

2015 NCIMS PROPOSALS
FINAL ACTION TAKEN
JOINT COUNCIL

Legend
S=Support
N=Neutral
O=Oppose
T=Tabled

# COM.	POS	DESCRIPTION	SUBMITTED BY	COUNCIL ACTION			FINAL ACTION		
				NA	PAS	PAA	NA	PAS	PAA
JC-1 COUNCIL III LIAISON		PMO (Page vi) INTRODUCTION: The <i>Ordinance</i> has stood decades long the test of time as the industry's <i>food safety plan</i> . This proposal formally recognizes the <i>Ordinance</i> as such	NCIMS LIAISON COMMITTEE						
JC-2 COUNCIL III LIAISON		PMO (Page vi) INTRODUCTION: Recognizing that PMO requirements provide a comparable degree of food safety assurance with respect to, at a minimum, microbiological hazards and drug residues as FDA's requirements for Preventive Controls under the Food Safety Modernization Act (FSMA).	ALLEN SAYLER- CFSRS- WOODBRIDGE, VA						
JC-3 COUNCIL II LIAISON		PMO (Pages 4, 15, 81 and 89) SECTIONS 1 and 2 AND ITEM 15p: This Proposal seeks to align the PMO with the requirements of FSMA's Proposed Rule for Preventive Controls for Human Food that a food facility shall have a food allergen control plan and written recall plan.	NCIMS LIAISON COMMITTEE						
JC-4 COUNCIL I LIAISON		PMO (Pages 69-70) ITEM 9p: This Proposal seeks to align the PMO with the requirement of the FSMA's Proposed Rule for Preventive Controls for Human Food for an	NCIMS LIAISON COMMITTEE						

# COM.	POS	DESCRIPTION	SUBMITTED BY	COUNCIL ACTION			FINAL ACTION		
				NA	PAS	PAA	NA	PAS	PAA
		environmental monitoring program.							
JC-5 COUNCIL III LIAISON		<p>PMO (Pages 129-131)</p> <p>SECTION 11: This Proposal seeks to align PMO with the requirements of FSMA’s 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 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.</p>	NCIMS LIAISON COMMITTEE						
JC-6 COUNCIL II LIAISON		<p>PMO (Page 226)</p> <p>APPENDIX G: This Proposal seeks to align PMO with the FSMA’s Proposed Rule for Preventive Controls for Human Food that a hazard analysis consider radiological hazards.</p>	NCIMS LIAISON COMMITTEE						
JC-7 COUNCIL III HACCP		<p>PMO (Pages 349-351)</p> <p>APPENDIX K: This Proposal aligns the PMO’s voluntary HACCP-based Appendix K Program for Grade “A” Milk Plants with the FSMA’s Proposed Rule for Preventive</p>	HACCP COMMITTEE						

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				NA	PAS	PAA	NA	PAS	PAA
LIAISON		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.							
JC-8 COUNCIL III LIAISON		NO DOCUMENT This Proposal would authorize the NCIMS Executive Board to schedule a special NCIMS Conference in calendar year 2016 to deliberate and accept Proposals to align the PMO with the new Preventive Control) under FSMA.	ALLEN SAYLER- CFSRS- WOODBRIDGE, VA						

2015 NCIMS PROPOSALS
FDA POSITIONS
COUNCIL I

Legend
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#	POS	DESCRIPTION	SUBMITTED BY	COUNCIL ACTION			FINAL ACTION		
				NA	PAS	PAA	NA	PAS	PAA
101 TECH SCIENCE		PMO (Page 32) SECTION 7: To include micro-droplet formation for the purpose of removing or deactivating microorganisms in the pasteurization processes. ATTACHED DOCUMENTS CITED IN THE PROPOSAL TO BE PROVIDED BEFORE 3/1/2015.	PHILLIP FRECHETTE-JCS PROCESS AND CONTROL SYSTEMS ENGINEERING -ROCHESTER, NY						
102		PMO (Pages 33-34 (Table 1)) TABLE 1: To recognize somatic cell count (SCC) limit for cow (Bovine) milk of >400,000/mL and report results to producer’s COOP or processor.	ALF REEB-NM DEPT OF AG						
103		PMO (Pages xvi, 33-34 (Table 1), 212 (Appendix E) and 380-381 (Appendix P)) TABLE 1 AND APPENDIXES E AND P: Lower the somatic cell count (SCC) limit for cow (Bovine) milk to >600,000/mL by 1/1/2016 and to >400,000/mL by 1/1/2017.	IDFA						
104		PMO (Page 34-Table 1) TABLE 1: To add consistency to the coliform requirements for Grade “A” bulk shipped condensed whey and/or whey products as is other bulk	MIKE WIGGS-ID DEPT OF AG						

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				NA	PAS	PAA	NA	PAS	PAA
		shipped Grade “A” milk products.							
105		PMO (Page 38) ITEM 3r: To remove out dated or not needed language. “Scrub the floor of the barn with a stiff-bristle brush.”	KELLY BENCH- BENCH DAIRY EQUIPMENT- ONTARIO, OR						
106		PMO (Page 40) ITEM 5r: Remove the requirement for a two (2) compartment wash vat.	KELLY BENCH- BENCH DAIRY EQUIPMENT- ONTARIO, OR						
107		PMO (Page 42) ITEM 5r: To require seven (7) day temperature-recording charts, for all Grade “A” dairy farms, to record the CIP cleaning return temperature.	WARREN TAYLOR- SNOWVILLE CREAMERY LLC- POMEROY, OH						
108		PMO (Page 42) ITEM 5r: To require Grade “A” dairy farms to have, maintain, and use approved indicating thermometers to confirm the minimum CIP return temperatures required for adequate cleaning in raw milk piping systems.	WARREN TAYLOR- SNOWVILLE CREAMERY LLC- POMEROY, OH						
109 OTHER SPECIES SCIENCE		PMO (Page 50) ITEM 10r: A Proposal to exempt raw goat milk storage/holding tank from the seventy-two (72) hour cleaning requirement, allowing raw goat milk to be stored in a farm milk storage/holding tank for a maximum of seven (7) days. Raw goat milk storage/holding tanks shall be clean and sanitized when emptied. Partial pickups may	TERRY PHILIBECK- MI DEPT OF AG AND RURAL DEVELOPMENT						

