



National Milk Producers Federation

2101 Wilson Blvd., Suite 400, Arlington, VA 22201

703-243-6111 • www.nmpf.org

"Connecting Cows, Cooperatives, Capitol Hill, and Consumers"

November 18, 2013

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

Submitted electronically via regulations.gov

Re: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (Docket No. FDA-2011-N-0920; RIN 0910-AG36)

Dear Sir or Madam:

The National Milk Producers Federation, 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.

NMPF supported passage of the Food Safety Modernization Act (FSMA) and recognizes that a robust food safety system is crucial for both public health and the success of our member cooperatives. In these comments we specifically ask for clarification around the definition of "farm" as it applies to the production of raw milk for direct sale to consumers.

The link between raw milk, or milk that has not been pasteurized, and foodborne illness has been well-documented in the scientific literature with evidence spanning nearly 100 years. Raw milk is a key vehicle in the transmission of human pathogens, including *E. coli* O157:H7, *Campylobacter*, *Listeria monocytogenes*, and *Salmonella*.

Current statistics estimate only 1-2% of reported foodborne outbreaks are attributed to dairy products. However, of those, over 70% have been attributed to raw milk and milk products. In a 2012 report¹, the Centers for Disease Control and Prevention (CDC) attributed 73 known outbreaks and 1,571 cases of foodborne illness between 1993 and 2006 to unpasteurized dairy products. The CDC also concluded that unpasteurized milk was 150 times more likely to cause

¹ Langer, AJ, et al. Non-pasteurized dairy products, disease outbreaks, and state laws – United States, 1993-2006. *Emerging Infectious Diseases*. 2012; 18(3):385.

Agri-Mark, Inc.
Arkansas Dairy Cooperative Association
Associated Milk Producers Inc.
Continental Dairy Products, Inc.
Cooperative Milk Producers Association
Dairy Farmers of America, Inc.
Dairylea Cooperative Inc.
Dairymen's Marketing Cooperative, Inc.
Ellsworth Cooperative Creamery
Farmers 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 Dairymen's Company
Northwest Dairy Association
Prairie Farms Dairy, Inc.
Premier Milk Inc.
St. Albans Cooperative Creamery, Inc.
Scioto County Cooperative Milk Producers' Association
Select Milk Producers
Southeast Milk, Inc.
Swiss Valley Farms Company
Tillamook County Creamery Association
United Dairymen of Arizona
Upstate Niagara Cooperative, Inc.
Zia Milk Producers, Inc.

foodborne illness outbreaks than pasteurized milk, and such outbreaks had a hospitalization rate 13 times higher than those involving pasteurized dairy products.

By any science-based metric, raw milk would be classified as a high-risk food. It is not surprising that consumption of raw milk has been opposed by every major health organization in the United States, including the American Medical Association and the American Academy of Pediatrics, as well as FDA, which has referred to raw milk as being “inherently dangerous²”.

FDA has the legal authority to regulate on-farm activities and, in fact, has proposed safety standards for other raw agricultural commodities (i.e., produce, animal feed, etc.). However, it is surprising, despite the clear risk represented by raw milk, that the Agency has omitted to address this sector of the food system in their regulations with the proposed definition of “farm”.

FDA should not consider any activities that result in the preparation of an inherently unsafe product for sale to consumers to be within the “farm” definition (i.e., production of raw milk for direct human consumption should not be considered “harvesting” or “packing”), rather FDA should consider such activities to be outside the traditional business of a dairy farm (e.g., packaging/processing) and subject them to preventive controls requirements as a means of advancing public health.

Given the high-risk nature of raw milk and in the interests of protecting public health, we respectfully urge FDA to re-consider the definition of “farm” as it applies to the production of raw milk for human consumption.

Sincerely,



Jim Mulhern
Chief Operating Officer
National Milk Producers Federation

² Testimony of John F. Sheehan, BSc (Dy), JD, Director of Plant and Dairy Food Safety, Office of Food Safety, Center for Food Safety and Applied Nutrition, US Food and Drug Administration, before the Health and Government Operations Committee of the Maryland House of Delegates, Mar. 15, 2007, <http://www.fda.gov/downloads/Food/FoodbornellnessContaminants/UCM185696.pdf>, accessed 11/8/2013.