the effectiveness of the actions taken when the environmental monitoring program identifies the presence of the test organism in the processing environment.

IDFA also recommends that FDA work with the dairy industry to develop an LM-focused Environmental Monitoring Program guidance document.

FOOD ALLERGEN MANAGEMENT PROGRAM:

General Comments on Food Allergen Management:

Undeclared food allergens can be a serious health concern for allergic individuals. Therefore, food processors should address allergens in their facilities in order to reduce the risk of undeclared food allergens. The regulations governing Good Manufacturing Practices should require companies to take steps to minimize undeclared allergens through development of a written food allergen management program that addresses methods of controlling cross-contact during storage, handling of food, processing of food, and a supplier management program. This requirement for a written plan should allow flexibility in how each segment of the industry and individual companies choose to control allergens.

IDFA believes that manufacturers should maintain and allow FDA access to a general plan (i.e. an outline, template or summary) that indicates a written allergen monitoring plan is in place and maintained by food processors and food ingredient suppliers, but not extend or expand FDA access to the specific plan or records that supports the plan. This general plan or template would be available for review on-site by FDA for the purposes of proving compliance with the regulation. It would not be available for copying or removing from the premises nor should the specific details of the plan be available to FDA. IDFA believes that the regulations are promulgated to protect public health, and will be enforced by FDA ensuring that there is a written allergen management program. In no case should voluntary records access be understood as giving FDA authority to approve or disapprove such plans.

IDFA agrees a written allergen management plan needs to address the eight major allergens*. The plan should include information that addresses most of the six components outlined by the Food CGMP Modernization Working Group including:

1. Training of processing and supervisory personnel;
2. Segregation of food allergens during storage and handling;
3. Validated cleaning procedures for food contact equipment;
4. Prevention of cross contact during processing through measures such as scheduling of production runs and control of rework;
5. Product label review and label usage and control; and
6. Supplier control program for ingredients and labels.

* The eight major food allergens (“allergens”) defined within The Food Allergen Labeling and Consumer Protection Act (PL 108-282) that amends Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) Section 102(b)) new subsection (qq) states:

- (1) Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.
- (2) A food ingredient that contains protein derived from a food specified in paragraph (1), except the following:
 - (A) Any highly refined oil derived from a food specified in paragraph (1) and any ingredient derived from such highly refined oil.
 - (B) A food ingredient that is exempt under paragraph (6) or (7) of section 403(w).

However, IDFA does not believe that the specific content of the allergen management plan should be dictated by regulation as management of allergens is product and process specific. Food manufacturers and even dairy processors are very different from each other in the layout of their plants, the allergens they deal with, and the equipment they use. Therefore, they must have the flexibility to design allergen management plans that will best address their specific needs and requirements. As stated in the FDA White Paper "Food cGMP Modernization-- A Focus on Food Safety" from the Food CGMP Modernization Working Group, "food processing establishments that produce food containing [the eight major] allergens need to have appropriate control programs, yet they should have the flexibility to adapt those programs to their unique circumstances." We also agree with the FDA White Paper that it is appropriate for the processor's allergen management plan to be updated as required by changes in ingredients, products, processes or labeling.

Specific Comments on Food Allergen Management:

IDFA is recommending the following topics be addressed in an allergen management program:

1. Training of processing and supervisory personnel: Training is important in order to help employees understand and implement the company's allergen management program. Since allergen management has so many facets, the content of the training should vary based on the employee's needs and tools. These needs could vary with the specific allergen, job, equipment, process, product and the allergen control policy of the company. Presently, IDFA is unaware of accredited training in the area of allergens and would not support any government-sponsored accreditation program for allergen training.

The allergen training requirements should be similar to the requirements of FDA's Dairy and Juice HACCP. Dairy and Juice HACCP recognizes experience and on-the-job training. This

would be appropriate for allergens, especially as on-the-job training and experience would focus on the allergen issues that would be most appropriate for the particular employee.

