



National Milk Producers Federation

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Agri-Mark, Inc.
Associated Milk Producers Inc.
Bongards' Creameries
California Dairies, Inc.
Cayuga Marketing
Cooperative Milk Producers Association
Dairy Farmers of America, Inc.
Ellsworth Cooperative Creamery
FarmFirst Dairy Cooperative
First District Association
Foremost Farms USA
Land O'Lakes, Inc.
Lone Star Milk Producers
Maryland & Virginia Milk Producers Cooperative Association
Michigan Milk Producers Association
Mid-West Dairy Farmers' Company
Mount Joy Farmers Cooperative Association
Northwest Dairy Association
Oneida-Madison Milk Producers Cooperative Association
Prairie Farms Dairy, Inc.
Premier Milk Inc.
Scioto Cooperative Milk Producers' Association
Select Milk Producers, Inc.
Southeast Milk, Inc.
Tillamook County Creamery Association
United Dairywomen of Arizona
Upstate Niagara Cooperative, Inc.

August 26, 2020

Dr. Elizabeth Briczinski
Senior Science Advisor
Center for Food Safety and Applied Nutrition
5001 Campus Drive, HFS-009
College Park, MD 20740-3835

Dear Dr. Briczinski:

The National Milk Producers Federation (NMPF) is writing to you on a matter of urgent concern. Throughout 2020, as a result of COVID-19, the dairy industry has suffered great losses associated with supply chain disruptions that has forced our industry to dump large quantities of milk at a time when millions of Americans have scrambled to get food on their tables. Thankfully, government and private feeding programs have gone a long way to improve the situation for both consumers and the dairy industry. However, we now face a situation that could potentially impact the industry in an even more damaging way, and we need your help to avoid that.

As you may know, the dairy industry has experienced numerous economic challenges over the last few years which have taken a toll on both dairy producers and dairy processors. These challenges have only been compounded by the COVID-19 challenges of 2020. Since 2016 nearly 10,000 dairy farms have gone out of business. In addition, several large Grade A dairy processing companies have declared bankruptcy or otherwise been forced to sell their operations. Currently, NMPF is aware of an unprecedented 58 dairy plants and 56 Bulk Tank Unit(s) that have been impacted by recent changes in ownership. While ownership changes are generally routine business transactions, in the dairy industry, it is often more complex.

Recently, we have been informed by state officials that as a result of an FDA Memorandum of Information (aka an M-I, in this case M-I-15-3) the transfer of ownership of a Grade A dairy processing facility from one owner to another, without any changes that would affect food safety, would be delisted as an Interstate Milk Shipments (IMS) facility. The facility would need to await the issuance of a new permit to operate after the facility is re-inspected and re-rated. This would occur despite a plant having been recently inspected and/or rated. The consequences of this approach are potentially dire. Each affected facility would not be able to process and ship milk or other Grade A dairy products in interstate commerce, and as a result, most plants would shut down or dramatically cut back their ability to receive and process farm-level milk. This would lead to reduced processing, negatively impacting shipments of milk to retail and food service and causing milk that can no longer be processed to be dumped. As noted above, the dairy industry has already faced lost revenue because of the dumping of milk this year. If producers are forced to dump milk again because of FDA's failure to help, it could be much worse, and won't be caused by a pandemic, but by unfounded

action by the industry's own regulatory agency. Execution of the current M-I-15-3 is simply unreasonable - it will demoralize farmers, processors and consumers at a time when we are facing the biggest pandemic in 100 years which has and is taking a huge toll on our society.

Over the last few months, many state and federal agencies have worked with the food industry to provide flexibility in their regulations and processes to ensure food from the farms reaches consumers' tables and refrigerators. Unfortunately, we must now request that the agency further adopt a posture of flexibility in resolving this change of ownership issue without shutting down plants or disrupting the flow of milk from farms to processors and across state borders.

NMPF and the dairy industry strongly urge FDA to suspend any requirement, perceived or otherwise, to shut down a milk plant or prevent it from shipping in interstate commerce due to ownership changes and eliminate any negative impacts on BTU's. This can be a temporary solution until this matter can be taken up at the next National Conference on Interstate Milk Shipments (NCIMS), where we believe it should be handled. NMPF would be happy to work with FDA and the delegates to come up with a more palatable permanent solution.

As you are aware, an M-I is not a legal document, it is a document that attempts to convey FDA's thinking on a particular issue, given particular criteria on a particular day. In this case, we have not been able to identify any provision of the Pasteurized Milk Ordinance (PMO) or related documents, that when applied either through statute or regulation would require the delisting, shutdown, re-rating and re-listing of a milk plant due to a change of ownership authority. Unfortunately, many state authorities who actually perform the inspections and ratings read an M-I as the prescribed legal process that must be followed while in actuality, they should follow state laws and procedures as well as the specific procedures provided in the PMO, Procedures and Methods documents. To be clear, we do not object to a state choosing to re-rate a facility at any time, but we do not want the state to feel obligated to re-rate a facility due to unsubstantiated language in an M-I much less for the facility to be delisted until that re-rating is completed. The re-rating could take days or even weeks to complete while facing COVID-19 constraints which could become worse this fall as the seasonal flu emerges and complicates matters.

Further, on November 16, 2017, the Attorney General issued a memorandum ("Guidance Policy") prohibiting Department components from issuing guidance documents that effectively bind the public without undergoing the notice-and-comment rulemaking process. The Policy states:

“Under the Guidance Policy, the Department may not issue guidance documents that purport to create rights or obligations binding on persons or entities outside the Executive Branch (including state, local, and tribal governments), or to create binding

standards by which the Department will determine compliance with existing statutory or regulatory requirements.

The Guidance Policy also prohibits the Department from using its guidance documents to coerce regulated parties into taking any action or refraining from taking any action beyond what is required by the terms of the applicable statute or lawful regulation. And when the Department issues a guidance document setting out voluntary standards, the Guidance Policy requires a clear statement that noncompliance will not in itself result in any enforcement action.

The principles from the Guidance Policy are relevant to more than just the Department's own publication of guidance documents. These principles also should guide Department litigators in determining the legal relevance of other agencies' guidance documents in affirmative civil enforcement ("ACE").

Guidance documents cannot create binding requirements that do not already exist by statute or regulation [Emphasis Added].”

While the Policy was issued to address matters involving “affirmative civil enforcement” the underlying principle is that guidance is guidance, it is not the law and should not be treated as the law.

Given the foregoing and in the best interests of all stakeholders concerned – especially during this period of unprecedented ownership changes in processing facilities and BTU operations -- we strongly encourage FDA to demonstrate sufficient flexibility with respect to streamlining the process for the transfer of ownership without resorting to shutting down dairy processing facilities or stopping the transportation of milk across state borders. Without such flexibility, substantial harm to consumers, processors and dairy farmers will be the end result. We greatly appreciate your time on this matter and are happy to meet with you to discuss the matter further.

Sincerely,

A handwritten signature in black ink, appearing to read "Clay Detlefsen". The signature is fluid and cursive, with a prominent initial "C" and "D".

Clay Detlefsen
Senior Vice President & Staff Counsel

NMPF was organized in 1916 to provide a forum for dairy producers and the cooperatives they own to participate in public policy discussions. NMPF advocates

policies to Congress, U.S. and foreign government agencies, industry organizations, the news media, and the public.