

35th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #: JC-1-Council III

Committee: Liaison

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

The *Grade "A" PMO* is incorporated by reference in Federal specifications for procurement of milk and milk products; is used as the sanitary regulation for milk and milk products served on interstate carriers; and is recognized by the Public Health Agencies, the milk industry, and many others as the national standard for milk sanitation. The *Grade "A" PMO* adopted and uniformly applied will continue to provide effective public health protection without being unduly burdensome to either Regulatory Agencies or the dairy industry. It represents a "grass-roots" consensus of current knowledge and experiences and as such represents a practical and equitable milk sanitation standard for the nation. The *Ordinance* has stood decades long the test of time as the industry's *food safety plan*. This proposal formally recognizes the *Ordinance* as such.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

Despite the progress that has been made, occasional milkborne outbreaks still occur, emphasizing the need for continued vigilance at every stage of production, processing, pasteurization and distribution of milk and milk products. Problems associated with assuring the safety of milk and milk products have become extremely complex because of new products, new processes, new materials and new marketing patterns, which must be evaluated in terms of their public health significance.

The United States Public Health Service (USPHS) activities in the area of milk sanitation began at the turn of the century with studies on the role of milk in the spread of disease. These studies led to the conclusion that effective public health control of milkborne disease requires the application of sanitation measures throughout the production, handling, pasteurization, and distribution of milk and milk products. These early studies were followed by research to identify and evaluate sanitary

measures, which might be used to control disease, including studies that led to improvement of the pasteurization process.

The USPHS/FDA alone did not produce the *Grade "A" PMO*. As with preceding editions, it was developed with the assistance of Milk Regulatory and Rating Agencies at every level of Federal, State, and Local Government, including both Health and Agriculture Departments; all segments of the dairy industry, including producers, milk plant operators, equipment manufacturers, and associations; many educational and research institutions; and with helpful comments from many individual sanitarians and others.

Recognition of the *Ordinance* as a facility's food safety plan will continue to keep time and attention focused on the complex issues of milk safety which are addressed in this *Ordinance*.

C. Proposed Solution

Changes to be made on page(s):	vi (Introduction)	of the (X - one of the following):
X 2013 PMO	2011 EML	
2013 MMSR	2400 Forms	
2013 Procedures	2013 Constitution and Bylaws	

Inserted the underlined text in the Introduction Section of the Ordinance as indicated below:

The following *Grade "A" PMO*, with Appendices, shall constitute the facility's food safety plan as required by 21 CFR 117.126 and is recommended for legal adoption by States, Counties, and Municipalities, in order to encourage a greater uniformity and a higher level of excellence of milk sanitation practice in the United States.

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35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: JC-2-Council III

Committee: Liaison

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This proposal would add language to the Grade “A” Pasteurized Milk Ordinance (PMO) recognizing that PMO requirements provide a comparable degree of food safety assurance with respect to, at a minimum, microbiological hazards and drug residues as the Food and Drug Administration’s (FDA) requirements for Hazard Analysis and Risk-Based Preventive Controls (Preventive Controls) under the FDA Food Safety Modernization Act (FSMA).

**B. Reason for the Submission and
Public Health Significance and/or Rationale Supporting the Submission**

FSMA was enacted to enable FDA to better protect public health by strengthening the food safety system. One key provision of FSMA’s Preventive Controls, requires science-based preventive controls across the food supply. It places the responsibility on food facilities to identify and evaluate hazards that could affect food safety, and then implement preventive measures to significantly minimize or prevent those hazards resulting in a safe food product.

The PMO similarly takes a preventive approach to food safety by requiring numerous preventive measures that contribute to producing a milk product that is free of microbiological hazards and illegal drug residues. Those measures include, but are not limited to, requirements for facility structures, equipment, sanitation practices, employee hygiene, time and temperature process controls, and good manufacturing practices. The PMO also contains extensive and very specific testing frequencies and acceptable levels for microbiological contaminants in raw milk as well as finished Grade “A” milk and milk products. In addition, state regulatory agencies inspect all processors of Grade “A” milk and milk products a minimum of once every three months. In sum, there is a comprehensive regime in place for consistently delivering milk safety.

As a result, the PMO has a historical track record that demonstrates a high level of food safety for

Grade “A” milk and milk products. In fact, recent information reveals that milk and milk products continue to be associated with less than one percent (<1%) of reported disease outbreaks. Nonetheless, without further action by this Conference, FDA could feel legally obligated to implement and enforce the FSMA Preventive Controls regulations in Grade “A” dairy plants at the same time that State Dairy Regulatory Agencies enforce the PMO. This could result in unnecessary and/or duplicative requirements that will not improve food safety and will be costly to implement for FDA, State Dairy Regulatory Agencies, and dairy plants.

Although the PMO and FDA’s Preventive Controls regulations use different food safety “tools,” they provide a similar set of protections and a comparable degree of food safety assurance. Accordingly, the PMO should be recognized as using its requirements to provide a comparable degree of food safety assurance with respect to, at a minimum, microbiological hazards and drug residues consistent with the Preventive Controls provision of FSMA (proposed 21 CFR Part 117 Subpart C). As a result, FDA should recognize that proposed 21 CFR Part 117 Subpart C does not need to apply to Grade “A” dairy plant microbiological hazards and illegal drug residues since these are addressed in the PMO.

This recognition of comparability and the federal/state partnership would be consistent with FSMA. First, FSMA points directly to the PMO as a model that FDA should consider in preparing the Preventive Controls regulations. Second, FSMA directs FDA to leverage and integrate state food safety systems, which includes utilizing the existing NCIMS program. Third, FDA’s regulations under FSMA must acknowledge the differences in risk posed by different foods, such as the low risk presented by Grade “A” milk and milk products under the PMO regulatory scheme. Fourth, FSMA explicitly allows FDA to rely on state inspections in order to meet its inspection frequency mandate. If FDA can rely upon a state inspection under the PMO for inspection frequency purposes, then the PMO should be recognized as a comparable food safety regime.

Finally, FSMA’s expressed exemption from the proposed Preventive Controls requirements for facilities in compliance with other food safety regimes such as the FDA Seafood HACCP Program (21 CFR 123), the FDA Juice HACCP Program (21 CFR 120), the FDA Infant Formula requirements (21 CFR 106 & 107), the FDA Low Acid Canned Food requirements (21 CFR 108, 110 & 113) (for microbiological hazards), and FDA’s Dietary Supplements regulations (21 CFR 111), illustrates Congress’s desire to prevent duplicative regulatory requirements that would not advance food safety when there is an existing set of requirements in place that achieves a comparable level food safety assurance.

