



NATIONAL MILK
PRODUCERS FEDERATION

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

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Cooperative
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Associated Milk
Producers Inc.
Continental Dairy
Products, Inc.
Cooperative
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Association
Dairy Farmers of
America, Inc.
Dairymen's Marketing
Cooperative, Inc.
Ellsworth
Cooperative
Creamery
Farmers
Cooperative
Creamery
FarmFirst Dairy
Cooperative
First District
Association
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Farms USA
Land O'Lakes, Inc.
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Maryland & Virginia
Milk Producers
Cooperative
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Michigan Milk
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Prairie Farms
Dairy, Inc.
Premier Milk Inc.
Scioto County
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Milk Producers'
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Select Milk
Producers, Inc.
Southeast Milk, Inc.
St. Albans
Cooperative
Creamery, Inc.
Swiss Valley Farms
Company
Tillamook County
Creamery
Association
United Dairymen
of Arizona
Upstate Niagara
Cooperative, Inc.
Zia Milk
Producers, Inc.

June 30, 2014

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

Re: Docket No. FDA-2013-N-1425: Focused Mitigation Strategies to Protect Food Against Intentional Adulteration.

Dear Sir or Madam:

The National Milk Producers Federation welcomes the opportunity to provide comments to the Food and Drug Administration (FDA) on the proposed rule to address intentional adulteration of the food supply, specifically with respect to dairy farms. 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.

On-farm milk destined for pasteurization is not a high-risk food.

While farms are not "facilities" as defined in this rule, Section 420(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) provides FDA with the authority to determine whether dairy farms may be subject to certain aspects of the intentional adulteration regulations. In considering whether activities that occur on dairy farms represent a high risk for intentional adulteration, FDA concluded fluid milk storage and loading in a dairy farm operation pose a significant vulnerability. However, for a number of reasons, we disagree with the premise that on-farm milk destined for pasteurization is a high-risk food and, therefore, we maintain that activities on dairy farms should not be addressed through this rule.

First and foremost, on-farm milk destined for pasteurization would be a poor choice of vehicle for an act of intentional adulteration. The geographic distribution pattern of raw fluid milk for pasteurization is generally both broad (moving between various regions of the country) and constantly fluctuating (moving to meet specific processing demands), which presents a serious challenge in determining the ultimate destination of farm milk. Likewise, without necessarily knowing the precise processing facility or the finished product to which on-farm milk is destined and given the varying shelf-lives of different dairy products, it is difficult to predict the length of time that will lapse

between adulteration of milk on the farm and the consequences of that act through consumption. For example, fluid milk has a shelf life of a few weeks; products like ice cream, nonfat dry milk or whey powder may have shelf-lives of two years; and some cheeses may be aged for even longer.

Secondly, many dairy products are used as ingredients in other foods. For example, milk may be manufactured into mozzarella cheese which, moving through distribution channels, could be shredded and added to frozen pizzas which are then further distributed. The broad distribution of these final products to consumers over such a large geographic area severely limits the shock value that may result from an act of intentional adulteration. Also, because of their use in other foods, in addition to pasteurization, dairy ingredients may be exposed to multiple heating steps (for example, pizzas prepared at high baking temperatures or, in the case of milk powder being added to the dough of a snack or grain-based dessert, the milk would have been pasteurized and dried before being baked in the final food). This would limit the risk of an intentional adulteration event caused by heat-labile agents.

Additionally, dairy farmers currently implement a number of general security strategies to protect the investment of their property, equipment, animals, and milk supply, which further reduce any risk that may be otherwise represented by on-farm milk destined for pasteurization and which we will discuss in later in these comments. Some of these have been implemented at FDA's direction (for example, "Guidance for Industry: Dairy Farms, Bulk Milk Transporters, Bulk Milk Transfer Stations and Fluid Milk Processors: Food Security Preventive Measures Guidance"), while others have been industry-led efforts (for example, seals on tanker trucks or the Secure Milk Supply Plan).

