



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

August 4, 2003

Docket #98N-0359
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rockville, Maryland 20852

To the Dockets Management Branch:

The International Dairy Foods Association (IDFA) welcomes this opportunity to submit the following comments on the Center for Food Safety and Applied Nutrition's (CFSAN) proposed program priorities for fiscal year 2004 (FY04), docket number 98N-0359. I am writing on behalf of IDFA and IDFA's constituent organizations, the Milk Industry Foundation, National Cheese Institute, and International Ice Cream Association whose approximately 850 members operate more than 1500 processing facilities producing eighty-five percent of all dairy products consumed in the United States.

IDFA looks forward to continuing its cooperative working relationship with CFSAN into FY04, on the following priority areas for the US 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 developing food security preventive 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 do not impose unworkable and unnecessary burdens. That need not be the case, IDFA believes, if final regulations build upon the relationship industry and government have developed in tackling previous food security and protection problems. 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.

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IDFA Comments -- Docket #98N-0359

August 4, 2003

2

In examining CFSAN's record of work in FY03 in preparation for commenting on FY04 priorities, IDFA is especially pleased in progress the agency made in this fiscal year, and intends to execute before the end of the fiscal year, on petitions for amending standards of identity for cheese to permit the use of filtered milk and to amend the standards of identity for yogurt. With respect to the petition for permit the use of filtered milk in cheeses, IDFA reminds CFSAN that this petition has the support of the entire dairy industry, processors and producers alike, and that the Department of Agriculture (USDA) has extended temporary approval of the process under its plant inspection and grading program. In FY04, the petition will have been pending approval for five 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 conclude action on this petition in FY04.

In FY04, IDFA recommends that CFSAN bring the yogurt petition and, in particular, the petition from the International Ice Cream Association to modernize the standards of identity for ice cream and frozen desserts to the next stage in the approval process. In spite of the fact that the latter petition, IDFA regrets, has been the subject of apparent misunderstanding and unfortunate mischaracterization, the need for its approval is especially pressing. IDFA is confident that a deliberate, dispassionate review of the facts driving the rationale supporting the petition will dispel the unfortunate rhetoric and compel its approval. Specifically, IDFA recommends that CFSAN issue the standard as a proposed rule in FY04 to expedite action on it.

These petitions illustrate an underlying priority IDFA urges CFSAN to undertake in FY04. The ice cream petition, for example, 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. IDFA is acutely aware of the fact that the onus of this problem falls particularly heavy on the dairy industry, subject of more than forty percent of all standards of identity.

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 process to amend them. Modernized standards should account for scientific and technological advances as well as enable manufacturers to respond effectively and quickly to changes in consumer preferences. In examining the director's report on FY03 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 pursue this initiative in FY04, especially incorporating the aforementioned points.

The recommendations on these specific petitions as well as the matter of general reform of the standards of identity and the process for modernizing them

IDFA Comments -- Docket #98N-0359

August 4, 2003

3

are consistent, IDFA believes, with one of the underlying principles of the agency's emphasis on enhancing consumer health information for better nutrition -- to bring to consumers the latest developments in food science. IDFA has three further comments on this aspect of CFSAN's priorities: qualified health claims, biotechnology, and trans fatty acids content disclosure.

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 FY04 to ensure that claims the industry generates are reviewed as expeditiously as possible.

In reviewing FY03 priorities, IDFA noted CFSAN's mention of its intent to undertake a number of activities with respect to foods derived from biotechnology. IDFA and its members have a strong interest in such an initiative and equally strongly urge CFSAN to place highest priority in this regard on ensuring that any future policy pronouncements are predicated on an abundance of overwhelmingly convincing and unequivocal body of science that such foods pose no public health or safety concerns. IDFA believes that information industry and government provide to consumers about such foods will be critical in determining the future of this technology and the foods that might be derived from it. Thus CFSAN must place a high priority in ensuring that consumers questions are answered by an irrefutable accumulation of scientific analysis.

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 on such a requirement balance providing consumers appropriate information with its regulatory compliance burden -- a goal which should continue to guide CFSAN's work on this project in FY04.

IDFA remains keenly interested in CFSAN's food safety initiatives and has several comments, which follow, on this area of endeavor in FY04.

IDFA wants to work with CFSAN as it considers implementing a new National Drug Residue Milk Compliance Program in FY04. Presently, industry and state regulatory agencies conduct annually over 100,000 tests for non beta lactam residues, a comprehensive data base available to CFSAN that can provide an informed analysis of residue compliance. IDFA believes CFSAN should convincingly demonstrate the need for additional testing beyond this voluntary program. Should that premise be established, IDFA strongly recommends that CFSAN consult closely with industry on the most appropriate and effective method for implementing additional testing and monitoring. In particular, IDFA would take strong exception to any such program that unnecessarily imposes an undue and singular burden on the processing industry.

IDFA has been among the strongest proponents of the hazard analysis and critical control point (HACCP) methodology of dairy plant safety. IDFA remains committed to that principle. For FY04, IDFA makes two recommendations in this

IDFA Comments -- Docket #98N-0359

August 4, 2003

4

regard: one, that CFSAN work with the industry in furthering acceptance and implementation of HACCP for dairy processors especially in view of actions of the National Conference of Interstate Milk Shippers 2003 conference and two, CFSAN should place high priority on providing field staff best available education and training on HACCP methods and principles.

IDFA's members continue to monitor closely CFSAN's listeria action plan. As it did last year, IDFA urges that the agency give high priority to completion of the final draft of the Assessment of the Relative Risks to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods. In setting future policy, this scientific assessment will be critical to determine risk management practices, including assessing regulatory action limits for foods that do not support growth of the organism.

In the international arena, IDFA continues to support strongly CFSAN's support for the work of Codex Alimentarius Commission and the interests of the US dairy industry in the Commission's work. IDFA also urges CFSAN to continue to work to complete determinations of equivalency for European Union and Canadian dairy safety and inspection regimes. As the US industry continues to expand its export opportunities and industry and consumers increase demand for imported products, this function will grow in importance.

Finally, IDFA calls to CFSAN's attention comments on a proposed rule pending since 1987 that would authorize the use of safe and suitable antimycotic agents on the surface of bulk cheddar and colby cheeses and permit uniform declaration of milkfat and nonfat milk or nonfat milk and milkfat as dairy ingredients on the label of colby cheeses. Agency officials committed to considering final action on this proposal for FY04. IDFA strongly encourages CFSAN's bringing this matter to a satisfactory in next year's program.

In closing, IDFA notes again that in many important areas of CFSAN's mandate, industry-government cooperation has been critical in meeting the needs of all interested parties -- consumers as well as manufacturers. That will continue to be the case, IDFA is confident, as CFSAN undertakes new, more challenging priorities and as industry and its consumers evolve. Accordingly, IDFA has welcomed this and past opportunities to comment on the agency's priorities and places highest priority in FY04 in continuing the cooperative relationship between CFSAN and the dairy processing industry.

With best personal regards, I am

Sincerely,



Greg Frazier
Senior Vice President for
International and Regulatory Affairs



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

FAX TRANSMISSION

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Date: August 4, 2003

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Pages: 5

Re: *Docket #98N 0359*

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Please note the attached letter from Greg Frazier, Senior Vice President, International and Regulatory Affairs, International Dairy Foods Association, Washington, DC

Please let me know if I can provide further assistance.

Mary C. Smith
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