We agree that supervisors and managers in food production plants should be trained in each of the allergen management areas so that they have the knowledge and ability to train production workers. Food production workers should have appropriate training in each of the key areas relevant to their job responsibilities. Please refer to the training section of these comments for additional details on employee allergen training.

2. Segregation of Food Allergens During Storage and Handling: IDFA agrees that the segregation of the eight major food allergens during storage and handling can be effective in managing cross contact of food allergens in the food manufacturing setting. Good Manufacturing Practices should require that allergenic ingredients be received, stored and used in a manner that will reduce the risk of cross-contact and unlabeled allergens. There are many ways that facilities can effectively segregate allergens, depending on the allergenic ingredients, plant layout and existing plant procedures. As long as the segregation of allergens is effective in preventing cross-contact, GMP regulations should not detail how that segregation is accomplished. Using some or all of the following practices, as applicable, can be an effective tool in an allergen management program within a processing facility.

- Proper identity of containers, within a processing facility, holding materials that contain any of the eight major food allergens. This may include containers for ingredients, rework and “in process” materials.
- Minimize cross-contact exposure to allergenic ingredients. At a minimum, this means storage within sealed, intact containers, and where appropriate, physical separation in designated areas in the plant.
- Identify food-handling tools and sanitation devices used with one or more of the eight major food allergens or products containing one or more of the eight major allergens, e.g., color-coding, labeling, dedication, single use containers, etc.

Depending on the allergens present in the plant, the processes used, and the space available for storing materials, a given facility may use some or all of these methods of segregation. The regulations should not require that certain methods be used, but instead focus on the final outcome of allergen management program.

3. Validated Cleaning Procedures for Food Contact Surfaces: IDFA agrees that validated cleaning procedures are an effective tool in a food allergen management program. Validation can be addressed by experience, testing, or by collecting and evaluating scientific and technical information to determine that a process, when properly implemented, will effectively manage or produce a desired endpoint. Within an allergen management program, a cleaning procedure would be “validated” when the procedure is shown to adequately remove food allergen residues from food contact surfaces of processing equipment and utensils. Scientific, analytical and/or validated methods may not be readily available or appropriate for all allergens. Therefore, validation may depend on using a combination of visual, technical, scientific and/or analytical methods. The agency should not prescribe specific methods. A validated process needs to be documented to assure consistent implementation. FDA access to these validation records should be limited to confirming that they exist. The GMPs should not expand FDA industry records

access authority in this area, beyond what is commonly allowed under the Food, Drug & Cosmetic Act.

IDFA agrees that food processors and manufacturers should have cleaning procedures that reduce the risk of unlabeled allergens in food products. These cleaning procedures should be validated through experience, testing, or by collecting and evaluating scientific and technical information. The process should be re-validated if the equipment, cleaning procedure, or other variables that would affect the efficacy of the cleaning process, change. However, this should be the only time that re-validation is required. One-time validation is currently required in HACCP programs and in drug manufacturing procedures and this model should be acceptable for food processors as well.

It is recognized that some allergens can be detected by rapid test kit methods. Many problems exist with the use of allergen test kits as a validation tool. Some include performance variability, sensitivity variability, improper use, lack of thorough evaluation and approval by FDA for all major food allergens, variability of test environments and food products on which they are used. IDFA does not believe that FDA should mandate allergen rapid detection test kits as a mandatory or voluntary tool in an allergen monitoring program.

4. Prevention of Cross Contact During Processing: IDFA recommends that the FDA wait for the public release of the Report on Food Allergens before developing this aspect of the food GMPs. The Report is required by the Food Allergen Labeling and Consumer Protection Act (FALCPA) (Sec. 204) to address the cross contact issue and evaluate the effectiveness of GMPs in the context of labeling (including advisory labeling), consumer expectations, inspections, violations and recalls.

