



National Milk Producers Federation

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

Agri-Mark, Inc.
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Associated Milk Producers Inc.
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Cooperative Milk Producers Association
Dairy Farmers of America, Inc.
Dairyalea Cooperative Inc.
Dairymen's Marketing Cooperative, Inc.
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FarmFirst Dairy Cooperative
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Southeast Milk, Inc.
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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:

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.

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 dairy cooperative and dairy producer members. We appreciate the need for an enhanced food safety system and support the Food and Drug Administration's (**FDA**) efforts as the agency promulgates rules to implement the FSMA. NMPF will submit comments on the suite of FDA proposed rules to implement FSMA. These comments pertain to the proposed rule on *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety Rule)*, issued under authority of the FSMA.

Overview

Due to the definition of "farm"¹, some licensed dairy farms will be subject to the Produce Safety Rule because they have ancillary or incidental sales of fresh produce. These operations are primarily dairy enterprises but may sell some fruits and vegetables, through on-farm stands, local farmers' markets, Community Supported Agriculture share programs, direct sales to markets or restaurants, or other distribution streams. Other small farms with sales levels of fruits and vegetables identical to or greater than these licensed dairy farms will be exempt from part or all the Produce Safety Rule due to the FDA proposed exemptions.^{2,3}

¹ Produce Safety Rule §112.3 defines "farm" as a "facility (as defined in §1.227 of this chapter) in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood) or both."

² Produce Safety Rule §112.4(a) provides a full exemption from the Produce Safety Rule based on a three-year sales average for "food" of \$25,000 or less per year.

³ Produce Safety Rule §112.5 provides a qualified exemption from the Produce Safety Rule based on a three-year sales average for "food" of \$500,000 or less per year if a majority of the food is sold to a qualified end user as defined in §112.3(c).

Since under the proposed rule, sales of all “foods”⁴ are cumulated to determine the exemption (as a result of the definition of “farm”), virtually all dairy farms with ancillary or incidental sales of fresh produce will be ineligible for the exemptions entirely due to sales of milk (even without consideration of dairy animal sales). This result is anomalous, in that the *quantity* of produce sales from the dairy operation would pose no more or less public health risk than identical quantities of sales from the other farms that FDA has determined to exempt from its rule.

Additionally, licensed dairy farms typically sell their milk to a farmer-owned cooperative or other first handler, which does not appear to meet the proposed rule’s test for “qualified end-user.”⁵ Therefore, even if they have total “food” sales substantially below \$500,000 (but above \$25,000), dairy farms with ancillary or incidental sales of fresh produce will be subjected to the Produce Safety Rule’s requirements, even though similar non-dairy farms producing equal or *larger* quantities of produce will be exempt.

This result is all the more ironic in that the dairy sales themselves are highly regulated under the Grade “A” Pasteurized Milk Ordinance (**PMO**) adopted by all states in cooperation with and oversight by FDA. States license and inspect all commercial dairy farms and Grade “A” processing plants to assure a safe milk supply for the U.S. FDA is well aware of the extensive on- and off-farm food safety protections afforded by the PMO.

To treat the produce output of comparable farms in an equitable fashion, **FDA should not include milk sales from licensed dairy farms toward the threshold for exempting farms from the Produce Safety Rule.** Inasmuch as the exemption threshold is intended to represent a regulatory judgment about public health risks from fresh produce, balancing risk mitigation with administrative feasibility, the same level of regulation should apply to farms with the same level of produce sales.

Regulatory Burden

The Produce Safety Rule applies only to fruits and vegetables grown for human consumption. Thus, the rule itself would not subject farms to any direct regulation of their *dairy* production. However, an unnecessary regulatory burden is placed on dairy farms with ancillary or incidental sales of fresh produce because the rule considers all “food” sales from a farm (including dairy sales) in determining whether the farm is exempt from its fruit and vegetable provisions.

This unnecessary regulatory burden for both the full exemption and the qualified exemption is easily demonstrated based on current milk price (\$20.30/cwt October 2013)⁶ and average milk production (21,697 lbs. per cow 2012).⁷ A full exemption from the Produce Safety Rule is based on a three-year sales average for “food” of \$25,000 or less per year. Based upon the

⁴ Produce Safety Rule §112.3 defines “food” as “§201(f) of the Federal Food, Drug, and Cosmetic Act to wit “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.” This clearly includes milk in the definition of “food” for the Produce Safety Rule.

⁵ Produce Safety Rule §112.3 defines “qualified end-user” as “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 (ii) Not more than 275 miles from such farm. The term “consumer” does not include a business.”

⁶United State Department of Agriculture (USDA), National Agricultural Statistics Service (NASS), Agricultural Statistics Board. Agricultural Prices. ISSN: 1937-4216. October 31, 2013.

