NATIONAL MILK PRODUCERS FEDERATION

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Associated Milk Producers Inc.
Bongards' Creameries
Cooperative Milk Producers Association
Cortland Bulk Milk Producers Cooperative
Dairy Farmers of America, 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.
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Maryland & Virginia Milk Producers Cooperative Association
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Select Milk Producers, Inc.
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St. Albans Cooperative Creamery, Inc.
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Tillamook County Creamery Association
United Dairymen of Arizona
Upstate Niagara Cooperative, Inc.
Zia Milk Producers, Inc.

December 15, 2014

Submitted Electronically Via Regulations.gov

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

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); Food and Drug Administration

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. 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 companies. We appreciate the need for enhanced preventive controls and support the Food and Drug Administration's (FDA) efforts as it promulgates rules to implement the FSMA.

We also greatly appreciate the lengths that FDA has gone to by engaging stakeholders, soliciting input, and responding to feedback. We commend the Agency for their change in the thinking on key provisions of the proposed rules and the reopening of the comment period. We offer the following general comments on the supplemental proposed rule on current good manufacturing practice (CGMP) and preventive controls.

As NMPF has requested in other comments submitted on the proposed preventive controls rule, farm establishments and dairy processing facilities participating in the Grade "A" program and regulated by the Pasteurized Milk Ordinance (PMO) should be exempt from, or otherwise be deemed compliant with, the FSMA preventive controls rule. After months of review and discussion, we still feel that addressing food safety of Grade "A" facilities is best under the regulations of the PMO, and any minor adjustments needed be handled through the process established by the National Conference on

Interstate Milk Shipments (NCIMS). Therefore, while we offer the following thoughtful comments on the supplemental proposed rule, we do so from the perspective that Grade "A" farm establishments and dairy processing facilities will continue to be regulated under the PMO, while non-Grade "A" farms and dairy facilities will not be exempt from the FSMA preventive controls rule.

DEFINITION OF "FARM"

NMPF acknowledges that today dairy farms with cropland are frequently comprised of multiple, often non-contiguous fields due to geographic and topographic conditions, local development patterns, and other factors. Additionally, some dairy farm owners may have multiple dairy farm establishments either in close geographic proximity (e.g., same county) or very disparate geographic areas (e.g., separate states) which may have some management and movement of animals and/or feed in common.

Under the Grade "A" program and regulated by the Pasteurized Milk Ordinance (PMO), each of the dairy farm establishments will have a separate and unique state permit to operate and produce milk. For the purposes of the definition of "farm" for dairy farm establishments, NMPF proposes that each unique and individually state permitted dairy farm establishment is an individual "farm" regardless of common ownership or geographic proximity. This will prevent conflict and interference with the permitting and inspection activities of the Grade "A" program while maintaining food safety.

SIGNIFICANT HAZARD

NMPF prefers the use of the phrase "Significant hazard" and believes it is an improvement over a hazard "reasonably likely to occur". A significant hazard is defined as:

> a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the control.

NMPF believes the phrase and the definition provide a great deal more clarity and certainty for determining what hazards should be part of the preventive controls plan and what hazards need not be addressed.

With respect to potential hazards that might be considered for inclusion in a food safety plan, we request that milk and dairy product temporal hazards – specifically, aflatoxin, pesticides, and radiological contamination – should be addressed on a temporal basis and not require monitoring and verification activities on an ongoing basis.

We note that what is foreseeable can in fact change over time – as FDA learned with respect to peanut butter. Further, the mere fact that something is foreseeable does not mean that it is actionable, which is significant. For example, in 2007, NMPF staff were

involved in an instance where naturally-occurring radiation raised a possibility of contaminating milk on two farms. In over 25 years of working in the dairy industry, that is the only time we are aware such situation has arisen. Prior to 2007, the notion of milk being contaminated with radiation from groundwater would not have been foreseeable to most or all knowledgeable persons in food manufacturing. It was ultimately determined that the naturally-occurring radiation was well below the derived intervention level and there was no need for any mitigation whatsoever. Therefore, while foreseeable, it was not significant.

In recent years, the dairy industry was faced with another radiation issue, radiation from Fukushima, Japan's damaged nuclear reactors which became airborne and were deposited on U.S. soil and crops. Ultimately those crops were consumed and infinitesimally small amounts of Japanese radiation showed up in a handful of fluid milk samples taken by EPA and other authorities. All test results were again below the derived intervention level and rather quickly, as radiation does for short half-life isotopes, the radiation disappeared altogether. This is an example of another source of radiation that is foreseeable, though again not significant.

