



## National Milk Producers Federation

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703-243-6111 • www.nmpf.org  
“Connecting Cows, Cooperatives, Capitol Hill, and Consumers”

Agri-Mark, Inc.  
Arkansas Dairy Cooperative Association  
Associated Milk Producers Inc.  
Continental Dairy Products, Inc.  
Cooperative Milk Producers Association  
Dairy Farmers of America, Inc.  
Dairyalea 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.

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

**Re: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Docket No. FDA-2011-N-0921)**

Dear Sir or Madam:

These comments are an addendum to the original comments filed by the National Milk Producers Federation on November 15, 2013. In evaluating the impacts of the *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety Rule)* on licensed dairy farms with ancillary or incidental sales of fresh produce, our proposed regulatory solutions did not address the needs of Grade “B” licensed dairy farms.

The Grade “A” Pasteurized Milk Ordinance (**PMO**) is adopted by all states in cooperation with and oversight by FDA. The USDA requirements for *Milk for Manufacturing Purposes and its Production and Processing (MMPPP)* provides is adopted by the states for regulation of manufacturing grade milk – Grade “B”. Each state licenses and inspects all commercial Grade “A” and Grade “B” dairy farms and Grade “A” processing plants to assure a safe supply of milk for the U.S. FDA is well aware of the extensive on- and off-farm food safety protections afforded by the PMO and the MMPPP.

### **Regulatory Solution**

This addendum provides a regulatory solution for licensed Grade “A” and Grade “B” dairy farms with ancillary or incidental sales of fresh produce. The first solution is a clarification in the definition of “qualified end-user” as it pertains only to the Produce Safety Rule. Section 419(f)(4) of the Food Drug & Cosmetic Act provides the minimum that FDA must include in the definition of “qualified end-user”. NMPF believes that in the Produce Safety Rule, FDA may interpret this definition without infringing upon Congressional intent to provide appropriate regulatory relief for dairy farms with ancillary or incidental sales of fresh produce.<sup>1</sup> NMPF suggests the following Food Safety Rule §112.3(c) definition of “qualified end-user” (***additions in bold italic***):

“Qualified end-user with respect to a food means the consumer of the food; or a restaurant or retail food establishment (as those terms are defined in § 1.227) that is located:

(i) In the same State as the farm that produced the food; or

<sup>1</sup> FDA tacitly acknowledges the ability to interpret terms and definitions in Food Safety Rule §112.3(a) which states “The definitions and **interpretations [emphasis added]** of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) apply to such terms when used in this part.”

(ii) Not more than 275 miles from such farm.


The term “consumer” does not include a business. ***Additionally, a dairy cooperative or dairy manufacturer is a qualified end-user for milk from a Grade “A” or Grade “B” licensed dairy farm.***

The second solution is a change in the definition of “food” as it pertains only to the Produce Safety Rule. Section 201(f) of the Food Drug & Cosmetic Act provides the minimum that FDA must include in the definition of “food”. NMPF believes that in the Produce Safety Rule, FDA may interpret this definition without infringing upon Congressional intent to provide appropriate regulatory relief for dairy farms with ancillary or incidental sales of fresh produce.<sup>2</sup> NMPF suggests the following Food Safety Rule §112.3(c) definition of “food” (***additions in bold italic***):

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act, includes seeds and beans used to grow sprouts ***and excludes milk from a Grade “A” or Grade “B” licensed dairy farm.***

Thank you for the opportunity to comment to comment on the Produce Safety Rule and its impact on dairy farms with ancillary or incidental sales of fresh produce. These comments are an addendum to the original comments filed by the National Milk Producers Federation on November 15, 2013. We are happy to discuss any of our comments or suggestions.

Sincerely,



Jamie Jonker  
Vice President, Scientific & Regulatory Affairs

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<sup>2</sup> *Ibid.*