This proposal also does have precedent in that FDA has already recognized that regulatory programs with different food safety “tools” than those prescribed in FSMA and its proposed Preventive Controls regulations are acceptable (i.e., FDA’s recognition that New Zealand has a comparable food safety system). If this recognition can be achieved with a foreign country, it would seem appropriate to achieving such recognition for a long-standing, successful dairy regulatory program in the US (i.e., NCIMS and the PMO).

In sum, by formally recognizing the PMO as a proven and historically effective food safety regulatory system that delivers a comparable level of microbiological and drug residue safety as the proposed Preventive Controls requirements under FSMA, the food safety resources of FDA, State Dairy Regulatory Agencies, and Grade “A” dairy plants can be better utilized and leveraged. As such, the PMO should be amended to state that facilities in compliance with it are in compliance with FDA’s Preventive Controls regulations with respect to those activities concerning microbiological hazards and illegal drug residues.

C. Proposed Solution

Changes to be made on page(s): vi (Introduction) of the (X - one of the following):

X	2013 PMO	2011 EML
	2013 MMSR	2400 Forms
	2013 Procedures	2013 Constitution and Bylaws

Inserted the underlined text as the last complete sentence of the first paragraph in the Introduction Section of the Ordinance as indicated below:

Grade "A" dairy plants complying with the most current edition of the NCIMS Grade "A" PMO, shall be recognized as also being in compliance with the FDA's regulations on Hazard Analysis and Risk-Based Preventive Controls under the FDA Food Safety Modernization Act's (FSMA) found at 21 CFR Part 117 Subpart C with respect to microbiological hazards and illegal drug residues in Grade "A" milk and milk products.

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35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: JC-3-Council II

Committee: Liaison

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This proposal seeks to align the Pasteurized Milk Ordinance (PMO) with the requirements of the Food Safety Modernization Act (FSMA) Proposed Rule for Preventive Controls for Human Food that a food facility shall have a food allergen control plan and written recall plan.

**B. Reason for the Submission and
Public Health Significance and/or Rationale Supporting the Submission**

In comments submitted on October 28, 2013 by the NCIMS to the FDA on the Proposed Rule for Preventive Controls for Human Food, the NCIMS Executive Board made the following recommendation:

“The NCIMS submits that FDA should recognize that the PMO and NCIMS milk safety program already meet the intent of the preventive food safety control strategies contained within FSMA and strongly urges FDA to exempt PMO-regulated facilities from the Proposed Rule, or to otherwise determine that milk product facilities that are compliant with the PMO, and regulated under the NCIMS system, to also be in compliance with FSMA’s preventive controls provision. Should FDA find it necessary, as an interim step, NCIMS requests that the agency stay the application of the Proposed Rule to facilities regulated under the PMO and work with the NCIMS cooperative program to *enact any minor modifications to the PMO as may be needed to warrant an exemption or comparability determination by FDA.*” (emphasis added)

The FSMA Proposed Rule for Preventive Controls for Human Food requires a food facility to have a food allergen control plan to protect foods from allergen cross-contact, including during storage and use, and to ensure proper declaration of allergens on product labeling. The Proposed Rule also requires facilities to establish a written recall plan that describes procedures for direct notification of consignees and the public about the affected food, recall effectiveness checks and appropriate disposal of recalled food products.

While Item 15p of the PMO currently requires that milk plant operations must be conducted to prevent any contamination of milk or milk products, ingredients, containers, utensils and equipment, the protection from cross contact with undeclared food allergens is not specifically addressed. The PMO also does not require plants to establish a written recall plan. The current proposal acknowledges the importance of protecting milk and milk products from unintentional cross-contact with nondairy food allergens by updating the definition of food allergens in the PMO, and by specifying that milk plants handling such allergens shall implement a written food allergen control plan. Consistent with the FSMA Proposed Preventive Controls Rule, the food allergen control plan would be required to address protection from food allergen cross-contact, labeling practices and procedures to prevent undeclared food allergens in milk and milk products, and proper identification and handling of raw materials and ingredients that are food allergens. This proposal would also require milk plants to have a written recall plan that addresses specified notification, effectiveness checks and product disposal procedures to ensure affected products are rapidly and effectively removed from the market to protect public health.

C. Proposed Solution

Changes to be made on page(s): 4, 15, 81, 89 of the (X - one of the following):

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|-----------------------------------|--|
| <u> X </u> 2013 PMO | <u> </u> 2011 EML |
| <u> </u> 2013 MMSR | <u> </u> 2400 Forms |
| <u> </u> 2013 Procedures | <u> </u> 2013 Constitution and Bylaws |

P. FOOD ALLERGENS: Are proteins in foods that are capable of inducing an allergic reaction or response in some individuals. Foods that are considered allergens are defined in Reference the Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282) and Section 201(qq) of the Food Drug & Cosmetic Act. ~~Information about Food Allergens~~ <http://www.efsa.europa.eu/en/wh-alrgy.html>. Information about Food Allergens may also be found at:

<http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAllergens/default.htm>

P-1 **Allergen cross-contact:** Allergen cross-contact means the unintentional incorporation of a food allergen into a food.

SECTION 2. ADULTERATED OR MISBRANDED MILK AND/OR MILK PRODUCTS

Not any person shall, within the ... of ...1, or its jurisdiction, produce, provide, sell, offer, or expose for sale or have in possession with intent to sell any milk or milk product, which is adulterated or misbranded. Provided, that in an emergency, the sale of pasteurized milk and milk products, which do not fully meet the requirements of this *Ordinance*, may be authorized by the Regulatory Agency.

NOTE: The option for the emergency sale of pasteurized milk and/or milk products as cited above shall not be applicable to a Milk Company (MC) that is Interstate Milk Shipper (IMS) listed under the National Conference on Interstate Milk Shipments (NCIMS) voluntary International Certification Program (ICP).

Any adulterated or misbranded milk and/or milk products may be impounded by the Regulatory Agency and disposed of in accordance with applicable laws or regulations.