During the rulemaking process much has been said about including radiological hazards in food safety plans, but based on the current proposed definition and considerable experience with radiation in the dairy industry, it is fairly clear to NMPF that, while radiologic hazards can exist from time to time, they are unlikely to result in being determined to be a significant hazard which would require mitigation on an ongoing basis and need to be addressed through a food safety plan. This is especially true due to the robust radiological surveillance programs that occur in the U.S. EPA and the states monitor the drinking water; EPA monitors air, water and soil under the RadNet program. FDA monitors milk under the Total Diet Study, and nuclear power plants monitor the milk from dairy farms within 5 miles twice a month. Given all these surveillance programs, the likelihood that milk could get contaminated with radiation unknowingly to the point it rose to the level of being a significant hazard is largely unthinkable.

That said, we acknowledge a nuclear disaster here in the U.S., or in a relatively nearby country, or the detonation of a nuclear weapon or dirty bomb could alter that and then and only then should a preventive controls plan require mitigation against this hazard.

Aflatoxin is another hazard that is temporal in nature and, therefore, should be minimally addressed in a food safety plan. Aflatoxin contamination is currently addressed by USDA's monitoring of grain crops for the presence of aflatoxin, in conjunction with monitoring by USDA and state Departments of Agriculture for drought conditions. The individual states determine what monitoring of raw milk, if any, is necessary to best protect health and minimize risk. We request that FDA concur with our assertion that, as such, aflatoxin in milk does not represent a "significant hazard" that would require ongoing monitoring by dairy processing facilities.

Similar monitoring programs for pesticides and chemical contaminants are implemented by individual states, as well as by USDA (USDA-AMS Pesticide Data Program) and FDA (Total Diet Study). Given the historically low incidence and low significance of this contamination in milk and dairy products, we request that FDA recognize these monitoring programs as sufficient for addressing these contaminants for the dairy industry as a whole, rather than by requiring individual dairy processing facilities to implement an ongoing monitoring program.

NMPF requests FDA acknowledge that temporal contaminants (such as radiological hazards, aflatoxin or pesticides) are frequently not "significant hazards" in milk and dairy products. Further NMPF seeks FDA's recognition and acknowledgement that in many cases the testing done by FDA and others is sufficient for protecting public health and not require ongoing monitoring by individual dairy facilities in order to be compliant with the FSMA preventive controls rule.

One way to address this is to use placeholders. For example, for aflatoxin, the food safety plan could state it is a known potential hazard but mitigation could be reserved or addressed as "to be implemented as directed by the state authorities when necessary", which is in essence how it is being handled today, which has worked well for a very long time. This alternative would work for the other temporal contaminants as well.

PRODUCT TESTING

NMPF is pleased that FDA recognizes that product testing is broader than finished product pathogen testing. In general, finished product pathogen testing is not used with great frequency in the dairy processing industry, largely because it generally will not detect a problem unless the production run was highly contaminated and the contaminant was homogeneous throughout.

NMPF and IDFA previously commented extensively that a broad-based mandate to conduct finished product pathogen testing is unsound. The key points we made in those comments which bear repeating here are:

1. It is common practice in the dairy industry to use environmental monitoring/testing in our plants, and we support its use in our industry.

2. The dairy industry also uses product testing on a regular basis, and we support its use in our industry. Specifically, the dairy industry conducts extensive testing on raw milk prior to pasteurization.

3. The dairy industry does not view product testing as being synonymous with finished product pathogen testing. "Product testing" for us is very broad and includes many types of tests. We test raw milk prior to pasteurization for a number of substances and parameters and we conduct in-process tests as well. In-process testing can be used to look for chemical, physical and microbial contaminants. Indicator tests like coliform testing can be used for determining proper sanitation. Finally, alkaline

phosphatase testing is a check for proper pasteurization. Many of these tests are done in our plants on a daily basis and will continue to be performed to assure our systems are operating properly. It is important to point out that Congress never used the term "finished" or "finished product" in FSMA.

4. FDA has repeatedly rejected the notion that finished product testing is a means to establish that a product is pathogen-free, and we concur. Moreover, conducting finished product testing on a pasteurized dairy product, where the pasteurization process has been properly validated, provides no added public health benefit and would incur significant, unjustified costs.

