NATIONAL MILK PRODUCERS FEDERATION

James Mulhern, *President & Chief Executive Officer* | Randy Mooney, *Chairman*

November 2, 2015

Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA–2015–N–2596; Understanding Potential Intervention Measures To Reduce the Risk of Foodborne Illness From Consumption of Cheese Manufactured From Unpasteurized Milk

Dear Sir or Madam:

The National Milk Producers Federation welcomes the opportunity to provide comments to the Food and Drug Administration (FDA) on the notice published in the *Federal Register* of August 3, 2015, "Understanding Potential Intervention Measures To Reduce the Risk of Foodborne Illness From Consumption of Cheese Manufactured From Unpasteurized Milk". The National Milk Producers Federation (NMPF), 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 more than 32,000 dairy producers on Capitol Hill and with government agencies. Visit www.nmpf.org for more information.

The public health risks associated with consumption of raw milk and raw milk products are significant and have been reported in the literature. For example, while current statistics estimate 1-2% of reported foodborne outbreaks are attributed to dairy products, of those, about 70% are attributed to raw milk and inappropriately-aged raw milk cheeses[1]. In 2012, the Centers for Disease Control and Prevention (CDC) published a 13-year review (from 1993 to 2006) in the journal *Emerging Infectious Diseases*[2], which is one of the largest done to date. The authors concluded that raw milk is 150 times more likely to cause food-borne illness outbreaks than pasteurized milk, and such outbreaks had a hospitalization rate 13 times higher than those involving pasteurized dairy products.

[1] Centers for Disease Control and Prevention (CDC). 2014. Surveillance for Foodborne Disease Outbreaks, United States, 2012, Annual Report. Atlanta, Georgia: US Department of Health and Human Services, CDC.
[2] Langer, A.J. et al. 2012. Nonpasteurized Dairy Products, Disease Outbreaks, and State Laws – United States, 1993-2006. Emerging Infectious Diseases. 18(3):385-391.

Similarly, in a later review by CDC of foodborne disease outbreaks attributed to cheese between 1998 and 2011, 46% of outbreaks were caused by cheese made from unpasteurized milk and 54% of outbreaks were by cheese from pasteurized milk[3]. It was also noted that 21% of the illnesses in outbreaks caused by cheese made from raw milk resulted in hospitalization versus 6% in outbreaks due to cheese made from pasteurized milk, suggesting the infections caused by pathogens from raw milk are more severe.

There is a preponderance of evidence – of both current scientific literature, as well as recent outbreaks – to indicate that pathogens can survive a 60-day aging process for cheese manufactured using unpasteurized milk. As NMPF has stated repeatedly in past comments to FDA, a robust food safety system is crucial for both public health and the success of the dairy industry overall. NMPF commends FDA for taking steps to identify and evaluate intervention measures that might have an effect on the presence of bacterial pathogens in cheeses manufactured from unpasteurized milk and, toward that objective, NMPF respectfully submits the following comments.

NMPF supports the concept of a performance objective or performance standard for cheeses manufactured from unpasteurized milk.

NMPF would support FDA in developing a performance objective or standard as a replacement for the 60-day aging requirement for cheeses manufactured from unpasteurized milk. To evaluate whether or not a specific intervention or process is sufficient to reduce the risk of foodborne illness from consumption of cheeses manufactured from unpasteurized milk, NMPF refers to a 2004 report from the National Advisory Committee on Microbiological Criteria for Foods[4]. The NACMCF recognized that, while some pasteurization processes (e.g., milk) are based on traditional thermal pasteurization, "alternative non-thermal processes and combinations of processes and treatments for pathogen reduction can be equally effective".

The NACMCF identified four general premises to be applied when considering the efficacy of a process other than thermal pasteurization of milk for assuring protection of public health. These premises, which could be modified based on a proposed technology or intervention, represent a reasonable and science-based approach to

[3] Gould, L.H. et al. 2014. Outbreaks Attributed to Cheese: Differences Between Outbreaks Caused by Unpasteurized and Pasteurized Dairy Products, United States, 1998-2011. Foodborne Pathogens and Disease. 11(7):545-551.

[4] National Advisory Committee on Microbiological Criteria for Foods. 2004. Requisite Scientific Parameters for Establishing the Equivalence of Alternative Methods of Pasteurization. Washington, DC.

evaluate intervention strategies and controls during the manufacture of cheeses made from unpasteurized milk.