NOTE: Adulterated and/or misbranded milk and/or milk products from MCs IMS listed under the ICP shall not gain entry into the U.S.

Milk plants shall establish and maintain a written recall plan for initiating, and effecting, the recall of adulterated milk or milk products from the market when appropriate for the protection of public health.

ADMINISTRATIVE PROCEDURES

IMPOUNDS: This Section of the *Ordinance* shall be used in impounding the milk and/or milk products of, or preferring charges against, persons who adulterate and/or misbrand their milk and/or milk products; or label them with any grade designation not authorized by the Regulatory Agency under the terms of this *Ordinance*; or who sell or deliver ungraded milk and/or milk products, except as may be permitted under this Section in an emergency. An emergency is defined as a general and acute shortage in the milk shed, not simply one (1) distributor's shortage.

NOTE: The option for the emergency sale of pasteurized milk and/or milk products as cited above, shall not be applicable to a MC IMS listed under the ICP.

RECALL PLAN: A milk plant shall establish a written recall plan that shall include procedures that describe steps to be taken, and assign responsibility for taking those steps, to perform all of the following actions when appropriate to protect public health:

- (i) Directly notify the direct consignees of the product being recalled and how to return or dispose of the affected milk or milk product.

(ii) Notify the public about any hazard presented by the milk or milk product.

(iii) Conduct effectiveness checks to verify that the recall is carried out.

(iv) Appropriately dispose of, or divert to safe alternative uses, recalled milk or milk products

For additional information and guidance from FDA regarding product recalls, milk plants should also refer to the current Guidance for Industry: Product Recalls, Including Removals and Corrections at <http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm>

ITEM 15p. PROTECTION FROM CONTAMINATION

Milk plant operations, equipment and facilities shall be located and conducted to prevent any contamination of milk or milk products, ingredients, containers, utensils and equipment. All milk or milk products or ingredients that have been spilled, overflowed or leaked shall be discarded. The processing or handling of products other than Grade "A" milk or milk products in the milk plant shall be performed to preclude the contamination of such Grade "A" milk and milk products. The storage, handling and use of poisonous or toxic materials shall be performed to preclude the contamination of milk and milk products, or ingredients of such milk and milk products, or the product-contact surfaces of all containers, utensils and equipment. Milk plant operations that handle nondairy food allergens shall have a written food allergen control plan to protect milk and milk products from allergen cross-contact, including during storage and use, and to ensure proper declaration of allergens on product labeling.

PUBLIC HEALTH REASON

Because of the nature of milk and milk products and their susceptibility to contamination by bacteria, chemicals, undeclared food allergens and other adulterants, every effort should be made to provide adequate protection for the milk and milk products at all times. Cross contact with undeclared food allergens, and Misuse misuse of pesticides and other harmful chemicals can provide opportunities for contamination of the milk and milk product or equipment with which the milk or milk product comes in contact. Food allergies affect a small portion of the population and can cause mild to severe and sometimes life threatening reactions.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

15 p. (C)

Food Allergen Control

A milk plant operation that handles nondairy food allergens shall implement a written food allergen control plan that includes procedures, practices, and processes to control food allergens. Food allergen controls shall include those procedures, practices, and processes employed for:

1. Ensuring protection of food from allergen cross-contact, including during storage and use.

Examples of specific food allergen controls that a milk plant may use to control allergen cross-contact include, but are not limited to, the following:

- (a) Provide physical barriers;
- (b) Eliminate or minimize the formation of dust, aerosols, or splashes;
- (c) Conduct manufacturing/processing of foods in different parts of a facility;
- (d) Emphasize separation in time, such as by production sequencing or by cleaning equipment between production runs;
- (e) Emphasize storage and handling appropriate to reduce the potential for cross-contact (including raw materials and ingredients); and
- (f) Control the movement of tools and personnel that might carry allergens when the same production lines are used for both foods that contain allergens and foods that do not, or when the same production lines are used for foods that contain different allergens.

2. Labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act with an undeclared food allergen.

Examples of specific food allergen control procedures, practices, and processes that a milk plant may use to address labeling include, but are not limited to, the following:

- (a) Ensure that the food label correctly declares all of the food allergens present (including those contained in flavorings, colorings, and incidental additives);
- (b) Ensure that the correct food label is applied to a food;
- (c) Ensure that the correct food is in the correct package (e.g., by checking that the correct packaging is used for each food); and
- (d) Review formulations and compare them to the labels (especially when new batches of labels are received or when formulas change).

3. Raw materials and ingredients that are food allergens, and rework that contains food allergens, must be identified and held in a manner that prevents cross-contact.

The NCIMS Liaison Committee requests an effective date for this proposal to be August 30, 2016 – or one year after the final rule is published. If, in the final rule for Preventive Controls for Human Food, FDA does not exempt PMO-regulated facilities or otherwise deem facilities compliant with the PMO and regulated under the NCIMS system to also be in compliance with FSMA’s Preventive Controls provision, then this modification will self-terminate and will be stricken from future versions of the PMO. If the final Preventive Controls for Human Food Rule does not include mandatory provisions analogous to the allergen control plan and written recall plan in the Proposed Rule, this modification will also self-terminate and will be stricken from future versions of the PMO.

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35th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #: JC-4-Council I
Committee: Liaison

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This proposal seeks to align the Pasteurized Milk Ordinance (PMO) with the requirement of the Food Safety Modernization Act (FSMA) Proposed Rule for Preventive Controls for Human Food for an environmental monitoring program.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

In comments submitted on October 28, 2013 by the NCIMS to the FDA on the Proposed Rule for Preventive Controls for Human Food, the NCIMS Executive Board made the following recommendation:

“The NCIMS submits that FDA should recognize that the PMO and NCIMS milk safety program already meet the intent of the preventive food safety control strategies contained within FSMA and strongly urges FDA to exempt PMO-regulated facilities from the Proposed Rule, or to otherwise determine that milk product facilities that are compliant with the PMO, and regulated under the NCIMS system, to also be in compliance with FSMA’s preventive controls provision. Should FDA find it necessary, as an interim step, NCIMS requests that the agency stay the application of the Proposed Rule to facilities regulated under the PMO and work with the NCIMS cooperative program to *enact any minor modifications to the PMO as may be needed to warrant an exemption or comparability determination by FDA.*” (emphasis added)

The Food Safety Modernization Act (FSMA) Proposed Rule for Preventive Controls for Human Food requires environmental monitoring, which is not directly addressed in the current PMO.