Section 420(c) of the FD&C Act directs FDA to apply intentional adulteration regulations "only to food for which there is high risk of intentional contamination". We believe the inclusion of dairy farms would be outside of the scope of this rule because of the existing industry practices cited above, as well as the uncertainty around the fate of on-farm milk prior to pasteurization (unknown point/time/form of consumption). NMPF maintains that on-farm milk destined for pasteurization would not represent a food having a high risk of intentional adulteration and, therefore, we recommend that FDA exempt dairy farms from food defense regulations.

Should FDA decide to require dairy farms to comply with specific aspects of food defense regulations, we recommend such requirements be developed in close collaboration with the dairy industry as well as other state and federal stakeholders through the National Conference on Interstate Milk Shipments (NCIMS). NCIMS provides an ideal forum to address the risk of intentional adulteration posed by dairy farms. Given the complexities around trying to identify, implement and regulate appropriate and effective mitigation strategies on dairy farms, FDA would be wise in seeking the collective expertise of this unique food safety partnership of Federal and State regulators, academia and industry. With that in mind, we also offer the following comments on other details of the proposed rule:

Economically motivated adulteration.

NMPF agrees with FDA not to require dairy farms to employ measures to address economically motivated adulteration through this rule. As FDA noted, there are not appropriate science-based strategies or measures intended to protect against economically motivated adulteration that can be applied at the dairy farm, and preventive controls would not address such adulteration when committed by the farm itself. We also agree with FDA's conclusion about the lack of inputs into milk on a dairy farm that could be subject to economically motivated adulteration that could cause serious adverse health consequences or death.

Addressing dairy farms through CGMPs.

As farms are not subject to the HACCP-type system of preventive controls prescribed in section 418 of the FD&C Act, NMPF agrees that, should FDA establish food defense requirements for dairy farms, they should not mandate HACCP-type controls. Instead, a Current Good Manufacturing Practice approach (CGMP) could identify the broad, generally applicable mitigation strategies that dairy farm operators must implement without specifying how those strategies must be accomplished. Given the diversity in size, location, and physical structure/layout of dairy farms, a CGMP approach must allow for a variety of site-specific considerations and, if FDA opts for this approach, as no singular mitigation strategy would be appropriate for all dairy farms, NMPF recommends a suite of focused mitigation strategies be considered acceptable for implementation.

Limiting access to the milkhouse and bulk milk storage tank.

In the preamble to the rule, FDA discusses the concept of limiting access to raw milk storage as one potential food defense measure that dairy farms may take to minimize the risk of raw fluid milk from intentional adulteration. FDA also acknowledged the difficulties involved in limiting access to the milkhouse on dairy farms – the milkhouse includes multiple routes of entry as well as multiple non-farm personnel with regular or expected access (e.g., state food safety sanitarians inspectors, veterinarians delivering medications, equipment repair personnel, chemical suppliers, bulk milk weighers and samplers, drivers collecting bulk milk for transport to processing and storage facilities, etc.).

The preliminary regulatory analysis estimated locking the bulk milk tank would cause farm workers an average of 15 minutes of lost productivity per day (91 hours per year, \$1,700 per year per farm) and \$5,000 per farm in initial costs (locks, training, etc.). However, this does not take into account the lost productivity of state inspectors (decreased number of farm visits each day, etc.) and the lost productivity of milk truck drivers. The start-up costs could be much higher considering the current shortage of FSMA educational materials directed at dairy farms, the price of milk tank locks (and multiple keys), and the impact on dairy farmer margins. The estimated \$2,400 per farm

per year annualized cost (\$140 million per year for all dairy farms) is not a reasonable cost with a true food safety benefit.

A requirement to severely limit access to the milkhouse (for example, through locking the milkhouse or locking the bulk milk tank) would not be recommended by NMPF. Locking the milkhouse presents logistical challenges to dairy farm operations and would not be practical given the access that is readily needed by various personnel (and is, in fact, expected by some state food safety inspectors) as well as that, while locking the door to the milkhouse might deter a random act of intentional adulteration by an outsider, it would not discourage someone with inside knowledge from accessing the raw milk storage tank via other routes. Limiting access to the bulk milk tank through tank locks only mitigates threats from a single access point, while hampering state inspectors, farm operators, milk tanker drivers, and others.

