



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

Mount Joy Farmers
Cooperative Association

Northwest Dairy
Association

Oneida-Madison Milk
Producers Cooperative
Association

Prairie Farms Dairy, Inc.

Scioto Cooperative Milk
Producers' Association

Southeast Milk, Inc.

Tillamook County
Creamery Association

United Dairymen
of Arizona

Upstate Niagara
Cooperative, Inc.

September 14, 2024

Dockets Management Staff
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5630 Fishers Lane Rm. 1061
Rockville, MD 20852

Re: Requirements for Additional Traceability Records for Certain Foods; Proposed Exemption for Cottage Cheese Regulated by the National Conference on Interstate Milk Shipments Grade "A" Pasteurized Milk Ordinance. Docket Number: FDA-2024-N-1939

Dear Sir/Madam:

The National Milk Producers Federation (NMPF) is writing in support of the proposed exemption for Grade "A" cottage cheese regulated by the National Conference on Interstate Milk Shipments (NCIMS) Grade "A" Pasteurized Milk Ordinance (PMO). This exemption from the additional traceability records will reduce the recordkeeping burden on Grade "A" cottage cheese manufacturers who are already meeting the highest standards set by the PMO. As pointed to in NMPF's comments on the proposed traceability rule, NMPF believes that including the majority of cheese products was an overstep to begin with.

NMPF, established in 1916 and based in Arlington, VA, develops and carries out policies that advance the well-being of dairy producers and the cooperatives they own. The members of NMPF's cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of dairy producers on Capitol Hill and with government agencies.

21 CFR Section 1.1360(a) states, in part, that FDA will exempt a food or type of entity from the requirements of subpart S when the agency determines that application of the requirements that would otherwise apply to the food or type of entity is not necessary to protect the public health. As stated in the proposed exemption, Grade "A" cottage cheese is regulated under the PMO. The PMO includes requirements specific to cottage cheese to work to decrease any risk of post-pasteurization contamination. These critical factors include pH, filling temperature, and microbial inhibitors and preservatives. The specific actions taken are outlined in the proposed

exemption and PMO. Through these steps and the additional regulatory oversight that comes from being regulated under the PMO which includes inspections by the Regulatory Agency every 3 months, there is no need for the extra steps the traceability rule would impose.

NMPF agrees with FDA's proposal, and we concur with FDA's logical conclusion to exempt cottage cheese. FDA's rationale is correct and is identified below:

We are proposing to exempt IMS listed Grade "A" cottage cheese from the requirements of the Food Traceability Rule because of the specific processing requirements specified in the PMO that address the risk factors that resulted in the commodity "Cheese (made from pasteurized milk), fresh soft or soft unripened" being on the FTL, and because of the enhanced regulatory oversight of the manufacturing of such products. As discussed in the following paragraphs, manufacturers of IMS listed Grade "A" cottage cheese must comply with requirements intended to control pathogens during pasteurization and to prevent contamination during post-pasteurization processing. Additionally, there are requirements pertaining to information that must be documented in records, and provisions that dictate inspectional and sampling frequencies (Ref. 3).

Pasteurization. Both the milk and creaming mixture used in making cottage cheese must be pasteurized. The PMO requires that all pasteurization equipment be tested and inspected by the relevant Regulatory Agency every 3 months.

*Post-pasteurization processing requirements. The cottage cheese processing steps that occur after milk pasteurization prior to packaging can be performed in vessels that are open to the environment, which presents a risk for contamination of in-process food with environmental pathogens, such as *L. monocytogenes*, if sanitary conditions are not maintained. The PMO contains specific requirements for the control of critical factors including, but not limited to, pH, filling temperature, and the use of microbial inhibitors and preservatives to address post-pasteurization contamination (Refs. 3 and 6). These requirements include:*

- *Ensuring that all critical factors are monitored and documented by the processing facility, the records of which are verified by the Regulatory Agency;*
- *Ensuring that capping, closing, and sealing of containers is done in a sanitary manner by approved mechanical equipment (hand capping of IMS listed Grade "A" cottage cheese is not permitted);*
- *Ensuring that Grade "A" cottage cheese is at a pH of 5.2 or below and is either:*
 - *Hot-filled at a temperature at or above 145 °F for containers of 4 ounces or larger, and at a temperature of 155 °F or above for containers of 2.9 ounces (these temperatures prevent the survival of *L. monocytogenes*, a pathogen that might have been introduced into the product from the environment); or*