5. Under FSMA, it is the dairy company's responsibility to incorporate environmental monitoring and product testing, as appropriate, to verify that its preventive controls are working. This is consistent with FSMA's overall approach to the food safety plan which places primary responsibility on the manufacturer to establish an appropriate food safety program, of which verification is a part.

In addition we presented information about how costly finished product pathogen testing could be for the fluid milk industry alone – over $600 million per year – with little or no gain in public health. Besides factoring in the high cost of testing, FDA should consider what additional information, if any, such testing would reveal. For example, in 2006, a prison dairy in California was implicated in an illness outbreak that involved 11 different prisons and sickened as many as 1,300 inmates. Yet investigators never found any pathogens in the milk samples that were collected. This is an excellent example of where finished product testing has a high false-negative rate, thereby significantly diminishing its value. It obviously would be a wrong conclusion to say that these samples verified that there was nothing wrong with the milk when, according to all regulatory authorities involved, that was clearly not the case.

Outside of prison dairies, illness outbreaks associated with pasteurized fluid milk are rare. An outbreak in 2009 was ultimately found to have occurred due to external contamination of the product packaging. Had the fluid milk been tested, the tests would have come back negative. In an outbreak in 2007 involving fluid milk (Whittier Farms), it was ultimately determined that the facility did not have any environmental monitoring program whatsoever. If that facility had had a robust environmental testing program, as is the standard in our industry, that outbreak in all likelihood would not have occurred. This example underscores the point that environmental monitoring is precisely where resources and efforts should be directed.

Yogurt is another product where it makes very little sense to employ finished product pathogen testing. As presented in a journal article by Dr. Kathleen Glass and Dr. Russell Bishop, it was determined that yogurt with active cultures at a pH of 4.6 or below before storage, which was processed in compliance with the GMPs prescribed by the Pasteurized Milk Ordinance (PMO), is inherently safe and does not support the growth of pathogenic organisms. (See Glass KA, Bishop JR, Food Protection Trends. [2007, 27(6):380-388]). The

article goes into great detail as to why this is the case and, in fact, presents evidence that even post-pasteurization contamination in many cases is eliminated. For example, *Listeria monocytogenes*-inoculated yogurt showed a 3-log decrease over a 12-hour period at 4°C. Similar reductions were shown for *Staphylococcus aureus*, *Salmonella* and *E. coli* O157:H7. This is yet another example of a food where finished product pathogen testing would produce absolutely no benefit, though it certainly would come with a cost.

NMPF is not opposed to all finished product pathogen testing. There are clearly situations where finished product testing is beneficial, in particular for products that have not been subjected to a "kill step". For example, while FDA and NMPF both strongly oppose the sale and consumption of raw milk on public health grounds, that type of product would be an excellent candidate for a broad and robust pathogen testing program. But in any FDA regulations implementing FSMA, the need for finished product testing must be the exception and not the general rule. As described above, there is no scientific basis for requiring routine finished product testing for pasteurized milk or yogurt products.

In 2010, *Food Safety Magazine* published a very insightful article entitled "Shifting Emphasis from Product Testing to Process Testing", by William H. Sperber, Ph.D. Dr. Sperber posits that "HACCP is a preventive system designed to control significant identified hazards by means of validated process control measures. It does not depend on product testing to assure food safety. In fact, HACCP was developed precisely because product testing cannot reliably detect low-level defects such as low-incidence pathogen contamination in foods." He also states that "Pathogen testing in pasteurized dairy products is not required or necessary." Dr. Sperber points out the numerous shortcomings of product testing and advocates testing the process as is done under the PMO. In his conclusion, Dr. Sperber states "To more effectively assure the safety of all foods, I believe that we must spend more effort on validating and implementing process controls and process testing measures while eliminating unnecessary product testing." Dr. Sperber is a former chair of the IFT Division of Food Microbiology and was appointed five times by the U.S. Secretary of Agriculture to the National Advisory Committee on Microbiological Criteria for Foods.

We concur with Dr. Sperber's views on product testing. We support an integrated approach to testing as a verification activity (not as a "control" step), applied as appropriate and necessary depending on the risk and value of test results to improving food safety. FSMA itself is very general as to the role of testing, and FDA should take a risk-based approach and allow each facility to customize its testing program to take into account the unique circumstances within that facility. This is particularly important given the sliding scale of benefits and costs for different types of testing. Specifically, environmental testing is often the most beneficial type of testing in terms of verifying the effectiveness of sanitation and other preventive controls and is also cost-effective. There are also important roles for the testing of incoming raw materials/ingredients, particularly where the manufacturing process does not apply a "kill step" to control or prevent the presence of pathogens in finished product. Finally, finished product testing has very severe statistical limitations as a testing program, as acknowledged by the

agency in the Appendix to the proposed rule. In most cases, lot-by-lot testing of finished products does not help improve food safety. Facilities should be given the flexibility to determine whether finished product testing will improve food safety for their products and apply it only in those circumstances. Without substantial evidence that the facility determinations are unsound, FDA inspectors should not second-guess a facility's reasoned approach.