The proposal requires all Grade “A” milk plants have an environmental monitoring program to verify the effectiveness of pathogen controls in processes where a food is exposed to the environment. Dairy plants who have voluntarily utilized a similar environmental monitoring program have found great benefit in using such a program to serve as an early warning system to identify areas of concern and to mitigate potential contamination of finished product. This proposal will increase confidence in the safety of Grade “A” milk and milk products while maintaining the NCIMS’ status as an outstanding example of a cooperative regulatory program that delivers safe and wholesome products to the consumer.

C. Proposed Solution

Changes to be made on page(s): 69, 70 of the (X - one of the following):

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|-----------------|-----------------|-----------------|------------------------------|
| <u>X</u> | 2013 PMO | <u> </u> | 2011 EML |
| <u> </u> | 2013 MMSR | <u> </u> | 2400 Forms |
| <u> </u> | 2013 Procedures | <u> </u> | 2013 Constitution and Bylaws |

ITEM 9p. MILK PLANT CLEANLINESS

All rooms in which milk and milk products are handled, processed or stored; or in which containers, utensils and/or equipment are washed or stored, shall be kept clean, neat and free of evidence of insects and rodents. Only equipment directly related to processing operations or the handling of containers, utensils and equipment shall be permitted in the pasteurizing, processing, cooling, condensing, drying, packaging, and bulk milk or milk product storage rooms. An environmental monitoring program shall be implemented and supported by records for foods exposed to the environment when the food does not subsequently receive a treatment that would significantly minimize the pathogen.

PUBLIC HEALTH REASON

Clean floors, free of litter, clean walls, ceilings and all other areas of the milk plant are conducive to clean milk and milk product handling operations. Cleanliness and freedom from insects and rodents reduces the likelihood of contamination of the milk or milk product. Excess or unused equipment or equipment not directly related to the milk plant operations can be detrimental to the cleanliness of the milk plant. Public health officials have long recognized that raw milk contains microorganisms of public health concern and it is important to understand that these organisms may be found in the dairy plant environment if measures are not taken to minimize the risk of contamination by these microorganisms.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. Only equipment directly related to processing operations or the handling of containers, utensils and equipment is permitted in the pasteurizing, processing, cooling, condensing, drying, packaging, and bulk milk or milk product storage rooms.
2. All piping, floors, walls, ceilings, fans, shelves, tables and the non-product-contact surfaces of other facilities and equipment are clean.
3. No trash, solid waste or waste dry product is stored within the milk plant, except in covered containers. Waste containers at the packaging machine or bottle washer may be uncovered during the operation of such equipment.
4. All rooms in which milk and milk products are handled, processed or stored; or in which containers, utensils, and/or equipment are washed or stored, are kept clean, neat and free of evidence of insects and rodents.
5. Excessive product dust shall be kept under effective control by the use of exhaust and collective systems designed for in-plant dust control. Tailings and materials collected from exhaust collective systems shall not be used for human consumption.
6. A dairy plant environmental monitoring program shall be implemented and supported by records that, at a minimum:
 - a. Identifies environmental monitoring locations and the number of sample sites to be tested during routine environmental monitoring.
 - b. Identifies the frequency for collecting and testing samples.
 - c. Identifies the target microorganism(s).
 - d. Identifies the test(s) conducted, including the analytical method used, and the test result.
 - e. Identifies the laboratory conducting the testing.
 - f. Includes corrective action procedures for environmental monitoring results that are at a level and/or in a location of concern for food safety.

The NCIMS Liaison Committee requests the effective date for this modification to be August 30, 2016, or one year after final rule is published. If, in the final rule for Preventive Controls for Human Food (to be codified in 21 CFR part 117), FDA does not exempt PMO-regulated facilities or otherwise deem facilities compliant with the PMO and regulated under the NCIMS system to also be in compliance with FSMA's Preventive Controls provision, then this modification will self-terminate and will be stricken from future versions of the PMO. If the final Preventive Controls for Human Food Rule does not include mandatory provisions analogous to the environmental monitoring requirements in the Proposed Rule, this modification will also self-terminate and will be stricken from future versions of the PMO.

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35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: JC-5-Council III

Committee: Liaison

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This proposal seeks to align the Pasteurized Milk Ordinance (PMO) with the requirements of the Food Safety Modernization Act (FSMA) Proposed Rule (to be codified in 21 CFR part 117) for Preventive Controls for Human Food. The existing NCIMS Program has extensive supplier management programs related to the sourcing and supply of milk and milk products by Grade “A” milk plants. There are limited requirements specifically addressing the risk and severity of food safety hazards associated with non-dairy ingredients used in Grade “A” milk plants. This proposal adds language to the Pasteurized Milk Ordinance (PMO) to establish clear and simple requirements to ensure that Grade “A” milk plants evaluate the risk and manage food safety hazards related to the use of non-dairy ingredients.

**B. Reason for the Submission and
Public Health Significance and/or Rationale Supporting the Submission**

In comments submitted on October 28, 2013 by the NCIMS to the FDA on the Proposed Rule for Preventive Controls for Human Food, the NCIMS Executive Board made the following recommendation:

“The NCIMS submits that FDA should recognize that the PMO and NCIMS milk safety program already meet the intent of the preventive food safety control strategies contained within FSMA and strongly urges FDA to exempt PMO-regulated facilities from the Proposed Rule, or to otherwise determine that milk product facilities that are compliant with the PMO, and regulated under the NCIMS system, to also be in compliance with FSMA’s preventive controls provision. Should FDA find it necessary, as an interim step, NCIMS requests that the agency stay the application of the Proposed Rule to facilities

regulated under the PMO and work with the NCIMS cooperative program to *enact any minor modifications to the PMO as may be needed to warrant an exemption or comparability determination by FDA.*” (emphasis added)

The Food Safety Modernization Act (FSMA) Proposed Rule for Preventive Controls for Human Food requires verification of suppliers, including suppliers of non-dairy raw materials and ingredients, which is not fully addressed in the current PMO.

A review of FDA food recall data, electronic information sources, and information from the Centers for Disease Control and Prevention points to the fact that almost all recalls, particularly those related to human foodborne illness or death, resulted from non-dairy foods, ingredients or raw materials. The NCIMS has strict controls and requirements related to a milk plant’s sourcing and supply of milk and milk products, but there are only limited requirements related to a Grade “A” milk plant’s use of non-dairy ingredients.