<http://usda01.library.cornell.edu/usda/current/AgriPric/AgriPric-10-31-2013.pdf>

⁷ USDA, NASS, Agricultural Statistics Board. Milk Production. ISSN: 1949-1557. February 20, 2013.
<http://usda01.library.cornell.edu/usda/nass/MilkProd//2010s/2013/MilkProd-02-20-2013.pdf>.

aforementioned milk price and production, a dairy farm with six (6) cows would surpass the “food” sales threshold on sales of milk alone. Based on dairy industry structure, NMPF analysis indicates that virtually no dairy farm with ancillary or incidental sales of fresh produce would qualify for this exemption.

A qualified exemption from the Produce Safety Rule is based on a three-year sales average for “food” of \$500,000 or less per year if a majority of the food is sold to a “qualified end user”. Based upon the aforementioned milk price and production, a dairy farm with 114 cows would surpass the “food” sales threshold just on sales of milk. Based on dairy industry structure with an average herd size of 187 cows per farm⁸ and the previously stated fact that milk sales are not to a “qualified end-user”, NMPF analysis indicates that nearly all licensed dairy farms with ancillary or incidental sales of fresh produce would not qualify for this exemption.

Regulatory Impact

According to the *2007 Census of Agriculture*⁹ (see **Table 1**): 1,315 dairy farms reported vegetable (vegetables, melons, potatoes, and sweet potatoes) sales of \$35.3 million in 2007 (\$26, 900 per dairy farm); 783 dairy farms reported fruit (fruits, tree nuts, and berries) sales of \$58.1 million (\$74,200 per dairy farm); and 57,237 dairy farms reported milk (milk and other dairy products from cows) sales of \$30.9 billion (\$539,400 per dairy farm). Additional data from the *2007 Census of Agriculture* on dairy farm numbers and sales for milk, fruits, and vegetables by state are appended to these comments. NMPF analysis indicates that licensed dairy farms with ancillary or incidental sales of fresh produce are not eligible for a full exemption and few if any will receive a qualified exemption (see **Regulatory Burden**); therefore, based on data from the *2007 Census of Agriculture*, between 1,315 and 2,098 licensed dairy farms (between 2.3% and 3.7%)¹⁰ will be subject the proposed Produce Safety Rule.

FDA utilized the *2007 Census of Agriculture* as a data source for the *Analysis of Economic Impacts – Standard s for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption (Economic Analysis)*¹¹ – the same source NMPF used for its analysis. In this Economic Analysis, FDA has estimated that the Produce Safety Rule will cover 4,693 small farms (“food” sales less than \$500,000 per year) and 8,571 large farms (“food” sales \$500,000 or more per year)¹² – 13,264 small and large farms. This would suggest between 9.9% and 15.8% of all small and large farms subject to the Produce Safety Rule are dairy farms.

Based upon our review of the Economic Analysis, NMPF believes that FDA omitted most if not all of the 1,315 and 2,098 licensed dairy farms with ancillary or incidental sales of fresh produce in this Economic Analysis. This omission is likely due to the definitions of “farm”, “food”, and “qualified end-user” resulting in FDA significantly overestimating the number of licensed dairy

⁸ *Ibid.* Calculated from 9,203,000 dairy cows on 49,331 licensed dairy farms in 2012.

⁹ The Census of Agriculture, taken every five years, is a complete count of U.S. farms and ranches and the people who operate them. The Census looks at land use and ownership, operator characteristics, production practices, income and expenditures, and many other areas. <http://www.agcensus.usda.gov/Publications/2007/index.php>

¹⁰ Some licensed dairy farms may have both vegetable and fruit production, however this cannot be delineated from the *2007 Census of Agriculture*. Therefore the universe of dairy farms subject to the Produce Safety Rule is cannot be precisely determined, so a range is provided.

¹¹ FDA. *Analysis of Economic Impacts – Standard s for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption*. <http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM334116.pdf>

¹² *Ibid.* Table 1: Covered Domestic Farms and Farms Eligible for Qualified Exemptions and Farms Not Covered: Summary of Costs for Proposed Produce Safety Rule.

farms with ancillary or incidental sales of fresh produce which would be eligible for either a full or qualified exemption (see **Overview** and **Regulatory Burden**).

In the Economic Analysis, FDA has estimated an average annual regulatory cost of compliance of \$12,972.36 for a small farm (“food” sales less than \$500,000 per year) and \$30,566.23 for a large farm (“food” sales \$500,000 or more per year).¹³ As previously stated, NMPF believes that the Economic Analysis does not accurately reflect the economic impact on licensed dairy farms with ancillary or incidental sales of fresh produce due to exclusion of milk sales. Using this information from the Economic Analysis, NMPF has analyzed the economic burden of the Produce Safety Rule on dairy farms with ancillary or incidental sales of fresh produce (see **Table 2**).