ENVIRONMENTAL MONITORING

NMPF agrees with FDA and supports the concept of environmental monitoring being required when a ready-to-eat (RTE) product is exposed to the environment prior to packaging and the packaged food does not receive a heat treatment that would significantly minimize an environmental pathogen that could contaminate the food when it is exposed.

We appreciate FDA's recognition that an environmental monitoring plan be specific to the facility, the food, and the nature of the preventive controls applied. NMPF supports a qualified individual determining the details of an environmental monitoring program, and emphasizes that FDA not be overly prescriptive with respect to corrective actions to address the presence of an environmental pathogen or appropriate indicator organism. Any positive results from environmental monitoring should be addressed by the corrective action procedures developed by the qualified individual and not addressed by FDA through enforcement action without consideration of the uniqueness of the facility, food and preventive controls. As with product testing, without substantial evidence that the facility determinations are unsound, FDA inspectors should not second-guess a facility's reasoned approach.

SUPPLIER VERIFICATION

NMPF is not clear on the applicability of the supplier verification requirements for dairy, especially with respect to raw material receiving (e.g. incoming raw milk for pasteurization). As FDA is undoubtedly aware, pasteurization is a critical control point in the dairy processing industry and there is ample evidence, historic and otherwise, to attest to the fact that it works well as a preventive control. If pathogens were our only concern as a potential significant hazard, it is clear that we would not need a supplier verification program for raw milk because we adequately control that inherent significant hazard at our receiving facilities through pasteurization.

Pasteurization is, however, not a solution for all hazards. Generally it is not seen as a mitigating factor with respect to antibiotic and pesticide residues or for addressing trace chemicals or toxins. There are a number of mechanisms that are in use to address those hazards and, as stated in our comments above, we do not believe some of these hazards (specifically temporal hazards of aflatoxin, radiological contaminants, and pesticides) rise to the level of being a "significant hazard" that would trigger a risk-based supplier program, although we acknowledge some uncertainty here. So there may be a potential for a need for a supplier verification program that involves suppliers of raw milk.

One additional, non-temporal category of hazards that should be included for consideration in a food safety plan for dairy processing facilities is veterinary drug residues. The PMO Appendix N Program addresses the testing and surveillance of bulk milk tankers for the presence of drug residues. Given the extensive distribution network for raw milk destined for pasteurization (varying widely over geographic distance as well as varying with time), it makes the most sense for this hazard to be addressed with a program that is uniform across the country for all dairy farms and dairy processing facilities. While an exemption to the preventive controls rule for Grade "A" facilities would include many dairy processing facilities, NMPF respectfully requests that FDA recognize the PMO Appendix N Drug Residue Testing Program, including where Appendix N has otherwise been adopted (as is the case for non-Grade "A" dairy processing facilities when residue testing programs are overseen by the state), as adequate for controlling drug residues in milk and dairy products.

The potential implementation of a supplier verification program for a raw milk supply raises a somewhat frightening prospect given the way milk is commingled on a daily basis and the fact that a plant may be supplied by different farms on any given day, a pattern that could also change daily, depending on supply and demand. This further begs the question of who the supplier is in many cases, as the majority of milk in the U.S. moves through a cooperative system. In those circumstances, is the coop the supplier or is the supplier the farms that supply to the coops? The actual business transaction in a coop system is that the coop and the processing entity enter into a supplier agreement. The farm supplies its milk to the cooperative under a second agreement.

Further, we note that FDA's Grade "A" milk safety program under the PMO requires inspection of each dairy farm in the program twice annually, and if the farm has deficiencies FDA delists that establishment thereby preventing milk from the farm from being shipped in interstate commerce. As such, we believe a risk-based supplier program is unwarranted for raw milk supplied to a dairy processing facility regardless of whether the preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the significant hazards. In essence, we believe that FDA's Grade "A" activities match precisely with the substitution provision proposed as §117.136 (e) which reads:

> Substitution of inspection by FDA or an officially recognized or equivalent food safety authority. (1) Instead of an onsite audit, a receiving facility may rely on the results of an inspection of the supplier by FDA or, for a foreign supplier, by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted.

