

# National Milk Producers Federation

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Agri-Mark, Inc.  
Arkansas Dairy Cooperative Association  
Associated Milk Producers, Inc.  
California Dairies, Inc.  
Cass-Clay Creamery, Inc.  
Continental Dairy Products, Inc.  
Cooperative Milk Producers Assn.  
Country Classic Dairies, Inc.  
Dairy Farmers of America, Inc.  
Dairymen's Marketing Cooperative, Inc.  
Dairyalea Cooperative Inc.  
Ellsworth Cooperative Creamery  
Farmers Cooperative Creamery  
First District Association  
Foremost Farms USA  
Land O'Lakes, Inc.  
Lone Star Milk Producers, Inc.  
Manitowoc Milk Producers Coop.  
MD & VA Milk Producers Cooperative Association, Inc.  
Michigan Milk Producers Assn.  
Mid-West Dairymen's Company  
Milwaukee Cooperative Milk Producers  
Niagara Milk Cooperative, Inc.  
Northwest Dairy Association  
Prairie Farms Dairy, Inc.  
St. Albans Cooperative Creamery, Inc.  
Scioto County Co-op Milk Producers' Assn.  
Select Milk Producers, Inc.  
Southeast Milk, Inc.  
Swiss Valley Farms, Co.  
Tillamook County Creamery Assn.  
United Dairymen of Arizona  
Upstate Farms Cooperative Inc.

July 19, 2005

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

RE: Docket No. 1998N-0359

Dear Sir/Madam:

The following comments are being submitted on behalf of the National Milk Producers Federation (NMPF) to FDA's Request for Comments; Program Priorities in the Center for Food Safety and Applied Nutrition (CFSAN) (Docket No. 1998N-0359). NMPF, headquartered in Arlington, VA, develops and carries out policies that advance the well-being of U.S. dairy producers and the cooperatives they collectively own. The members of NMPF's 33 cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of 50,000 dairy producers on Capitol Hill and with government agencies. NMPF member cooperatives also manufacture a number of dairy products regulated by FDA, including milk, cheese, ice cream, and butter, so CFSAN's priorities are of great interest to NMPF.

Overall, NMPF believes that CFSAN's priorities are appropriate and those items listed as "A" priorities should be the area of focus for CFSAN. Food safety and food security are certainly areas that need a great deal of priority and CFSAN has done a good job of devoting resources to these necessary areas. These activities will be equally important in the next fiscal year and any activities related to food safety and food security should remain as "A" list priorities.

An "A" priority that involves publishing a proposed rule on general principles for standards of identity with USDA (Section 4.4.1) has been conducted. This effort should now shift to addressing the comments received and finalizing the rule. As CFSAN undertakes this effort, care should be taken to ensure that the importance of standards of identity in maintaining product integrity is not lost. The "A" priorities to address cheese (Section 4.4.2) and frozen dessert (Section 4.4.3) standards via a proposed rule and advanced notices of proposed rulemaking are appropriate, as well.

NMPF is concerned that labeling enforcement/compliance is not listed as a priority and encourages CFSAN to make it an "A" priority. CFSAN should add

an “A” priority in this section for addressing enforcement of standards of identity and labeling. Specifically, CFSAN has been inadequate in enforcing compliance in the area of imitation dairy products. There are many non-dairy foods in the market place that use standardized dairy terms as the name of their food. These non-dairy products have continued to blatantly violate the current standards of identity and labeling regulations. As a result of CFSAN’s lack of activity to enforce the current regulations, more and more imitation dairy products have been introduced. Examples of these products include vegetable-based beverages purporting to be milk, cheese, sour cream, butter, and yogurt. NMPF has sent numerous letters to CFSAN and met with CFSAN staff to discuss these egregious violations. No enforcement action has been seen and these products continue to violate the current regulations. NMPF also encourages CFSAN to take the steps necessary to bring these imitation dairy products into compliance with current labeling regulations as soon as possible. Lack of enforcement will only allow these products to proliferate and merely adds to consumers being misled. NMPF has made this request for a number of years in our comments to FDA Priorities and, thus far, our request has been ignored.