IDFA members typically apply the following cross contact prevention measures:

- Scheduling production runs to minimize allergen cross-contact potential;
- Managing rework such that it will not result in an undeclared allergen; and
- Minimizing situations where product flow might allow allergen cross contact.

A food processor's allergen plan should address the prevention of allergen cross-contact during processing, but should not dictate how or what measures should be taken in order to prevent cross-contact. For example, a requirement that rework policies should only allow "exact into exact" would be unnecessarily strict and burdensome for many companies who have effective rework policies that are not "exact into exact." Additionally, any GMP processor requirement to prevent cross-contact should not detail specific contents of this plan, such as scheduling of production runs or use of dedicated production lines. Effective plans to prevent cross-contact may not include these elements. The plans should be evaluated based on their effectiveness, not their content.

The issue of dedicated production lines is particularly troublesome. In some facilities, dedicated production lines may be appropriate. However, for the majority of dairy facilities, dedicated lines are not cost-effective, especially when there are other methods to control allergens. For example, a fluid milk facility that produces eggnog should not be required to have a separate production line for the eggnog that would be used only for a few months each year. The cost of this separate line could be so expensive as to make the production of eggnog unfeasible.

Meanwhile, state of the art cleaning systems (Clean-In-Place) along with manual cleaning procedures and other management tools significantly reduce the risk of cross-contact without resorting to a dedicated production line. Good Manufacturing Practices regulations should not require dedicated production lines. In the dairy industry, the validated cleaning procedures referenced above can result in the same outcome as dedicated equipment. Therefore, IDFA does not support any requirement for dedicated production lines. This step would be unnecessary, impractical, and would defeat the purpose of this whole effort by making the cost-benefit of additional allergen oversight by FDA questionable.

5. Product Label Review and Label Usage and Control: As of January 1, 2006, all food products must comply with the labeling requirements of the Food Allergen Labeling and Consumer Protection Act (FALCPA). FALCPA requires that all allergens added to a product be declared in plain English on the label. Therefore, the Good Manufacturing Practice regulations should require companies to comply with the existing legislation in this area.

FALCPA also required FDA to undertake a study on advisory labeling and report to Congress. Any GMP requirements on advisory labeling Statements, such as "may contain" should be delayed until after the results of this study are finalized.

Labels should be received, stored and utilized in a manner that prevents undeclared allergens in a finished dairy product. This requirement should address the potential problem of incorrect labels or packaging being used for products, but should not mandate details of how this could be achieved. This approach would allow companies flexibility to meet the intent, while still maintaining flexibility on how to reach the desired outcome.

IDFA endorses the need to clearly label the eight major food allergens when present at levels that cause an allergic response that poses a risk to human health as required by FALCPA. IDFA is in agreement with FDA Guidance released on October 5, 2005 and updated in December 2005 and April 2006, "[*Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 \(Edition 3\)\(April 6, 2006\).*](#)" According to the most recent version (Edition 3), "FALCPA's labeling requirements do not apply to major food allergens that are unintentionally added to a food as the result of cross-contact. In the context of food allergens, "cross-contact" occurs when a residue or other trace amount of an allergenic food is unintentionally incorporated into another food that is not intended to contain that allergenic food. Cross-contact may result from customary methods of growing and harvesting crops, as well as from the use of shared storage, transportation, or production equipment." Therefore, labeling allergens that result from cross-contact is not required.

6. Supplier Control Programs for Ingredients and Labels: Suppliers that provide ingredients or packaging to food manufacturers and processors should be required to abide by the same Good Manufacturing Practices as required of food manufacturers. Therefore, a separate supplier control program for allergens that puts the burden on the food processor should not be required. Suppliers need to meet the same training, segregation, cleaning, cross-contact and labeling requirements of this section, so ingredients and packaging entering dairy processing facilities will be appropriately regulated. The GMP regulations should focus on the desired outcome, i.e. foods ingredients containing allergens must declare these allergens so the food processor is aware of the issue. Current business practice for processors and manufacturers

is to require their suppliers to be compliant with applicable current federal and state food and drug regulations, including current Good Manufacturing Practices.