A requirement that all Grade “A” milk plants have an effective supplier management program for non-dairy raw materials and ingredients will increase confidence in the safety of Grade “A” milk and milk products while maintaining the NCIMS’ status as an outstanding example of a cooperative regulatory program that delivers safe and wholesome products to the consumer.

C. Proposed Solution

Changes to be made on page(s): 129, 131 (Section 11) of the (X - one of the following):

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|-----------------|-----------------|-----------------|------------------------------|
| <u>X</u> | 2013 PMO | <u> </u> | 2011 EML |
| <u> </u> | 2013 MMSR | <u> </u> | 2400 Forms |
| <u> </u> | 2013 Procedures | <u> </u> | 2013 Constitution and Bylaws |

SECTION 11. MILK AND/OR MILK PRODUCTS, AND OTHER ADDED INGREDIENTS, FROM POINTS BEYOND THE LIMITS OF ROUTINE GRADE “A” INSPECTION.

(I) Milk and /or milk products, from points beyond the limits of routine inspection of the ...

(Page 131)

(II) A supplier management program for raw materials and ingredients which are not milk or milk products shall be implemented to control food safety hazards.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when the milk plant has determined that all ingredients which are not milk or milk products as defined in Section 1 of this Ordinance have:

Documentation that a supplier of ingredients which are not milk or milk products has, at a minimum, a functional risk-based program with appropriate controls to significantly minimize hazards for all ingredients which are not milk or milk products utilized in the milk plant's Grade "A" products.

The NCIMS Liaison Committee requests the effective date for this modification to be August 30, 2016, or one year after final rule is published. If, in the final rule for Preventive Controls for Human Food (to be codified in 21 CFR part 117), FDA does not exempt PMO-regulated facilities or otherwise deem facilities compliant with the PMO and regulated under the NCIMS system to also be in compliance with FSMA's Preventive Controls provision, then this modification will self-terminate and will be stricken from future versions of the PMO. If the final Preventive Controls for Human Food Rule does not include mandatory provisions analogous to the supplier verification requirements in the Proposed Rule, this modification will also self-terminate and will be stricken from future versions of the PMO.

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35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: JC-6-Council II
Committee: Liaison

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This proposal seeks to align the Pasteurized Milk Ordinance (PMO) with the requirement of the Food Safety Modernization Act (FSMA) Proposed Rule for Preventive Controls for Human Food that a hazard analysis consider radiological hazards.

**B. Reason for the Submission and
Public Health Significance and/or Rationale Supporting the Submission**

In comments submitted on October 28, 2013 by the NCIMS to the FDA on the Proposed Rule for Preventive Controls for Human Food, the NCIMS Executive Board made the following recommendation:

“The NCIMS submits that FDA should recognize that the PMO and NCIMS milk safety program already meet the intent of the preventive food safety control strategies contained within FSMA and strongly urges FDA to exempt PMO-regulated facilities from the Proposed Rule, or to otherwise determine that milk product facilities that are compliant with the PMO, and regulated under the NCIMS system, to also be in compliance with FSMA’s preventive controls provision. Should FDA find it necessary, as an interim step, NCIMS requests that the agency stay the application of the Proposed Rule to facilities regulated under the PMO and work with the NCIMS cooperative program to *enact any minor modifications to the PMO as may be needed to warrant an exemption or comparability determination by FDA.*” (emphasis added)

The Food Safety Modernization Act (FSMA) Proposed Rule for Preventive Controls for Human Food requires that a hazard analysis consider radiological hazards, which are not directly addressed in the current PMO.

While the PMO does not currently address radiological hazards, there are a number of ongoing surveillance programs (e.g., U.S. EPA and the states monitoring of drinking water; EPA's RadNet program which monitors air, water and soil; FDA's Total Diet Study which monitors milk; nuclear power plants monitoring of milk from dairy farms in close proximity) that do adequately monitor baseline levels of radiation in the environment and in the food supply. Imposing additional, ongoing monitoring requirements in the PMO would be duplicative of current efforts to address a hazard that is not significant.

The current proposal acknowledges the level of public health protection afforded by current monitoring programs and affirms that, should the need arise, additional testing or monitoring will be conducted at the direction of federal and state regulatory authorities.

C. Proposed Solution

Changes to be made on page(s): 226 of the (X - one of the following):

- | | | | |
|-----------------|-----------------|-----------------|------------------------------|
| <u>X</u> | 2013 PMO | <u> </u> | 2011 EML |
| <u> </u> | 2013 MMSR | <u> </u> | 2400 Forms |
| <u> </u> | 2013 Procedures | <u> </u> | 2013 Constitution and Bylaws |

VII. DETECTION OF RADIONUCLIDES IN MILK

Low levels of radiation are present in the environment but generally do not pose a problem associated with milk due to robust surveillance systems that are in place to detect radiation from a variety of sources including naturally-occurring, fugitive emissions from nuclear power plants, and accidental releases.

The Environmental Protection Agency maintains the RadNet system which for decades has monitored air, water, and soil for radionuclides and provides detailed information about the presence or lack of detectable radiation. EPA and the states also monitor drinking water for radionuclides. In addition, the Nuclear Regulatory Commission requires nuclear power plants to sample and test milk from farms within a five-mile radius of their facilities twice per month.

In the event of a radiological incident or the detection of radiation in drinking or well water in excess of EPA's drinking water standards, testing for radioactive isotopes may be required at the direction of state or federal authorities.

The NCIMS Liaison Committee requests the effective date for this modification to be August

30, 2016, or one year after final rule is published. If, in the final rule for Preventive Controls for Human Food (to be codified in 21 CFR part 117), FDA does not exempt PMO-regulated facilities or otherwise deem facilities compliant with the PMO and regulated under the NCIMS system to also be in compliance with FSMA's Preventive Controls provision, then this modification will self-terminate and will be stricken from future versions of the PMO.

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35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: JC-7-Council III

Committee: HACCP/Liaison

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This proposal aligns the PMO’s voluntary HACCP-based Appendix K Program for Grade “A” Plants with the Food Safety Modernization Act’s (FSMA’s) Proposed Rule for Preventive Controls for Human Food by incorporating requirements for allergen and radiological hazards; a written recall plan, employee training, supplier management, and environmental monitoring. It also aligns Appendix K with proposals being submitted by the NCIMS Liaison Committee.