- cold-filled at a temperature of 55 °F or less, with addition of the microbial inhibitor potassium sorbate at a minimum concentration of 0.06 percent, or another approved inhibitor that provides sustained inhibition of *L. monocytogenes*; and
- Communicating to the Regulatory Agency if there are any formulation or processing changes that affect critical food safety factors (Ref. 3).

Enhanced regulatory oversight. IMS listed Grade “A” cottage cheese manufacturers are subject to stringent regulatory oversight. All milk and milk products manufacturers regulated by the PMO, including IMS listed cottage cheese manufacturers, are subject to a three-tier inspection oversight program that includes inspections by the Regulatory Agency every 3 months, a rating performed by FDA-certified State Rating Officers every 2 years for IMS listing purposes, and check ratings performed by FDA Milk Specialists every 3 years (Refs. 1, 3, and 8). Additionally, during any consecutive 6 months, at least four samples of packaged cottage cheese made from pasteurized milk from each plant that manufactures IMS listed cottage cheese is collected by the Regulatory Agency for analysis (Ref. 3).

*Considering the aforementioned features of regulation of IMS-listed Grade “A” cottage cheese, we tentatively conclude that application of the subpart S requirements to IMS listed Grade “A” cottage cheese is not necessary to protect the public health. As described above, the primary hazard associated with “Cheese (made from pasteurized milk), fresh soft or soft unripened,” which includes cottage cheese, is the risk of post-pasteurization, in-process contamination, specifically with *L. monocytogenes*. This hazard is well controlled when cottage cheese is manufactured in accordance with the PMO. The post-pasteurization processing requirements in the PMO (e.g., requirements for processing steps, including container filling, to be performed under sanitary conditions; requirements relating to pH; requirements for hot-filling and cold-filling; and the requirement that all critical factors are monitored and documented by the manufacturing facility, the records of which are verified by the Regulatory Agency) provide effective control measures for this hazard. Furthermore, cottage cheese with a maximum pH of 5.2 and containing a minimum of 0.06 percent potassium sorbate, when stored at appropriate refrigeration temperature, will prevent *L. monocytogenes* growth. More generally, the PMO imposes stringent food safety requirements at every stage of the manufacturing process, covering both pasteurization and post-pasteurization processing, and also requires labeling to include the plant name or IMS number for product traceability. Frequent inspections that include reviewing production records documenting control of critical factors by both the States and FDA Milk Specialists provide a high level of oversight of these cottage cheese manufacturers. FDA’s own involvement in the PMO and the Grade “A” program—along with the involvement of other public health governmental entities, such as USPHS and our State, Territorial, and municipal partners—provides a high degree of confidence regarding the safety of Grade “A” dairy products. Therefore, we propose to exempt from the Food Traceability Rule IMS listed Grade “A” cottage cheese that is produced and distributed in accordance with the PMO.*

As active participants in the NCIMS cooperative program, NMPF and its dairy producing and dairy processing members strongly value and appreciate the enhanced food safety that is

created and ensured in the cooperative program as reflected by the PMO. The PMO originated as the Standard Milk Ordinance in 1924, and it significantly reduced the risk for foodborne illness in dairy products, thus strengthening consumer confidence in the safety of the milk we drink. Now in 2024, the PMO has stood the test of time and has reached its 100th Anniversary - a tribute to the hard work, diligence and partnership between the federal and state government agencies and the dairy industry.

NMPF thanks FDA for following through with the exemption that was suggested in the preamble of the final traceability rule which identified Grade "A" cottage cheese as suitable for being exempted from the requirements of the Traceability Rule.

Sincerely,

A handwritten signature in dark blue ink, reading "Miquela Hanselman". The signature is written in a cursive, flowing style.

Miquela Hanselman, MPH
Director, Regulatory Affairs