



National Milk Producers Federation

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

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Associated Milk Producers Inc.
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Cooperative Milk Producers Association
Dairy Farmers of America, Inc.
Dairylea Cooperative Inc.
Dairymen's Marketing Cooperative, Inc.
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First District Association
Foremost Farms USA
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Maryland & Virginia Milk Producers Cooperative Association
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Prairie Farms Dairy, Inc.
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Scioto County Cooperative Milk Producers' Association
Select Milk Producers
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Tillamook County Creamery Association
United Dairymen of Arizona
Upstate Niagara Cooperative, Inc.
Zia Milk Producers, Inc.

November 30, 2011

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

Re: Food and Drug Administration Docket No. FDA-2011-N-0529, Burden of FDA FSMA Fee Amounts on Small Business

Dear Sir or Madam:

The National Milk Producers Federation (NMPF) respectfully submits the following comments regarding the Food and Drug Administration's (FDA) request for information about the burden of FDA Food Safety Modernization Act (FSMA) fee amounts on small businesses. 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 31 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.

Section 107 of FSMA amends section 743 of the Federal Food, Drug, and Cosmetic Act to provide FDA with authority to assess and collect fees from industry for the agency's costs associated with certain activities – specifically, for costs associated with certain domestic and foreign facility reinspections, failure to comply with a recall order, and certain importer reinspections. FDA was also directed to propose guidelines in consideration of the burden of fee amounts on small businesses.

With respect to dairy processing facilities, we encourage FDA to define a small business consistent with the Small Business Administration's (SBA) standard, which is 500 employees or less. Application of this same definition for purposes of FSMA's fees would provide consistency between federal regulations and certainty for small businesses.

However, with respect to dairy farms, NMPF maintains that the SBA standard – a dairy farm must have revenues of less than \$750,000 per annum – is outdated, and that its application in this would be inequitable. In 2011, this standard will represent, on average, a farm with about 170 cows and no non-dairy-related revenue. This is less

Jerry Kozak, President/Chief Executive Officer

Randy Mooney, Chairman

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than the average licensed dairy herd, and considerably less than the minimum size to capture maximum economies of scale in milk production. To date, modification of this standard has not been sought in most farm industries, because there is little application to farming of the Federal contracting and regulation to which the SBA standards are most commonly applied. One exception is the egg business, which bears considerable similarity to dairy farming; the SBA size standard for egg production is \$12.5 million, and the standard for cattle feedlots is \$2.5 million. (See http://www.sba.gov/sites/default/files/Size_Standards_Table.pdf)

Applying the SBA standard of 500 employees or less to the proposed fee structure for reinspections and recall orders for food processing businesses is appropriate, and we encourage FDA to use this standard, or a roughly equivalent revenue-based standard, for dairy farms, as well. Therefore, NMPF maintains that small business consideration should be given to all, or to nearly all, dairy farm operations. To apply a different, smaller standard to dairy farms than to dairy processing plants under the same program would be inequitable, and would represent a significant burden in a very competitive business with very low margins.

Thank you for the opportunity to provide comments and your continued efforts to engage industry stakeholders on issues related to food safety and public health. NMPF is available to provide additional information.

Sincerely,

A handwritten signature in red ink that reads "Jamie Jonker". The signature is written in a cursive, flowing style.

Jamie Jonker, Ph.D.
Vice President, Scientific & Regulatory Affairs
National Milk Producers Federation