**B. Reason for the Submission and
Public Health Significance and/or Rationale Supporting the Submission**

In comments submitted on October 28, 2013 by the NCIMS to the FDA on the Proposed Rule for Preventive Controls for Human Food, the NCIMS Executive Board made the following recommendation:

“The NCIMS submits that FDA should recognize that the PMO and NCIMS milk safety program already meet the intent of the preventive food safety control strategies contained within FSMA and strongly urges FDA to exempt PMO-regulated facilities from the Proposed Rule, or to otherwise determine that milk product facilities that are compliant with the PMO, and regulated under the NCIMS system, to also be in compliance with FSMA’s preventive controls provision. Should FDA find it necessary, as an interim step, NCIMS requests that the agency stay the application of the Proposed Rule to facilities regulated under the PMO and work with the NCIMS cooperative program to *enact any minor modifications to the PMO as may be needed to warrant an exemption or comparability determination by FDA.*” (emphasis added)

The Food Safety Modernization Act (FSMA) Proposed Rule for Preventive Controls for Human Food requires several elements that are not fully addressed in Appendix K of the current PMO.

This proposal seeks to align the Pasteurized Milk Ordinance (PMO) voluntary Appendix K with the requirements of FSMA’s proposed rule for “Preventive Controls for Human Food” and the changes to the PMO submitted by the NCIMS Liaison Committee. This rule contains a number of required written operational programs that together comprise a complete “Food Safety Plan.”

Table 1 below is a simple, side-by-side comparison of FSMA’s Proposed Rule for Preventive Controls for Human Foods and the existing requirements in Appendix K (see 2013 PMO) for the purpose of identifying differences between each of these regulatory programs. The table identifies most of the proposed written operational programs in the left column and describes whether Appendix K covers these programs in the middle column.

Table 1.

FSMA Proposed Preventive Controls Requirement	2013 PMO Appendix K Voluntary HACCP Program for Grade “A” Dairy Plants	Action
Supplier Management	Already required for all sources of dairy-based ingredients – shall be Grade “A” unless no Grade “A” source exists. Also, packaging must originate from an NCIMS-listed source. There is no “Supplier Management” requirement in Appendix K for non-Grade “A” dairy ingredients and non-dairy ingredients.	Add Supplier Management to Appendix K for non-Grade “A” dairy and all non-dairy ingredients
Allergen Control Program	Appendix K requires that all chemical hazards in a Grade “A” dairy product be addressed in a Hazard Analysis. Since “allergens” are a chemical hazard, these are covered in Appendix K	Add specific reference to allergen hazards in Appendix K
Radiological Hazards	According to FDA, “Radiological Hazards” are another type of chemical hazard. Appendix K requires that all chemical hazards in a Grade “A” dairy product be addressed in a Hazard Analysis. However, “Radiological Hazards” have not been recognized specifically in Appendix K.	Add specific reference to radiological hazards in Appendix K
Process Controls	The requirements for Grade “A” dairy plants found in section 7 of the PMO are recognized as the minimum acceptable “Process Control” requirements for Grade “A” dairy plants operating under Appendix K.	No action required
GMP Program as defined in 21 CFR 110 (117)	Same as immediately above	No action required
Product Traceability	No comparable requirement in Appendix K. FDA has not published any proposed regulations to address this component of FSMA.	No action required
Recall Plan	No comparable requirement in Appendix K	Add Recall Plan requirement to Appendix K
Employee Training (GMPs, HACCP, sanitation, allergens, environmental monitoring, food defense, food regulations, chemical use)	Appendix K does requires designated and responsible plant staff be trained to develop, implement and update the Appendix K hazard analysis, HACCP Plan, corrective action program, verification program and validation program. It does not address training of processing staff in general.	Add Employee Training Program requirement to Appendix K
Processing & Laboratory Equipment Calibration	Appendix K requires this as part of the written Verification Program	No action required

Pathogen Reduction Method	The PMO (including Appendix K) require FDA-validated heat treatment requirements including minimum holding times and product temperatures for pathogen reduction for ingredients used to make Grade "A" finished products	No action required
Validation of Processing Equipment Cleaning & Sanitizing	Appendix K does require a complete written validation plan that is updated at least annually.	No action required
Hazard Analysis	Appendix K requires a Hazard Analysis for each distinct type of Grade "A" dairy product produced.	No action required
Monitoring Records to Prove Controls Effective	Appendix K requires that monitoring records be maintained for all CCPs and mandatory Prerequisite programs.	No action required
Corrective Actions	Appendix K requires a written Corrective Action Plan and a record of each incident where the plant took "Corrective Action".	No action required
Verification	Appendix K requires a complete written verification plan that is updated at least annually.	No action required
Validated Controls	Appendix K requires a complete written validation plan that is updated at least annually.	No action required
Recordkeeping	All of the Appendix K requirements must be supported by records that verify a Grade "A" dairy plant is operationally compliant.	No action required
Food Transport Safety	The NCIMS program in the PMO and Appendix B of the PMO contain specific construction and operational requirements related to vehicles that transport raw milk to Grade "A" dairy plants as well as temperature criteria for transporting Grade "A" milk and milk products to customers. These requirements also address the training of the transport drivers for proper sampling.	No action required

C. Proposed Solution

Changes to be made on page(s): 349-351 of the (X - one of the following):

- X 2013 PMO 2011 EML
 2013 MMSR 2400 Forms
 2013 Procedures 2013 Constitution and Bylaws

MAKE THE FOLLOWING CHANGES TO THE 2013 PMO.

Strike through text to be deleted and underlined text to be added.

Pages 349-351:

PREREQUISITE AND OTHER PROGRAM PROGRAMS: HACCP is not a stand-alone program, but is part of a larger control system. PPs are the universal procedures used to control the conditions of the milk plant environment that contribute to the overall safety of the milk or milk product. They represent the sum of programs, practices and procedures that shall be applied

to produce and distribute safe milk and milk products in a clean, sanitary environment. They differ from CCPs in that they are basic sanitation programs that reduce the potential occurrence of a milk or milk product safety hazard. Frequently, both HACCP Plan CCPs and PPs control measures are necessary to control a food safety hazard.