TEMPERATURE MONITORING:

General Comments on Temperature Monitoring:

IDFA recommends that 21 CFR Part 110 be amended to address food ingredient and food temperatures in broad conceptual statements. The amendment would utilize the approach outlined in the December 2001 IFT Task Order No. 4 Report to FDA on “Evaluation and Definition of Potentially Hazardous Foods,” parts of which have been incorporated into the Retail Food Code and the Pasteurized Milk Ordinance (PMO).

Specific temperatures should not be included in the GMPs, as they do not provide industry or FDA with the flexibility to change temperature recommendations when scientific data suggest there is a need, especially when such a change affects food safety. An example of the inappropriateness of including specific processing times and temperatures is the recognition, through scientific assessment of the hazard, that the hot hold temperatures specified in the Model Food Code could be reduced from 140°F to 135°F with no risk to public health. The GMPs still specify the need to maintain hot foods at 140°F or above. Similarly, the requirement in the GMPs to maintain refrigerated foods at 45°F or below, while suitable for some dairy foods, is not scientifically justified for others.

Specific Comments on Temperature Monitoring:

More specifically, our recommendations on food temperatures are as follows:

- 1. Specific Temperature References.** Delete all specific temperature references from the current GMPs. The regulation should instead state, “All foods shall be held at temperatures that will prevent them from becoming adulterated or from causing illness when consumed, including during storage and distribution.” Manufacturers should maintain records as needed to achieve and monitor their basic adherence to general GMP guidance. Absent specific statutory authority, however, we believe FDA should not routinely have access to a manufacturer’s temperature control records.
- 2. Temperature Guidance Document:** In lieu of specific temperatures, we recommend that a guidance document be developed that clearly outlines the relationship of microbial growth to time, temperature and intrinsic product characteristics. This document should apply the approach outlined in the IFT report referenced above for determining the need for temperature control(s) for safety. The guidance can describe temperatures considered appropriate for controlling microbial growth in these food products. This type of document is much easier to update and modify as food processing technology and science advance. See Appendix 1 for details on the section of the IFT report that would be helpful if incorporated into a guidance document. FDA should work with the food processing industry and other stakeholders in the development of this guidance
- 3. Scientific Validity of Temperatures:** If it is determined, based on product characteristics, that a dairy product is a TCS food (requires time/temperature control for safety), the validity of the specific temperatures used to ensure product safety, would need to be supported by scientific information or analysis (e.g., published papers, scientific studies). Specific times and

temperatures found in the Retail Food Code, the PMO and other nationally recognized and accepted regulatory documents for specific foods should be "safe harbor" and require no further validation by food processors and distributors. The dairy industry would be responsible for determining the validity of the temperatures used in manufacturing, storage and distribution.

4. Modeling: While the use of theoretical models has some value in validating the temperatures utilized by the food industry are appropriate, we do not believe that theoretical models should be referenced or mandated in the revised GMP regulation. Likewise, models may be appropriate for FDA to evaluate temperature information to determine that products are not held in a manner that would allow them to become adulterated through microbial growth. Theoretical temperature models for predicting microbial growth will become more sophisticated and thus require continuous updating if referenced in the GMP regulation. Therefore, it would be more appropriate to address the use of temperature models in a follow-up guidance or supporting document, but have no direct references to modeling in the revised GMPs.

5. Reference to Nationally Recognized Documents. We have a concern with the updated food GMPs containing direct references to other model food safety regulations or scientific reports (i.e. Model Retail Food Code or Pasteurized Milk Ordinance). These references tend to be limited to specific foods or applications, can quickly become outdated, and do not always provide or recognize the latest scientific information. The food GMPs can be difficult to modify and update, complicating future revisions. It would be more appropriate, if there was a compelling reason, to reference the above-described documents in a guidance document, since it would be much easier to update and modify as new food processing technology and science information become available.

