



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

August 9, 2004

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

**Re Docket No. 1998N-0359
Program Priorities in the Center for Food Safety and Applied Nutrition;
Request for Comments**

Dear Sir or Madam:

The International Dairy Foods Association (IDFA) appreciates the opportunity to comment on the "2005 Program Priorities in the Center for Food Safety and Applied Nutrition (CFSAN)." These comments 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 the dairy products consumed in the United States.

IDFA looks forward to continuing its cooperative working relationship with CFSAN into FY05 on priority areas for the U.S. dairy processing industry, as well as the other program priorities the agency undertakes. In particular, IDFA commends CFSAN for the cooperation it has extended to the industry on counterterrorism priorities, including implementing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and implementing food security preventative guidance for the industry.

As noted in previous filings, while IDFA strongly supports improving the security of the nation's food supply, the dairy processing industry wants to ensure the regulations implementing the Bioterrorism Preparedness Act and related activities do not impose unworkable and unnecessary burdens. Also, IDFA looks forward to working with CFSAN's leadership on improving the food security guidance in particular with respect to research and analysis of methods of detecting and preventing unconventional threats to the food supply. Dairy processors recognize that a strong and effective food safety

agency is necessary to give the public confidence that government is effectively monitoring and ensuring a safe food supply.

The U.S. dairy industry is continually expanding its product lines, modernizing its manufacturing technology and addressing consumer trends and food preferences. The large number of CFSAN-administered dairy product standards, developed almost 30 years ago, with few updates since, is proving to be a significant hindrance to industry innovations. IDFA is acutely aware of the fact that this problem falls particularly heavily on the dairy industry, with more than forty percent of all standardized products. IDFA would like to work with CFSAN to develop a comprehensive strategy to modernize dairy standards.

Listed below are general recommendations and also specific suggestions that address CFSAN program priorities that are critical to the dairy industry.

I. Assuring Food Safety and Security

Listeria

IDFA commends FDA's activities related to completing and publishing the Risk Assessment of the Relative Risk to Public Health From Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-eat Foods. This document can now serve as an important foundation for future work that is needed for consumer messages and professional health care information and educational efforts that are targeted for at-risk populations. This new scientific information should be used for future hazard evaluations that are undertaken for recall classification for certain foods such as ice cream, frozen dairy desserts, and some varieties of cheeses that do not support the growth of *Listeria monocytogenes*.

As a member of the Alliance for Listeriosis Prevention, IDFA and its constituent organizations the National Cheese Institute (NCI) and International Ice Cream Association (IICA) were co-petitioners seeking the proposed regulatory limit. The members of the NCI and IICA fully support adoption of the proposed regulatory limit and urge the Food and Drug Administration (FDA) to move forward as soon as possible.

The proposed regulatory limit will facilitate adoption of targeted, science-based measures by permitting FDA and the dairy industry to focus resources and attention on levels of *Listeria monocytogenes* that reach public health significance. Accordingly, as a result of the risk assessment and other data and information described in the Petition, there is now a compelling scientific basis upon which FDA policies on *L. monocytogenes* may be reexamined.

The proposed regulatory limit would also offer several additional public health benefits that may facilitate a reduction in listeriosis. The proposed limit would, for example, provide a strong incentive for development of products that do not support growth of *L. monocytogenes*, encourage aggressive sampling programs, and facilitate collection of better quantitative data on *L. monocytogenes*. These positive consequences should be taken into account as FDA considers the Petition.

IDFA urges FDA to establish a science-based standard for the control of *L. monocytogenes* in food and prevention of listeriosis by adopting the proposed regulatory limit as soon as possible.

Additionally, we agree that CFSAN resources are needed to support the regulatory enforcement and surveillance on high-risk foods, the review of current regulatory policies related to eliminating the production, sale and importation of unlawful raw milk cheese, and to target inspections of dairy product manufacturers that produce raw milk. IDFA supports work to develop *Listeria* guidance specifically for the dairy industry and welcomes the opportunity to work with FDA to provide industry assistance and view points on this matter.