HACCP may be implemented only in a facility that is constructed and operated to provide a sanitary environment. Milk plant, receiving station or transfer station premises, building construction, maintenance, and housekeeping shall be maintained in a manner sufficient to provide such an environment. These factors shall be controlled by effective milk plant, receiving station or transfer station programs or by PPs, as the milk plant, receiving station or transfer station chooses.

The exact set of PPs will vary since their application is milk and/or milk product and process specific. The existence and effectiveness of PPs should be assessed during the design and implementation of each HACCP Plan. PPs should be documented and regularly audited. An audit review consists of verifying that the company has a program implemented that indicates how the company monitors and controls each of the PPs. PPs are established and managed separately from the HACCP Plan.

In addition to PPs, other programs may be necessary to assure the HACCP system is operating as intended, including environmental monitoring programs, supplier programs, and recall plans.

1. Required PPs: The following required PPs shall have a **brief written description or checklist** that the PPs can be audited against to ensure compliance. PPs shall include procedures that can be monitored; records that specify what is monitored; and how often it will be monitored.

Each milk plant, receiving station or transfer station shall have and implement PPs that address conditions and practices before, during, and after processing. The PPs shall address:

- a. Safety of the water that comes into contact with milk and/or milk products or product-contact surfaces, including steam and ice;
- b. Condition and cleanliness of equipment product-contact surface;
- c. Prevention of cross-contamination from insanitary objects and or practices to milk and/or milk products or product-contact surfaces, packaging material and other food-contact surfaces, including utensils, gloves, outer garments, etc., and from raw product to processed product;
- d. Maintenance of hand washing, hand sanitizing, and toilet facilities;
- e. Protection of milk or milk product, packaging material, and product-contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate and other chemical, physical and biological contaminants;
- f. Proper labeling, storage, and use of toxic compounds;
- g. Control of employee health conditions, including employee exposure to high risk situations, that could result in the microbiological contamination of milk and/or milk products, packaging materials, and product-contact surfaces; and
- h. Pest exclusion from the milk plant.
- i. An employee training program shall at a minimum address the following:
 - (1) All employees directly responsible for the unloading and storage of raw materials and ingredients, storage and loading of the Grade "A" milk and/or milk product as well as any processing, receive annual food safety training that includes food GMPs, Appendix K requirements, an overview of HACCP, and allergens.
 - (2) Reference log of all employees identified in #1 above and the date and type of training received.

In addition to the required PPs specified above, any other PPs that are being relied upon in the Hazard Analysis to reduce the likelihood of hazards such that they are not reasonably likely to

occur, shall also be monitored, audited, and documented as required PPs.

2. **Monitoring and Correction:** The milk plant, receiving station or transfer station shall monitor the conditions and practices of all required PPs with sufficient frequency to ensure conformance with those conditions and that are appropriate both to the milk plant, receiving station or transfer station and to the safety of the milk and/or milk product being processed. Each milk plant, receiving station or transfer station shall document the correction of those conditions and practices that are not in conformance. Devices, such as indicating and recording thermometers that are used to monitor PPs shall be calibrated to assure accuracy at a frequency determined by the milk plant, receiving station, or transfer station.

3. **Other Programs:** Each milk plant shall have and implement other programs that are necessary to ensure the HACCP system is operating as intended. The other programs shall include:

a. An environmental monitoring program for milk plants. An environmental monitoring program shall be implemented and supported by records for foods exposed to the environment when the food does not subsequently receive a treatment that would significantly minimize the pathogen. The program shall, at a minimum:

- (1) Identify environmental monitoring locations.
- (2) Identify the frequency for collecting and testing samples.
- (3) Identify the target microorganism(s).
- (4) Identify the test(s) conducted, including the analytical method used, and the test result.

b. A supplier program that shall, at a minimum, address the following:

- (1) Document that all milk and/or milk product ingredients are obtained from an IMS listed source or, when no IMS source exists, that the supplier has, at a minimum, a functional risk-based program with appropriate controls to significantly minimize hazards for all milk and/or milk product ingredients obtained from non-IMS listed sources utilized in the milk plant's Grade "A" products.
- (2) Document that a supplier of non-milk and/or milk product ingredients has a functional and written food safety program that includes allergen management, if utilized in a Grade "A" product.

c. A written recall plan that, at a minimum, addresses the following:

- (1) Immediate segregation of any Grade "A" milk and/or milk product under the milk plant's control that may be adulterated or misbranded.
- (2) Upon confirmation of Grade "A" milk and/or milk product adulteration or misbranding, immediately:
 - i) Directly notify the direct consignees of the product being recalled and how to return or dispose of the affected milk and/or milk product;
 - ii) Contact the Regulatory Agency; and
 - iii) Contact the FDA Regional Recall Coordinator.
- (3) Notify the public about any hazard presented by the milk and/or milk product.
- (4) Conduct effectiveness checks to verify that the recall is carried out.
- (5) Appropriately dispose of, or divert to safe alternative uses, recalled milk and/or milk products.
- (6) Maintain records of the location, disposition and destruction of all affected product (coordinated with the Regulatory Authority and FDA District Recall Coordinator).

~~3.~~ 4. **Required Records:** Each milk plant, receiving station or transfer station shall maintain records that document the monitoring activities, corrections, and additional food safety programs required by this Appendix. These records are subject to the record keeping requirements of this Appendix.

HAZARD ANALYSIS: Each milk plant, receiving station or transfer station shall develop, or have developed for it, a **written hazard analysis** to determine whether there are milk and/or milk product hazards that are reasonably likely to occur for each type of milk and/or milk product processed or handled by the milk plant, receiving station or transfer station and to identify the control measures that the milk plant, receiving station or transfer station can apply to control those hazards.

The hazard analysis shall include hazards that can be introduced both within and outside the milk plant, receiving station or transfer station environment, including hazards that can occur during handling, transportation, processing and distribution.

A hazard that is reasonably likely to occur is one for which a prudent milk plant, receiving station or transfer station operator would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that, in the absence of these controls, the hazard will occur in the particular type of milk and/or milk product being processed. The hazard analysis shall be developed by an individual(s) trained in accordance with this Appendix and shall be subject to the record keeping requirements as described in this Appendix.