NMPF believes that the area of dairy product and raw milk product imports continues to be a challenge for State Regulatory Agencies to address. CFSAN can assist them through a number of priority items. CFSAN should develop a procedure for notifying States that Grade “A” dairy products are being imported. These products are permitted entry by FDA and States are left to address the fact that the products do not meet the requirements of the *Pasteurized Milk Ordinance*. In most cases, the State does not know that the product was imported. CFSAN should develop a method for taking the information gathered from the prior notification requirement and provide it to the States if a Grade “A” product is imported. In addition, the priorities to develop an action plan to address the unlawful importation of cheeses (Section 1.7.4), to issue a field assignment regarding “gourmet” raw milk soft cheeses (Section 1.7.5), and to establish processes and procedures for import enforcement resources (Section 1.3.2) will assist in identifying imported dairy products that do not meet the regulatory requirements of the U.S. The scope of work should also be expanded to include all unlawful dairy products, not just cheeses.

Under Cooperative Programs, CFSAN has identified an “A” priority to develop a strategy to engage stakeholders in meeting WTO commitments related to the regulatory structure of Cooperative Programs. NMPF believes that this effort must be undertaken with great care. The dairy industry relies heavily on Cooperative Programs to regulate the production and processing of safe and wholesome dairy products. There are many activities that we conduct under this program that other countries do not. Any changes to the program or allowances for other countries must be made with care to ensure that U.S. dairy producers and manufacturers are not economically disadvantaged.

NMPF also believes that CFSAN should provide assistance to states that are experiencing an increase in sales of raw milk through cow leasing programs. Raw milk sales directly to consumers have challenged the regulatory system of many States and these sales put the dairy industry's excellent safety record at risk. CFSAN should seek regulations that can help State regulatory agencies address how to best prohibit or regulate raw milk sales to consumers.

CFSAN's "A" priorities addressing dairy safety also appear to be appropriately prioritized. The "B" priority to develop a statistically-based animal drug residue monitoring plan should be changed to reflect the fact that the National Conference on Interstate Milk Shipments has formed a committee to conduct this task. FDA should participate on the committee and provide technical assistance in this effort, rather than undertake it themselves. NMPF believes that CFSAN has placed appropriate priority to validate a test method for the new National Drug Residue Milk Compliance Program (Section 1.13.6) by placing it as a "B" priority and would suggest that this remain a "B" priority for 2006. The current requirement to test every tanker of milk for animal drug residues, coupled with other voluntary testing already conducted by States and industry result in over 4.5 million tests for animal drug residues being conducted each year. Any new program implemented by CFSAN will not add significant numbers to this testing and will not provide any additional data than already exists. NMPF suggests that CFSAN's resources could be better placed elsewhere and that this program should be a low priority item.

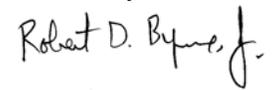
CFSAN's current "A" priority of updating the Federal Import Milk Act Compliance Policy Guide (Section 1.13.3) was completed last year and should be removed from the priority list. This Compliance Guide, however, is the result of outdated regulations and should be updated to better reflect the current practices in the dairy industry. In addition, the current requirements under the Federal Import Milk Act do not reflect the regulations enforced in the U.S. CFSAN should ensure that foreign entities that ship milk into the U.S. under the Federal Import Milk Act are not given preferential treatment nor have lower standards for safety than the domestic dairy industry.

In 2004, CFSAN met the "A" priority to publish for comment the citizen petition to establish a regulatory limit for *Listeria monocytogenes* in foods that do not support its growth (Section 1.7.6). For 2006, CFSAN should address the comments and publish a proposed rule.

Lastly, NMPF encourages CFSAN to complete the work on Bovine Spongiform Encephalopathy that is listed as an "A" priority (Section 1.10). This effort is one of the many safeguards we have to ensure that BSE does not spread in the U.S.

Thank you for the opportunity to submit these comments. If you have any questions or would like additional information, please contact me.

Sincerely,

A handwritten signature in black ink that reads "Robert D. Byrne, Jr." The signature is written in a cursive style with a prominent initial 'R' and a trailing flourish.

Robert D. Byrne, Ph.D.

Vice President, Scientific & Regulatory Affairs