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				NA	PAS	PAA	NA	PAS	PAA
		be permitted when the milk storage/holding tank is equipped with a seven (7) day recording device compliant with the specifications of Appendix H.							
110		PMO (Pages 51-52) ITEM 12r: To eliminate the requirement to maintain a complete separation between the milking area and cattle housing area due to milking equipment being cleaned and stored in the milking area, on a year around basis rather than on a seasonal basis. On modern dairy facilities proper ventilation in the milking parlor and covered holding areas can be achieved and maintained at all times of the year with the use of various facility ventilation systems.	SHANNON HOUSELOG- GLOBAL DAIRY, LP- ESTELLINE, SD						
111 HAULING		PMO (Pages 58-59) ITEM 18r: To require approved seven (7) ay temperature-recording charts for all Grade “A” dairy farm bulk tanks and removing the “grandfather clause” for the implementation of raw milk bulk tank temperature-recording charts.	WARREN TAYLOR- SNOWVILLE CREAMERY LLC- POMEROY, OH						
112		PMO (Page 59) ITEM 18r: To specify the applicable requirements of electronic data collection and storage in Appendix H, IV and V.	BRIAN WISE- OH DEPT OF AG						
113		PMO (Page 75)	CHERIE HOUSER-						

# COM.	POS	DESCRIPTION	SUBMITTED BY	COUNCIL ACTION			FINAL ACTION		
				NA	PAS	PAA	NA	PAS	PAA
HAULING		ITEM 12p: To ensure milk tank trucks are washed properly in a timely manner.	INTERNATIONAL MILK HAULERS ASSOCIATION-MIDDLETON, WI						
114		PMO (Page 75) ITEM 12p: This Proposal would clarify that sanitizing drying and dry product equipment is only necessary after the equipment has been wet cleaned.	JOE DITTRICH-MN DEPT OF AG						
115		PMO (Page 75) ITEM 12p: This Proposal would clarify that sanitizing drying and dry product equipment is necessary after the equipment has been either wet cleaned or dry cleaned.	JOE DITTRICH-MN DEPT OF AG						
116		PMO (Page 83) ITEM 15p: This Proposal provides for the use of cheese cloth or strainer bags that are single use and constructed of non-toxic materials to be used for the purposes of straining whey during the production of yogurt within Item 15p-Protection from Contamination, Administrative Procedures #10 of the PMO.	FDA						
117		PMO (Page 93) ITEM 16p: Pasteurized cream should not have to be re-pasteurized when bought from a second party to churn into butter.	BRAD SINKO-FACE ROCK CREAMERY-BANDON, OR						
118		PMO (Pages 119 and 136)	IDFA						

# COM.	POS	DESCRIPTION	SUBMITTED BY	COUNCIL ACTION			FINAL ACTION		
				NA	PAS	PAA	NA	PAS	PAA
SCIENCE		ITEM 18p: Permit the transfer of yogurt to a separate plant for retail/consumer packaging without requiring additional pasteurization, if the product can be transported in a sanitary manner and protected from contamination through to its final packaging.							
119 OTHER SPECIES		<p>PMO (Pages 124-125)</p> <p>SECTION 8: The USDA APHIS Programs on Tuberculosis and Brucellosis eradication were designed for cattle and bison. While there is little known risk from TB or brucellosis in areas where the diseases have been eradicated in cattle and bison there is a concern that there is not sufficient data to prove there is no risk. This proposal follows the same options as the conference has allowed on other species for brucellosis and extends the testing requirements for TB. This includes an option that puts the specifics of each State plan into the hands of the State Veterinarian as they are the most knowledgeable of the risks in their State.</p>	DAN SCRUTON- OTHER SPECIES COMMITTEE						
120 OTHER SPECIES SCIENCE ICP		<p>PMO (Pages 124-127)</p> <p>SECTION 8: This Proposal removes the current language and replaces it with updated language which addresses animal health programs more generally and refers these issues to the Federal and State animal health officials. By</p>	NICOLE NESSER- MN DEPT OF AG						

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				NA	PAS	PAA	NA	PAS	PAA
		making this change it will still emphasize animal health for the purposes of food safety, but defer the specifics of these programs to the experts in this area.							
121		PMO (Pages 164-165) <u>APPENDIX C:</u> Remove the statement quoting the NMC Milking Methods indicating a thirty (30) second preparation time, stripping the cow and the number of units.	KELLY BENCH- BENCH DAIRY EQUIPMENT- ONTARIO, OR						
122 TECH		PMO (Page 235) <u>APPENDIX H:</u> This Proposal would clarify that the PMO does not allow any flow promoting device(s) on a continuous flow pasteurization system, which utilizes a magnetic flow meter based timing system (MFMBTS), to be installed between the timing pump and the magnetic flow meter.	JOE DITTRICH- MN DEPT OF AG						
123 TECH		PMO (Page 235) <u>APPENDIX H:</u> This Proposal would clarify that the PMO does allow a flow promoting device on a continuous flow pasteurization system, which utilizes a magnetic flow meter based timing system (MFMBTS), to be installed between the timing pump and the magnetic flow meter, if properly inter-wired with the flow diversion device (FDD).	JOE DITTRICH- MN DEPT OF AG						
124		PMO (Pages 244-250) <u>APPENDIX H:</u> This Proposal	BRIAN MOYER-WI DEPT OF AG,						