1. In evaluating what milk and/or milk product hazards are reasonably likely to occur, at a minimum, consideration should be given to the following:
 - a. Microbiological contamination;
 - b. Parasites;
 - c. Chemical contamination, including allergenic and radiological*
 - d. Unlawful drug and pesticide residues;
 - e. Natural toxins;
 - f. Unapproved use of food or color additives;
 - g. Presence of undeclared ingredients that may be allergens; and
 - h. Physical hazards.

* Low levels of radiation present in the environment generally do not pose a problem for milk due to robust government surveillance systems (EPA's RadNet, FDA's Food Marketbasket Surveys & the Nuclear Regulatory Commission's operational requirements for nuclear power plants) that are in place to detect radiation from a variety of sources including naturally-occurring as well as fugitive or accidental emissions from nuclear power plants.

NOTE: In the event of a radiological incident, US government agencies may require testing of raw milk for radioactive isotope presence.

2. Milk plant, receiving station or transfer station operators should evaluate product ingredients, processing procedures, packaging, storage, and intended use; facility and equipment function and design; and milk plant sanitation, including employee hygiene, to determine the potential effect of each on the safety of the finished milk and/or milk product for the intended consumer.

The NCIMS HACCP Implementation Committee requests an effective date for this proposal to be August 30, 2016 – or one year after the final rule is published. If, in the final rule for Preventive Controls for Human Food, FDA does not exempt PMO-regulated facilities or otherwise deem facilities compliant with the PMO and regulated under the NCIMS system to also be in compliance with FSMA's preventive controls provision, then this modification will self-terminate and will be stricken from future versions of the PMO.

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35th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #: JC-8-Council III

Committee: Liaison

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This proposal would authorize the NCIMS Executive Board to schedule a special NCIMS Conference in calendar year 2016 to deliberate on and accept proposals to align the Pasteurized Milk Ordinance (PMO) with the new Food and Drug Administration (FDA) regulatory framework for Hazard Analysis and Risk-Based Preventive Controls (Preventive Controls) under the FDA Food Safety Modernization Act (FSMA).

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

This proposal seeks to synchronize the timing of the publication of the final FDA Preventive Controls regulations under FSMA with a timely and constructive discussion by the NCIMS, FDA, and the dairy industry of how best to harmonize the implementation and enforcement of the Grade "A" PMO with the new FSMA Preventive Controls regulations. FDA will still be in the middle of its rulemaking proceedings when the NCIMS meets in the spring of 2015 and, therefore, the agency will be unable to actively participate in substantive discussions on the relationship between the PMO and FSMA at that time. The next regularly scheduled NCIMS Conference is not until the spring of 2017, which is after the new FDA regulations are expected to be implemented and enforced. Accordingly, a special interim meeting in 2016 is needed to consider the final Preventive Controls regulations and engage the FDA in a direct dialogue on how to preserve the historic strengths of the Grade "A" PMO while meeting any needed legal responsibilities under FSMA.

The Grade "A" PMO has a strong historical track record that delivers a high level of food safety for Grade "A" milk and milk products. In fact, recent information reveals that milk and milk products continue to be associated with less than one percent (<1%) of reported disease outbreaks.

In addition to the strong regulatory framework contained in the PMO, the Grade “A” dairy plant regulatory program also consists of rigorous quarterly plant inspections by highly knowledgeable state inspectors.

Although PMO requirements for Grade “A” dairy plants and FDA’s proposed Preventive Controls regulations have a different structure and use slightly different food safety “tools,” both have the capability to deliver a high and acceptable level of food safety. Indeed, the PMO contains the necessary elements both to ensure the microbiological safety of fluid, cultured, and dry milk products and to protect against chemical (i.e. illegal drug residues) and physical hazards in such products.

One of the reasons the Grade “A” dairy plant regulatory program has been so successful is that it has been a cooperative program between the State Dairy Regulatory Agencies, the dairy industry and FDA. Yet, a constructive dialogue between these parties has not yet been possible due to the limitation on comments by FDA staff during the FSMA rulemaking process as required under the Administrative Procedure Act. FDA is likely to issue the final Preventive Controls regulations by August 30, 2015, with enforcement starting one year later. This will occur between NCIMS Conference cycles (2015 & 2017) which limits the NCIMS from interacting in a meaningful way with FDA.

One example of possible discussion points that needs some resolution is the possibility of amending Appendix K to the PMO to make it mandatory. This idea has raised several concerns, including its effect on the PMO itself and the cost to both the states and the dairy industry to implement such an approach. Another important example needing further discussion between FDA and the NCIMS is the possibility that FDA could feel legally obligated to implement and enforce the FSMA Preventive Controls regulations in Grade “A” dairy plants at the same time that State Dairy Regulatory Agencies enforce the PMO, resulting in potentially unnecessary, costly, and duplicative requirements that will not improve food safety. Thus, substantive dialogue between all parties is critical and yet the process has not allowed for such dialogue to-date, necessitating a special NCIMS Conference in 2016.

If a special NCIMS conference is held in 2016, FDA’s regulations to implement FSMA’s requirements for Preventive Controls will be finalized and public, allowing the FDA to discuss them openly. The Agency will have a better understanding of how it wants to enforce these new requirements. Therefore, a special NCIMS conference in 2016 would be able to primarily address the interaction and interface between the PMO’s regulatory requirements for dairy plants and FSMA’s provisions for Preventive Controls. The collaborative dialogue that will take place leading up to and during the Conference will be much more likely to lead to a successful outcome (i.e. no duplication of regulatory programs affecting Grade “A” dairy plants, full utilization of the PMO and recognition of the important role played by State Dairy Regulatory Agencies). This timing will also facilitate the cooperative process between FDA, State Dairy Regulatory Agencies, and the dairy industry, which has been at the core of the success of the NCIMS program and the PMO as an effective food safety system.

C. Proposed Solution

Changes to be made on page(s):		No PMO Language Changes	of the (X - one of the following):
X	2013 PMO		2011 EML
	2013 MMSR		2400 Forms
	2013 Procedures		2013 Constitution and Bylaws

This proposal authorizes the NCIMS Executive Board to schedule a special NCIMS Conference in calendar year 2016 for the primary purpose of accepting and deliberating on proposals that will preserve the NCIMS Grade "A" dairy plant regulatory program within the new FDA regulatory framework created by the Preventive Controls regulations under the FDA Food Safety Modernization Act.

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