Food Allergens

Following the passage of the Food Allergen Labeling and Consumer Protection Act, many companies will be updating their labels with allergen information. The law allows ingredients to be exempt from required allergen labeling through a petition submitted to FDA, or a definitive statement from FDA that the ingredient is not allergenic. We encourage FDA to devote appropriate resources to this process. Since companies are beginning to change labels in preparation for the 2006 deadline, the sooner exemptions become available; the fewer label changes will be needed. Additionally, as FDA updates regulations to incorporate the food labeling bill language, we urge consideration that the ingredient "cream" be exempt from the declaration of "milk" as consumers understand that cream is derived from milk and because declaring the word "milk" in parentheses after the name of the ingredient (i.e., "cream (milk)") might be confusing to the consumers.

Dairy Food Safety

Juice HACCP: IDFA is very supportive of finalizing the 1st Edition of the Juice Hazards and Controls Guide and listing it as an "A" priority. We strongly recommend the addition of an "A" priority item for training of FDA field staff on the Juice HACCP Regulation. IDFA members have been subjected to juice HACCP inspections by district FDA staff untrained and without knowledge of fluid product processing. Since IDFA members produce around 30% of the retail juice products covered under Juice HACCP regulation, our experience is probably representative of the industry as a whole. This lack of training and experience has resulted in extra effort by dairy companies to correct erroneous FDA field reports.

NCIMS & Dairy Cooperative Programs: IDFA has been a leader in dairy HACCP since the early 1990s. As such, we strongly support development of training for stakeholders on the NCIMS voluntary HACCP program. Because this program is in a critical phase of beginning and growth, it is important that CFSAN raise the commitment and resources from a "B" priority to an "A" priority for FY05.

Additionally, one of the challenges faced by CFSAN is that the enforcement of dairy product safety is split between two groups, the Milk Safety Branch and the Division of

Dairy and Egg Safety. While establishing a process for consensus-building is appropriate, we believe it would be much more efficient for CFSAN to combine all dairy product cooperative and enforcement activities into one group within CFSAN.

NDRMMP: IDFA supported the suspension of the National Drug Residue Milk Monitoring Program (NDRMMP) in early 2001. The NDRMMP was part of CFSAN's effort to validate the effectiveness of the NCIMS drug residue program and the National Milk Drug Residue Database (NMDRD), but was a hold-over from the early and mid-1990s when both programs were in their infancy. Since that time the NCIMS drug residue program has become a model for the rest of the world and the NMDRD, with millions of regulatory and industry dairy samples validates the effectiveness of the program. It is completely unnecessary and a drain on limited CFSAN resources to resurrect the NDRMMP and it should be dropped out of all current and future CFSAN priority lists.

Federal Import Milk Act (FIMA): IDFA has strongly supported the establishment of food safety equivalency agreements with other qualified countries. Until such time as that effort proves to be more effective and CFSAN develops a strategy on how to accomplish this, we support drafting of a FIMA Compliance Policy Guide. We suggest the dairy industry and other stakeholders be allowed to have input. A number of IDFA members hold FIMA permits and IDFA staff have worked closely with CFSAN staff to interpret and meet all FIMA requirements.

II. Improving Nutrition and Dietary Supplement Safety -Nutrition Health Claims and Labeling

IDFA supports the work CFSAN has undertaken to extend the applicability of qualified health claims to conventional foods and urges the agency to devote sufficient resources to the project in FY05 to ensure that claims the industry generates are reviewed as expeditiously as possible.