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				NA	PAS	PAA	NA	PAS	PAA
COM. TECH		<p>clarifies language with regard to Appendix H – Section II – Air Under Pressure – Milk Product-Contact Surfaces, final filter efficiency.</p> <p>This Proposal also updates the “commercially sterile air” filter efficiency criteria, so that it is consistent with the current 3-A Accepted Practice (604-05) criteria.</p>	TRADE AND CONSUMER						
125 TECH		<p>PMO (Pages 278, 287 and 298)</p> <p>APPENDIXES H and I: This Proposal would add text to Appendix H and test procedures for Steam-Block Type Flow Diversion Devices (SB-FDD) to Appendix I.</p>	JOE DITTRICH-MN DEPT OF AG						
126 TECH		<p>PMO (Page 304)</p> <p>APPENDIX I: This Proposal would add additional options to perform HTST Test 9.2.2. The option would allow for usage of the raw regenerator section differential pressure controller sensing element.</p>	DANA MOCK-MN DEPT OF AG						
127 TECH		<p>PMO (Pages 312 and 315-316)</p> <p>APPENDIX I: This Proposal will add an additional procedure for testing pasteurization holding times (Tests 11.1 and 11.2).</p>	DANA MOCK-MN DEPT OF AG						
128 TECH		<p>PMO (Pages 312 and 315-316)</p> <p>APPENDIX I: This Proposal would allow equipment for testing the holding time on a pasteurization system that does not conform to equipment that has been used in the past. The start of the pasteurization</p>	GLENN GOLDSCHMIDT -QUEST INDUSTRIAL, LLC-MONROE, WI						

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				NA	PAS	PAA	NA	PAS	PAA
		system is important because it uses the operation of a valve to begin the holding time test.							
129 TECH		<p>PMO (Page 312)</p> <p><u>APPENDIX I:</u> This Proposal would clarify that timing pumps controlled by variable frequency drives (VFD) would not be required to have milk-to-water adjusted pasteurization holding time tests done on the quarterly pasteurization tests.</p>	JOE DITTRICH- MN DEPT OF AG						
130 TECH		<p>PMO (Page 312)</p> <p><u>APPENDIX I:</u> This Proposal would clarify that timing pumps controlled by variable frequency drives (VFD) would be required to have milk-to-water adjusted pasteurization holding time tests done on the quarterly pasteurization tests.</p>	JOE DITTRICH- MN DEPT OF AG						
131 TECH		<p>PMO (Page 335)</p> <p><u>APPENDIX I:</u> To add additional clarification within Appendix I-Test 15, further defining which control devices require testing for Electromagnetic Interference.</p>	GARY RATAJCZAK- ANDERSON INSTRUMENTS CO., INC.- FULTONVILLE, NY						
132 SSCC SCIENCE		<p>PMO (Page 344)</p> <p><u>APPENDIX J:</u> The Society of the Plastics Industry's (SPI) Food, Drug, and Cosmetic Packaging Materials Committee (FDCPMC) proposes that the NCIMS clarify the status of regrind and its use under Appendix J, to permit the use of production scrap as regrind, provided that</p>	COUNSEL FOR THE SOCIETY OF THE PLASTIC INDUSTRY- KELLER AND HECKMAN LLP- WASHINGTON, DC						

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				NA	PAS	PAA	NA	PAS	PAA
		<p>manufacturers comply with the proposed Good Manufacturing Practices for the proper handling of the source material. The attached GMP could be considered to constitute a protocol for recycling that has been reviewed and accepted by FDA.</p>							
<p>133</p> <p>SSCC</p> <p>LAB</p>		<p>PMO (Pages 339-340)</p> <p><u>APPENDIX J:</u> The purpose of this Proposal is to bring Appendix J and the FDA 2400 Forms into agreement on sample size.</p> <p><u>FDA-NCIMS Form 2400i, Pasteurized Milk Containers, rev 10-13, item 26a</u> states one sample is 5 – 50 square centimeter (cm²) areas or 250 cm² of product contact surface. A sample set is 4 times one sample or 4 – 250 cm² areas. Appendix J, repeatedly bases regulatory action on 3 out of 4 samples where a sample size is given to be 4 - 50 cm² areas.</p> <p>Since the 2400 forms are based on science it would make sense to change the definition of a sample set for the swab test to agree with the 2400 forms.</p>	<p>DEB HALL- IN STATE BOARD OF ANIMAL HEALTH</p>						
<p>134</p> <p>TECH</p>		<p>PMO (Pages 383-384)</p> <p><u>APPENDIX Q:</u> This Proposal addresses concerns cited in Appendix Q, Item 1r, Item 13r, and provides guidance for written procedures for milk with abnormalities, computer</p>	<p>FDA</p>						