Current mitigation strategies employed on dairy farms to limit access to and secure raw milk storage include both physical and best practice protocols. Examples of physical elements used to limit access to and secure raw milk storage include security lighting, limiting farm site access to a single point of entry, and posted signs regarding farm site security. Best practice protocols used to limit access to and secure raw milk storage include employee training and visitor access standard operating procedures.

It is also notable that many elements of food defense (i.e., mitigation strategies) are often already being employed on dairy farms for reasons related to biosecurity, one example being the Secure Milk Supply (SMS) Plan (for more information, please refer to <http://securemilksupply.org/>). Through the cooperation of industry, state and federal animal health officials, in an effort to prevent, minimize, and control the spread of animal diseases, a basic framework and set of support tools have been developed to aid the industry in the event of an FMD (foot-and-mouth disease) outbreak. Biosecurity performance standards and general protocols have been developed for the dairy industry to limit the entry and/or spread of FMD virus on dairy farms, via milk tankers, and at processing plants.

As noted in our comments above, NMPF recommends that FDA exempt dairy farms from food defense regulations or, should FDA decide to include dairy farms, further drawing on the concepts of the SMS Plan, we would encourage FDA to adopt an approach whereby dairy farms would have a food defense plan (a suite of risk-based CGMPs) that is implemented only when a credible threat of intentional adulteration against the milk supply is identified. As is done with the SMS Plan, these enhanced biosecurity measures would take into consideration existing production practices and could be rapidly implementable. Industry is able to work collaboratively within specific states and regions to customize the application and implementation of SMS performance standards. Given the diverse nature of the dairy industry (farm size, distance to processing plants, climatic differences, variations in management practices, local regulations, etc.), it is important to recognize that there are multiple ways to

accomplish the same standard, and are best developed with this flexibility in mind at the local/regional level.

Food defense training requirement.

As an alternative to requiring CGMPs or focused mitigation strategies to limit access to and secure raw milk storage, FDA has suggested a requirement that dairy farm operators receive food defense awareness training. NMPF would not recommend food defense training as a requirement and questions the food safety benefit of such a criterion. It would not be practical to require dairy farms to have the trained dairy farm operator or other designated and trained individual(s) present on the farm at all times. Likewise, given the short-term nature of some dairy farm workers, it would not be reasonable to include food defense training as a pre-requisite for all employees on dairy farms.

Scope of requirement.

FDA also requested comment on the scope of dairy farms that should be subject to any requirements that may be established in a final rule. For example, dairy farms (n=28,500) with less than 50 dairy cows contribute only 4.2% of total US milk production, while dairy farms (n=3,300) with 500 or more dairy cows contribute 63% of the total US milk production by volume (see Table 1). However, milk from even very small dairy farms may be pooled with milk from other farms in raw milk transport trucks and storage tanks at milk processing and storage facilities, potentially resulting in a public health impact from intentional adulteration that is disproportionate to the size of the dairy farm. Additionally, current market conditions can result in significant mobility of milk from an individual dairy farm to differing processing plants. As a result, schemes whereby certain dairy farms are excluded from requirements based on marketing stream would be extremely challenging to implement consistently (e.g., direct sale to consumers or other end users; pooling with milk from other farms; supplied to the Grade A Milk system for the production of fluid milk; or use in production of cheese). NMPF recommends that if any requirements are established in a final rule related to dairy farms, they are applied regardless of size or marketing stream, with flexibility in allowing individual dairy farms to best determine how those general requirements can be met.