Given the frequency of state and FDA farm inspections and the decades of experience behind them, we are comfortable that the PMO adequately addresses supplier verification requirements of FSMA. Rather than require implementation of a supplier verification program that would have little utility and would be extremely complex, NMPF again strongly reiterates in these comments that, with respect to PMO-regulated dairy processing facilities, FDA should exempt them from FSMA's Preventive Controls rule or otherwise deem them to be in compliance.

FDA also requested comment on examples of circumstances when it would be necessary and appropriate to receive raw materials and ingredients on a temporary basis from an unapproved supplier. If the Interstate Milk Shippers (IMS) list is considered a list of approved suppliers, when a dairy farm is de-listed, it may potentially be viewed as an "unapproved supplier" to Grade "A" processing facilities. However, while a de-listed farm cannot ship milk to Grade "A" facilities, milk from that farm may be shipped to non-Grade "A" processing facilities provided that they continue to hold a valid state permit to produce milk for manufacturing (non-Grade "A") purposes. NMPF submits this as one example where milk from an "unapproved" dairy farm may be reasonably processed until the farm is able to be re-inspected and be re-listed.

With respect to ingredients from non-dairy or non-PMO facilities and outbound non-PMO products from our processing facilities, we are pleased that FDA has increased the flexibility in the manner in which a facility can verify its supplier. Whereas the previous proposal appeared to mandate an initial and an annual onsite audit, we note that is not the case here – though it is clear that FDA has a strong preference for such activity. Given that strong preference, as NMPF and IDFA expressed during the comment period for the Foreign Supplier Verification Rule, we are now reiterating our concern about over-auditing – sometimes referred to as "audit fatigue". Inasmuch as this is a separate rulemaking we feel compelled to raise our concern here as well. If a facility supplies to hundreds of customers, theoretically such a facility could be exposed to having hundreds of initial and annual audits. We do not believe that such a volume of audits would enhance food safety; rather, it would distract facility personnel from their duties and in all likelihood detract from food safety.

FDA should develop industry guidance which encourages collaboration and information sharing so as to prevent redundant and counterproductive audits. Further, FDA should make clear such guidance applies to both domestic and foreign operations.

Even today over-auditing is a problem. Currently, a domestic dairy facility may be audited or inspected over a dozen times a year by a variety of government and third party auditors. Those audits take precious resources and can constitute a burden. FDA should encourage those subject to the rule to accept an audit performed by any of the bona fide authorities where it is warranted. That said, certain food manufacturers conduct their own audits and have developed extensive expertise in doing so. Under no circumstances should this rule or a corresponding domestic supplier verification requirement affect those audits.

EXISTING RECORDS

NMPF supports the addition of §117.330 to subpart F as drafted. §117.330 reads as follows:

Use of existing records.

(a) Existing records (e.g., records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this subpart F. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this subpart F.
(b) The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing records.

We appreciate FDA's thoughtful clarification on this point.

EMA INCLUSION

NMPF appreciates FDA's recognition that milk and dairy products produced in the United States have not been associated with a pattern of economically motivated adulteration (EMA) involving melamine. We agree with FDA's conclusion in the preamble to the proposed rule that melamine would not be considered a significant hazard that must be addressed in a food safety plan when using domestically-produced milk and milk products.

Overall, NMPF does not believe that EMA should be included in dairy food safety plans. While EMA for milk and dairy products is a significant issue outside the U.S., it is not a problem domestically. In part, this is a result of the robust regulatory scheme and inspections provided for under the PMO as well as the ample criminal sanctions for tampering with the food supply. In addition, milk is routinely screened for one of the most common economic adulterants – water. The U.S. dairy industry ensures that its milk has not been "watered down" by routinely scrutinizing raw milk tankers for added water with a cryoscope which will indicate whether the freezing point of the milk has been increased by the addition of water.

HOLDING HUMAN FOOD BY-PRODUCTS INTENDED FOR USE IN ANIMAL FOOD

NMPF appreciates FDA's reconsidering the impact of FSMA regulations on holding human food by-products intended for use in animal food. Not imposing additional requirements to human food processors already complying with human food safety requirements when supplying food processing by-products for animal food is a common sense approach.

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If we may provide any further information to assist the agency, please do not hesitate to contact us.

Respectfully submitted,

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