# COM.	POS	DESCRIPTION	SUBMITTED BY	COUNCIL ACTION			FINAL ACTION		
				NA	PAS	PAA	NA	PAS	PAA
		system(s) verification, and general computer requirements for Automatic Milking Installations (AMI).							
135		<p>PMO (Page 383)</p> <p>APPENDIX Q-ITEM 1r: M-I-14-8 was issued with guidance on how AMI abnormal milk installations should be evaluated. The M-I demonstrated a major shift from the intent of the language in Appendix Q. This Proposal is an attempt to clarify the requirements for an AM) with regards to abnormal milk sensing. The MI is incorrect in its inclusion of milk conductivity under its verification requirements as conductivity is not required in conventional systems or AMI. It is also going beyond what is required of conventional milkers in suggesting that producers need to have written records on any changes they make to abnormal milk sensors as we do not require conventional milking systems to track all the training they give to each milker and any time they give further instruction to the milkers. Ultimately it is the milk in the bulk tank that is the judge. The only time a conventional system would be marked for abnormal milk is if an inspector observed abnormal milk going into the milk for sale or if the bulk milk tank is off in color or texture. The only real requirement should be that the system has a sensor and that the</p>	DAN SCRUTON- VT DEPT OF AG, FOOD AND MARKETS						

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				NA	PAS	PAA	NA	PAS	PAA
		sensor is turned on. Even that is more stringent than we hold conventional systems to but is reasonable given that the producer does not have someone there to observe milking.							
136		<p>PMO (Page 385)</p> <p><u>APPENDIX Q-ITEM 18r:</u> To keep the requirements of Appendix Q, Item 18r the same as Section 7, Item 18r.</p>	BRIAN WISE- OH DEPT OF AG						
137 SCIENCE		<p>NO DOCUMENT</p> <p>To update guidance (M-I-06-5) regarding Item 15r of the PMO to better reflect organic dairy production practices under the Organic Foods Production Act by developing guidance acceptable to FDA that licensed veterinarians may prescribe certain safe and effective GRAS and plant-based substances (draft list attached) in accordance with State veterinarian practice requirements, for use in maintaining animal and herd health. Guidance is sought that will recognize these substances may be regulated differently than unapproved animal drugs under the PMO.</p> <p>Organic Valley requests the Chair assign this proposal to an NCIMS standing committee, special committee, or ad hoc committee as approved by the NCIMS Executive Board. We request development of appropriate language for adoption at the</p>	GENERAL COUNSEL- CROPP COOP/ ORGANIC VALLEY FAMILY OF FARMS						

# COM.	POS	DESCRIPTION	SUBMITTED BY	COUNCIL ACTION			FINAL ACTION		
				NA	PAS	PAA	NA	PAS	PAA
		earliest possible opportunity.							

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				NA	PAS	PAA	NA	PAS	PAA
COM. 201		PMO (Pages 1, 33 and 224-225)	WARREN TAYLOR- SNOWVILLE CREAMERY LLC- POMEROY, OH						
LAB SCIENCE		<u>SECTION 1, TABLE 1 AND APPENDIX G:</u> Require testing of milk and/or milk products for glyphosate residues.							
202		PMO (Pages 1 and 36)	WARREN TAYLOR- SNOWVILLE CREAMERY LLC- POMEROY, OH						
LAB SCIENCE		<u>SECTION 1 AND ITEM 1r:</u> Require testing for glyphosate residues in the feed and forage used as a feed ingredient for any portion of the total ration of the lactating dairy animal. Confirm: that feed and forage do not contain levels of glyphosate which result in glyphosate being secreted in the milk at any level, which may be deleterious to human health.							
203		PMO (Page 6)	TERRY PHILIBECK- MI DEPT OF AG AND RURAL DEVELOPMENT						
		<u>SECTION 1:</u> A Proposal to add the definition for “inspection/audit report”.							
204		PMO (Pages 6, 27 and 138)	STEVE DIVINCENZO -IL DEPT OF PUBLIC HEALTH						
		<u>SECTIONS 1 AND 6 AND APPENDIX B:</u> Allow the States the <i>option</i> of having dairy plants collect finished product samples for regulatory purposes. The							

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				NA	PAS	PAA	NA	PAS	PAA
		dairy plant personnel must be certified as a dairy plant sampler by delegation of a State Rating Officer. A permit shall be issued upon satisfactorily completing the dairy plant sampling procedures. A list of these samplers shall be maintained by the regulatory agency. The regulatory agency shall notify the dairy plant when and what samples to collect. The notification shall be the same day the samples are collected. There shall be no advanced warning as to when the samples are to be collected. Periodically, the State Regulatory Agency shall review the sample collections performed by industry. Whenever there is a sample has been issued a warning letter, the subsequent sample shall be collected by the Regulatory Agency. Samples shall be accompanied with documentation of chain of custody and tamper evident tape or seals when necessary.							
205		PMO (Pages 7, 9, 135 and 136) <u>SECTION 1 AND FOOT-NOTES:</u> This Proposal would eliminate Footnote #2 (cottage cheese option) from the text of the PMO and from the listing of Footnotes on page 135 of the PMO and renumber the remaining Footnotes accordingly.	FDA						
206		PMO (Page 11)	ALLEN SAYLER-						

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				NA	PAS	PAA	NA	PAS	PAA
SCIENCE		SECTION 1: This Proposal is to identify acceptable uses for milk and milk products rinsed from farm bulk trucks, over-the-road tankers, transfer-station, receiving station and milk plant storage silos and similar vessels by adding a definition in the PMO which identifies “Reclaimed Milk & Milk Products” and establishes conditions for their use in Grade “A” Milk and Milk Products.	CFSRS- WOODBRIDGE, VA						
207 OTHER SPECIES		PMO (Page 2) SECTION 1: Defining camel milk. Proposal to add the definition of camel milk to the PMO.	GENE WISEMAN- MO MILK BOARD						
208		PMO (Page 22) SECTION 5: A Proposal to allow electronically generated or hand written inspection/ audit reports of all dairy facility inspections to be provided to the establishment, operator, or other responsible person.	TERRY PHILIBECK- MI DEPT OF AG AND RURAL DEVELOPMENT						
209		PMO (Page 23) SECTION 5: To allow the Regulatory Agency discretion, in accordance with the Regulatory Agency’s State administrative procedures and hearing proceedings, in the enforcement procedures which currently require automatic permit suspension if the same non-critical requirement is found on two (2) successive inspections of a	STEVE DIVINCENZO -IL DEPT OF PUBLIC HEALTH						