Table 1. Number of Milk Cow Operations, Percent of Inventory, and Percent of Milk Production by Size Group - United States: 2011 and 2012¹

Head	Operations		Percent of Inventory		Percent of Production	
	2011	2012	2011	2012	2011	2012
1-29	19,400	18,800	1.6	1.6	1.0	1.0
30-49	10,100	9,700	4.3	4.3	3.2	3.2
50-99	14,800	14,500	11.2	11.3	9.4	9.5
100-199	8,300	7,900	11.9	11.8	10.9	10.7
200-499	4,000	3,800	12.5	12.5	12.6	12.6
500-999	1,6500	1,570	12.3	11.9	12.6	12.4
1,000-1,999	950	950	13.7	14.0	15.7	15.9
≥2,000	800	780	32.5	32.6	34.6	34.7
Total	60,000	58,000	100.0	100.0	100.0	100.0

Proposed Animal Food Exemption.

When it comes to the particular risk of intentional adulteration, there is separation between humans and animals as the proposed rule is aimed at preventing intentional adulteration from acts intended to cause massive public health harm. Congress recognized this in creating Section 418(m) in the FD&C Act, which provides for the option for exemption or changes between animal and human preventive control rules. Because risk is significantly different between humans and animals, Congress specifically allowed for modified requirements for animal food.

In Section 420(c) of the FD&C Act, FSMA required FDA to establish regulations for facilities to consider the potential risk of intentional adulteration of food, applicable only to food “for which there is a high risk of intentional contamination... that could cause serious adverse health consequences or death to humans or animals”. FDA has concluded in this proposed rule that animal food is not at a high risk for intentional contamination.

NMPF supports this conclusion by FDA and its proposed exemption for animal food. FDA has made the appropriate distinction in determining the level of risk between humans and animals in consultation with the Department of Homeland Security, and is recognizing this distinction as Congress intended. This distinction between human and animal food is supported by the purpose of the proposed rule – which FDA has indicated is “to protect food from intentional adulteration when the intent is to cause large-scale public harm.” More specifically, FDA should distinguish between human food and animal food in this intentional adulteration proposed rule because animal food has a significantly lower risk of impacting *human* health. The effects of contaminants fed to dairy animals would likely be observed in those animals well before any risk to humans would occur.

¹ U.S. Department of Agriculture, National Agricultural Statistics Service. Farms, Land in Farms, and Livestock Operations 2012 Summary. February 2013.

Clearly, a terrorist organization contaminating animal food could cause harm to animals, however, it is highly unlikely any contaminant would have the same effect on humans. Ultimately, this proposed rule is about health safety risks to humans. Animal food does not present a high health safety risk to humans.

Raw milk for direct consumption should not be exempt from food defense requirements.

In contrast to raw fluid milk destined for pasteurization, NMPF recommends FDA not exempt dairy farms producing raw milk for direct human consumption from food defense regulations. Unlike as was discussed previously, raw milk for direct human consumption and raw milk products represent very attractive targets for intentional adulteration. Because they will not be pasteurized prior to human consumption, raw milk and raw milk products have an expanded list of potential contaminants, including those that are heat-sensitive. There is also no significant amount of dilution of contaminants, as would occur with milk that is commingled prior to pasteurization and processing. Raw milk has the additional vulnerability of having a short shelf-life, and, additionally, some states do allow for retail sales of raw milk, which expands the potential geographic range of an attack beyond on-farm sales. For these reasons, we strongly urge FDA to consider taking an approach to minimize the specific vulnerabilities of what is clearly a high-risk food and, recognizing that these farms are outside of the scope of the NCIMS process, we encourage FDA to address this vulnerability through the traditional rulemaking process.

Conclusion.

NMPF maintains that on-farm milk destined for pasteurization would not represent a food having a high risk of intentional adulteration and, therefore, we recommend that FDA exempt dairy farms from food defense regulations. We would welcome the opportunity to further engage in productive dialogue and collaborate with FDA on the issue of protecting the food supply from acts of intentional adulteration and to determine how to best achieve our common goal of assuring a safe and wholesome supply of milk and dairy foods.

Please contact us if you have additional questions.

Sincerely,



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