1. The most resistant human pathogen must be identified.

   There may be multiple performance standards necessary, depending on the treatment or intervention being applied, and more than one organism may need to be considered for an individual product. For example, application of a bacteriocin with specific activity against Gram-positive bacterial pathogens would suggest a Gram-negative organism be identified as the most resistant pathogen of concern; while a low pH may be more suitable at controlling for pathogenic *E. coli* and, thus, would suggest a Gram-positive pathogen be identified as the most resistant pathogen of concern.

2. The process must be applied at levels of intensity that will assure the safety of the product.

   The manufacturer would need to demonstrate that the interventions or control measures, applied at the specific levels in their product, achieve a specific log reduction of the most resistant pathogen(s). As the NACMCF noted, the level of inactivation needed – and consequently, the level of intervention to be applied – will vary depending on the matrix of the product. This information will be both product- and process-specific and would require verification or, at a minimum, strong supporting scientific evidence.

3. The process must be applied in properly designed and operated equipment, and is dependent on raw material quality.

   While non-thermal technologies applied to milk (e.g., UV light, pulsed electric field, etc.) may not include the well-developed fail-safe systems of the pasteurization process, a cheese manufacturer should be able to consistently demonstrate, as well as appropriately document, the proper function of any equipment upon which they are basing their performance standard.

   This premise from the NACMCF also suggests that raw milk quality should be part of a total quality control system, but not the sole component. Measuring raw milk quality, by itself, is not a sufficient control measure.

4. There must be some means for regulators to verify that the process has been adequately applied.

This is a more difficult premise to apply to product when there is no suitable marker that can easily be measured on a regular basis. For example, while measuring phosphatase inactivation may be appropriate after a thermal treatment, this would not be suitable for use with a non-thermal intervention. Should FDA decide to verify that a process has been adequately applied, NMPF would suggest that this be considered in light of the combination of individual processes or interventions that are applied, to address the overall safety of the product.

NMPF does not support finished product testing as a control measure.

As NMPF commented throughout development of the regulations stemming from the Food Safety Modernization Act (FSMA), finished product testing is not a suitable means to establish that a product is pathogen-free. Finished product testing has a known, high false-negative rate, which limits its utility. Conducting finished product testing on a product that has received a validated intervention or control measure, or combination of measures, provides no added public health benefit.

Finished product testing does have a place – perhaps as part of an overall food safety system when a valid "kill step" has not been applied to a product, or when a product-contact surface of a piece of equipment is inaccessible for environmental swabbing – but should not be considered a control measure on its own.

NMPF supports clear labeling of cheeses made from unpasteurized milk.

FDA requested comment on the extent to which consumers understand the risk of foodborne illness from consumption of cheeses manufactured from unpasteurized milk. For some consumers, specifically those at increased risk and more susceptible than the general population to the effects of foodborne illnesses, food safety advice often includes recommendations to avoid cheeses made from unpasteurized milk (e.g., the *2010 Dietary Guidelines for Americans*). It is imperative that information be available to allow individuals to make informed decisions when consuming dairy products, lest they avoid dairy products altogether.

The 2014 CDC report called for labeling of cheese to include whether the milk used to make it was pasteurized or unpasteurized. As the authors noted in their survey, for a number of cheese-related outbreaks, the pasteurization status of the milk was unknown. Additionally, NMPF has also noted a lack of clear identification of the pasteurization status of milk when cheese is implicated in an outbreak or a recall. Many recall notices distributed by the agency do not indicate whether or not the implicated cheese was made from unpasteurized milk.

Therefore, as this information (e.g., pasteurization status, aging, etc.) seems to be lacking in a consistent manner, NMPF would strongly support this recommendation to increase transparency and to provide this information to consumers, especially for those persons in high-risk groups for foodborne illness. This labeling need not be strictly limited to the pasteurization status of the milk, but could also include the specific technology or intervention(s) employed to assure the safety of the product.

In conclusion, NMPF appreciates the opportunity to provide comments on intervention measures to reduce the risk of foodborne illness from consumption of cheeses manufactured from unpasteurized milk. We recognize that not all cheese is manufactured from milk that has received a pasteurization treatment. There are a variety of thermal and non-thermal interventions that can be implemented, alone or in combination, to reduce the risk of foodborne illness. NMPF looks forward to continuing to work collaboratively with the agency to assure a supply of safe dairy products.

Thank you for the opportunity to share our perspectives. Please contact us if you have additional questions.

Sincerely,

Beth Panko Briczinski, PhD
Vice President, Dairy Foods & Nutrition