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				NA	PAS	PAA	NA	PAS	PAA
		dairy farm, bulk milk/hauler sampler, milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor. Many States are unable to comply with this provision because their administrative procedures do not allow for this type of enforcement action.							
210 APP. N LAB		PMO (Pages xiv, 26-30 and 363-374) <u>SECTION 6 AND APPENDIX N:</u> This Proposal addresses Appendix N testing to require that at least one (1) of the following drug families (Beta-lactams, Amphenicols (<u>florfenicol</u>) and any three (3) of the following: NSAIDs (flunixin), Sulfonamides, Macrolides, Tetracyclines, Aminoglycosides, or Avermectins) be conducted on each milk tank truck and/or each raw milk supply that has not been transported in bulk milk pickup tankers; or on a statistical basis calculated by FDA statisticians (the number of milk tank truck loads (percentage) based on the total number of milk tank truck loads received and/or each raw milk supply that has not been transported in bulk milk pickup tankers utilized from the previous year) employing a random testing program.	FDA						
211		NO DOCUMENT	APPENDIX N MODIFICATION						

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				NA	PAS	PAA	NA	PAS	PAA
APP N LAB		This Proposal will establish a pilot program to be developed through the Appendix N Modification Committee and implemented with approval of the NCIMS Executive Board. The pilot program will develop <u>the regulatory requirements by which testing raw milk for drugs other than beta-lactams would be required</u> , the premise of which is primarily grounded on the FDA's risk ranking analysis that is as yet to be finalized.	COMMITTEE						
212 APP N		PMO (Pages 30, 363 and 374) <u>SECTION 6 AND APPENDIX N:</u> Require testing of all raw milk for sulfonamides, especially sulfamethazine.	WARREN TAYLOR- SNOWVILLE CREAMERY LLC- POMEROY, OH						
213 APP N LAB		PMO (Pages xiv, 28-30 and 363- 374) <u>SECTION 6 AND APPENDIX N:</u> This Proposal addresses Proposal 220 from the 2013 NCIMS Conference that was assigned to the Appendix N Modification Committee addressing the procedure to follow when using a drug testing method that has NOT been evaluated and accepted by FDA and the NCIMS when there is a drug testing method AVAILABLE that has been evaluated and accepted by FDA and the NCIMS (M-a-85, latest revision, and M-I-92-11).	FDA						

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		It further addresses a request from FDA to the Appendix N Modification Committee and accepted by the Appendix N Modification Committee to develop a procedure to follow when using a drug testing method that has NOT been evaluated and accepted by FDA and the NCIMS when there is NOT a drug testing method that has been evaluated and accepted by FDA and the NCIMS available.							
214 APP N LAB		NO DOCUMENT This proposal will establish a pilot program to be developed through the Appendix N Modification Committee to review the effectiveness of a <u>voluntary program for the rapid screening of raw milk for drugs other than beta-lactams (where an evaluated and accepted methodology exists in M-a-85 or M-I-92-11)</u> ; allowing time to work through issues that may arise; and to fully develop language that would be recommended to the 2017 NCIMS Conference.	APPENDIX N MODIFICATION COMMITTEE						
215 APP N LAB		NO DOCUMENT This Proposal requests a pilot program be developed with the oversight of the Appendix N Modification Committee in consultation with FDA to create and further refine the regulatory framework to	APPENDIX N MODIFICATION COMMITTEE						

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		<p><u>voluntarily test raw milk for the presence of drugs other than beta-lactams using unreviewed tests when approved (M-a-85) tests do not exist.</u></p> <p>The ultimate goal of such a program once developed and implemented would be to prevent potentially adulterated milk from entering the human food chain.</p>							
216 APP N LAB		<p>PMO (Pages xiv and 374)</p> <p><u>APPENDIX N:</u> This Proposal seeks to modify the minimum sensitivity requirement, the 50% detection level of the safe/tolerance level rule, for the acceptance of test methods for drug residue analysis by making safe levels of drugs not applicable with the exception of penicillin G. The proposal would delete the word “safe” from the 50% rule and from the text of the PMO, where appropriate.</p> <p>For test methods for tetracycline drugs, modify the minimum sensitivity requirement. Test methods that meet or exceed the 90/95 detection levels for oxytetracycline and tetracycline of the currently accepted test kit may be accepted for Appendix N testing. The 90/95 detection levels for chlortetracycline for the currently accepted test kit</p>	FDA						

# COM.	FDA POS	DESCRIPTION	SUBMITTED BY	COUNCIL ACTION			FINAL ACTION		
				NA	PAS	PAA	NA	PAS	PAA
		meet the 50% rule.							
217 APP N LAB		<p>PMO (Pages xiv, 28-30 and 363- 374)</p> <p><u>SECTION 6 AND APPENDIX N:</u> This Proposal combines the text from the three (3) Appendix N Proposals that FDA submitted to provide an all-encompassing Proposal to indicate how Section 6 and Appendix N of the PMO would read with the potential passage of these three (3) Proposals.</p> <p>This Proposal addresses Appendix N testing to require that at least one (1) of the following drug families (Beta-lactams, Amphenicols (florfenicol) and any three (3) of the following: NSAIDs (flunixin), Sulfonamides, Macrolides, Tetracyclines, Aminoglycosides, or Avermectins) be conducted on each milk tank truck and/or each raw milk supply that has not been transported in bulk milk pickup tankers; or on a statistical basis calculated by FDA statisticians (the number of milk tank truck loads (percentage) based on the total number of milk tank truck loads received and/or each raw milk supply that has not been transported in bulk milk pickup tankers utilized from the previous year) employing a random testing program.</p>	FDA						