IDFA has followed CFSAN's work on the matter of trans fatty acids, especially on changing requirements for disclosing foods' content of trans fatty acids, with great interest. As noted in previous submissions, IDFA has concerns that any future policy, such as the requirement of a daily value, may be premature based on the lack of scientific consensus. All future policies should also balance the interest in providing consumers appropriate information with the regulatory compliance burden of a label change. There are a number of smaller companies that are finding the January 1, 2006 implementation date a burden because of the large number of products with labels that will need to be changed to meet the new requirement. The goal of balancing the interests of consumer's right to know with the expense of complying with regulation should continue to guide CFSAN's work on this project in FY05.

As Americans become more conscious of their weight and what they can do to prevent obesity, more consumers are following low sugar and carbohydrate eating plans and are interested in buying low carbohydrate foods. Without nutrient content claims for carbohydrates, there is no uniform way for dairy processors to inform consumers that their products are low in carbohydrates. We support FDA's expressed intention to take action to define nutrient content claims for carbohydrates, such as carbohydrate free, low

carbohydrate, and reduced carbohydrate, as well as issuing guidance on "net carb" statements.

Last year, FDA solicited comments regarding the prominence of calorie information on food labels. IDFA believes that no changes to the food label are needed. Serving size and calorie content are already available on every food label, giving consumers information on the calories they take in. Nutrient content claims are available to assist consumers in identifying low fat and low calorie foods, if consumers are interested in such foods. For individuals interested in weight control, all the information they need is already clearly stated on the package. However, consumers need to understand the importance of their personal choices on their health. This understanding cannot come solely from food labels. Labels are only a tool to inform people's choices. Consumers must be educated about what the food label means to their diet and their health. We believe that FDA's resources would be better spent on consumer education about the food label, rather than another expensive label change for food manufacturers and processors.

III. Assuring Food Safety: Cross Cutting Areas - International

Codex Committees and Working Groups: As an active player in Codex, IDFA is very supportive of including the Codex Committees and working groups as part of the "A" Priority List. It is important that scientifically based U.S. food safety standards are reflected in international standards such as Codex.

Equivalency Determinations: We are very concerned that "Equivalency Evaluations," more particularly, the almost ten year effort by CFSAN's Milk Safety Branch to determine Grade "A" equivalency with Canada, was not put on the "A" list. The lack of a completed Grade "A" equivalency has been hindering trade of dairy products between Canada and the United States for years and has negatively impacted U.S. dairy processors. This trade has suffered primarily because CFSAN's focus has been on compliance, not equivalency, but also from inadequate CFSAN resources, a lack of an overall CFSAN equivalency strategy and wavering Canadian commitment. We strongly recommend that the "Canadian Equivalency Evaluation" for dairy products be put on the International "A" Priority List. We further support continued efforts to finalize FDA's "International Equivalence Criteria" as this document would provide criteria for evaluating foreign food safety systems to determine their equivalence to that of the U.S.

International Trade Agreements: IDFA would also like to commend FDA's participation in U.S. trade negotiations. We believe that pursuing trade agreements with our economic partners is a benefit to the U.S. dairy industry. FDA's participation in drafting sanitary and phytosanitary articles of the agriculture chapters of future trade agreements is crucial to ensure that public health protections are harmonized as the U.S. enters into a deeper economic integration with its trading partners.

Prioritizing Domestic Inspection Site Selection: IDFA supports CFSAN's development of a system to prioritize the selection of inspection and sampling sites, based on statistical methods, to target limited resources at high-risk foods and processing facilities. IDFA members are receiving increased FDA field investigator inspections and sampling without any justification or recognition of the fact that our industry has not had significant food outbreaks since the late 1990s. A system of prioritizing inspection and

sampling sites would rationalize the process to the benefit of both the consuming public and the U.S. dairy processing industry.

Tiered Foreign Food Inspection: IDFA supports the prioritizing of foreign food inspections and an overall increase in all foreign food inspections to create a level playing field for U.S. food processors, who not only are inspected by FDA, but by a variety of state food regulatory agencies.

