



National Milk Producers Federation

National Milk Producers Federation 2101 Wilson Blvd., Arlington, VA 22201 703-243-6111 FAX 703-841-9328

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.
Dairylea 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 County 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.

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

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 32 cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of 60,000 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.

There is one area of "A" list priorities, however, in which NMPF believes CFSAN has done an inadequate job. This is in the area of Nutrition, Health Claims, and Labeling related to Enforcement/Compliance (Section 2.1.6). While not necessarily related to food safety or security, food labeling is very important to ensure consumers are not being misled by the products they purchase. As CFSAN attempts to "do the most good for consumers," a recommitment to ensuring that foods are appropriately labeled is necessary. In fact, CFSAN acknowledges this by including enforcement/compliance as an "A" priority. While this was a top priority last year, FDA has not taken any action with respect to blatant labeling violations and disregard for standards of identity. NMPF believe that this must be addressed.

Jerry Kozak, President/Chief Executive Officer

James P. (Tom) Camerlo, Chairman

One example of CFSAN's poor performance in labeling enforcement/compliance is 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. Although we reach agreement in meetings that some of the products are mislabeled, no enforcement action has been seen and these products continue to violate the current regulations. NMPF encourages CFSAN to keep enforcement/compliance as an "A" priority. 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 made this request last year in our comments to FDA Priorities and, thus far, our request has been ignored.

An "A" priority that is new involves publishing a proposed rule on general principles for standards of identity with USDA (Section 4.5.3). NMPF is unclear as to the nature of this priority item. Standards of identity exist and should be enforced by CFSAN. NMPF does not understand the intention of a general principles proposed rule.

NMPF believes that the area of dairy product and raw milk imports continues to be a problem for State Regulatory Agencies to address. CFSAN can assist them through a number of priority items. As CFSAN develops the final guidance for notification of imported food shipments, consideration should be given to how to best inform States that Grade "A" dairy products are being imported. These products are permitted entry by FDA and States are left to deal with 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 and provide it to the States if a Grade "A" product is imported. In addition, the current "B" priorities to develop an action plan to address the unlawful importation of cheeses (Section 1.8.7) and to work with the states to eliminate the production and sale of unlawful raw milk cheeses (Section 1.8.8) should be upgraded to "A" priorities. The scope of work should also be expanded to include all unlawful dairy products, not just cheeses. This includes providing assistance to States that are experiencing an increase in sales of raw milk through cow leasing programs.

CFSAN's current "A" priority of updating the Federal Import Milk Act Compliance Policy Guide (Section 1.14.1) was appropriately upgraded last year. This Compliance Guide 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. As the Compliance Policy Guide is updated, CFSAN should ensure that foreign entities that ship milk into the U.S. under the Federal Import Milk Act are not given preferential treatment over the domestic dairy industry.

The "A" priority related to perchlorate (Section 1.10.7) should be expanded to include other areas of the country. CFSAN should conduct a general exploratory survey to determine if a background level exists or if there are areas of the country that have higher levels than others.

CFSAN met the 2004 "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 1.8.1). For 2005, CFSAN should address the comments and publish a proposed rule.

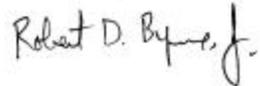
NMPF believes that CFSAN has placed appropriate priority to the implementation of a new National Drug Residue Milk Compliance Program (Section 1.14.3) by placing it as a "B" priority and would suggest that this remain a "B" priority for 2005. The current requirement to test every tanker of milk for animal 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.

NMPF believes that CFSAN has placed the equivalence determination with Canada and the EU (Section 1.14.7) appropriately in the "B" priority level. Much of FDA focus in the new security regulations is to better track and regulate imported products, including dairy products. A determination of equivalence with either Canada or the EU will make this effort even more daunting. Furthermore, NMPF has concerns that, in this era of free trade, equivalence should not be determined in an effort to only allow for more trade. Equivalence should only be determined if the foreign government regulations are, in fact, doing all of the regulatory work that the U.S. regulatory agencies conduct. If U.S. farmers and manufacturers are required to meet a set of regulations to produce and process dairy products, then farmers and manufacturers in other countries must be required to do the same if they intend on competing in the U.S. market place.

Lastly, NMPF believes that the current “B” priority to develop a response to a petition regarding “soymilk” (Section 4.5.6) should not be acted on by CFSAN. In fact, NMPF believes that CFSAN should be taking enforcement action against these illegally labeled products (as discussed previously). While we understand that a petition has been submitted, this does not give companies the permission to violate the current regulations.

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." with a stylized flourish at the end.

Robert D. Byrne, Ph.D.
Vice President, Regulatory Affairs