# COM.	FDA POS	DESCRIPTION	SUBMITTED BY	COUNCIL ACTION			FINAL ACTION		
				NA	PAS	PAA	NA	PAS	PAA
		<p>This Proposal addresses Proposal 220 from the 2013 NCIMS Conference that was assigned to the Appendix N Modification Committee addressing the procedure to follow when using a drug testing method that has NOT been evaluated and accepted by FDA and the NCIMS when there is a drug testing method AVAILABLE that has been evaluated and accepted by FDA and the NCIMS (M-a-85, latest revision, and M-I-92-11).</p> <p>It further addresses a request from FDA to the Appendix N Modification Committee and accepted by the Appendix N Modification Committee to develop a procedure to follow when using a drug testing method that has NOT been evaluated and accepted by FDA and the NCIMS when there is NOT a drug testing method that has been evaluated and accepted by FDA and the NCIMS available.</p> <p>This Proposal also seeks to modify the minimum sensitivity requirement, the 50% detection level of the safe/tolerance level rule, for the acceptance of test methods for drug residue analysis by making safe levels of drugs not applicable with the exception of penicillin G. The</p>							

# COM.	FDA POS	DESCRIPTION	SUBMITTED BY	COUNCIL ACTION			FINAL ACTION		
				NA	PAS	PAA	NA	PAS	PAA
		<p>proposal would delete the word “safe” from the 50% rule and from the text of the PMO, where appropriate.</p> <p>For test methods for tetracycline drugs, this Proposal seeks to modify the minimum sensitivity requirement. Test methods that meet or exceed the 90/95 detection levels for oxytetracycline and tetracycline of the currently accepted test kit may be accepted for Appendix N testing. The 90/95 detection levels for chlortetracycline for the currently accepted test kit meet the 50% rule.</p>							
218 APP N LAB		<p>PMO (Page 374)</p> <p>APPENDIX N: This Proposal clarifies the scope of the current drug residue test kit requirements contained in Appendix N for drug residue testing.</p>	NMPF						
219 LAB		<p>PMO (Page 28)</p> <p>SECTION 6: The PMO requires the Regulatory Agency to do the arithmetical averaging of sample results from producers shipping multiple tanks/loads of raw milk in a day. This Proposal is to allow personnel in an Official, Commercial or Industry Laboratory approved by the Milk Laboratory Control Agency to do the arithmetical averaging.</p>	STEVE INGRAM- WI- DEPT OF AG, TRADE AND CONSUMER						

# COM.	FDA POS	DESCRIPTION	SUBMITTED BY	COUNCIL ACTION			FINAL ACTION		
				NA	PAS	PAA	NA	PAS	PAA
220 OTHER SPECIES		<p>PMO (Page 28)</p> <p>SECTION 6: For sheep milk producers who do not sell nor ship their milk; and who use all of their milk for their own cheese-making; and who are seasonal; and who suspend their milking operations for at least 6 consecutive months of the year: the sample history of somatic cell counts will not carry forward through the months where no product was available to sample and instead the sampling counts will begin afresh with each new milking season.</p>	<p>PAUL BORGHARD- THREE CORNER FILED FARM, LLC- SHUSHAN, NY</p>						
221 LAB		<p>PMO (Page 29 and EML-Page 10)</p> <p>PMO-SECTION 6 AND EML SECTION 2: This Proposal introduces a new method, the TEMPO laboratory instrument, used for the enumeration of aerobic mesophilic flora in pasteurized milk and milk products.</p>	<p>JOHN MILLS- bioMERIEUX, INC.- HAZELWOOD, MO</p>						
222 LAB		<p>PMO (Page 29)</p> <p>SECTION 6: This Proposal introduces a new method, the TEMPO laboratory instrument, used for the enumeration of coliform bacteria in pasteurized milk and milk products.</p>	<p>JOHN MILLS- bioMERIEUX, INC.- HAZELWOOD, MO</p>						
223 OTHER SPECIES		<p>PMO (Pages 30 and 34- (TABLE 1))</p> <p>SECTION 6 AND TABLE 1: To raise the Somatic Cell</p>	<p>PAUL BORGHARD- THREE CORNER FILED FARM,</p>						

# COM.	FDA POS	DESCRIPTION	SUBMITTED BY	COUNCIL ACTION			FINAL ACTION		
				NA	PAS	PAA	NA	PAS	PAA
LAB		Count (“SCC”) limit for sheep milk from the current 750,000/mL to 1,000,000/mL for sheep milk producers who do not sell nor ship their milk; who use all of their milk for their own cheese-making; who are seasonal; and who suspend their milking operations for at least 6 consecutive months of the year.	LLC-SHUSHAN, NY						
224 LAB		PMO (Page 30) SECTION 6: Revise wording to allow new simplified methods for bacterial detection that have been FDA/NCIMS evaluated published in M-a-98, latest revision, and accepted into a 2400 series form.	ROBERT SALTER- CHARM SCIENCES, INC.- LAWRENCE, MA						
225 OTHER SPECIES LAB		PMO (Page 30) SECTION 6: The Proposal is to include the appropriate somatic cell counting method and appropriate somatic cell count standard for use with camel milk.	LYNN HINCKLEY- OTHER SPECIES COMMITTEE						
226 LAB		PMO (Pages 46, 47, 67, 87, 169, 223 and 194) ITEM 8r and 7p; and APPENDIXES D and J: Change the bacteriological water standards to address EPA’s elimination of the MCL for Total Coliform and the implementation of an E. coli MCL	LYNN YOUNG- MILK REGULATORY CONSULTANTS, LLC- RUSSELLVILLE, MO LAURA TRAAS- WI DEPT OF AG, TRADE AND						