6. Specific Temperature Recommendations for Different Processing Steps and Food: It is important that general recommendations addressing food temperature controls in the GMPs be performance based and outcome orientated. We do not believe specific times and temperatures for the various steps during processing (in-process) and for different foods are needed because of the huge variability in food processing, processing equipment, processing technology, and monitoring equipment and characteristics of the individual food. General language such as "All foods shall be held at temperatures that will prevent them from becoming adulterated or from causing illness when consumed, including during storage and distribution" would address all temperature needs in the GMPs.

7. Temperatures for Product in Distribution Vehicles: The current wording in 21 CFR 110.93 already addresses this issue in broad flexible terms. While we believe there is no need to change or add wording to the GMPs for this issue, the language could be updated by a short statement such as "All foods shall be held at temperatures that will prevent them from becoming adulterated or from causing illness when consumed, including during storage and distribution."

8. Temperature Monitoring Equipment Specifications: If it is determined that the revised regulation should contain information on specifications for temperature monitoring equipment, we recommend that the wording be general, e.g., "Temperature monitoring equipment and devices should be as accurate and reliable as necessary to document that foods do not become adulterated." More specific details may be incorporated into the guidance document noted previously.

9. Product Shelf Life: Shelf life of food products has historically been based on the time period that the product retains its best quality. Foods that have exceeded a manufacturer's code date (e.g., "best before," "use-by," etc) are not unsafe or otherwise adulterated. Therefore, the revised GMPs should not address shelf life in detail or with specificity, but should use general language such as "All foods shall be held at temperatures that will prevent them from becoming adulterated or from causing illness when consumed, including during storage and distribution." Manufacturers typically take account of time in addition to temperature when establishing the target consumers, intended use of the product, product characteristics, and acceptable levels of quality to determine shelf life. The dairy industry track record of voluntarily using shelf life has been effective in communicating to consumer that the product is within its life cycle for acceptable quality and it not adulterated.

10. Frequency of Temperature Control Records. The GMP regulation should require that establishments monitor the food temperature and maintain records to the extent needed to demonstrate the product has not become adulterated. IDFA does not believe this extends to mandating frequency or allowing access to industry temperature records by FDA.

Measuring Success:

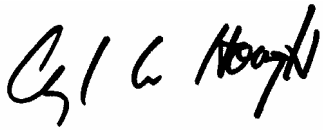
To measure the compliance of food companies with food GMPs, FDA should consider using its existing information-gathering abilities. Specifically, because GMPs are the criteria that constitute the basis for most regulatory inspections, FDA should rely upon its inspection authority. Currently, FDA classifies its inspectional findings into three categories: "No Action Indicated (NAI), Voluntary Action Indicated (VAI), and Official Action Indicated (OAI)." When an FDA investigator classifies its inspectional findings at a particular firm as OAI, the firm is deemed out of compliance with FDA regulations. FDA could track the number of firms receiving an OAI inspection as a barometer of GMP compliance. Similarly, FDA could track the number of firms that move from the VAI category to the NAI category as a secondary indicator of improvements.

An additional approach would be for FDA to redesign its inspection sheet to include specific GMP items and then electronically track their occurrence frequency against some pre-established baseline or target. Frequencies for targeted inspection items could be compared to averages for these same items from prior years so that a statistical evaluation could be performed to determine if yearly differences were significant, indicating either success or problems. This might be a very effective way to determine successful GMP compliance by the food industry.