CFSAN Laboratory Quality Assurance System: Over the past two years, a few IDFA members have been subject to analysis or reporting errors by FDA's laboratories that have resulted in significant financial losses and destruction of safe dairy products. IDFA strongly support CFSAN's efforts to improve its laboratory quality assurance by implementing an internationally recognized quality assurance system such as ISO. In addition, the turn-around time from FDA field investigator sampling until a dairy plant receives the results from that sampling is still not consistently at 30 days or less. Different protocols in different FDA regions and districts also create a regulatory hurdle when dairy plants try to obtain the results of product samples. CFSAN needs to establish as an "A" priority the monitoring of FDA laboratory turn-around time and the development of consistent nationwide procedures for reporting sample results back to the dairy plant where the product was sampled.

Economic Based Regulations

Petition on Liquid Filtered Milk: For FY04, IDFA was disappointed in the lack of progress and down grading to a "B" priority of the National Cheese Institute's (NCI) petition for expanding the definition for "milk" to include liquid filtered milk for cheese making. With respect to this petition, IDFA reminds CFSAN that this petition has wide support within the dairy industry and that the Department of Agriculture (USDA) has extended temporary acceptance of the process under its plant inspection and grading program. In FY05, the petition will have been pending approval for four years, a delay that has unnecessarily encumbered the industry's ability to adapt the most modern and efficient food technology and bring those benefits to consumers. IDFA strongly urges CFSAN to reinstate this petition as an "A" priority and conclude action on this petition in FY05.

Petition on Yogurt: IDFA commends CFSAN for listing this as an "A" priority and moving forward with publishing an advanced notice of proposed rule making. We strongly urge FDA to move forward with the proposed rulemaking to modernize the standards of identity for yogurt. IDFA hopes that FDA will be able to publish those proposed changes in the standards where there is agreement. IDFA feels that it is very important to provide the yogurt industry with a coherent set of provisions that accurately represent FDA's current enforcement policy.

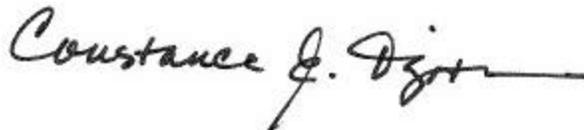
Petition on Ice Cream and Frozen Desserts: IDFA urges FDA to undertake action on the petition from the International Ice Cream Association. This important petition needs to be added to the CFSAN priority list as an "A" priority in FY05 to modernize standards of identity for ice cream and frozen desserts. Specifically, IDFA recommends that CFSAN prepare and publish a Federal Register notice requesting comments on this

petition to update the ice cream and frozen desserts standard as a proposed rule in FY05, and to expedite action on it. The ice cream petition seeks to modernize standards that have remained static and unchanged for over twenty-five years, in stark contrast to the remarkable advances the food industry has experienced in that same period. Food technology, processing methods, ingredient science, and consumer preferences have truly revolutionized the modern food industry, which remains, in far too many instances, bound to operate within the restrictive confines of outdated federal standards of identity.

CFSAN Standards Modernization Initiative: IDFA would strongly support CFSAN's initiation of a proposal to make a general, wholesale modernization of the standards, with special emphasis on a more facile, flexible and efficient mechanism and processes to amend them. Modernized standards should account for scientific and technological advances as well as enabling manufacturers to respond effectively and quickly to changes in consumer preferences. In examining the Center Director's report on FY04 priorities, IDFA was pleased to note mention of a joint CFSAN-USDA project to develop general principles of standards of identity and encourages the agency to complete this initiative in FY05, especially incorporating the aforementioned points.

IDFA appreciates the opportunity to comment on the proposed changes to the program priorities in the Center for Food Safety and Applied Nutrition and would welcome the opportunity to discuss these issues. We are also glad to answer questions or provide additional information.

Respectfully submitted,

A handwritten signature in cursive script that reads "Constance E. Tipton". The signature is written in black ink and includes a horizontal line at the end.

Constance E. Tipton
President & CEO

cc: C. Hough
C. Frye