# COM.	FDA POS	DESCRIPTION	SUBMITTED BY	COUNCIL ACTION			FINAL ACTION		
				NA	PAS	PAA	NA	PAS	PAA
			CONSUMER						
227 HAULING		PMO (Page 144) APPENDIX B: Change the annual milk tank truck inspection to a 3 year inspection.	CHERIE HOUSER- INTERNA- TIONAL MILK HAULERS ASSOCIATION- MIDDLETON, WI						
228 MMSR		PMO (Page 223) MMSR (Pages 87 and 95) PMO-APPENDIX G AND MMSR-APPENDIX A: This Proposal would limit the number of consecutive bacteriologically unsatisfactory water sample test results to three (3) before a farm and/or milk plant would lose their Grade “A” permit.	JOE DITTRICH- MN DEPT OF AG						
229 LAB		PMO (Page 365) APPENDIX N: A Proposal to require records of all drug residue sample results shall be maintained for a minimum of two (2) years by the industry at the location where the tests were run, and/or another location as directed by the Regulatory Agency.	PAULA DANKERT- MI DEPT OF AG AND RURAL DEVELOPMENT						
230 MMSR		MMSR (Page 14) SECTION C: This Proposal would add a clarification when a Grade “A” milk plant is de-listed for inadequate sampling, only one re-sample (within the limits) of each debited product would be needed prior to the re-rating.	JOE DITTRICH- MN DEPT OF AG						

#	FDA POS	DESCRIPTION	SUBMITTED BY	COUNCIL ACTION			FINAL ACTION		
				NA	PAS	PAA	NA	PAS	PAA
COM. 231		EML (Entire Document) This Proposal is to revise the 2011 EML to include changes passed at the 2013 NCIMS Conference and add other edits.	CATHERINE HALL- NCIMS LABORATORY COMMITTEE						
LAB									
232		EML (Page 3) <u>SECTION 1:</u> Update to allow FDA certified State LEOs to evaluate and conditionally certify new analysts at the State central milk laboratories.	CYNTHIA MANGIONE- NY DEPT OF AG AND MARKETS						
LAB									
233		EML (Pages 10-11) <u>SECTION 2:</u> Add PeelPlate methods to the EML as techniques for evaluating aerobic bacteria and coliform counts.	ROBERT SALTER- CHARM SCIENCES, INC.- LAWRENCE, MA						
LAB									
234		EML (Pages 16-17) <u>SECTION 3:</u> Established that fully certified LEOs be allowed to be certified for a period of 5 years instead of the present 3 years. Change the on-site check evaluation to a mock survey situation that could be set up as part of the FD373 course.	DEB HALL- IN BOARD OF ANIMAL HEALTH						
LAB									
235		ESCC 2400 FORM Omit the requirement for DMSCC certification as a co-requisite for ESCC certification in laboratories that purchase certified somatic cell standards for instrument calibration and verification.	CARLY ZMIJEWSKI- SILLIKER, INC.- SALIDA, CA						
LAB - 2400									

# COM.	FDA POS	DESCRIPTION	SUBMITTED BY	COUNCIL ACTION			FINAL ACTION		
				NA	PAS	PAA	NA	PAS	PAA
236 LAB - 2400		2400 FORM (8 of Cultural Procedure-General Requirements) Increase the required autoclave temperature for media sterilization by moist heat by 1°C from 120±1°C to 121±1°C.	CARLY ZMIJEWSKI-SILLIKER, INC.- SALIDA, CA						
237 LAB - 2400		2400 FORM (In Pasteurized Milk Containers) Update 2400 Pasteurized Milk Containers, Closures and Packaging with new bacterial methods.	ROBERT SALTER-CHARM SCIENCES, INC.- LAWRENCE, MA						
238 LAB - 2400		2400 FORM (11, 17 AND 18 of Cultural Procedure-General Requirements) Update 2400 Cultural Procedures-General Requirements with information about new approved simplified methods for bacteria testing.	ROBERT SALTER-CHARM SCIENCES, INC.- LAWRENCE, MA						
239 LAB - 2400		NEW 2400 FORM Approve a 2400 Form for the new bacterial methods, PeelPlate-AC for aerobic bacterial count and PeelPlate-EC and PeelPlate-EC-HVS coliform count, for milk products. Update M-a-98, Table 3 with the new methods and the validated matrices.	ROBERT SALTER-CHARM SCIENCES, INC.- LAWRENCE, MA						
240 LAB - 2400		2400 FORM (Page 6 of Appendix N-General Requirements) <u>SECTION 10:</u> To expand training requirements and documentation for	MICHAEL HYDOCK-PA DEPT OF AG						

