

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.
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
Just Jersey Cooperative, Inc.
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
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.
Zia Milk Producers

November 29, 2004

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

RE: Docket No. 2004D-0453

Dear Sir/Madam:

The following comments are being submitted on behalf of the National Milk Producers Federation (NMPF) to FDA's Notice; Draft Revised Compliance Policy Guide "Sec. 560.400 – Imported Milk and Cream – Federal Import Milk Act (CPG 7119.05);" Availability (Docket No. 2004D-0453. 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 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 the Federal Import Milk Act regulations are of great interest to NMPF.

The Federal Import Milk Act (FIMA) requirements are out of date. U.S. producers and processors must meet stringent requirements under the *Pasteurized Milk Ordinance*. These requirements exceed those that are required under the FIMA. The plant sanitation scores, microbiological test requirements, and temperature limits are much too high in the FIMA. In addition, there is no somatic cell count limit, animal drug residue testing, coliform count, or phosphatase testing requirement in the FIMA. These requirements should be updated to reflect the same requirements that the U.S. industry must meet and to adequately protect consumers. Specifically, the following changes are needed to make the FIMA consistent with the U.S. domestic requirements:

1. Add a requirement for Brucellosis-free determination. Currently, there is no requirement for a determination as to the brucellosis status of animals, but the U.S. regulations require that milk come from healthy cows with a brucellosis and tuberculosis determination annually.
2. Raise the sanitation score to ≥ 90 . In addition, the inspection sheet used by the foreign country must be similar to what is used domestically. The

Jerry Kozak, President/Chief Executive Officer

Charles Beckendorf, Chairman

current requirements are for a score of 50 out of 100 and the score sheet is not specifically mentioned. U.S. producers and processors must score 90 out of 100 on a specific score sheet.

3. A FIMA permit is issued by the U.S. upon review of records and a new permit is required each year. Inspections must be required each year, rather than relying on a previous year's data to be used on a new permit. The FIMA regulations do not specifically state an inspection time-frame.
4. Change raw milk bacteria count to 300,000/ml for commingled milk and 100,000/ml for individual producers. This will make the FIMA requirements identical to the U.S. Grade "A" requirements.
5. Add a Somatic Cell Count (SCC) standard of 750,000/ml. The FIMA currently does not have a SCC requirement, but U.S. producers must meet the 750,000/ml level.
6. Change raw cream bacteria count to 300,000/ml for commingled milk and 100,000/ml for individual producers for the reasons stated in point 4 above.
7. Add an animal drug testing requirement that is identical to that in the U.S. In addition, add a requirement that milk be tested for any animal drugs not approved for use in lactating animals that are approved in the exporting country. The FIMA does not have any requirement for animal drug residue testing of tankers whereas the U.S. program is very specific and stringent. Also, other countries allow for some animal drugs to be used in lactating animals that the U.S. has specifically prohibited. Milk should be screened for these drugs prior to it entering the U.S.
8. Change pasteurized milk Standard Plate Count to 20,000/ml. The FIMA currently has a requirement of 100,000/ml, which is much higher than the U.S. level for fluid milk.
9. Add pasteurized milk Coliform Count standard of 10/ml. There is no requirement for a coliform count on products under the FIMA.
10. Change pasteurized cream Standard Plate Count to 20,000/ml. The FIMA requirement is 500,000/ml, which is inconsistent with the U.S. requirements.
11. Add pasteurized cream Coliform Count standard of 10/ml. There is no requirement for a coliform count on products under the FIMA.
12. Change pasteurized product temperature requirement to 7°C. Finished products in the US must be kept at or below 7°C whereas the requirement in the FIMA is 10°C.
13. Add a phosphatase testing requirement. There are currently no phosphatase test requirements under the FIMA, but the U.S. has a specific test requirement.
14. Remove the two footnotes which provide exemptions from the microbiological and temperature requirements if the milk is going for specific uses or if the farm is in a close proximity to the processing plant. No such exemption exists for products in the U.S., particularly for the microbiological requirements. Raw milk temperatures may be flexible in the U.S. if the milk is to be processed within a certain period of time, but this is independent of the proximity to the processing plant.

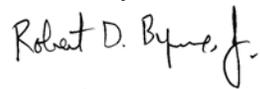
NMPF does not agree with FDA's intention to not subject some products to the FIMA permit requirement. The FIMA specifically addresses milk and cream. Some of the dairy products exempted in the draft CPG fall into the milk and cream category. Sour cream, cultured milk, yogurt, eggnog, acidified milk, dried milk, nonfat dry milk, fortified nonfat dry milk are all milk and cream products. Many of these have standards of identity that are contained in 21 CFR 131 – Milk and Cream. It is clear the FDA considers these to be in the Milk and Cream category. FDA has not provided any rationale for exempting these products from FIMA permit requirements. If these products are to be provided to U.S. consumers, then they should meet the same stringent regulatory requirements expected of the U.S. dairy industry, regardless of where they are produced and processed.

The draft CPG only addresses cow's milk. Any non-bovine milk should also be required to obtain a FIMA permit.

The CGP exempts commercially sterile dairy products. This is not provided for in the FIMA and should be removed from the CPG.

Thank you for the opportunity to provide these comments. If you have any questions or need 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