Conclusion:

IDFA and its members thank FDA for its efforts to solicit stakeholder input into the process of modernizing the food GMPs. Our comments are intended to be constructive so that the flexibility of the existing GMP language can be retained, while improving its applicability to today's diverse and sophisticated food processing industry. Please feel free to contact us regarding any of our comments or recommendations and we would be willing to discuss these directly with FDA staff as this effort moves to the next step. If there are any questions, please contact Allen Sayler at (202) 220-3544 or asayler@idfa.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Clay Hough". The signature is written in a cursive, somewhat stylized font.

Clay Hough

Senior Vice President and General Counsel for Regulatory Affairs

Cc: Connie Tipton
Allen Sayler
Cary Frye
Michelle Matto
IDFA GMP Task Force

Appendix 1:

Comprehensive Reviews in Food Science and Food Safety

Evaluation and Definition of Potentially Hazardous Foods

A Report of the Institute of Food Technologists
for the Food and Drug Administration
of the United States Department of Health and Human Services

December 31, 2001

IFT/FDA Contract No. 223-98-2333
Task Order No. 4

Vol. 2 (Supplement), 2003—COMPREHENSIVE REVIEWS IN FOOD SCIENCE AND FOOD SAFETY 13

Figure 1—Framework for determining if time/temperature is required for safety

The food in question may already be held hot or cold for safety reasons. In this case, and if there is no desire for ambient temperature storage, an analysis using this framework is not needed. If the need to control the temperature of the product for safety reasons is unknown, a review of the food, its ingredients, and general methods of preparation should precede the evaluation of the food. If the food, as described, has a substantial and extensive history of safe use without time/temperature control, and there is enough scientific rationale that supports such safe history of use, then the food may continue to be classified as not requiring temperature control for safety, or non-TCS (see also Chapter 3, section 4.2.).

If there is no known history of safe use, proceed with Step 1.

The panel's framework on time/temperature control of foods for safety was critiqued by applying it to a variety of foods. Each step of the framework has been described as it applies to the food under consideration. Most of the data on the individ-

ual foods were from industry studies submitted to the panel.

In summary, the panel introduced a new approach for evaluating foods that may need time/temperature control for safety. This framework was based on scientific data from peer-reviewed publications that were further evaluated by the panel. The panel recognizes that the implementation of its approach in the field may not be an easy task. For example, although some of the considerations introduced in the proposed framework require careful evaluation and assessment by an expert microbiologist, this report does not attempt to propose who would be responsible for deciding the time/temperature status of a food. The panel also did not address the implications of the framework at the retail level. The panel believes, however, that in light of the complexity of the food systems and the confusion over the interpretation of the term "potentially hazardous foods," a science-based framework such as the one proposed here would be a more accurate, comprehensible, and clear alternative to the current definition and application of the term.

Step 1—Was the food treated to destroy vegetative cells of potential pathogens and packaged to avoid recontamination? If yes, position your product in Table A according to its pH and water activity (a_w). If not, position your product in Table B according to its pH and a_w.

Table A—Control of spores: Product treated to control vegetative cells and protected from recontamination.

Critical a _w values	Critical pH values		
	4.6 or less	> 4.6 to 5.6	> 5.6
0.92 or less	Non-TCS	Non-TCS	Non-TCS
> 0.92 to .95	Non-TCS	Non-TCS	?
> 0.95	Non-TCS	?	?

Table B—Control of vegetative cells and spores: Product not treated or treated but not protected from recontamination

Critical a _w values	Critical pH values			
	< 4.2	4.2 to 4.6	> 4.6 to 5.0	> 5.0
< 0.88	Non-TCS	Non-TCS	Non-TCS	Non-TCS
0.88 to 0.90	Non-TCS	Non-TCS	Non-TCS	?
> 0.90 to .92	Non-TCS	Non-TCS	?	?
> 0.92	Non-TCS	?	?	?

Step 2—If the food is classified as a non-TCS food according to Step 1 above, it may be stored and held safely without regard to time or temperature. If the need for time/temperature control is questionable, the food should be held either hot or cold for safety, or subjected to a product assessment as the next step in determining the appropriate classification.