# COM.	FDA POS	DESCRIPTION	SUBMITTED BY	COUNCIL ACTION			FINAL ACTION		
				NA	PAS	PAA	NA	PAS	PAA
		performance testing under Appendix N General Requirements.							
241 LAB - 2400		2400 FORM (Page 7-Dairy Water) To allow the use of an alternative pre-incubation step to the Colilert-18 method.	JENNIFER RAKOWSKI-PA DEPT OF AG						
242 LAB - 2400		2400 FORM (Page 5 of Cultural Procedure-General Requirements and Page 6 of Appendix N-General Requirements) To clarify the procedure for the accuracy check of dairy pipettors in regards to the matrix used.	JENNIFER RAKOWSKI-PA DEPT OF AG						
243 LAB - 2400		2400 FORM (Page 6 of Appendix N-General Requirements) To state the sample temperature and time requirements for raw milk in the Appendix N testing program, as well as wording to reflect single producer/farm bulk tank sampling and testing.	JENNIFER RAKOWSKI-PA DEPT OF AG						
244 LAB - 2400		2400 FORM (ESCC-Page 1) Eliminate the DMSCC certification prerequisite for an ESCC method when a laboratory is purchasing certified Somatic Cell Standards.	DAVID PATTERSON-AGRI-MARK CENTRAL LABORATORY -WEST SPRINGFIELD, MA						
245 LAB - 2400		2400 FORM (3 DMSCC) Give the option of standardization temperatures on the immersion oil on the	CATHERINE HALL-TX DEPT OF STATE HEALTH						

# COM.	FDA POS	DESCRIPTION	SUBMITTED BY	COUNCIL ACTION			FINAL ACTION		
				NA	PAS	PAA	NA	PAS	PAA
		DMSCC Form.	SERVICES						
246 (231/2013) SCIENCE LAB - 2400		2400 FORM (Dairy Waters) Extend the allowable time for the transportation of water samples from 30 hours to 48 hours for water samples tested in IMS listed laboratories.	LYNN YOUNG- MILK REGULATORY CONSULTANTS, LLC- RUSSELLVILLE, MO						

2015 NCIMS PROPOSALS
FINAL ACTION TAKEN
COUNCIL III

Legend
S=Support
N=Neutral
O=Oppose
T=Tabled

#	FDA POS	DESCRIPTION	SUBMITTED BY	COUNCIL ACTION			FINAL ACTION		
				NA	PAS	PAA	NA	PAS	PAA
COM. 301 ASEPTIC		PMO (Page 130) SECTION 11: This Proposal requests a two (2) year extension of the NCIMS Aseptic Pilot Program (APP) to specifically address aseptically processed and packaged Grade “A” fermented high-acid milk and/or milk products. The NCIMS AC is discontinuing their evaluation of aseptically processed and packaged Grade “A” acidified milk and/or milk products.	ASEPTIC COMMITTEE						
302 CONST./ BYLAWS		PROCEDURES (Pages 77 and 81) CONSTITUTION/BYLAWS: This Proposal formalizes the appointment of Chairs and Vice Chairs to NCIMS Committees.	NMPF						
303 CONST./ BYLAWS		PROCEDURES (Pages 74 and 80) CONSTITUTION/BYLAWS: This Proposal allows a vacant elected Board seat to be filled between Conferences.	NMPF IDFA CASEY McCUE- NY DEPT OF AG AND MARKETS STEVE INGRAM- WI DEPT OF AG, TRADE AND CONSUMER						
304		PROCEDURES (Pages 81, 84 and 85)	DAVID LATTAN-						

# COM.	FDA POS	DESCRIPTION	SUBMITTED BY	COUNCIL ACTION			FINAL ACTION		
				NA	PAS	PAA	NA	PAS	PAA
CONST./ BYLAWS		BYLAWS: The Parliamentarian has suggested the following changes to the BYLAWS in order to clarify the role of the Parliamentarian, insure that we do not prematurely adjourn the Conference, and to explain the intersection of the Conference documents, past practices, and Roberts Rules of Order.	PRAIRIE FARMS DAIRY, INC.- CARLINVILLE, IL						
305 CONST./ BYLAWS		PROCEDURES (Pages 74-75) CONSTITUTION/BYLAWS: To add the Chair of the NCIMS Laboratory Committee to the NCIMS Executive Board.	FRANK BARCELLOS- NCIMS LABORATORY COMMITTEE CHAIR						
306		PMO, PROCEDURES, METHODS AND EML (Page- Multiple) NEW PROCEDURE This Proposal adds to the Table of Contents of each NCIMS document a listing of abbreviations and acronyms that are used throughout the individual PMO, MMSR, Procedures and EML documents.	FDA						
307 ICP		PROCEDURES (Page 16) PROCEDURES CHANGE JOINT COUNCIL This Proposal clarifies that drug residue summary data shall be collected by Third Party Certifiers (TPCs) and reported to the third party database.	NMPF						
308		PROCEDURES (Page 25) PROCEDURES CHANGE JOINT COUNCIL	BRIAN MOYER- WI DEPT OF AG, TRADE						

# COM.	FDA POS	DESCRIPTION	SUBMITTED BY	COUNCIL ACTION			FINAL ACTION		
				NA	PAS	PAA	NA	PAS	PAA
		This proposal will reduce the number of bulk milk hauler/samplers evaluated during Sampling Surveillance Officer re-certification. This will make the re-Certification process similar to the current re-delegation to state regulatory personnel process as established by the 2007 NCIMS found in the “Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments (2013 Revision)” document.	AND CONSUMER						
309 SSCC MMSR		<p>PMO, PROCEDURES, ANDMETHODS (Pages-Multiple) NEW PROCEDURE</p> <p>1. To develop listing and withdrawal of listing criteria for SSCC manufacturers.</p> <p>2. To develop qualifications, authorization, certification/recertification procedures, etc. for consultants that currently certify or wish to certify SSCC manufacturers located outside the geographical boundaries of NCIMS Member States.</p>	NCIMS SSCC AND METHODS COMMITTEES						