NMPF estimates the economic burden of the Produce Safety Rule to be between \$17.1 million and \$64.1 million annually for licensed dairy farms with ancillary or incidental sales of fresh produce.¹⁴ This represents between 18.3 to 68.6 percent of the total value of fruit and vegetable sales on these farms – a significant and perhaps prohibitive compliance burden for those dairy farms that will affect the economic viability of their fruit and vegetable enterprises. **NMPF believes that the significant compliance burden of the Produce Safety Rule will force the vast majority of licensed dairy farms with ancillary or incidental sales of fresh produce to cease fruit and vegetable production**

Table 1. Profile of U.S. Dairy Farms (NAIC Code 11212, "Dairy cattle and milk production") with Fruit and Vegetable Production, 2007

	United States
Market value of agricultural products sold and government payments \ Total \ Total sales \ Vegetables, melons, potatoes, and sweet potatoes (farms)	1,315
Market value of agricultural products sold and government payments \ Total \ Total sales \ Vegetables, melons, potatoes, and sweet potatoes (\$1,000)	35,312
Market value of agricultural products sold and government payments \ Total \ Total sales \ Vegetables, melons, potatoes, and sweet potatoes (\$1,000 per farm)	26.9
Market value of agricultural products sold and government payments \ Total \ Total sales \ Fruits, tree nuts, and berries (farms)	783
Market value of agricultural products sold and government payments \ Total \ Total sales \ Fruits, tree nuts, and berries (\$1,000)	58,093
Market value of agricultural products sold and government payments \ Total \ Total sales \ Fruits, tree nuts, and berries (\$1,000 per farm)	74.2
Market value of agricultural products sold and government payments \ Total \ Total sales \ Milk and other dairy products from cows (farms)	57,237
Market value of agricultural products sold and government payments \ Total \ Total sales \ Milk and other dairy products from cows (\$1,000)	30,872,020
Market value of agricultural products sold and government payments \ Total \ Total sales \ Milk and other dairy products from cows (\$1,000 per farm)	539.4

¹³ *Ibid.* Table 123: Summary of Costs for Proposed Produce Safety Rule.

¹⁴ The number licensed of dairy farms classified as small or large (per FDA Economic Analysis) cannot be delineated from the *2007 Census of Agriculture*. Therefore the compliance cost universe for dairy farms subject to the Produce Safety Rule cannot be precisely determined, so a range is provided. See Footnote 10 for additional detail.

Table 2. Compliance Cost of Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Dairy Farms with Fruit and Vegetable Production

	FDA Small Farm Definition	FDA Large Farm Definition
Total Produce Sales (2007 Census of Agriculture)	\$93.4 million	\$93.4 million
Compliance Cost (Low Estimate 1,315 Dairy Farms)	\$17.1 million	\$40.2 million
Compliance Cost to Sales Ratio (Low Estimate 1,315 Dairy Farms)	18.3 percent	43.0 percent
Compliance Cost– High Estimate (High Estimate 2,098 Dairy Farms)	\$27.2 million	\$64.1 million
Compliance Cost to Sales Ratio (High Estimate 2,098 Dairy Farms)	29.1 percent	68.6 percent

Regulatory Solution

There certainly is a sales threshold volume of produce that would justify regulation under the Produce Safety Rule, whether or not the produce farm also had a dairy operation. However as proposed, the Produce Safety Rule places an unnecessary compliance burden on dairy farms with ancillary or incidental sales of fresh produce (see **Overview, Regulatory Burden, and Regulatory Impact**) when non-dairy farms with comparable or greater produce sales are exempted. NMPF believes that one or both of the following proposals is necessary to address this issue.

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.¹⁵ 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
- (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” Pasteurized Milk Ordinance 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

¹⁵ 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.”

regulatory relief for dairy farms with ancillary or incidental sales of fresh produce.¹⁶ 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” Pasteurized Milk Ordinance licensed dairy farm.”**

Summary

NMPF supported passage of the Food Safety Modernization Act and recognizes that a robust food safety system is crucial for both public health and the success of our dairy cooperative and dairy producer members. Through our support for the Pasteurized Milk Ordinance for many decades, we have amply demonstrated our dedication to supplying a wholesome, safe product to consumers. We appreciate the need for an enhanced food safety system and support the Food and Drug Administration's efforts as it promulgates rules to implement the FSMA. In analysis of the Produce Safety Rule, NMPF has identified a significant compliance burden of the Produce Safety Rule that will force the vast majority of licensed dairy farms with ancillary or incidental sales of fresh produce to cease produce production.

This compliance burden is due to the definition of “food” and “qualified end-user” which results in milk sales from licensed dairy farms counting towards the threshold for full and qualified exemptions from the Produce Safety Rule. NMPF analysis indicates this will require between 1,315 and 2,098 licensed dairy farms with ancillary or incidental sales of fresh produce to experience Produce Safety Rule compliance costs of \$17.1 million and \$64.1 million annually. This represents from 18.3 to 68.6 percent of fruit and vegetable sales on these farms – a significant compliance burden for those dairy farms that will affect the economic viability of their fruit and vegetable enterprises. NMPF believes that FDA can address this issue with the suggested minor changes in the definitions of “food” and “qualified-end user”.

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. We are happy to discuss any of our comments or suggestions.

Sincerely,

A handwritten signature in purple ink that reads "Jamie Jonker". The signature is cursive and stylized.

Jamie Jonker
Vice President, Scientific & Regulatory Affairs

¹⁶ *Ibid.*